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WHO'S AFRAID OF THE USMCA?

Why the intellectual property provisions in the US Mexico Canada Agreement are good for Canada and its trading partners

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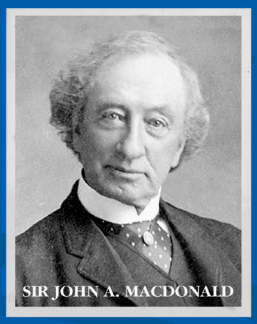
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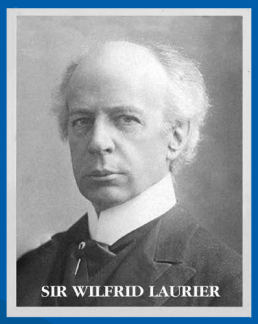
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Executive Summary

The US Mexico Canada Agreement (USMCA) to replace the North American Free Trade Agreement (NAFTA) was signed by the parties on November 30, 2018. But ratification is by no means assured. While a deal on steel and aluminum tariffs was reached between the three countries in May 2019, eliminating one hurdle to its ratification, certain provisions are controversial in Canada with an election pending, and it will be an uphill battle in the US Congress.

Yet passage of the agreement is vitally important. The US, Canada, and Mexico are natural trading partners with integrated economies. The previous NAFTA has done much to reinforce and deepen this reality. We cannot abandon the great advances that the USMCA makes over the earlier agreement.

The US, Canada, and Mexico are natural trading partners with integrated economies.

In particular, this paper focuses on Chapter 20 of USMCA, which contains the intellectual property (IP) provisions. Vocal critics in Canada have claimed that Chapter 20 will add billions of dollars to our health care costs, limit creativity, and unfairly constrain online platforms. The paper addresses each of these.

In sum, the USMCA's IP provisions largely elevate Canadian and Mexican IP laws towards the US standard. The Washington-based Global Innovation Policy Center (GIPC), which ranks countries based on the strength of their intellectual property regimes, has found that by adopting the measures in the USMCA, Canada will improve its current score of roughly 66 to 80 out of 100 in the GIPC Index. Canada was most recently ranked 19th out of 50 countries by the GIPC, suggesting that there is significant room for improvement if we want to join the world's most innovative economies.

The US leads Canada in innovation and IP protection in part because Canada has had a follower mentality and has tended to negotiate for weaker IP provisions in trade talks. This is largely because influential opinion within and outside government in Canada runs counter to Canada's best interests. The strength of that opinion, the great complexity of the issues, and political inertia, all conspire to clamp Canada in innovation irons.

Perhaps the most talked about IP provision in USMCA is additional **data protection for biologic drugs**, requiring that they enjoy 10 years of data protection, up from the current 8 years in Canada (currently 12 in the US).

A "biologic" is a large molecule drug made from complex biological processes. Data protection prevents a biosimilar (the biologic equivalent of a generic drug) from being approved on the basis of the clinical trial and related data submitted by the original biologic until the expiry of the data protection term.

Data protection is a better form of protection for biologics than patents, owing to weaknesses in the patent system relating to biologics. While 10 years of data protection may seem long, research indicates that it commonly takes drugs more than 12 years to recoup the investment in research that makes them possible.

Moreover, the market for biosimilars will not be the same as for generic versions of simpler, old-style drugs. It costs far more to develop and seek approval for a biosimilar and cost reductions compared to innovative biologics will be in the order of 30 percent. So, to delay the entry of a biosimilar by USMCA's required two years of additional market exclusivity will be far less costly than is the case with small-molecule generics.

The enormous costs of developing and seeking marketing approval for a biologic militate strongly in favour of a longer term of additional exclusivity. A longer term will also create better conditions for innovation in Canada.

The other major change for Canada is **increasing the term of copyright protection** to life of the author plus 70 years, from the current life plus 50 years. There are many reasons why this is good for Canada – including in particular access to similar protections from nations that offer them only reciprocally. It will be a boon to Canadian authors, and Canada's Report of the Standing Committee on Canadian Heritage recently recommended this change, irrespective of the USMCA requirement.

Excessive exemptions from liability for intermediaries, or platforms, as allowed for in USMCA, cause mischief. In particular, they have created very high levels of piracy of music, movies, and other content on services like YouTube, which have resulted in plummeting revenues for artists. Accordingly, Canada must not interpret the **safe harbour provision** of the USMCA broadly, as it will undoubtedly be under pressure to do, but narrowly, requiring no further legislative implementation.

That said, our **notice and notice system** of dealing with copyright infringement and protecting Internet service providers is an embarrassment. It needs to be fixed. It need not be fixed precisely as the provisions of Article 20.89 of the USMCA require – the provisions forgiven Canada by Annex 20A – but they would be a good start and should be implemented by Canada despite being exempted by USMCA.

Canada's current **exclusions from patentable subject matter** are too broad. It should not enact the exclusions, including especially diagnostic methods, that are permitted under the USMCA. Indeed, Canada urgently needs to remedy the illegal and ill-advised exclusion of diagnostic methods from patentability currently applied by Canada's Patent Office.

In sum, criticism of the IP provisions of the USMCA is unwarranted. The provisions will not cause the harms the anti-IP critics claim. To the contrary, they will do much to benefit creators and innovators not just in Canada, but in the US and Mexico. They are good for Canada and this country must not delay ratification of this critical trade agreement.

Sommaire

L'Accord États-Unis–Mexique–Canada (AEUMC) visant à remplacer l'Accord de libre échange nord américain (ALENA) a été signé par les parties le 30 novembre 2018. La ratification de cet Accord n'est toutefois en aucune façon assurée. Bien qu'en mai 2019, les États Unis, le Canada et le Mexique soient parvenus à une entente visant à lever les tarifs douaniers sur l'acier et l'aluminium, éliminant un obstacle à cette ratification, certaines dispositions suscitent la controverse au Canada à la veille des élections, et la bataille prévue devant le Congrès américain sera difficile.

Cependant, l'adoption de l'Accord est d'une importance vitale. Les États-Unis, le Canada et le Mexique sont des partenaires commerciaux naturels dont les économies sont intégrées. L'ancien ALENA avait beaucoup contribué à renforcer et à approfondir cette réalité. Nous ne pouvons pas renoncer aux améliorations importantes proposées dans le nouvel AEUMC comparé au précédent Accord.

Ce document porte en particulier sur le chapitre 20 de l'AEUMC, lequel contient les dispositions relatives à la propriété intellectuelle (PI). Certains farouches détracteurs au Canada ont affirmé que le chapitre 20 fera augmenter nos coûts en soins de santé de plusieurs milliards de dollars, qu'il entravera la créativité et qu'il fera peser des contraintes inéquitables sur les plates-formes en ligne. Ce document aborde chacun de ces aspects.

En résumé, les dispositions de l'AEUMC sur la PI alignent essentiellement les lois canadiennes et mexicaines sur la norme américaine. Le *Global Innovation Policy Center* (GIPC) basé à Washington, qui classe les pays en fonction de la robustesse de leur régime de PI à l'aide de son indice GIPC, a établi qu'en adoptant les mesures proposées dans l'AEUMC, le Canada améliorerait sa note actuelle d'environ 66 à 80 sur cent. Le Canada s'est classé récemment au 19e rang parmi 50 pays qui composent l'indice du GIPC, ce qui laisse à penser qu'il y a encore beaucoup à faire pour que nous puissions rejoindre les économies les plus novatrices au monde.

Les États-Unis devancent le Canada en matière d'innovation et de protection de la PI, en partie parce que le Canada souscrit à la stratégie du suiveur et que dans ses pourparlers commerciaux, il a eu tendance à négocier des dispositions peu contraignantes relativement à la PI. Cela tient en grande partie au fait que les opinions influentes à l'intérieur et à l'extérieur du gouvernement au Canada vont à l'encontre des meilleurs intérêts du Canada. La force de cette opinion, la grande complexité des questions en jeu et l'inertie politique se sont conjuguées pour limiter l'innovation au Canada.

La nouvelle *protection des données relatives aux médicaments biologiques* est probablement la disposition de l'AEUMC relative à la PI dont on a le plus parlé. Les données bénéficieront d'une période de protection de 10 ans, contre 8 ans au Canada à l'heure actuelle (mais 12 ans aux États Unis).

Un « biologique » est un médicament à grande molécule fabriqué à partir de processus biologiques complexes. La protection des données empêche l'approbation d'un biosimilaire (l'équivalent biologique d'un médicament générique) sur la base de l'essai clinique et des données connexes rattachées au biologique d'origine jusqu'à la fin de la période de protection des données.

La protection des données offre une meilleure forme de protection que les brevets, en raison des faiblesses du système de brevets en ce qui concerne les produits biologiques. Bien que 10 ans de protection des données puisse sembler long, les études indiquent qu'il faut généralement plus de 12 ans pour rentabiliser les investissements dans la recherche visant à offrir un nouveau médicament.

