GENERAL ISSUES COMMITTEE PRESENTATION

JANUARY 18, 2017

Introduction

The Hamilton, Burlington and Oakville Chapter of the Congress of Union Retirees of Canada [HBO CURC] represents thousands of retired union members in the greater Hamilton, Burlington and Oakville area. HBO CURC acts as an advocacy organization to ensure that the concerns of seniors are heard and addressed. Specifically, CURC's mandate is to petition legislators for the introduction and support of measures to improve the health and welfare of all retired persons; and to fight for the rights of all retired persons to have retirement security and an equitable standard of living.

General Observations

The Trans-Pacific Partnership Agreement [TPP] was negotiated over eight years behind closed doors with hundreds of corporate advisors, while the public and media were shut out.

The TPP is a wide-ranging deal that extends beyond traditional issues of market access. It is estimated that the TPP would leave tens of thousands of Canadians unemployed, hike prescription drug costs, affect environmental standards, undermine procurement policies and compromise the rights of local municipalities to adopt regulations and policies in the public interest.

The TPP is being promoted as a free trade agreement. It is not. It is about entrenching and expanding the powers and rights of foreign corporations and investors.

The TPP confirms sweeping new powers on transnational investors, codified in their "right" to sue governments in closed arbitration tribunals for any laws, regulations, domestic court decisions or actions which fail to meet their "expectations" as investors--the infamous Investor-State Dispute Mechanism.

Specific Concerns

HBO CURC is particularly concerned about the healthcare implications and increased drug costs if the TPP is ratified by Canada.

The TPP would require Canada to extend patent terms to compensate brand-name pharmaceutical companies for regulatory delays in approving drugs. This will result in lengthening the time that life-saving drugs can be patented by allowing 'patent term extensions' for regulatory delays and by loosening the criteria by which existing pharmaceuticals can be re-patented for new uses-so-called 'evergreening'.

Some of the TPP provisions Canada has already agreed to in the *Comprehensive Economic and Trade Agreement [CETA]* with the European Union will further increase the costs for pharmaceuticals. The additional costs of these concessions, now embedded in the TPP, have been estimated at between $850 million and $1.6 billion annually. Canada already has the second-highest drug prices in the world, and these further increases will undermine the sustainability of Canada's publicly funded health system. [Note: Open Letter to Minister Freeland from the University of Ottawa School of Epidemiology, January 27, 2016].

Increased drug costs will have serious financial implications for all Hamilton citizens, especially for seniors on fixed incomes and those living on low incomes. There will also be significant cost implications for the City of Hamilton's employees benefit plans, local hospitals, other local health agencies and services.

HBO CURC is aware of reports that some Canadians are currently having trouble paying for their prescriptions. There are reports that some seniors have been forced to split doses to make the medication last longer, or not fill the prescription at all because it costs too much. This situation will become worse if the TPP is ratified.

According to Health Canada, 10 per cent of Canadians are not covered by any type of drug plan. Canadians spent $29 billion in 2015 on prescription drugs-the equivalent of $814 a year per Canadian, according to the Canadian Institute for Health Information.

Even more concerning is the fact that the TPP could undermine Minister Jane Philpott's plan to reduce drug costs across Canada and the creation of a national pharmacare program which would save Canada close to $11 billion annually in drug costs.

Finally, pharmaceutical companies would be able to use an expanded Investor-State Dispute Settlement [ISDS] mechanism. Canada is already the most sued country under NAFTA's Chapter 11 provisions and is currently being sued for $500 million by pharmaceutical company Eli Lilly after Canadian courts refused to extend patents on several of the company's drugs. [Note: Eli Lilly files $500 million NAFTA suit against Canada over drug patents, September 13, 2013]

It is Big Pharma that is pushing for the TPP to be ratified. We need good Pharma, not Big Pharma. The TPPA will weaken the the Canadian public health system, undermine health regulations, and obstruct efforts to renew and expand public health care. [Note: The Trans-Pacific Partnership threatens the health of Canadians, September 30, 2015.]

The TPP like CETA is bad medicine.

Recommendations

That Hamilton City Council speak out about the need for affordable prescriptions for the citizens of Hamilton and call on the federal government to act in the public's interest by not ratifying the Trans-Pacific Partnership Agreement.

