Slow and Steady Will Not Win the Race

Trade Negotiations, IP Protections and Canada’s Pharmaceutical Industry
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Executive Summary

Intellectual property (IP) protection is the medium that, when supported with investment and research, produces breakthroughs in the pharmaceutical industry.

International trade negotiations have driven Canada’s IP regime over several decades. The resulting changes have helped generate investment and progress in Canada’s innovative pharmaceutical sector. Through agreements such as the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the North American Free Trade Agreement (NAFTA), and the Comprehensive Economic and Trade Agreement (CETA), Canada gradually has brought its IP protections closer in line with those of its major trading partners. Still, the constant push and pull between the generic and research-based industries means that Canada never leads the pack on IP protection.

Canada’s incremental approach to IP protection might have been sufficient when the pharmaceutical industry was less dynamic. But the country is now faced with a rapidly evolving biopharmaceutical market: new product development is on the rise in areas such as biologic medicines and orphan drugs, aging baby boomers are increasing the demand for drugs, new markets are rising out of emerging economies in Latin America and Asia, and countries such as China and India are becoming highly competitive pharmaceutical manufacturers.

In face of this market vigor, Canada remains hindered by weaker IP rights and onerous patentability requirements.

The driving forces behind Canada’s potential to foster investment and innovation include the quality of its universities and the excellence of its researchers. Decisive government action could turn the tide in Canada’s favor with a more robust approach to life sciences IP protection. In a competitive and rapidly changing global market, slow and steady will not win the race.
Slow and Steady Will Not Win the Race: 
Trade Negotiations, IP Protections and Canada’s Pharmaceutical Industry

By Laura Dawson¹

Introduction

In Aesop’s fable about the tortoise and the hare, the slow and steady tortoise ultimately triumphs over the swift but showy hare. Canada’s approach to improving intellectual property protection for pharmaceutical products has followed the tortoise’s mantra: reactive and incremental. This approach has kept the country more or less in line with international legal norms, but is the measured approach sufficient to attract and sustain investment in a competitive global economy?

This report explores how international trade negotiations have driven and shaped Canada’s intellectual property regime for patents and examines whether the pace and content of these reforms are serving Canada’s needs as an innovation economy. In the first section we discuss the changing landscape of global pharmaceutical production and consumption and the technological and demographic factors that influence it. The second section looks at how free trade agreements (FTAs) drive, block, or change the direction of domestic regulation. The final section discusses the link between domestic IP protections and pharmaceutical trade and investment, providing a set of recommendations to help position Canada’s research-based pharmaceutical industry within the context of these changes.

¹ Thanks to the Dawson Strategic team for their contributions to this report: Justin Bedi, Yamily Camacho, and Jeffrey Phillips. Graphic design by Foothills Graphics.

Pharmaceutical Market Overview and Future Trends

Market Demand – New Markets and New Products

Pharmaceuticals make an important contribution to human health. On average, for every $24² spent on new drugs for cardiovascular diseases in OECD countries, $89 are saved in hospitalization and other healthcare costs.³ Because of its importance to patients and healthcare providers, the global pharmaceutical market will reach nearly $1.2 trillion by 2016, an increase of nearly 250 billion from 2011.⁴

The pharmaceutical industry is a classic example of private enterprise wedded to public interest. For more than a century, nearly all of the medicines and vaccines on the market were produced by the private sector.⁵ Today, new technologies, new markets, and changes to traditional markets are propelling the pharmaceutical industry into a period of profound transformation.

² All figures in U.S. dollars unless otherwise indicated.
⁵ IFPMA 2012, 7.
Twenty main therapeutic areas account for more than 40 percent of global spending on pharmaceutical products, led by treatments for cancer, diabetes, and asthma. European and North American markets tend to focus on aging baby boomer populations who demand the most effective, leading edge treatments for chronic diseases. Some of the most promising therapeutic products are biologic drugs that are the result of advances in human genomic research. Although relatively new, biologic drugs are already providing better interventions to cure or manage illness and disease.

Small-Molecule Versus Biologic Drugs

Most traditional drugs are small molecules (such as aspirin), though some drugs can be proteins (such as insulin). Small molecule drugs are produced through stable and predictable chemical processes that are relatively simple to replicate, which makes it easy to develop generic copies of innovative drugs. Most drugs sold today are small molecules.

Biologic drugs are complex, often heterogeneous mixtures that can include whole cells or derivatives from human, animal, plant or micro-organism sources. Many biologic drugs are actually manufactured within cells, each of which imposes its own variabilities on the process. Even minor changes in manufacturing can cause significant changes in efficacy. They are highly sensitive to external conditions and it is impossible to ensure the production of identical copies. All of these factors make biologic drugs more challenging to replicate than traditional small molecule drugs, and so the transition from biologic to biosimilar drugs is much more difficult than transitioning from small molecules to generics.

The global pharmaceutical industry is in a period of transition. Innovative pharmaceuticals accounted for nearly two-thirds of global pharmaceutical spending in 2011, but as patents expire that share is expected to decline in favor of generic substitutes.

More than half of global demand comes from developed countries but the relative importance of developed country sales is shrinking. Government spending by the EU, United States, and Japan is set to decline from 73 percent of the global total in 2006 to 57 percent in 2016. While declines in the United States and EU are more pronounced, Canada’s spending has remained relatively consistent at 2 percent of the global total.

In the United States, the successful implementation of health care reform could mean access to medicines for an additional 30 million people, but increased sales from market expansion are tempered with bulk purchasing initiatives by governments in the United States and Canada (discussed later in this report) that put downward pressure on prices.

FIGURE 1: Percentage of Global Spending for Pharmaceutical Products, 2006-2016 (US$ billions)

Source: (IMS Institute 2012).

7 Some of the top selling biologic drugs offer treatments for rheumatoid arthritis, Crohn’s disease, diabetes and various types of cancer.
8 (IMS Institute 2012, 9).
9 Generics and Biosimilars Initiative, “Small molecules versus biological drugs”, (June 2012).
10 (IMS Institute 2012, 9).
11 (IMS Institute 2012, 3). See discussion of biosimilar (subsequent entry biologic) drugs later in this report.
12 Patent expiration between 2008 and 2016 is expected to reduce brand spending in favour of cheaper pharmaceuticals by $106 billion. See (IMS Institute 2012, 3). At the same time, declining revenues decrease the capacity of innovative pharmaceuticals to invest in new R&D. See discussion of the patent cliff later in this report.
13 (IMS Institute 2012, 7).
14 (IMS Institute 2012, 7).
TABLE 1: Projected Annual Pharmaceutical Spending by 2016

<table>
<thead>
<tr>
<th>Category</th>
<th>2016 Spending</th>
</tr>
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<tbody>
<tr>
<td>Global</td>
<td>$1.2 trillion</td>
</tr>
<tr>
<td>Innovative Drugs</td>
<td>$645 billion</td>
</tr>
<tr>
<td>Generic Drugs</td>
<td>$430 billion</td>
</tr>
<tr>
<td>Developed Country Spending Per Person</td>
<td>$609</td>
</tr>
<tr>
<td>Emerging Market Spending Per Person</td>
<td>$91</td>
</tr>
</tbody>
</table>

Source: (IMS Institute 2012).

Emerging Markets

As incomes increase in the developing world, there is unprecedented demand for health and pharmaceutical products. Growth in pharmaceutical spending in emerging markets will more than double the global average and triple U.S. spending growth (see Table 2). Emerging markets will account for around 30 percent of global spending on pharmaceuticals by 2015.16


<table>
<thead>
<tr>
<th>Category</th>
<th>Growth Rate</th>
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<tbody>
<tr>
<td>Global Spending Growth</td>
<td>3 – 6 percent</td>
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<tr>
<td>U.S. Spending Growth</td>
<td>1 – 4 percent</td>
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<tr>
<td>Emerging Market Spending Growth</td>
<td>12 – 15 percent</td>
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Source: (IMS Institute 2012).

Emerging market consumption is driven by rising incomes and government commitments to provide basic health care to all citizens.17 Even though developing country incomes are rising, developing country consumers pay less for drugs than their developed country counterparts. This is related to the fact that lower-cost generics tend to have an advantage in developing countries, except in markets such as China where consumers view the quality of brand-name innovative drugs as more trustworthy.18

Since providing universal access to healthcare in the developing world remains a challenge, policymakers at international forums from the World Health Organization to the World Trade Organization are grappling with mechanisms to provide access to medicines for the world’s poor. Access in developing countries has become a central issue in the Trans-Pacific Partnership (TPP), a proposed Asia-Pacific trade and investment treaty.

Supply – New Products and New Competitors

On the supply side, the expiration of patents for a number of top-selling drugs means declining market share for the innovative, research-based pharmaceutical companies as a percentage of demand shifts to generic alternatives. This loss of market share dramatically changes the way these companies operate, including their capacity to invest in new therapies.