De surcroît, le marché des biosimilaires ne sera pas le même que pour les versions génériques de médicaments traditionnels plus simples. Il en coûte beaucoup plus pour développer un biosimilaire et le faire approuver, alors que les réductions de coûts par rapport aux produits biologiques novateurs seront de l'ordre de 30 pour cent. Ainsi, prolonger l'exclusivité commerciale d'un biosimilaire de deux années supplémentaires comme le propose l'AEUMC sera bien moins coûteux que ce n'est le cas d'un médicament générique à petite molécule.

Les coûts énormes engagés pour développer un produit biologique et obtenir l'autorisation de le commercialiser militent fortement en faveur d'une période d'exclusivité plus longue. Une période plus longue sera également propice à un meilleur climat d'innovation au Canada.

L'autre changement majeur pour le Canada est la **prolongation de la durée du droit d'auteur**, qui passe à 70 ans après la vie de l'auteur par rapport à la norme « vie + 50 » actuellement en vigueur. Il y a de nombreuses raisons pour lesquelles cette mesure est bonne pour le Canada – notamment l'accès à des protections similaires de la part des pays offrant une protection réciproque. Ce sera une bénédiction pour les auteurs canadiens et, d'ailleurs, un rapport du Comité permanent du patrimoine canadien a récemment recommandé cette modification, quelles que soient les exigences de l'AEUMC.

Par contre, les exemptions de responsabilité excessives pour les intermédiaires ou les plates-formes, comme le prévoit l'AEUMC, causent des dommages. Elles ont mené notamment à des niveaux très élevés de piratage dans les domaines de la musique, des films et d'autres contenus de services tels que YouTube, ce qui a fait chuter les revenus des artistes. Par conséquent, le Canada ne doit pas interpréter la disposition **relative à la sphère de sécurité** de l'AEUMC au sens large, comme il sera sans aucun doute appelé à le faire, mais de manière étroite, ce qui ne nécessitera aucune autre mise en œuvre législative.

Cela dit, notre **système « avis et avis »** traitant des violations du droit d'auteur et de la protection des fournisseurs de services Internet est une source d'embarras pour le Canada. Il doit être corrigé. Cette correction n'a pas besoin d'être alignée étroitement sur les dispositions de l'article 20.89 de l'AEUMC –, car l'annexe 20A dispense le Canada –, mais ces dispositions constitueraient un bon point de départ et devraient être adoptées par le Canada malgré l'exemption prévue dans l'AEUMC.

Au Canada, **les exclusions portant sur l'objet brevetable** sont trop étendues à l'heure actuelle. Le Canada ne devrait pas adopter les exclusions qui sont autorisées par l'AEUMC, notamment en ce qui concerne les méthodes de diagnostic. En effet, le Canada doit voir de toute urgence à ce que les méthodes de diagnostic ne soient pas illégalement et injustement exclues de la brevetabilité mise en application par le Bureau canadien des brevets.

En somme, il est injustifié de dénoncer les dispositions de l'AEUMC relatives à la PI. Ces dernières ne causeront pas les torts décriés par les opposants à la PI et seront, au contraire, très avantageuses non seulement pour les créateurs et les innovateurs au Canada, mais aussi pour ceux aux États-Unis et au Mexique. Elles seront profitables pour le Canada, et notre pays ne doit donc pas retarder la ratification de cet accord commercial crucial.

Introduction

The United States Mexico Canada Agreement (USMCA), aka NAFTA 2.0, must be a good agreement: it faces a level of dislike that could only arise from bitterly thorough negotiation and exacting compromises. Dislike particularly adheres to the provisions dealing with intellectual property (IP) and innovation, always hot button topics. In this it continues the tradition of the original North American Free Trade Agreement (NAFTA), the first trade agreement to deal with IP.

The USMCA (the Canadian Government calls it CUSMA, but I opt for the more usual name, both to avoid confusion and given the fact of Canada's accession to a *fait accompli*), is to replace the original NAFTA, to which the present US administration takes exception. The USMCA was signed by the parties on November 30, 2018. It has not been ratified by any of the three signatories. It requires passage through the US Congress, which is not assured. Once ratified, it will be implemented by legislation.

Negotiation of the USMCA took over a year. In the end Mexico reached a bilateral agreement with the US, to which Canada subsequently acceded, essentially without further negotiation. Once the US and Mexico had an agreement, it was very difficult for Canada to negotiate substantive amendments. Fortunately, it is a good deal for Canada. Very good.

This paper focuses on certain significant IP and related provisions of the USMCA, which have been somewhat controversial. They are not necessarily the most significant aspects of the USMCA overall. The USMCA is vital across Canada's economy. Key provisions include an expanded tariff exemption on Canadian automobiles, an expanded US share of the Canadian dairy market, improved dispute resolution, a 16-year sunset clause, a limitation on Canada's free trade negotiations with non-market countries, and cultural exemptions for Canadian productions. It is important to keep USMCA's wide reach in perspective; even if Canadian opposition to the IP provisions of the USMCA had merit, it should not delay ratification since the USMCA overall is far too important to the country.

The chapter in the USMCA on IP, Chapter 20, is extensive. Some of its provisions are directed at Mexico more than Canada, and *vice versa*. The US has the strongest IP rules and institutions among the parties and is not itself required to make any material changes. The USMCA, however, does set floors for certain periods of protection – such as 10 years for market exclusivity for biologic drugs – which would mean that the US could not shorten its current 12-year period of protection below 10 years, without the other parties' agreement. To this, objection has been raised in the US (AFL-CIO et al. 2019).

The USMCA's IP provisions largely elevate Canadian and Mexican IP laws towards US standards. Most of the USMCA's data and IP provisions were copied from the original *Trans-Pacific Partnership* (TPP) agreement, subsequently renegotiated as the *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (CPTPP) when the US, under newly elected President Donald Trump, decided it did not wish to participate in the original TPP agreement. While Canada has already criminalized video recording in a cinema, Mexico has not and will be required to do so by the USMCA. It will also be required to provide legal protection for technological measures that deter piracy of copyright-protected goods, as Canada already does, having implemented the *WIPO Copyright Treaty* with the *Copyright Modernization Act*. Conversely, Mexico already has a copyright protection term of life of the author plus 100 years

for copyright-protected works, while the USMCA will require Canada to increase its term from life-plus-50-years to life-plus-70-years for most works.

The impact of these changes on Canada's IP regime is illustrated in a recent and very useful study titled *Setting a New Standard* by the Global Innovation Policy Center (GIPC), which is affiliated with the US Chamber of Commerce in Washington. The study scored the USMCA on the many criteria used to calculate national scores for the annual GIPC International IP Index, which ranks 50 countries on the strength of their IP protection. The USMCA scored 80 out of 100, much higher than the original NAFTA at 48.3. In other words, by adopting the measures in the USMCA, Canada will improve its current score of roughly 66 out of 100 to 80. Canada was ranked 19th out of 50 countries in the latest GIPC Index (GIPC 2019b), suggesting that it has significant room to improve if it wants to join the world's most innovative economies with the strongest IP regimes. USMCA will go a long way to helping Canada achieve that.

The US leads Canada in innovation and IP protection in part because Canada has a follower mentality.

The US leads Canada in innovation and IP protection in part because Canada has a follower mentality. There is nothing to stop Canada from dramatically improving its innovative economy by promptly adopting IP protection as strong, or stronger, than its neighbour's. And why not? The reason seems to be that influential opinion in Canada, both within and outside government, runs counter to Canada's best interests. The force of such opinion, the great complexity of the issues, and political inertia, all conspire to clamp Canada in innovation irons. Would it not be wonderful to aspire to more – and give our innovation economy a boost – with a leap of faith into world-leading IP protections?

Canada has, however reluctantly, negotiated a great benefit for itself in the USMCA. Historically, Canada's increases in IP protection have come after negotiations and not of its own initiative (Owens and Robichaud 2017b). There is much opinion that the USMCA itself represents a significant loss by Canada on the IP front. As this paper will demonstrate, in substance it does not.

The outcome is far better for Canada than the negotiators apparently intended. Which, of course, raises the question of whether they initially used Chapter 20 as part of the bargaining process – accepting its provisions because they could get concessions elsewhere by doing so, and not because they truly wanted weak IP. Evidence for the government's opposition to the IP provisions may be found in the great energy and goodwill it expended to have the IP provisions of the CPTPP suspended before signing it – IP provisions substantially similar to those in the USMCA (Geist 2017).

The value of stronger IP provisions

The USMCA helps to drag Mexico and Canada towards US standards of IP protection. The US always ranks among the very highest scores of nations protecting IP and it has the highly innovative, highly profitable economy to show for it (GIPC 2019a). There are great benefits to emulating or exceeding US standards.

