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Protecting Access to Medicines in CUSMA Renegotiations

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Abstract

The renegotiation of the Canada-United States-Mexico Agreement (CUSMA) is slated to begin in 2026. The US pharmaceutical industry has voiced a number of concerns about various aspects of Canadian pharmaceutical policy including intellectual property rights and drug prices. These issues are likely to figure prominently in the talks. Here we argue that a Canadian priority should be to ensure that IPR on pharmaceutical products are not strengthened in order to keep drug prices at an affordable level. We conclude by offering our recommendations about what actions Canada should take as a result of its review.

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Introduction

The Canada-United States-Mexico Agreement (CUSMA) will be up for renegotiation in 2026. Although it's not possible to be 100% sure, it is highly likely that pharmaceutical policy issues, particularly those related to intellectual property rights (IPR), will feature prominently in these talks. However, IPR is only one of many issues that will be on the table and Canadian negotiators will be faced with making a decision about which issues to prioritize. Here we argue that in order to keep drug prices at an affordable level, a Canadian priority should be to ensure that IPR on pharmaceutical products are not strengthened.

At present, Canada offers at least 20 years of patent protection on pharmaceuticals from the time that a patent application is filed, consistent with what is required under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (World Trade Organization, 1994) and in addition, along with many other high-income countries, has pledged not to use the compulsory licensing provisions of TRIPS to import drugs into the country (World Trade Organization, nd). One of the consequences of stronger IPR is typically the delay in the introduction of generic drugs and increased overall drug spending in Canada. Generic drugs are used in over 75% of prescriptions filled in Canada (CGPA, 2025) and generics are at least 45% less expensive than the equivalent brand-name drug (pan-Canadian Pharmaceutical Alliance, 2025). We focus on the existing or proposed IPR clauses in CUSMA that potentially affect access by Canadian citizens to essential medicines at affordable prices and other possible measures that may increase drug prices. We conclude by offering our recommendations about what actions Canada should take as a result of its review.

Changes that the US Pharmaceutical Industry Is Lobbying for

The Office of the US Trade Representative is an agency of the US federal government responsible for developing and promoting US foreign trade policies. Each year it prepares a report outlining US

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views about the trade practices of other countries. In its submission to the US Trade Representative (USTR) 2025 Special 301 Report, PhRMA (Pharmaceutical Research and Manufacturers of America), the US lobby organization that represents the major pharmaceutical companies, enunciated a series of complaints about what it termed "unfair and non-reciprocal [Canadian] trade practices" (PhRMA, 2025b). Among the allegations that PhRMA made were that: (i) Canada "does not provide regulatory data protection terms that are reciprocal to those provided in the US and other developed economies"; there are significant issues with how Canada ensures effective patent enforcement; Canada's system of patent term restoration that compensates companies for lengthy development and regulatory approval delays suffers from several deficiencies; Canada's method of ensuring that the price of new patented drugs is not excessive is dysfunctional; Canada's system of health technology assessment demands excessive discounts from manufacturers; and there are bureaucratic barriers that prolong the time between when companies apply to have a new drug approved and when the drug is publicly funded. The USTR report (Office of the United States Trade Representative, 2025) did not pick up on all of PhRMA's complaints, but it did note that "stakeholders have raised concerns on the limited duration, eligibility, and scope of [patent] protection in Canada's system" and that there are problems with how Canada provides patent term extensions for unreasonable patent office delays. Subsequently, PhRMA's submission to the USTR consultation on the Agreement (PhRMA, 2025a) ahead of the 2026 Joint Review demonstrates that the industry sees the review as an opportunity to strengthen IP protection and enforcement in both Canada and Mexico, urging the Trump Administration to reverse amendments that were made during congressional debate in 2019 and return to President Trump's original vision for the Agreement.

Areas of Concern for Canada

Patentable Subject Matter

Originally, CUSMA contained a clause that would have allowed patents for new uses of a known product, new methods of using a known product or new processes of using a known product. These types of patents, commonly known as secondary patents, enable the patent life of many products to be extended long after the expiry of the patent on the active ingredient (Kapczynski et al., 2012). The clause was removed by the *Protocol of Amendment* as agreed to between the USA, Mexico and Canada in December 2019 (Government of Canada, 2022). The impetus for the *Protocol of Amendment* was concerns among US Congressional Democrats about its effect on drug prices (Labonté et al., 2020). This removal provided Canada with domestic flexibility about allowing patenting for new methods and uses of existing products. While Canada's Patent Act currently allows for secondary patents in certain limited circumstances (*Patent protection for a new use of a known compound*, 2012), it is not required to provide this by either its agreement with the European Union, or its World Trade Organization commitments (Gleeson et al., 2019). Canada needs to be sure that expanded access to patents is kept out of any renegotiated CUSMA especially since the Republicans now control Congress.

