



Montreal, February 6, 2012

The Honourable Christian Paradis
Minister of Industry
Édifrice C.D.-Howe
253, rue Queen
Ottawa, Ontario K1P 5G8

Minister,

We are writing on behalf of BiopolisQuébec, the alliance of leading life sciences regions in the province of Québec, and Life Sciences Ontario (LSO), the voice of life sciences in Ontario. Together, our organizations represent the majority of stakeholders in the Québec-Ontario Life Sciences Corridor.

We wish to express our common vision on the importance of protecting intellectual property in the life sciences and health technologies (LSHT) sector in Canada.

The provinces of Québec and Ontario account for about 62 % of the total Canadian population and contribute about 57 % of the country's total GDP. More specifically, the Québec-Ontario Life Sciences Corridor represents over 1,100 companies, generating over \$ 17 billion in annual revenues. The sector includes large pharmaceutical companies, SMEs which develop new drugs or new diagnostics, contract research or custom manufacturing companies, organizations specializing in agriculture and clean technology, as well as firms offering consulting services to the sector such as lawyers, accountants, engineers, information technology firms, etc. Universities, hospitals and research centres within the Corridor are among the leaders in North America in life sciences and play a key role in research and development in our sector. Moreover, the life sciences industry is the country's second largest contributor in terms of R & D spending; 7 of the 10 companies that spend the highest percentage of their revenues in R & D are from the life sciences sector.

To ensure that Québec, Ontario and Canada continue to see this vital economic sector grow and generate more wealth, it is important to develop a good working relationship with various levels of government, particularly with the federal government, in order to support innovation and commercialization. The role of the Canadian intellectual property regime is critical to ensure that our sector is competitive on the international stage.

It is clear that Canada's regulatory framework on intellectual property makes our industry less competitive, compared to our main international trade partners, such as the European Union.

It is well known that research and development are key to ensuring a strong knowledge economy in Canada. The significant investments in research throughout the country, particularly in universities and research centres, should create opportunities in research product commercialization. This cannot materialize without a clear and competitive framework on intellectual property protection at the national and international levels.

More specifically, the problems faced by the biopharmaceutical sector within the Canadian life sciences landscape can be summarized as follows:

- **Deficiency in the Patented Medicines Regulations (notice of compliance)** - Even though their systems differ, the U.S. and Europe have implemented processes to prevent generics from entering the market when a patent is still valid, including, in particular, the existence of an effective right of appeal for innovators. The Canadian Patented Medicines Regulations (notice of compliance) do not provide for this right of appeal for innovators. This results in a less effective system than that of our competitors when it comes to protecting the value of the innovators' intellectual property.
- **A Canadian data protection system less efficient and less competitive than that of our competitors** - The United States and Europe have recognized the complexity, the level of investment and time required to market biopharmaceutical products, by providing a longer data protection period. In Canada, data protection is only eight years for biologic products. It is 12 years in the United States and more than 10 years in Europe, with the possibility of an extra year for new indications. This imbalance makes Canada a less attractive country for investments in the sector.
- **Absence of a term restoration system for biopharmaceutical patents** - The United States and Europe have both implemented systems that extend patent protection periods for innovative products for up to five years, to account for market access delays caused by clinical studies, record examinations and regulatory approvals. Canada does not have such a system and is not competitive with the major jurisdictions of its competitors.

Opponents of a stronger intellectual property protection regime usually cite an increase in health budgets because of the proposed changes. This argument is inaccurate and shows a lack of vision. Innovation is the key to the sustainable and efficient development of our health system. A lack of innovative technologies to improve its efficiency and the health of Canadians will compromise our current health system.

Generic products also have a role to play in achieving sustainability, but this role must be accompanied by adequate support for innovative products.

Support for innovation through an intellectual property protection system is key to such sustainability.

The ongoing negotiations in the framework of a comprehensive economic and trade agreement between Canada and the EU offer opportunities to correct these deficiencies and put Canada in the forefront in supporting the LSHT sector. The harmonization of the intellectual property protection framework with the European Union will improve Canada's economic environment and will make our markets more attractive to investments in research and development, a sector highly coveted by competition from other countries.

We hope that your Government will heed this request.

Sincerely yours,



Michelle Savoie
General Manager
Montréal InVivo



Jason Field
Executive Director
Life Sciences Ontario



Carl Viel
President and CEO
Québec International



Pierre Bélanger
General Director
Sherbrooke Innopole

[Please note that a copy of this letter will be posted online]

C.C.:

Hon. Sam Hamad, Quebec Minister of Economic Development, Innovation and Export Trade.
Hon. Brad Duguid, Ontario Minister of Economic Development & Innovation.