Strong, and shared, IP standards increase trade and foreign direct investment (FDI); they aid small firms in capital acquisition and in their negotiations with larger ones, thereby facilitating the establishment and growth of small and medium sized (SME) firms and incidentally checking monopolistic and predatory behaviour of larger firms; and they provide incentives to invest in innovation (Owens and Robichaud 2017a, Barnett 2011, Hall and Harhoff 2012, Varsakelis 2001, Park and Ginarte 1997, Hall and Ziedonis 2001, Putnam and Tepperman 2011, Schnaars 1994, Rivera-Batiz and Romer 1990). Increased transfer of technologies and FDI in turn enhance the overall innovation environment of the country, create spin-offs, and improve total factor productivity (Owens and Robichaud 2017a, Greenhalgh and Rogers 2010, Putnam 2006, Nunnenkamp and Spatz 2003, Gould and Gruben 1996).

There are great benefits to emulating or exceeding US standards.

Stronger IP raises investment in research and development, a metric which has declined in Canada, alone among its OECD brethren except South Africa (GIPC 2017, Owens and Robichaud 2017a, Kanwar and Evenson 2003, Allred and Park 2007, OECD 2016). In 2018, however, this trend somewhat reversed, with an anticipated scant 2 percent improvement in private R&D investment (Statistics Canada 2018) although the OECD shows a continued decline overall (OECD 2019).

Research demonstrating the importance of strong IP rights to both trade and economic development continues to develop apace. Work by Lee, Alba and Park (2018) demonstrates the strong impact of IP rights on American FDI. Lerner and Wu (2017) demonstrate that innovation in China responds directly to the levels of local IP protection. They also demonstrate that innovation levels are much higher, and innovation of much higher quality, in private firms over state-owned ones (which should surprise no one).

Tsakelerlou (2018) demonstrates the very positive impact of strong IP on economic growth and competitiveness in Singapore. Ghosh and Ishikawa (2018), in a nicely nuanced economic study, show that IP rights not only drive economic growth but do so across a wide range of economic preconditions. Chun (2017) convincingly demonstrates that strong IP, and the *Treaty on Trade Related Intellectual Property Rights* (TRIPS) of the World Trade Organization (WTO) strongly increase trade in IP-intensive goods. Saito's recent work (2018) demonstrates a very similar impact of strong patent rights and also the strong impact on local productivity of such rights.

It is broadly true that Canada has been wary of strong IP protection for a long time, particularly for pharmaceuticals. In that case, political economy issues have led to lacklustre support for strong IP when pharmaceutical companies seemed unwilling to invest in return. (In fact, this is not entirely true. First, companies do not invest where protection is poor. But second, the so-called failure to invest may actually indicate, at least to some extent, that investment profiles have changed in such a way that traditional measures to track such investment are now less effective (Owens and Robichaud 2017a).

But in the face of traditionally wary approaches to IP we now have a plethora of substantive research underpinning its importance to trade and innovation. Nothing arcane here; the research is widely known and reported, and it is constantly growing.

On the face of it, a more robustly favourable attitude to stronger IP should be our outlook. Indeed, the days when we could beg off agreeing to IP concessions until our price was met may well be numbered. Who should believe us now? Why should the US and others be in the position of having to push us in the direction we should most naturally and beneficially travel?

From here, we will examine the various provisions of the IP chapter, albeit not in the order in which they appear in the USMCA.

Data protection for biologics

The protection of data related to new biologics is perhaps the most significant provision of the IP chapter. Data protection prevents a biosimilar (the biologic equivalent of a generic drug) from being approved on the basis of clinical trial and related data submitted by the original biologic until the expiry of the data protection term. **Article 20.49 (1) of the USMCA sets a new, 10-year floor on data protection for biologics**. This is as compared to 12 years in the US and eight years as is currently the case in Canada.

Pursuant to the transitional provisions, Canada is not required to fully implement Article 20.49(1), the 10-year protection for biologics, until five years after the date that the USMCA comes into force. We do not know if the government will avail itself of all or part of this period. If it does, then the actual costs, if any, of the additional period of data exclusivity will be postponed up to five years and, therefore, of course, will be of much less impact on a present value basis.

A "biologic" is described in the USMCA to include:

> a product that is produced using biotechnology processes and that is, or, alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition. (Article 20.49(2))

Biologics differ dramatically from the conventional, small molecule pharmaceuticals to which IP and other drug policies have historically been tailored. They are far more sensitive to slight changes in production processes, and their molecular structures are more variable than those of small molecule drugs. Biologics are unique, in that their extreme complexity does

not permit the production of generic copies. However, as noted above, it is often possible to make "biosimilars," which effect the same or similar therapeutic result as the originator. These biosimilars are not identical copies, unlike generic copies of more familiar, small molecule medicines.

Among the best-selling biologics in Canada are Remicade, Humira, Enbrel, and Rituxan, which are used to treat a range of conditions including Crohn's disease, rheumatoid arthritis, and psoriasis. Biosimilars include Inflectra (Remicade) and Hadlima (Humira).

The variability of molecules with similar therapeutic effect also has an impact on patent protection. Because of the difficulty of describing the full range of molecular structures which would deliver therapeutic efficacy, patent protection is in some respects thinner for biologics than for small molecule pharmaceuticals. In other words, it may be possible to avoid a patent claim for a biologic by designing a similar drug with a sufficiently different, but still effective, molecular structure.

Biological medicines also rely on very complex biological processes for their manufacture:

> Specifically, most biologic medicines are developed using recombinant DNA (rDNA) technology. They are produced by genetically engineering living cells to create the required proteins… They are… manufactured inside animal cells or micro-organisms such as bacteria or yeast… (Lybecker 2016).

These processes themselves are often patentable. They cannot be avoided in making a biosimilar. Therefore, the cost base of a biosimilar is far greater than for a small molecule generic. A consequence of this, of course, is that cost savings can never be as great as the differences between most small molecule brand drugs and their generic equivalents.

It has been argued that data protection is the most efficient way to protect biologics (Morgan 2010), particularly given the current judicial and legislative trends to weaken patent rights (Morgan 2010, Barnett 2016). Data protection prevents the data submitted to regulators for pharmaceutical marketing approval of a new biologic drug (Health Canada in Canada and the FDA in the US) from being used by a competing biosimilar for a defined period of time. For economic and ethical reasons, it is generally impractical for a biosimilar (or conventional generic drug) to duplicate an originator's clinical trials (Grabowski 2008), although they are otherwise free to do so if they want to go to market before the expiry of the data protection period.

Grabowski notes that pre-approval development of a biologic can cost as much as US$1.33 billion, while other estimates reach US$2.8 billion (Rawson 2019). Other estimates for regulatory approval *alone* range from US$1.3 to $2.56 billion (Sands 2016).

In addition to the cost of development, there are the risks. Tens of thousands of compounds may be reviewed for every one that goes to trial (Globerman 2016), and of those that go to trial, a study of 522 biologics demonstrated only a 30 percent success rate reaching phase III clinical trials (on humans) (Grabowski 2008). While the rate for reaching phase III trials is better than for small molecule drugs, the rate of success in those trials is considerably worse (Grabowski 2008). While some object to longer market protection for drugs, it is worth remembering that the shorter the term, the higher initial prices need to be to compensate the innovator for the up-front costs of developing the drug (Rawson).

Debating the costs of extended data protection

In Canada, the National Prescription Drug Utilization Information System (NPDUIS) found that the potential savings gained by the introduction of biosimilar competition vary depending on "the market size, the timing of biosimilar availability, the uptake and the price discount" (PMPRB 2018a). The NPDUIS has therefore provided a range of potential savings, finding that biosimilars could cut costs by 8 to 43 percent. Such savings are not in the league of those from generic versions of small molecule drugs. Deborah Gleeson and Ronald Labonté (2018), on the other hand, argue that the expense of biologics means that the introduction of biosimilars to the market can cut costs substantially). They support this claim with research conducted in Australia and in Canada.

Due to the difficulty in estimating the savings from biosimilars and myriad other factors, it is difficult to determine what kind of impact the change from 8 years of data protection to the 10 years required by USMCA will have on drug prices, but some warnings have been dire.

The Canadian Generic Pharmaceutical Association warns: "If Canada were to adopt the proposals, every single Canadian would be negatively impacted by the billions of dollars in additional drug costs created through delayed access to generic and biosimilar medicines" (CGPA 2018). University of Ottawa law professor Michael Geist has suggested that the Canadian government "caved" on the issue of biologic protection when it negotiated USMCA (Boutilier 2018, Macleod 2018). Geist has also stated that each year added to the data protection terms could potentially add billions to health care costs (Proudfoot and Markusoff 2018).

Putting a more reasonable and specific number on it, Richard Gold claims that the two extra years could end up costing the taxpayers tens of millions of dollars annually (Husser 2018) — although this is not a great deal of money considering that Canada spends many billions of dollars annually on pharmaceutical drugs (Lybecker 2016). Others, like Amir Ataran and Paul Grootendorst, argue that there would be no additional cost (Husser 2018).

