Canada: Review of recent and upcoming changes to Patent Law

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Introduction

Intellectual Property (IP) is a key component of an innovation economy and the Canadian government has recently recognized the importance of IP with the recent launch of an IP strategy[1]. As a part of the growing internationalization of the field of IP, Canada has also acceded to a series of international conventions and agreements bringing changes to the Canadian patent law . This article provides a review of the most important changes already in force or in the makings.

First discussed in this article, the *Canada-European Union Comprehensive Economic and Trade Agreement* (CETA) introduced in 2017 an extension of the protection of pharmaceutical products in the form of Certificates of Supplementary Protection (CSP) and radically changed the regime for pharmaceutical patent litigation. The second section of this article covers the implementation of the *Patent Law Treaty*, the goals of which will lead to simplified and harmonized administrative practices with regards to patent applications. The recent *Canada-United States-Mexico Agreement* (CUSMA) not only affects the national treatment and market access for goods, it also features important changes relating to patents in general and patented biological, and pharmaceutical products. Finally, Canada is also contemplating a new series of changes as proposed on October 30, 2018 in the *Budget Implementation Act, 2018, No. 2*., to better protect intellectual property and promote of innovation in Canada.

Changes associated with the Canada-European Union Comprehensive Economic and Trade Agreement

The Canada-European Union Comprehensive Economic and Trade Agreement (CETA) is in force since September 21, 2017. This agreement offers a new patent term extension for pharmaceuticals in the form of CSP. The CSP will act as the only form of patent term extension or restoration available. A maximum extension of 2 years is instituted to account for delays in regulatory approval with respect to the making, constructing, using and selling of any drug that contains a medicinal ingredient, or combination of medicinal ingredients, by itself or in addition to any other medicinal ingredient.

The regime requires the filing of an application for marketing approval in Canada within 12 months of submission of the first marketing authorization application in the

1. See press release issued in the Innovation, Science and Economic Development Canada on April 26, 2018.

United States, Japan, Switzerland, Australia and any country of the European Union. With such a timeline, we recommend adjusting any regulatory approval plans for Canada in order to benefit from CSP.

CETA has also introduced a new regime for pharmaceutical patent litigation, replacing the regime that has been in place for the past 25 years. Full rights of action, including effective rights of appeal to all litigants, accompanying procedural guarantees and discovery obligations replace summary proceedings. This new regime is intended to end the practice of dual litigation whereby an innovator would seek an order from the Federal Court to prevent the Minister of Health from issuing a marketing authorization to a second person under summary proceedings and subsequently introducing a full patent infringement action.

Changes associated with the Patent Law Treaty

The Patent Law Treaty (PLT) is a treaty administered by the World Intellectual Property Organization. Done in Geneva on June 1st 2000, 40 countries have already ratified the PLT including several of Canada's main trading partners such as the United States, France, the United Kingdom and Japan. The clear ambition of the PLT is to simplify and harmonize a number of administrative practices with regards to the formalities of patent applications.

On June 22, 2019, Canada was finally authorized to ratify the TDB. The changes proposed for the implementation of the PLT to the Patent Act and Patent Rules will come into force on October 30, 2019.

A series of obligations will be softened and procedures standardised. For instance, the requirements to obtain a filing date will be reduced. Payment of the filing fee and translation into English or French will be deferred. Subsequent addition of a specification or drawing(s) will be permitted within two months of filing if added content is present in the priority document. It will be possible to make a claim for restoration of priority for an earlier application filed up to 14 months before a Canadian or Patent Cooperation Treaty (PCT) filing date.

Applicants should be aware that the term for a national phase entry will be reduced in certain circumstances. Particularly, the current 42-month period that is available conditional on payment of a small late fee will be limited to only 30 months, unless unintentional and justified delay is proven. The Patent Office will be required to provide notice that deadlines, such as payments or requests of examination, have been missed before an application is abandoned or expired. The Commissioner of Patents will also have new powers to provide extensions of time limits in exceptional circumstances, such as in severe illness, accident, death, bankruptcy or other serious and unforeseen circumstances.

With regards to reinstatement of abandoned cases, more stringent conditions will be instituted. Where reinstatement was possible within a 12-month period as of right, a due care standard will need to be proven[2]. For reinstatements 6 months after the due date, the applicant will need to state reasons for the failure, in spite of due care.

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2. For this standard, the Commissioner will assess whether the applicant took all measures that a reasonably prudent applicant / patentee would have taken - given the particular set of circumstances related to the failure- to avoid the failure, and despite taking those measures, the failure occurred.

In line with the effort of standardisation and simplification, the payment of the maintenance fee will be liberalized. Whereas only Patent Agents could pay for pending patent applications, annuity services will be allowed to pay for both issued patents and pending applications.

Finally, a new infringement exception will be established for infringements made during a prescribed period where the patent application was abandoned because the applicant missed a deadline, such as the deadline for paying an annuity or for requesting examination.

Changes associated with the Canada-United States-Mexico Agreement

The Canada-United States-Mexico Agreement (CUSMA) was signed on October 1, 2018 to replace the *North America Trade Agreement* (NAFTA). This agreement is important for patent stakeholders because it features important changes relating to patents in general and patented biological pharmaceutical products. Providing its ratification by all parties, it should be in force in January 2020[3].

