CGPA
Making Patient Care Affordable

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CGPA Submissions on the Regulatory Framework for Additional Patent Terms and Other Amendments to the Patent Rules

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Introduction

The Canadian Generic Pharmaceutical Association (CGPA) appreciates the opportunity to provide these submissions in response to the Canadian Intellectual Property Office (CIPO) and Innovation Policy Sector consultation document *Additional Term and Miscellaneous Amendments to the Patent Rules*.

As part of its obligations under the Canada-United States-Mexico Agreement (**"CUSMA"**), Canada agreed to adopt a system for patent term adjustment (**"PTA"**) that allows patentees to apply for an extension to their patent terms in circumstances where there has been "unreasonable" delay in the issuance of a patent caused by the Patent Office. The general framework for this new PTA regime was set out in recent amendments to the *Patent Act,* R.S.C., 1985, c. P-4 (the ***"Patent Act"***), which received Royal Assent on June 22, 2023 and will come into force on or before January 1, 2025.

As the CGPA has stressed in its prior submissions, the implementation of a PTA regime in Canada has the potential to further delay the entry of lower-cost generic drugs and biosimilar medicines. Any such delay in competition from generic and biosimilar medicines increases the cost of pharmaceutical products in Canada as monopoly periods for brand-name drugs are extended. Canada is already recognized as a jurisdiction that has high barriers to entry for generic and biosimilar medicines, with increasing regulatory costs, complex intellectual property rules, high-risk exposure on launch, and low prices for second-entry products.

The CGPA recognizes and appreciates the work that has already been done by ISED and the Patent Office to ensure that the Patent Office provides timely responses to patent applications. Given that the average application pendency from the request for examination date to the issuance of the patent was 32.3 months in 2022/2023, the CGPA is optimistic that recourse to Canada's new PTA regime will not be frequently required, if at all. However, the CGPA believes that ISED should continue to advocate internally for increased resources for the Patent Office, to ensure that it is able to continue to provide timely responses to patent applications.

While the CGPA generally believes that the recent amendments to the *Patent Act* create a framework with the potential to both fulfill Canada's obligations under CUSMA and limit unnecessary delays to generic market entry, careful drafting of the regulatory framework will be critical to ensuring that this balance is realized in practice.

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Accordingly, the CGPA provides the following submissions for consideration by ISED when drafting the amendments to the *Patent Rules* that will accompany Canada's new PTA regime. The comments below are responsive to the questions outlined in ISED's Consultation Document.

Section 1: Regulations Related to Additional Term

(a) Periods to be Subtracted in the Determination of Additional Term

The amendments to the *Patent Rules* should strive to avoid unnecessarily increasing drug costs for Canadians by ensuring that generic and biosimilar medicines are not unnecessarily delayed from entering the market. It is accordingly critical to ensure that the *Patent Rules* only award PTA where delay is both *unreasonable* and *attributable solely to the Patent Office*.

In general, the CGPA agrees with the examples provided in Annex A to ISED's Consultation Document, which outlines examples of periods of time that may be subtracted in the determination of PTA. However, it is the CGPA's position that it is impossible for any list to comprehensively outline every circumstance in which a delay might be either reasonable, or attributable to a patentee.

While the examples in Annex A provide welcome predictability regarding how PTAs will be calculated, the *Patent Rules* should also ensure that the PTA system remains flexible enough to adapt to unique or unforeseen circumstances that may arise during the review and processing of a patent application. Accordingly, the CGPA suggests the following principles should be reflected in the *Patent Rules*.

(i) *The Guiding Framework*

The CGPA suggests that the *Patent Rules* should clearly state as a guiding principle that PTA should only be awarded where delay is both *unreasonable* and *attributable solely to the Patent Office.* Identifying these two criteria as the cornerstones of the PTA regulatory framework will ensure that Canada both fulfils its obligations under CUSMA and designs a PTA regime responsive to the needs of Canadians.

