TRADING UP:
THE EVOLUTION AND IMPLEMENTATION OF INTELLECTUAL PROPERTY RIGHTS IN U.S. FREE TRADE AGREEMENTS
Implementation of IP Obligations in U.S. Trade Agreements: An Assessment of U.S. Agreements with Australia, Canada, Chile, and Korea

November 2014
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Executive Summary

Intellectual property (IP) is a critical driver of economic growth and the development of new ideas, technologies, and solutions globally. The increasing importance of IP in a global economy was recognized and advanced with the successful negotiation of the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Concluded almost 20 years ago, TRIPS established an important global baseline of IP protection and enforcement.

For the United States, IP-intensive industries are the foundation of its global competitiveness. Recognizing the increasing growth of innovative and creative exports, a U.S. priority has been to negotiate robust IP protections through its bilateral and regional trade agreements. If U.S. trade agreements are to meaningfully expand market access for these industries, modern and predictable IP rights, and the enforcement of those rights, are critical.

Yet negotiating high standard agreements is not enough. The question is whether innovative and creative industries can rely on the commitments made on paper to be faithfully implemented and enforced.

The purpose of this report is to provide an initial assessment of whether U.S. FTA partners are abiding by their IP commitments. To provide a snapshot of progress to date, this study covers four regionally and economically diverse countries - Australia, Canada, Chile, and Korea - which have negotiated trade agreements with the United States over the past 20 years. For each country, this study examines implementation of ten core IP obligations across IP disciplines.

Overall, the study highlights that, while there are both positive implementation developments and challenges across all four countries, Australia has most successfully implemented its FTA obligations thus far. Korea is a close second; however, given that the agreement only recently entered into force, it is still too early to tell whether Korea is faithfully implementing and enforcing all of its obligations. Both Chile’s and Canada’s implementation track records lag significantly behind those of Australia and Korea.

Moreover, since the North American Free Trade Agreement (NAFTA), of which Canada is a party, was concluded a decade before the next agreement assessed (Chile), the IP chapter of NAFTA does not include many of the IP provisions assessed in this study. For a better understanding of how Canada’s IP system would stack up against more recent U.S. FTA IP provisions, we also assessed Canada’s laws and practices against those obligations found in many of the United States’ post-NAFTA agreements. Benchmarked against more recent FTAs, Canada would fall short in a number of categories.

Based on this assessment, this report offers the following observations and recommendations:

- **Over the past 20 years, the U.S. has secured more robust protections for innovators and creators through bilateral and regional FTA negotiations.** While the evolution of these provisions has not always been linear, the general trend in U.S. FTAs has been toward the inclusion of more detailed and robust FTA IP obligations.
More robust FTA obligations have translated into improved protections for innovators and creators. Achieving high standards for IP protection in FTAs is not the entire story, but it is an important first step. Efforts of U.S. negotiators to secure strong IP commitments have led directly to positive results.

Despite the benefits secured by U.S. FTAs, there are significant failures in implementation by some countries. While Chile stands out in particular for its failure to implement the majority of the commitments assessed in this study, implementation challenges exist across all four countries.

FTA commitments are meaningless if they are not consistently implemented and effectively enforced over time. This assessment highlights the need to remain vigilant to ensure continued implementation of commitments even beyond entry-into-force. For example, over the past nine years, Canada has departed from faithful implementation of NAFTA’s patentability standards, while reviews of IP laws in Australia are causing uncertainty for innovators and creators and could risk undermining FTA implementation efforts to date.

To achieve economically meaningful results, U.S. FTAs should be implemented fully and in a timely manner, and transition periods should be avoided or, where necessary, as short as possible. This is critical to maintaining momentum for implementation of the agreement and securing durable and commercially meaningful new market access for innovators and creators as quickly as possible.

Further consideration should be given to how best to ensure ongoing implementation of robust IP commitments in U.S. trade agreements. In light of the observations above, it is critically important that the U.S. ensure that its trading partners have the appropriate laws and regulations in place to implement their FTA obligations fully before entry-into-force. If those efforts fall short as a practical matter, or a country becomes non-compliant with its FTA commitments after entry-into-force, the U.S. should use all tools at its disposal to ensure the United States’ trading partners are living up to their IP obligations.

These lessons are particularly important as the United States and 11 other Asia-Pacific countries are seeking to conclude an ambitious Trans-Pacific Partnership (TPP) Agreement. The TPP could achieve significant new market access opportunities for IP industries provided the agreement includes enhanced, specific, and enforceable IP commitments. At the same time, this assessment demonstrates that it will be critical to ensure implementation of those commitments before the agreement enters into force with each country. More broadly, this study highlights the need for continued vigilance and, where appropriate, action after the ink on the FTA is dry. Without a commitment to enforcement, the promise of a high-standard IP chapter risks going at least partially unfulfilled.
Overview

Intellectual Property and Trade

Intellectual property (IP) is a critical driver of economic growth. In the United States, IP-intensive industries account for almost 35 percent of U.S. Gross Domestic Product (GDP), more than one quarter of U.S. jobs, and approximately 60 percent of U.S. exports. Indeed, the capacity to innovate and create is one of the United States’ most important comparative advantages in the global economy.