The main changes this new treaty brings to IP are: an extended 10-year period of data protection for biologics; a patent-term restoration system; and increased protection for industrial designs.

The new decade-long data protection for biologics

Currently, 8 years of data protection is provided for innovative drugs, i.e. "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister". Exclusions include minor variations such as salts, esters, enantiomers, solvates or polymorphs. Only one term of protection is granted for any given medicinal ingredient not previously approved in a drug in Canada. It is not available for drugs containing a combination of medicinal ingredients which have previously been approved in Canada.

The 8 years of protection include a no-filing period of six years during which generic manufacturers are not authorized to file a submission with the Minister. There is also a no-marketing period of two years during which the Minister will not grant a Notice Of Compliance (NOC) to generic manufacturers. There is an exception providing for an additional six months protection period for pediatric studies granting exclusivity for new drugs which have been the subject of clinical trials for children.

Under CUSMA, the data protection period is extended to ten years. However, this longer term is granted only to new pharmaceutical products that are biologics or contain biologics. While there is no definition of biologics, the treaty provides for the protection of "at a minimum, a product that is produced using biotechnology processes and that is, or, alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein,

3. Ratification is still uncertain. The Democratic-led U.S. House of Representatives may still refuse to sign off on the agreement. In addition, both Canada and Mexico have delayed ratification because of the U.S. tariffs on global metal imports imposed last year. Since the U.S. administration recently lifted these tariffs, the Canadian government has been the first to react by introducing on May 29, 2019 Bill C-100 in order to implement the agreement.

or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition".

The date of entry into force of the new decade-long data protection for biologics is yet unknown as Canada has five years to fully implement this provision after the date CUSMA comes into force .

New Patent-term restoration system

The USMCA also aims to introduce a patent Term Restoration (PTR) system that will apply to all patents, generally to compensate for delays in the issuance of a patent caused by the Patent Office[4]. Namely, a period longer than five years from the filing date or more than three years after a request for examination will be compensated. However, any lateness attributable to the applicant will be excluded. This prolongation is additional to any CSP that are available for pharmaceutical patents.

Implementation of the PTR system should be carried out 4.5 years after the date that CUSMA comes into force and encompasses all patents filed after the date of entry into force of the treaty or two years after its signing date, whichever is later for that party[5].

Increased protection for industrial designs

For industrial designs, the CUSMA includes the incorporation of a one-year grace period and a minimum standard of 15 years of protection. This extension has already been implemented in Canada by the new legislation in force since November 2018 as part of Canada's accession to the *Hague Agreement*[6].

Changes proposed on October 30, 2018

In the context of the national IP strategy aiming at better protection of intellectual property and promotion of innovation in Canada, amendments to the *Patent Act* were proposed by the government on October 30, 2018 as part of the *Budget Implementation Act, 2018, No. 2*. The final adoption of the proposed measures has not yet been set and may take 12 to 24 months since it will require the adoption of implementing regulations. The amendments namely propose four significant changes to Canadian patent law[7].

Firstly, the act creates a rule of "file wrapper estoppel" which will hold the applicant to representations made during the patent application process. This change will thus harmonises Canada's practice with the existing U.S. practice. Accordingly, statements made by an applicant during prosecution of a patent application will become admissible evidence of claim construction and could be used to rebut any representation made by the patentee during litigation.

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4. The PTR will be somewhat similar to the Patent Term Adjustment (PTA) that is currently available in the U.S. for USPTO delays.
5. Accordingly, the date will be October 1st 2020, unless the agreement comes into force only after that date. If such a delay occurs the PTR will thus apply to patents filed after the date the agreement comes into force.
6. Details about the Hague Agreement and the changes made to the *Industrial Design Act* can be found here.
7. These changes have been presented in more details in one of Fasken's previous bulletin

Secondly, a regulatory framework for all patent demand letters will be introduced to regulate the increasing number of demand letters alleging infringement sent by non-practicing entities sometimes referred to as “patent-trolls”. This regime will apply to anyone sending a demand letter to a Canadian resident or entity, irrespective of whether it alleges infringement of a Canadian or foreign patent. Recipients of improper letters will be entitled to seek relief before the Federal Court.

Thirdly, the current safe-harbour exceptions to infringement for so-called “regulatory use” such as drug approval and non-commercial experimental use, will be extended to any type of experimentation. This will encompass any “act for the purposes of experimentation related to the subject matter of a patent”. Courts will have the authority to determine whether an act amounts to experimentation or not.

And finally, the current non-infringement exception for prior users, applying to use before the claim date and limited to physical objects, will be broadened to use prior to the date of publication of the patent and encompass a wider range of activities, including services, resales and use after an initial transfer. However, this extension of the prior user right exception will include the requirements for users to not have relied on information knowingly obtained from the patentee.

Conclusion

As a part of the growing internationalization of the field of IP, the Canadian government has taken measures to improve the patent law and to simplify and harmonize its practices .

With the many actual and upcoming changes , we recommend readers to take into account the changes in the development and implementation of their IP strategy, the CSP for drugs and the restoration of patent term for a maximum of 2 years. In the next few years, readers should particularly consider the new CSP available for drugs and keep an eye on the extended ten-year period of data protection for biologics, the new patent term restoration scheme for Patent Office delays and the file wrapper estoppel which are yet to be introduced.

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