



EU Proposals Threaten Canada's Life Sciences Success Story

February 16, 2012
Remarks by Barry Fishman for
Economic Club of Canada
President & CEO, Teva Canada Limited

Thank you for the kind introduction Rhiannon. And thank you to the Economic Club for inviting me to speak today.

Good afternoon everyone. It is a pleasure to have the opportunity to talk about some important issues affecting health care, and some opportunities to create positive change.

It is clear that aging populations and rising treatment costs are creating an enormous burden on our health care systems. To ensure their sustainability, we must find creative ways to save money, without sacrificing patient care.

The Drummond Report, release yesterday, contains over 100 recommendations for health care in Ontario. It suggests an annual cap of 2.5% in overall spending, compared to a previous five year average of 6.3%. It appears Mr. Drummond believes Ontario can take the lead, as not one jurisdiction has been able to achieve this over the last three decades.

A strong focus on value for money for all of our health care spending is essential. Generic medicines are an important part of the solution – both now and in the future.

With prices that typically range from 60 to 75% below the equivalent brand name product, generics save Canadian patients and our health care systems \$10 billion per year. As health care costs continue to rise, the savings offered by generic medicines become even more critical.

To start, I am going to outline the Canadian generic industry's contribution to health care and the economy.

I will follow by going over the real impact of the European Union pharmaceutical IP proposals – three changes that are included in the current trade agreement discussions (known as CETA for short) that will stifle the development and manufacturing of generic products in Canada - and add unnecessary costs to our health care system.

Generic Drugs: Part of the Solution to Sustainable Health Care

Let's start with a quick overview of our industry.

The generic pharmaceutical industry exists for one main reason: to develop, produce and market high-quality affordable pharmaceuticals.

Our industry helps to ensure essential medications are available to people who might otherwise not be able to afford them.

Using generic products in place of the brand name medication provides patients with the same treatment at a much lower cost. That is excellent value for our health care dollar and the money saved can fund other much needed health priorities.

I am often asked by family, friends and, believe it or not, even some doctors that I know --- are generic drugs really the same as brands? My answer is that Health Canada will only approve a generic drug after they are confident in three primary areas:

1. Scientific studies demonstrate the same therapeutic outcome as the brand product
2. The generic manufacturer can produce the product to the same rigorous quality standards as the brand company and
3. All relevant patents have been dealt with under the existing regime.

More than 300 million prescriptions are dispensed each year in Canada with affordable generic products. It is significant to note that although generic drugs are used to fill 60% of all prescriptions, they account for less than a quarter of the \$23 billion Canadians spend each year on pharmaceuticals.

You might think that a generic utilization rate of 60% is a positive result. But consider that in the US, generic drugs are used in 78% of all prescriptions. If the use of generics in Canada was equal to US levels, and if we closed this 18% gap, Canadians could save a further \$3 billion per year.

We are working with pharmacy and payers on solutions to realize this opportunity to help provide the maximum value for our future health care spending. Our goal is to work with key stakeholders to influence the structure of drug plans and reimbursement systems that encourage the appropriate use of generics.

You may be surprised to hear that generic pharmaceuticals represent less than 3% of the \$200 billion total that is spent in Canada each year on health care.

The role of the generic industry has never been more crucial. Our products are a solution for payers who are under intense pressure to control health care costs.

Generics: Canada's Life Sciences Success Story

Canada is home to one of the largest and most significant clusters of generic pharmaceutical R&D and manufacturing in the world.

Our industry is a significant provider of Canadian jobs. We directly employ more than 10 thousand Canadians, many in product development, manufacturing and quality control positions. Our companies also support at least another 10 thousand employees who work for our Canadian supplier partners.

And I know first-hand that Canadian generic companies are benefiting from hiring many of the top talent who were impacted by recent brand industry job reductions.

We offer highly skilled jobs that support families and that Canada needs, particularly in the current economic climate. These employees pay taxes, support other businesses, and play an important role in supporting their communities.

Generic Companies: We Fight For Health Care Savings

I have spent the last 29 years in the Canadian pharmaceutical industry - starting with a leading brand company, with the last 12 years in the generic industry.

It always amazes me when people think that brand products have a single patent and that generic companies easily obtain and copy the brand product “manufacturing recipe”. Then once the single patent’s 20 year period expires, many people think that generic products come to market with no risk and very minimal investment.

