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# Patents, Copyright and Competition: Assessing the Impact of Trade Deals on Canada

*Recent trade deals have seen Canada agree to strengthened protection for drug patents and an extended term of copyright. What will the impact be on Canada and are the side effects manageable?*

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## THE STUDY IN BRIEF

The intellectual property (IP) provisions of the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union, and of the Trans-Pacific Partnership (TPP), were among their most controversial features. Critics focused notably on strengthened protection for pharmaceutical patents in the CETA, and on the extended term of copyright in the TPP. While the TPP as negotiated may have been sunk by the withdrawal in January of the United States' signature, its IP provisions will very likely resurface in the context of the re-opening of the North American Free Trade Agreement demanded by the new US administration.

In this paper, we review in detail the claims that strengthened protection for pharmaceutical patents would result in an increase in health care costs, and provide some estimates of our own. We also examine claims about the cost to Canadians of copyright term extension.

In both cases, we find that the cost of these changes is likely to be well under what their critics have claimed, and considerably lower than the net gains for Canada otherwise offered by agreements like CETA and the TPP. Furthermore, we note that some changes to Canadian law under CETA actually support competition in the pharmaceutical industry.

The cost of the IP provisions examined here could be reduced or offset by a variety of government policies: speeding up patent approval, promoting competition in the pharmaceutical industry, negotiating lower prices for drugs or, in the case of copyright, promoting the public domain or the accessibility of copyrighted material.

There is little, in other words, suggesting insuperable costs to Canada from these provisions.

Meanwhile, harmonizing basic IP rules with those of our trade partners and increasing our access to these large markets, is expected to have a positive effect on domestic innovators and copyright holders.

Canada is a net importer of intellectual property, and in that sense, will incur some short-term costs as a result of higher net payments to patents and rights holders abroad. Yet Canada is also a net exporter of research and, increasingly, of culture. This indicates the potential for Canadians in the long term to become more active exporters of IP, and in that sense benefit from stronger IP protection themselves.

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## The intellectual property (IP) provisions of major trade agreements Canada has recently signed – namely, the Comprehensive Economic and Trade Agreement (CETA) and the Trans-Pacific Partnership (TPP)<sup>1</sup> – have aroused much controversy.

Their treatment of pharmaceutical patents and copyrights, in particular, has come under fire. Critics of CETA and the TPP charge that these agreements strengthen the rights of patent and copyright holders,<sup>2</sup> thereby making Canadians' access to medicines and cultural content more difficult and more costly, and even hampering innovation in Canada.<sup>3</sup> Some even cite these IP provisions as reasons for rejecting the agreements altogether.

These fears, in our view, are much exaggerated. The agreements do require Canada to take measures that will impose costs on some Canadians, but on balance these costs must be seen in light of the agreements' overall beneficial impact, including advantages that might accrue to Canadians now and in the future from stronger IP protection. As important, the costs of stronger IP protection could be offset by the wide array of policy options Canadian governments will retain, including the implementation details of IP policies; robust competition policy; policies to facilitate access to medicine and culture; and policies to encourage the

generation and transmission of knowledge as well as innovation more broadly.

In short, the IP-related provisions of CETA and the TPP have both costs and benefits, and should be evaluated on that basis, against the broader framework of the trade agreements themselves and of the mitigating tools governments have at their disposal.

Accordingly, this *Commentary* begins by looking at what the CETA and TPP's changes to Canadian law would mean for pharmaceutical patents and the process of generic entry – and, therefore, the cost of medicines. Specifically, we focus on the interplay among trade agreements, domestic competition and the domestic processes under which the validity of pharmaceutical patents is contested. We review existing estimates of the costs of provisions affecting pharmaceutical patents in CETA – which likely will have more impact on Canada in this respect than the TPP – and conclude that they have been exaggerated and that other available policies could easily offset these costs. We then look at changes affecting copyright, focusing mainly on innovation

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- 1 The TPP was signed in February 2016 by Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. US president Donald Trump, however, has signed an executive order withdrawing the United States' signature, without which the agreement cannot go forward. The switch by the United States to a more bilateral approach to trade agreements means, ironically, that Canada likely will be subject to US demands to agree to the type of IP provisions found in the TPP.
- 2 In a nutshell, patents confer on their owners a limited period in which to market a new invention exclusively, and copyrights do the same for the right to reproduce a non-tangible creation.
- 3 See, for example, Balsillie (2016); Geist (2016); and Lexchin and Gagnon (2013).

and on the dissemination of information, as well as on the enforcement question. We examine estimates of the costs of copyright extension, and review ways the federal government could offset these costs.<sup>4</sup>

We conclude that the IP provisions of CETA and the TPP would be considerably less costly than their critics have suggested, that any such costs would be manageable, and that in any event they do not negate the net benefits of the two trade agreements. CETA's provisions are due to come into effect starting this year; the TPP seems to be a dead letter, but a number of its provisions, including those pertaining to copyright, might well resurface in other trade negotiations, including a reopened North American Free Trade Agreement (NAFTA).