Patent Term Adjustment for Unreasonable Granting Authority Delays

Article 20.44 of CUSMA requires the Parties to provide patent term adjustment (PTA) to compensate the patentee for unreasonable patent office delay. Under the agreement an "unreasonable delay" includes "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"(*Protocol replacing the North American Free Trade Agreement with the Agreement Between Canada, the United States of American, and the United Mexican States*, 2018). The PTA provisions of CUSMA came into force on January 1, 2025, and they will apply to all Canadian patent applications filed on or after December 1, 2020. In the opinion of Canada's largest and highest-ranked IP firm, it is likely that few patents will be affected by this clause because of an extensive number of excluded time periods, i.e., time periods that are excluded from the

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duration of the additional patent term (Schwartz, 2024), however there has not been any formal investigation into this question. Therefore, Canada should undertake a formal investigation of the impact of this Clause to inform its position ahead of the CUSMA review and, in any case, if the number of affected patents is low, needs to ensure that the PTA provision in CUSMA is not made more expansive. PhRMA's submission to the USTR consultation on the Joint Review complains that Canada's implementation of CUSMA Article 20.44 is "riddled with deficiencies" and targets the way the term is calculated and "inadequacies in the processes for applicants to seek a redetermination of the term"—suggesting that the US is likely to seek additional commitments from Canada in these areas.

Patent Term Adjustment for Unreasonable Curtailment

CUSMA Article 20.46 provides for an adjustment to the patent term to compensate the patent owner for "unreasonable curtailment of the patent term as a result of the marketing approval process". Importantly, the CUSMA *Protocol of Amendment* (FN40) made explicit certain conditions and limitations that Parties could apply to the scope of the patent term adjustment for unreasonable curtailment of the effective patent term as a consequence of the marketing approval process. FN40, introduced through the *Protocol* into CUSMA, allows Parties to provide only a single patent term adjustment for each pharmaceutical product, requires the adjustment to be based on the first marketing approval, limits the adjustment to 5 years, and if there is an additional period of sui generis protection, limits this to a maximum of 2 years. Canada needs to ensure the continuation of FN40 to mitigate the impact of Article 20.46.

The PhRMA submission to the USTR on the Joint Review complains that the patent term adjustments for patent office delays and for marketing approval delays operate concurrently in Canada, arguing that this deprives patent owners of the full benefits they are entitled to under the Agreement. It also seeks changes to FN40 to remove the text limiting sui generis protection to a maximum of 2 years.

Regulatory Review Exception

CUSMA provides for a regulatory review exception which allows generic manufacturers to make small batches of a drug and apply for marketing approval before the patent expires without the risk of liability for infringement. This exception is important to allow for the rapid introduction of lower cost generic equivalents onto public provincial and territorial drug plans. The *Protocol of Amendment* introduced the following text at Article 20.47: "Without prejudice to the scope of, and consistent with, Article 20.39 (Exceptions), each Party shall adopt or maintain a regulatory review exception for pharmaceutical products that permits a third person to make, use, sell, offer to sell, or import in the territory of that Party a product covered by a subsisting patent solely for purposes related to generating information to meet requirements for marketing approval for the product."

It is ambiguous whether the text only applies in case of tests conducted with the intent of seeking domestic regulatory review or if it extends to exports as well. Canada's existing regime applies to products submitted for domestic regulatory review as well as products submitted for regulatory review in foreign jurisdictions" (Kilic, 2019). It is conceivable that the renegotiated CUSMA might apply a limitation for exports in the Canadian system. PhRMA's USTR submission on the Joint Review argues that Canada's exception for exports is not consistent with CUSMA's obligations. In addition, Trump has threatened to impose a 100% tariff on drugs exported to the US (Boak, 2025). Should this tariff actually go ahead, it could also seriously affect the $3 billion drugs that Canada exports to the US (Tadrous et al., 2025).

Protection of Test or Other Data

CUSMA provides for at least five years of data protection for data about the safety and efficacy of a pharmaceutical product under Article 20.48 that a manufacturer generates during premarket

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testing and clinical trials. Until a data protection period ends, generics cannot be approved even if the patent has expired, unless the generic company undertakes the costly process of repeating the clinical trials something that is almost never done. What is more concerning about data protection, is that unlike patents, it cannot be challenged in the courts. CUSMA originally included a provision that would have required the Parties to provide either three years of additional exclusivity for new clinical information submitted for a previously approved product (Labonté et al., 2020). However, the *Protocol of Amendment* removed the text regarding three years of exclusivity for new clinical information—a provision which PhRMA argues in its submission should be reinstated. Canada must ensure that data protection is not expanded beyond what already is allowed.

