Update on forthcoming patent term adjustment in Canada

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Patent term adjustment (PTA) is coming to Canada on or before January 1, 2025. Canada is required to implement PTA to offset administrative delay in granting patents under the terms of the Canada-U.S.-Mexico Agreement (CUSMA). Proposed amendments to Canada's *Patent Rules* have been published for a public consultation that ends on July 4, 2024. The amendments accompany changes to the *Patent Act* effected by Bill C-47, which received royal assent last year.

Patents filed on or after December 1, 2020 are potentially eligible for additional term. Thus, prosecution decisions made in the last three and a half years could impact PTA term and eligibility.

Final details of the new system of PTA will only be known once the amendments to the *Patent Rules* are published in their final form. An overview of key features as proposed for consultation is provided below.

Timing and fees for an application for PTA

The patentee must submit a request for PTA with the applicable fee within three months of the date of grant of the patent. The fee is C$2,500 (C$1,000 for small entities).

Eligibility for PTA

A patent application will be eligible for PTA if the underlying application was filed on or after December 1, 2020. For PTA to be available, the patent must be granted after the later of:

- five years from the date of national phase entry date (for a PCT application), the presentation date (for a divisional application), or filing date (for other applications), and
- three years from examination request date.

The timing requirements for the application for PTA must also be met.

Duration of PTA

The term of PTA is calculated from a start date, which is the later of the two dates indicated above, to the date of issuance, minus “days to be subtracted” which will be defined in the amended *Patent Rules*. There are 38 categories of days to be subtracted, making the calculation potentially onerous.

Briefly, these subtracted days include:

- the period from the date of national phase entry (for a PCT application), the presentation date (for a divisional application), or filing date (for other applications) to the date of the examination request;
- the period commencing on the mailing date of notices and requisitions issued by CIPO (*e.g.*, office actions, late fee notices, notices of allowance, and conditional notices of allowance) and ending on the date of responsive action or abandonment;
- any days of extension granted by the Commissioner;
- any days the patent is in abandonment;
- the period initiated by a request for continued examination (RCE) and ending on the date that the final fee is paid;
- if the RCE regime does not apply, the period beginning on the date of issuance of the third office action and ending on the date that the final fee is paid;
- the period beginning on the date of an examiner interview in which the applicant agrees to consider making amendments and ending on the date of the written submission; and
- days designated by the Canadian Intellectual Property Office (CIPO).

Days that fall in more than one category are counted only once.

If the days to be subtracted result in a negative value, such that the term would end before the start date, then the number of days of PTA is considered to be zero.

Unlike the U.S. system of PTA, which permits three months following the mailing date of an office action before patent term is reduced, the proposed Canadian system will subtract days of PTA commencing on the mailing date of a CIPO requisition.

Certificate of PTA

Following an application for PTA, CIPO will issue a notice containing a preliminary determination of the duration of the adjusted term. The patentee and any other party may then submit observations within two months prior to issuance of a certificate of PTA or dismissal notice.

The period of PTA will run concurrently with patent term restored under Canada's Certificate of Supplementary Protection (CSP) regime, which addresses delays in obtaining marketing authorization.

Maintenance of PTA

To maintain the rights accorded by PTA, the patentee will be required to pay an annual maintenance fee on the anniversary of the filing date. This fee is currently set at C$1000 (C$400 for small entities) for each of the 20th and subsequent anniversaries.

Obligations under PTA

If a patent is listed on the Patent Register under Canada's linkage regime (the *Patented Medicines (Notice of Compliance Regulations* or *NOC Regulations*), the Minister of Health must be informed of the new expiry date of any PTA granted in respect of the patent.

Likewise, the patentee is obligated to report the new expiry date pursuant to a grant of PTA to the Patented Medicines Prices Review Board (PMPRB) within 30 days. The PMPRB's jurisdiction over pricing will apply to the adjusted term.

Summary

Given the retroactive nature of the system once it comes into force, applicants should immediately start considering these provisions during prosecution.

It seems likely that key details of the "days to be subtracted" will survive public consultation. This is because CUSMA states that periods of time attributable to the patent applicant can be subtracted the adjusted patent term. It can therefore be expected that well-known flexibilities of the Canadian patent system, such as deferred examination and "as of right" reinstatement within one year of a missed office action deadline, will count against PTA. Timely action following receipt of a notice or requisition will be important to minimize impact on PTA.

That said, it appears that PTA will rarely be available under CIPO's current client service standards for patents. Thus, the reduction to an unlikely PTA caused by deferring Canadian examination will have to be balanced against the advantages of keeping Canadian applications on the back burner as foreign examination proceeds.

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