

# Regulations Amending the Patent Rules and Certain Regulations made under the Patent Act

CANADIAN BAR ASSOCIATION INTELLECTUAL PROPERTY LAW SECTION

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#### PREFACE

The Canadian Bar Association is a national association representing 40,000 jurists, including lawyers, notaries, law teachers and students across Canada. The Association's primary objectives include improvement in the law and in the administration of justice.

This submission was prepared by the CBA Intellectual Property (IP) Section, with assistance from the Advocacy Department at the CBA office. The submission has been reviewed by the Policy Committee and approved as a public statement of the CBA Intellectual Property (IP) Section.

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# Regulations Amending the Patent Rules and Certain Regulations made under the Patent Act

#### I. INTRODUCTION

The Canadian Bar Association's Intellectual Property Section (CBA Section) is pleased to submit comments on the *Regulations Amending the Patent Rules and Certain Regulations made under the Patent Act* (Proposed Regulations).<sup>1</sup> The Proposed Regulations were published in *Canada Gazette*, Part I on May 18, 2024, for a 45-day period of consultation that closes on July 2, 2024.

In June of 2023, the federal government amended the *Patent Act* to introduce a framework for patent term adjustment (PTA) to compensate for unreasonable delays in patent issuance by the Canadian Intellectual Property Office (CIPO). The federal government agreed to implement a PTA regime by no later than January 1, 2025 under the Canada-United States-Mexico Agreement (CUSMA).<sup>2</sup>

The Proposed Regulations accompany changes made to the *Patent Act* by further specifying how PTA will operate and be administered. The proposed key regulatory changes involve amendments to the Patent Rules, with minor consequential amendments made to the *Patented Medicines (Notice of Compliance) Regulations, the Certificate of Supplementary Protection Regulations* and *the Patented Medicines Regulations*. The Proposed Regulations also make other amendments to the Patent Rules that are unrelated to PTA.

The CBA Section is focused on substantive changes proposed to the Patent Rules to further implement PTA. Overall, we are concerned that PTA is not implemented by the Proposed Regulations in a balanced manner consistent with Canada's CUSMA obligations to compensate patentees for unreasonable delays. These following key points are addressed in these comments:

- The PTA application procedure is onerous and expensive for applicants
- The third-party observation procedure is duplicative and improper

<sup>&</sup>lt;sup>1</sup> *Regulations Amending the Patent Rules and Certain Regulations made under the Patent Act, Canada Gazette, Part I, Vol. 158, No. 20, pp. 1247-1264.* 

 <sup>&</sup>lt;sup>2</sup> Canada-United States-Mexico Agreement (CUSMA) - Chapter 20 - Intellectual Property Rights, Article 20.44(3) (<u>link</u>).

- Depriving applicants of any reasonable response time implements a zerodelay policy that is contrary to Canada's PTA obligations under CUSMA
- Extensive subtracted periods will deny PTA to patentees who experience unreasonable delays
- PTA should compensate for significant disruptions at CIPO
- Subsection 117.3(8) requires further clarification
- Patentees should be charged proportional maintenance fees for additional term
- Other inequities in the *Patent Act* reinforce an overall restrictive approach
- Conclusion: changes to the Proposed Regulations are needed

# II. PTA APPLICATION ONEROUS AND EXPENSIVE

The Regulatory Impact Analysis Statement (RIAS) that accompanies the Proposed Regulations states that the purpose of the PTA regime is to "provide an additional term to compensate patent owners for unreasonable delays in the issuance of their patents."<sup>3</sup> However, the proposed amendments to the Patent Rules set out an expensive, and time-consuming application procedure for PTA, rather than have CIPO automatically determine PTA for patentees when warranted under the *Rules*.

As per proposed section 117.01, a patentee must apply in writing for the additional term and pay the prescribed fee within three months of the patent being issued. Proposed paragraph 41 of Schedule 2 lists the application fee as \$2,500 (\$1,000 for a small entity). The patentee must decide to take this step and pay this non-refundable fee in the absence of any PTA eligibility calculation from CIPO. After receiving an application, the Commissioner of Patents (Commissioner) will either dismiss the application for failing to meet the requirements set out in paragraphs 46.1(a) to (c) of the *Patent Act* or provide a notice of preliminary determination of the duration of the additional term. The patentee, or any other person, may then make observations regarding that preliminary determination within two months of the date of notice. The Commissioner will then issue either a certificate of additional term or dismiss the application. The entire PTA application process could take years. The "service standards" described in the RIAS, only require that CIPO make a "preliminary determination" within one year of filing the application for additional term. There is no service standard for rendering a final decision.