Intellectual property plays a central role in all modern economies, regardless of a country’s level of development. A recent study conducted by the European Union (EU), for example, found that IP-intensive industries produced almost 39 percent of EU-wide GDP and generated 35 percent of all EU jobs. Similarly, another recent study confirmed the correlation between intellectual property and economic growth in developing countries as well. The 2010 Organization for Economic Cooperation and Development (OECD) study found that increases in IP protection were associated with increases in inbound investments, service imports, and domestic Research and Development (R&D).

Protecting intellectual property globally through effective laws and enforcement is essential to encouraging its development and capturing its benefits. Recognizing the growing role of IP in the global economy and the significant global costs of weak or uncertain IP enforcement across jurisdictions, members of the World Trade Organization (WTO) negotiated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 to establish minimum levels of IP protection and enforcement. The TRIPS Agreement was also the first multilateral IP treaty of its kind to include mandatory dispute settlement procedures. By securing core global protections for IP, TRIPS established the legal infrastructure necessary for a globalized economy increasingly reliant on innovation.

The United States has continued to build upon the IP protections in TRIPS through subsequent bilateral and regional trade agreements. The Trade Act of 2002, which provided “fast-track”

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4 Cavazos Cepeda, supra, at 21 (finding that a one percent change in the strength of a country’s IP rights environment as measured by patent rights was associated with a 2.8 % increase in inflows of FDI and that a 1% increase in copyright protection correlated to a 6.8% increase in FDI).
authority for considering U.S. trade agreements, called for heightened protection of intellectual property rights as a key negotiating objective.\textsuperscript{5} Consistent with this mandate, the U.S. government has negotiated trade agreements that would “complement and enhance” TRIPS and other existing international IP standards, protections and enforcement tools.\textsuperscript{6} For U.S. right holders, the bilateral and regional trade agreements provided important opportunities for ensuring that the standards of IP protection and enforcement keep pace with technological developments.\textsuperscript{7}

**Purpose of this Study**

Given the importance of IP industries to the U.S. economy and global competitiveness, trade agreements will continue to play an important role in ensuring expanded market access by securing modern and predictable IP rights and enforcement of those rights. Indeed, in its current negotiations with 11 other Asia-Pacific countries on the TPP, the U.S. Administration is seeking to secure “state-of-the-art, high-standard IP provisions.”\textsuperscript{8}

A great deal of energy has been invested in crafting and advancing robust IP standards through U.S. trade agreements. At the end of the day, however, whether these agreements are working for the United States’ innovative and creative industries comes down to not just the commitments on paper but whether those commitments are being meaningfully and effectively implemented. As trade in IP-intensive goods and services increases, improving substantive IP standards in trade agreements and assuring their effective enforcement are becoming all the more critical.\textsuperscript{9}

Significant efforts have been made by the Office of the U.S. Trade Representative (USTR) and stakeholders to assess U.S. trading partners’ performance in the area of IP as a general matter. USTR’s annual Special 301 and Notorious Markets Reports, for example, are vital tools that shed light on key IP protection and enforcement challenges globally. The U.S. Chamber’s Global IP Center (GIPC) publishes an annual “International IP Index” measuring the extent to which numerous countries live up to IP best practices, even if they are not necessarily required under U.S. trade agreements. This study, significantly, is the first to focus solely on whether the IP chapters of U.S. FTAs are being implemented sufficiently to assure that U.S. trading partners are abiding by their IP obligations.

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\textsuperscript{9} *Id.*
Methodology

Assessing a U.S. trading partner’s implementation of its IP obligations is an important but challenging task. The United States has free trade agreements in force with twenty countries, and the IP provisions in U.S. FTAs have grown over time in scope, detail, and complexity. To adequately assess whether an FTA partner is living up to its IP obligations requires not simply determining if the country’s laws reflect its FTA commitments, but also whether the laws are being meaningfully implemented and enforced.

The goal of this report is to provide an initial, rather than a comprehensive, assessment of whether, and to what extent, U.S. FTA partners are abiding by their IP commitments. In the interest of economy, we have selected a sample of four countries, and evaluated each country’s implementation of ten IP obligations. Our criteria for selecting the countries and indicators, as well as our methodology for the assessment itself, are outlined below.

Countries Selected (4)

Our assessment focuses on four countries: Korea, Australia, Chile, and Canada. These countries were chosen on the basis of two primary criteria.

First, we sought to include countries representing the various “generations” of FTAs. One of the United States’ earliest FTAs to include a substantive IP chapter was NAFTA (1994). However, this agreement, which entered into force before TRIPS, reflects a significantly less comprehensive and specific set of IP obligations compared to recent U.S. FTAs. The U.S.-Chile (2004) and U.S.-Australia (2005) FTAs include more robust IP commitments, while the U.S. agreement with Korea (2012) is the most detailed and comprehensive IP chapter to date.

Second, we wanted the selected countries to reflect a degree of geographical and economic diversity.

While it is difficult to capture a fully representative sample across all possible metrics, we believe that focusing our analysis on the four countries selected has allowed us to conduct a manageable but meaningful study.