As demand is heating up in emerging countries, growing productive capacity in the developing world is changing the geography of global pharmaceutical production. The consulting firm PwC predicts that India and China will dominate global generic production and exports by 2020.19 Labour and material costs are relatively inexpensive, and India and China together already produce more than 80 percent of the active ingredients of all drugs used in the United States.20

Despite the shift to generics and competition from emerging market suppliers, the contribution of Canada’s research-based pharmaceutical sector will continue to be significant even without major growth in small-molecule drugs.21 Expansion of efforts within the biologic sector can be expected to yield even greater returns, especially given demand for these products among the aging and middle class populations in emerging markets.22

Canada is home to both research-based and generic
pharmaceutical companies, but the latter generates a smaller share of investment and employment. In addition to direct employment, the research-based pharmaceutical industry generates an equal or greater share of indirect jobs than the generic sector.\(^\text{23}\)

In the future, the Canadian population may theoretically benefit from growth in the subsequent entry biologic (SEB) drugs\(^\text{24}\) sector, but right now these account for only about 2 percent of spending on biologic drugs.\(^\text{25}\) This sort of expansion is expected to remain modest in the near term because of the cost and complexity of producing SEBs.\(^\text{26}\) With respect to the production of SEBs in Canada, SEBs require a very different business model than small molecule biologics, so it does not necessarily follow that Canadian generic manufacturers will be able to compete in this market. The complexities inherent in SEB manufacturing are clear: in late 2013, Canadian generic company Apotex agreed to sell its controlling interest in biologic company Cangene to U.S.-based Emergent Biosolutions.\(^\text{27}\)

### Medical Innovation, Health, and the Economy

Breakthrough therapies are making significant contributions to quality of life and health. Between 1910 and 2010, global life expectancy increased by 62 percent.\(^\text{28}\) While public health factors such as sanitation and nutrition contributed much to this increase, medicines such as penicillin, and vaccinations against influenza, measles, yellow fever and hepatitis have also played a major role. The role of technological breakthroughs in medicines is now the most significant single contributor to improving human health and longevity. Between 1986 and 2000, new therapies were responsible for 40 percent of the increase in life expectancy in developing and high-income countries. Between 2000 and 2009, that share increased to 73 percent.\(^\text{29}\)

There are long-term socioeconomic gains for human health and efficient treatment of disease. Economic analysis suggests that every dollar invested in medical innovation generates an average of three dollars in future health benefits.\(^\text{30}\) These benefits are not limited to the health sphere, but produce significant spillovers into the broader economy. Murphy and Topel, in their economic framework for valuing improvements to health and life expectancy, argue that between 1970 and 2000, medical innovation was the source of more than half of all economic growth.\(^\text{31}\)

### The Promise and Peril of Drug Development

Pharmaceutical researchers continually review compounds for new or novel traits that could contribute to improved human health. Research and development (R&D) begins when researchers identify a promising compound among the tens of thousands screened. In a process that can take up to 15 years, researchers then test the compound to ensure its efficacy and safety. The chances of success are miniscule. Globally in 2011 more than 3200 compounds were at different stages of development but only 35 new medicines were launched.\(^\text{32}\)

It takes an estimated $2.6 billion and more than 10 years to develop a new drug through to marketing approval.\(^\text{33}\) IMS Health reports that up to 37 new products will be launched in 2016, up from an average of 25 to 30 products

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\(^{24}\) Sometimes referred to as “biosimilar drugs” or, and incorrectly, as “generic biologic drugs”. SEBs are not bioequivalent to innovative biologics in the way that small molecule generic drugs are to the original innovative drug that was copied. See Health Canada, “Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)”, (2010).

\(^{25}\) (IMS Institute 2012, 3).

\(^{26}\) (IMS Institute 2012, 9).


\(^{32}\) (IFPMA 2012, 7).

\(^{33}\) The Tufts Center study further estimates that post approval costs could exceed $300 million, bringing lifecycle costs to more than $2.8 billion. See Tufts Center for the Study of Drug Development, “Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion”, (November 2014).
Innovative therapies are anticipated for Alzheimer’s and autoimmune diseases, diabetes, cancer, cardiovascular and respiratory conditions, as well as orphan diseases that affect small percentages of the population. \(^{36}\)

The number of new medicines in development is rising, but testing is rigorous and many drug development projects are discontinued before the product stage. This situation is aggravated by the fact that clinical trials have increased in cost and complexity. Between 1999 and 2005, the number of procedures per trial and length of clinical trial increased by more than 60 percent while the number and retention of trial volunteers decreased by more than 20 percent. \(^{38}\)

**Pharmaceutical Firms and the Canadian Economy**

The Canadian pharmaceutical sector includes a research-based pharmaceutical industry, a generic industry made up of both domestic and multinational firms, and an emerging biologic drug sector that includes a number of small domestic enterprises. According to Industry Canada, Canada’s domestic pharmaceutical production was valued at $7.7 billion in 2013 and total pharmaceutical sales in Canada were $22 billion, nearly double 2003 levels. Innovative products account for 77 percent of sales, representing nearly $17 billion. \(^{37}\) The Patented Medicine Prices Review Board (PMPRB) estimates that 2013 sales for innovative products was $13.6 billion. \(^{38}\) Using this figure, the Canadian Health Policy Institute (CHPI) estimates that innovative products account for about 40 percent of drug sales in Canada and about 6.5 percent of public and private health spending in Canada. \(^{39}\)

In 2014, more than 26,000 Canadians were employed in the manufacturing portion of the Canadian pharmaceutical sector, mostly clustered around Toronto and Montreal. \(^{40}\)

More than half of Canadian production is exported, mostly to United States, while about 85 percent of the drugs consumed in Canada are imports, either from the United States or European Union. Although Canada imports more than twice as much as it exports, pharmaceutical exports have risen by 155 percent since 2001, reaching $5.6 billion in 2013. \(^{41}\)

The pharmaceutical industry is one of Canada’s leading sources of research and development. Twenty pharmaceutical companies were among Canada’s Top 100 R&D spenders in 2013. \(^{42}\) Research-based pharmaceutical companies in Canada invest in basic research, but most investment is concentrated in applied research (which includes clinical trials and manufacturing processes).

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**The pharmaceutical industry accounts for around 10 percent of Canada’s business-based R&D and a quarter of its venture capital, but Canada has relatively low absolute levels of both when compared with other developed countries, particularly the United States.**

In 2012, research-based pharmaceutical companies invested over three times more than generic companies in Canada ($1 billion versus $300 million). However, new drug developments cost between ten and thirty times more than generic production and that cost is doubling every decade. \(^{44}\)

Canada lags behind major trading partners such as United States, EU and Japan in the protection of intellectual property in the life sciences, and this affects the pharmaceutical industry. Research-based pharmaceutical

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34 (IMS Institute 2012, 14).
35 (IMS Institute 2012, 15).
36 (IFPMA 2012, 11).
40 (Industry Canada 2014).
41 (Industry Canada 2014).
43 Conference Board of Canada Briefing, “CETA and Changes to Canada’s Pharmaceutical Regime: Too Much or Not Enough IP?”, (March 26, 2014).
44 (Conference Board 2014).
companies argue that increased levels of protection stimulate investment in R&D in new and innovative drugs. For example, the 1987 and 1992 changes to Canada’s Patent Act that tightened IP protections were followed by a 1500 percent increase in pharmaceutical R&D investment between 1998 and 2002. 45

While it exceeds $1.3 billion annually, the share of investment by research-based pharmaceuticals in Canada has been declining as the global pool of $135 billion migrates to other jurisdictions. Meeting the demand for new innovative therapies requires considerable investment by research-based companies, many of which are facing declining revenue streams because of their patents expiring on key products (a phenomenon known as the “patent cliff”). Innovative therapies also require strong patent protections and streamlined regulatory and approval processes to ensure that inventors can benefit from billions of dollars spent in new drug development.

**FIGURE 2: R&D Spending by Canada’s Research-Based Pharmaceutical Firms ($US billions)**

Source: (KPMG 2013). 46

**Research-Based Pharmaceuticals**

The research-based pharmaceutical industry employs 15000 Canadians directly and contributes to the employment of 46,000 more workers across the value chain, providing more than C$3 billion to the Canadian economy. 47

The industry invested more than C$1 billion in R&D in Canada in 2013. About 75 percent went to clinical trials and the other 25 percent to patient and community contributions. Globally, the innovative pharmaceutical industry invests over $135 billion annually in drug discovery, development, and commercialization. 48 To put this into the context of spending by high-tech industries, annual spending by the pharmaceutical industry is five times greater than the aerospace and defence industries, 4.5 times more than the chemicals industry and 2.5 times more than the software and computer services industry. 49

Despite having strong university and hospital research programs and internationally renowned researchers, less than one percent of global pharmaceutical R&D is spent in Canada. Canada lags behind peer countries in its ability to attract and maintain clinical trials. Some of the reasons for this gap, as cited by industry, are Canada’s lengthy and overlapping drug approval, health technology assessment, and listing processes, difficulty retaining clinical trial subjects, and, compared with its trading partners, a relatively weak and unstable IP system.

**Generic Pharmaceuticals**

Generic drugs represent about 72 percent of overall drug consumption in Canada, but only about 39 percent of prescription drug spending. 50 The generic industry is also in a transitional phase. Where previously they reproduced products on the basis of R&D done by others, they are now involved in a limited amount of their own R&D. Canada’s generic industry is seeking new export markets but is reluctant to accept changes to intellectual property rules that would delay their entry into the Canadian market.