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Requiring patentees to undertake a lengthy and costly application process for PTA improperly shifts the burden from the party who caused the unreasonable delay (*i.e.*, CIPO) to the party suffering from the unreasonable delay. Determining whether any PTA is warranted should be a simple administrative bookkeeping exercise well within the purview of CIPO. The Proposed Regulations could have been drafted to require CIPO to make a preliminary PTA determination prior to requiring the patentee to file the PTA application. Instead, the Proposed Regulations require the patentee to determine, apply (and pay) CIPO to remedy its own unreasonable delay.

Additionally, the cost of the application fee will act as a deterrent. The fee to apply for a PTA (\$2,500/\$1,000) is much higher than most other fees paid during prosecution. For example, the cost of the proposed PTA application fee is greater than the sum of a patent filing fee, examination fee and issue fee (total \$2,081). This fee will discourage patentees from filing a PTA application, even if the patentee is entitled to an additional term.

Requiring a patentee to file an application in the manner proposed requires the patentee to evaluate not only whether PTA is warranted but also whether the patentee, in their particular circumstances, considers the potential additional term worth the cost of drafting an application in writing, paying the associated fee, and responding to the Commissioner's preliminary determination.

The CBA Section believes that requiring a patentee to make this kind of cost-benefit evaluation is contrary to the intended purpose of PTA and the Proposed Regulations to compensate patentees for unreasonable delays in the issuance of a patent.

#### III. THIRD-PARTY OBSERVATIONS DUPLICATIVE AND IMPROPER

As described above, the Proposed Regulations allow for third-party input ("observations") on the PTA term calculation prior to any PTA grant. The CBA Section questions why a third-party proceeding is necessary at the application phase, when sections 46.3 to 46.4 of the *Patent Act* already provide for third-party reconsideration. Notably, *any* party that pays the applicable fee can apply to have a PTA term shortened.

Third-party observation will only prolong what is already a complicated application procedure for the applicant. In accordance with its remedial objectives, the PTA application process should remain administrative in nature. Introducing yet another third-party dispute mechanism into the PTA process is duplicative of the procedures that are already available to third parties and contrary to the objectives of implementing a compensatory regime.

## IV. ZERO-DELAY POLICY CONTRARY TO PTA OBJECTIVES UNDER CUSMA

The CBA Section is mindful that Canada is required to implement a PTA regime to comply with its treaty obligations under CUSMA:

# Article 20.44: Patent Term Adjustment for Unreasonable Granting Authority Delays

1. Each Party shall make best efforts to process patent applications in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.

2. A Party may provide procedures for a patent applicant to request to expedite the examination of its patent application.

3. <u>If there are unreasonable delays in a Party's issuance of a patent, that Party shall</u> provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for those delays. [emphasis added]

4. For the purposes of this Article, an unreasonable delay at least shall include a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later. A Party may exclude, from the determination of those delays, periods of time that do not occur during the processing<sup>4</sup> of, or the examination of, the patent application by the granting authority; periods of time that are not directly attributable<sup>5</sup> to the granting authority; as well as periods of time that are attributable to the patent applicant.<sup>6</sup>

CUSMA Article 20.44 requires Parties to "compensate" patentees for "unreasonable delays" in patent issuance. This treaty language demonstrates that PTA has a remedial purpose. PTA should restore a patent term that is unjustifiably lost due to delays experienced during patent prosecution by CIPO.

The CBA Section is concerned that the PTA regime, as set out in the *Patent Act* and the Proposed Regulations fails to fulfill Canada's CUSMA obligation to restore lost patent term.

<sup>&</sup>lt;sup>4</sup> For the purposes of this paragraph, a Party may interpret processing to mean initial administrative processing and administrative processing at the time of grant.

<sup>&</sup>lt;sup>5</sup> A Party may treat delays "that are not directly attributable to the granting authority" as delays that are outside the direction or control of the granting authority.