This over simplified view of the generic business, held by many in the general public, tells me that our industry must do a better job in our communications.

I want to take this opportunity to set the record straight.

In Canada, virtually all major generic drug launches are achieved through lengthy and costly litigation - and many undergo complex and expensive product development.

A powerful (and little known) statistic is that 8 of the current top 10 selling generics were launched as a result of one or more patent litigation challenges. And through this litigation, generics have generated cumulative savings of >\$20 billion compared with not litigating and waiting until patent expiry to launch.

I think the actual situation can be best illustrated by talking about a product we have all heard of. Lipitor - a Pfizer product - has set records worldwide as the top selling drug in history. At its peak in 2009, sales of Lipitor in Canada exceeded \$1.3 billion per year, which is equivalent to over \$3.5 million per day!

When generic versions of Lipitor entered the Canadian market in 2010, the cost savings to the health care system on this one product was approximately \$800 million per year!

But generic versions of Lipitor did not come to market because a single patent expired 20 years after the patent filing date.

Generic Lipitor actually came to market as the result of lengthy and expensive litigation by several generic firms. It is typical that a blockbuster drug is protected by numerous patents, with a variety of expiry dates. In fact, Pfizer has over 100 patents on Lipitor and 16 are currently listed on the Health Canada Patent Register - which blocks the entry of generics until these patents are successfully litigated or cleared.

A Uniquely Canadian “Second Kick at the Can”

Even after winning the initial court case, which clears the generic product to enter the market, our patent system allows for the brand company to sue the generic firm, yet again, on the exact same patents in the same Federal Court of Canada.

This dual litigation, or sometimes referred to as a “second kick at the can” is unique to Canada - and unique to the Canadian Pharmaceutical Industry. It is a highly unusual and a completely wasteful anomaly in our legal system.

If after a generic company wins in the first round of litigation, and subsequently a different decision occurs in the second round of litigation, the brand company is entitled to collect damages that reflect several multiples of what the generic company earned while on the market.

The pharmaceutical industry in Canada is one of the most litigious industries, and I might add, that is much to the delight of many of the lawyers I see in the audience today!

The monumental business risk associated with dual litigation stifles investments in future generic products and ultimately results in Canadians paying more (in some cases 4 times as much) for the brand product for a much longer period of time.

During the last 10 years, the Canadian Generic Industry has an overall success rate of over 70% in our patent challenge efforts. That kind of track record proves that continuing to challenge weak pharmaceutical patents is necessary. Government policies need to ensure that the right business incentives are in place to justify and fund this effort.

In the US, for example, the first generic to file and successfully win the patent challenge is granted 180 days of market exclusivity. This period is extremely valuable as it allows the first generic company to enter the market early, and provides a reasonable return on investment.

In its June 2010 report, *Generic Drug Pricing and Access in Canada*: the Health Council of Canada recognized that it is beneficial to the health care system for generic manufacturers to challenge patents - and that there must be incentives to encourage generic market entry at the earliest opportunity. It does not make sense to allow patents that are not valid or not infringed to block the entry of lower priced generics.

At the end of the day, the right balance must be found. Good public policy needs to ensure that there are incentives for generics to challenge patents and launch a steady flow of new products. At the same time, I believe we need to ensure that appropriate incentives drive the discovery of future medical breakthroughs. This competitive tension will ensure that true innovation happens.

The Teva Story

When I tell most people that I work for Teva, they usually are very excited to tell me that we make the most comfortable sandals in the world - and many of them want to know if I am able to get them a discount on their future “Teva” shoe purchases!

However, as everyone in this audience knows, Teva is a leading global pharmaceutical company that started in Israel over 100 years ago and grew primarily through a disciplined series of acquisitions and company integrations. Each year, over the last 25 years, Teva has made a significant acquisition somewhere in the world. In the summer of 2010, we acquired Ratiopharm, which enhanced our Canadian product line and strengthened our organization.

Last year, over 100 billion Teva tablets and capsules were used by patients across the globe. And, closer to home, 250 thousand Rx’s are filled every day with Teva products by Canadian Pharmacists.