Even though mandatory substitution policies are increasing the number of generic drug prescriptions, generics companies are concerned about decreasing profit margins. Provincial bulk purchasing arrangements vary according to province but generally reduce generic prices to approximately 18 percent of branded prices for a core

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45 Paul Grootendorst and Livio Di Matteo, “The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada”, Healthcare Policy 2:3 (2007), 84. As part of the compromise on legislative changes, innovative pharmaceutical companies promised to spend 10 percent of their after-sales revenue in Canada on R&D.

46 Note that the KPMG figures are 40-50 percent higher than those of PMPRB because the latter only records expenditures eligible for SR&ED tax credits. The KPMG survey includes research not linked to patent medicines and research-related donations.


48 (Rx&D 2014).

49 (IFPMA 2012, 12).

group of the most popular innovative products. Higher prices are permitted when there are only one or two generics available.

**Contribution of Pharmaceuticals to an Innovation Economy**

Investment in manufacturing and R&D is the most direct and visible effect of the pharmaceutical industry on the national economy but there are other indirect effects, which include improvements to academic research and creation of companies that support research and production. New business models such as joint-ventures and public-private partnerships (P3s) have the potential to enhance the productivity of pharmaceutical research even further.

Canada possesses the key ingredients needed for pharmaceutical innovation: world-class researchers, and political and financial stability. But it also requires a regulatory framework that protects and rewards innovation. It is in this area that Canada has not kept pace with its global peers and competitors. Rx&D, the industry association for Canada’s research-based pharmaceutical companies, argues that a globally competitive intellectual property regime will help to reverse the decline of R&D investment in Canada. This position is also supported by BIOTECanada, which affirms that a “strong intellectual property regime is essential to the success of Canada’s biotechnology industry.”

**Does Higher IP Protection Increase Drug Prices?**

The argument, favoured especially by the generic industry, is that if Canada has already passed its “peak R&D” it makes sense to orient national policies around lower-cost access for consumers and abandon the notion of Canada as a hub for pharmaceutical development.

But between 2007 and 2014, the cost of patented medicines grew by only 4.1 percent in Canada, while spending on the healthcare system as a whole increased by 28.5 percent during the same period. A comparison can be drawn with the EU, which has a higher level of patent protection than Canada and even lower health care costs as a percentage of GDP.

The theory behind the claimed link between strong IP and high prices assumes that national and international patent regimes are biased towards protecting monopoly rights, but a closer look shows that government negotiators are more often attempting to balance access with incentives that lead to invention and discovery.

**Joint Price Negotiation by Provinces**

The Inter-Jurisdictional Joint Pharmaceutical Purchasing Initiative (or Pan Canadian Drug Purchasing Alliance) seeks to reduce provincial drug expenditures through joint price negotiations. Many companies are now involved in this process and the industry has noted that there are already rigorous price controls in place and a rush towards the lowest cost options does not serve the long term health care interests of Canadians.

In Canada, the prices of patented medicines are monitored by the PMPRB to ensure that prices are in line with other markets and other drugs in a therapeutic class. In addition to negotiated agreements with payers on pricing, manufacturers offer additional patient support and compassionate programs to optimize access to appropriate care.

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52 (IFPMA 2012, 42).
53 (IFPMA 2012, 10).
54 (IFPMA 2012, 12).
55 Testimony by Russell Williams, President, Rx&D, and Darren Noseworthy, Vice-President and General Counsel, Pfizer Canada, to House of Commons Standing Committee on International Trade, (December 10, 2013).
57 PMPRB data as noted by Williams and Noseworthy in their testimony to SCIT in December 2014.
58 As noted by Williams and Noseworthy in their testimony to SCIT in December 2014.
The industry maintains that health care professionals, not government bureaucrats, should be the best judge of appropriate care for patients. According to an OECD analysis, a rush to lower-cost options in the short term may result in negative long-term effects including worse patient health outcomes, reduced access to new technologies and demand for higher spending in the future.60

According to Nanos Research, 79 percent of Canadians polled believe that Canada’s IP protection ought to be the same as, or better than, that offered in the United States and European Union. The greatest percentage of these individuals (64 percent) think that Canada’s level of IP protection ought to be the same as the United States and European Union.

Around 32 percent of Canadians are concerned that stronger IP safeguards will have a negative impact on access to new medicines but 37 percent think there is a positive link between IP and protections and new medicines.

Forty-four percent believe that stronger IP will create more Canadian jobs in the pharmaceutical sector (Only five percent believe that stronger IP discourages jobs, the rest are unsure or believe it has no effect).

A clear majority of respondents (56 percent) believe that stronger IP encourages the discovery of new medicines in Canada.

Fifty-nine percent of Canadians believe that strong IP encourages private sector investment in R&D (an increase over similar polls in 2013 and 2012).

Source: Nanos Research Group Research for Rx&D, Telephone survey of 1000 Canadians, (December 2014).

Overview

International trade negotiations provide momentum and focus to Canada’s domestic trade policy agenda, particularly in the area of intellectual property protection for pharmaceuticals. The globalized character of pharmaceutical production and consumption means that many regulatory aspects are better handled in a coordinated manner to ensure cross-border continuity. The greatest pressure for reform occurs when Canada is negotiating with trading partners that have IP intensive industries such as the United States, the European Union, and Japan.

Since the mid-1980s, Canada has made significant changes to its IP regime in order to comply with international commitments that were ultimately codified in the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), as well as the North American Free Trade Agreement (NAFTA).

The TRIPs agreement modernized and consolidated multinational regulation of intellectual property, including patent protection for pharmaceuticals, and it forms the negotiating template upon which subsequent reforms are based. The NAFTA provisions are largely based on, and in some cases are identical to, the TRIPs Agreement.

Implementation of these international agreements as well as earlier reforms to the Patent Act (Bill C-22) in 1987 helped to bring Canada’s domestic regime into compliance with international commitments and pressures for reform subsidised. For the next decade, Canada’s external trade negotiations focused mostly on developing countries whose IP aspirations did not exceed the TRIPs. (In many of these negotiations, Canada would be the party demanding that the developing country work harder to enforce its TRIPs commitments.)

The lull came to an end in 2009 when Canada and the European Union launched negotiations for the Comprehensive Economic and Trade Agreement (CETA), and it became clear that the EU would be demanding

upgrades to Canada’s pharmaceutical IP regime that would provide even higher standards of protection than afforded by TRIPs. The pressure for IP reform redoubled in 2012 when Canada entered the Trans-Pacific Partnership. The IP agenda in these negotiations is largely guided by the United States and Japan with a focus on deeper commitments to expand trade and investment among partnership countries.

As the pressure for reforms in these new agreements increased, so did the size of the prize. The countries that Canada had previously negotiated FTAs with (Colombia, Honduras, and Peru) do not come close to the EU or the United States in market potential, nor did they provide the same sort of opportunities for pharmaceutical supply chain development or joint ventures.

While both the EU and the United States have demanded deeper IP-related commitments from Canada, their priorities have been somewhat different due to differences in their domestic IP regimes and industries. Having completed the CETA in 2014 and with the TPP negotiations still ongoing, it may be that Canada’s CETA reforms will be sufficient to meet the final TPP standard. The following section describes these dynamics and provides a more detailed account of Canada’s current and recently completed negotiations.

CETA

CETA Market Opportunities

The European Union is the world’s largest single common market, comprising 28 Member States, a total population of 511 million, and a GDP of nearly US $17.6 trillion in 2014. Although Canada’s trade with the United States is larger, the EU is Canada’s second-largest export market. According to a joint study by the Canadian and EU governments conducted during CETA negotiations, the agreement was projected to provide a 20 percent boost in Canada’s exports to the EU, thereby generating more than $11 billion annually.

In the field of pharmaceuticals, the EU is a global powerhouse, characterized by a relatively small number of very large, capital-intensive enterprises. Total EU pharmaceutical exports were valued at $129 billion in 2013.

With increased competition from emerging market producers, the EU’s relative market share is declining (see Figure 3). However, Canada-EU pharmaceutical trade remains robust. Canada imported nearly $4.6 billion from the EU in 2013 while pharmaceutical exports to the EU were $1.6 billion. In fact, Canadian pharmaceutical exports to the EU grew by an average of 10 percent per year between 2003 and 2013.

Even though EU demand is not expected to grow much in the coming years, it will remain a relatively large, stable and prosperous global market, offering Canada an opportunity to diversify and reduce its reliance on trade with the United States.

FIGURE 3: Change of Pharmaceutical Production Market Share (%)
Negotiating Outcomes

A conclusion was reached for the CETA in mid-2014 after five years of negotiations. The following is a summary of the CETA outcomes (see also Table 3).

Market Exclusivity – The term of patent protection was relatively non-contentious since the WTO TRIPs agreement had previously helped to harmonize patent terms among member states. Specifically, TRIPs Article 33 requires a term of patent protection for not less than 20 years from filing date. Canada’s Patent Act accordingly provides 20 years of market exclusivity for pharmaceutical products that are novel, useful, and non-obvious.

Patent Term Restoration – Patent term restoration is remedial time that can be added at the end of a company’s patent life to help compensate for clinical development time and the time required to obtain approval from regulatory authorities.