That the Mayor of the City of Council and Councillors express their opposition to the Trans-Pacific Partnership Agreement in its present form and communicate this decision to Prime Minister Trudeau, Federal Cabinet Ministers, and area MPs'.

That the resolutions be sent to the Association of Municipalities of Ontario and the Federation of Canadian Municipalities for consideration and support.

Malcolm Buchanan

President: Hamilton, Burlington and Oakville Chapter of the Congress of Union Retirees of Canada

Mayor Fred Eisenberger,

Members of Hamilton City Council,

Hamilton City Hall

71 Main Street West

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December 19, 2016

Dear Mayor and City Councillors

On behalf of the Hamilton District Labour Council, the Hamilton Chapter of the Council of Canadians, the Hamilton Brantford Building Trades Council and the Hamilton Chapter of the Congress of Union Retirees of Canada we are requesting the opportunity to make a presentation before the General Issues Committee regarding the Trans-Pacific Partnership Agreement.

The Trans-Pacific Partnership Agreement [TPP] was negotiated over eight years behind closed doors with hundreds of corporate advisors, while the public and media were shut out. The TPP would reward a handful of international corporations at the expense of the Canadian economy, environment, intellectual property rights, labour rights, sovereignty, public health and governments' procurement policies.

The TPP is not a fair trade deal. It is about protecting corporate interests against interventionist governments' laws and regulations designed to protect workers' rights and domestic jobs and production, public health and the environment. The TPP is about limiting national sovereignty and enabling international companies to sue governments [ISDS mechanism] for loss of potential future profits, that might or might not have been made.

Impact on Municipalities -Procurement Practices

We are concerned that as a democratically elected body the Hamilton City Council will have to exercise its mandate within the strict policy and regulatory boundaries set by the TPP in which it had no role in negotiating, and that its decision-making will be seriously compromised.

A major concern we have is that Canadian municipalities stand to lose their longstanding ability to use the procurement of goods and services to maximize benefits to the local economy or support policy goals such as environmental protection, health costs and local job creation. We do not accept the rationale that the gains will be lower prices with competition from the TPP partners companies; the lowest price is not always the best deal for local businesses or the community.

Article 9.2: Scope of the TPP states: 2. A Party's obligation under this Chapter shall apply to measures adopted or maintained by: [a] the central, regional or local government or authorities of that Party;..... This clause does not exist under NAFTA and specifically implicates the decisions made by local levels of government in the investment-state dispute settlement [ISDS] mechanism. This means that decisions made by local government that do not give foreign corporations from TPP partner countries the same rights as local companies could trigger a suit with damages for the "loss of potential profit" which would have to be paid by local taxpayers to foreign corporations.

Terms embedded in the TPP such as National Treatment, Most Favoured Nation Status, Minimum Standard of Treatment and Indirect Expropriation will bind municipal governments and make it detrimental for taxpayers, if for example Hamilton City Council uses its procurement policies to enhance local economic activity among a number of other types of decisions which may protect the health of citizens or the local environment. The Investor-State Dispute Settlement (ISDS) provisions in the Investment chapter of the TPP are the enforcement mechanism for the provisions embedded within the other 29 chapters of the agreement.

Article 10.1: Definitions: Includes measures adopted or maintained by a Party means measures adopted or maintained by: [a] central, regional, or local governments or authorities;..... This will bind municipalities to open up bidding for services from foreign corporations in any TPP countries and our local companies will have to compete for service contracts with corporations in Vietnam, Brunei and Malaysia where labour standards are very low and unenforced.

Many municipalities, including Hamilton, use a procurement system that focuses on the lowest price instead of the highest value. This low price procurement practice opens the door for companies from TPP countries that have significant labour-cost advantages without being able to properly evaluate whether these firms are providing greater value or lesser value. Procurement practices must be changed to protect against foreign companies bidding on contracts who have limited or no experience designing and building projects in a Canadian climate, to Canadian standards and processes.

Investor State Dispute Settlement

ISDS is also a tool used by corporations to put a chill on local regulations. Just the threat of an ISDS claim against a country or municipality has stopped the enactment of good legislation that protects the public interest.

Democratically elected municipal governments making prudent and transparent policy decisions should not be held more accountable to foreign corporations and secret tribunals than to their own citizens and domestic courts. Public services and policies such as health, environment, transportation, water and procurement should have clear exemptions in the TPP to protect them from foreign investors. There should be a binding Interpretative Declaration providing a clear and unambiguous statement of the meaning of the TPP's provisions, including an affirmation of the rights of all levels of government to regulate in the public interest.

