

AIPPI Canada Response to Consultation Document – Additional Term and Miscellaneous Amendments to the Patent Rules

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Introduction to AIPPI

AIPPI, the *Association Internationale pour la Protection de la Propriété Intellectuelle*, is the world's leading non-profit association dedicated to the development and improvement of laws for the protection of intellectual property. AIPPI is a politically neutral, non-profit organization, domiciled in Switzerland which currently has over 8,000 members worldwide, representing more than 110 countries. The objective of AIPPI is to improve and promote the protection of intellectual property on both an international and national basis. It pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and also of national laws relating to intellectual property. It operates by conducting studies of existing national laws and proposes measures to achieve harmonization of these laws on an international basis. The members of AIPPI are people actively interested in intellectual property protection on a national or international level. They include lawyers, patent attorneys and trademark agents (both outside and in house counsel) as well as judges, academics, scientists and engineers. They also include corporations and other IP owners.

AIPPI has not yet prepared a study of existing national laws on Patent Term Extension, nor has AIPPI prepared a resolution or a formal position on this topic. Due to the short timeline for responding to the Consultation Document, combined with the timing (August), it was impossible to obtain a comprehensive response from all AIPPI membership, nor to prepare an official position of AIPPI. AIPPI is organized into National and Regional Groups, each with their own Executive, Statutory and Study Committees. This Response was prepared by a sub-group of the AIPPI Canada Patent Committee, under the leadership and with the vetting of the National Executive Committee.

Background to Additional Term and Miscellaneous Amendments to Patent Rules

The Canada-United States-Mexico Agreement (CUSMA) which entered into force July 1, 2020, provides a requirement to provide a patent term adjustment to compensate patent owners for unreasonable delays in the processing of their patent applications. Article 20.44(4) of the CUSMA states (in part) "A Party may exclude, from the determination of those delays, periods of time that do not occur during the

processing of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable to the granting authority; as well as periods of time that are attributable to the patent applicant." Footnote 2 to this passage states that "A Party may treat delays "that are not directly attributable to the granting authority" as delays that are outside the direction of control of the granting authority.

In our view, it should be considered that a statutorily determined period of time to request examination, respond to an Examiner's Requisition, pay an issue fee, and the like, are periods of delay directly attributable to the granting authority, since the due dates are set by the granting authority. Further to this, it is noted that the Patent Office has already done an excellent job of reducing such delays, in previous recent amendments to the Patent Act and Rules, which *inter alia* have:

- Decreased the due date for requesting examination from 5 years to 4 years from the filing or international filing date;
- Decreased the due date for responding to an Examiner's Requisition from 6 months to 4 months;
- Introducing a Request for Continued Examination scheme encouraging compact prosecution;
- Reduced the "late" period for maintenance fee payments from 12 months to 6 months;

In addition, the Patent Office has made valiant attempts (which are appreciated) to shorten timelines to first Examiner's Requisition and to make Examiner's Requisitions more complete and less piecemeal. That said, piecemeal examination remains an issue, especially in certain art groups.

*It is noted that a key provision that would greatly aid in compact prosecution, and missing from the current legislative framework, is a provision for terminal disclaimers and a solution to the "double patenting" risks borne by applicants in the current environment.

Since CUSMA stipulates a patent term adjustment to compensate patent owners for <u>unreasonable</u> delays [on the part of the Office] in the processing of their patent applications, it is submitted that any time spent by an Applicant within the normal timelines <u>set by the Patent Office</u> are not unreasonable, and aught not be subtracted from the patent term adjustment.

In addition, it is our position that since the patent term adjustment is provided specifically <u>to compensate</u> patent owners for unreasonable delays [on the part of the Office], patent owners should not be unduly prejudiced by the cost of applying for or obtaining such patent term adjustment. As such, patent term adjustment should follow simple and non-discretionary rules, and the cost of the initial calculation of such adjustment should be borne by the party creating the unreasonable delays – the Patent Office. If the cost of the initial calculation is borne by the Applicant, this will result in additional cost for nearly <u>every patent application</u> regardless of entitlement to PTA – making the PTA scheme unnecessarily onerous and costly to Applicants who do not even benefit from it. It is noted that section 46.1 (1) of the Patent Act provides that "The Commissioner <u>shall</u> grant an additional term for patent if" (emphasis added), clearly requiring a positive obligation of the Office. Simple and non-discretionary rules would also reduce or eliminate the need for third party reconsideration as provided by s. 46.3 of the Patent Act.