At the outset of negotiations, Canada did not provide any patent term restoration and was the only country in the G7 that did not. The EU and United States in comparison both offer patent restoration terms of up to five years, depending upon the length of the clinical and/or regulatory delays. The EU asked Canada for patent term restoration of up to five years, comparable to its own system. Canada agreed to a maximum of two years for products protected by eligible patents.

The resulting period of protection will be calculated using reference points including the filing of the application for the patent and the first authorization to place the product on the Canadian market. Exceptions have been negotiated to allow for Canadian generic medicines to be exported during the period of additional protection. Pharmaceutical products that are already approved and on the Canadian market will not receive additional protection.

The Department of Foreign Affairs, Trade and Development (DFATD) estimates that any impact to pharmaceutical product costs as a result of this change will not be felt until at least 2023.

Patent Linkage refers to systems in which the regulatory approval of a generic drug cannot take place until the innovator’s applicable patent has expired, been invalidated, or the patent holder provides consent.

In the United States, the Food and Drug Administration (FDA) maintains a list of pharmaceutical patents and approved uses in the ‘Orange Book’ and will not provide marketing approval for a generic copy of innovative products that would infringe a patent listed therein.

The EU does not have a formal patent linkage mechanism but, when a generic launches a drug before the expiry of a patent, the innovator may sue for infringement and apply for an interlocutory injunction that preserves the status quo and prevents the generic from launching until litigation is complete or the parties have settled.

Canada’s linkage proceedings are similar to those in the United States and governed by the Patented Medicines (Notice of Compliance) Regulations (PM(NOC)). Under these regulations, Health Canada will deny regulatory approval for a generic drug until the patent is expired, invalidated or a patent holder consents. The regulations provide up to a maximum of 24 months for an expedited judicial process to test infringement and/or invalidity, and during this process the generic drug may not be introduced to the market.

FIGURE 4: Typical Canadian Patent Timeline (years)

Source: The Conference Board of Canada.

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67 Information about the content of ongoing negotiations is highly speculative. Statements in this briefing about CETA and TPP pharmaceutical offers and requests are drawn from leaked texts, public documents and government briefings.

68 All CETA and TPP states are also WTO members.

69 In Canada, a product must be reviewed by various regulatory authorities before it can be listed on a public formulary. Health Canada is the federal safety regulator of pharmaceuticals, a federal/provincial/territorial body known as the Canadian Agency for Drugs and Technologies in Health makes recommendations with respect to product safety and efficacy, and the provincial/territorial governments make the ultimate decisions regarding product listings.

70 Department of Foreign Affairs, Trade and Development [DFATD], “CETA Technical Summary of the Final Negotiated Outcomes”, (October 2014).

71 Estimate uses eight as the average number of years that a pharmaceutical product would be on the market before becoming eligible for additional protection, and will depend on the ratification date of the CETA, which is now likely to occur in the latter half of 2016.

One of the most contentious patent linkage issues is the right to appeal the outcome of a notice of compliance (NOC) proceeding under Canadian law. According to this procedure, any innovative company seeking a NOC must report the results of its clinical tests to Health Canada in a new drug submission. Health Canada sets a safety and efficacy regulatory review target time of 300 days (less than 10 months) to decide whether a submission merits an NOC. This process often takes more than 18 months and the total time between filing a patent application and receiving an NOC may take between 11 and 13 years. If the tests prove safety and efficacy, Health Canada issues a NOC allowing the drug to be sold in Canada.

Prior to CETA, if an innovator failed in its NOC application, a generic may be granted an NOC shortly thereafter and the Canadian Federal Court had held that it would not hear any appeal by an innovator company. Conversely, should a generic lose its NOC proceeding, it retained its right to appeal. Under the terms of the CETA, both the patent holder and the generic challenger are entitled to equivalent and effective rights of appeal. It is still unclear how this will be implemented within Canadian IP legislation.

Data Exclusivity – When an innovator is seeking regulatory approval for a new innovative drug, the company is required to submit the results of their clinical testing data to Health Canada so that it may verify the product’s safety. Generic drug companies wishing to market copies of the original product would incur significant costs if they had to conduct their own tests, so they rely on the innovator’s clinical testing data when submitting their own applications.

Under the Canadian regime, generic companies could not use the innovator’s testing data for product approval for a period of eight years (plus a possible additional six months for pediatric studies). The EU, by contrast, offered a base data exclusivity period of 10 years (plus a possible additional year for new indications). The EU requested that Canada offer an equivalent term of data protection but did not succeed in changing the Canadian position. The CETA text does, however, require both parties to maintain a minimum of eight years of data protection. CETA data protection applies to all drugs, including biologics.

Implementation – The Government of Canada announced an agreement in principle in September 2013 but the text was not fully complete until August 2014. Ratification of the CETA still requires the approval of the Council of the EU and the European Parliament as well as Canada’s Parliament. The soonest it could come into effect would be the latter half of 2016.

**TABLE 3: Major Results of the CETA Pharmaceutical Negotiations**

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>EU (unchanged from previous)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patent Term Restoration</strong></td>
<td>Canada will move from 0 to 2 years. (EU requested 5).</td>
<td>Up to 5 years; as long as total marketed period with patent protection does not exceed 15 years.</td>
</tr>
<tr>
<td><strong>Right of Appeal on Patent Term Linkage</strong></td>
<td>Canada grants effective and equivalent rights to both parties to the dispute. Previously, generics and patent holders had different appeal rights.</td>
<td>The EU does not have a linkage system, but equivalent measures (e.g. interlocutory relief) are available as part of its patent infringement regime.</td>
</tr>
</tbody>
</table>
| **Data Protection / Exclusivity** | Unchanged. Maximum term of 8.5 years:  
- No submission from generic manufacturer for 6 years  
- No regulatory approval of a generic equivalent for an additional 2 years  
- An additional 6 months is granted for submissions related to pediatric studies  
Canada refused to agree to a longer term but agreed a minimum requirement of data protection at eight years, maintaining the status quo. | Maximum term is 8 + 2 + 1 = 11 years:  
- No submission from generic manufacturer for 8 years  
- No regulatory approval of a generic equivalent for an additional 2 years  
- An additional 1 year data exclusivity for a new indication |


74 The innovative company may, however, sue for patent infringement, but innovators have argued that this remedy is ineffective because it is costly, time consuming and does not prevent the generic from taking over the innovator’s product market in the meantime.
Discussion
Canada’s negotiating position in the CETA was pulled in two directions by competitive pressures from the research-based and generic industries, as well as the presence of the budget-conscious provinces at the table. The research-based and biotechnology companies promoted reforms as a way to stimulate investment and innovation, while the generic industry tried to block proposals that would limit the scope for generic activity or reduce their prices.

At the outset of the CETA negotiations, Canada lagged behind both the European Union and the United States in such areas as patent term restoration, right of appeal, and data exclusivity. But by the end of the talks Canada had agreed to a patent term restoration regime, albeit one offering less restoration than its peers, and improvements were made to guarantee an equitable right of appeal by both innovators and generics. Data exclusivity remained unchanged, with Canada and the EU agreeing to a minimum base period of 8 years.

The government has stated it will take steps to mitigate potential costs arising from changes to patent term restoration or other reforms. The Conference Board of Canada has found no evidence that CETA will increase drug costs, but it does conclude that CETA will “boost Canada’s innovation ecosystem by making the country a more attractive place to make R&D investments.”

CETA to TTIP
Just as Canada was trying to complete its free trade negotiations with the European Union, the United States was starting its own negotiations with the EU. Launched in 2013, the proposed U.S.-EU Transatlantic Trade and Investment Partnership (TTIP) promises to be an unprecedented agreement between two of the world’s economic giants. What makes it unique is that both economic regions are globally dominant and have highly developed – but often divergent – economic regulatory systems.

In the CETA negotiations, Canada sidestepped hard concessions on regulatory issues by claiming that such concessions would prejudice its trade with the United States. Canada was able to punt on issues such as biotechnology and the scientific standards of risk assessment but, at the TTIP talks, the EU and the United States will have to meet them head on, making the negotiations a very long but potentially interesting exercise, especially as global traders focus more attention on cross-border regulatory alignment.

For the pharmaceutical sector, this suggests that the focus of trade negotiations is expanding from patent-related measures to harmonization of regulatory standards and mutual recognition of certification and inspection practices. This affects the Canadian pharmaceutical and health industries given its interest in regulatory harmonization with the U.S. Food and Drug Administration and with the European Medicines Agency. To this end, Industry Canada is looking at mechanisms such as the Canada-U.S. Regulatory Cooperation Council as a way to align assessment, approval and monitoring practices in both countries.