Health Care Implications

Hamilton is an Age Friendly City. It is the regional centre for providing public health care services for hundreds of thousands of Ontario citizens. The TPP demands patent protection for foreign pharmaceutical companies. If the patent term restoration required by the TPP [and CETA] were implemented today it would increase the average market exclusivity for patented drugs by 287 days. By further delaying the availability of cheaper generic medicines, this would result in an annual cost increase of $636 million, or 5% of the annual coat of patented drugs in Canada, beginning in 2023. This will add considerable and continuing costs to the City's employee benefit plans and for local health care providers and consumers.

The TPP erodes the flexibility that Hamilton City Council needs to promote economic development and it is not a sound basis for a progressive and sustainable 21st century economy that addresses climate change, social inequalities, environmental degradation and other challenges.

For additional resources and references see below.

CETA Resolution

The provisions in the TPP are similar to those incorporated in the Canada-EU Comprehensive Economic and Trade Agreement [CETA]. The General Issues Committee on December 12, 2011, adopted the following motion which was subsequently passed by City Council:

[a] That Council support the approaches taken at the federal level by the Federation of Canadian Municipalities [and their guiding principles], and at the provincial level by the Association of Municipalities of Ontario;

[b] That at the local government level, request that the Province of Ontario issue a clear, permanent exemption for the City of Hamilton from the Canada-EU CETA, and that it otherwise protect the powers of municipalities to use public procurement, services and investment as tools to create local jobs, protect the environment, and support local development;

[c] That the Province of Ontario disclose its initial procurement, services and investment offers to the EU, explain the impacts CETA would have on municipal governance, and give M.U.S.H sector entities the freedom to decide whether or not they will be bound by the procurement, investment and regulatory rules in the agreement;

[d] That this resolution be sent to the Association of Municipalities of Ontario, the Federation of Canadian Municipalities, and area M.P.s, and area M.P.Ps.

The TPP is not a trade agreement. It is an agreement designed to protect and enhance corporations' and investors' powers and profits.

Proposed TPP Resolution

We are therefore respectfully requesting that Hamilton City Council adopt the following motion:

Whereas the International Trade Minister Chrystia Freeland signed the Trans-Pacific Partnership Agreement [TPPA] in Auckland, New Zealand on February 4, 2016; and

Whereas the Canadian government may be close to ratifying the Trans-Pacific Partnership Agreement; and

Whereas the City of Hamilton recognizes the importance of trade to local, provincial and national economies but also the impact that trade agreements can have on the powers of local governments; and

Whereas the TPP will extend to pharmaceutical company monopolies the power to preventing people from accessing life-saving medicines by blocking or delaying the availability of price-lowering generic drugs thereby increasing the costs of prescriptions, especially for low-income earners and seniors; and

Whereas democratically elected municipal governments making prudent and transparent policy decisions should not be held more accountable to foreign corporations and investors and secret tribunals than to their own citizens and domestic courts; and

Whereas numerous municipalities in Ontario, including the City of Welland, City of Thorold, Victoria and Nanaimo, have adopted resolutions calling on the federal government not to ratify the TPPA in its present form; and

Whereas in the United States, New York City, Los Angeles, San Francisco, Pittsburgh and Seattle have passed resolutions creating local 'TPP-Free Zones'; and

Whereas the TPPA's investor-state dispute settlement provision allows transnational corporations to sue federal, provincial, territorial and municipal governments over legislation, regulations or policies made in the public interest, giving multinational corporations excessive power to undermine the authority of our city, province and country to create reasonable rules and regulations regarding environmental health and labour safeguards, climate policy, food safety standards and protection for local jobs and businesses.

Therefore Be It Resolved that the Mayor of the City Of Hamilton and Councillors express their opposition to the Trans-Pacific Partnership Agreement in its present form and communicate this decision to Prime Minister Trudeau, Federal Cabinet Ministers, and area MPs'; and

Be It Further Resolved that the resolution be sent to the Association of Municipalities of Ontario and the Federation of Canadian Municipalities for consideration and support.

Thank you for considering our request.

