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Major Changes to Canada's Intellectual Property and Patent Landscape with the Implementation of CETA

A. Chandimal Nicholas

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September 21, 2017 marks the provisional entering into force of the *Comprehensive Economic and Trade Agreement* ("CETA") between Canada and the European Union, and concurrently the coming into force of Bill C-30, the Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act (the "CETA Implementation Act"), an act which implements Canada's obligations under *CETA*.

The implementation of *CETA* brings a number of amendments to Canadian laws and regulations, with notable changes to Canada's intellectual property ("IP") and patent regime as it relates to the pharmaceutical industry. This article highlights a number of key changes to Canada's IP and patent regime which have been brought about by *CETA* and the *CETA Implementation Act*.

1. Implementation of a Certificate of Supplementary Protection Regime

One of the key changes brought about by the *CETA Implementation Act* is the amendment of the *Patent Act*, in conjunction with the introduction of Certificate of Supplementary Protection Regulations (the "CSP Regulations"), to introduce a framework for the issuance and administration of a certificate of supplementary protection ("CSP") for certain eligible human and veterinary drugs. The implementation of a CSP system is intended not only to harmonize the Canadian and European patent regimes, but is a response to the reality for many pharmaceutical patent holders that with long regulatory approval processes, patent protection often expires shortly after a drug is approved for market.

The new CSP system provides an additional period of patent-like protection for patentees after the date of expiry of certain eligible pharmaceutical patents. Eligibility for a CSP is subject to the satisfaction of a number of conditions including, but not limited to:

- the filing of an application and payment of a fee in accordance with the law and regulations;
- the requirement that the patent pertains to a medicinal ingredient or combination of medicinal ingredients contained in a drug for which an authorization for sale of the prescribed kind was issued on or after the day on which the regime comes into force;
- the requirement that the patent is not void and otherwise meets all of the necessary requirements; and
- that no other CSP has been issued for the particular medicinal ingredient or combination of medicinal ingredients, as applicable.

Under the new regime, the CSP takes effect upon the expiry of the patent. The term of the CSP is calculated by taking the difference between the date of the filing of the application for the patent and the date of issuance of the authorization for sale, reduced by five years, and capped at two years.

2. Overhaul of the Patented Medicines (Notice of Compliance) Regulations

As part of Canada's obligations under *CETA*, Canada has amended its *Patented Medicines (Notice of Compliance) Regulations* (the "PMNOC Regulations") to streamline and clarify the process by which patent infringement and validity disputes under the *PMNOC Regulations* are resolved.

The *PMNOC Regulations* create a patent linkage regime, tying regulatory approval of generic medicines to the protection of patent rights. The previous *PMNOC Regulations* enabled a summary legal proceedings process that allowed patent holders to commence legal proceedings for an order prohibiting the granting of regulatory approval for a generic version of the patented medicine. While this process was intended to balance patent protection with timely access to generic medicines, there were a number of concerns with the summary proceedings process, including concerns that the process did not allow for full consideration of patent issues, that the lack of ability of patent holders to appeal under the *PMNOC Regulations* led to the commencement of further litigation under the *Patent Act*, and concerns regarding lack of legal certainty prior to generic market entry (see here for additional background).

The amended *PMNOC Regulations* implement Canada's obligations under *CETA* to ensure that "all litigants are afforded equivalent and effective rights of appeal" (*CETA*, Article 20.28) under Canada's patent linkage regime. Accordingly, the *PMNOC Regulations* enable full actions (rather than summary proceedings) that allow for discoveries to be conducted, live witnesses to be examined, a full and final determination of the validity of the patent(s) at issue and provide a right of appeal to all litigants. Thus, the *PMNOC Regulations* relieve certain evidentiary constraints related to the previous summary proceedings process, lay out a number of procedural rules related to actions, and also address the assessment of damages arising from delayed market entry.

3. Amendment of the Patent Rules

In addition to the amendments to the *Patent Act*, the *CSP Regulations*, and the overhaul of the *PMNOC Regulations*, certain housekeeping amendments made to the *Patent Rules* came into force on September 21, 2017 which removed references to "representatives" in the *Patent Rules* in order to make the *Patent Rules* consistent with the newly amended *Patent Act*. The *CETA Implementation Act* repeals section 29 of the *Patent Act* in order to accommodate the introduction of the CSP regime and avoid consequential amendments to the *Patent Act* that would be necessary because of section 29.

For additional guidance and specific advice on *CETA* and the amendments to Canada's IP and patent regime, please contact Chandimal Nicholas.

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