(ii) *The Patent Rules Should Maintain Flexibility for the Commissioner to Assess Complex Cases*

There will be cases where a delay by the Patent Office is not unreasonable simply because it took longer to examine an application than an objective deadline prescribed by the *Patent Act* or the *Patent Rules*. In these cases, it will be both reasonable and necessary for the Patent Office to exceed the usual timelines for completion to ensure that a careful and comprehensive review of the patent is completed.

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The CGPA submits that the regulatory framework for PTAs should maintain some discretion and flexibility for the Commissioner to determine whether delay occasioned by the Patent Office was truly unreasonable.

A central consideration in whether the Patent Office's delay was reasonable will be the complexity of the patent application. Certain patent applications are inherently more complex than others. For example, patents on biologics, patents with DNA sequences, patents with more than 20 claims, and patents exceeding 20 pages, are all more likely to reasonably require longer and more intensive examinations than other types of patent applications.

While the *Patent Rules* should strive to pre-emptively recognize and define "complex" patent applications (such as the examples provided above), no definition will be able to capture all the circumstances which could reasonably necessitate a longer examination process. Accordingly, the Commissioner should retain some residual discretion to determine whether delay occasioned by the Patent Office in the examination period was truly unreasonable in view of the complexity of the patent application.

The CGPA submits that the most straightforward way to account for the complexity inherent in the examination phase would be to only award ½ a day of additional PTA for each day of delay occasioned during this period. In contrast, where the Patent Office delays in completing simple administrative steps, patentees may be granted up to 1 day of additional PTA for each day of delay.

(iii) *The Patent Rules Should Maintain Flexibility for the Commissioner to Determine whether a Delay was caused by the Patentee*

As ISED's Consultation Document recognizes, delays attributable to the patentee should not be considered when determining PTA. The foregoing is necessary to ensure that Canada's PTA regime does not unintentionally incentivize patentees to delay in advancing their patent applications.

It is important to emphasize that, in the pharmaceutical context, the majority of profits earned by a patentee are received at the end of a patent's life cycle. This is because early in a pharmaceutical patent term, the product is undergoing marketing approval, and thereafter, initial market penetration. Full maturation of a product does not typically occur until between two to three years prior to patent expiry. Since pharmaceutical patent rights are the most valuable near the end of a patent's term, PTAs provide particularly attractive financial benefits for patentees, particularly for follow-on patents, e.g., polymorphs and salt forms of active ingredients.

To avoid inadvertently incentivizing patentees to slow down their patent applications, it is critical that only those steps that are directly attributable to the Patent Office should be counted towards calculating unreasonable delay. For example, some stages in the administrative processing of a patent application are necessitated by the actions of the applicant and should not be directly attributable to the Patent Office. These include the initial administrative processing of assignments of the patent application, changes to inventorship and voluntary amendments made to the patent application by the applicant.

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Other examples of steps that are outside the direction or control of the Patent Office or within the power of the patent applicant that presently do not appear to be included in Schedule A include the following:

a. *Examination of the Patent Application:* Delays in examining patent applications should not be presumptively attributed to the Patent Office. There are a number of factors that are attributable to the patent applicant that could result in the delay of the examination of the patent application. These include the following:

- *The Number of Claims at Issue:* The number of claims in a patent application may have a significant impact on the time required to review the patent application. Accordingly, to the extent that additional time is required to examine claims in excess of the base number (i.e., in excess of 20 claims), the additional time should be attributed to the patentee and not the Patent Office.

- *Subject Matter of the Claims at Issue:* A set of claims that covers different types of subject matter (e.g., product by process claims and product for use claims) will require additional time by the Patent Office to examine as they may require additional prior art searches and different examiners to address the different types of subject matter. Accordingly, the additional time required to examine claims having disparate subject matter should be attributed to the patentee and not the Patent Office.

  Other examples of circumstances where the subject matter of the claims at issue may result in delay include claims with impenetrable, complex, or convoluted language that requires additional time to examine on the part of the examiner, or claims with crowded art fields where additional time is required to assess whether there are differences in the art and the claimed subject matter.

