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Making Sense of the CETA

An Analysis of the Final Text of the Canada-European Union Comprehensive Economic and Trade Agreement

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CCPA
CANADIAN CENTRE
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Intellectual Property Rights

Pharmaceuticals

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Key Points

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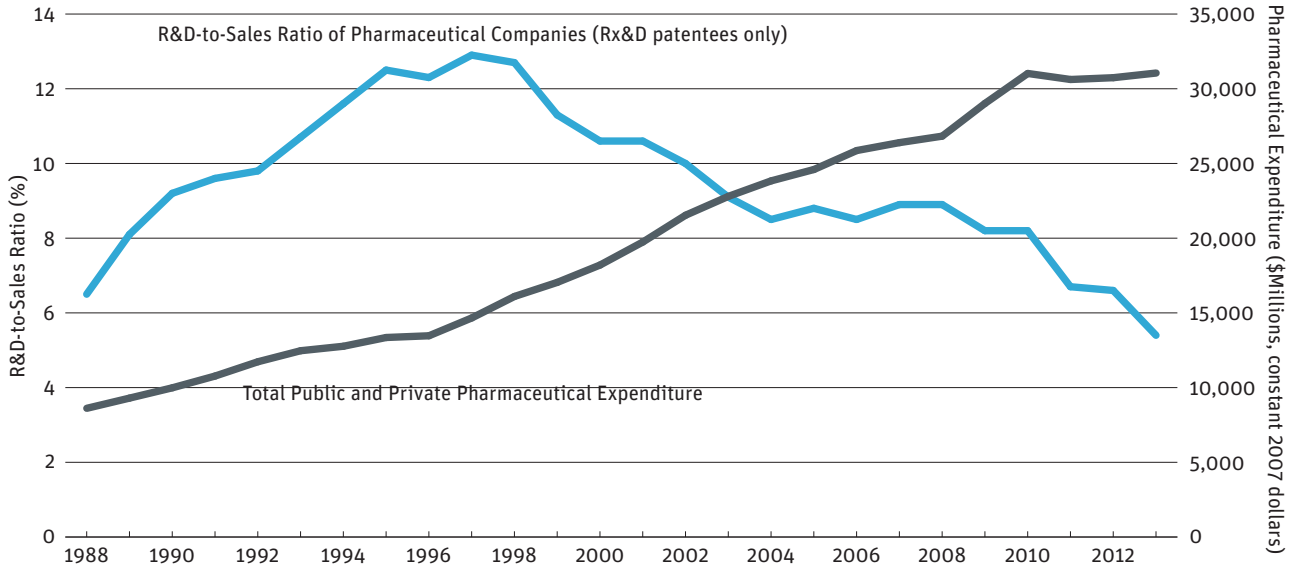
- Canada has the second highest per capita drug expenditures in the world.[42] Moreover, Canada already provides an industry-friendly system of intellectual property protection for pharmaceutical patent holders.

- The changes to Canadian patent protection for pharmaceuticals required by the CETA will delay the availability of cheaper, effective generic drugs, driving up health care costs for Canadians.
- A 2013 CCPA study by Joel Lexchin and Marc-Andre Gagnon concludes that if the CETA was "fully implemented today, it would increase the average market exclusivity for patented drugs by 383 days, or 1.05 years, which would bring an additional yearly cost of $850 million, or seven percent of total annual costs for patented drugs."[43]
- Provinces have demanded compensation for the fiscal impacts of these changes. Yet even if the federal government agrees to and honours such a commitment, it simply means that Canadian taxpayers would pay at the federal rather than the provincial level in order to boost the profits of the brand name pharmaceutical industry. Whether paying for their drugs out-of-pocket or through private insurance, people will be hit twice — through higher drug costs *and* increased federal taxes.
- Despite claims to the contrary by brand name manufacturers, higher drug costs are unlikely to be offset by additional research and development (R&D) expenditures. Since 2003, Canadian brand name manufacturers have consistently failed to meet previous pledges to invest 10% of their sales revenues in R&D. According to the latest data from the Patent Medicines Prices Review Board, the R&D-to-sales ratio for Canadian pharmaceutical companies fell to 5.4% in 2013, the lowest level on record (see *Figure 1*).
- The CETA is the first Canadian trade agreement since the NAFTA to include an Intellectual Property Rights (IPR) chapter.[44]
- Canadian negotiators made unilateral concessions in the CETA that will only affect Canada and will not require changes to the intellectual property rights regime for pharmaceuticals in the European Union.
- Canadian negotiators failed in their efforts to exclude court decisions regarding patents from the CETA's contentious investor-state dispute settlement (ISDS) mechanism. Consequently, the CETA will provide more investor-friendly grounds for challenging decisions made by the Canadian courts that limit IPRs, as the U.S. pharmaceutical giant Eli Lilly has done under Chapter 11 of the NAFTA.