IP Obligations Assessed (10)

The study focuses on ten specific IP obligations (“indicators”) reflecting priority areas of IP (patents, copyrights, trademarks, and enforcement). To help identify issues of top concern to the greatest number of industries, we surveyed USTR’s most recent Special 301 Report, public comments submitted to USTR through the Special 301 process, the GIPC’s International IP Index, and the relevant International Trade Advisory Committee (ITAC) reports on IP. With

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10 This year indicates the year in which the agreement entered-into-force as opposed to the year in which the agreement was signed. In order for an agreement to enter-into-force, parties to the agreement must demonstrate that they are in compliance with those obligations in the agreement slated to take effect on day one.
respect to trademarks, we did not include a separate substantive category for protection of trademarks, but rather focused on the adequate and effective enforcement of FTA trademark protection obligations. In addition, while we recognize the importance of enhanced trade secret protections, we did not include trade secrets in our assessment because the United States’ existing FTAs generally do not include specific obligations in this area.

In brief, for each country selected, we examined whether the country has implemented and continues to implement and enforce the following FTA obligations:

**Patents and Related Rights**

- **Criteria for Patentability**: to make patent protection available for all inventions that are new, involve an inventive step, and are capable of industrial application.

- **Discrimination Based on Field of Technology**: to make patents available in all fields of technology, including with respect to computer-implemented inventions.

- **Patent-Linkage**: to implement an effective system to prevent the marketing of a third party product without the consent of the patent owner during the term of the patent.

- **Regulatory Data Protection**: to prohibit third parties from using data submitted in support of an innovator’s application for marketing approval of a new pharmaceutical product for a period of five years.

**Copyrights**

- **Technological Protection Measures**: to implement protections against the circumvention of technological protection measures as well as against the manufacture, importation, or other distribution in devices or the provision of services for the purpose of circumvention.

- **Frameworks for Cooperative Action Against Piracy**: to provide legal incentives for cooperation between online service providers (OSPs) and copyright-holders to permit effective action against copyright infringement.

- **Government Legalization of Software**: to issue appropriate laws, regulations, decrees, or other orders requiring that government agencies use only properly licensed software.

**Enforcement**

- **Effective Border Measures**: to authorize its border officials to act *ex officio*, without the need for a prior request from a right holder, to take measures against infringement.

- **Civil and Procedural Remedies**: to provide for certain civil and procedural remedies for IP infringement, including appropriate damages, injunctions, and the destruction of infringing products.
• **Availability of Pre-Established Damages:** to make available in civil judicial proceedings pre-established statutory damages at least in cases of copyright and trademark infringement actions.

**Nature of the Assessment**

For each country and indicator, we have measured the country’s performance against the relevant FTA obligation.\(^{11}\) In carrying out this analysis, we looked at a variety of readily available sources, including the relevant laws and regulations, case law, regulatory interpretations, or more informal practices.

The fact-intensive nature of this inquiry points to an important caveat of this study. In general, we have attempted to make judgments as to whether a country’s laws and practices appear to implement its FTA obligations for each indicator. However, it was beyond the scope of this project to conduct detailed case law reviews or undertake other analyses to conclusively rule out FTA non-compliance. Moreover, practices can change over time, and in some countries (particularly Korea, where the FTA only recently entered into force) it is too soon to tell whether implementation problems will develop. Thus, our assessments are not intended as final conclusions regarding a country’s compliance with their FTA commitments.

In addition, although the IP chapters of U.S. FTAs have enhanced or clarified protections over time, many still do not necessarily reflect optimal IP protection for all industries. Where we conclude that a country appears to be implementing its U.S. FTA obligations, that is not intended as a judgment that its practices are necessarily consistent with TRIPS or other international obligations, or that there is no room for improvement as a policy matter.

**Assessment Summary**

Appendix I details our implementation analysis for each obligation assessed by country. In summary, as demonstrated by Figures 1 and 2 below, for the IP criteria selected, Australia has done the most consistent job of the four countries with respect to implementation of its FTA obligations. Korea is a close second; however, given that the agreement only recently entered into force, it is still too early to tell whether Korea is faithfully implementing and enforcing all of its obligations. Both Chile’s and Canada’s implementation track records lag significantly behind those of Australia and Korea.

\(^{11}\) There is one partial exception. NAFTA does not include certain IP obligations that were assessed in this study and which were all included in the other three FTAs assessed (Australia, Chile, and Korea). Nevertheless, we have also considered whether Canada’s practices would be consistent with obligations under the United States’ more modern FTA IP chapters, without suggesting that Canada is legally bound by these provisions.
### Implementation of Certain FTA IP Obligations

*As of November 2014*

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**Legend:**
- **Green** = No significant implementation concerns
- **Yellow** = Some implementation concerns
- **Red** = Significant implementation concerns
- **N/A** = No FTA Obligation
What is also notable is the absence in NAFTA of many core IP obligations included in the Australia, Chile, and Korea FTAs. NAFTA was the United States’ first FTA to include a chapter devoted entirely to IP protection. While significant at the time, NAFTA lacks important provisions that are necessary in practice to promote innovation and creativity. For example, NAFTA includes a certain level of protections for copyright and related rights but does not address online piracy or evasion of technological protection measures; it includes international patentability standards but lacks complementary provisions necessary to promote innovation in the pharmaceutical sector; and it requires certain general enforcement measures but lacks critical tools such as ex officio authority to initiate border measures.