Teva has a strong commitment to growth, investment and jobs in Canada. In 2010, we announced an investment of over \$50 million, with important support from the Ontario Government, for a High Potent Manufacturing Centre. This facility, which is opening in a few weeks, is one of the largest, most advanced pharmaceutical manufacturing centres in North America. Also of note, Teva Canada operates the largest penicillin facility in the Americas, and supplies over 50% of all penicillin-based products that are used in North America.

Teva is a strong believer in innovation. In addition to our generic business, we have a growing line of branded products, including the leading product for the treatment of Multiple Sclerosis. Teva is also expanding our global focus on R&D and our product offering in the areas of oncology, women’s health, respiratory and biologics. In addition, we are proud to work with our pharmacy partners to develop and support patient-focused programs in areas such as diabetes and heart health.

A quality orientation and a focus on excellence and integrity are core values that form the foundation of the Teva organization.

CETA IP Proposals: A Call for Action

Now, for the “call to action” and my most important topic for today...

Canada is currently negotiating a comprehensive economic and trade agreement with the European Union. Three proposals that are part of the current package threaten to increase drug costs in Canada and negatively affect economic development in Canada.

This will have a serious impact on all of us.

The Government of Canada has stated that it hopes to conclude this negotiation this year, which means the time to influence is right now.

And before I continue, I want to make one thing clear: The Canadian Generic Industry supports efforts by our Government to reduce trade barriers and enter into favourable trade agreements.

Our industry, like many others is becoming more global. More than 40% of our industry's Canadian production is exported, with the U.S. being the largest of those markets. In fact, almost two-thirds of Teva Canada's output from our four manufacturing plants is exported. The Generic pharmaceutical manufacturing presence and exports are of great benefit to the Canadian economy.

The CETA IP provisions will hurt the Canadian generic industry's ability to attract export manufacturing mandates - and that means Canadian jobs.

Access to foreign markets is absolutely essential for the Canadian generic pharmaceutical industry. To survive, we must be able to compete on the world stage to attract sufficient volume to allow us to be cost competitive. We have thousands of employees and their families who are counting on a sustainable Generic Pharmaceutical manufacturing presence in Canada!

Our current IP system is already tipped in favor of the brand industry. In fact, we have been working very hard as an industry to influence important changes to the current pharmaceutical patent regime to achieve a better balance.

Over the past few years, most provinces have introduced generic drug price reforms. According to a report issued earlier this month by Ontario's Health Minister Deb Matthews, these reforms saved Ontarians \$500 million in 2011. The significant savings achieved through these reforms will be totally wiped out if the EU's patent extensions are adopted.

Not surprising, the Drummond Report recommendation 5-93 states "Work with the federal government to ensure that Ontario's interests in expanding use of generic drugs are not undermined by a Canada-European Union Free Trade Agreement".

A summary of the quantifiable outcomes for Canadians of these proposals are two-fold:

First, they will increase prescription drug costs in Canada at a time when both governments and businesses are struggling to control them.

Second, they will lead to a decline in jobs and investment in the strategically important generic pharmaceutical sector in Canada.

A February 2011 report by well-known Professors Hollis from the University of Calgary and Grootendorst from University of Toronto concluded that the EU IP proposals would extend periods of market monopoly by an average of 3.5 years and add approximately \$3 billion annually to Canada's drug bill.

I have still not yet heard any credible evidence supporting the benefit to Canada of these proposals - other than the flawed conclusion that they are linked directly to Brand R&D spending in Canada - a topic that I will cover in a few minutes.

Several of the companies that would benefit from these extensions are large, influential organizations headquartered in Europe. It is estimated that revenues for brand name companies would increase by roughly \$5 billion per year if the current proposals are implemented.

Canada's IP Regime Already Exceeds International Standards

According to a May 2011 report published by Edward Iacobucci from the University of Toronto's Faculty of Law, Canada's IP system for pharmaceuticals is already stronger than in any other industrial sector in Canada, and is, in many ways, stronger than pharmaceutical IP in the EU and the U.S.

For example, the Canadian pharmaceutical patent regime provides an automatic injunction which blocks generic entry for up to 24 months while the first round of litigation takes place - which is not the case in the EU. Even the Supreme Court of Canada describes this regulation using words such as "extraordinary" and "draconian".