## WHY PROTECT INTELLECTUAL PROPERTY IN TRADE AGREEMENTS?

Why are trade agreements concerned with protecting intellectual property in the first place? International trade and investment give consumers access to better or less expensive goods and services than those the domestic market alone provides. They also allow firms to combine input – including designs, data, scientific formulas and other products of research and development (R&D) – across borders to develop such goods and services. A minimum level of protection for IP or IP-intensive products as they cross borders facilitates the beneficial international exchange of goods, services

and inputs. Indeed, trade historically has tended to increase between countries that strengthen their IP protection (Akkoyunlu 2013). Harmonization of IP laws between countries also might reduce the costs of compliance that face firms engaged in trade. Given the relevance of intellectual property to trade flows, modern international trade agreements typically require signatories to comply with a number of stand-alone provisions concerning the protection of IP,<sup>5</sup> including setting a minimum duration for patent or copyright protection, and addressing cooperation and enforcement issues between them around IP protection. The thrust of these measures is to set the “minimum floor” level of protection across countries.<sup>6</sup>

One question that naturally arises is to whose policies should IP laws be harmonized? In the case of CETA and the TPP, harmonization involves raising the “minimum floor” toward the levels of the European Union, the United States and Japan. These economies' export structures are more IP-intensive than are those of most of their trading partners, including Canada. So there is little question that these economies are more motivated to negotiate IP provisions that will increase the value of their IP in foreign markets than to maximize opportunities for mutually beneficial trade per se. That is, the stronger IP protection these large economies demand in trade agreements should be seen as an attempt by global IP owners in these countries to increase their terms of trade.

4 Trade agreements have also affected Canadian law and practice concerning trademarks, geographic indications, industrial designs and other forms of IP, but we omit these from the current discussion.

5 The most important of these is the Trade-Related Aspects of Intellectual Property Rights agreement, binding on all 164 members of the World Trade Organization, requiring adherence to most of the Berne Convention (see footnote 6) and to the Paris Convention for the Protection of Industrial Property (which includes patents). Other examples, as in the CETA, include compliance with key parts of the World Intellectual Property Organization Performance and Phonograms, and Patent Law treaties.

6 Patents are territorial in application, so the basic idea of international cooperation in that area is to ensure that patent owners in one country can easily apply for and receive a minimum level of protection in a partner country when they apply for a patent there. Under the Berne Convention for the Protection of Literary and Artistic Work, copyright protection in any signatory country is automatically extended to work protected in the others. Rules and enforcement still vary significantly across countries.

Since Canada is a net importer of IP,<sup>7</sup> Canadians pay more for IP and IP-intensive products than they would otherwise because such products cannot be easily replicated as long as they are protected, and from that static perspective stand to lose under more protective regimes.

However, that cannot be the end of the story. The core economic argument for IP protection is that we ought to endure the short-term, “static” costs of a monopoly for the (larger) long-term, “dynamic” benefits of the innovation<sup>8</sup> it encourages. Patent protection can also encourage the disclosure and spread of technology more generally (Gallini 2002). To the extent these social benefits override the social costs, the world – including potentially those who are net importers of IP-intensive products – is better off. Could trade agreements be said, then, ultimately to support a more innovative world economy by requiring parties to them to subscribe to minimum levels of IP protection? This question requires us to say a bit more about the benefits and costs of patents and copyright, respectively.

## Patents

To be awarded a patent, an invention must be deemed new, useful and non-obvious, in addition to coming under matters that are considered patentable.<sup>9</sup> The key social reason to award and protect patents, apart from any incentive they provide to invent or innovate, is that they reveal the secret of the invention they protect. Patent holders

are awarded a time-limited monopoly over their inventions – a monopoly that in other respects might be considered economically inefficient – in exchange for this socially beneficial information.

The value of this monopoly for patent holders will vary. Competing products or technologies might emerge and reduce the expected market value of the patented product, and hence of the patent. Such competition thus will tend to reduce the private benefits and social cost of a patent. The flip side of this is that a proliferation of patents – especially patents of questionable quality, for example with regard to their non-obviousness – around a certain type of application can inhibit innovation due to its anti-competitive effects, and thus have a socially negative impact (Brander 2010). This is the problem of “patent thickets”: groups of patents accumulated as much with a view to using them as to keeping potential competitors at bay with the threat of patent infringement.

## Copyright

The economic argument for copyright protection rests on the view that individual creators and those who employ them would be reluctant to offer the market original creative work, especially work that can be easily replicated, if their rights to benefit economically from the use of their work were not recognized. This economic argument is distinct from that of the moral right of authors to their work, which is provided for under the Berne

7 In 2015, Canada’s payments for patents and industrial designs, copyright and related rights, and software and other royalties, exceeded receipts on those same items by \$5 billion, or one-quarter of 1 percent of gross domestic product (Statistics Canada 2016, and authors’ calculations).

8 Innovation means, more broadly, the application of new practical ideas, or the new application of existing ideas, to privately or socially desirable objectives.

9 In Canada, according to the *Patent Act*, inventions must fall under one of the following five categories: “art, process, machine, manufacture, or composition of matter.” The Canadian Intellectual Property Office publishes numerous guidelines on what does or does not fall under one of these categories.

Convention and in many countries' copyright laws, including Canada's.

The view that increased economic incentives through strengthened copyright would result in a larger supply of creative or scientific work is often disputed, especially where copyright terms and enforcement are seen as limiting the dissemination of culture or information. That is why copyright laws tend to allow unauthorized copying for many non-commercial and socially useful uses.<sup>10</sup> As well, there is the question of whether copyrightable material produced thanks to a public subsidy, such as certain scientific papers, should benefit private copyright owners at the expense of wider public dissemination. Last, but not least, there are serious doubts that copyright protection extending well beyond an author's likely death induces additional creative effort.

