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2019 Global Trends Report

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Canada's Progressive Trade Agenda and Global Health

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Issue

Canada's progressive trade agenda champions Canadian values, including gender equality and environmental protection; however, the adoption of more stringent intellectual property (IP) rights in Canadian trade agreements has threatened domestic and global health.

Background

Canada's progressive trade agenda promotes "Canadian values," such as gender equality, environmental protection and Aboriginal rights. It is intended to counter growing resistance, both domestic and international, to free trade agreements. That being said, one crucial element is still lacking. This brief recommends a new dimension that is fundamental to a progressive trade agenda, and that could also be relatively easy to implement: promoting the value of the right to health. Canada's recent trade agreements have had a negative impact on health and restrict access to the latest advances in medicines, diagnostic tools and other life-saving medical technologies. These developments are hindering Canada's ability to fulfill its human rights obligation to provide access to essential medicines as part of the right to health.

Canada's most recent plurilateral trade agreements — the Canada-European Union Trade Agreement (CETA), Trans-Pacific Partnership (TPP) and the ongoing North American Free Trade Agreement (NAFTA) negotiations — have seen the attempt to incorporate provisions of stricter IP that arguably pose a threat to both the Canadian health care system and the accessibility of medicines in lower- and middle-income countries. Canada's capitulation to pressure from these trading partners poses a danger to the future of global health. Canada should shift gears towards leveraging the flexibilities built into World Trade Organization (WTO) rules on IP, instead of imposing enhanced protection of IP within its trade agenda.

The Evolution of Rules on IP Rights

Intellectual property provisions have featured prominently in trade agreements since the mid-1980s. In 1994, the WTO Uruguay Round saw the finalization of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), thanks in part to concerted lobbying by the business network, which was alarmed by the extent to which new technologies were facilitating the appropriation of IPR (Sell and Prakash 2004). There was immediate backlash to TRIPS in civil society, where it was strongly criticized as generating clear gains for the developed world and its pharmaceutical industries to the detriment of global health, particularly in lower- and middle-income countries. The bulk of the criticism stemmed from the challenges of the HIV/AIDS crisis and the high prices of antiretroviral medicines. One notable example would be the price of certain antiretroviral drugs, where in one case, the patented version cost a full USD$30,000 per year, while an equivalent generic drug cost a mere $140 (Kerry and Lee 2007). Backlash against TRIPS led to the Doha Declaration of 2001, wherein the WTO reaffirmed guidelines for countries to employ certain flexibilities within the TRIPS agreement in

order to overcome patent barriers and promote access to medicines. The Doha Declaration was a significant sign of support for countries that were struggling to provide access to important medicine while still complying with WTO regulations.

From 2001 to 2016, there were 176 instances of the use of TRIPS flexibilities in cases of public health ('t Hoen et al. 2018). The most frequently used measures were compulsory licensing, public non-commercial use licensing and the least-developed countries pharmaceutical transition measure, a component of the TRIPS agreement that eliminated the obligation to enforce medicine patents and data protection in countries classified by the United Nations as least developed.

The most recent developments in IP have seen the United States and the European Union fighting for greater IP provisions in their bilateral and plurilateral trade agreements beyond what is required by TRIPS. These have been dubbed TRIPS Plus provisions. Canada is already committed to sufficient IP rights in its trade agreements, and instilling greater measures would cause more harm than good.

The Economic Debate surrounding TRIPS and Law: Have We Gone too Far?

In the ongoing debate on the benefits of IP protection versus the costs of barriers to the dissemination of knowledge, the general consensus among economists is that the current balance is tilted too far towards protective measures to the overall detriment of public well-being, and that proponents of enhanced IP protection paint a too-simplistic view of what is in truth a far more complicated issue (Dosi and Stiglitz 2013; Blit 2017).

The basic argument made by supporters of strong IP is one of market failure, in which the free availability of created knowledge leads to lowered incentives to invest in research and development (as everyone "free rides"), and by consequence leads to underproduction and underinvestment. By allowing creators to profit from their work through rents, the argument continues, IP rights provide an incentive to innovate. The problem with this argument, however, is that IP rights differ in one significant way from other types of property right: that is, knowledge is a non-rival resource, the value of which never diminishes in proportion to the number of people making use of it. The challenge of this issue is that the private sector often tends to be the source of innovation for a product that is considered to be a public good.