It is within the context of this position that we answer the specific Questions for Discussion provided in the Consultation Document as follows:

Questions for Discussion (Part I)

- 1. What are your views on the proposed regulatory framework and do you believe there is anything missing?
 - (a) PTA should be consecutive with, not concurrent with, CSPs. CSPs are for delay in the regulatory approval process, a completely different delay for the Applicant. Delays can exist both at the Patent Office <u>and</u> during the regulatory approval process, and both delays create financial hardship to the Applicant. PTA should be calculated, then the CSP calculation should be based on the new expiry date of the Patent post-PTA. In this manner, for concurrent delays, the term will be, in effect, concurrent, but for consecutive delays, the term will be consecutive. This is fairest for the Applicants. This will also make the payment of maintenance fees during the PTA period more equitable, since no maintenance fees are due during the CSP period.
 - (b) It would be beneficial for the PTA term to be clearly shown on the patent cover page on the CIPO site.
- 2. Do you have thoughts on which periods should result in days to be subtracted in the determination of additional term?

As discussed above, the CUSMA stipulates that the provision of a patent term adjustment (PTA) is to compensate the Applicant for <u>unreasonable</u> delays attributable to actions by the Office. It is, therefore, understandable that any calculated PTA may be reduced owing to <u>unreasonable</u> delays attributable to the Applicant. The Consultation Document outlines a number of scenarios where a calculated PTA may be reduced. Many of these scenarios, however, cannot in any way be considered as "unreasonable delays", or even "delays" on the part of the Applicant.

For example, and as discussed above, any period of time allotted to an Applicant in accordance with the Act and/or Rules for filing a submission (such as a request for examination), responding to an Office notice (such as an Examiner's Report, a formality notice, or a Conditional Notice of Allowance), paying a fee (such as a Final Fee), or the like, would clearly not comprise an "unreasonable delay", or even a "delay". Indeed, such period of time is allotted to enable the Applicant to obtain the necessary information and to prepare a suitable reply to the Office. Clearly, within the scope of compact prosecution, it is also in the Office's interest that an Applicant provides a complete reply. Thus, an Applicant who avails themselves of an allotted period of time for filing a submission to the Office cannot be deemed to cause "delay". For example, for an Examiner's Requisition, in many cases, that requisition needs to be considered by three parties in six separate instances - the Canadian agent needs to review and consider it, report it to the foreign agent, who also reviews and considers it, and reports it to the Applicant, who reviews it and considers it, provides guidance to the foreign agent, who reviews and considers the guidance and prepares instructions for the Canadian agent, who ultimately prepares a response. Doing this in a complete and thorough manner within the four month timeline as currently stipulated by the Patent Rules does not provide any time for "delay", much less "unreasonable delay".

As mentioned above, it is understandable that certain actions of the Applicant may lead to "unreasonable delays" in the prosecution of an application and may therefore be taken into consideration for reducing a calculated PTA. Generally, actions of the Applicant that reduce any PTA would be those that are not in relation to submissions required by the Act and Rules. For example, the following situations may be considered for subtracting days from a calculated PTA: the days for which an extension of time was obtained; the days between abandonment and reinstatement of an application; the days during which an application is subject to a Request for Continued Examination; and, the days between the filing of post-allowance amendments and allowance of the application.

The proposed regulations suggest that the full time spent successfully appealing an Examiner's decision to the Patent Appeal Board should be considered unreasonable Office Delay. However, since a successful outcome means the Patent Appeal Board has determined that an Examiner's decision (and the delay caused by same) is unreasonable, such time during the appeal should not be taken into account for reducing any calculated PTA.