### Summary

The net economic effect of protecting intellectual property is not always clear. One recent study concludes that stronger IP protection induces more R&D spending in Canadian establishments (Blit and Zelaya 2015) – indeed, many economies with strong patent protection are among the world's most innovative.<sup>11</sup> Yet, at earlier stages of their industrial and scientific development, a number of these currently highly successful economies – among them the United States, Japan and Germany – facilitated the spread of knowledge through weak IP protection (Cadot, Carrère and Strauss-Khan

2011). Today, South Korea and Israel rank highly on the innovation index and China is coming up strongly, but none of these countries ranks highly on IP protection.

The impact of IP protection in any country over any given period seems to depend on the industry, the type of invention, market growth, the policies of trading partners and complementary domestic factors such as capacity to absorb knowledge and the vigour of the competition regime (Maskus 2000). The effect of stronger IP protection on Canada depends, therefore, on the country's economic development trajectory and its suite of other policies. The debate on IP policy – and hence on the net impact of IP protection in trade agreements – comes down to whether, in addition to smoothing international commerce, IP protection also induces the availability of new valuable products while not unduly limiting the spread and further use of the knowledge and information the IP contains.

Any change to IP policy due to a trade agreement therefore should be seen in the context of the effect of the entire agreement and indeed of other available policy tools to facilitate innovation. In this regard, we note that the market expansion resulting from trade agreements inherently promotes innovation, both because it allows firms to amortize research costs (Dinopoulos and Segerstrom 1999) and because it spurs competition (Howitt 2015). More generally, the debate speaks to the need for innovation policy to be tailored to some extent to each country's circumstances, and therefore to the need for international IP agreements to allow their

10 Canadian copyright law has always contained exemptions for unauthorized copying under the common law conception of "fair dealing," which is similar to "fair use" under US copyright law. The current *Copyright Act* carves out an exemption for research, private study, education, parody, satire, criticism or review and news reporting. Supreme Court of Canada decisions – for example, 2004 SCC 13 – indicate that this list is not exhaustive.

11 Seventeen of the world's most innovative economies, according to the Global Innovation Index, are also among the twenty most protective of IP, as identified by survey respondents for the World Economic Forum's Global Competitiveness Index. They include Canada, ranked 15th on the innovation index and 12th on IP protection.

members considerable flexibility in how IP policies are implemented, beyond a certain minimum level of protection.

## CETA, THE TPP AND THE BALANCE BETWEEN PATENT OWNERS AND USERS

The changes required under CETA's patents provisions exclusively concern their application to pharmaceutical products. The TPP's provisions affecting patents are broader in scope, but their effect over and above that of the CETA is likely to be small.

Pharmaceutical patents affect the very visible tradeoff between the shorter-term interest of consumers and insurance schemes in having access to cheaper medicines, and their longer-term interest in fostering new and innovative medicines – two laudable public goals. The trade agreements' provisions regarding patents seek, in the name of encouraging innovation, to tilt this tradeoff somewhat toward stronger protection for brand-name pharmaceuticals, although none would increase very substantially the IP-related protection of brand-name drugs in Canada.

### Key Issues in the Negotiations

Three key issues were at stake concerning pharmaceutical patents in the CETA negotiations; two were also substantive items in the TPP talks.

*Patent term restoration (PTR):* This provision extends the life of a patent when regulators take an excessive amount of time to approve and/or grant “market authorization” to a patented product – a process governed in this country by Health Canada and distinct from the granting of the patent.<sup>12</sup> Although CETA's PTR provisions apply specifically to pharmaceuticals and concern market authorization and patent approval jointly, the TPP includes both a general PTR provision that would apply to patent approval itself and a pharmaceutical-specific PTR provision that would apply to market authorization.<sup>13</sup> Under CETA's pharmaceutical-specific, extension – denoted *sui generis* protection to distinguish it from regular patent protection – a new patented medicine would be granted an additional period of exclusivity if Health Canada and the Patent Office take more than five years to approve it. Only a single period of *sui generis* protection would be available per drug in Canada, however, even if there were multiple patents protecting it. The CETA also caps this additional period of exclusivity at two years (the TPP mentions no cap), and permits Canadian generics to manufacture medicines for export during this period, alleviating some of the concerns about the fallout of PTR for that segment of the Canadian industry.

*The “right of appeal”:* Under this provision, brand-name producers who believe Health Canada has inappropriately permitted generic entry of their patented medicine would have recourse to appeal.

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- 12 The EU also sought, and Canadian negotiators resisted, an extension of patent terms in CETA. Similarly, in TPP negotiations, the United States sought to extend data protection for so-called biologics – those isolated from natural sources – to the 12 years now in effect in that country; its TPP partners resisted that demand, partly on the grounds that the United States' own Federal Trade Commission was arguing domestically for easing the path to market for generic versions of biologics (United States 2009).
- 13 A footnote in this section of the TPP explicitly allows a member country to fulfil this second obligation using *sui generis* mechanism such as the one in CETA.



Under the status quo, a manufacturer of generic drugs must notify the holders of any patents officially registered against the drug it wishes to produce; these patent holders – usually brand-name drug makers – may ask the Federal Court to prevent Health Canada from allowing a generic version of their product to enter the Canadian market if they believe their patent is being infringed. If the maker of the generic loses the case in the Federal Court, it can appeal to the Federal Court of Appeal and even seek leave to appeal to the Supreme Court of Canada. If the brand-name producer loses the case, however, the generic is allowed to enter the market immediately, and any appeal would be merely an academic exercise to show that the Federal Court was incorrect in its decision. Currently, the courts will not even hear these moot appeals. Not surprisingly, brand-name drug makers (many of them EU companies) have looked askance at this asymmetry.