When it comes to innovation, the greatest resource available is access to existing knowledge upon which to build. Every gain is based on what has been learned before; enhanced IP protection may stifle the sharing of research. Such knowledge as is produced and consequently patented by the private sector is kept out of the pool freely available to most researchers, in what has been called by some economists the tragedy of the anti-commons. This "fencing off" of access is an inefficient use of knowledge that could have otherwise contributed to the development of follow-on innovations by others. Furthermore, a strict IP regime creates monopolies on knowledge — by disincentivizing further innovation both for the firms holding the monopolies and for the smaller firms who know they will be outcompeted if they try — and by presenting a needless complication to technological advancement — as knowledge is divided and subdivided into many smaller separate claims, making the process of recombining them for further research an arduous one. The process of avoiding or searching out patent infringements has become its own industry, and sometimes researchers are given no choice but to spend their time finding ways to work around existing patents instead of using what has already been discovered.

Do Patents Lead to Greater Innovation?

Although there is no clear consensus on the question, the balance of studies suggests that there is not a direct causal relationship between enhanced IP protection and increased innovation. Proponents of strong IP rights maintain that the upsurge in patents filed in recent decades is the result of greater protective measures. On the other hand, it could be explained equally by the general uptick in new opportunities for technology, such as in the burgeoning fields of IT and biotechnology. The following section presents responses related to innovation from the Canadian Generic Pharmaceutical Association (CGPA) and Innovation Medicines Canada (IMC) to Bill C-30: "An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures."

The CGPA compiled a report analysing Bill C-30 that would see CETA implemented into law. Before CETA negotiations, Canada already had very strong levels of IP

protection, exceeding levels seen in the US. The biggest and most controversial change came from a new form of intellectual property protection called certificates of supplementary protection (CSP), which would see protection extended for an additional two years (CGPA 2016). The CGPA predicts that this additional level of protection will cost Canadian taxpayers upwards of $200 million annually (ibid.). An important note made in the report is that Bill C-30 will still allow generic manufacturers the ability to export during this additional period of protection. This will be vital in attracting and competing in new and existing markets going forward.

IMC is the association that represents Canada's brand-name pharmaceutical companies. Overall, IMC has been highly supportive of CETA and its regime of enhanced IP protection (IMC 2018). In particular, IMC has outlined the importance of patent term restoration, offering an additional two years of monopoly and the right of appeal that sees companies more easily able to appeal decisions where patents have been ruled to be invalid (Douglas 2016).

The claims made that higher protections for IP lead to job growth and investment, and through these concepts new innovations, is unsubstantiated. The lack of investment is seen in Canadian brand-name pharmaceutical companies who pledged to the government to invest 10 percent of all revenue in R&D in exchange for substantive legislation in 1987 (Lexchin and Gagnon 2014). However, the 2016 annual report conducted by the Patented Medicine Prices Review Board showed that the R&D-to-sales ratio had fallen to 4.9 percent, marking the fourteenth consecutive year that companies had failed to live up this commitment (Levine 2017).

While enhanced IP protection has been producing gains for companies based in the industrialized world, it has imposed costs on Canadian taxpayers and created losses for the Global South, all while stifling innovation.

IP Law and Development

Developed and developing countries are separated by a gap in the knowledge to which they have access. A poorly designed IP regime may present a major barrier to addressing this gap, and by extension to the development of emerging economies. Limiting the access of lower-income countries to life-saving medicines, for example, is not only endangering the right to life of their citizens, but also hampering knowledge that could have be used to contribute to their development, and even their capacity to build on that shared knowledge for further future innovations.

The strengthening of IP law in America has been followed by a drop in the rate of innovations by pharmaceutical companies. Part of this is that, as for-profit actors, the private sector is concerned not only with the genuine creation of new products, but also with marketing those products, asserting against infringements, finding similar products on which to capitalize ("me-too drugs") and the like — all of which divert resources away from innovation towards rent-seeking and weaken the overall social return. These concerns exert a considerable influence on the sorts of research and development projects that receive funding as well: in 2010, for example, the amount of money put towards finding a cure for male-pattern baldness was double that spent on HIV/AIDS research, and quadruple that spent on malaria. Given that most major pharmaceutical companies are located in the developed world, it seems unlikely that the social value of certain forms of medication — that, while they affect many times more people in the developing world, offer fewer potential returns on investment — will always be taken into consideration before deciding what research on which to expend resources.

