Submission of the Canadian Generic Pharmaceutical Association
to the Senate Standing Committee on Banking, Commerce and the Economy
Consideration of Bill C-47, Part 4, Division 26

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Contact: Jody Cox, CGPA Vice President Federal and International Affairs
jody@canadiangenerics.ca | 613.218.8839

Introduction

The proposed amendments to the *Patent Act* included in Bill C-47 as Part 4, Division 26 are intended to implement Canada's obligations under the Canada-United States-Mexico Agreement (CUSMA) to implement a system for patent term adjustment (PTA). This would allow patentees in all sectors to apply for an extension to their patent terms in circumstances where there has been "unreasonable" delay in the issuance of a patent caused by the Canadian Intellectual Property Office (CIPO).

Canada's intellectual property regime for pharmaceuticals is highly complex and includes several measures that are not available to patentees in any other sector. The new PTA regime will add a further layer of complexity to Canada's IP regime for pharmaceuticals.

As such, it is imperative that the new PTA regime is implemented in a manner that:

1. minimizes the potential for further delays in access to cost-saving generic and biosimilar medicines for Canadians, and
2. maintains the competitiveness of generic pharmaceutical manufacturers in attracting new production mandates for Canadian and export markets.

The recommendations outlined in this submission will help to achieve these objectives, and are fully compliant with Canada's international treaty obligations.

Canada's Generic Pharmaceutical Industry

Generic pharmaceutical companies are a strategic asset and play a vital role in Canada's economy and healthcare sector. Generic drugs are dispensed to fill more than 73 percent of all prescriptions but account for account for less than 20 percent of the $32-billion Canadians spend annually on prescription medicines. Our members directly employ some 11,000 Canadians in well-paying life sciences, technology, and manufacturing-based jobs.

Made-in-Canada generic medicines are exported to more than 100 countries worldwide, with the United States comprising our single largest export market. The ability to access global markets in a timely and

competitive manner is critical to the domestic generic pharmaceutical industry's ability to attract and retain manufacturing mandates from their global headquarters.

The importance of having strong domestic generic pharmaceutical manufacturing was underscored during the pandemic. These manufacturing facilities were able to respond to disruptions in global supply chains and prioritize the domestic production of both the regular day-to-day medication needs of Canadians and the increased demand for other medications needed by hospitals to treat COVID-19 and related illnesses, thus avoiding domestic drug shortages.

The generic pharmaceutical industry is also of strategic importance to the Government of Canada's priorities of maintaining and expanding investments in the pharmaceutical sector through its Biomanufacturing and Life Sciences Strategy, and the expansion of pharmacare across Canada.

Canadian Pharmaceutical Patent Law

Canada is internationally recognized as a jurisdiction that has significant barriers to entry for generic and biosimilar medicines, with elevated regulatory costs, complex intellectual property rules, high-risk exposure on launch, and low prices for these second-entry products.

Canadian pharmaceutical law is complex, and pharmaceutical patentees enjoy rights in Canada that are different and extend far beyond the measures available to patentees in other sectors. In addition to the 20-year patents available to all patentees, these include:

- A **patent linkage system**, which links pharmaceutical patents listed on a register at Health Canada to the regulatory review and approval process. This provides pharmaceutical patentees with an automatic 24-month court injunction against generic market entry.
- A **Certificates of Supplementary Protection (CSP) regime** implemented under the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union, which provides pharmaceutical patentees with up to two additional years of protection – beyond the 20-year patent period – for delays in the regulatory review process at Health
- Additional intellectual property and other rights, such as **pharmaceutical data protection and market exclusivity**, enacted under the *Food and Drug Regulations*.

To counterbalance these extraordinary rights that are provided only to pharmaceutical patentees, the Government of Canada has also implemented:

- An **early working exception** of subsection 55.2(1) of the *Patent Act* that allows a generic pharmaceutical manufacturer to use a patented invention for the purpose of seeking regulatory approval of that product:

  Exception

  55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

- An **export exception to a Certificate of Supplementary Protection** under subsection 115(2) of the *Patent Act* allows a generic pharmaceutical manufacturer to use a patented invention for the purpose of export during this CSP period:

  No infringement — export

  (2) Despite subsection (1), it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.