To understand how Canada’s IP laws on the selected criteria would stack up against more modern U.S. FTAs, we also assessed their laws and practices for the selected obligations against those obligations found in many of the United States’ post-NAFTA agreements.

With respect to this particular assessment of ten obligations, NAFTA did not include IP obligations on the following: (1) patent linkage; (2) government legalization of software; (3) technological protection measures; (4) frameworks to promote cooperative action on piracy; (5) ex officio authority for customs officials; and (6) pre-established damages. As demonstrated in Figure 3 below, using more modern U.S. FTA IP obligations as a benchmark, Canada would fall short in a number of these categories.
Key Findings and Recommendations

Based on this assessment, we make the following observations and recommendations.

- **Over the past 20 years, the U.S. has secured more robust protections for innovators and creators through bilateral and regional FTA negotiations.** While the evolution of these provisions has not always been linear, the general trend in U.S. FTAs has been toward the inclusion of more detailed and robust FTA IP obligations. Appendix II highlights examples of this trend, such as:

  - **Patentability:** Confirming that patents shall be made available for any *new uses* or *methods of using a known product* (Australia and Korea only).

  - **Patent Linkage:** Requiring that a patent owner be notified of the identity of a person requesting marketing approval during the patent term (Australia and Korea), as opposed to requiring simply that such identity be made available to the patent holder (Chile) or no linkage requirement at all (Canada).

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12 For example, the 2004 U.S.-Chile FTA requires that border officials be provided with the authority to act *ex officio* with respect to imported, exported or in-transit goods, while the 2005 U.S.-Australia FTA only requires parties to provide this authority for imported merchandise.
• **Regulatory Data Protection**: Specifying that data protection applies: (1) *to information or evidence of prior marketing approval in other territories*, where required (for a period of five years), and *to new clinical information* required in certain circumstances (for a period of three years) (Australia and Korea only).

• **Technological Protection Measures**: Prohibiting circumvention of access control measures if conducted with *knowledge or reasonable grounds to know* (Australia and Korea) as opposed to with *knowledge only* (Chile) or no TPM requirements at all (Canada).

• **Frameworks for Cooperative Action against Piracy**: Including a side letter agreement providing more detail about *implementation of an effective “notice and takedown” system* modeled on the 1998 Digital Millennium Copyright Act (DMCA) (Australia and Korea only).

• **Government Legalization of Software**: Specifying that appropriate laws, orders, etc., provide that government agencies *not use infringing computer software* (Australia, Chile) and that they not use *other materials protected by copyright or related rights* (Korea only).\(^\text{13}\)

• **Effective Border Measures**: Requiring that authority be given to border officials to act *ex officio* with respect to *imported, exported, and in-transit goods* (Chile and Korea) and also in *free trade zones* (Korea) as opposed to only *imported goods* (Australia) or no requirement at all (Canada).

• **Civil and Procedural Remedies**: Requiring that in civil judicial proceedings goods found to have been pirated or counterfeit shall be destroyed at the right holder’s request (Australia and Korea) as opposed to requiring only that *judicial authorities be provided with the authority to order destruction* of such goods (Canada and Chile).

• **Pre-Established Damages**: Requiring that pre-established damages be available on the *election of the right holder in an amount sufficient to constitute a deterrent and to compensate fully for right holder harm* (Australia and Korea) as opposed to the more discretionary requirement that pre-established damages be awarded *in an amount that judicial authorities deem reasonable* (Chile) or no requirement at all (Canada). However, of note, the U.S.-Australia FTA (AUSFTA) also allows Australia in the alternative to maintain a system of “additional damages” for copyright violations so long as such damages are “regularly awarded.”

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\(^\text{13}\) According to the IP industry advisory report, this expansion was “intended to safeguard against illegal P2P file sharing activities and capture published material and protected databases.” ITAC-15 KORUS Report at 13.
More robust FTA obligations have translated into improved protections for innovators and creators. Achieving high standards for IP protection in FTAs is not the entire story, but it is an important first step. Efforts of US negotiators to secure strong IP commitments have led directly to positive results. For example:

- **Australia**: Australia amended its copyright laws in 2006, shortly after the FTA entered into force, to strengthen protections against circumvention of technological protections measures, as required by the FTA and in a manner consistent with U.S. implementation of these obligations in the DMCA.\(^\text{14}\)

- **Korea**: Under recent amendments to the Copyright Act intended to implement its FTA obligations, Korea enacted a detailed regime for fostering cooperation between right holders and online service providers, including with respect to the takedown of infringing material. Korea also illustrates the sort of significant reforms that can be triggered by a high-standard FTA, although implementation of the recent agreement is still a work in progress. For example, regulatory activity is underway to implement an effective patent linkage system; while concerns remain in this area, Korea is making improvements to its linkage system.

- **Chile**: In Chile, even though compliance problems are substantial, the FTA has nevertheless served as a focal point for needed reforms. For example, while the version of patent linkage Chile has established does not fully implement its the FTA obligations, there is pending legislation that recognizes and seeks to correct these deficiencies. In addition, Chile amended its copyright regime to address some of the challenges of today’s digital age, although these amendments still fall short of requirements in the FTA to combat online piracy.