<sup>&</sup>lt;sup>6</sup> Notwithstanding Article 20.10, this Article shall apply to all patent applications filed after the date of entry into force of this Agreement, or the date two years after the signing of this Agreement, whichever is later.

Although the CUSMA text permits parties to exclude certain periods from the determination of delay, including periods of time that are not directly attributable to the granting authority and periods of time that are attributable to the patent applicant – the Proposed Regulations extend beyond these permitted exemptions.

The Proposed Regulations define "unreasonable" delay in a complex and stringent manner that imposes considerable burden on applicants and their patent lawyers. Notably, paragraph 117.03(1)(z.09) of the Proposed Regulations stipulates that the PTA period is reduced by one day for each day the applicant takes to respond to any notice or requisition from the Commissioner or the Patent Office (e.g., patent examiner).<sup>7</sup> The applicant is consequently granted no allowance to respond to notices or requisitions from CIPO within a reasonable timeframe.

The Proposed Regulations effectively institute a policy of zero-delay, rather than accounting for instances of "unreasonable" delay. Implementing a zero-delay policy to respond to notices and requisitions from the patent examiner fails to recognize the practical challenges faced by applicants and patent lawyers, such as the need for thorough review, coordination amongst legal teams, and potential logistical challenges for international applicants that must contend with time zone differences.

This proposed practice will create needless pressure on patent lawyers to rush responses due to the substantial value potentially lost for each day a response is delayed. This heightened time pressure is impractical given the high-volume nature of patent prosecution practices. It also unjustly creates significant liability concerns for patent lawyers in a manner contrary to the fundamental principles of fairness and due process in patent prosecution.

Moreover, it cannot be that any notice under the *Patent Rules* or the *Patent Act* is never *directly attributable* to the Patent Office. Paragraph (z.09)'s broad brush approach is in stark contrast to the detailed periods described in the other paragraphs of subsection 117.03(1) (and addressed in the section directly below). Implementing this type of "catch-all" approach under paragraph (z.09) creates ambiguity and regulatory burden for applicants and their patent lawyers.

<sup>7</sup> 

Or the final day of the specified period, or the day on which the application is deemed abandoned if applicable, whichever is earlier.

The interpretation of "unreasonable delay" deserving of compensation in the Proposed Regulations is particularly harsh when compared to the corresponding PTA rules adopted by Canada's partners in CUSMA:

- Applicants in the U.S., under 35 U.S.C. § 154(b)(2)(c)(ii), for example, are afforded a three-month period to respond to a notice or an examiner's report before it is deemed an applicant-caused delay.
- Applicants in Mexico, under Articles 117 and 132 of the Laws for the Protection of Industrial Property (LPIP), are permitted two months to comply with or respond to requirements or requisitions from the Mexican patent office.

In contrast to the onerous terms imposed on the applicant, CIPO faces no obligations to ensure prompt action during patent prosecution. This is unlike the assurances provided by the U.S. Patent and Trademark Office outlined in 35 U.S.C. § 154(b)(1), which provides a "[g]uarantee of prompt patent and trademark office responses".

The patent application process dictated by the *Patent Act* and the Patent Rules requires applicants to take certain steps within a specified time. Therefore, an assessment of when that application process has been "unreasonably" delayed should account for the time that applicants reasonably need to respond to the patent examiner. Otherwise, providing applicants with no reasonable response time will likely counteract any actual unjustified CIPO delays and disentitle applicants to PTA.

The section that follows considers other proposed subtracted periods in more detail.

# V. EXTENSIVE SUBTRACTED PERIODS WILL DENY PTA TERM OWED TO PATENTEES

Subsection 117.03(1) sets out a list of no less than 38 categories of periods to subtract when calculating the duration of PTA term under subsection 46.1(4) of the *Patent Act*.

The stated purpose of section 117.03(1) in the RIAS is:

The proposed number of days to be subtracted includes days in periods that do not occur during the processing of, or the examination of, the patent application by CIPO, periods that are not directly attributable to CIPO as well as periods that are attributable to the patent applicant.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> RIAS, pp. 1252-1253.