CGPA Comments on Bill C-47, Part 4, Division 26 (*Patent Act*)

The proposed amendments currently do not include an export exception that would permit Canadian pharmaceutical companies to manufacture a product for export during the time that a PTA is in place. If a PTA export exception for pharmaceuticals is not added, the current Certificates of Supplementary Protection export exception implemented under CETA will be rendered meaningless in many circumstances.

Other major jurisdictions, such as the European Union, do not have a PTA system. The absence of an PTA pharmaceutical export exception would place Canadian pharmaceutical companies at a significant competitive disadvantage relative to their foreign competitors. Without a robust commercial export exception, it is likely that Canadian generic drug manufacturing facilities would be unsuccessful in their efforts to compete with facilities in other jurisdictions for production mandates.

Export exceptions are already a feature of the *Patent Act* under the Certificate of Supplementary Protection regime, as noted above. While generic and biosimilar medicines companies are unable to receive domestic approval from Health Canada during a CSP period, they are permitted to manufacture for export purposes during this extended period of protection. Such an amendment would be consistent with Canada's international treaty obligations.[1]

The proposed amendments to the *Patent Act* currently contemplate that PTAs will run *concurrently* with any existing CSP.[2] This is an important provision, as it prevents the unnecessary duplication of extensions to patent terms (i.e., by permitting one extension to follow the other). If the CSP and PTA regimes are not aligned, circumstances may arise where third parties will be unable to utilize the CSP export exception due to a concurrently running PTA. This is inconsistent with the purpose and structure of the existing CSP export exception and accordingly undermines Parliament's intentions in designing the CSP regime.

In addition, the total PTA period granted should not exceed two years. A two-year maximum CSP period was implemented under CETA to ensure that Canadian generic companies would remain competitive with their foreign counterparts. Failing to adopt a two-year maximum limit on PTAs would be inconsistent with the government's prior commitments to support the international competitiveness

[1] Information regarding the consistency of a PTA pharmaceutical export provision and other CGPA recommendations with Canada's treaty obligations can be found in Annex A of the Submission.

[2] Bill C-47, Division 26, section 497.

of Canada's generic manufacturing facilities. PTA periods that are longer than two years would result in longer patented drug monopolies in Canada, and create significant increases in drug costs for Canadians through the delayed market entry of cost-saving generic and biosimilar medicines.

CGPA Recommendations

Recommendation #1: Include an Export Exception for Pharmaceuticals to PTA Period

Division 26 to Bill C-47 should be amended to include a pharmaceutical export exception to the PTA period, in a manner that mirrors the export exception language found in subsection 115(2) of the *Patent Act* that provides an export exception in respect of Canada's Certificate of Supplementary Protection regime for pharmaceuticals:

> ***Exception***
>
> *It is not an infringement of the certificate of additional term granted under section 46.1 for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.*

This proposed amendment is fully compliant with Canada's treaty obligations, as outlined in Annex A.

Recommendation #2: PTA and CSP Periods Must Run Concurrently

The proposed amendments to the *Patent Act* currently contemplate that PTAs will run *concurrently* with any existing Certificate of Supplementary Protection.[3] This is an important provision as it prevents the unnecessary duplication of extensions to patent terms (i.e., by permitting one extension to follow the other), which would increase drug costs through delayed access to cost-saving generic and biosimilar medicines for Canadians and be harmful to generic pharmaceutical manufacturers. The current wording is fully compliant with Canada's treaty obligations.

Recommendation #3: Two-Year Cap on PTA Period

In addition to ensuring that PTA and CSP periods run concurrently, the maximum length of PTA granted should align with the current maximum CSP period of two years. This will avoid further delays in the availability of cost-saving generic and biosimilar medicines for Canadians while ensuring that generic pharmaceutical manufacturers can remain internationally competitive in attracting new production mandates.