- **Canada**: In 2006, Canada amended its Food and Drug Regulations to provide effective data protection for a period of eight years. Although it took more than a decade for Canada to fully implement this NAFTA obligation, ultimately, Canada did implement its commitments (and indeed even went beyond them by establishing an eight-year period of protection, which is three years longer than the traditional requirement in U.S. FTAs).

Despite the benefits secured by U.S. FTAs, there are significant failures in implementation by some countries.

- **Chile**: Chile stands out for its failure to implement a majority of the obligations assessed. In some cases, Chile has simply not implemented in its law particular FTA obligations – for example, it has not adopted any legislation to address circumvention of technological protection measures, or provided for pre-established damages in infringement actions.

  In other cases, while some changes to Chile’s laws have been made to implement certain IP obligations, particular loopholes in such laws undermine the effective implementation of the commitment. For instance, under Chile’s 2010 copyright amendments, its OSP liability limitations regime appropriately requires takedown of infringing material based on “actual knowledge,” yet it goes on to adopt an extremely narrow and self-defeating definition of “actual knowledge” limited to the existence of a court order. Similarly, Chilean efforts to create an effective patent linkage system also appear to have stalled.

- **Australia**: In a few cases, Australia also appears not to have implemented some aspects of the assessed IP obligations. For example, Australia has a patent linkage system, but a seemingly inadequate mechanism for notifying patent holders of applications to mark unauthorized copies of drugs; in addition, the deterrent effect of Australia’s unduly high damages on those seeking to enforce patent rights, appear to be in tension with its FTA commitments. And while Australian law provides for most of the civil and procedural remedies contemplated by the AUSFTA, they do not appear to require the destruction of goods as a remedy for trademark infringement despite a clear requirement to do so under the FTA.

FTA commitments are meaningless if they are not consistently implemented and effectively enforced over time: This assessment highlights the need to remain vigilant to ensure continued implementation of commitments even beyond entry-into-force. For example:

- **Canada**: When NAFTA entered into force, Canada’s patentability standards were applied in a manner consistent with NAFTA. Starting in 2005, however, Canada began applying a burdensome and unpredictable utility standard that has led to the revocation of patents found useful in jurisdictions around the world.

- **Australia**: Recent proposals to Australia’s patent laws and Australia’s current review of its copyright laws have created some uncertainty for innovative and creative industries. IP reform efforts should be monitored to ensure that these efforts do not lead to changes that would be inconsistent with Australia’s U.S. FTA commitments.
Chile: Chilean laws governing trademarks, copyrights, and patents make available a range of civil remedies required by the FTA, including damages, injunctions, and the destruction of infringing goods. However, industry groups have reported that enforcing intellectual property rights in Chile is hindered by procedural obstacles, delays, and a lack of judicial capacity regarding complex intellectual property matters. Thus, while Chile has adopted laws providing remedies for intellectual property infringement, in practice, right holders have experienced difficulties that raise questions about Chile’s full implementation of its commitments in a meaningful and effective way.

To achieve economically meaningful results, FTAs should be implemented fully and in a timely manner, and transition periods should be avoided or, where necessary, as short as possible. This is critical to maintaining momentum for implementation of the agreement and securing durable and commercially meaningful new market access for innovators and creators as quickly as possible.

What is most notable when comparing Chilean implementation of its FTA commitments to implementation by Australia, Canada, and Korea is that the FTA with Chile includes the most expansive transition periods for the IP obligations assessed. Seven out of ten of the assessed obligations for Chile were subject to transition periods of between two to five years from entry-into-force. In contrast, Canada was not afforded any transition periods, Australia was provided a transition period only for the TPM provisions, and Korea only for its patent linkage obligations.

This analysis suggests that U.S. negotiators should avoid, wherever possible, agreeing to considerable transition periods to implement IP protections because such transition periods often undermine needed momentum to ensure implementation of the agreement. Where such transitions cannot be avoided, such periods should be as short as possible to avoid delay in securing the full benefits anticipated under the agreement. This important lesson should be taken into account as the U.S. seeks to conclude a TPP agreement with high standard IP provisions.

Further consideration should be given to how best to ensure ongoing implementation of robust IP commitments in U.S. trade agreements. In light of the observations above, it is critically important that the U.S. ensure that its trading partners have the appropriate laws and regulations in place to implement their FTA obligations fully, before entry-into-force. This is important for all trading partners at all levels of development. If those efforts fall short as a practical matter, or a country becomes non-compliant with its FTA commitments after entry-into-force, the U.S. should use all tools at its disposal to ensure the United States’ trading partners are living up to their IP obligations. Such tools include bilateral engagement, the Special 301 process, and, where necessary, dispute resolution.

Conclusion

Bilateral and regional FTAs have become critical tools for securing stronger protection for U.S. IP abroad. The overarching lesson to emerge from this study is that high-standard IP chapters
are a catalyst for reforms and should continue to be an important U.S. negotiating objective. At the same time, the job is not done when the United States’ trading partners sign on to a robust set of obligations. If negotiating high standards is one side of the coin, enforcing those standards is the other.