- *Voluntary Amendments to the Patent Application:* Annex A of ISED's Consultation Document at subsection 4(b) suggests that voluntary amendments will only be attributable to the patentee if they are made during "certain periods". The CGPA believes that the Patent Rules should clearly identify what "certain periods" will result in a subtraction and which will not. Without a clear definition of "certain periods", an unwelcome incentive could be created for patentees to amend their patent applications or delay amendments in order to receive additional PTA.

- *Deficiencies in the Patent Application:* There may be circumstances in which multiple office actions are the result of obvious deficiencies in the patent application. In those cases, all of the time that it takes to resolve those obvious deficiencies should be excluded from the

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calculation of unreasonable delay, as those deficiencies are attributable to the applicant, not the Patent Office.

- *Response to Final Action:* If the Patent Office issues a final action without a Request for Continued Examination having been required, the calculation of unreasonable delay should not include the time it takes for the applicant to request that its application be reviewed by the Patent Appeal Board.
- *Appeals to the Patent Appeal Board (PAB):* Annex A of ISED's Consultation Document at subsection 2(b) suggests that the time to respond to a notice from the PAB related to proceeding with a Commissioner review or in relation to an oral hearing would be subtracted from any award of PTA. However, the CGPA believes that if the patentee requests an appeal to the PAB, none of the time it takes for the proceeding or decision should be attributed to the Patent Office or included in the calculation of PTA unless deemed otherwise by the PAB.

  Excluding the time related to an appeal to the PAB would align with ISED's proposals in subsections 5(c) and 5(d) of Annex A to the Consultation Document, which deduct from any award of PTA the time taken to judicially review decisions taken by the Commissioner and appeals to court after the refusal of a patent application. The reasoning behind these subtractions is sound - appeals do not necessarily signify unreasonable conduct on the part of the Patent Office. The only exception to this rule should be circumstances in which the Commissioner has made a decision in bad faith.

The foregoing paragraphs are only intended as examples of types of delay that may be attributed to the patentee. As described above, the CGPA submits that the Commissioner should retain the discretion to determine whether any delays were attributable directly to the patentee.

(iv) *Two-Year Maximum Cap on PTA*

In addition to describing how PTA is to be calculated, the *Patent Rules* should provide a cap on the maximum possible PTA. The CGPA submits that in order to ensure that generics remain competitive in the global market, and appropriate cap on PTA would be 2 years. A similar 2-year maximum was imposed in respect of Certificates of Supplementary Protection (**"CSPs"**) which were created as part of Canada's implementation of the Comprehensive and Economic Trade Agreement (**"CETA"**).

(b) ***The Patentee Should Bear the Burden of Submitting a Request for Additional Term or a Reconsideration***

ISED's Consultation Document suggests that the patentee or their assigned patent agent would be required to make an application for additional term that includes "basic information" such as the patent number, and a clear expression that the communication

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relates to an application for additional term. In addition, the Consultation Document suggests that the patentee *may* need to include reasons or detailed calculations to support their request for additional term.

The inclusion of reasons and detailed calculations by the patentee should not be optional – it should be mandatory. As it is the patentee that stands to benefit from any PTA, the patentee ought to bear the burden of demonstrating why a PTA is appropriate by providing a detailed request setting out the basis for the request for extension coupled with the calculations of the total PTA being requested and the basis therefor.

The detailed request by the patentee requesting a PTA should take into account the periods outlined in the *Patent Rules* and comprehensively set out why the patentee claims that the delay was both unreasonable and attributable to the Patent Office. There should not be any presumption that a particular delay is unreasonable or attributable to the Patent Office.

Paragraph 46.1(1)(c) of the amendments to the *Patent Act* will require the patentee to apply for additional patent term within three months after the day on which the patent is issued. Considering the potential impact a PTA can have on third-parties, this three month deadline should not be subject to an extension of time.