However, even if the stated purpose of subsection 117.03(1) is fair and consistent with CUSMA in theory, subsection 117.03(1) as drafted does not achieve this purpose because some of the periods are in fact *directly attributable* to CIPO. In particular:

**Paragraph (w)** subtracts the time taken to appeal the Commissioner's refusal to grant a patent. This proposed deduction is particularly egregious as any successful appeal would only proceed by way of an erroneous decision by the Commissioner and would thus be *directly attributable* to CIPO. Delays owing to an appeal are also likely to be lengthy. These are precisely the types of delays that an effective PTA regime should remedy.

**Paragraph (z.1)** similarly subtracts the time taken to apply for judicial review of a decision of the Commissioner or the Patent Office. But in any case, where the application for judicial review is allowed, that time is *directly attributable* to CIPO: if CIPO had not erred, there would have been no application for judicial review.

**Paragraph (z.08)** subtracts time where a "notice was not sent to the applicant as a result of an error by the Patent Office". Even where the Patent Office has admitted it erred – such that any resulting delay is *directly attributable* to CIPO – that time can still be subtracted from the PTA term owing. Paragraph (z.08) also imposes an obligation on applicants to monitor "the records associated with the patent application on the website of the Canadian Intellectual Property Office" and to then alert the Patent Office that it has failed to send a notice.

The above paragraphs plainly contradict the stated purpose of subsection 117.03(1) set out in

the RIAS. In addition, other paragraphs in subsection 117.03(1) undermine the objective in

Article 20.44 of CUSMA of compensating patent owners for "unreasonable delays" in issuing a

patent. In particular:

**Paragraph (k)** subtracts the period from the "applicable day" (*e.g.*, the filing date for a regular Canadian application) and the day examination is requested. This period is subtracted regardless of whether additional term is calculated starting from the fifth anniversary of the applicable day or the third anniversary of the examination request. This undermines Article 20.44(4) of CUSMA – which requires compensation for unreasonable delays *after* examination is requested – by subtracting supposed delays that occurred *before* examination is requested. In concrete terms, for a regular Canadian application, if examination is requested four years after the filing date,<sup>9</sup> then the Patent Office will have seven years after examination is requested to issue the patent before any additional term can arise.

Paragraph (k) would appear to incentivize applicants to request examination as soon as possible. However, this may well result in much greater volumes of work – and greater delays – at the Patent Office. In Canada, patent applicants often delay requesting examination to make the examination process more efficient or to await resolutions in other jurisdictions: the applicant and the patent examiner can both benefit from the work carried out in and the outcomes reached in these other jurisdictions.

<sup>9</sup> Rules, paragraph 81(1)(a).

**Paragraphs (m), (n) and (o)** subtract the period from the date of a third Examiner's report until the final fee is paid, just prior to the patent granting. In effect, these paragraphs mean that the Patent Office is only accountable for the time taken to provide three examiner reports. CUSMA does not limit "unreasonable delay" to the first three examiner reports. These paragraphs allow examiners to take unreasonable positions or cause unreasonable delays without worrying about an additional term arising – so long as the first three reports are collectively issued within 36 months.

The CBA Section urges Canada to remove these sections from the Proposed Regulations to comply with its obligations under CUSMA.

#### VI. PTA SHOULD COMPENSATE FOR SIGNIFICANT DISRUPTIONS AT CIPO

Subsection 117.03(3) of the Proposed Regulations grants the Commissioner discretion to designate a day to be subtracted from PTA term if operations at the Patent Office are significantly disrupted for all or part of the day during ordinary business hours due to circumstances beyond the control of the Patent Office.

Subsection 117.03(3) does not contain any limitation as to the minimum length of time required for operations to be "significantly disrupted" for the day to be designated as a day to be subtracted. Additionally, there is no maximum time period of days that may be designated due to the same issue or disruption. Should there be a significant disruption to the operations at the Patent Office for an extended period, for example due to measures taken in response to another pandemic, months of time could be designated as being subtracted through no fault of the patentee.

Subsection 117.03(3) effectively deprives the patentee of an additional term that should be owing, despite the patentee having no control over the Patent Office and its operations. This reflects a dispiriting theme running throughout the Proposed Regulations: additional term is viewed as a "punishment" for CIPO, rather than as compensation for a patentee whose patent has issued late through no fault of its own.

