The Canada-European Union Comprehensive Economic and Trade Agreement (CETA) is coming into force today!

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It is today, September 21st 2017, that Bill C-30 [1] comes into force. As a result of its provisions, several Canadian laws are amended in order to allow for implementation of the *Canada–European Union Comprehensive Economic and Trade Agreement* "CETA" [2].

Chapter 20 of the CETA deals with the commitments made by signatories in relation to intellectual property rights. Here is a summary of the principal changes brought to the legislative schemes governing these rights:

Trade-marks

Expressions that depict the place of origin of goods are not registrable as trade-marks under the *Trade-marks Act* [3]. Only the designation of wines and spirits by Geographical Indications "GIs" can be protected under this act [4]. CETA broadens the protection to more than 170 GIs, which are listed under Annex 20-A of the agreement.

From this day forward, in Canada, it is prohibited to use a GI in association with a product if it does not originate from the territory specified in Annex 20-A, or if it does originate from the specified territory but was not produced in accordance with the laws and regulations governing the specified territory. Subject to certain exceptions provided by law, the use of terms such as "kind", "type", "style" or "imitation" in combination with a listed GI is also prohibited.

These prohibitions will undoubtedly prompt changes in advertising, packaging and procurement of

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food-related products sold in Canada. Therefore, agri-food companies can benefit from a better understanding of their rights in relation to the use of GIs and should consider taking concrete actions in response to imminent competition. Our previous newsletter provides a series of recommendations to that effect.

Patents

The legal regime governing patent protection of innovative drugs and marketing of generic equivalents has been considerably modified in order for Canada to meet its CETA undertakings. A more detailed analysis of the new provisions will be published shortly; however it is relevant to summarize their substance as follows:

– Patent Term Extension

In order to compensate for time spent in research and obtaining marketing authorization [5], that is, a Notice of Compliance "NOC", Canada's Minister of Health is now authorized to issue a certificate of supplementary protection "CSP" to patentees with patents relating to new human and veterinary drugs. The term "new" refers to a drug containing active ingredients that have not been previously approved in a NOC.

A CSP confers the exclusive right to prevent the manufacture, use or sale of the patented drug. The CSP is also subject, like a patent, to a validity challenge.

Capped at a maximum of 2 years, the precise term of a CSP is set to be the difference between the date of the filing of the patent application and the date of issuance of the authorization for sale (NOC), minus five years. The Minister of Health can reduce this calculated term taking into account delays caused by the NOC applicant.

A single CSP may be requested for a product, even though the product may be protected by more than one patent. The term of protection takes effect upon the expiry of the basic patent and, in cases where several patentees hold a patent protecting their respective products, at the expiration of the patent of the holder who files the application for additional protection. Other conditions apply.

– Equal Rights of Appeal and the End of "Dual Litigation"

In Canada, the right of a pharmaceutical company to market a generic version of a patented drug product is conditional upon obtaining a NOC issued by Health Canada certifying the bioequivalence of the generic product.

Before proceeding with the sale of a generic version of a brand name drug, the generic company must provide the manufacturer of the brand name drug with a notice of allegation indicating "NOA": that it accepts that the generic product will not be sold before the patent expires, or that the patent is invalid, or that the generic company does not infringe any patent claim relating to the medicinal ingredient, the formulation, the dosage form or the use of the medicinal form.

Until now, the brand manufacturer could respond to the NOA by initiating a summary court proceeding to obtain a prohibition order preventing Health Canada from issuing a NOC to the generic manufacturer. If the Court application was rejected, the brand manufacturer could theoretically appeal the decision to higher Court. However, the appeals were generally rejected as rendered moot by the issuance of a NOC by Health Canada immediately after the first Court decision. Although the allegations of patent invalidity and infringement were examined by the Court in the proceedings described above, the decisions on these matters were not final. Consequently, the same parties could engage in an infringement or invalidity action, in parallel or subsequently, to debate the allegations. By ratifying the CETA, Canada committed to ensuring that the

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pharmaceutical linkage mechanism provides all litigants with equivalent rights of appeal. Accordingly, the *Patented Medicines (Notice of Compliance) Regulations* [6] were amended to allow the Court to grant an injunction against a generic company to stop acts of counterfeiting. This remedy can now be ordered despite the issuance of a NOC by Health Canada. The amended *Regulations* also replace the summary procedure described above by a complete action enabling the Court to rule definitively on issues of invalidity and infringement. This new framework will limit the parties from engaging in parallel actions on the same issues, thus reducing the risk of conflicting judgments.

Copyrights

The *Copyright Act* [7] has been amended in 2012 to reflect the standards established by the *World Intellectual Property Organization* [8]. No further modifications were required to ensure Canada's compliance with the CETA's requirements.

Industrial Design

Under the CETA, Canada has committed to make all reasonable efforts to accede to the *Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs*. Although the Hague System is not yet in force in Canada, many amendments have already been made to the *Industrial Design Act* [9] and proposed industrial design regulations have been drafted [10] to facilitate Canada's adherence to the Hague System.

Plant Varieties

By ratifying the CETA, Canada has committed to cooperating with the European Union countries to promote and strengthen plant variety protections on the basis of the 1991 Act of the *International Convention for the Protection of New Varieties of Plants*. Canadian legislation has not been affected by this commitment.

1. *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act,* L.C. 2017, c. 6.
2. The complete text of the CETA, online: http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng.
3. *Trade-marks Act*, R.S.C., 1985, c. T-13, section 12(1)b).
4. *Trade-marks Act, supra* note 3, section 2.
5. Government of Canada, « REGULATORY IMPACT ANALYSIS STATEMENT», *Canada Gazette,* Vol. 151, no 28, July 15, 2017, available online : http://www.gazette.gc.ca/rp-pr/p1/2017/2017-07-15/html/reg16-eng.php.
6. DORS/93-133.
7. R.S.C., 1985, c. C-42.
8. *WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty*.
9. R.S.C., 1985, c. I-9
10. Government of Canada, «Proposed Industrial Design Regulations draft», online : http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04255.html.

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