Anthony Marco, President, Hamilton and District Labour Council

M. E. Ellerker

Mark Ellerker, Business Manager and Finance Secretary-Treasurer, Hamilton Brantford Building Trades Council

Kathleen Clark

Kathie Clark, Trade Justice Group, Hamilton Chapter Council of Canadians

Malcolm Buchanan

Malcolm Buchanan, President, Hamilton, Burlington and Oakville Chapter of the Congress of Union Retirees of Canada

Sources and References:

What's the Big Deal? Understanding the Trans-Pacific Partnership.
https://policyalternatives.ca/newsroom/updates/what%E2%80%98s-big-deal-understanding-trans-pacific-partnership

Trade Deals Give Corporations the Power to Sue
http://canadians.org/sites/default/files/publications/cp-spring16-trade.pdf

The Trans-Pacific Partnership Erodes Public Policy to Benefit the World's Rich and Powerful
http://canadians.org/sites/default/files/publications/cp-spring16-tpp.pdf

Canada Centre for Policy Alternatives
https://www.policyalternatives.ca/publications/monitor-novemberdecember-2016

uOttawa

University of Ottawa
School of Epidemiology, Public Health and Preventive Medicine
Faculty of Medicine

January 27, 2016

OPEN LETTER

The Honourable Minister of International Trade, Chrystia Freeland, the Honourable Minster of Health, Doctor Jane Philpott, and Deputy Minister of International Trade, Christine Hogan.

Dear Minister Freeland, Minister Philpot, and Deputy Minister Hogan:

First, Minister Freeland, accept our congratulations on your election and acceptance of this challenging portfolio. As health researchers with a long record of work and engagement around issues of trade and health, we look forward to being able to work with your Ministry in the coming years.

Second, and specifically, we have recently completed a CIHR-funded health impact assessment of the Trans-Pacific Partnership (TPP) agreement and summarize here some of our findings. We believe this is timely given your stated intent to sign the TPP in early February. While we accept that signing and ratification are separate political stages, we are concerned with the signal that 'signing' sends before full public discussion of the agreement's potential health benefits and risks.

One area of concern for public health are changes that the TPP will bring to the Intellectual Property Rights (IPR) regime, and how such changes will translate into additional costs to the health care systems of TPP member countries including Canada. The TPP will lengthen the time that life-saving drugs can be patented by allowing 'patent term extensions' for regulatory delays and by loosening the criteria by which existing pharmaceuticals can be re-patented for new uses (so-called 'evergreening').

Some of the TPP provisions Canada has already agreed to in the Comprehensive Economic Trade Agreement (CETA) with the European Union signed by the previous government, although CETA remains to be ratified with some doubts about when this will, if ever, occur. The additional costs of these concessions, now embedded within the TPP, have been estimated at between $850 million and $1.6 billion annually. Canada already has the second-highest drug prices in the world, and further increases will undermine the sustainability of the publicly funded health system.

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The inclusion of biologics in the TPP is the first time these have been part of a trade agreement. The minimum 8 years of market exclusivity for these new generation drugs has raised additional public health concerns as these products are increasingly important for treatment of cancer and immune disorders. Indeed, the question of how best to incentivize and reward research and development (R&D) of new drugs outside of legally binding patent protection treaties has been a topic of global public health importance for some years and have led the UN General Assembly to search for alternatives, while TRIPS and TRIPS+ provisions have been the subject of intense debate at the World Health Assembly. The assumption that patent protection is the best way to incentivize R&D is by no means a universally accepted one.

Another widely shared concern is the role of Investor-State Dispute Settlement (ISDS) mechanisms in the TPP. The use of ISDS by foreign investors to sue governments over regulatory decisions that they believe have compromised the value of their investments has risen in the past decade. A 2013 review of ISDS claims found that 40 cases involved health or environmental protection, including food safety, pharmaceuticals and tobacco control measures. Most of the environmental disputes have important indirect health implications as well.

Official claims that the TPP ensures the rights of Parties to regulate in the public interest are based on Article 9.15 of the Agreement's ISDS Chapter, which states that "nothing in this Chapter shall be construed to prevent a Party from adopting, maintaining or enforcing *any measure otherwise consistent with this Chapter* that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental, health or other regulatory objectives" (our emphasis). The five italicized words effectively undermine the entire Article, since governments can undertake such regulations only if they abide by all the rules of the ISDS Chapter. This offers scant protection from investor suits over changes in health or environmental regulations or policy.