A preferred means of providing discretion to the Commissioner would be to allow it to reconsider whether a day should be designated as a day to be subtracted, when that subtraction would unjustly shorten the PTA period.

#### VII. SUBSECTION 117.3(8) REQUIRES FURTHER CLARIFICATION

Proposed subsection 117.03(8) appears to lack purpose. The effect of subsection 117.03(8) – "not to include the days preceding the applicable day" in "the periods referred to in subsection (1)" – appears to be redundant with the effect of subsection 117.03(7), which is "not to include any day prior to the applicable day" in "[t]he periods referred to in subsection (1)". The two provisions are set out below in their entirety, with the potentially redundant clauses underlined:

Days not included

117.03(7) **The periods referred to in subsection (1) are deemed not to include any day prior to the applicable day** under subsection 46.1(2) of the Act or any day after the day on which the patent is issued.

Previous days not included

117.03(8) If the day that is five years after the applicable day under subsection 46.1(2) of the Act falls on a day before the day that is three years from the day that, in respect of the application for the patent, a request for examination has been made under section 35 of the Act in respect of the application for the patent, the prescribed fee referred to in subsection 35(1) of the Act has been paid and, if applicable, the prescribed late fee referred to in paragraph 35(3)(a) of the Act has been paid, without taking subsection 35(4) of the Act into account, **the periods referred to in subsection (1) are deemed not to include the days preceding the applicable day.** 

Subsection 117.03(8) might contribute to the overall scheme of the Proposed Regulations if the ending phrase "deemed not to include the days preceding the applicable day", were replaced with the phrase "deemed not to include the days preceding the day that the request for examination was made":

Previous days not included

117.03(8) If the day that is five years after the applicable day under subsection 46.1(2) of the Act falls on a day before the day that is three years from the day that, in respect of the application for the patent, a request for examination has been made under section 35 of the Act in respect of the application for the patent, the prescribed fee referred to in subsection 35(1) of the Act has been paid and, if applicable, the prescribed late fee referred to in paragraph 35(3)(a) of the Act has been paid, without taking subsection 35(4) of the Act into account, the periods referred to in subsection (1) are **deemed not to include the days preceding the applicable day deemed not to include the days preceding the applicable day deemed not to include the days preceding the day that the request for examination was made.** 

This revised provision would prevent the subsection 117.03(1) periods that occurred *before* the examination request (e.g., paragraph 117.03(1)(k) discussed above) from being subtracted when the additional term is calculated starting from the third anniversary of the examination request.

# VIII. PATENTEES SHOULD BE CHARGED PROPORTIONAL MAINTENANCE FEES FOR ADDITIONAL TERM

Section 46.2 of the *Patent Act* requires the payment of prescribed fees for the patentee to maintain the rights accorded by a patent during an additional term granted under section 46.1 of the *Patent Act*. Under the proposed section 117.05 and paragraph 42 of Schedule 2, these prescribed fees are annual maintenance fees of \$1,000 (\$400 for a small entity).

Annual maintenance fees are payable on Canadian patents and patent applications from the second through nineteenth anniversaries of the filing date. The further maintenance fees for the additional term will also fall due on successive anniversaries of the filing date. This presumably means that if PTA is granted for 400 days, maintenance fees would be due on the 20th and 21st anniversaries of the filing date, despite the patent only being in force for 35 days of the last year.

There is nothing in the Proposed Regulations that would permit adjusting maintenance fees to be proportional to the time that is remaining of the adjusted term. This means, depending on the additional term remaining, there may be a perverse incentive for patentees to allow their patents to expire to avoid paying an unjustly high annual maintenance fee for the last year.