TPP
TPP Market Opportunities
The twelve Trans-Pacific Partnership negotiating parties are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States and Vietnam. The TPP countries represent a prospective free trade zone of over 785 million people with a $27 trillion GDP. For Canada, the TPP would not only deepen existing agreements with Chile, Peru, Colombia, Mexico and the United States, it would also open the doors for a liberalized trade with the Asian countries where Canada’s market share is relatively small. Petri and Plummer estimate that the TPP could

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75 Trade agreements are traditionally negotiated by Canadian federal negotiators with authority delegated by the provinces in areas of provincial jurisdiction in exchange for ongoing consultation.
78 While maintaining the status quo, this CETA provision has some defensive value for the innovative industry. The current level of protection in Canada is contained in the Food and Drug Regulations, which could always be potentially amended. However, if the level of protection is memorialized as part of the CETA, this term of protection will become far more difficult to reduce in future.
79 (Conference Board 2014, 3).
yield annual income gains of $9.9 billion for Canada and increase exports by some $15.7 billion.\textsuperscript{81}

The major attractions of the TPP are the size and dynamism of the Asian market together with the avoidance of preference erosion if Canadian trading partners complete a deal that Canada is not a part of. The emerging economies in the TPP have growth rates that are roughly double those of Canada’s traditional trading partners in the United States and Western Europe. The Asia-Pacific Economic Cooperation countries—of which the TPP members are a subset—account for 44 percent of world trade and 55 percent of global GDP.\textsuperscript{82} As emerging market consumers become relatively better off, their demand increases for consumer and luxury goods, including pharmaceuticals (see Figure 5).

**FIGURE 5: Annual Average Growth Rate of Per Capita Pharmaceutical Expenditure, Asian TPP Parties, 2000–2009 (%)**

![Chart showing annual average growth rate of per capita pharmaceutical expenditure for Asian TPP parties, 2000–2009.](source)


**TPP Negotiating Dynamics**

The current version of the TPP negotiations builds on the 2006 Trans-Pacific Strategic Economic Partnership Agreement (P4 Agreement) between Chile, Brunei, Singapore and New Zealand. Other members were added after the United States announced its intention to join in 2011. As late entrants to the negotiations, Canada and Mexico joined in 2012 and Japan in 2013. Concerns that newcomers would have little say over a deal negotiated by others have not amounted to much, as it has become clear that little was agreed upon before the new entrants arrived and that the target dates for agreement completion in 2012, 2013, or 2014 were wildly optimistic.

Senior U.S. Trade Representative (USTR) officials have threatened that Canada will be shut out of a soon-to-be completed deal unless it demonstrates greater negotiation flexibility, especially on dairy issues,\textsuperscript{83} but Canada appears to be biding its time in the belief that no serious concessions will be offered until the United States Congress passes Trade Promotion Authority (TPA) and the U.S.-Japan side agreements on market access have been completed.

Canada’s strongest interests in the TPP are defensive ones, notably with respect to agriculture, and to ensure that current NAFTA benefits are not eroded by a new agreement.\textsuperscript{84} The TPP would also provide Canada with direct benefits in such areas as goods and services in the extractive, transportation, and agricultural sectors.\textsuperscript{85}

The United States is leading the TPP agenda. With regard to intellectual property, it is seeking protections that meet or exceed its recent bilateral free trade agreements. The U.S. agreement with South Korea (KORUS), for example, is considered to be the operational model.\textsuperscript{86} Its TRIPs-plus coverage includes mandatory patent linkage, patent term restoration, and data exclusivity. The Australia-U.S. Free Trade Agreement is quite similar, so Australia is expected not to strongly resist the United States on KORUS-like measures.\textsuperscript{87}

Some developing country members (most of which are drug consumers, not manufacturers) are pushing towards a TRIPs-neutral agreement that requires little or no departure from their existing WTO commitments and supports access to lower-priced generic drugs.

As illustrated in Figure 6, the positioning of the TPP agreement relative to TRIPs and KORUS will depend on the

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\textsuperscript{82} Office of the United States Trade Representative, “U.S.-APEC Trade Facts.”

\textsuperscript{83} Barrie McKenna, “Harper’s Game Risks Losing Millions from the Trans-Pacific Partnership”, Globe and Mail, (March 5, 2015).

\textsuperscript{84} The market access provisions negotiated by Japan and the U.S. will form the basis of the broader TPP market access provisions, although it remains to be seen whether the same terms will be offered to all TPP members. At the time this report was written, TPA had passed the Senate but not the House. (Dawson 2012).


\textsuperscript{86} Ed Silverman, “PhRMA Wants 12 Years Data Protection in TPP Talks”, Pharmalot, (May 2, 2011).

ability of each side to move the final text toward or away from strong IP protections. Developing countries will resist change unless compensatory benefits are offered in other areas of interest.\(^89\)

**FIGURE 6: Continuum of Pharmaceutical Patent Protection**

![Continuum of Pharmaceutical Patent Protection](image)

Source: Author’s calculations.

**Japan-U.S. Alignment**

Japan is a relatively recent entrant to the TPP negotiations and represents a valuable market for TPP exporters because of its high demand for imported foreign drugs. Prime Minister Shinzo Abe has also identified support for the development of the country’s nascent research-based pharmaceutical manufacturers, suggesting that Japan’s continued support for strong patent protection is likely.

While the mechanisms are not identical, Japan’s effective level of patent protection is acknowledged to be at or above U.S. standards.\(^90\) For example, Japan does not have a directly equivalent data exclusivity system, but Japanese law prevents generic companies from applying for regulatory approval until the innovative drug has been on the market for the equivalent of eight years, with potentially up to four additional years for new indications, far in excess of the U.S. TPP proposal for five-year exclusivity.\(^91\)

Japan’s patent term restoration system is also roughly equivalent in terms of remedial assistance for delays to the system in the United States. With the entry of Japan to the negotiations, the United States has gained a potential ally with considerable market heft for its reformist proposals.

After nineteen formal rounds of negotiations and a large number of informal rounds and ministerials, there are still major differences to be worked out in IP protections for pharmaceuticals. The greatest differences seem to be in relation to data protection/exclusivity and in developing country access to medications. The following section provides an overview of the key issues.

**Data Protection** – Although other countries have not distinguished between biological and chemical drugs, the United States treats biologics as a special class in the 2010 *Affordable Care Act*, providing them with 12 years of data exclusivity. However, in annual budgets, the Obama White House has proposed scaling back data exclusivity for biologics to seven years in order bring generics to market faster and save on Medicare and Medicaid costs.\(^92\)

Accordingly, within the TPP, the U.S. proposals have tried to separate the terms for biologic drugs from traditional small-molecule drugs. The current U.S. proposal for traditional drugs is at least five years from the date of marketing approval for a new product, and at least three years from the date of marketing approval for a previously approved product if new clinical data or data from another territory is required.

The original U.S. request for data protection for biologic drugs was 12 years but it is not clear whether a separate treatment of biologics is going to be granted. At this point, negotiators are divided on the definition of biologic drugs and the appropriate term of protection. Even though biologics are not considered to be distinct from traditional pharmaceuticals under U.S. IP law, the United States has put forward a definition derived from consultation with its domestic public and private sector stakeholders.

One of the difficulties in coming up with a legal definition is that most biologic drugs are made by modifying the DNA of a bacteria or other living organism to produce proteins that it would not otherwise make (recombinant DNA technology). A vaccine using recombinant DNA technology would be considered a biologic drug but a vaccine using a protein extracted from a plant or other natural source would not be.

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89 At the time of writing, the TPP partners were exchanging information on their domestic systems of pharmaceutical protections but had not yet started text-based negotiations.

90 Author’s interview with specialist in Japanese pharmaceutical regulations, Paul King of King PLLC (www.kingpllc.com), on December 13, 2012.


92 Doug Palmer, “Washington said to be frustrating drug companies in Asia trade talks”, *Reuters*, (October 5, 2012).
The U.S.-proposed definition of biologics appears to try to strike this balance by including two main parts. The first part sets out an exceedingly broad definition, while the second part allows countries to limit it in order to exclude naturally occurring substances.93

Proponents of enhanced protection for biologic drugs are concerned that if special provisions are included in the TPP without a specific definition of biologics, any related obligations could be circumvented.

Critics of a firm definition say that states should have the flexibility to define the term as they choose. Canada, Australia, and Japan are advocating in favor of the U.S. definition with some moderating language.94 It is likely that some countries are opposing the definition in order to use their assent as a bargaining chip later in the negotiations.

Developing Country Access – Early in the negotiations, the U.S. prioritized developing country access to medicines. Central to the U.S. proposal is the offer to provide pharmaceutical companies with stronger IP protection in exchange for their commitment to seek marketing approval in developing TPP countries as quickly as possible. USTR claims that this will expedite the availability of lifesaving medicines in TPP markets and also speed up access for generics to enter those markets.95

The original “access window” approach faced skepticism from U.S. companies and strong resistance from TPP partners and seems to have been replaced by alternative proposals for how to transition developing countries from a lower level of intellectual property protection for drugs to the higher TPP standard.

One proposal put forward by the U.S. side but not supported by the innovative drug companies would require developing countries to achieve a certain Gross National Income per capita before they would have to adopt higher levels of patent protection. This approach is similar to what the U.S. used in bilateral free trade agreements with Colombia, Panama, and Peru.96

A second proposal, preferred by innovative drug companies, is a time-based transition where developing countries are given a longer phase-in period in which to reach levels of protection equivalent to those of developed countries.97

Leaked proposals show that most developed countries would be required to implement full commitments within two years. Middle-income countries such as Mexico would receive a longer time to comply, and the longest period of compliance, ten years, would be granted to Peru and Vietnam.98 Innovative companies believe time-based systems provide the certainty they require to market their products effectively in new markets. Canada is reportedly a supporter of this model.99

Figure 7: GDP Per Capita of TPP Parties (2014, Current $US)


Mexico is proposing a third option based on relative rankings in the UN Human Development Index. Opponents argue that it is flawed because one country can only move up if another party moves down on the Index and it does not accommodate growth by all parties.

