Canadian businesses want patent rights to match those in EU free trade talks
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The Canadian Chamber of Commerce, the country's largest business association with 192,000 members, wants significant improvement in Canada's intellectual property regime for the pharmaceutical industry – including patent term restoration and a right for R&D companies to appeal patent validity in generics cases. The Chamber wants IP rules in Canada to match those of other industrialised countries in order to boost investment and growth. However, the calls have been flatly rejected by the generics industry, which says it will increase healthcare costs by Can$3 billion a year.

The calls, published yesterday in a 21-page report, come at a crucial moment as Canadian trade officials are in Brussels this week negotiating the sixth round of the free trade agreement, the Comprehensive Economic and Trade Agreement (CETA), which contains IP provisions, with the EU. A leaked draft of CETA, seen by *Scrip,* reveals that the Chamber's IP requests are practically the same as those in CETA.

The report – written by the Canadian Intellectual Property Council, a coalition of business groups working under the Chamber to improve IP rights – makes three recommendations:

1. Canada should introduce a **patent term restoration** period of five years (on top of the basic 20-year patent term) to compensate pharma companies' lost time in the regulatory and government approvals procedure so it remains competitive with other G7 countries. Many industrialised countries, such as the US, the EU, Russia, Japan, Australia, Korea and Israel already have such a system in place. In Europe, this sort of protection is called a supplementary protection certificate (SPC) and gives companies a maximum five years additional market exclusivity. This recommendation is the most worrying for the generic sector.

2. The report says the government needs to grant R&D companies an **effective right to appeal** an adverse decision on a patent challenge as currently allowed for generic firms. By allowing R&D firms the same right, fairness and balance would be restored, it notes. Canada and the US are the only countries that apply "linkage" systems, which link the market approval of a drug to its patent validity; in Canada it comes under the Patented Medicine (Notice of Compliance) Regulations and in the US under the "Hatch-Waxman" system.

3. The government needs to implement **additional data protection** to the information supplied by R&D firms to drug regulators to match other industrialised countries, the report says. Since 2006, Canada's data exclusivity provision has provided data protection for eight years, but this is seen as "no longer competitive". The EU provides an extra two years of data protection over Canada, and the US gives a basic five years of data protection but up to an extra three years for new clinical indications and 12 years for biological medicines.

Émilie Potvin, director of public affairs for the Chamber, told *Scrip* that the report came out now "because the CIPC members think IP protection reform is good for Canada" and stressed the process predated the EU-Canada negotiations.

It is unclear to what extent the Canadian R&D pharmaceutical industry association, Rx&D, had a say in the report, which it described as the "right prescription for bridging Canada's innovation gap and promoting economic prosperity".

Ms Potvin said the CIPC conducted the report as part of its 2010 strategic approach set out by its steering committee. She said: "The pharmaceutical industry accounts for just four out of the 15 members of the committee. Each year the Council pursues a different theme. In 2011 it will be stopping counterfeiting at the border. The report was prepared in house and as part of our operating budget."

The Canadian Generic Pharmaceutical Association was not consulted. Jeff Connell, its vice president of corporate affairs, told *Scrip* that the report's recommendations were "exactly the same" as the IP provisions in the EU-Canada free trade agreement. He said he could understand why the EU was pushing for strong IP provisions as pharmaceuticals were the number one export to Canada from the EU, making up around 16% of total exports. "But it is puzzling why the Chamber would support this because they have drug benefit programmes for their employees, which would mean higher drug costs."

Asked whether implementing the recommendations would raise costs for the Canadian government healthcare payer, Ms Potvin said: "Reducing the intellectual property protection gap will result in a more advantageous investment climate. It will protect and create jobs and investment in our life-sciences and pharmaceutical sector. It will provide better health outcomes and a sustainable health care system."

The Chamber hopes the Canadian government will consider the report seriously. Chamber and CIPC members will be meeting with government and political leaders in the coming weeks. "We will also closely be following the negotiations between the EU and Canada," added Ms Potvin. It is expected that the trade negotiations, which started in May 2009, will conclude this year.