Finally, a study by the Parliamentary Budget Office (PBO) calculated an annual increase of $23.8 million. This reflects additional costs if the added two-year period of data protection had been in effect before 2015, based on a 30 percent savings from biosimilars, but only on a subset of the most expensive biologics (PBO 2019). The PBO made other assumptions, including especially much greater use of biologics. It also concluded:

> Given the rapidly evolving technology for developing and manufacturing biologics and the industry's concern regarding the weakness of patent protection, this longer-term estimate illustrates the cost exposure that the CUSMA has created. That is, if data protection becomes the primary source of market exclusivity for all innovative biologics, then the risk is that all biologics with data protection could cause additional expenditures. In that case, PBO estimates that by 2029, these additional expenditures would amount to $169 million, and would rise annually thereafter. (PBO 2019)

Most importantly, the PBO numbers do not account for system-wide cost savings from better therapies – only price differences with biosimilars. The question is, what additional system-wide cost savings will there be from additional encouragement of research into biologics arising from a longer period of protection? And how much will competition between originator drugs help to control such costs while the introduction of biosimilars is delayed?

While a conventional small molecule generic drug can be developed for $1 to $5 million over three to five years, the case is very different for biosimilars, which can take 8 to 10 years to

develop at a cost of $75 to $250 million (Lybecker). This fact, along with the greater costs in physician supervision and potential ill-effects from substitution, and the frequent inability altogether to substitute, demonstrate that the potential savings will be much less than for conventional generics. There are certain to be savings. How much, however, is at this point a matter of some guesswork.

A letter to the US Congress from unions, medical and faith-based groups, and civil society organizations opposes additional market exclusivity for biologics for America and its trading partners through the USMCA. The letter argues that the USMCA would "entrench and expand prescription drug monopoly protections, thwart competition and thus undermine efforts to expand access to affordable medicines" (AFL-CIO et al. 2019). While the letter expresses concerns for Canada and Mexico and other future partners in trade negotiations, it conveys particular concern that legislative initiatives to reduce the 12-year protections in the US to as low as seven years will be stymied as, indeed, they would be. (This has been proposed in fact in the 2016 *Price Relief, Innovation, and Competition for Essential Drugs Act*). The letter goes on:

> Expansive patent and marketing exclusivity rules are some of the major factors that have resulted in U.S. consumers and the U.S. government routinely paying more for prescription drugs than people and governments in other countries throughout the world. Locking the United States into the policies that have led to high medicine prices here will not remedy our problem, nor will trying to impose these U.S. policies on Mexico and Canada through NAFTA 2.0. The negative impact on access to medicines through the expansion of monopoly powers and limits on competition would be felt for years to come, and would not be limited to the 490 million people living in the U.S., Mexico and Canada. It would be a dangerous blueprint for future agreements. (AFL-CIO et al. 2019)

This is pessimistic and perverse. "Expansive patent and marketing exclusivity rules" are the reasons we have pharmaceuticals at all. Without them there would be no prices to fight over because there would be no drugs.

It is a complex process to be able to label any price excessive when it is for a new curative miracle (but see Dranitsaris et al. 2014). In any event, every drug has finite "value." Value may vary from patient to patient to some degree. Value will be easier to determine the more competing products there are. Value is effectively a cap on price. The ability to extort patients is more mythical than real. In a market without transaction costs every drug sale would be at the highest price any given patient would be willing to pay.

Of course, it is impossible to negotiate with every patient (and, given the medical circumstances, repugnant). Therefore, a common price is set – a price necessarily below the maximum value.

To take an example, an aspirin, however unique, is only worth so much, even under monopoly pricing power. Another month of life with cancer is worth more, but still only so much, either to a patient or insurer. The opportunity for complete remission would, quite reasonably, command a higher price. But given its tremendous value, shouldn't it?

It is meaningless, even disingenuous, to wring one's hands over price without looking at the whole-value proposition of a given product. What price life? Or freedom from crippling pain?

There is abundant evidence that new pharmaceuticals do, in fact, reduce health care costs (Lichtenberg 2014; Murphy and Topel 1999; MedPAC 2018; BIO 2018). For instance, in his article "The Impact of Pharmaceutical Innovation on Disability Days and the Use of Medical Services in the United States, 1997–2010," Lichtenberg (2014) finds that "the value of reductions in work loss days and hospital admissions attributable to pharmaceutical innovation was three times larger than the cost of new drugs consumed." Lichtenberg further finds that the mean number of work loss days, school loss days, and hospital admissions declined more rapidly among medical conditions with larger increases in the mean number of new (post-1990) prescription drugs consumed.

Indeed, when medicines help patients live longer, healthier lives, the economic benefits are considerable. For instance, improvement in US life expectancy from 1970 to 1990 added $2.8 trillion to US productivity, which equaled $12,000 per US citizen per added year of life expectancy.

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The conflict between market exclusivity (from patent term and data protection) and generic/biosimilar availability is often depicted as a conflict between competition and monopoly (Grabowski 2008). Not so. It is a conflict, rather, between competition by innovation and mere price competition by copying. It should be obvious which will provide greater long-term benefits. Biologics are "frequently 'best in class' or 'first in class' therapies," Grabowski notes, adding,

> When innovation has important benefits for overall social welfare, this provides support for a longer exclusivity period. There is accumulating empirical evidence that new medicines and therapies have played an important role in increased longevity, enhanced quality of life and improved labour-force productivity. Furthermore, recent studies have found that consumers have appropriated ***significantly more of the societal benefits than innovators in the case of new therapies for HIV/AIDS, as well as several other new technologies***. (Emphasis added).

Competition amongst proprietary biologic therapies also has been shown to be robust (Grabowski 2008). Such competition would generally limit pricing power even more than "value" would. As mentioned above, it should also be a significant factor (albeit difficult to quantify) influencing assumptions of the net cost of delayed introduction of biologics into the market.

The extraordinary cost of developing and marketing a biologic drug glaringly demonstrates the need for a longer term of exclusivity. The US's 12-year period of data exclusivity should be the minimum, not an aspirational goal. Indeed, economic analysis has demonstrated that it can take much more than 12 years to recoup the investment in the development of a pharmaceutical (Grabowski 2008).

Innovating and free-riding

In his illuminating paper on the international economics of pharmaceutical innovation, Christopher Sands classifies nations into three types:

1. Accommodator. These are countries whose policies favour pharmaceutical innovation, most notably including the United States, and also to degrees Japan and some EU states.

2. Bargainers. These are countries like Canada which have some biosimilar or generic production capacity but few if any originator companies. They may see the inevitability of the homogeneity of pharmaceutical rules among nations, but try to develop political capital by being seen to bargain for every concession.

3. Mendicants. These are poor nations seeking access to medications at concessionary pricing.

Canadians are bargainers because of the tenacity with which we cling to inadequate pharmaceutical protections in trade and IP negotiations. Furthermore, our insistence on a national 20 percent reduction, on average, on proprietary drug prices through the Patented Medicine Prices Review Board (PMPRB) puts us in the mendicant category (Critchley and Owens 2018).

We do not properly belong in either category; it is time we enacted more innovation-friendly policies to become an "accommodator." The problem with treating homogenization of rules as an imposition to be bargained for instead of what it ought to be seen to be – a foundation of Canada's innovation economy – is that it reinforces in the public mind the paradigm that innovation is bad for consumers. It is not. Moreover, the values of cost savings from the expropriation of pricing power are small potatoes compared to the wealth creation of a truly innovative economy and its power to lift all boats.

The international dynamics of Canada's adoption of IP protections at the apparent insistence of the United States are illuminated by Sands's taxonomy. What IP nationalists characterize as IP imperialism is actually more nuanced, especially with respect to pharmaceuticals. Accommodator nations like the US also want to be seen to address high drug prices for the consumer. For them, to improve IP protections in Canada is a means of more equitably distributing the costs of drug development, an international good which should not be entirely borne on the backs of US consumers. What is portrayed, with typical Canadian resentment, as a process captured by rapacious US capitalists is thus actually a broader social good.

In a pathbreaking paper, Egan and Philipson demonstrate and quantify the international impacts on pharmaceutical production of national IP and drug expenditure policies, illuminating the international interdependencies (Egan and Philipson 2013; Philipson 2016). In other words, the prices in one country have an impact on the prices in another.