## IX. OTHER INEQUITIES IN THE PTA REGIME REINFORCE AN OVERALL RESTRICTIVE APPROACH TO CALCULATING PTA

The CBA Section signals that the inequities addressed above in the Proposed Regulations are further magnified by Canada's overly restrictive implementation of the term adjustment regime to date under the *Patent Act.* 

## A. Concurrent term of PTA and Certificates of Supplementary Protection

In 2017, the *Patent Act* was amended to implement the Certificate of Supplementary Protection (CSP) regime to uphold Canada's commitment under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA). The CSP regime provides an additional maximum two-year period of patent-like protection for patented drugs containing a new medicinal ingredient. The CSP regime is intended to partly compensate pharmaceutical patentees for time spent in research and obtaining marketing authorization.<sup>10</sup>

Guidance document: Certificates of supplementary protection, Health Canada, 2023/12/20 (Link)

The CSP term commences upon the expiry of the original 20-year patent term. Like the CSP, subsection 46.1(3) of the *Patent Act* states that the additional PTA term also begins upon the expiry of the original 20-year patent term.

Despite their distinct compensatory purposes, the PTA and CSP terms nevertheless run concurrently. This concurrent timing undermines the intended purpose of the additional protection afforded to patents containing new medicines or combinations of medicinal ingredients, as it negates up to two years of any extra PTA term owing for eligible patents. Consequently, patents eligible for extensions under both the CSP and PTA regimes are deprived of an additional term where these terms overlap. This erodes incentives for innovation and undermines Canada's commitment to CETA, the framework that prompted the inception of the CSP.

Guidance should be gleaned from the system implemented in the U.S. Unlike Canada's PTA regime, in the U.S., time does not concurrently apply to Patent Term Extension (U.S. equivalent to CSP) and PTA for eligible patents (35 U.S.C. § 156(a)). They operate independently and do not overlap.

#### B. Reconsideration of PTA Duration by Commissioner or Federal Court

Subsections 46.3(2) and (4) of the *Patent Act* state that an application for reconsideration of the duration of the additional term granted under the PTA regime can be made on the Commissioner's own initiative or on application by "any person". The reconsideration can only shorten, but not lengthen the PTA period (see also section 117.11 of the Proposed Regulations).

In addition, section 46.4 of the *Patent Act* states that "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 under the PTA regime.

The *Patent Act* and Proposed Regulations do not provide any mechanism by which the applicant may apply to have the Commissioner reconsider the PTA duration. The absence of any such mechanism presents some significant issues:

• Upon receipt of the certificate of additional term or dismissal of the PTA application, and except by way of judicial review, applicants have no opportunity to contest or rectify errors or misjudgments in the calculation of the PTA duration, which could unjustly shorten the additional term;

- It may lead to an increase in judicial reviews and appeals, adding to the burden on applicants and patent lawyers, when PTA should be a remedial regime; and
- Without a formal process for reconsideration, decisions regarding PTA duration may lack consistency and transparency, which could lead to arbitrary or uneven application of the legislation, creating uncertainty in the patent system.

The combined effect of the *Patent Act* and Proposed Regulations will result in patent owners not being appropriately compensated for all unreasonable delays in the issuance of their patents.

## X. CONCLUSION

#### A. Changes to the Proposed Regulations are Needed

In closing, for all of the reasons described above, the CBA Section wishes to underscore that it has significant concerns with the federal government's proposed implementation of a PTA regime. The federal government should not take its treaty commitments lightly but should strive to implement a meaningful PTA regime that will serve the intended objective of restoring patent term lost to unreasonable delay.

The CBA Section suggests that the following changes be made to the Proposed Regulations to effect meaningful PTA for Canadian patentees:

- CIPO should provide applicants with a preliminary determination of PTA term *in advance* of requiring applicants to apply for PTA term. Alternatively, applicants should not be charged any PTA application fee, or should be charged a lower fee.
- CIPO service standards for rendering a preliminary PTA determination should be no longer than three months; a one-year service standard should apply to the final decision.
- There should be no third-party observation procedure at the PTA application stage.
- Applicants should be provided with a reasonable response time in accordance with the time-periods already stipulated by the *Patent Act/Rules* (excluding extensions). This response period should not be subtracted from any PTA term owing.
- CIPO should revisit CUSMA compliance in light of the extensive subtracted periods being proposed. Delays directly attributable to CIPO, including successful appeal periods, should not be subtracted. PTA should also compensate for significant disruptions at CIPO.
- Subsection 117.3(8) requires further clarification.

• The maintenance fee regime must be adjusted according to the term gained.

The CBA Section extends its thanks to CIPO for considering this submission and urges CIPO to carefully consider the proposed changes outlined above before finalizing *Canada Gazette, Part II.*