

Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up

by Kristina M. Lybecker

An extensive body of evidence demonstrates that patents and other intellectual property protections are critical to the future of innovation and the development of new treatments and cures. A strong legal regime is essential for a robust innovation-based biopharmaceutical industry. This study examines the legal architecture required for more effective intellectual property protection for the innovative biopharmaceutical industry. It also reviews the existing Canadian legal framework as well as global best practices, which leads to several recommendations for Canadian IP legislation.

For Canada, the legal architecture surrounding intellectual property rights protection and the national regulatory regime are powerful forces shaping the biopharmaceutical industry, its profitability, productivity, and innovative future. These dimensions also have consequences for Canadian patients, the Canadian economy, and access to future medical innovations. In the course of ongoing trade negotiations, several aspects of the Canadian IPR system have come under scrutiny and changes to these elements have become a central discussion point. This paper describes existing IP policy in Canada, compares it to global norms and regimes, evaluates the strengths and weaknesses of the Canadian system, and recommends improvements and reform.

There are five areas of concern regarding Canadian IP protection for the biopharmaceutical industry: (1) the period of patent term restoration (also called “sui generis protection”), (2) weak enforcement of patents (e.g., no patent linkage right of appeal for innovators), (3) a patent utility standard that is higher than and inconsistent with international norms, (4) the duration and scope of regulatory data protection, and

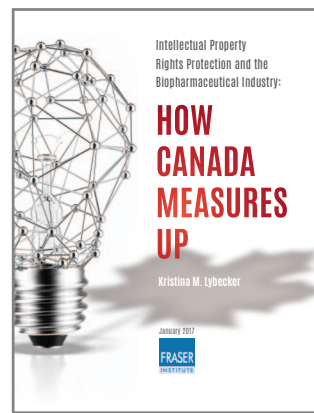
(5) the lack of an orphan drugs regime. The paper examines each of these in turn, analyzing the specific weaknesses of Canadian legislation and how these elements measure up against other nations.

The intellectual property environment in Canada clearly has consequences for this country’s global competitiveness. Overall, there are numerous deficiencies that weaken intellectual property protections within Canada relative to what is provided in other industrialized nations. The result is an IP regime characterized by significant uncertainty and instability for biopharmaceutical firms. Weaknesses such as onerous patentability requirements, insufficient enforcement mechanisms, and inadequate anti-counterfeiting measures place Canada in the company of Mexico, Malaysia, China, and Russia in the IP Index rankings. These rankings make a difference to prospective investors and signal Canada’s lack of support for knowledge-based industries, especially the biopharmaceutical industry. Fundamentally, Canada is a global outlier, providing inadequate intellectual property protection for the biopharmaceutical industry.

This paper also considers the consequences of changing the Canadian IP architecture and what Canada stands to gain. Benefits will include reduced legal ambiguity and litigation through increased predictability, greater research and development expenditures, increased foreign direct investment, additional job creation in the biopharmaceutical and related industries, productivity gains, greater biopharmaceutical self-sufficiency, faster launch times for new medicines, and additional innovation on cutting-edge treatments and therapies.

A comparison of Canada’s legal framework with global best practices leads to several recommendations for Canadian IP legislation. Specifically, Canada should provide innovative biopharmaceutical firms with patent term extensions in order to recover time lost due to mandatory governmental regulatory and marketing approvals. In addition, Canada should remedy issues of weak enforcement by providing patent owners with an effective patent linkage right of appeal. Changes must be made to Canada’s IP laws in order to restore certainty to Canada’s distorted patent system and clarify the expectations of the patent utility doctrine. Canada

should also extend data protection regulations and increase the scope of products that may be classified as “innovative drugs.” Finally, Canadian policymakers should enact legislation to define a rare disease and encourage Canadian firms to intensify their research and development of new therapies. The adoption of these changes would help to bring the Canadian regime in line with international standards.



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The Strength of Patents, Related Rights, and Limitations: Where Canada Stands

