NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Canada signs on to CETA and proposes amendments to the *Patent Act* affecting pharmaceuticals

Treaty/Act: CETA/Bill C-30 (*An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures*)

Date: October 30, 2016 CETA signed / October 31, 2016 Bill C-30 First Reading

Summary

On October 30, 2016, Canadian and European Union (**EU**) leaders signed the Comprehensive Economic and Trade Agreement (**CETA**), capping a seven-year negotiation process. On October 31, 2016, the Canadian government tabled Bill C-30 (First Reading), which is intended to implement CETA into Canadian law. Bill C-30 provides for certificates of supplementary protection for patents relating to pharmaceutical products (i.e., patent term restoration) and for proceedings under the *PM(NOC) Regulations* to proceed as full actions that will result in final determinations of patent infringement and validity. It appears that the detailed operation of both reforms will be addressed later by way of regulation.

Background

As we previously reported, CETA provides certain key reforms affecting the pharmaceutical industry, including:

- Patent term restoration capped at a maximum of two years for eligible "basic patents" covering eligible "products" that possess the first marketing authorization placing the medicinal ingredient on the market; and
- Equal access to effective appeal rights in court proceedings under the *Patented Medicines (Notice of Compliance) Regulations* (***PM(NOC) Regulations***).

Outside of the CETA text, in the context of providing effective appeal rights, Canada also indicated that it intended to "end the practice of dual litigation"[1] whereby decisions in proceedings under the *PM(NOC) Regulations* do not presently prevent parties from subsequently pursuing patent infringement/invalidity remedies under the *Patent Act*.

Changes to proceedings under the *PM(NOC) Regulations*

Bill C-30 will amend the *Patent Act* to provide further regulation-making authority under section 55.2(4) to permit the replacement of the current summary proceedings under the *PM(NOC) Regulations* with full actions resulting in a final determination of patent infringement and validity. Bill C-30 further provides that the *PM(NOC) Regulations* may be amended to include regulations regarding the conduct of such actions, including the decisions and orders the court may make and any appeals from those decisions and orders.

Patent term restoration

Bill C-30 introduces supplementary protection for inventions (also known as patent term restoration or patent term extension) into Canadian law by creating "certificates of supplementary protection" (**CSP**). Highlights of the CSP regime in Bill C-30 are discussed below.

Eligible Medicinal Ingredients

Medicinal ingredients or combinations of medicinal ingredients in drugs for human use are "different medicinal ingredients" than when approved for veterinary uses.

"Prescribed variations" of medicinal ingredients will be treated as the "same medicinal ingredient." What constitutes a "prescribed variation" has yet to be defined.

Combinations of medicinal ingredients that only differ with respect to a variation in the ratio between those ingredients will be treated as the "same combination of medicinal ingredients."

Conditions of the CSP Application

The eligible patent must be valid, and filed after October 1, 1989. It must pertain to a medicinal ingredient or a combination of medicinal ingredients contained in a drug for which the authorization for sale (e.g., **NOC**) issued on or after a date to be prescribed. The authorization for sale must be the first authorization issued by the Minister of Health for the medicinal ingredient or combination of medicinal ingredients, and no other CSP has previously issued for same. Each CSP application may only identify one patent.

CSP Application Priority on Same Authorization for Sale

CSP applications identifying patents granted on or before the day of authorization for sale will have the same priority. An application identifying a patent granted on or before the day of authorization for sale will have priority over an application identifying a patent granted after that date. Applications identifying a patent granted after the date of authorization for sale will have priority based on earliest date of patent grant.

Where two or more applications rely on the same authorization with the same priority, the Minister of Health will provide notice by identifying the competing applicants to each other. An applicant may seek to have a competing application declared void by the Federal Court for failing to comply with the CSP application requirements. Further, there are provisions addressing the expiry of all pending applications if resolution is not obtained within a period to be prescribed.

CSP Term and Protection

If the minister finds that a patentee has met all the requirements, it will issue a CSP setting out the period of supplemental protection. The CSP will take effect after the legal expiry of the patent, and will grant to the certificate holder "the same rights, privileges and liberties that are granted by the patent" as limited to "the making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal ingredient."

It will also not constitute an infringement of the CSP to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.

The term of the CSP will be calculated as the difference between the filing date of the patent application and the date of NOC issuance, minus five years, capped at a maximum of two years. The term may also be reduced at the minister's discretion if a failure to act resulted in a period of unjustified delay in obtaining the authorization for sale.

Actions for infringement of a CSP or to impeach a CSP will be subject to similar treatment as patent infringement and impeachment proceedings. A patent subject to a CSP term will remain under the jurisdiction Patented Medicine Prices Review Board.

It is unclear from Bill C-30 whether patent term restoration will be retroactively applicable to products that are already approved and on the Canadian market, as this appears to have been left to the regulations. Canada, however, has previously indicated that supplementary protection would not be applied retroactively.[2]

Implementation and ratification

The government has indicated that CETA implementation is expected in 2017. Bill C-30 is now in first reading and may be amended before implementation. The full impact of CETA and Bill C-30 on the pharmaceutical industry in Canada therefore remains to be seen.

CETA must still be ratified by the signatory countries. For the EU, this will mean ratification first by the European Parliament, following which CETA will need to be ratified by each of the individual EU member states. However, the Canadian government has indicated that the majority of CETA will be provisionally applicable upon the initial ratification by the European Parliament.

Links

CETA
Prime Minister's Office Press Release: "Canada and EU sign historic trade agreement during EU-Canada Summit"

Text of the final Comprehensive Economic and Trade Agreement

Bill C-30
Government of Canada Press Release: "International Trade Minister introduces legislation to Parliament to implement CETA"

Bill C-30, First Reading

Footnotes

1 Canada, *Technical Summary of Final Negotiated Outcomes CETA Agreement-in-Principle* (summarizing negotiated outcomes as of October 18, 2013) p. 19 [**Technical Summary**].

2 Technical Summary, *supra*.

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

For a complete list of our IP team, click here. For a complete list of our Life sciences and healthcare team, click here.