Signing on to the TPP could thus become a stumbling block for the Canadian government in its recently announced desire to introduce plain packaging of tobacco products, which have been challenged in other jurisdictions through ISDS. The tobacco exclusion offered in the TPP does not prevent 'treaty shopping' by tobacco firms from which launch a dispute, nor does the recent rejection of the Philipp Morris challenge to Australia's plain packaging law offer any assurances, since the tribunal ruled only on jurisdictional grounds and not on the substance of the claim. There is also concern that alcohol policy and regulations could similarly be undermined and thwarted through ISDS challenges.

Those are some of the more apparent health risks. We accept that there are potential health gains as well. Chief amongst these are the positive health externalities that may be associated with the economic growth and employment that are frequently claimed to follow from further trade and investment liberalization. The actual health impact will depend on the redistributive effects of such growth. To the extent that economic gains benefit all countries, are substantial and 'trickle down' in a somewhat equitable fashion to all workers, there is a potentially powerful health gain in people accumulating more of the resources needed to lead a healthy life.

However, the most widely cited estimate of TPP annual income gains (achieved only by 2025) average only 0.5% of GDP across the 12 Parties, just 0.2% more than global economic income gains (the background trend) over the same period. High-income TPP parties, such as Canada, will gain less while lower-income TPP parties, notably Vietnam, will gain more. However, the econometric models used to make this prediction are based on full employment—that all labour lost in non-competitive sectors will be absorbed by growth in the competitive ones. Empirically, this has rarely been the case. Governments appear to accept this with the TPP given, for example, Canada's commitment of over CDN 5 billion to two sectors (automotive and dairy farming) that are expected to lose as a result of the agreement. Another problem with most mainstream models is that they assume invariant income distribution.

Alternative, more dynamic econometric models based on more realistic assumptions come to even more sobering conclusions of the TPP's economic gains. A recent study using the United Nations Global Policy Model database predicts mild economic losses for developed TPP economies (-0.04% average annual GDP change) and insignificant growth for developing economies (+0.22% average annual GDP change). It expects a net loss of 650,000 jobs for all TPP countries and, while Vietnam's textile exports will benefit, other developing countries in the region with textile exports as one of their important employment sectors will lose.

For Canada, the study predicts negligible GDP changes (+0.03% annually), and a loss of 58,000 jobs. It also finds that inequality will increase as the share of GDP going to capital will rise and the share going to labour will decline, an upwards redistribution of wealth that has been unfolding globally, and within Canada, for the past two decades. Thus the TPP does not seem to align well with Prime Minister Trudeau's and the new Liberal government's commitment to rebuilding the middle class and addressing inequality head on.

To that end, we would urge that you withhold signing the TPP agreement in February and wait until these concerns receive greater evidence-informed public debate. We recognize this may no longer be feasible, nor is the government's intent. In any event, we are pleased to hear that signing the agreement should not be taken as Canada's intent to ratify it.

We therefore look forward to an opportunity to present our health impact assessment findings in greater detail when public and parliamentary hearings on the agreement are convened; and urge you to announce dates for these as soon as possible.

In conclusion, and to ensure that our letter is interpreted consistent with our intent, we are not 'anti-trade'. But as public health professionals and researchers we remain concerned that the potential health impacts of agreements such as the TPP (both direct via health system impacts, and indirect via effects on 'social determinants of health') are rarely given full consideration when such treaties are negotiated.

And so we welcome an opportunity to engage in a public discussion on these impacts prior to Canada's decision to ratify the agreement.

Yours respectfully,

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PS: If you have any questions or comments, or would like to discuss the issues raised here further, please contact either Professor Ronald Labonté at (613.562.5800 ext.2288 or rlabonte@uottawa.ca), Dr. Arne Ruckert at (613 562.5800 ext.7985 or aruckert@uottawa.ca), or Ashley Schram (ashleylgrau@gmail.com).

Eli Lilly files $500M NAFTA suit against Canada over drug patents

Compensation sought for Federal Court's invalidation of Straterra, Zyprexa patents

By Kazi Stastna, CBC News Posted: Sep 13, 2013 8:44 PM ET Last Updated: Sep 13, 2013 11:57 PM ET

Eli Lilly is accusing Canada of violating its obligations to foreign investors under the North American Free Trade Agreement by allowing its courts to invalidate patents for two of its drugs.