PTAs should also be awarded within a certain time frame following the application, as any delays create uncertainty for the public. The CGPA recommends that the PTA Regime provide 30 days for any comments from the Patent Office in response to the detailed request for a PTA by the patentee. The purpose of the response would be to justify, if appropriate, any delay occasioned during the course of the review that did not meet the objective timeline. This information could then be provided to the Commissioner, to assist with the Commissioner's determination of whether any PTA should be awarded.

Similarly, the Commissioner's decision ought to be issued within 60 days of the patentee filing the request for a PTA. Again, this timeline would limit the potential impact of PTAs upon third parties.

(c) *Information Contained in Certificates of Additional Term*

Subsection 46.1(7) of the amendments to the *Patent Act* requires a certificate of additional term to set out the number of the patent as recorded in the Patent Office, the duration of the additional term and any other prescribed information. It also requires the Commissioner to send the certificate to the patentee.

The CGPA has no substantive concerns about the information that should be included in the certificate of additional term. However, as will be described further below, the CGPA believes that it is imperative that the certificate of additional term, in addition to all other information about the application process, is made open and accessible to the public.

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(d) *Information CIPO should Convey to the Public Relating to Determinations of Additional Term*

ISED's Consultation Document suggests a two-step process for the determination of additional term, involving an initial review step prior to a comprehensive determination of additional term. If certain conditions to receive additional term are not met, the determination process would terminate and no further analysis would be completed.

The Consultation Document also suggests that following the initial determination of an additional term, there will be an observation period, where any person, including the patentee, may submit observations on the initial determinations. The Commissioner would consider those observations before making the required determination.

The CGPA believes that openness and transparency should be a cornerstone of Canada's PTA regime, and accordingly, supports both the two-step process for the determination of additional term and the observation period propose by ISED. However, the CGPA would like to re-iterate the importance of openness and transparency at *all stages* of the PTA process.

In particular, the CGPA notes that the amendments to the *Patent Act* presently provides two mechanisms to challenge an award of PTA: (1) pursuant to subsection 46.3(1), any person may apply to the Commissioner to reconsider the duration of additional term granted; and (2) pursuant to subsection 46.4(1), a person may bring an action in the Federal Court against a patentee for an order to shorten the duration of an additional term granted. In order for these challenge methods to be meaningful and effective, it is critical that all information relevant to the award of PTA be made publicly available.

To ensure that the PTA application process and any information relating to the determination of additional term is open and transparent, the CGPA submits that the Patent Office should maintain a register of granted and pending PTA applications in the same way that Health Canada maintains a Register of CSPs. This information should also be available on the Patent Office's website.

The information provided on the Patent Office's website should be as comprehensive as possible. Among other things, publicly available information should include:

- The detailed request by the patentee for PTA described above, which explains why the patentee did not contribute to any of the delay complained of;
- Any initial comments provided by the Patent Office at the first stage of the review process, prior to the observation phase;
- Any responding submissions made by the patentee or any other parties relating during the observation phase;
- Any comments from the Patent Office made in the second stage of the review process;

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- Any comments from the Commissioner relating to his or her decision to grant or decline a PTA; and
- The final certificate of additional term, if any.

(e) ***Export Exemption***

The proposed amendments currently do not include an export exception that would permit Canadian pharmaceutical companies to manufacture a product for export during the time that a PTA is in place.

Furthermore, because other major jurisdictions, such as the European Union, do not have a PTA system, the absence of an export exception would place Canadian pharmaceutical companies at a significant competitive disadvantage relative to their foreign competitors.

The proposed amendments to the *Patent Act* currently contemplate that PTAs will run *concurrently* with any existing CSP. This is an important provision, as it prevents the unnecessary duplication of extensions to patent terms (i.e., by permitting one extension to follow the other). If the CSP and PTA regimes are not aligned, circumstances may arise where third parties will be unable to utilize the CSP export exception due to a concurrently running PTA. This is inconsistent with the purpose and structure of the existing CSP export exception and accordingly undermines Parliament's intentions in designing the CSP regime.