The Congressional Research Service reports that the U.S.-Peru Agreement is the likely model for most U.S. proposals

93 Inside U.S. Trade, (February 6, 2015).
94 2014 Wikileaks draft - Because texts are not available for negotiations still in progress, this section relies on news reports and leaked negotiating texts whose veracity is uncertain.
96 This concept was used in the May 10, 2007 agreement between the George W. Bush administration and House Democrats. The so-called May 10, 2007 deal also made patent linkage and patent term extension optional for developing countries. KORUS contained tougher provisions.
97 Inside U.S. Trade, “In TPP, Big Pharma Seeks Time-Based Transitions; Hints at Biologics Flexibility”, (October 24, 2014).
98 Inside U.S. Trade, “TPP Ministers Set To Discuss Transition Mechanism For Pharma IP Provisions”, (October 26, 2014).
for differential treatment for developing countries.\footnote{Congressional Research Service [CRS], “The Trans-Pacific Partnership Negotiations and Issues for Congress”, (November 7, 2014), 31.} If so, other TPP provisions for developing countries may include optional patent term extension, optional patent linkages, and data exclusivity terms tied to timely market approval.

**Pricing** – National regimes for drug pricing are also under scrutiny in the TPP. The United States has proposed a transparency chapter that would require countries with national drug pricing and reimbursement programs (such as Canada, Japan, and New Zealand) to establish a system of best practices covering such issues as decision-making processes, use of information, and appeal of pricing decisions.

**Scope of Patentability/ Exclusions from Patentability** – The United States has proposed to expand the scope of patentability by requiring countries to permit patent applications on modifications or variations of existing medicines. Critics charge that such measures will prevent the efficient introduction of generic equivalents.\footnote{Doctors Without Borders, “Countries Must Fix Critical Access to Medicines Flaws in Trans-Pacific Trade Pact”, Press Release, (May 14, 2013).} Innovators maintain that such changes legitimately protect incremental innovations to existing medicines that provide important therapeutic benefits for patients (such as time-release dosages) and ultimately improve health outcomes.\footnote{(IFPMA 2013).}

The United States is also seeking to limit possible exclusions from patentability. Under the TRIPs agreement, countries are permitted to make a broad range of exclusions from patentability including plants, animals, and diagnostic, therapeutic and surgical methods.\footnote{Sean M Flynn, Brook Baker, Margot Kaminski, and Jimmy Koo, “The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement”, American University International Law Review, 28(1), (2012), 105-202.} Under the TPP, the U.S. wants to now include surgical, diagnostic and therapeutic methods, or new forms or uses of an existing product. The U.S. appears to have withdrawn earlier proposals to make patents available for plants and animals, replacing the latter with provisions to protect plant-based innovations. The latter would include genes and DNA.

**Patent Term Restoration** – The TPP parties are considering seeking patent term restoration from all TPP countries in cases where best efforts have not been made to process patent applications in an efficient and timely manner.

**Patent Linkage** – The TPP parties are considering mandatory measures to prevent the market approval of a generic drug until the relevant patent expires unless the patent is invalidated or consent is given by the patent owner. The alternative, which occurs in many developing countries, is for health authorities to grant marketing approval to generics without verifying the status of the innovators’ patents.

**TABLE 4: State of Play of the TPP Pharmaceutical Negotiations**

<table>
<thead>
<tr>
<th>Section</th>
<th>Dominant Position</th>
<th>Canada Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Protection/Exclusivity</td>
<td>Consensus around 5 years for traditional medicines; US proposal for 12 years for biologics is problematic.</td>
<td>Canada already providing 8 years but makes no distinctions for biologics.</td>
</tr>
<tr>
<td>Developing Country Access</td>
<td>Developing countries accept full commitments based on fixed income levels, fixed time periods or relative development levels.</td>
<td>Canada favors fixed time periods.</td>
</tr>
<tr>
<td>Pricing</td>
<td>United States proposes transparency chapter for national drug purchase schemes.</td>
<td>Canada, Japan, and New Zealand schemes under scrutiny.</td>
</tr>
<tr>
<td>Scope of Patentability</td>
<td>U.S. proposal to limit exclusions; include methods and plant-based innovations.</td>
<td>Canada’s position not known.</td>
</tr>
<tr>
<td>Patent Term Restoration (PTR)</td>
<td>Growing consensus in favor of PTR.</td>
<td>Canada provided 2 years in CETA; U.S. and Japan provide 5 years.</td>
</tr>
<tr>
<td>Patent Linkage</td>
<td>Growing consensus in favor of patent linkage.</td>
<td></td>
</tr>
</tbody>
</table>

**Comment**

The U.S. Congressional Research Services notes that in its international trade negotiations, the United States is increasingly attempting to extend a U.S. standard of
protection into the IP rules of its trading partners with measures that exceed the TRIPs Agreement. The TPP is an example of United States exercising market dominance to push the boundaries of patent protection.

Due in part to reforms achieved through the CETA, Canada appears to be relatively well placed to support most U.S. requests in principle, although the specifics of data protection for biologics and scope of patentability may present some challenges.

American promotion of an inclusion agenda for developing countries suggests that the United States expects longevity and transferability from the TPP, establishing it as a successor to the largely out-of-date WTO Agreements.

### Canada-Japan Economic Protection Agreement (CJEPA)

#### Market Opportunities

Japan is a large player in the global pharmaceutical industry both in production and consumption terms. An area of interest to Canada is Japan’s growing attention to biologic drugs. Japanese pharmaceutical and medical device companies are seeking opportunities for strategic partnerships, licensing, and research collaboration with foreign biotechnology companies and research organizations.

While Japan’s population as a whole is declining, its aging population is expected to drive up demand for medicines. Demand growth is projected to increase gradually, ranging between 1 and 4 percent. Reforms initiated in 2010 have expanded the use of new medicines. Manufacturers agreed to increase the number of innovative drug launches in return for access to premium pricing for new drug development. Meanwhile, the use of generics is expected to increase as the government launches a campaign to promote generic use, and thus major products will face generic competition for the first time.

#### CJEPA

Canada and Japan have been negotiating a free trade agreement since 2012. Even though seven rounds of negotiations have been completed, finalization of the deal seems to be on hold until after the completion of the Trans-Pacific Partnership. However, the two agreements are not mutually exclusive and it is expected that the CJEPA will yield deeper and more specific commitments on matters of joint interest.

Although most of Canada’s exports to Japan are in raw materials and food products, Canada and Japan have a common interest in innovative and high value-added business and investment. Both countries have acknowledged the link between intellectual property rights and economic development.

The precursor to the intellectual property rights measures in the CJEPA is the Canada-Japan bilateral Agreement on Science and Technology, signed more than 25 years ago. It facilitates research activities in a variety of fields, including life sciences, through joint funding projects. The science agreement was augmented by a 2005 Cooperation Agreement on Anticompetitive Activities and helped remove a range of competitive barriers between the two countries.

Negotiations for a CJEPA began in November 2014 in order to reduce tariff and non-tariff barriers across a range of trading areas. Some of the anticipated benefits for the pharmaceutical sector are closer cooperation for product testing, labeling and approvals. In the area of patent protection, the Canadian Intellectual Property Office and the Japan Patent Office are consulting on information sharing and patent processing mechanisms to make it easier to obtain patents in each other’s market.

Both countries also work together on intellectual property issues in global fora such as the G8, the Asia-Pacific Economic Cooperation Forum, and the Organization for Economic Co-operation and Development.

#### Other Issues

##### Patent Utility Doctrine

Over the past decade, Canadian Federal Court decisions regarding descriptions of a compound’s utility in patent applications have led to the invalidation of a number of pharmaceutical patents. The Federal Court of Appeal in *Eli Lilly Canada v Novopharm*, 2010 describes the utility requirement in Canadian law:

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103 (CRS 2014, 29).
105 Completion of the TPP is conditioned upon the completion of a bilateral U.S.-Japan Economic Partnership Agreement, since the latter contains the framework upon which the TPP market access chapter will be based.
Where the specification does not promise a specific result, no particular level of utility is required; a “mere scintilla” of utility will suffice. However, where the specification sets out an explicit “promise”, utility will be measured against that promise. The question is whether the invention does what the patent promises it will do.\(^\text{109}\)

Critics charge that the utility doctrine puts many patents at risk because any language within the application that professes a benefit from the invention could be interpreted or implied by the courts as a promise.\(^\text{110}\) Also, innovators are not allowed to introduce evidence derived from testing in support of utility after the initial patent filing.

Recent cases, including the Plavix case,\(^\text{111}\) suggest the possible return to a more moderate interpretation by the courts whereby a promise of utility should not be assumed unless the inventor makes an explicit promise of a specific result. However, one of the lasting effects of the current debate is that new patent applicants are uncertain about how to draft a patent in order to meet the utility standard.\(^\text{112}\)

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**Eli Lilly takes on the Government of Canada’s Utility Doctrine**

In September 2013, Eli Lilly filed a Notice of Arbitration under NAFTA Chapter 11 claiming that Canada violated its obligations to Eli Lilly as a foreign investor by taking away its patent rights to the drugs Strattera and Zyprexa. Although the drugs had been used safely in Canada for many years as a treatment for ADHD, schizophrenia, and psychotic disorders, Eli Lilly claims that Canadian courts applied a new patent utility doctrine to deem the drugs not useful.