There is not necessarily a one-size-fits-all solution for each of the deficiencies identified in this report. Taken together, they illustrate the need for continued vigilance and, where appropriate, action after the ink on the FTA is dry. Without a commitment to enforcement, the promise of a high-standard IP chapter risks going at least partially unfulfilled.
Appendix I: Detailed Country Assessments

KOREA

Patents

Criteria for Patentability

FTA Obligation: The United States-Korea Free Trade Agreement (KORUS FTA) requires Korea to make patents available for inventions that are new, involve an inventive step (are non-obvious), and are capable of industrial application (useful). It also specifically clarifies that patents must be available for “new uses or methods of using a known product.”

Implementation: Korean law sets out these three requirements for patentability. Although Korea’s implementation of these requirements to date does not appear to present many significant issues, some concerns have been raised with respect to Korea’s practice of requiring the submission of quantitative pharmacological data for a pharmaceutical product’s active ingredient in the original patent application. This data requirement appears to impose more burdensome patent disclosure standards by preventing a patent holder from relying on additional evidence during patent prosecution for a biopharmaceutical invention, or in a post-issue invalidation proceeding. This requirement has posed a particular burden in establishing that the “inventive step” standard is satisfied, and so risks weakening patentability standards in Korea.

Assessment: The criteria for patentability under Korean law do not appear problematic with regard to the KORUS FTA, but Korea’s requirements concerning pharmacological data may create additional hurdles related to patentability that are potentially in tension with Korea’s obligations under the agreement.

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Discrimination Based on Field of Technology

FTA Obligation: The KORUS FTA requires patents to be available for any invention under the patentability requirements “in all fields of technology,” creating a non-discrimination rule.\(^{19}\)

Implementation: It is possible that Korea’s requirements related to pharmacological data, discussed above, could be viewed as discriminating against pharmaceuticals vis-à-vis other areas of technology. There do not appear to be significant concerns related to discriminatory treatment in other sectors, including with respect to software.\(^{20}\) In fact, the Korean Intellectual Property Office recently issued detailed guidance clarifying how it reviews patent applications for computer-implemented inventions.\(^{21}\) The new guidance makes it easier for patent applicants to claim software patents, allowing the patent applicants to claim directly “[a] computer program stored on the media in combination with hardware.”\(^{22}\)

Assessment: Korea’s implementation of its patent law in a non-discriminatory manner does not appear generally problematic, although its requirements with respect to pharmacological data could suggest discriminatory treatment of the pharmaceutical sector.

Patent Linkage

FTA Obligation: The KORUS FTA requires Korea to implement a system of patent linkage. Specifically, Korea is obligated to “provide that the patent owner shall be notified” of the identity of other persons requesting marketing approval during the term of a patent and to “implement measures in its marketing approval process to prevent such other persons” from marketing a product without the consent of the patent owner during the term of the patent.\(^{23}\) As part of a February 10, 2011 exchange of letters, Korea was afforded three years from the date of entry-into-force to implement its linkage system. Korea therefore has until March 2015 to implement this commitment.

Implementation: In 2012, Korea amended the Korea Pharmaceutical Affairs Act (KPAA) to create a framework for implementing its patent linkage obligations under the KORUS FTA. Under this system, patent holders may submit an application to the Commissioner of the Korea

\(^{19}\) KORUS FTA art. 18.8.1.


\(^{23}\) KORUS FTA art. 18.9.5.
Food and Drug Administration to list their patents on a Pharmaceutical List. The Commissioner determines whether the patent meets applicable standards and then lists the patent, with the ability to amend the patent information that is included. A third-party filing for approval based on safety and efficacy information of a Listed Pharmaceutical is required to notify the patent owner within seven days of its application, unless the patent has been held invalid by the Intellectual Property Tribunal or a court or is outside the scope of the patent.

Korea is also considering amendments to the KPAA aimed at further bringing its system in line with KORUS. These amendments could significantly advance the creation of an effective and FTA-compliant linkage system that would provide for an effective patent enforcement mechanism. For example, the proposed amendments would allow patent holders to seek a 12-month stay restricting sale of a new product while the patent issue is adjudicated. While this would be an important measure to ensure that infringing products are not marketed, the patent holder would not, under the amendments, be entitled to the stay as an automatic matter but would have to make a showing of “significant damage.” If this feature is retained, it may dilute the effectiveness of the linkage system. It will therefore be important to monitor how these amendments are implemented and applied.

**Assessment:** It remains too early to tell whether Korea’s adoption and implementation of amendments to its patent linkage system will be consistent with its FTA obligations.

**Regulatory Data Protection**

**FTA Obligation:** The KORUS FTA obligates Korea to ensure that, for a period of five years, a third party applicant may not rely on an innovator’s undisclosed safety and efficacy data submitted in support of the innovator’s application for marketing approval of a new pharmaceutical product. This protection applies to products that do not contain a chemical entity that has been previously been approved. The KORUS FTA also specifies that this protection applies: (1) to information or evidence of prior marketing approval in other territories, where required (for a period of five years) and (2) to new clinical information required in certain circumstances (for a period of three years).

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25 Id.