FIGURE 1 R&D Spending vs. Drug Costs in Canada



Source Patented Medicine Prices Review Board. 2013. Patented Medicine Prices Review Board Annual Report 2013. p. 33. http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2013/2013-Annual-Report_2013-09-15_EN.pdf; Canadian Institute for Health Information. 2013. National Health Expenditure Trends, 1975 to 2013: Complete data tables. http://www.cihi.ca/CIHI-ext-portal/zip/internet/nhex_datatables_2013_en.zip

- Canada's concessions on intellectual property and drug patents in the CETA could set the stage for further gains by the multinational drug lobby in the Trans-Pacific Partnership (TPP) negotiations, where the U.S. is pushing for even higher standards of intellectual property protection.

Analysis of Key Provisions

Patent term extension (a.k.a. patent term restoration)

- Canada has agreed to extend the term of patents by up to two years (Article 9.2). This was supposedly done to compensate brand name drug manufacturers for the time expired between the filing for patent protection and the granting of market authorisation by Health Canada. It should be noted, however, that patents can be extended even if the patent holder itself is responsible for the delay.
- Brand name manufacturers will be able to apply for patent term extension when they submit new drugs for market authorisation (Articles 9.2.3 and 9.2.4). Where a drug is protected by more than one pat-

ent, no "stacking" of patent term extensions will be permitted. But, in such instances, brand name drug manufacturers will be able to choose the most favourable patent for extension.

- The increased costs related to patent term extension will begin to kick in eight to 10 years after the CETA enters into effect.
- It is curious that the CETA labels this system as *sui generis* (of its own kind; unique), since it replicates the European system of patent term restoration, with the exception that Canada has capped the term at two years, rather than five, as in the EU.

Data protection

- The CETA locks in Canada's current terms of data protection at eight years, with an extra six months for pediatric drugs. This refers to the data submitted to Health Canada by a drug company seeking authorization for a new drug in order to demonstrate that it is safe and effective.
- Canada rejected the EU's push for a ten-year period of "data protection," but agreed to lock in its current terms of data protection, making it virtually impossible for any future government to shorten this time period.
- These provisions go beyond the NAFTA and the WTO Agreement on Trade-related Intellectual Property Rights (TRIPS), which only require five-year terms of data protection.
- In 2006, Canada extended data protection to eight years of market exclusivity with an extra six months if companies have studied a drug in a pediatric population. Generic companies are not allowed to make use of the brand name companies' data in their applications for a minimum of six years.
- It remains unclear if the range of products available for eight years of data protection will be expanded to include products representing a minor change to an existing drug. This is likely not the case, but the text of the CETA is unclear. This point should be clarified either by amending the text, or through a formal exchange of letters between the Parties.

Patent linkage and right of appeal

- Before Health Canada can grant marketing approval to a generic version of a brand name drug, the generic company must obtain a Notice of Compliance, which affirms that all of the relevant patents on the brand name product have expired.
- The *Patented Medicines (Notice of Compliance) Regulations* allow a brand name drug manufacturer whose drug is under patent and listed on the patent register (a list maintained by the Minister of Health of drugs under patent in Canada) to apply to the Federal Court for an order prohibiting the Minister of Health from issuing a Notice of Compliance to a generic drug manufacturer.
- Under this special summary procedure, brand name manufacturers can obtain an automatic stay of two years. The stay expires either at the end of this period, when the patent expires or when the court case is decided, whichever comes first.
- If, at the end of this stay, the generic drug manufacturer wins the summary proceeding, the Minister of Health can issue a Notice of Compliance for the drug in question. Currently, the brand name drug company has no right of appeal. It can, however, still sue the generic manufacturer for patent infringement in the regular courts.
- If the brand name drug company wins the summary proceeding, the Minister of Health is ordered not to issue a Notice of Compliance to the generic drug manufacturer for its drug until the expiry of the patent in question. However, unlike the brand name drug manufacturer, the generic drug manufacturer has the right to appeal.
- The CETA stipulates that brand name manufactures must be provided an equal right of appeal (Article 9 *bis*). "In practice, this means that under CETA there could be a further delay of 6–18 months before generics appear, as the appeal makes its way through the court system."[45]
- Remarkably, despite the fact that the EU itself has no patent linkage system it was able to pressure Canada into changing its own system.
- As Lexchin and Gagnon explain: "CETA will now allow brand name companies the right to appeal decisions made under the *Patented Medicines (Notice of Compliance) Regulations*. However, the generic