While the TRIPS agreement contains crucial flexibilities to ensure access to medicines, many countries have failed to take advantage. This is often attributed to a lack of technical expertise and institutional capacity (Matthews 2005). Research has indicated that developed countries could play a greater role by implementing policies that promote technology transfers and strategic R&D spending. Therefore, the provisions allowing for the access to medicines among developing nations would be fully utilized (Hopkins 2006).

The Impact of Increased IP on Developing Countries

Millions of people across the world lack access to pharmaceuticals, and as a result many die every year from curable or treatable diseases like tuberculosis and AIDS. Additionally, non-communicable diseases are on the rise in all parts of the world, hitting hardest in the Global South. These trends pose grave threats to public health and have increased the need for pharmaceuticals to prevent and manage illness.

A strong IP regime such as that encompassed by TRIPS and TRIPS Plus — while it may be of benefit to private companies seeking to maximize the rents they receive — threatens to ignore or impede the most successful ways in which knowledge transfer enables the development of emerging economies. It is, moreover, a barrier to development that is being enforced by countries which themselves used those very same methods (such as reverse engineering, imitation and open source knowledge) to industrialize in their own right before IP law gained traction. Indeed, the US itself openly considered compulsory licensing in 2001 to reduce the price of a drug used to treat anthrax (Sell and Prakash 2004). By demanding high rents from developing countries for patented medications — some by a mark-up of up to 400 percent since TRIPS was introduced — we arrive at a situation where "to decrease the gap in knowledge, developing countries are being asked to increase the gap in resources…without evidence that these higher prices have led either to more drug innovation in general, let alone more innovation attempting to address the needs of those in developing countries" (Dosi and Stiglitz 2013).

The Impact of Increased IP Protection in Canada

At over $700 per person per year (USD purchasing power parity), Canada spends more per capita on pharmaceuticals than any other country in the world except the United States. CETA is estimated to exacerbate this problem, increasing drug costs from 6.2 percent to 12.9 percent starting in 2023 (Lexchin and Gagnon 2014). There are concerns that the future impact of CETA threatens the viability of the single-payer health care system, restricts the availability of affordable medicines that the provinces can offer, and shifts the burden of cost to everyday Canadians. Additionally, adopting higher IP provisions may negatively impact Canada's generic pharmaceutical industry, which exports generic medicines to over 115 different countries (CGPA 2016).

Scott Smith, the director of intellectual property and innovation policy at the Canadian Chamber of Commerce, is in favour of strengthening IP within CETA, claiming that the treaties have improved the IP regime: "With the CETA agreement, we're going to be improving some of our patent terms on the pharmaceutical side. There are some positives there" (INDU-66, June 8, 2017). The patent developments are considered beneficial for promoting innovation within Canada's technology sector.

Other parliamentary witnesses have expressed skepticism. Dr. Michael Geist, Canada Research Chair in Internet and E-commerce Law, was especially critical of CETA's innovation argument. He testified that Canada has become the "target of intense lobbying campaigns from large trading partners who see their national interests, and in a sense, try to take their rules and off-load them into Canada." (INDU-64, June 1, 2017). Additionally, the Canadian Federation of Nurses Unions (CFNU) submitted a response to the House of Commons Committee on International Trade. In the report, the group details that CETA will have damaging effects, and argues for public health to be exempted from future trade agreements (CFNU n.d.). The Federation argues that expansion of patent protection will see increased drug costs and could threaten policy sovereignty and public health.

The IP chapter in the first iteration of the CPTPP (the TPP) is another case in point. The chapter was particularly restricting to access to the latest advances in medicine and medical technologies. This version of the agreement drew criticism from global health agencies and advocacy groups. Further negotiation saw Canada suspend 11 of the original provisions, a move which indicates that Canadian government, in pursuing its progressive trade agenda recognizes the importance of protecting access to medicines.

Conclusion

The goal of Canada's progressive trade agenda should be to ensure that we "do no harm," meaning that the trade deals that Canada negotiates and commits itself to should not negatively impact on its partners. Canada should not commit itself to increased IP protections without a complete assessment of their impact on development, as employing more stringent IP laws would undoubtedly harm the world's most vulnerable peoples. Canada has threatened to compromise the viability of its own health care system, committing to terms of protection that will have significant impacts on health care costs and do not serve the national interest. As part of trade negotiations, Canada will be pressured to give way to enhanced IP protection in order to secure other interests. However, Canada should give priority to our recommendation if it is sincere in its promotion of progressive trade.