The Consultation Document also suggests that certain scenarios outside the control of both the Office and the Applicant would be taken into account for reducing any calculated PTA. This, however, unduly penalizes the Applicant through no fault of their own. The Consultation Document, for instance, refers to "force majeure" situations, delays in Office correspondence reaching the Applicant, and "normal operations at the Patent Office being disrupted". In all of these situations, there would clearly be no "delay" on the part of the Applicant.

3. Do you have views on the requirements for submitting a request for additional term or a reconsideration?

Additional term should be calculated based on objective, simple and non-discretionary rules. Reconsideration of that decision should be a straightforward application process, and only required where an error has been made.

Request for additional term

The suggested process for processing an application for additional term seems overly complex.

In view of the provision for reconsideration by the Commissioner on application of a person, there seems no need for an observation period. There has never been such an observation period and a requirement the Commissioner take it into consideration in relation to other major steps, such as amending the claims during examination. The request for an additional term will be made public in the file, which is now published and can be accessed by anyone following the application. There is no need for a separate notice.

A request for additional term should, as suggested, include basic information such as the patent number and a clear expression that the communication relates to an application for additional term may be required. The request reasonably could include the requesting party's preliminary calculation of additional term, but (i) since the requesting party may not readily have all the information, for example where maintenance fees are paid by a third party maintenance fee

provider, and (ii) since CIPO will itself do a detailed calculation, the calculation by the requesting party should not be limiting and Commissioner should determine a longer or shorter or the same period based on the facts before the Commissioner.

It is submitted that the processing of additional term requests should involve the following steps:

Receive request - initial review (as in Fig. 3) - preliminary determination of additional term - advise requesting party of the preliminary determination and allow period for response (e.g. 2 months) - determination of additional term - notify requesting party of determination with reasons and, if additional term granted issue certificate.

The Supreme court of Canada in *Canada v. Vavilov* 2019 SCC 65 emphasized the importance of reasons in an administrative decision.

Reconsideration of an Additional Term

The request for reconsideration reasonably could include the identification of the patent, a detailed explanation of any alleged error(s) in the previous determination or previous reconsideration of additional term.

It is submitted that the processing of requests for reconsideration should involve the following steps:

Receive request - initial review for compliance with the regulations - preliminary determination - notify the requesting party and patentee of the preliminary determination and allow period for response (e.g. 2 months)- determination of the request for reconsideration with reasons - notify the requesting party and patentee of the determination and, If the Commissioner determines that the additional term should be shortened, issue an amended Certificate of Additional Term.

As discussed with respect to the request for additional term, there is no need for public observations in relation to a reconsideration application. An interested member of the public can request reconsideration.

4. What information should be contained in certificates of additional term?

The patent number, and the length of the additional term and/or the expiry date of the patent. It should not contain anything else.

5. What information do you feel is important for CIPO to convey to the public in relation to determinations of additional term?

Nothing more than what is usually conveyed regarding the patent system in general.

Questions for Discussion (Part II)

1. What are your thoughts on the possible regulatory amendments discussed?

The regulatory amendments discussed are:

(a) Extensions of time to request examination beyond the current deferred examination term (4 years for applications filed post October 3, 2019 and 5 years for those filed prior).

Extensions of time to request examination will, in many cases, ease the administrative burden on CIPO during prosecution, as well as costs to both the Applicant and CIPO, especially if such extensions are requested in order to allow for examination in other jurisdictions. This is especially true (for example) to align Canadian prosecution to that of the U.S., in consideration of U.S. continuation and divisional practice and our own "double patenting" restrictions.

We would suggest the ability to request an extension of time once, for 2 years beyond current 4 year deferral period. Possibly a second 2 year extension could be contemplated, with justification (for example, where U.S. prosecution has not yet terminated).

- With regard to third party protests to the extension:
- (i) Section 35 (1) of the Patent Act, already states that: *The Commissioner shall, on the request of any person made in such manner as may be prescribed and on payment of a prescribed fee, cause an application for a patent to be examined by competent examiners to be employed in the Patent Office for that purpose.*

A such an additional protest regime is not required for third parties. Anyone is permitted to request examination at their cost, at any time, thereby "protesting" any extension with a 100% success rate.