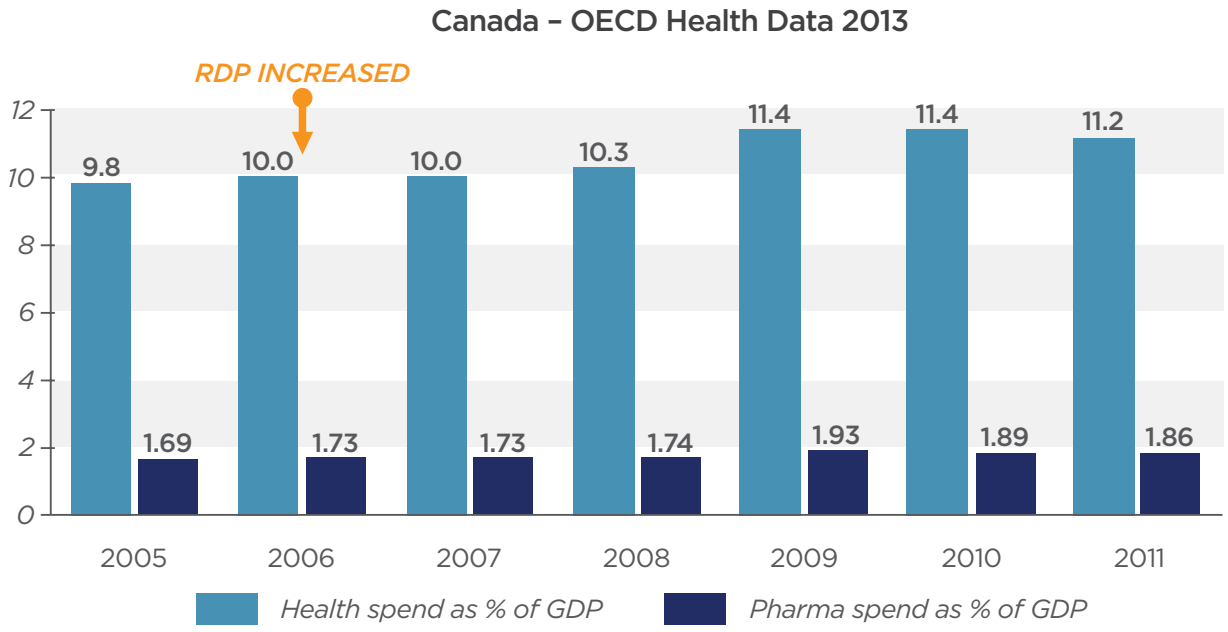
President Trump and others refer to the fact that the US bears an outsized share of the costs of developing drugs that benefit nations around the world (Owens and Ezell 2018; Almazora 2017). They're right. Price-setting for pharmaceuticals is not a government exercise in the US the way it is in Canada. Thus, the US market widely bears the true costs of drug development; it may be the only place where proper pricing power exists. Canada and other countries simply free-ride on the (relative) willingness of the US to require its consumers to pay full price.

To suggest that this is actually in Canada's interest is cynical, and a little dangerous. Dangerous because of the consequences if the US followed the rest of the world in introducing price controls. It would be wholly warranted in doing so. Were it to do so, the politics of drug pricing would assume a very different colouring. Every country would be starving drug development, and our weakness and hypocrisy would really come home to roost. Are we prepared to sacrifice pharmaceutical development to populist pandering?

Meanwhile, our government seems to wish to do just that, risking not only a further decline in drug development but with it the lives of Canadians who will never benefit from the drugs that will never be, and even the ones that do exist but are not imported into Canada, or not imported in a timely fashion, because of more severe price controls (Critchley and Owens 2018).

However, the USMCA may not in itself betoken increases in those high biologic prices. Research by the Geneva Network demonstrated that Canada's government expenditures for drugs did not increase when Canada's data protection period was last extended (Ellis 2017). Figure 1 illustrates the results.

FIGURE 1: HEALTH AND PHARMACEUTICAL EXPENDITURE AS % OF CANADA'S GDP (2005-2011)



Source: "Will increasing the term of data exclusivity for biologic drugs in the TPP reduce access to medicines?" Philip Stevens, Geneva Network, July 2015

We should let drug prices find their own market level now. Were we to do so, we would have no further need of the PMPRB. It is time to lift that bureaucratic monkey off the backs of Canadian innovators and taxpayers and euthanize it.

Proper drug prices may be stiff medicine, but they are for our own good. This is well recognized in the US where federal law mandates that certain Medicare drug purchases are not to be interfered with by government to lower prices. Only Congress can change that law (*Medicare Modernization Act* of 2003).

In the United States, with its robust drug development protections, more than 900 biologic drugs were in development in 2015 for over 100 diseases (Lybecker 2016). Imagine the positive impacts for Canada and the world if this country could develop an innovation system to contribute proportionately. Instead, as Lybecker sadly concludes, referring to provincial encouragement of the off-label use of Avastin over a more expensive, approved drug as an eye treatment:

> This seems to indicate that cost-containment is more important in Canada's public drug plans than incentivizing innovation or patient health.

IP and market exclusivity matter greatly to the attractiveness of a jurisdiction – like Canada – to innovation investment. Israel's efforts to attract capital to biotechnology largely failed until data protection was extended, after which investment rapidly increased well over 800 percent (Ellis 2017). Canada should learn from this example.

Patentable subject matter

The question of what ought to be patentable is an easy one that courts and governments have made complex. Scientific principles are clearly excludable. But what about life forms, methods of medical treatment, business methods, computer algorithms, and medical diagnostics, for instance, which are excluded in various jurisdictions, including, to varying degrees, Canada?

This is the problem of so-called "patentable subject matter." **The USMCA explicitly permits exclusions from patentable subject matter.** Section 20.36(3) permits parties to exclude from patentability:

> diagnostic, therapeutic and surgical methods… [and] animals other than microorganisms and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.

Patentability should be as broad as possible. One reason is our need to encourage inventions in all fields. Another is the benefit of public disclosure of inventions attendant on a patent filing; without access to the patent system many inventions would be kept secret, or simply not pursued.

Yet another reason is the extraordinary difficulty of discriminating between patentable and non-patentable. For instance, what is a "higher life form" and how does it differ from a lower one?

Activists object to patenting life, but it does no harm and in fact results in the science becoming known and hence potentially subject to regulation, unlike the consequences of the secrecy attendant on unpatentability. Moreover, higher life forms were excluded from patentability on

the basis that they were not anticipated in the enactment, in the 19th century, of the *Patent Act* (Canada). Well, what was? The whole point of a patent law is to deal with things not anticipatable. This establishes a most unfortunate precedent that, in theory, could allow exclusion of almost any invention if a court found it objectionable for some reason (*Harvard College v. Canada*).

Exceptions from patentable subject matter, if any, should be enacted by the legislature, not courts.

The Canadian Patent Office (CPO) already excludes diagnostic methods from patenting based on an unduly narrow Patent Practice Notice (Boocock 2016, Marsman 2017; Canada 2015). This is an ill-advised exclusion. We need to think carefully before making any exclusion from patentability. To be patentable there must, after all, first be an "invention," in whatever field. Doesn't mankind benefit from all manner of inventions? Which ones can we categorically exclude, as though knowing clairvoyantly nothing important will ever come from them to the Patent Office?

Under the present procedure, for instance, promising diagnostic methods are staying in the lab because it is worth no one's while to commercialize them. Also, under case law, higher life forms, including plants, are excluded from patentability in Canada (*Harvard College v. Canada*).

The Supreme Court of the US (SCOTUS) issued a ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* that may have the effect of excluding in the US a wide swath of diagnostic methods as lacking an inventive step. The ruling was unanimous. It held that claims for a method of dosing a patient with a drug and then measuring its metabolites to determine if an efficacy metric were met and then deciding whether to increase or decrease the dosage of the drug, were not patent-eligible subject matter.

Some argue that the decision frees clinicians, while others, myself included, argue that it creates an excessive exclusion from patentability and is bound to stunt investment and research into diagnostic methods.

Exceptions from patentable subject matter, if any, should be enacted by the legislature, not courts.

Absent a legislative override of that SCOTUS decision, the US may have to rely on this exclusion – as Canada may for plants and animals, for instance, for the same reason (SCC ruled them unpatentable) (*Harvard College v. Canada*).

Ideally, the exclusions permitted in the USMCA would not be necessary, and most of the current exclusions in the parties reversed by legislation. The problem of patentable subject matter is admittedly esoteric, but it matters, and we should be continually alert to avoid exclusions.

Take diagnostic methods, for instance. Excluding them from patentability may be to serve the freedom of clinicians to make diagnoses, but it inadvertently robs them of the necessary tools to do so, because the diagnostic methods they need are never made available because they are not protectable. Science suffers and patients suffer.

The same is true of patenting higher life forms. Such patents are permitted almost everywhere and our Supreme Court erred in excluding them. Ironically, though, it excluded patents over the life form but not the constituent cells. In effect, then, it left in place essentially the monopoly it meant to exclude, creating an unnecessary and unprincipled mess.

This is the sort of thing that happens with uninformed, *ad hoc* exclusions. It should be remembered that patented inventions are always subject to regulation. They can even be made illegal. Nothing in a patent guarantees you the right to exploit the invention, only to exclude others from doing so. There is no harm to a principled, inclusive approach to patentable subject matter.