companies have received written assurances from the Government of Canada that its implementation of the "Right of Appeal" treaty commitment will also address excessive and duplicative litigation by ending the practice of dual litigation. Dual litigation means that even if brand name companies lose under the NOC linkage regulations, they can launch a separate case under Canada's general patent law. It is this ability to launch a second court case that the federal government has pledged to end." Whether, and how, this pledge to the generic companies will be implemented remains unclear.

ISDS and patent disputes

- Leaked drafts of the investment chapter indicate that the Canadian government had demanded that court and administrative tribunal decisions related to IPRs be excluded from investor-state challenge.[46] This Canadian demand was dropped in the final text. Instead, there is a separate declaration that provides for a future joint review of the operation of the investment rules related to IPR and the possibility of jointly agreed binding interpretations (Chapter 10, Declaration to Investment Chapter Article X.11 Paragraph 6). This declaration is little more than a face-saving gesture for Canada, which provides no substantive protection for court decisions related to IPRs.

Geographical Indications

Karen Hansen-Kuhn, *Institute for Agriculture and Trade Policy*

Key Points

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- The central idea behind protections for Geographical Indications (GIs) is that certain products have inherent qualities related to their place of production such as soil or climatic conditions (called *terroir*), as well as cultural knowledge and traditions, that differentiate them from similar products. That designation creates a kind of place-based "brand"

that informs consumers about their special qualities and allows producers to charge a premium price.[47] As opposed to the trademark system used in Canada and the U.S. (e.g. Idaho Potatoes or Maine Lobster), where the names are owned by a particular company or trade association, GIs are a collective right. They cannot be bought, sold or assigned to other rights holders. Also unlike trademarks, the EU government takes a direct role in enforcing their protection through international treaties such as the CETA or bilateral agreements.

- The EU has separate registration and protection regimes for more than 1,200 wines, spirits, and agricultural and food products. They are produced and marketed locally or regionally, but some categories, especially wines and cheeses, are widely exported as well. The EU has been seeking to expand protections of geographical indications in its negotiation of bilateral free trade agreements. One of the key points of controversy is whether particular goods, such as "Feta" cheese, are protected GIs or actually common food names, which would not be protected.

Analysis of Key Provisions

Protections for European products

- The CETA would establish protections for a broad range of European products. A leaked technical summary by the European Commission gloated about the outcomes of the CETA talks:

  Another very positive result is the outcome on Geographical Indications (GIs). It is remarkable that Canada — not traditionally a friend of GIs — has accepted that all types of food products will be protected at a comparable level to that offered by EU law and that additional GIs can be added in the future. This is a very satisfactory achievement in itself, but at the same time also a useful precedent for future negotiations with other countries.[48]

- Annex 1 Part A of Article 7 on Geographical Indications lists protections for 173 European food names for products sold in products in Canada. The governments would take action to prevent the use of a GI unless they are produced according to specific standards and from the specific countries identified in the Annex, even when the product is identified as being from Canada. So Canadian producers of, for example, Roquefort cheese, would need to relabel that prod-

uct with a different name. Canadian companies could, however, still use those names for goods outside the protected product class, so the name "Roquefort Bar and Grill" would still be acceptable (although perhaps unappetizing). Annex B has a blank chart for GIs identifying products originating in Canada meaning that no Canadian products are protected. Article 7.7.1 indicates that more items could be added in the future, presumably for either side.

