Trade deal is riding on changes to Canada's drug-patent laws

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Later this month, inside a stylish Ottawa office complex overlooking the Rideau River, a marathon session of trade talks is set to take place between representatives from Canada and the European Union.

While previous negotiations have roused little interest from ordinary Canadians, this round promises to be different. At stake: the future cost of health care. Also at stake: high-end research jobs.

EU negotiators are asking for big changes to Canadian laws that govern intellectual property and patent protection for brand-name prescription drugs. They argue that Canada's legal regime for intellectual property is lax and out-of-step with European norms.

Critics, however, argue the proposals will heave billions of dollars in added costs on public and private drug plans at a time when an aging population is already causing health-care spending to spike.

Some experts warn the issue could make or break the entire trade pact.

"If you are looking at this negotiation, [a trade deal] is something that Canada wants and needs more than the Europeans do," said Peter Clark, a former Canadian trade negotiator who is now president of Grey, Clark, Shih and Associates, Ltd., an Ottawa-based trade consultancy. The Europeans "are going to play their cards as hard as they can and they are doing that in a number of areas and this is one of them."

While Canada, like other industrial countries, provides a 20-year life for patents on brand-name drugs, the lengthy clinical trial and regulatory approval processes mean a product has a much shorter period of exclusivity on the market – usually about nine years – before cheaper generic versions are allowed, according to the drug industry.

Generic companies can pursue a legal challenge of patents at any time during the 20-year period. The Big Pharma companies, in turn, can launch litigation to block a generic's market entry for up to 24 months, and sue for lost profits.

With that backdrop, EU negotiators are looking for three key changes to Canada's IP regime.

First, they want Canada to provide brand-name pharmaceutical companies with a robust appeals process against generic manufacturers.

Second, they want Canada to extend how long Big Pharma can protect the data from its clinical drug trials. It is currently eight years in Canada versus 10 years in the EU.

Third, they want Canada to provide "patent term restoration" – a measure that exists in Europe and the United States and gives big pharmaceutical companies up to five years of extra market exclusivity for their drugs to credit them for time lost when obtaining regulatory approval.

"They are going to need at least two of three, is my guess, for it to be acceptable to the Europeans," said Jason Langrish, executive director of The Canada Europe Roundtable for Business.

"I just think the lobby in Europe is too strong for them to sign a deal, just say, [that] gives a right of appeal because this is considered more of a housekeeping issue, just levelling the playing field than anything."

A spokeswoman for Foreign Affairs and International Trade Canada stressed Ottawa recognizes the importance of taking a "balanced approach" to pharmaceutical protection: "This government always protects and advances Canada's interests during international negotiations and will only enter into an agreement that is in Canada's best interests."

Still, achieving that balance is no easy feat. Provinces and territories, which are sending envoys to attend this round of trade talks, are already struggling to contain health care spending. Businesses, meanwhile, are paring benefits to keep their own costs in check.

Out-of-pocket spending on prescribed drugs is on the rise, totalling $4.6 billion in 2010, according to the Canadian Institute for Health Information. Complicating matters further, there are no firm statistics on how many Canadians lack prescription drug coverage altogether – although there are suggestions their ranks will swell as baby boomers exit the workforce and companies increasingly rely on contract and casual work to fill new vacancies.

The European push for IP reform has already sparked a fierce lobby war, pitting Canadian subsidiaries of multinational drug companies against their generic counterparts. Strikingly, though, their arguments are mirror images of each other with both sides purporting to champion the interests of Canadians by arguing that innovation, investment and jobs are all at risk in their respective sectors.

The Canadian Generic Pharmaceutical Association, for one, estimates the European proposals will add $2.8-billion a year in extra costs to Canadian drug plans – mostly by delaying the sale of generic drugs by an average of 3.5 years.

"The impact is going to be very clear – higher drug costs and much increased revenues going to brand-name pharmaceutical companies," said association president Jim Keon.

In some cases, generic drugs can cost up to 75 per cent less than the corresponding brand-name medication. Mario Deschamps, president and chief operating officer of generic firm Pharmascience, argues that such savings could free up funds to hire more doctors, nurses or enable hospitals to purchase equipment.

Barry Fishman, president and CEO of Teva Canada Ltd., was more blunt arguing the European’s proposals will “completely wipe out all of the savings due to the recent generic drug reforms” in Ontario.

Canada’s Research-Based Pharmaceutical Companies, the industry organization for brand-name drug companies, argues that patent protection gives companies incentives to fund Canadian-based research and development.

“You are not going to build the economy of the future based on a strategy of copying somebody else’s hard work,” said president Russell Williams. “There is a role for it – there is no debate that there is a role for generics and after a patent is finished.”

Paul Levesque, president of Pfizer Canada Inc., says strong patent protection ought to be the just reward for funding costly innovation, noting it costs $1.2-billion to develop a medicine.

“Obviously, the EU commissioners, they’ve taken a look at the Canadian situation and they have highlighted our IP regime not being on par with theirs, so it is on the table at the moment … It is a going to be a very, very hot fall and winter,” said Mr. Levesque.

Hugh O’Neill, president and chief executive officer of Sanofi Canada, said Canada’s current IP and patent rules make it difficult for him to convince head office in France to earmark more funds for Canadian-based research and jobs.

“It’s a constant battle to be able to bring an appropriate level of resources and investment into Canada when the IP regime is at such a disconnect between the European market and the U.S.,” he said.