The company officially filed a complaint this week with NAFTA seeking $500 million US in compensation.

The Indianapolis-based pharmaceutical giant had already notified the federal government in June of its intention to submit a NAFTA complaint, but filed the formal "notice of arbitration" on Thursday after it failed to settle the dispute through negotiation.

A three-member international tribunal made up of arbitrators chosen by the disputing parties will hear the complaint.

The NAFTA claim alleges that several Canadian court rulings invalidating the patents for Eli Lilly's drugs Straterra and Zyprexa were illegal under international law because they violated Canada's obligations under Chapter 11 of NAFTA, the international trade treaty that covers the U.S., Canada and Mexico.

Chapter 11 protects the investments of companies and investors from NAFTA countries that operate in other NAFTA states. Eli Lilly alleges Canada violated the provisions of Chapter 11 that guarantee fair and equal treatment to foreign investors and protect them from expropriation of their investments.

"Patent decisions in Canada over the last decade not only fly in the face of long-established international standards, but they're subjective and completely unpredictable," Doug Norman, vicepresident and general patent counsel for Eli Lilly, said in a statement issued Friday.

"The standard seems to be that there is no standard."

A Federal Court decision in 2010 invalidated Eli Lilly's patent for Strattera (atomoxetine), a drug used to treat attention deficit hyperactivity disorder (ADHD), six years before it was due to expire.

Federal Court decisions in 2009 and 2011 voided the patent for Zyprexa (olanzapine), an anti-psychotic drug used to treat schizophrenia, which was to expire in April 2011.

The challenges to both patents were initiated by the generic drug company Novopharm (later renamed Teva Canada Ltd.).

Drugs did not fulfil promise of patents, courts find

In the Straterra case, the Federal Court judge found that the drug did not meet the threshold of "utility" for the long-term treatment of ADHD and did not fulfil the implied "inventive promise" of the patent — that is, it did not do what the inventor said, or implied, it would do when it applied for the patent.

The court found that the clinical trial used to demonstrate the drug's utility — a seven-week, double-blind placebo-controlled study of 22 patients — was "too small and too short in duration to provide anything more than interesting but inconclusive data."

The judge hearing the Zyprexa patent challenge found that the drug did not meet the implied promise Eli Lilly made that the drug is markedly superior to other drugs for the long-term treatment of schizophrenia. (The Zyprexa case was initially ruled on in 2009 but then sent back to Federal Court after an Appeal Court judge found the original reason for invalidating the patent was not legally sound but that it could be challenged on the grounds of utility.)

The company's attempts to appeal the rulings to the Supreme Court of Canada failed, which is why it turned to the NAFTA arbitration process.

It initially announced it would be filing a NAFTA challenge in December 2012 and demanded $100 million in compensation for the Straterra decision but amended its complaint in June to include the Zyprexa case and upped the compensation demand to $500 million after the Supreme Court refused to hear its final appeal of the Zyprexa decision in May.

Government 'expropriated' drug maker's rights

Ely Lilly is contending that the court decisions constitute an expropriation of the "exclusive rights" conferred to Eli Lilly under the two drug patents, the company said in the notice of intent to submit a NAFTA claim filed June 13.

By stripping the company of its patents before they were expired, the courts deprived Eli Lilly of its "exclusive rights to prevent third parties from making, using or selling its patented product during the patent term" and cost the company money, the drug maker said.

The global sales of Straterra were $620.1 million in 2011 and sales of Zyprexa totalled $5.026 billion in 2010, the company said in its June document, which has the Canadian sales figures blacked out.

The company argues that by not rectifying the "judge-made law" on utility that expropriated Eli Lilly's exclusive rights as the patent holder, the government was guilty of expropriating Eli Lilly's investments, the company said, which is prohibited under Chapter 11 and entitles the company to compensation "equivalent to the fair market value of the expropriated investment."

Eli Lilly objects to the way Canadian courts interpret whether a drug has fulfilled its promise of being useful in the treatment of a certain condition. It argues that unlike other jurisdictions, Canada has an "elevated standard" when it comes to demonstrating the utility of a new drug and doesn't use the widely accepted threshold that demands only that patent holders show their invention has a "scintilla" of utility.

