AIPLA
American Intellectual Property Law Association

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Via Email
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RE: AIPLA Comments on Regulations Amending the Patented Medicines Regulations, Canada Gazette, Part I, Vol. 151, No. 48, December 2, 2017

Dear Executive Director Reynolds:

American Intellectual Property Law Association ("AIPLA") welcomes the opportunity to submit these comments on the proposed regulatory text published in Canada Gazette I, Vol. 151, No. 48 on December 2, 2017 regarding the *Regulations Amending the Patented Medicines Regulations* ("the *Regulations*").

Executive Summary

Innovation drives the modern economy, and patents provide innovators with the necessary private rights to protect their investment in innovation. Regulatory changes that diminish or devalue the patent right jeopardize a modern innovation economy. It is therefore requested that the Governor in Council reconsider the proposed changes that devalue the patent right, either by maintaining the *status quo* or developing a different regulatory framework that does not devalue the patent right.

Interested Person

AIPLA, headquartered in the United States, is a national bar association of approximately 13,500 members who are primarily practitioners engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property, including in Canada. Many of our members represent companies with sizable intellectual property interests and business investments in Canada. Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness. As such, AIPLA is an interested party regarding the proposed changes to the Patented Medicines regulations.

Patents and an Innovation Economy

Patents are at the heart of an innovation economy. The object and purpose of a patent is to provide a time-limited, statutory, private right of action to exclude others from making, using or selling the patented invention.[1] This fundamental private right has been recognized around the globe, including in Canada and in numerous treaties to which Canada is a signatory.[2]

A patent right is therefore intended to provide its owner with a time-limited competitive advantage in order to recoup its investment. This was clearly recognized in the Government of Canada's Federal Budget 2017:[3]

> Canada's intellectual property regime provides a framework that supports innovation across all sectors of the economy. ***Intellectual property rights*** incentivize creativity and the development of new ideas and technologies by ***helping*** companies, academics and inventors ***recoup their investment once new products reach the marketplace***.
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> In recognition of the importance of a well-functioning intellectual property regime, Budget 2017 announces the Government will develop a new intellectual property strategy over the coming year. The strategy will help ensure that Canada's intellectual property regime is ***modern and robust and supports Canadian innovations*** in the 21st century.

In order to provide a modern and robust intellectual property regime, all patentable innovations must be given equal protection under the law, and a patent cannot be used as a tool to devalue the product of innovation.

The Proposed Changes to the Patented Medicines Regulations

According to the Regulatory Impact Analysis Statement (RIAS) accompanying the *Regulations*, the proposed changes will result in lost revenues to industry of $8.6 billion, present value, over 10 years. Others have suggested that the impact will likely be almost three times larger, in the order of $26.1 billion dollars.[4]

The proposed changes to the *Regulations* will therefore result in a significantly diminished ability for pharmaceutical innovators to recoup their investment in innovation. This diminishes and devalues the patent right, creating a disincentive to innovate and to sell the products of their innovation in Canada. The result of this disincentive will necessarily be fewer new life-saving and health-enhancing drugs, being developed in Canada and being available to Canadians.

The current regulatory framework was created in 1987, and the policy makers at the time were cognizant of developing a system that would encourage research and development in Canada. The RIAS indicates that there is no evidence of a link between prices and R&D investment, with the implication that a change to price will not impact on R&D investment. However, AIPLA strongly disagrees with this conclusion, as lower prices over patented technology cannot possibly support an increased investment in R&D. The impact of these proposed changes will surely decrease investment, and are inconsistent with the underlying rationale originally supporting the regulatory control over pricing of patented medicines.

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[1] Patent Act, R.S.C., 1985, c. P-4, as amended
[2] See, for example, the North American Free Trade Agreement (NAFTA), Part Six, Chapter 17, Article 1709; and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Part II, Section 5.
[3] Budget 2017, "Building A Stronger Middle Class," Chapter 1, Part 2, https://www.budget.gc.ca/2017/docs/plan/chap-01-en.html (emphasis added)
[4] http://www.pdci.ca/wp-content/uploads/2018/01/20180129_PDCI-Critical-Assessment-PM-Regs-Amendments_Report-Final.pdf

Moreover, devaluing the patent right for one technological sector—here pharmaceuticals—is contrary to a fair and equitable, modern patent system. Indeed, according to Article 27(1) of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced." [5] As a member of the WTO, Canada is obligated to make patents available for inventions in all fields of technology, and the proposed regulatory change is therefore further inconsistent with this principle, which implies equal treatment.

Furthermore, a regulatory environment that creates a disincentive to develop and sell a patented product may delay or prevent access to the product in Canada. This changed regulatory regime may therefore also effectively negate the *sui generis* protection for pharmaceuticals that Canada recently adopted,[6] to honor its promises under the Comprehensive Economic and Trade Agreement (CETA) with Europe.

For a product to be protected with a Certificate of Supplementary Protection, further to Canada's CETA obligations, a new drug submission must be timely filed with Health Canada,[7] but the changed economics of marketing a drug in Canada may make it economically unfeasible to do so. This further diminishes and devalues the patent right.

Concluding Remarks

The proposed changes to the *Regulations* diminish and devalue the patent right, which is the right provided by the Federal Government to allow a patentee to recoup the investment made in developing its technology. This affects innovators both domestically and internationally, and undermines the objective of creating a modern and robust IP economy. Domestic innovators will not be able to compete with their international counterparts if they are unable to rely on a robust Canadian patent system, forcing Canadian innovators to go elsewhere, diminishing the Canadian economy.

There are numerous means for addressing the high cost of goods and services in a modern economy, but the use of a patent to do so is inconsistent with, and counter to, developing a national innovation strategy.

AIPLA therefore requests that the Governor in Council reconsider the proposed changes to the *Regulations*, either by maintaining the *status quo* or developing a different regulatory framework that does not devalue the patent right. Thank you for considering AIPLA's comments.

Very truly yours,

Myra McCormack

Myra H. McCormack
President, American Intellectual Property Law Association

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[5] Article 1709(1), North American Free Trade Agreement; Section 5, Article 27(1) of Annex 1C ("Trade-Related Aspects of Intellectual Property Rights") of the Marrakesh Agreement Establishing the World Trade Organization.

[6] *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*, S.C. 2017, c. 6; *Certificate of Supplementary Protection Regulations*, SOR/2017-165 ("*CSP Regulations*")

[7] Subsection 6(3), *CSP Regulations*