Section 2: Miscellaneous Amendments to the Patent Rules

(a) What are your thoughts about the possible regulatory amendments discussed?

(i) *Deferred Examinations*

The CGPA does not support the regulatory amendments suggested by ISED for deferred examinations. It takes no position on the proposals regarding the suspension of examinations and priority requests.

The CGPA's belief is that allowing deferrals for examinations will create an undesirable lack of certainty for the public as it will be deprived of knowing the form of claims, if any, that will be granted for a given patent application. This will impact both product development and business decisions for CGPA's members as well as the public. Further, deferred examinations will add unnecessary complexity and bureaucracy to the examination process.

Although ISED's Consultation Document suggests some efforts to mitigate the potential adverse effect of such changes, such as a statement of intention to align the Canadian application to a corresponding application in a foreign jurisdiction when requesting a deferral, the CGPA is nonetheless concerned that this approach still raises significant concerns. For example:

1. The applicant may delay or defer prosecution of the foreign application which could amount to years of uncertainty for the Canadian public.

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2. The foreign application may be delayed by appeals (either through an equivalent mechanism to the PAB or by judicial review), which could amount to additional requests by the domestic applicant to defer prosecution. In addition, in such instances, the issue being determined on appeal might not be relevant to the Canadian application, given differences in law or the claims to be pursued.

3. The applicant may also face impracticalities if the patent unexpectedly issues first in a jurisdiction not identified as the corresponding application. If it is not possible to change the jurisdiction, both the applicant and the public could be harmed as the pendency of the Canadian application would be prolonged.

4. If multiple foreign applications can be designated, it is unclear whether there would be a requirement that the applicant has to request examination following the first allowance, or whether they could wait for the application with the most favourable claims.

5. With reference to the United States, it is unclear how a deferred examination would be affected by a continuation application. For example, if the parent application is abandoned in favour of a continuation, it is unclear whether the applicant would need to immediately request examination of the Canadian application, the deferral could be transferred, or whether a new deferral could be requested.

6. The effect of subsequently filed divisional applications on the initial designation is unclear. For example, if the initial designation is filed with broad, general claims, followed by the filing of one or more divisional applications with narrower claims that are prosecuted quickly, the pendency of the Canadian application could be prolonged while the parent foreign application is prosecuted.

In addition, although ISED's Consultation Document also suggests an ability for a third party to protest delay as another potential mitigation strategy, the benefit of this provision or how it would be implemented is unclear as the assessment of any protest could itself serve to create delay. As well, it is unclear whether the ability of an applicant to defer examination could co-exist with the ability of any person to request examination of an application under subsection 35(1) of the *Patent Act*. In particular, would a request for examination by the public override a request for deferment by the applicant, or, could the applicant override a request for examination by the public.

Further, the CGPA is concerned that there may be a burden placed on the requesting party to show that they will be harmed by the delay caused by the deferral. A consequence of this is that it will alert the applicant to potential competitors, which could have the effect of putting the requesting party at a commercial disadvantage as it may reveal early development plans or a new entrant to a market. Also, having knowledge of a party that wants an application examined quickly could lead to the opposite effect, where the applicant seeks to prolong prosecution by other means in order to maintain the uncertainty of patent scope for as long as possible.

While the CGPA recognizes that the recent reduction from a 5-year examination request deadline to a 4-year examination request deadline has resulted in less time for an applicant

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to obtain a final determination in another jurisdiction, the CGPA submits that the adverse consequences of creating a new deferred examination regime outweigh the benefits.

The change from a 5-year examination request deadline to a 4-year examination request deadline is relatively recent. As a result, the long-term effects of this change are not yet known. Accordingly, it is the CGPA's position that making additional changes to the examination request regime at this stage is at the very least premature.

Conclusion

Thank you for considering these submissions of the Canadian Generic Pharmaceutical Association and their importance in ensuring timely access to affordable medicines for Canadians. The CGPA looks forward to meeting with ISED and CIPO to discuss these submissions in greater detail.

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