Eli Lilly further claims that the original test for usefulness found in the Canadian Patent Act was “capable of industrial application.” They claim that any higher standards of utility are based on subjective legal interpretations of whether the “promise of the patent” has been demonstrated or is based on sound prediction. They also claim that these standards were imposed after Eli Lilly’s patent applications were filed and the Government’s invalidations are retroactive.\(^\text{113}\)

The Government of Canada’s response is that the Chapter 11 investor-state dispute settlement mechanism is not the correct venue to resolve a patent rights issue. However, the larger issue of patent utility and whether or not Canadian courts are targeting pharmaceutical patents has important implications for future investment in research-based pharmaceuticals in Canada.

The Government claims that this is an instance where a company has attempted to broaden its monopoly rights over the patented medical compounds by filing multiple patent applications for alternative uses of the compounds with little or no testing data to support these uses. The government defends the decision of the Canadian courts, maintaining that the applicant failed to provide sufficient evidence of new uses for the compounds. The company, meanwhile, asserts that the Government’s standards fail to recognize the risk\(^\text{114}\) and cost of patent medicine development and the need for protection of patent rights before all testing has been carried out such as, for example, conducting human trials.

Eli Lilly raises a compelling point: since 2005, the purported emergence of the promise utility doctrine, 18 pharmaceutical patents have been invalidated. In the previous 25 years only two pharmaceutical patents were invalidated for lack of utility.\(^\text{115}\)

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\(^\text{110}\) Melanie Szweras and Amar Rana, “Promise of the Patent Post Plavix: three steps forward, one step back”, *Bereskin and Parr LLP Biotechnology Focus*, (June-July 2014).


\(^\text{112}\) (Szweras and Rama 2014).


\(^\text{115}\) (Government of Canada, Eli Lilly NOA 2013, 5).
Orphan Drugs

The term “orphan drug” refers to a medication used to treat rare diseases, typically affecting fewer than 5 in 10,000 people. The vast majority of these diseases are linked to genetic factors so development of new treatments is very costly and the market is small. In order to encourage research and investment in orphan drugs, many governments have launched incentive programs, several of which focus on offering longer periods of market exclusivity to help drug developers recover their costs. The United States offers seven years of market exclusivity. The EU offers 10, and Japan offers comparable benefits.

Canada, by contrast, currently offers no incentives to encourage orphan drug development, but the government’s promised Orphan Drug Regulatory Framework promises to provide enhanced access to information about clinical trials elsewhere in the world and streamlined regulatory processes. However, as of the date of writing, Health Canada has not yet introduced the new regulations that are needed to implement the framework.

The Canadian Organization for Rare Disorders reports that only 60 percent of rare disease treatments are available in Canada and they usually arrive several years later than in other countries. While information sharing is a useful first step, the absence of financial incentives for Canadian industry suggests that uptake will be limited.

Conclusions

The Changing Landscape

Changes in global demand are being shaped by aging baby boomers in wealthy countries and a burgeoning consumer class in emerging markets. In both types of markets there is a relatively affluent group of consumers who wants leading edge treatments – biologic drugs are increasingly in demand – and they prefer innovative products (especially in emerging markets where name brands are associated with status and quality). There is also a large segment for whom affordable access is key. They want access to as many kinds of products as possible but they would also prefer lower-cost generics when available.

Canada’s research-based pharmaceutical industry is a strong player in Canada’s innovative economy, accounting for a large share of Canada’s private sector R&D. However, that share is shrinking. The patent cliff, increasing competition from developing country competitors, a sluggish regulatory system and the increasing international perception that Canada consciously lags in life sciences IP protections for pharmaceutical products are not helping.

Rather than providing regulatory and legal protections that anticipate market direction, Canada’s policymakers are followers, utilizing the pressure of trade negotiation fora to shape domestic reforms.

This approach might be justified in part by Canada’s relatively small market size in a global economy dominated by the often diverging EU and United States. However, there is not much daylight between the two giants on pharmaceutical issues. For example, the EU and the United States both provided patent term restoration terms with a maximum of 5 years of exclusivity. Until the CETA changes are implemented, Canada is one of the very few OECD nations with no patent term restoration period.

The CETA provided Canada with a vehicle to once again catch up with international norms. Unless pushed by the United States on data protection for biologics, it is unclear
whether Canada will have to make any more substantive IP improvements for the TPP than were required by the EU in the CETA.

At the same time, negotiations between the United States and EU in the TTIP may be creating a new level of convergence in international rules and standards, making it easier for Canada to align with the dominant states but pushing the compliance bar even higher.

**Canada’s Response**

Canada’s incremental approach to IP regulation generates adequate results in terms of international compliance, but is it sufficient to attract investment. Trade negotiations have provided Canada with a forum to upgrade its IP regime on an as-needed basis, but the push and pull between the generic and research-based industries means that Canada never leads the pack on IP protection. To the extent that the United States and the EU can agree on harmonized regulatory standards, there will be significant incentives and pressures for Canada to modify its domestic regime to these new trans-Atlantic standards.

The 2014 Index released by the U.S. Chamber of Commerce depicts Canada as middling at best in its IP protection.\(^{119}\) Weaknesses in the areas of rights enforcement, anti-counterfeit measures and onerous patentability requirements keeps Canada ranked in the same category as Russia and China.\(^{120}\) These rankings make a difference to prospective investors.

The perception of Canada as an IP laggard has been reinforced by the issues surrounding the promise doctrine. Even though the Federal Court seems to be recently taking “a more restrained approach,”\(^{121}\) significant damage has been done in terms of international reputation. Canada is perceived to have deviated from international legal standards of patentability\(^{122}\) and, when 18 pharmaceutical patents have been invalidated by the courts since 2005 (and only 2 in the prior 25 years),\(^{123}\) it is hard to make the case that Canada is pharma friendly.

When combined with potential downward pressure on prices due to provincial joint price negotiation and a lukewarm approach to orphan drugs, the total picture is not one that encourages robust investment in the Canadian pharmaceutical industry.

... When 18 pharmaceutical patents have been invalidated by the courts since 2005 (and only 2 in the prior 25 years), it is hard to make the case that Canada is pharma friendly.

The factors that attract investors to Canada’s pharmaceutical industry include researchers and research centers and proximity to U.S. scientists and markets. Thus, a more robust approach to patent protection, increased investment in R&D incentives, and a focus on cross-border regulatory alignment and research collaboration are areas where government action could turn the tide in Canada’s favor.

Will these actions guarantee increased R&D investment in Canada? While there are no guarantees, it is nearly certain that investment will not increase without significant, demonstrative actions to create an investment friendly ecosystem.

In the face of rapid changes to global production and consumption patterns and technological breakthroughs in medicines to sustain and protect human health, Canada cannot afford to lag behind its competitors in promoting Canada as a world-class site for pharmaceutical research, including offering best-in-class intellectual property protections. In a competitive and rapidly changing global market, slow and steady will not win the race.

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120 (U.S. Chamber of Commerce 2014).
121 (Szweras and Rama 2014).
122 (U.S. Chamber of Commerce 2014).
123 (Government of Canada, Eli Lilly NOA 2013, 5).