Patent term adjustment

Patent Office delay

To obtain a patent entails a long and difficult process. Even with the assistance of the most able patent agent, it can, and usually does, take years of arguing with patent examiners before a patent is issued. This is not necessarily altogether bad; we want patents to be right.

But efforts are being made to speed up examination. *The Patent Law Treaty* (PLT) is intended to improve and accelerate Patent Office procedure. Canada is a signatory to this treaty but has not yet fully implemented it.

The USMCA is intended to encourage more efficient Patent Office conduct by compensating patentees who are the victims of undue Patent Office delay. It will do this by providing patent term adjustments – increases – in certain circumstances.

One such circumstance is for unreasonable granting authority delays (Article 20.44). This section of USMCA requires that each party shall make "best efforts" (a high standard) to process patent applications in an efficient and timely manner (20.44(1)). It also requires that **if there are unreasonable delays in a party's issuance of a patent, that party must provide the means to adjust the term of the patent to compensate for such delays** at the request of the applicant. This provision applies generally to all patents, including pharmaceutical patents.

Patent Offices are part of the underpinning of a strong and meaningful innovation economy, and this section of the USMCA imposes terrific discipline on them. If patentees know that they can get additional time on their patents when examiners unnecessarily delay them, there will be somewhat less of a concern on their part and, more importantly, a surer expectation of promptness.

Canada currently has no process for general patent term adjustment, but it does for pharmaceuticals. The USMCA does not specify what procedural and administrative improvements should be made to avoid having to adjust patent terms. However, the PLT, according to the WIPO:

> …was adopted in 2000 with the aim of harmonizing and streamlining formal procedures with respect to national and regional patent applications and patents and making such procedures more user friendly. With the significant exception of filing date requirements, the PLT provides the maximum sets of requirements the office of a Contracting Party may apply. (WIPO 1996)

Unreasonable curtailment

Another problem that is specific to the highly-regulated pharmaceutical industry is that the process of regulatory approval to market a drug can have a very detrimental impact on the benefit of a patent – using up years of precious market monopoly. Therefore, the USMCA also provides specifically for an increase in pharmaceutical patent terms for delays in obtaining marketing approval.

Specifically, **a party must make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process** according to section 20.46 (2). Footnote 39 to this section explains that the additional protection may be *sui generis* instead of a patent term extension – presumably, additional marketing exclusivity would qualify, rather than additional patent term *per se*.

We must await legislation to see how this provision will be implemented, and what "unreasonable" curtailment is, over and above normal delays. Again, this provision will be a good discipline on the market approval process. Regulatory delay is often overlooked as a barrier to therapeutic availability. The US has taken steps to shorten regulatory barriers to access. Canadian improvements too could save lives.

Since the implementation of the Comprehensive Economic and Trade Agreement with Europe, (CETA) Canada has had in place the ability to extend most of the patent monopoly for a pharmaceutical. This is pursuant to a Certificate for Supplemental Protection, which a drug maker can apply for under the Patent Act (Section 106(3)). The maximum period for a certificate is 2 years (it is 5 in Europe).

Any period of delay caused by the behaviour of the applicant is deducted from the time period allowed and an application must be made in a "timely" fashion or it will be disallowed. The extension begins from the date on which the original patent expires (Health Canada 2019a). So far 36 extensions have been applied for (Health Canada 2019b) since the Certificates became available.

Such Certificates, once they kick in, will of course delay introduction of generic drugs. Perhaps because they are granted because of government delays, they do not yet, at least, seem to have stirred up controversy like longer data protection. A report by the PBO examined the impact of CETA on drug prices and found:

> If expenditures on patented drugs keep increasing at that rate, then at the time that the measures are fully implemented (roughly 2037) the additional cost will be $209 million annually (again, using 2015 dollars) (PBO 2017).

It is unclear whether the USMCA will result in substantial change to the Certificate system. The language implies open-ended adjustment depending on how long approval is delayed, but subsection (3) explicitly allows "conditions and limitations" provided the party gives effect to the article. The article speaks also of responding to the article with "procedures that effect the processing of marketing approval applications" but such procedures, in themselves, would not appear to be enough if they were not actually effective.

Copyright term

Article 20.63 of USMCA provides that the minimum copyright terms shall be life of the author plus 70 years, where calculated on the basis of the life of the author, or 75 years otherwise. Most works in Canada, including literary works, are currently governed by a term of life plus 50 years; certain other works, such as sound recordings, are protected currently for 70 years from the release date.

To the USMCA's proposed 20-year extension, activists strenuously object, putatively out of concern for a poor, weak Canada put upon by the culturally hegemonic US. In a conversation with BNN Bloomberg, Jim Balsillie, a Canadian ex-business executive, stated:

> I think it's a mistake to call it NAFTA 2.0. I think it's NAFTA 0.7. It's degrading and we're worse off from it… It was a difficult situation and there were hard trade-offs and one of the things that we've sacrificed in the trade-offs was innovation. Specifically, they raised the IP rights and protections that benefit those who own IP, and Canada is by far a pauper on these things, which means that we're going to be permanently writing more cheques than collecting them. (Maclean 2018; Balsillie Undated)

His "balance of trade" argument is common but misplaced for many reasons, including that strengthening IP laws has been shown to generate productivity gains which exceed balance of payments losses (Barker 2015, Hollander 2011). Even if the argument had merit, it strains credulity to call Canada an IP pauper, and the USMCA "degrading" to us. Are we paragons of innovation? No, but we're far from paupers.

Recent Statistics Canada data demonstrate that our digital economy is bigger than our natural resources industries combined (Evans 2019). And even if we were paupers, it is a grievous error to suppose that we are a static state, unalterable, and that the best way to remedy it would be to create protectionist IP policies. To suggest we are "degraded" because we were not afforded the indulgence of weak IP protection is completely wrong; weakening IP degrades a nation rather than strengthening it.

Michael Geist's assessment was consistent with Balsillie's:

> The cost will be significant, locking down works from the public domain for decades and potentially increasing educational costs by millions of dollars… (Proudfoot and Markusoff 2018)

Both allude, albeit in Balsillie's case not exclusively, to the extension of copyright term. Geist focuses on costs to Canadians, like Balsillie does. But are costs more important than the revenues that offset them?

By adopting policies to encourage innovation, we aspire to revenues that grow faster than costs. That is our business as a productive, creative economy. And we cannot have revenues without bearing costs. Exploiting our IP deficits to beg handouts from the international IP community isn't a strategy.

In fact, the change to 70 years is very good for Canada. Our copyright industries are robust and will become more so with the additional incentive. We are an outlier in having a term that remains at merely life plus 50 years, and it is past time that we caught up. I have argued, and

still believe, that there is no good reason to limit the term of copyright; however, another 20 years is better than nothing (Owens 2017a).

At the margin, the incentive effects of a longer copyright term diminish, but they nonetheless persist (Barker 2015). Therefore even the difference between 50 and 70 years is significant from a social utility perspective. Those years mean more investment in works, and in their distribution and promotion, which in turn means greater resources for Canadian artists.

Moreover, the life-plus-70-year-term has the major benefit of gaining our copyright-protected exports additional protection in the many jurisdictions, such as Europe, where the "rule of the lesser period" is in force. Pursuant to this rule under the *Berne Convention*, a jurisdiction may protect foreign works to the lesser of the term of protection in the jurisdiction of origination of the foreign work, and the term of protection in the jurisdiction importing it. In the extant example, Europe has a term of life plus 70 years; Canada, a term of life plus 50 years. Thus in Europe, Canadians, whose works could have life plus 70 years of protection, have at present only life plus 50. Not only is the additional 20 years of market power potentially valuable in Canada, but there is also a huge multiplier effect occasioned by the additional protection in all the jurisdictions with the rule of the shorter term. In fact, adoption of the life-plus-70-year term was recently recommended by Canada's Heritage Committee in its report about the ongoing copyright review (Canada 2019).

Copyright need be no different than any other type of personal property.

In any event, copyright is about more than utilitarian incentives; it is also in place to protect authorial dignity and integrity. Really, copyright need be no different than any other type of personal property, the holding of which is in perpetuity.

What is the overall value of the "public domain" so celebrated by modern IP scholars? It may not be nil – but then, it may even be less than nil. There are negative impacts to a work entering the public domain that are typically not accounted for by these anti-IP advocates. To the extent that the public domain allows the appropriation of the work of others, it discourages creativity. Entry into the public domain hinders continued commercial distribution. It imposes an arbitrary cut-off of ownership, potentially robbing works of their value and creators of a just return.

