

Patent term adjustment in Canada: More of a unicorn than a safety net

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The legislation to implement Canada's new system of Patent Term Adjustment (PTA) has been registered with the Privy Counsel and has published. The system will come into effect on January 1, 2025. Canada is required to implement PTA in 2025 to offset administrative delay in granting patents under the terms of the Canada-U.S.-Mexico Agreement (CUSMA). Draft amendments to Canada's Patent Rules were published earlier in the year.

The final legislation contains few changes of substance, meaning that additional term will not be available for the vast majority of patents.

Eligibility for PTA

A patent will be eligible for PTA if the underlying application was filed on or after December 1, 2020 and if the patent is granted after the later of:

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

These timing requirements mean that no patent granted prior to December 2, 2025 can be eligible 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).

Duration of PTA

The duration of the adjustment is calculated from a start date, which is the later of the bulleted dates listed above, up to the date of grant of the patent, minus "days to be subtracted". There are 38 categories of days to be subtracted. This makes the calculation of PTA extremely onerous, in particular because not all information required



for the calculation is straightforwardly presented on the Canadian Patents Database (CPD).

These days to be subtracted include, for example:

- days of deferred examination, i.e., the period from the date of national phase entry (for a PCT application), the filing date (for a non-PCT application), or the presentation date (for a divisional application) up 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) up to the date of the responsive action or fee payment effectively all of the time that prosecution in the hands of the applicant (despite the timelines permitted for response);
- days of extension;
- days of abandonment;
- the period initiated by a request for continued examination (RCE), or, if the RCE regime does not apply, the period beginning on the mailing date of a third office action and ending on the date that the final fee is paid; and
- 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.

Days that fall in more than one category are counted only once. If the days to be subtracted result in a negative value then the term of PTA is considered to be zero days.

However, days to be subtracted that fall prior to the examination request are not counted if the date of the examination request is more than two years from the date of national phase entry date (for a PCT application), the filing date (for a non-PCT application), or the presentation date (for a divisional application). Accordingly, it may be desirable to delay requesting examination, such as requesting examination closer to the deadline, in order to give CIPO the shortest period of examination time.

PTA will rarely apply

The days to be subtracted effectively mean that an examiner will always have a minimum of three years with the application on their desk to issue a notice of allowance or a third Office Action. An applicant in Canada, therefore, has little influence over the PTA calculation because there is no way to decrease the applicable basic examination period below three years with timely action. Even with the <u>unprecedent delays</u> at CIPO at the time of writing, it is unlikely that examiners will need more than three years of cumulative time to consider an application and reach allowance or a third Office Action.

Issuance and maintenance 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.



If the patent has been granted a Certificate of Supplementary Protection (CSP), the period of PTA will run concurrently with patent term restored under the CSP regime. This regime applies to certain types of patents for pharmaceutical and biotechnology inventions, and addresses delays in obtaining marketing authorization.

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\$1,000 (C\$400 for small entities) for each of the 20th and subsequent anniversaries.

Obligations and benefits under PTA for pharmaceutical and biotechnology inventions

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 expiry date of any PTA term granted in respect of the patent.

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

Other miscellaneous changes to the Patent Rules

Loss of expedited examination status

Under the revisions to the Patent Rules, once an RCE has been made, an application will no longer be entitled to expedited examination status. This does not apply to RCEs made prior to January 1, 2025, nor to applications with fast-track status under the Patent Prosecution Highway.

Corrective mechanism to avoid excess claims fees

The legislation also provides a corrective mechanism to remove claims inadvertently added during examination, and thereby avoid excess claims fees. This requires the applicant to file a statement confirming the amendment was made in error along with amendments to remove the claims. The submission must be made without undue delay and correction is at the discretion of the Commissioner of Patents.

Summary

PTA will only be available in rare circumstances of outstanding delay at CIPO, due the lengthy time period allocated to CIPO for examination and the fact that action by the applicant does not affect the basic three-year examination time period available to the Examiner.

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