Biologics

The original CUSMA deal provided ten years of effective market protection for biologics, the longest period negotiated for any trade agreement (Labonté et al., 2019). While this obligation was deleted by the *Protocol of Amendment*, PhRMA is arguing for its reinstatement. Canada's existing laws provide eight years of market protection for biologics. Currently, Canada spends $15 billion on biologics or 38.6% of all pharmaceutical sales (Zhang, 2025). Estimated actual savings from just three biosimilars in 2023 were $1.7 billion with $2.2 billion more if biosimilar uptake was maximized across Canada (Zhang, 2025). Any increase in drug spending owing to longer data protection for biologics and a consequent delay the appearance of biosimilars could be another factor putting pressure on Canada to further delay expanding its nascent national pharmacare plan (Minister of Health, 2024).

The demand to increase the exclusivity period also rests on the argument that biologics require more time and resources to develop and have weaker patent protection than small-molecule drugs. A review of 159 biologics and 440 small molecule drugs approved by the FDA from 2009 to 2023 concluded that biologics had higher clinical trial success rates at every phase of development (Wouters et al., 2024). Although they had higher median R&D costs, they were also protected by a median of 14 patents compared with 3 patents for small-molecule drugs. The median time to biosimilar competition was 20.3 years compared with 12.6 years for small-molecule drugs. Finally, biologics achieved higher median peak revenues than small-molecule drugs and had higher median revenues in each year following FDA approval. Finally, there is a wide divergence between the estimated mean $2.8 billion cited by the pharmaceutical industry to bring a new drug to market and the $1.34 billion figure that an independent academic study found (Wouters et al., 2020).

Research and Development Costs

PhRMA argues that Canada (and other countries) should increase spending on innovative pharmaceutical products, i.e., allow higher prices, in order to alleviate American patients of the burden of paying for a disproportionate amount of global pharmaceutical R&D. There has not been any credible evidence presented to show that pharmaceutical companies will lower US prices if other countries raise their prices. Moreover, an analysis of 14 major pharmaceutical companies listed on the S&P 500 Index showed that between 2012-2021 these companies used more of their profits for share buyback and dividends than they did for R&D (Lazonick & Tulum, 2022). Based on prices reported to the IQVIA MIDAS database, Canadian list prices for patented drugs are already the 4th highest in the OECD (*Annual report 2023*, 2024). Canada needs to resist false arguments like this as a rationale to further raise prices.

Market Access

PhRMA cites CUSMA Article 12.F.6 (on marketing authorization for pharmaceutical products) and argues that Canada violates this article because of the burdensome nature of obtaining public funding for drugs, with listing on public formularies taking 25 months on average after approval by Health Canada and ultimately only 20% of new medicines launched globally since 2014 being publicly reimbursed. However, late manufacturer submissions to Canada's Drug Agency, which

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conducts a health technology assessment prior to recommending whether drugs should be listed on public formularies, accounts for 49% of overall delays (Gaudetter et al., 2025). Moreover, of the 399 drugs available in the US but are not on the Canadian market, only 9 were unavailable as an active pharmaceutical ingredient in Canada and 6 of these offered little to no therapeutic value compared to existing products (Tadrous et al., 2024).

While Canada needs to take steps to publicly pay for therapeutically valuable drugs more rapidly, at affordable prices, necessary changes are internal to Canada and should not be part of any trade deal.

Conclusions and Recommendations

The US position in the upcoming renegotiation of CUSMA is likely to be influenced by its pharmaceutical industry's calls for stronger IP protection and its complaints about deficiencies in the duration, eligibility, and scope of patent protection in Canada. In order to preserve maximum policy flexibility to ensure timely generic entry and contain drug costs Canada must act to ensure that:

* Expanding length and scope of patent protection is kept out of any renegotiated CUSMA;

* Canada should undertake a formal investigation of the impact of the Clause related to PTAs ahead of the CUSMA review and needs to ensure that the PTA provision in CUSMA is not made more expansive;

* FN40 is continued to limit the scope of patent term adjustment for unreasonable curtailment of the effective patent term;

* Canadian drug exports are protected;

* Data protection is not expanded beyond what already is allowed;

* A special period of market protection for biologics is not reinstated; and

* Efforts to raise drug prices to help fund R&D are resisted. Further, Canada should develop its own independent method of ensuring rapid public payment for valuable new drugs.

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