*The duration of data protection:* In Canada, when a brand-name pharmaceutical enters the market, no generic producer may use the data – typically, scientific evidence on the efficacy and safety of the drug – in its own application for Health Canada’s approval for eight years. This provision constitutes the grant of a monopoly similar to a patent, but independent of the delay between patent filing and market entry. Both EU and, in the TPP, US negotiators wanted to extend this data protection to ten or, in the TPP, twelve years. Unlike patent term restoration and the right of appeal, stronger data protection might have resulted in an across-the-board increase in the number of years generic drugs would have been kept off the market, which

could have been quite costly. The final CETA and TPP agreements, however, provided for eight years of protection, which is in line with Canada’s current domestic regime. In turn, Canada’s eight years of data protection itself rarely delays the entry of generics into the Canadian market since the remaining patent term is usually longer than eight years anyway.<sup>14</sup>

### **Estimating the Impact of Patent Term Restoration**

The argument for PTR is that it discourages patent offices or other regulators from dragging their feet on approving innovations. For products that need government approval before they can be sold at all (notably pharmaceuticals), there is a more specific argument for additional time to bring the “effective patent term” up to par with other inventions and put investments in these products on a more level playing field. Many countries, including the United States, the United Kingdom, the EU, Japan, South Korea, Israel and Australia, already have provisions equivalent to patent term restoration for pharmaceutical products, most of which have been in place for decades. Without exception, all these countries cap the extension at five years and, for the most part, seek to limit the period between patent filing and market authorization at five years (United States 2016). CETA, however, caps PTR at only two years. The TPP’s two PTR provisions differ from CETA’s in that they do not mention caps, and apply separately to the market authorization process and for unreasonable delays in the patent office process, with the latter applying to all patents.

14 Of the drugs listed as having data protection terms on Health Canada’s website at the time of writing, only about 17 percent have terms that exceed the expiry of all patents listed against the drug in the Patent Register. This fact undermines the complaint by Lexchin and Gagnon (2013) that CETA locks in an existing Canadian policy of “excessive” data protection. If the term were to increase to the 12 years proposed by the United States during the TPP negotiations, on the other hand, the share of current drugs with data protection exceeding their patents would rise to about 45 percent.

Of course, the economic effect of note for these extensions is that Canadians would face a longer period of monopoly prices for some drugs. More long-term or indirect benefits, such as a possible increase in research spending in Canada in response to longer effective patent terms, are uncertain. Estimating the impact of PTR then comes down to estimating how much longer patented medicines would be protected and how much Canadians would have to spend on them over and above generic prices during that period. To do so, we first need a sense of how often the different PTR provisions of the TPP and CETA would be used in Canada.

Although the TPP would extend PTR to products other than pharmaceuticals in the case of patent office delays, much of the discussion on PTR should focus on the price of medicines, for a number of reasons. First, pharmaceuticals are among the most prolific users of the patent system in terms of sheer applications (Brydon et al. 2014). Second, medicines are acutely affected by monopoly prices, which often drop 50 percent or more as generic versions enter the market,<sup>15</sup> and account for large absolute expenditures by individuals and governments.

PTR that focuses on delays to “market authorization,” as in the TPP, is unlikely, however, to see much use. Health Canada reports that new patented medicines recently are being approved in less than a year and a half, on average (Canada 2015). Under the TPP, however, PTR would be triggered only if this process exceeded five years. Indeed, since 2009, only one or two drugs have seen approval take more than the allotted market authorization period under either CETA or the TPP, likely due to a request for more information from the brand-name producer (Canada 2015). This last point bears consideration, because CETA, the

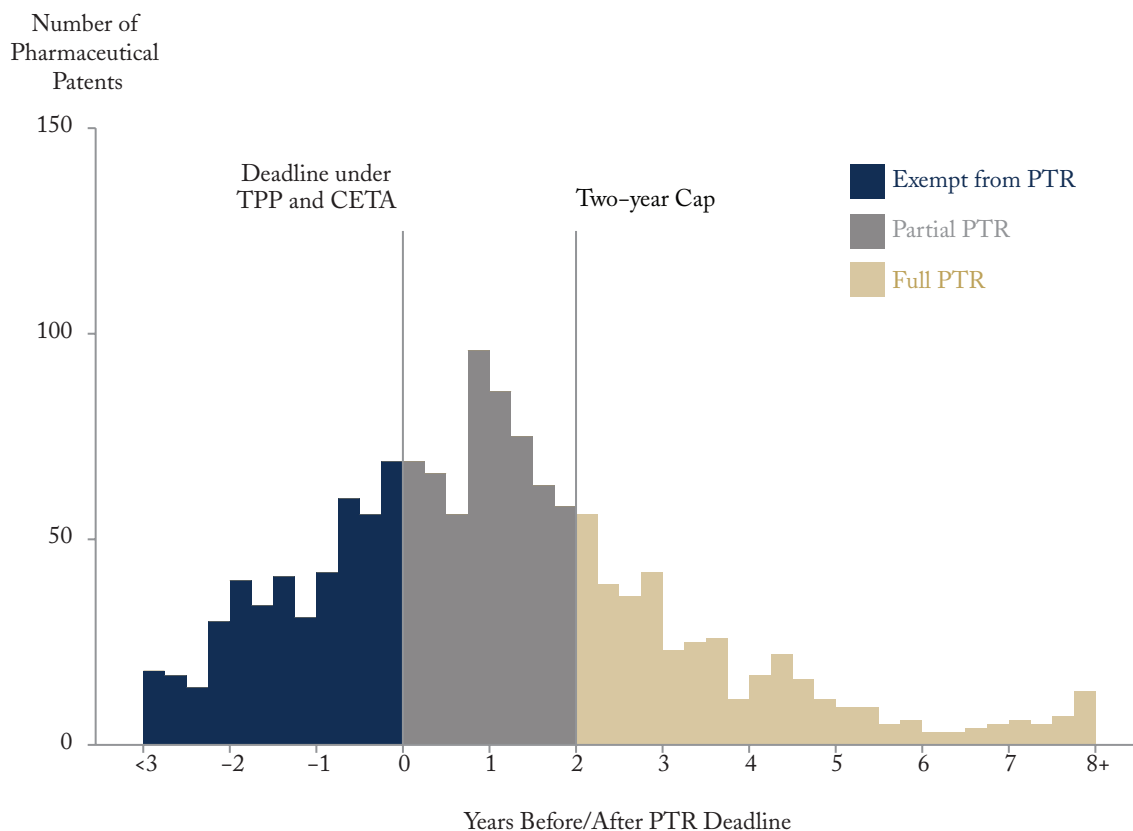
TPP and the implementation legislation for CETA prohibit restoration of patents when the patent owner is the cause of the delay, which likely will reduce the possibility of abuse of these provisions by applicants.