26 Id. art. 31(4). Under proposed amendments, these aspects of the linkage system will appear in Articles 50(2)-(16).

27 Id. art. 50(9) (proposed).

28 Id.

29 KORUS FTA art. 18.9.1.
Implementation: Korean law sets forth a six-year period of protection post-marketing approval for new drugs.\textsuperscript{30} Under applicable regulations, a manufacturer cannot obtain marketing approval for a version of a product during the six-year period unless it submits data that is different from that submitted by the innovator.\textsuperscript{31}

Assessment: Korea’s implementation of its data protection commitments under the FTA does not appear problematic.

Copyrights

Technological Protection Measures (TPMs)

FTA Obligation: The KORUS FTA requires Korea to provide for liability for any person who knowingly, or having reasonable grounds to know, circumvents TPMs; who manufactures, imports, distributes, or otherwise traffics in devices; or who provides services for the purpose of circumvention. It also sets out specific exceptions and limitations with respect to the TPM obligations.\textsuperscript{32}

Implementation: Korea amended the Copyright Act in 2011 to prohibit circumvention of TPMs, as well as the production and sale of devices for purposes of circumvention of TPMs.\textsuperscript{33} We are not aware of implementation or enforcement concerns with respect to these relatively new provisions.

Assessment: Korea’s implementation of the FTA’s anti-circumvention requirements does not appear to cause concern.

Frameworks for Cooperative Action Against Piracy

FTA Obligation: The KORUS FTA requires legal incentives for cooperation between online service providers (OSPs) and copyright-holders to permit effective action against copyright infringement, including by requiring that a safe harbor from liability be based in certain cases on “expeditious removing or disabling access to the material . . . on obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement was apparent, such as through effective notifications of claimed infringement.”\textsuperscript{34}

Implementation: Under recent amendments to the Copyright Act, Korea provided detailed provisions related to limitations on service provider liability, including a safe harbor under which

\begin{itemize}
  \item[30] Korea Pharmaceutical Affairs Act art. 32.
  \item[31] Ministry of Food & Drug Safety, Rules Regarding the Product Category Approval, Filing, and Examination of Drug Products, art. 25 (S. Kor.).
  \item[32] KORUS FTA art. 18.4.7.
  \item[34] KORUS FTA art. 18.10.30.
\end{itemize}
service providers are required to immediately remove or disable access to the works upon receiving notice of infringement.\footnote{Korea Copyright Act art. 102(2)(f).} We are not aware of any significant enforcement concerns related to these relatively new provisions.

**Assessment:** We are not aware of concerns about Korea’s implementation of its FTA obligations to promote cooperative action against piracy, including with respect to its notice and takedown system.

*Government Legalization of Software*

**FTA Obligation:** The KORUS FTA requires Korea to provide appropriate laws, orders, regulations, government-issued guidelines, or executive decrees providing that central government agencies not use infringing computer software and only use computer software and other materials protected by copyright or related rights as authorized by the relevant license, and to provide for the regulation of the acquisition and management of software for government use that are protected by copyright or related rights.\footnote{KORUS FTA art. 18.9.5.}

**Implementation:** In 2011, the Ministry of Culture, Sports, and Tourism announced a regulation applicable to all central government agencies. The regulation created a position within each agency to ensure the proper cataloging and monitoring of software, and prohibited all individual employees from installing unlicensed software.\footnote{Regulation on Managing Genuine/Licensed Software and Related Accessories, Ministry of Culture, Sports, and Tourism, art. 4 (S. Kor.).} A related presidential regulation applied similar rules to all public institutions.\footnote{Regulation on Managing Software By Public Institutions (S. Kor.).}

According to studies by the Korean government, these regulations have resulted in substantial reductions in public sector use of unlicensed software.\footnote{Ahn Ho-cheon, *Korea’s Public Institutions Cut Software Piracy by over 50%*, Korea IT News, Feb. 13, 2013, http://english.etnews.com/policy/2720506_1302.html.} Additionally, in 2013, the Ministry of National Defense reached agreement over a long-running dispute regarding the use of unlicensed software.\footnote{USTR, *2014 National Trade Estimate Report on Foreign Trade Barriers*, at 210 http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB.pdf.} However, concerns remain that Korea is not fully enforcing the new regulations and that further steps are necessary, such as ensuring that government agencies purchase a sufficient number of licenses to cover all copies of software they use, and that government software use is subject to periodic audits.\footnote{Id.}

**Assessment:** Korea appears to have taken significant steps toward implementing its obligations to promote government legalization of software under the KORUS FTA, and there is at least
some initial indication that these measures are having an effect. However, further steps are needed to ensure that Korea enforces its commitments on government legalization of software.

**Enforcement**

**Effective Border Measures**

**FTA Obligation:** The KORUS FTA requires Korea to provide border officers with *ex officio* authority to take measures against infringement.\(^\text{42}\)

**Implementation:** Korean law provides authorization for officials to initiate border measures *ex officio*.\(^\text{43}\)

**Assessment:** We are not aware of concerns with Korea’s implementation of this FTA commitment.

**Civil and Procedural Remedies**

**FTA Obligation:** The KORUS FTA requires the availability of damages, injunctions, and the destruction of infringing goods as a remedy for infringement of intellectual property rights.\(^\text{44}\)

**Implementation:** Korean laws governing trademarks, copyrights, and patents make available the full range of civil remedies required by the FTA, including damages, injunctions, and the destruction of infringing goods.\(^\text{45}\)

**Assessment:** Korean laws appear to generally satisfy this FTA commitment.

**Pre-Established Damages**

**FTA Obligation:** The KORUS FTA requires Korea to make statutory damages available at least in copyright and trademark infringement actions.\(^\text{46}\)

**Implementation:** Korean law provides for such damages at the election of the right holder.\(^\text{47}\)

\(^{42}\) KORUS FTA art. 18.10.22.