About the Canadian Generic Pharmaceutical Association

The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic pharmaceutical industry. The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill more than 73 percent of all prescriptions but account for account for less than 20 percent of the $32-billion Canadians spend annually on prescription medicines.

[3] Bill C-47, Division 26, section 497.

Annex A: CGPA Recommendations Are Consistent with Canada's International Treaty Obligations

Canada-United States-Mexico Agreement (CUSMA)

CUSMA outlines certain minimum obligations that Canada must fulfill in relation to the creation of a PTA regime.[4] These obligations do not in any way preclude the inclusion of an export exception.

Canada's obligations with respect to the PTA regime can be found in Article 20.44 of CUSMA. Section 3 states that the parties to CUSMA must provide a means for patentees to adjust their patent terms to compensate for "unreasonable delays" in the issuance of a patent:

> 3. If there are unreasonable delays in a Party's issuance of a patent, that Party shall provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for those delays. [Emphasis added.][5]

Section 4 of Article 20.44 provides certain requirements as to what would constitute "unreasonable delay". It states that an unreasonable delay "shall include a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later."[6]

Outside of these requirements, Canada has the latitude and discretion to determine the parameters of its PTA regime based on what is in the public interest of Canadians. This includes the ability to create an export exception to protect the global competitiveness of Canada's pharmaceutical manufacturing sector.

WTO Trade-Related Aspects of International Property Rights (TRIPS) Agreement

The WTO TRIPS Agreement does not include any impediment to creating an export exception in the PTA regime. Put simply, TRIPS is not applicable to Canada's PTA regime because it is only intended to set *minimum standards* of protection for intellectual property rights. Canada already exceeds these minimum standards and is thus compliant with TRIPS. As stated in Article 1, "members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement." [Emphasis added][7]

TRIPS does not specifically include any requirements for patent term adjustment or extension, nor do many signatories to TRIPS have any patent term adjustment regime. Accordingly, TRIPS does not contemplate what can and cannot be done during a patent term adjustment period.

The extension period contemplated by the new PTA regime is "more extensive protection" than what is required by TRIPS. Pursuant to Article 33, the "minimum" requirement for a patent term is a period of

[4] Article 20.44., Canada-United States-Mexico Agreement ("CUSMA").
[5] Article 20.44, s. 3, CUSMA.
[6] Article 20.44, s. 4, CUSMA.
[7] Article 1, TRIPS.

20 years, counted from the filing date. Canada already has a patent term of 20 years, before PTA adjustments are taken into consideration.

The introduction of a PTA regime will therefore *exceed* the minimum standard required by TRIPS by permitting the extension of a patent term *beyond* 20 years. Accordingly, whether or not an export exception is created for the period of the extended patent term is irrelevant to Canada's treaty obligations under TRIPS.

Regardless of whether TRIPS applies during the time of a PTA, Article 30 of TRIPS empowers Canada to create an exception to the exclusive rights conferred by a patent. This power could be used to create an export exception during the period of time when a PTA is in place. Article 30 empowers Canada to create an exception to the exclusive rights conferred by a patent where the exception meets a three-step test: (1) it is limited; (2) it does not unreasonably conflict with the normal exploitation of the patent; and (3) it does not unreasonably prejudice the legitimate interests of the patent owner.[8]

Comprehensive Economic and Trade Agreement between Canada and the European Union (CETA)

There is nothing in CETA which would prevent a similar export exception from being created in respect of PTAs. As part of its obligations under CETA, Canada implemented a regime that allows patentees to obtain a Certificate of Supplementary Protection that can extend patent terms of certain pharmaceutical products for up to two years to compensate for unreasonable delays in obtaining marketing approvals from Health Canada. As described above, the Canadian CSP regime specifically includes an export exception. Similarly, the European Union implemented an export exception to their own Supplementary Protection Certification (SPC) regime.

[8] TRIPS at Article 30.