Moreover, if PTR grants for “market authorization” delays do become common enough to warrant concern, there is an obvious solution: ensure that Health Canada is sufficiently well-resourced to review drug applications in a timely manner. This approach has been articulated by New Zealand’s Ministry of Foreign Affairs and Trade in its costing of the TPP’s PTR implementation in that country; small investments in operating budgets for their equivalent of Health Canada are estimated effectively to eliminate the need to grant PTR terms.

PTR grants that relate to patent office delays, on the other hand, likely will have a very real impact. The patent-office-specific provision of the TPP and the *sui generis* protection in CETA – which combines the patent approval and market authorization period – are both likely to be used for pharmaceutical patents if history is any judge, because a large number of patents currently registered against Canadian medicines took more than five years to approve (see Figure 1). In fact, quite a number took more than a decade, despite the patent office’s recent reporting that more than 90 percent of biotechnology patents see “substantive office action” within 19 months (Canada 2016). Under CETA’s *sui generis* protection, a drug gets only one period of protection, so a general sample of pharmaceutical patents (as in Figure 1) is somewhat misleading. This is because many pharmaceuticals have more than one patent attached to them. Moreover, CETA’s two-year cap appears modest in light of the common practice of attaching a second,

15 For example, the Pan-Canadian Pharmaceutical Alliance has orchestrated bulk purchases at 18 percent of the brand-name price for many provincial governments’ most-used generics (PCPA 2016).

**Figure 1: The Hypothetical Effect of Patent Term Restoration on Current Canadian Pharmaceutical Patents**



Sources: Authors' calculations from Health Canada and Canadian Intellectual Property Office data.

third or even more patents to a drug – all of which might have filing dates long after the first patent – that extend the effective period of protection by many years.

Parallel to the argument for better resourcing market authorization bodies, some of these costs could be avoided by providing enough resources to the Canadian Intellectual Property Office to review patents in a more timely manner, although it is clear that more catch-up is required in this case than for the typically-faster market authorization process.

The effect of the TPP's more general PTR is more difficult to judge. Since the agreement makes no mention of a cap, it is reasonable to assume that Canada could adopt the same two-

year policy as under CETA. The TPP contains no corresponding "one-time-only" rule as in CETA's *sui generis* provision, so it is possible that, under the TPP, all a drug's patents could be extended. Yet, in practice, it is the expiry date of the youngest patent listed against a drug that determines how long it is protected from generic competition, so it is only the possible extension on this youngest patent that really matters.

What, then, is a reasonable estimate of the gross cost of PTR in terms of the period medicines are insulated from generic competition? Grootendorst and Hollis (2011) estimate that implementing some of CETA's provisions – they use a PTR of five years, longer than the two years actually agreed

on – would have delayed the entry of generics by more than three years, on average, for their sample of 13 drugs – not necessarily a good representation of all patented medicines in Canada – and increased the cost of Canadians’ pharmaceutical spending by about 7 percent. Our recalculations from their data indicate that a two-year cap would drop this figure quite substantially – in fact, to zero in many of the sample cases.

A better sense of how much difference a longer period of monopoly prices for PTR drugs might mean comes from the Australian Pharmaceutical Patents Review Panel report (Harris, Nicol and Gruen 2013). The panel, which had access to the full spending data for Australia’s national drug plan, concluded that PTR – in Australian law called “extension of term” – increased costs by about 0.5 percent of the drug plan’s budget for each of the five years of PTR available in the country (for a total of 2.5 percent). There are reasons to think costs might be slightly higher in Canada – for example, because Canadian generics are generally cheaper than Australian generics, so the savings would be a bit higher – but these figures are likely to be a much better ballpark estimate of Canada’s likely experience, since the Australian study profiled all patented medicines.

Provincial drug plans, however, cover only about a third of what Canadians spend on drugs. The remaining costs are carried by private drug plans or paid out-of-pocket, which means patients are not always able to take advantage of the lowest generic drug prices available (Blomqvist and Busby 2015). In 2015, Canadians spent about \$34 billion on drugs (CIHI 2015), so a middle-of-the-road estimate of a 2 percent increase in costs (weighing the differences between the Australian panel’s data and our own) would mean about \$700 million per year. This assumes that the mix of drugs used by those under private plans or paying out-of-pocket would be much like those faced by government plans. To put this sum in perspective, it is worth mentioning that the cost of Australia’s national drug plan was growing at about 4 or 5 percent per

year at the time of the panel’s report – close to the historical growth in most Canadian provinces as well, though it has slowed more recently. Any cost pressure the PTR might create would not add significantly to other, more mundane pressures facing pharmaceutical spending in Canada and, given the other factors we discuss below, might not result in actual price increases.