Global Affairs Canada currently spends roughly $625 million on health-based aid per year. This money should

be directed to increasing the capacity of and providing technical assistance to our lower- and middle-income trading partners, for instance, through information-sharing, skills training or consulting services. Countries in the Global South often lack the institutional capacity and technical expertise to translate TRIPS flexibilities into policy and legislation. In line with the aims of the Sustainable Development Goals, Canada should focus its foreign aid strategy on building the capacity of these states so that they are better positioned to leverage the flexibilities within the TRIPS agreement.

The idealistic provisions of the progressive trade agenda venture into territory that may be interpreted as challenging the sovereignty of Canada's trading partners. Additionally, elements within the agenda are proving to be challenging in terms of enforcement. To collect pledges from our trading partners on gender equality standards and environmental protections sounds good on paper; what complicates the achievement of this objective, however, is how to hold these partners accountable. Instead, a focus on health accessibility would be seen as a universal and palatable goal, through resisting pressure to implement higher intellectual property rights and ensuring that TRIPS flexibilities are able to be fully utilized. As Canada continues to pursue the goals of the progressive trade agenda, the recommendations below are intended not only to benefit everyday Canadians, but also to uphold Canada's place as a recognized and valued leader in the field of global health.

Recommendations

- Incorporate IP considerations into the progressive trade agenda.
- Focus on capacity-building and technical assistance for lower- and middle- income countries so they are better able to leverage TRIPS flexibilities.
- Do not implement further barriers within Canada's trade agenda that prevent the production of generic drugs, thereby hindering the accessibility and affordability of medicine.
- Do not sign onto any agreements that enforce TRIPS Plus-level IP provisions with respect to pharmaceuticals.

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Acknowledgements

The authors would like to thank John Ravenhill for his guidance and mentorship as a supervisor throughout the development of this policy brief. Special thanks to the BSIA and Global Affairs Canada for their knowledgeable feedback and support throughout the course of this project.

Works Cited

Blit, Joël. 2017. "Are Patents Really Necessary?" In *New Thinking on Innovation Special Report*. Centre for International Governance Innovation. www.cigionline.org/articles/are-patents-really-necessary.

CFNU. n.d. "Canadian Federation of Nurses Unions (CFNU)'s Submission Regarding Canada's Participation in the Trans-Pacific Partnership (TPP)." www.ourcommons.ca/Content/Committee/421/CIIT/Brief/BR8592372/br-external/CanadianFederationofNursesUnions-e.pdf.

CGPA. 2016. "Submission of the Canadian Generic Pharmaceutical Association to the Standing Committee on International Trade." www.ourcommons.ca/Content/Committee/421/CIIT/Brief/BR8680557/br-external/CanadianGenericPharmaceuticalAssociation-e.pdf.

Dosi, Giovanni and Joseph Stiglitz. 2013. "The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction." LEM Working Paper Series, No. 2013/23. Scuola Superiore Sant'Anna, Laboratory of Economics and Management (LEM), Pisa. http://hdl.handle.net/10419/89516.

Douglas, Sarah. 2016. "Innovative Medicines Canada Welcomes CETA." Innovative Medicines. http://innovativemedicines.ca/innovative-medicines-canada-welcomes-the-signing-of-the-comprehensive-economic-and-trade-agreement/.

Hopkins, Victoria. 2006. "Analysis of International Patent Protection and Global Public Health." *Journal of Public and International Affairs* 17: 83–109. https://jpia.princeton.edu/sites/jpia/files/2006-5.pdf.

IMC. 2018. "Intellectual Property." http://innovativemedicines.ca/innovation/intellectual-property/.

Kerry, Vanessa and Kelley Lee. 2007. "TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?" *Globalization and Health* 3 (3).

Levine, Mitchell. 2017. "Annual Report 2016." Patented Medicine Price Review Board. www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2017/2016_Annual_Report_Final_EN.pdf.

Lexchin, Joel and Marc-André Gagnon. 2014. "CETA and Pharmaceuticals: Impact of the Trade Agreement between Europe and Canada on the Costs of Prescription Drugs." *Globalization and Health* 10 (1).

Matthews, Duncan. 2005. "TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements." *European Intellectual Property Review* 27.

Sell, Susan and Aseem Prakash. 2004. "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights." *International Studies Quarterly* 48: 143–75.

't Hoen, Ellen, Jacquelyn Veraldi, Brigit Toebes and Hans Hogerzeil. 2018. "Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016." *Bulletin of the World Health Organization* 96 (3): 185–93.