There is also the "overgrazing" problem, in which poor treatment of works that are out of protection may greatly diminish their cultural value. The paradigmatic example, which appears in a landmark paper by Landes and Posner, is of Mickey Mouse (Landes and Posner 1989):

> If because copyright had expired anyone were free to incorporate the Mickey Mouse character in a book, movie, song, etc., the value of the character might plummet. Not only would the public rapidly tire of Mickey Mouse, but his image would be blurred, as some authors portrayed him as a Casanova, others as catmeat, others as an animal-rights advocate, still others as the henpecked husband of Minnie. In effect, there would be both a movement along and shift downward in the demand curve...until Mickey Mouse's commercial value was zero.

Commentators often opine that copyright somehow takes from the public domain, and that the shorter its term, the better off is society. This, as I have strenuously argued, is far from the truth (Owens 2017a). Copyright is thin protection that only applies to the specific original expression in a work and it effects no monopoly, since anyone else is free to express themselves in exactly the same way (without, of course, copying). Properly construed, copyright interferes with absolutely no one's ability to express herself, except by plagiarism. Plagiarism is not expression at all. For instance, simple copying would never meet the *Copyright Act* test of originality.

Inevitably, the public domain crowd resorts to complaining about copyright locking up information. It is their universal complaint, and it ignores such a fundamental principle of copyright law that it is frankly more a desperate deception than a mistake. Copyright does not apply to information, full stop.

Notice and notice

The USMCA requires parties to have a system for providing notice of infringement of copyright online (20.89(4)).Canada has a system of sending notices to infringers under the *Copyright Act* that is weak. It is called "notice and notice." It could not be said to be effective and so almost certainly offends this section of the USMCA. Canada's "notice and notice" system under the *Copyright Act* simply provides for a notice of infringement from a rights holder to be passed on by the Internet Service Provider (ISP) to the infringing customer, without any requirement to take down any infringing material or site, and no penalty for illegal downloading. It is just a notice. Moreover, the customer can reply denying wrongdoing, and that is an end of it unless the rights holder initiates a full-blown lawsuit.

The Heritage Report recommends review of the notice and notice procedure: "the Government of Canada [should] review the safe harbour exceptions and laws to ensure that Internet service providers are accountable for their role in the distribution of content" (Canada 2019).

This is the Canadian Independent Music Association's (CIMA) assessment of notice and notice:

> Again, CIMA believes the Act as written may lead to significantly less protection and compensation for its small business members, and as described earlier, will force copyright owners to repeatedly pursue expensive litigation against those that may misuse or misappropriate their intellectual property – with very little hope of recovering the true value of their loss. Specifically…. The "notice-and-notice" provision puts an unreasonable burden on copyright owners and creators to self-police infringements – while essentially allowing ISPs once notified of an infringement, to have no further involvement and thereby creating the untenable situation whereby infringements will continue. (CIMA 2014)

To have a remedy, the rights holder must first sue to have the identity of the user revealed then issue a demand letter to the user and then sue her for posting infringing material or downloading or streaming it, as the case may be. It is very involved and expensive, and satisfactory from the perspective of nobody.

Article 20.89 would, if implemented, result in material improvements to Canada's notice and notice system. It would require legal incentives for ISPs to deter infringement; removal of infringing material by ISPs; inefficacy of counter notice (notice denying infringement by a customer) if legal proceedings are begun; monetary remedies for a misleading counter notice; termination of accounts of repeat infringers; accommodation of technological protection measures by ISPs; and introduction of means for rights holders to "expeditiously" obtain the names of infringers from ISPs.

These measures, some improvements by degree to Canada's existing system and some altogether new to it, would be great improvements. However, this is all moot. An annex to the article, Annex 20A, explicitly carves out and preserves Canada's notice and notice system, saving it from the manifest improvements of Article 20.89.

According to Michael Geist:

> The government has been a strong supporter of the notice-and-notice system – it insisted that it remain in place as part of recent trade negotiations on the CPTPP and CUSMA – and has now taken long overdue steps to stop the abuse by establishing requirements that effectively ban the inclusion of settlement demands. (Geist 2018c)

He's right on both counts, demonstrating how perversely the Canadian government behaves in regard to Internet piracy.

To properly understand Geist's reference to the inclusion of settlement demands, some history is necessary. The notice and notice system was improved when demands for damages were attached to the notices passed on by the ISPs. This approach grew up informally; it was efficient and there was nothing to prevent it. However, recent changes to the *Copyright Act* have made this illegal (S. 41.25(3)). These changes were inspired by anti-copyright activists evoking the spectres of so-called "copyright trolls" (this is what anti-copyright activists call legitimate rights holders). The result is to remove flexibility and lower-cost options from the system so that rights holders, in the first instance, and ultimately the infringers to whom they are passed on in litigation, must bear the full brunt of litigation costs.

The notice and notice system was improved when demands for damages were attached to the notices passed on by the ISPs.

In the US there is a system called "notice and takedown." It at least requires an ISP to remove infringing material, subject to a counter notice (*Digital Millennium Copyright Act*). That system is also widely criticized and has long been under review in the US (US Copyright Office Undated). The problem with it is that it doesn't seem to work. It creates an onus on the copyright holder to police the Internet and issue notices. This onus has resulted in widespread automation of the issuance of such notices. In 2016, for instance, Google received 345 million of the things. In spite of this, and Google's efforts to comply, its services, notably YouTube, and the Internet generally, teem with pirated

content. This is a significant part of the "value gap" – the problem that artists' work is being used more and more, while artists themselves get less and less money for it. This has to change. In that regard, it is significant that Google, intensely resistant to blocking piracy web sites in Canada, has begun to do so in Australia.

By far the most promising development in this regard is Chapter 17 of Europe's new *Copyright Directive*. Chapter 17 requires, among other things, that intermediaries such as YouTube and Facebook ensure that third party content on their services be properly licensed, or be taken down. This is the direction Canada must take – and the US too. Were such a requirement coupled with a notice and takedown system that included real penalties for repeat infringers and downloaders, great strides would be taken towards a sustainable Internet. Hopefully Canada's ongoing *Copyright Act* review will lead to such improvements.

Safe harbour provisions

Article 20.89 of the USMCA requires parties to implement safe harbours for "legitimate online services operating as intermediaries" – often called "platforms" – and for those providing Internet access and routing services, together with Internet Service Providers (ISPs). Examples of platforms include YouTube, Facebook, and Amazon. Article 20.89 deals essentially with copyright infringement and notices thereof, as described in the previous section. However, it could be read more broadly. It absolutely should not be.

The salient precedent for an ISP safe harbour for non-copyright liability like libel is section 230 of the *US Communications Decency Act* (CDA). It provides blanket immunity to Intermediaries. Section 230 seeks to ensure that:

> No provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider.

Intermediaries love it. With this simple formulation, in 1996, emerging law holding the "bulletin boards" and other user services of the day liable for posted content was reversed, and the path laid for what are widely seen to be the tremendous abuses of today. These abuses include widespread piracy and under-compensation to artists on YouTube.

Implementation of Article 20.89 of the USMCA requires nothing new of Canada; however, on a generous interpretation, it could be used as a basis to broaden the safe harbours in which ISPs shelter in Canada. Given Canadian policy's tendency to favour big tech over SMEs, vigilance is warranted (Snyder 2018, Sookman 2018a). Indeed, there are those who hope for implementation more protective of big tech (Geist 2018a):

> Digital policy expert Michael Geist said such safe harbour rules haven't been part of the Canadian landscape, which is why content like critical, over-the-top restaurant reviews are more swiftly removed in Canada than in the United States.
>
> The wording is a first for the North American trading partners and could set the stage for it to be embedded in Canadian law, said Geist...
>
> "This, I think, is actually a good provision. It helps freedom of expression online, it

> provides some amount of a safe harbour for internet companies that try to do the right thing by removing content in appropriate circumstances and it's the sort of thing that Canadian law has been missing…" (Canadian Press 2018)

The safe harbour provision, on its face, applies to copyright infringement and not the libel issues to which Geist refers. No doubt activists hope that the safe harbour provisions can be exploited to entrench broader protections for Google and others in Canadian law. This would be bad.

The pendulum is swinging rapidly away from blanket immunity. Section 230 is under review in the US. Europe is moving in an opposite direction. With Article 17 of its recently passed *Copyright Directive*, platforms hosting third party content will be required to ensure it is copyright compliant or obtain licences for it (European Commission 2016).

Hopefully the significance and justice of this European initiative will register on this side of the pond. If it does, we have to be alert to extreme and underhanded lobbying efforts to stymie the development of such a provision, as was the case in Europe (Owens, 2018b).

Other Provisions

The foregoing are the key provisions of Chapter 20. The chapter is long and there is much more to it. However, the rest of the chapter appears not to affect Canada very much.

Another positive provision, however, is section 20.14, which establishes a **Committee on Intellectual Property Rights** to "exchange information, pertaining to intellectual property rights matters, including how intellectual property protection contributes to innovation, creativity, economic growth, and employment."