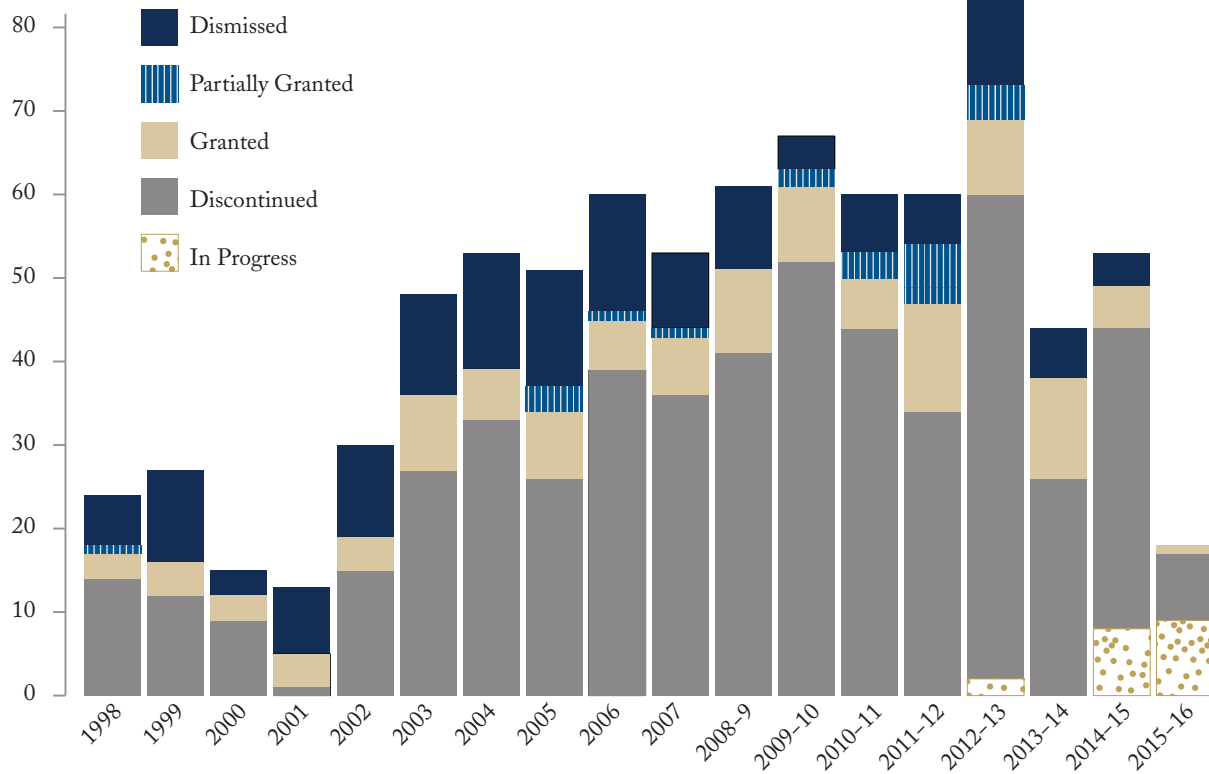
### **Brand-Name Manufacturers’ Right of Appeal**

CETA’s resolution of the asymmetry between brand-name manufacturers’ right of appeal and that of generic manufacturers could be interpreted simplistically to mean that generic entry is to be prohibited until the strengthened appeals process has concluded. Indeed, if this were the case, it could extend brand-name drug protection by an estimated 6 to 18 months (Grootendorst and Hollis 2011). However, that interpretation would be inaccurate. Only the reasonably small number of drugs whose patents are challenged (as opposed to expiring) would be affected, and even then only in cases where the generic was successful – in precise terms, the brand’s case is “dismissed” or only partially “granted” – would the brand-name manufacturer be able to appeal. Fewer than 15 percent of cases commenced since 2008, or about eight per year, would have presented any opportunity for an appeal (see Figure 2). The large majority of suits are either settled or won (“granted”) by brands.

One can measure the new right of appeal’s effect in much the same way as the PTR and *sui generis* protection detailed above: by an increase in the costs of drugs for the period that generics are kept off the market. By the same argument we outlined above, an additional six months (very generously applied to all possible medicines) might increase drug costs in Canada by up to 1 percent, or about \$350 million per year.

On the other hand, the implementation of the right of appeal might well ameliorate another long-standing issue in the generic entry process. The lack of a meaningful appeals process has

**Figure 2: “Prohibition Applications,” that Would Potentially Be Subject to a “Right of Appeal” under CETA, 1998–2016**



Note: As a part of the generic approval process, patent owners (brand-name drug owners) ask the Federal Court to prohibit Health Canada from allowing the generic to enter the Canadian market (hence “prohibition applications”). This application is either “dismissed,” in which case the generic is permitted to enter the market, or “granted,” in which case it is not. Cases that are “partially granted” generally involve more than one patent, and may allow the generic to enter the market with some conditions. Only cases that are “dismissed” or “partially granted” would be subject to changes to the appeal process under CETA.

Sources: Authors’ calculations from Health Canada data.

meant that brand-name producers have pursued an alternative strategy peculiar to the Canadian regulatory environment: launching patent infringement cases after the generic enters the market. It is not uncommon for these later cases to come to a conclusion at odds with earlier “prohibition application” cases, and the threat of this “dual litigation” process for patented medicines is a considerable source of anxiety for the generic industry – likely reducing the number of patents they challenge for fear of paying full infringement damages.