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### Annex 1: National Positions on Patent Protection for Pharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>United States</th>
<th>Europe</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patent Term</strong></td>
<td>20 years (for patent applications filed in October 1989 and onwards)</td>
<td>20 years</td>
<td>20 years</td>
<td>20 years</td>
</tr>
<tr>
<td><strong>Entitlement to Patent</strong></td>
<td>First to file</td>
<td>First to file (as of March 2013)</td>
<td>First to file</td>
<td>First to file</td>
</tr>
<tr>
<td><strong>Patent Term Restoration</strong></td>
<td>A maximum extension of 2 years in Canada has been agreed to in principle in CETA. Canada has agreed to extend the life of patent protection by up to 2 years at the request of the EU. It’s still uncertain how it will be applied until amendments to legislation are made available. Regarding generic drug manufacturers, they can continue to make the drug and export it during this extended period.</td>
<td>Maximum extension of 5 years but total patent term (including extensions) from date of marketing approval cannot exceed 14 years.</td>
<td>Maximum extension of 5 years as long as total marketed period with patent protection does not exceed 15 years. (15.5 years if a pediatric investigation plan has been implemented.) Patent restoration comes in the form of a supplementary protection certificate.</td>
<td>Maximum extension of 5 years. Application must be made within 3 months of the approval of pharmaceutical; submission is not possible after the term of the patent right has expired. May be able to extend multiple patents for related compound, use and process patents.</td>
</tr>
<tr>
<td><strong>Permanent Injunction</strong></td>
<td>Discretionary (i.e. at the discretion of the courts).</td>
<td>Discretionary, not granted routinely.</td>
<td>Availability determined based on national case law in patent matters of the respective member states.</td>
<td>Yes, when there is an actual or threatened infringement of IP rights.</td>
</tr>
<tr>
<td></td>
<td>Canada</td>
<td>United States</td>
<td>Europe</td>
<td>Japan</td>
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<tr>
<td><strong>Interlocutory Injunction</strong></td>
<td>Discretionary, and difficult for a patent holder to obtain.</td>
<td>Discretionary, granted sparingly.</td>
<td>Governed by national law, and the ease of obtaining interlocutory injunction varies by jurisdiction.</td>
<td>Yes. The following three requirements need to be met: the patent right exists; the act infringes the patent right; and the need for injunction is clarified by showing prima facie evidence.</td>
</tr>
<tr>
<td><strong>Data Protection / Exclusivity</strong></td>
<td>The maximum term for innovative drugs including biologics is 6 + 2 + 0.5 = 8.5 years: - No submission from generic manufacturer for 6 years; - No regulatory approval of a generic equivalent for additional 2 years; and - An additional 6 months is granted for submissions that include pediatric studies.</td>
<td>The maximum term is 5 + 3 + 0.5 = 8.5 years: - No submission from generic manufacturer for 5 years, unless patents are challenged (patents cannot be challenged within first 4 years of drug approval); - An additional 3 years data exclusivity for significant changes (new indications); and - An additional 6 months for submissions that include pediatric studies.</td>
<td>The maximum term is 8 + 2 + 1 = 11 years: - No submission from generic manufacturer for 8 years; - No regulatory approval for an additional 2 years; and - An additional 1 year data exclusivity for significant changes (new indications).</td>
<td>The maximum term is 4-10 years. A formal data exclusivity regime is not in place in Japan. Instead, Japan has a system of “re-examination.” As a result, the period for data exclusivity for new drugs is 8 years, 4-6 years for new indication or routes for drugs, and 10 years for orphan and pediatric drugs.</td>
</tr>
<tr>
<td><strong>Patent Linkage</strong></td>
<td>Patent linkage is available via the Patented Medicines (Notice of Compliance) Regulations. Maximum duration is 24 months. In practice this is similar to interlocutory injunction.</td>
<td>Patent linkage is available. Maximum duration is 30 months. The courts examine these disputes as patent infringement cases.</td>
<td>No patent linkage but the use of interlocutory injunction prevents a generic from launching until the litigation is complete or the parties have settled.</td>
<td>Japan doesn’t provide for patent linkage. However, it has well-established patent laws and legal institutions which resulted in the development of a reliable process for adjudicating patent rights either prior to or upon generic entry. Additionally, interlocutory injunctions are used to prevent generics from launching.</td>
</tr>
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</table>
## Appeals

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<tr>
<th>Canada</th>
<th>United States</th>
<th>Europe</th>
<th>Japan</th>
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<tr>
<td>The generic may appeal an adverse NOC decision. If the generic is successful, the government will normally issue drug approval almost immediately. Once the approval has been issued the Federal Court of Appeal will refuse to hear the appeal on the basis that it is moot.</td>
<td>Yes, any unsuccessful party may appeal.</td>
<td>Yes, any unsuccessful party may appeal.</td>
<td>Yes, any successful party may appeal in the High Court.</td>
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</table>

## Patent Utility

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<tr>
<th>Canada</th>
<th>United States</th>
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<tr>
<td>The utility of each claim is assessed against “the promise of the patent.” The patent and its context are purposively construed assisted by factual evidence and expert testimony, like the state of the art and the research conducted until the Canadian filing date, and based in objective and subjective considerations.</td>
<td>There is a lower standard of utility than in Canada. To be useful, the invention must have a “practical or real world application.”</td>
<td>The invention must be “susceptible of industrial application.” This standard has been interpreted to be a low threshold. The use must be plausible.</td>
<td></td>
</tr>
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## Orphan Drug IP Incentives

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<tr>
<th>Canada</th>
<th>United States</th>
<th>Europe</th>
<th>Japan</th>
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<tbody>
<tr>
<td>None.</td>
<td>7 years market exclusivity.</td>
<td>10 years market exclusivity.</td>
<td>Extension of re-examination period up to 10 years.</td>
</tr>
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## Remedies

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<tr>
<th>Canada</th>
<th>United States</th>
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<th>Japan</th>
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<tbody>
<tr>
<td>Damages are the standard remedy for patent infringement. While the general principles of damages are the same in all jurisdictions, there is considerable variation in the detailed rules used by the courts to calculate damages.</td>
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1 The U.S. offers a shorter term of data protection for small molecule drugs than for biologic drugs based on the rationale that development of a biologic drug is far more complex and costly than for small molecule drugs such that a longer minimum term of market exclusivity is required for biologic drugs to provide an adequate incentive to innovate in this field.
Annex 2: Negotiating Positions on Patent Protection for Pharmaceuticals from Pending and Completed FTAs

<table>
<thead>
<tr>
<th>Patent Term</th>
<th>Comprehensive Economic and Trade Agreement (CETA)</th>
<th>Transatlantic Trade and Investment Partnership (TTIP)</th>
<th>Trans-Pacific Partnership (TPP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entitlement to Patent First to file versus first to invent</td>
<td>N/A</td>
<td>N/A</td>
<td>In principle, first one to file an application found to be patentable.</td>
</tr>
<tr>
<td>Patent Term Restoration</td>
<td>Maximum extension of 2 to 5 years. Can have a maximum of 2 years. The EU already has 5 years in place.</td>
<td>N/A</td>
<td>In principle, each Party shall make best efforts to process patent applications for marketing approval in an efficient and timely manner, avoiding unreasonable delays. In case of such delays, the Party shall make available an adjustment of the patent term to compensate the patent owner.</td>
</tr>
<tr>
<td>Permanent Injunction</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Interlocutory Injunction</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</table>

1 Canada and Japan are also currently negotiating an Economic Partnership Agreement (CJEPA). However, because the negotiations are still in the early stages, there is no public information on what changes may occur to either country’s intellectual property regime.

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<table>
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<tr>
<th><strong>Data Protection / Exclusivity</strong></th>
<th><strong>Comprehensive Economic and Trade Agreement (CETA)</strong></th>
<th><strong>Transatlantic Trade and Investment Partnership (TTIP)</strong></th>
<th><strong>Trans-Pacific Partnership (TPP)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>A period of time following market authorization of a drug which a generic manufacturer cannot rely in whole or in part on the clinical data generated and submitted to authorities by the innovator</td>
<td>In Principle: CETA states that the current maximum term in Canada (6-8.5) years will be maintained.</td>
<td>It is unclear what the positions of the EU and United States are on data protection under TTIP, however it appears as though negotiators and the European Federation of Pharmaceutical Industries and Associations are pushing for harmonization of the two nation’s policies on this issue.</td>
<td>In principle, at least 5 years from the date of marketing approval of the new pharmaceutical product in the territory of the Party, and at least three years from the date of marketing approval by the Party regarding previously approved pharmaceutical products, if a Party requires the submission of new clinical information, trials, or evidence of prior approval of the product in another territory. (U.S. Proposal). It appears that the term and definition for biologics are still under negotiation.</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Patent Linkage</strong></th>
<th><strong>Comprehensive Economic and Trade Agreement (CETA)</strong></th>
<th><strong>Transatlantic Trade and Investment Partnership (TTIP)</strong></th>
<th><strong>Trans-Pacific Partnership (TPP)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevents market approval of a generic drug until the relevant patent expires</td>
<td>N/A</td>
<td>N/A</td>
<td>In principle, a Party shall provide measures in its marketing approval process to prevent other persons from marketing the product where that product is claimed in a patent; or marketing a product for an approved use, where that approved use is claimed in a patent during the term of that patent, unless by consent or acquiescence of the patent owner (CAD Proposal).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Appeals</strong></th>
<th><strong>Comprehensive Economic and Trade Agreement (CETA)</strong></th>
<th><strong>Transatlantic Trade and Investment Partnership (TTIP)</strong></th>
<th><strong>Trans-Pacific Partnership (TPP)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Related to patent linkage system. Allows for an effective right of appeal by a patent holder from an adverse decision in an NOC proceeding in the Federal Court</td>
<td>Where a Party has a patent linkage system it must provide equivalent and effective rights of appeal for both parties to the dispute.</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Special Terms for Developing Countries</strong></th>
<th><strong>Comprehensive Economic and Trade Agreement (CETA)</strong></th>
<th><strong>Transatlantic Trade and Investment Partnership (TTIP)</strong></th>
<th><strong>Trans-Pacific Partnership (TPP)</strong></th>
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<tr>
<td>N/A</td>
<td>TBD</td>
<td>TBD</td>
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References


Canadian Organization for Rare Disorders. www.raredisorders.ca


For more information please visit: www.dawsonstrat.com
Slow and Steady Will Not Win the Race: Trade Negotiations, IP Protections and Canada’s Pharmaceutical Industry


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Dawson Strategic is a policy research and consulting company focusing on cross-border trade, economic and border issues. We have expertise across a range of sectors, including transportation, finance, energy, food and agriculture, and labour mobility.

Dawson Strategic draws upon a broad network of contacts in business and policy communities across the hemisphere. We apply our comprehensive research and strategic analysis to create thoughtful and effective advocacy strategies for our clients.

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