

## **52. Pharmaceuticals – Life Sciences as an Economic and Competitive Driver**

### **Issue**

This resolution is seeking to increase industry investments into the research and development of innovative medicines and vaccines. Improved protection of intellectual property (IP) is necessary to achieve this objective and to encourage life sciences innovation in Canada. This resolution replaces a similar resolution that is falling off the books for 2017.

### **Background**

IP is the economic engine of progressive countries. IP rights can drive job creation, economic growth and innovation. 45,000 people in Canada are directly and indirectly employed by innovative pharmaceutical companies. If we properly protect IP in Canada, we can grow jobs and investment in the knowledge-based economy. It's clear – proper IP protection equals jobs and investments in a nation.

Currently, generic drug manufacturers have the right to appeal an adverse court ruling on a patent challenge, whereas the innovative companies do not have the equivalent right. Allowing innovative companies an effective right of appeal, as Canada committed to do under the Comprehensive Economic and Trade Agreement (CETA) with the European Union, would help to restore fairness and balance and put Canada within the mainstream of international IP law.

Another key IP concern relates to the Canada's interpretation of the patent utility standard, which due to legal decisions is now higher than the equivalent standard in other nations, which in turn has resulted in the invalidation of important life sciences patents upheld elsewhere in the world. Canada's patent utility standard must be brought into line with those of our major trading partners.

Similarly, a 5-year patent term restoration (PTR) system would put Canada on the same competitive level with other developed countries. PTR is required to offset the overall regulatory approval process, including lengthy and costly clinical trials, in the approval of a medicine. The complete absence of PTR in Canada discourages investment, job creation and early adoption of new medicines that bring innovation to the Canadian health care system. The proposed 2-year PTR period set out in the CETA is a step forward, but even if implemented, Canada remains uncompetitive when compared to other developed nations.

Canada is also one of the few developed countries which provides no incentives to facilitate the development and approval of orphan drugs. A regime that provides effective incentives would benefit both companies and patients.

Finally, improving data protection, equivalent in both scope and duration to that provided by our key trading partners and competitors, would raise our level of protection, making it consistent with that of other industrialized nations with whom we compete for investments and highly skilled jobs.

The federal government must ensure that Canada's pharmaceutical intellectual property protection regime is 'best in class' in all material respects with the regimes of Canada's key competitors.

### **Recommendations**

That the federal government:

1. Increase the present term and scope of data protection for new innovative medicines;
2. Introduce a system of patent term restoration to compensate innovators for patent time expended due to clinical trials and regulatory approval processes similar in duration to those of our major trading partners;

3. Restore equity and balance under the Patented Medicines (Notice of Compliance) Regulations by providing innovators with an effective right of appeal;
4. Address the issue of heightened patent utility standards created by recent case law by aligning Canadian utility standards with those of our major trading partners; and
5. Introduce an extended exclusivity period in conjunction with any new regulatory pathway for orphan drugs.