In this context, and in a bid to improve the operating environment for both brand-name and generic industries, the Canadian government committed during the negotiation of CETA to modifying existing regulations to resolve the “dual litigation” phenomenon when creating the new appeal process. The CETA implementation legislation does indeed empower the regulator to create these changes, although what form this will take is not yet clear. Insofar as these changes would reduce the risks when generics challenge patents (and sometimes succeed), the delay to generic entry

posed by the right of appeal might be offset in whole or in part by more entry overall.

### Overall Impact and Mitigation

As these changes to patent protection will not apply retroactively, either under CETA or the TPP, Canadians will not see any resulting increased drug costs until five years from the implementation date of CETA – the allotted period for patent approval and market authorization. If CETA comes into effect in 2017, the first *sui generis* applicants for PTR will not appear until after 2022. Most applicants, however, likely will qualify for data protection as well, so the effects of this regime unique to pharmaceuticals probably will not be felt until after 2025, when the eight-year data protection periods granted in 2017 end.

For the most part, Canada will not have to make major changes around patents based on the provisions of either CETA or the TPP because its regime already meets most of the agreements' criteria – for example, on the duration of data protection. Changes that would be required – namely, a new right of appeal and new patent term restoration provisions – might be quite limited in their impact, with a number of exceptions and clarifications added to limit their potential for misuse. *Sui generis* protection is limited to a single application per medicine, and is capped at two years. Both CETA and the TPP contain measures designed to reduce strategic delays on the part of patent holders to extend their terms of protection. Finally, delays that accompany the new right of appeal might be offset by positive changes to Canadian law that eliminate the “dual litigation” problem.

In short, the economic impact of changes under CETA and the TPP would push up the annual cost of drugs by at most 3 percent, or \$1 billion in today's terms, beginning in 2026, an amount equivalent to a typical yearly increase in spending on prescription pharmaceuticals (CIHI 2015): the actual amount will likely be considerably less. More

important, governments have other tools at their disposal to limit any resulting increase in drug costs, including reducing delays in approval in the first place and adding to the resources of Health Canada and the patent office. Governments can also set public healthcare expenditures and, indeed, regulate drug prices. Given these and other factors, some analysts have suggested that changes under the two trade agreements would not lead to any increase at all in drug costs (Skinner 2012), pointing to the experience of NAFTA, the last time Canada strengthened its pharmaceutical patents regime in conjunction with a trade agreement.

### The Role of Competition Policy

One area overlooked in the discussion of the IP regime is the role of competition policy. Discussion about the impact of CETA and the TPP is often couched in terms of increased drug costs. Yet it is not precisely true that the price of drugs would go up; rather, higher-priced brand-name drugs would enjoy a longer period of monopoly before cheaper generic versions may be sold. Historically, the affordability of drugs has depended on generic drug companies entering the market and driving down the price of a drug after its patents expire. Indeed, generics sometimes claim that a patent is invalid in an attempt to enter the market immediately – precisely the legal process that the right of appeal in CETA affects. It does not seem unreasonable to suggest, therefore, that much of the discipline on pharmaceutical patent quality in Canada is thanks to competition from these private-sector actors.

To illustrate the positive role effective competition policy can play, we point to the Commissioner of Competition's recent concern that settlements in the “prohibition application” cases between generic and brand-name manufacturers – which make up about 65 percent of the outcomes, as seen in Figure 2 – present an opportunity for moral hazard on the part of both participants. Since the brand-name company stands to gain much more profit than the generic, it makes sense

for it simply to pay its competitor to desist quietly (Canada 2014). Whether this actually occurs is heavily disputed, and the formal guidelines on this issue released two years later by the commissioner are much milder in their comment on this possibility. But the commissioner's claims aside, it is clear that the cost of medicine in Canada is strongly tied up with the aggressive entry of generics into previously monopolistically priced drug markets.

For Canadian governments, then, nothing could be more relevant to a discussion of institutions that affect the cost of drugs than ensuring that generics continue to compete vigorously, both with brands and with each other, while leaving the door open to efficiency-enhancing arrangements between the two market segments. Neither CETA nor the TPP materially limits Canada's ability to pursue positive policy in this regard.

### **Summary Discussion on Pharmaceutical Patents**

Although it is true that CETA and the TPP will tend to delay slightly the entry of generic drugs into the Canadian market, the upper bound of what this delay might cost Canadians, beginning in 2026, is significantly lower than the estimates of often-quoted reports. Moreover, these exaggerated estimates were themselves less than a third of the \$7 billion expected annual boost to Canada's GDP from CETA (European Union 2011). As well, governments have significant tools at their disposal to limit any cost increase. How confident are we that the sky will not fall? We note that, although CETA is often criticized for bringing Canadian pharmaceutical patent protection more in line with that in the EU, the per capita cost of pharmaceutical prescriptions is lower in the EU than in Canada (see Morgan, Daw and Law 2013).

### **THE TPP AND THE BALANCE BETWEEN OWNERS AND USERS OF COPYRIGHTED MATERIAL**

The TPP is by far the more contentious of the two trade agreements regarding copyright, which is not surprising as CETA conforms almost entirely to existing Canadian copyright law. The main issues in the TPP were enforcement and the extension of the copyright term to 70 years.