"In a series of decisions issued since 2005, the Federal Court of Canada and the Federal Court of Appeal have created a new judicial doctrine whereby utility is assessed not by reference to the requirement in the Patent Act that an invention be 'useful' but rather against the 'promise' that the courts derive from the patent specification," Eli Lilly wrote in its June notice of intent.

"This non-statutory 'promise doctrine' is not applied in any other jurisdiction in the world."

Medical innovation at risk

In its statement Friday, the company's patent counsel said that the Canadian courts' approach to assessing the promise of drug patents could deter companies from developing new drugs for sale in Canada.

"It's impossible to know what specific 'promise' can be implied from an application, and how much data are needed to support it," Norman said. "If this pattern persists, the already challenging business of medical innovation will become all the more difficult in Canada."

But consumer rights groups and some patent lawyers say Canada's approach to patents is not that different in spirit to that of other countries and has generally worked in the favour of large drug companies like Eli Lilly, and that, in any event, countries have a right to define "usefulness" in their own way.

Various consumer advocacy organizations on both sides of the U.S.-Canada border have expressed concern over the company's attempts to challenge domestic court decisions before an international trade tribunal and over the broad investor rights that the NAFTA treaty affords to companies.

The Council of Canadians, the Washington, D.C.-based government watchdog organization Public Citizen and the global consumer rights group Sum of Us have all spoken out against Eli Lilly's complaint, and Sum of Us created an online petition calling on Eli Lilly to drop the suit.

Eli Lilly's NAFTA complaint is unprecedented and should worry the citizens of Canada and other NAFTA countries because the drug maker is not only challenging the invalidation of its particular patents but is challenging "Canada's entire legal doctrine for determining an invention's 'utility' and, thus, a patent's validity," Public Citizen wrote in a brief on the case.

"While pushing for an entirely different patent standard, Eli Lilly, the fifth-largest U.S. pharmaceutical corporation, is demanding [$500 million] from Canadian taxpayers as compensation for Canada's enforcement of its existing patent standards."

Eli Lilly seeking 'monopoly patent protections'

While the tribunal can only award damages and can't force Canada to change its laws, some argue that the latter is, ultimately, what Eli Lilly is after.

The company's so-called investor-state challenge "marks the first attempt by a patent-holding pharmaceutical corporation to use the extraordinary investor privileges provided by U.S. 'trade' agreements as a tool to push for greater monopoly patent protections, which increase the cost of medicines for consumers and governments," Public Citizen said.

If Eli Lilly is successful in getting the NAFTA tribunal to approve its claim for compensation, it "could expose Canada to a slew of investor-state attacks from other drug companies that have had patents invalidated because their patent applications failed to show or predict that the medicines would provide the promised benefits," the group said.

In an interview with the American online news magazine Politico, Toronto attorney Lawrence Herman, a former trade official with Canada's foreign service, agreed that Eli Lilly is less interested in compensation than in changing Canada's patent law so that judges no longer have the leeway to make the kind of rulings they did in its case.

Date:

September 30, 2015

Author:

Arne Rückert & Ronald Labonté (http://healthydebate.ca/author/ar)

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The Trans-Pacific Partnership threatens the health of Canadians

Canadian media coverage of the Trans-Pacific Partnership (TPP) agreement has almost exclusively focused on the effects the deal would have on the economy, especially the dairy industry (http://www.theglobeandmail.com/news/politics/final-round-of-tpp-talks-set-for-end-of-september/article26384370/) and auto sector. (http://www.theglobeandmail.com/news/politics/pacific-rim-trade-agreement-would-threaten-over-26000-canadian-jobs-unifor-warns/article26452860/) The implications for health and health care have hardly received any media attention in Canada. We feel this is a grave oversight.

After all, the economic impacts of the TPP are relatively small. One study estimated the TPP would add a mere 0.1% of GDP by 2035 to Canada's economy (http://poseidon01.ssrn.com/delivery.php?ID=56102912211511212302009908100506508502502406903903403112702308806808211209508306(Yet, the deal – expected to be signed later this year by Canada and 11 other countries – will have potentially serious implications for how health systems are governed. That's because the Trans-Pacific Partnership is less about increasing trade through reducing tarrifs (which have already been reduced substantially), but rather protecting the investments and intellectual property of multinational corporations.