Limited protections for common names

- Certain cheeses that many would consider to have common names have more limited protections, at least for now. Under Articles 7.6.1 and 7.6.2, companies that were selling Asiago, Feta, Fontina, Gorgonzola and Munster before October 18, 2013 can continue to use those names, but new entrants to the Canadian market will be required to add qualifiers such as "kind," "type," "style" or "imitation."

Potential for trade disputes

- These protections could lead to trade disputes by companies or countries exporting those goods to Canada. While European markets are already covered by existing GI protections, they would be new for Canada. Carleton University analyst Crina Viju notes that, "Unless the U.S. recognizes the EU's GIs, Canada will be in the middle and will most probably suffer the consequences of recognizing different intellectual property obligations in two different major bilateral trade agreements, the NAFTA and the CETA."[49] The U.S. Dairy Export Council describes the CETA rules, especially the restrictions on cheeses like Feta as "entirely unacceptable to the U.S."[50] The U.S. dairy industry has already complained to Office of the United States Trade Representative (USTR) about similar restrictions in the EU-South Korea Free Trade Agreement.

- The U.S. Congress has weighed in on the potential for similar restrictions in the Transatlantic Trade and Investment Partnership (TTIP). A May 2014 letter to USTR Michael Froman from 177 members of the House of Representatives focused on GIs for cheese names. That letter, led by the Congressional Dairy Farmers Caucus with support from the National Milk Producers Federation, asserts that, "The EU is taking a mechanism that was created to protect consumers against

misleading information and instead using it to carve out exclusive market access for its own producers. The EU's abuse of GIs threatens U.S. sales and exports of a number of U.S. agricultural products, but pose a particular concern to the use of dairy terms."[51]

Copyright and Related Rights

David Robinson, *Canadian Association of University Teachers*

Key Points

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- After several failed attempts to amend Canada's copyright laws, new legislation was finally enacted in 2012. While not perfect, the *Copyright Modernization Act* strikes an important balance between the rights of creators to protect and benefit from their works, and the rights of users to access copyrighted materials for non-commercial purposes, including personal use, education and research.
- Initial demands from the European Union in the CETA negotiations would have erased much of the progress made in updating Canada's copyright laws. EU demands included copyright term extensions, enhanced legal protections for broadcasters, strict liability rules for Internet service providers (ISPs), and new resale rights and royalties. Most of these provisions mirrored language in the controversial *Anti-Counterfeiting Trade Agreement* (ACTA), which was ultimately defeated in the European Parliament following strong public opposition.
- The result of many of these changes would have been diminished user rights, higher costs for consumers and governments, and a larger deficit of Canada's trade in copyrighted materials with the EU.
- While Canada largely ceded to EU demands on patent protection for pharmaceuticals (see section on Pharmaceuticals by Scott Sinclair), most of the initial EU requests on copyright and related rights have been withdrawn from the CETA text.

Analysis of Key Provisions

Copyright term extension

- Canada's copyright laws follow the international standard of the *Berne Convention for the Protection of Literary and Artistic Works* in granting copyright protection for life of the creator plus 50 years. According to earlier drafts of the CETA text, the European Union had demanded that Canada extend copyright term to life of the creator plus 70 years. This term extension was supported by the Canadian Publishers Council, the publishing industry's lobby group.
- The CETA does not require an extension of copyright terms. Instead, Article 5.1 states simply that the EU and Canada agree to comply with the Berne Convention.

Broadcasting rights

- The initial EU position in the CETA talks included demands for enhanced copyright protections for broadcasters that would have placed new restrictions on copying broadcast programs for personal use or other fair dealing purposes.
- CETA Article 5.2 makes no mention of enhanced copyright protections for broadcasters. Instead, the CETA requires both Parties to provide creators with the right to authorize or deny the broadcast of their works by wireless means and to ensure they are properly remunerated. This is consistent with current law and practice.

Protection of technological measures

- The CETA prohibits the distribution and use of devices that can be used to break digital locks placed on works in electronic format. While this is not a requirement under the international treaties of the World Intellectual Property Office (WIPO), it is consistent with Canada's new copyright legislation.
- This "anti-circumvention" rule is the key weakness of the *Copyright Modernization Act*. By making it illegal to break digital locks in any circumstances, the Act restricts the ability of users to access and reproduce material for non-commercial, fair dealing purposes. The CETA locks in this aspect of Canada's copyright law.