In October of last year, the Honourable Gary Goodyear, Canada's Minister of State for Science and Technology told The Hill Times, "**Canada currently provides strong protection for patented drugs**".

The bottom line is that Canada's IP system already gives more protection to brand name drug companies than our international treaties and trade agreements require, and more protection when compared to any other Canadian industry sector.

CETA IP Proposals: No Link to Increased Brand R&D in Canada

I know that brand name drug companies attempt to establish a direct link between increased IP protection and increased R&D in Canada.

There is, however, no real evidence to support these claims. In fact, the opposite appears to be true. During the last 10 years, Brand Pharmaceutical Companies are investing a growing % of sales in R&D in France, Germany, Switzerland, UK, US, India, China and Russia - yet this same ratio has fallen significantly in Canada.

The Brand R&D spending ratio in Canada is at its lowest level since 1988. The Patented Medicine Prices Review Board reports that in 2010, brand name drug companies spent less than 7% of their Canadian revenues on R&D in Canada, marking the 10th consecutive year that brand name companies have failed to reach their 10% spending commitment.

The 2011 Taylor Wessing Global Intellectual Property Index ranks Canada in the world's top five in IP protection with China and India ranking at the very bottom of the list, and with Russia not much higher.

If a link truly existed, then why have brand drug companies increased R&D spending in countries such as Russia, India and China, where IP protection ranks amongst the weakest in the world?

Among the many recent press articles released on the subject of pharmaceutical R&D, AstraZeneca announced a new \$1.2 billion Science Centre in Russia.

In Canada, a steady stream of job reductions continue in the Brand Pharmaceutical sector, especially in the areas of manufacturing and R&D. Just in the last 2 months we heard that J&J, Sanofi and AstraZeneca have all announced Canadian R&D job losses.

Last year, Merck announced the closure of their entire high profile 1 million square foot facility on the West Island of Montreal. This was formerly the largest brand pharmaceutical facility in Canada. At its peak, there were over 1,000 employees on that site.

I am confident that logic, a long-term view and fact-based decision making will prevail at the CETA negotiating table.

CETA IP Proposals: Hurt Canadian Jobs, Investments and Exports

The EU IP proposals, quite simply, will hurt the Canadian Generic Industry's global competitiveness.

In the short-term:

- Canadian generic companies will lose export mandates to other countries that do not have the restrictions that these proposals will create. And when you lose a production mandate at the start, you can usually count on it being lost forever.
- There will be less R&D spent on new generic products, as securing future product development and litigation financing will be difficult to justify.
- There will be a reduction in capital investments in manufacturing and R&D in Canada.
- With lower revenues and delayed market entry, there will be even less incentive for generic companies in Canada to challenge weak and frivolous patents.

In the long-term:

- Canadian generic plants will close unless we are able to fill our production facilities with products that generate an acceptable return. We have already seen too many pharmaceutical companies exit manufacturing in Canada.
- Canada will lose the flexibility of using our sizable generic pharmaceutical manufacturing resource in the event of a national emergency or pandemic.
- Payers will not be able to afford new innovative medicines and other essential health services as a result of having to fund the additional cost of these proposals.

CETA IP Proposals: Must be Rejected

The bottom line is that Canada cannot afford the proposed IP proposals. Canadian jobs, investments and health care savings are just too important to be traded away.

Now is not the time to introduce additional obstacles to delay the entry of lower priced generic products.

Now is not the time to hurt the Canadian economy or Canadian health care.

Now is not the time to introduce proposals which result in job losses and increased drug costs.

And I believe that now is the time to encourage and support Canadian-based manufacturers and exporters.

We are calling on the Government of Canada to hold firm and reject these harmful IP measures.

These proposals must be removed from the CETA negotiating table.

CETA IP Proposals: Make Your Voice Heard

With the trade deal likely to wrap up in the first half of this year, now is the time to act and for your voice to be heard.

I urge you to reach out to your local MP, or even better, to members of the Federal Cabinet and voice your concerns.

We want a trade deal with the EU that is good for Canada - and we want a trade deal that does not hurt Canadian jobs, health care costs, or economic growth.

We need health care policies that pave the way for the very best health care, for all of us and for future generations.

By using your influence, you can all help to protect jobs and contain health care costs.

And that will benefit all Canadians.

Thank you very much for your time today.