(b) Suspension of examination

Suspension of examination during "late fee" or abandonment period would likely have little push back from industry, while at the same time be quite advantageous to CIPO, since likely most cases in "late fee" or abandonment will not be reinstated, allowing Examiners to concentrate on cases more likely to proceed to issuance.

Allowing an Applicant to request deferral or suspension of examination will also alleviate burden on Examiners while allowing an Applicant to re-think claim strategy in light of commercial developments, clinical testing developments, and/or to align claims with foreign prosecution (which creates tremendous efficiency when enforcing patents). It is proposed that such suspension, at the Applicant's request, should be allowed for 2-3 years. It is also proposed that such suspension could be cancelled at the Applicant's (or any other party's) request.

(c) <u>Permitting an Applicant to submit a priority request on the same day as approval for public</u> inspection

We perceive no anticipated negative effect to this change.

2. What other changes might you propose to improve the existing regulatory including streamlining examination and lightening administrative burdens?

The most important change needed to Canadian patent legislation at this time, from the perspective of streamlining examination and lightening administrative burdens, as well as from the perspective of

harmonization with other jurisdictions, is a complete reconsideration and codification of Canada's "double patenting" practice. Terminal disclaimers should be allowable to address "obviousness-type" double patenting objections, and double patenting should not be a consideration in the invalidating of issued patents in litigation proceedings. Our current practices create unnecessary office actions (when Applicants add claims from corresponding U.S. divisionals in order to deliberately trigger unity of invention objections), otherwise unnecessary Requests for Continued Examination, otherwise unnecessary extensions of time, and the like. The Office also spends unnecessary resources and time in prosecution objecting to and addressing problems of double patenting, even in the earlier filed patent application. Risks, especially for obviousness-type double patenting, are very different than all other jurisdictions, which leads to a requirement for a Canada-specific strategy which is disproportionately costly to Applicants when compared to the size of our market.

3. How often do you expect applicants would request an extension of time to the deferred examination period and under which circumstances? What would be the positive and negative impacts on you if the Government permitted extensions of time to the deferred examination period?

How often applicants would request deferred examination would depend on a number of factors:

- Applicants like the PPH process to expedite examination. So if one defers examination to enable
 an Applicant to benefit from that process versus the regular examination route, intake would
 likely be relatively high. As noted by CIPO, it would lower CIPO's time and costs for review
 during prosecution as well as Applicant's costs.
- If CIPO's time for a first office action is longer than the request for deferral, and the corresponding foreign patent is close to allowance, then that may also influence if an Applicant would defer or pay any costs for deferral. The driving force may be the cost of requesting deferal, if any.
- The nature of the industry and market. A patent cannot be enforced until it issues, so any process that helps to expedite prosecution and allowance overall may prevail, especially in light of potential infringers.
- It would also be balanced on the benefit of having a granted patent to enforce against third parties, or impact on having granted patents to valuation of the patent asset for licensing/sale.
- In light of Canada's double patenting laws, Applicants who have filed continuations in the US, or divisional applications in the US or other jurisdictions, may benefit from deferral until all patent applications in a family have been allowed, so that the Canadian claims can be amended to include all of them for review *ab initio* of the examination process. Of course, this consideration would be moot if Canada performs a complete reconsideration and codification of "double patenting" practice, as suggested in our answer to (2), above. Requesting an extension for deferred examination would as mentioned above save CIPO and the Applicant time and money if it helps to hasten prosecution overall, especially if done to try to align claims to those in other jurisdictions. Allowing for a delay in incurring costs associate with prosecution/examination would be particularly beneficial for applicants with limited budgets such as start-ups.

It may benefit certain industries to request extensions to the deferral period, such as pharma, in light of the Canadian PMPRB regime.

Vis a vis CIPO, there would likely be no negative effects for implementing an extension of time to request examination. Vis a vis third parties, it may make the competitive landscape less clear for a certain period of time, however that can be mitigated if they are limited to aligning rights to claims as in other jurisdictions and granting the extension for only a certain period of time.

Respectfully submitted,

The Canadian Group of the International Association for the Protection of Intellectual Property (AIPPI Canada)