#### **Enforcement**

Most of the Canadian enforcement regime, in fact, would have been preserved under the TPP, remaining less stringent than some countries, notably the United States, had wanted. Among the provisions that would remain in any future TPP-like agreement in this respect is Canada's "notice-and-notice" system, whereby copyright owners notify Internet service providers of an alleged infringement, who in turn notify the web site, organization, or person using the service that an infringement is alleged. Under the US "notice-and-takedown" system, in contrast, the Internet service provider must take down any material that allegedly violates copyright. Some commentators who favour the Canadian "notice-and-notice" model – most prominently Michael Geist (2016) – complain that the Canadian negotiators failed to have this model adopted in other TPP signatories, but it is a stretch to argue that Canada had the power to do so anyway. And while the TPP would not shield Canada from continued US pressure to modify its regime and toughen enforcement, such pressure would exist with or without an agreement like the TPP.

The TPP would not have affected Canada's overall framework of "fair dealing," which permits unauthorized copying for some uses. The TPP emphasized penalties, including criminal penalties,

for copyright violations, but clearly only those on a commercial scale harmful to the copyright holder in the market where the violation takes place, reducing the risk of penalties disproportional to the effect of the violation. The TPP would have prevented the removal of embedded “rights management information” pertaining to authorship and ownership of a copyrighted work, even by institutions allowed unauthorized reproductions of copyrighted material under “fair dealing.” Otherwise, it would have left the Canadian copyright regime essentially intact (Turcotte 2016).

### **Length of Copyright: Impact and Mitigation**

The TPP would have extended the term of copyright protection to “not less than the life of the author and 70 years after the author’s death,” which exceeds the current level of Canadian protection by 20 years. At the outset, one must acknowledge that the benefits of this lengthening of protection, in terms of the generation of new creative work, likely would be very small (Akerlof et al. 2002; Hollander 2005) given the low returns on a discounted basis of the added 20 years of protection. In contrast, some argue that making protection available for longer, in the form of an indefinitely renewable copyright (but with potentially shorter copyright lengths than now) would lead to a more economically efficient use of protected works by copyright owners and an expansion of the public domain (Landes and Posner 2002). One thing is certain: although the TPP’s extension would deny the public free access to some copyrighted works for two decades beyond what is provided by the existing regime for up to another 20 years, it is not correct to suggest, as some have done, that the works will not be available at all: copyright holders presumably will wish to maintain prices low enough that there will be continued interest

in acquiring and using the work. The extension of copyright protection by 20 years would also benefit Canadian copyright owners in jurisdictions, such as the EU, that currently refuse to extend copyright protection to Canadians in their jurisdiction beyond what their authors are afforded in Canada.

How much would this change cost Canadians? Hollander (2005) suggests that it would increase the net outflow of royalty payments by 1.5 percent, or about \$3 million in 1997 dollars. An often-quoted New Zealand study concludes the extension of copyright protection under the TPP would result in net outflows to foreign rights holders and “deadweight” losses – that is, the cost of transactions forgone because of higher prices for copyrighted material – of about US\$10 per capita (New Zealand 2015). Applied to Canada, this would amount to some \$480 million. It should be noted, however, that the approach used to obtain such estimates appears to suffer from some mathematical inconsistencies,<sup>16</sup> and likely greatly exaggerates the estimated cost (Barker and Liebowitz 2016). Furthermore, we note that these cost estimates are not always, or even typically, borne out by actual experience. For example, Weatherall (2015) finds no evidence of an impact on Australian international copyright payments from the Australia-US Free Trade Agreement, despite predictions (for example, by Dee 2004) of a large negative effect. In short, however the cost is calculated, it would be well below the \$3 billion annual gain in income Canadians might expect from other aspects of the TPP (Ciuriak, Dadkhah and Xiao 2016).

It is possible that a negative effect might make itself felt in terms, not of increased payments, but of the opportunity cost of a derivative innovation’s not taking place as a result of the added period of protection of copyrighted material (Khanna 2014). The ability to measure such an effect,

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16 A description of these inconsistencies is available from the authors upon request.



however, is highly elusive, and not surprisingly no hard evidence has been produced showing such a negative impact. In the end, if an extended term were perceived as harmful to education and innovation, there is nothing preventing the Canadian government from encouraging the buildup of the public domain, particularly with work financed by public funds, or offering a subsidy for creators who forgo copyright protection and permit their material to be shared via a creative commons licence.

## CONCLUSION

There is no question that some intellectual property provisions of CETA and the TPP would lessen the availability of lower-cost imitations of patented and copyrighted material. Estimates of any costs such changes to patent and copyright laws might impose on Canadians, however, are dwarfed by the benefits of the two trade agreements, including the domestic innovation that access to larger markets has been shown to spur. More important, Canadian governments could significantly dampen, or even offset altogether, any costs that might arise

from extended patent and copyright protection. Canada also remains free to pursue, at the World Intellectual Property Organization and in other international forums, reforms that promote the public interest in the dissemination of knowledge and technology.

Pessimists about the structure of Canada's economy assume that it will always be a net importer of R&D-intensive, cultural and other copyrighted products. Yet Canadians, while not significant owners of intellectual property, are net sellers of their brainpower. Canada is a strong net exporter of R&D services to the rest of the world. Indeed, at \$4.2 billion, Canada's little-heralded trade surplus in such services almost offsets the cost of their use of intellectual property. This emphasis on producing, rather than exploiting, IP might indicate that something is wrong with Canadian entrepreneurship and innovation culture in general, but it also suggests a high potential for Canada's becoming a net IP exporter. In that context, Canada might well look back in a few years on improved IP protection in trade agreements as a major booster of Canadians' incomes.

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