Clearly the mandate of the committee is to advance the role of IP in the economies of the signatory states. The committee could play a useful role in that regard. However, many are the attempts to establish such committees in trade agreements and in others, such as joint ventures and services outsourcing agreements.

Often, they are ignored and simply fail. I hope that this one is properly staffed and resourced and that it can in fact encourage strong innovation policy in all member states. That could be a real contribution to the debate around IP and innovation policy in this country.

In respect of trademark counterfeiting, there was hope for a measure respecting **statutory damages**, to address the great difficulty of calculating actual damages in cases of trademark infringement. Unfortunately, while there is such a provision, it will likely not affect Canada. Article 20.82(7) requires "one or more of… pre-established damages… or additional damages." With its exemplary and punitive damages regime Canada already satisfies this provision, without, unfortunately, needing to provide statutory, or "pre-established" damages. Still, perhaps statutory damages will be on the table for future domestic reform.

Of course, no trade agreement would be complete without **cultural exemptions** for coddled Canadian content, and the USMCA is no exception. Ch. 32 contains a very broad exception to the provisions of the USMCA for Canada to protect its (broadly defined) cultural industries.

Protectionism continues. That said, Chapter 32 permits retaliatory measures of similar commercial impact by the US and Mexico. While these exemptions could even free Canada of the new copyright provisions, Canada has indicated that it will not apply the exemption (McGregor 2018).

There are extensive provisions on **trade secrets** which do not appear to require legislative change in Canada, but may (Section I, Article 20.70 *et seq*.).

Finally, Article 20.84(5) addresses a point long standing between the US and Canada, and a sore point at that. It provides that counterfeit goods landed in Canada but "in transit" to another country be subject to **customs seizure**. Because Canada is such a major trans-shipment point for Chinese goods, this is particularly important. Goods landed in Canada and transshipped to the US are, moreover, often re-distributed back to Canada, so that it is in our interests, given the severe safety issues with counterfeit goods, to interdict them. Still, there is an extent to which taking on this inspection burden is a matter of just being a good neighbour.

Conclusions

The USMCA contains measured, beneficial steps along the road to improving IP protection in Canada, and to enhance high-value trade among the parties. These steps will be good for trade and foreign investment and good for Canada's domestic IP economy. They will also further protect Canadian cultural goods traded with Mexico.

Pharmaceutical development is a privately-funded godsend that is falsely treated as a public good in many nations.

Perhaps most important in the USMCA is additional data protection for biologics. To a large extent, the biosimilar economy has yet to prove itself. It is a complex and uncertain proposition to copy an originator biologic. And it is an expensive one, which, among other factors, will certainly preclude health cost savings of the order offered by small molecule generics.

Therefore, to delay the entry of a biosimilar by USMCA's required two years of additional market exclusivity will be far less costly than in the case of a small-molecule generic. The enormous costs of developing and seeking marketing approval for a biologic militate strongly in favour of a longer term of additional exclusivity. Such a longer term will also create better conditions for innovation in Canada as demonstrated, for instance, by the Israeli experience.

Pharmaceutical development is a privately-funded godsend that is falsely treated as a public good in many nations, including Canada. Out of a sense of entitlement we force drug prices

lower, and shirk our share of development costs by foisting them, instead, on the US consumer. It is time to allow drug prices to find their market levels. This will bolster Canadian innovation, as will extending the period of protection for biologics to 10 years. Moreover, Canada would do well to exceed the minimum requirement and move to a 12-year period of protection such as is offered in the US.

To extend Canada's term of copyright to life-plus-70-years from life-plus-50 will add market incentive to the production and distribution of cultural and other copyright-protected goods. Moreover, it will gain equivalent protection in other nations which have the 70-year term but which deny it to authors from countries that do not offer at least the same. This will be a major boon to Canadian authors. A longer period of protection is consistent with copyright theory and with copyright being a human right under the UN Declaration on Human Rights.

Excessive exemptions from liability for intermediaries, or platforms, cause mischief. In particular they have created very high levels of piracy of music, movies, and other content on services like YouTube, which have resulted in plummeting revenues for artists. Accordingly, Canada must not interpret the safe harbour provision of the USMCA broadly, as it will undoubtedly be under pressure to do, but narrowly, requiring no further legislative implementation.

That said, our notice and notice system of dealing with copyright infringement and protecting ISPs is an embarrassment. It needs to be fixed. It need not be fixed precisely as the provisions of Article 20.89 of the USMCA require – the provisions forgiven Canada by Annex 20A – but they would be a good start.

Canada's current exclusions from patentable subject matter are too broad. Canada should not enact the exclusions, including especially diagnostic methods, permitted under the USMCA. Indeed, Canada urgently needs to remedy the illegal and ill-advised exclusion of diagnostic methods from patentability currently applied by the CPO.

Finally, criticism of the IP provisions of the USMCA is unwarranted. The provisions are good for Canada and we must not delay ratification of this critical trade agreement.

About the Author

Richard Owens is a Munk Senior Fellow with the Macdonald-Laurier Institute and a lawyer who has specialized in business and commercial law, regulation of financial institutions, intellectual property and technology. He has served financial services providers, technology companies, drug companies and others in Internet, technology, intellectual property strategy and patent law, M&A, outsourcing, strategic alliance and joint ventures, licensing and other areas. He has been repeatedly recognized as among Canada's best lawyers in technology law and attained the highest rating on Martindale Hubbell. He conducted his practice with three of Canada's leading law firms.

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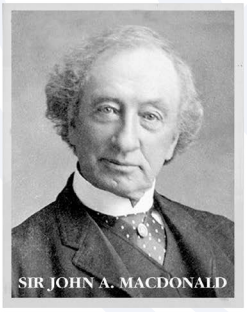
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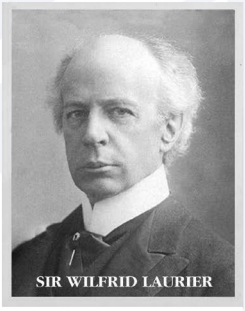
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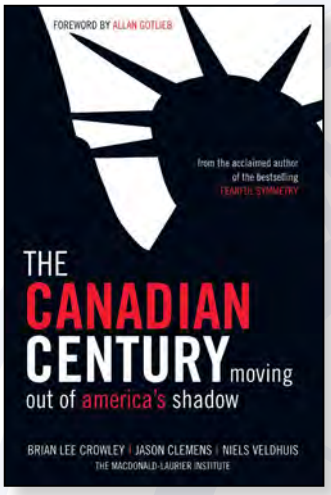

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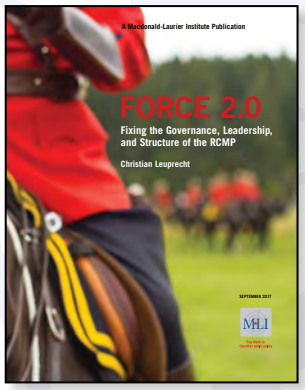

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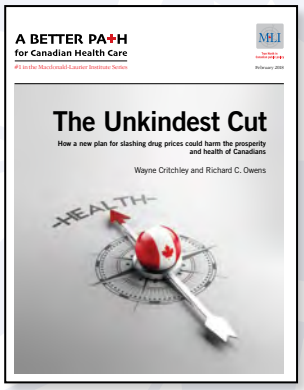

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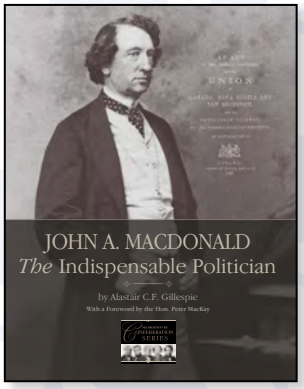

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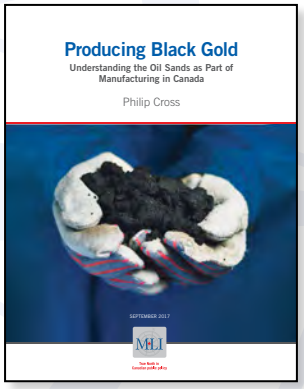

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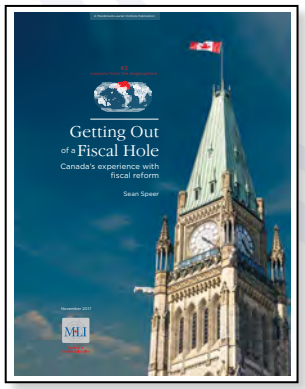

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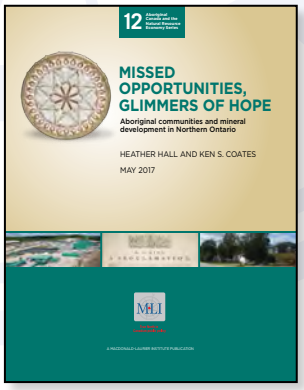

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