How do the proposed investment protections affect health? Firstly, the TPP can protect food, alcohol and cigarette companies' ability to freely market products that are harmful to health. Investor-State Dispute Settlement (ISDS) provisions will grant multinational corporations the right to sue TPP governments over public policy decisions perceived as damaging to their investments and business operations. A prominent litigation target has been plain packaging of tobacco (http://www.theguardian.com/society/2015/mar/12/plain-packaging-to-thank-for-australias-decline-in-smoking-says-labor), a promising public health policy advocated in the Framework Convention on Tobacco Control (http://www.who.int/fctc/en/), which requires tobacco companies to package cigarettes without branding elements such as logos, colours or promotional texts. Australia is currently facing a lawsuit from Phillip Morris (https://au.news.yahoo.com/thewest/a/29064155/tobacco-giant-sues-australia/) over plain packaging under a bilateral investment treaty with Hong Kong that contained similar ISDS stipulations as the TPP. Canada is already the most-sued developed country (https://www.policyalternatives.ca/publications/reports/nafta-chapter-11-investor-state-disputes-january-1-2015) in the world because of the ISDS process of the North American Free Trade Agreement (NAFTA), and has paid out over $170 million in compensation.

The TPP will significantly increase the number of foreign investors eligible to sue for compensation, opening up Canada to additional lawsuits from companies based in the 7 TPP countries that are not already part of NAFTA. We are concerned the TPP will thus engender regulatory chill – the unwillingness of policy makers to introduce novel health and other regulations for fear of litigation. Academic analyses have raised particular concerns about the TPP's potential chilling impact on future food policy (http://www.healthpolicyjrnl.com/article/S0168-8510%2814%2900203-6/references) and tobacco and alcohol regulations (http://tobaccocontrol.bmj.com/content/early/2013/06/19/tobaccocontrol-2012-050869.full).

In the draft chapter on intellectual property rights (IPRs), the TPP proposes to extend IPRs beyond current stipulations in World Trade Organization (WTO) treaties, increasing Canada's vulnerability to lawsuits from pharmaceutical companies. Already, under NAFTA, pharmaceutical giant Eli Lilly is suing Canada (http://www.thestar.com/business/2015/02/11/canadian-reply-to-500-million-us-pharma-suit-guesses-dont-make-valid-patents.html) based on patent decisions the federal government made for two of its drugs, and is claiming $500 million in damages. The TPP would make it even easier for companies to apply for drug patents and extend patents in comparison to other free trade agreements, including NAFTA and World Trade Organization (WTO) treaties. Proposed changes to patent law in the leaked IPR chapter (https://wikileaks.org/tpp/) could also delay the availability of cheaper generic medicines by up to five years due to the TPP's promotion of extended patents. Under the proposed IPR rules, patents may be granted for minor variations to existing products and patents could also be lengthened to compensate for delays in issuing patents or in obtaining marketing approval. Both of these moves would delay the entry of generic drugs to the market.

The costs associated with extended IPRs could be significant. An analysis of the signed, but not yet ratified, Canada-EU Comprehensive Economic and Trade Agreement (CETA) (https://www.policyalternatives.ca/newsroom/news-releases/ceta-will-result-higher-drug-costs-canadians-study) suggests that new IPR provisions under CETA, which are similar to, but may still be less stringent than those expected to be included in the TPP, will increase drug costs in Canada by anywhere between $850 million and $1.6 billion. Already, Canada has the second-highest drug prices in the world (https://www.policyalternatives.ca/newsroom/news-releases/ceta-will-result-higher-drug-costs-canadians-study).

In Europe, media scrutiny over ISDS has contributed to the development of a compromise amendment by the European Parliament which seeks to make health regulations exempt as law suit targets under the TPP. Canada should demand a similar compromise. In addition, some TPP member states have been publicly opposed to extended intellectual property rights, and Canadian negotiators can work with these country leaders to limit any extension of intellectual property rights in pharmaceuticals beyond those already present in WTO agreements.

Canada clearly does not want to be left behind in global trade negotiations. But it should not sign on to the TPP unless it can be sure that that the necessary policy space and flexibility to make healthy public policy remains, and unless drug costs will not be affected negatively. Ultimately, there is no point in signing on to a free trade agreement that represents little economic benefit to the Canadian economy, but has major political and social implications, including the potential to undermine the health of Canadians.

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