\(^{43}\) Customs Act (Korea) art. 235; Enforcement Decree of the Customs Act (Korea) art. 239.

\(^{44}\) KORUS FTA arts. 18.10 (5), (9), (14).


\(^{46}\) KORUS FTA arts. 18.10.6.

\(^{47}\) Korea Trademark Act (Korea) art. 67-2; Korea Copyright Act art. 125-2.
Assessment: We are not aware of significant problems with respect to Korea’s implementation of its FTA commitment on pre-established damages.
AUSTRALIA

Patents

Criteria for Patentability

FTA Obligation: The United States-Australia Free Trade Agreement (AUSFTA) requires Australia to make patents available for inventions that are new, involve an inventive step (are non-obvious), and are capable of industrial application (useful). It also specifically clarifies that patents must be available for “new uses or methods of using a known product.”

Implementation: Australian law sets out these three requirements for patentability. Historically, Australia implemented this test in a way that limited the ability to invoke prior art to undermine the non-obviousness of an invention. Australia amended these laws in 2012. While the amendments changed certain features of the law, the stated purpose of the amendments was not to re-define elements of the three-part test or make it unduly difficult to obtain patent protection, but rather to align Australia with international practice and standards, including those followed in the United States. Specifically, the 2012 law broadened consideration of prior art and clarified that “usefulness” requires a showing that the invention has a specific, substantial, and credible use.

With respect to new uses of known products, Australian case law has referred to a “mere” new use as not patentable. However, “there will be a [patentable] invention if the new use consists of taking advantage of a previously unknown or unsuspected property of the substance.” A government review of pharmaceutical patents also indicates that new uses for known medicines are patentable.

Assessment: Australia’s current implementation of its patentability obligations under the AUSFTA generally do not appear problematic.

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52 IP Australia, supra.
**Discrimination Based on Field of Technology**

**FTA Obligation**: The AUSFTA requires patents to be available for any invention under the patentability requirements “in all fields of technology,” creating a non-discrimination rule.\(^{55}\)

**Implementation**: Australian patent law does not appear to discriminate against software as a field of technology, as it has not excluded computer-implemented inventions from patentability. The specifics of Australian law are in flux as courts wrestle with fact-specific questions regarding business method patents, similar to current questions in U.S. courts. However, there does not appear to be any wholesale discrimination against computer-implemented inventions as a field.\(^{56}\)

Pharmaceutical companies have reported an uncertain and unstable environment with respect to pharmaceutical patents, pointing to a series of proposed patent law amendments reflecting hostility to the industry.\(^{57}\) For example, in 2011, the Australian Parliament considered a proposal to exclude all biological materials from patentability.\(^{58}\) At present, no such amendments have been passed, and Australia does not appear to have undertaken specific conduct that would be inconsistent with the FTA’s non-discrimination principle.

**Assessment**: Australian law does not currently appear to discriminate against a particular field of technology. However, the general atmosphere with respect to pharmaceuticals indicates a need to closely monitor evolving Australian practice with respect to this field of technology for FTA compliance.

**Patent Linkage**

**FTA Obligation**: The AUSFTA requires Australia to implement a system of patent linkage. Specifically, Australia is obligated to “provide for the patent owner to be notified” of the identity of a third person requesting marketing approval during the term of a patent, and to “provide measures in its marketing approval process to prevent” third persons from marketing a product during the term of the patent without consent of the patent owner.\(^{59}\)

\(^{55}\) AUSFTA art. 17.9.1.


\(^{58}\) Id.

\(^{59}\) AUSFTA art. 17.10.4.
Implementation: Australia maintains a patent linkage system under which a manufacturer seeking approval must submit a certificate that: (1) it believes on reasonable grounds that it is not infringing a valid patent; or (2) that it proposes to market the product before the end of a patent term, and it has notified the patentee. According to a government study, non-innovative producers in practice do not notify the patent holder, but instead certify their belief that their product does not infringe a valid patent. As a result, the government recognizes that the notification system “does not appear to work well.” Patent holders only learn of the application when the unauthorized copy of a drug appears on the Australian Register of Therapeutic Goods, often leaving insufficient time to take action.

The Australian linkage system also lacks an automatic stay provision to prevent the marketing of products covered by a patent, but it appears to pursue this result in a different way through the use of preliminary injunctions. However, the Australian government currently has a practice of pursuing inordinately high damages in the event an injunction is granted but the patent is later invalidated, without apparent distinction between bad faith and good faith efforts to enforce the patent. For example, in one recent case the government intervened to seek AUD 450 million in damages after a patent was invalidated despite the fact that the trial court originally found the patent valid. In practice, patent holders may be deterred from making use of available procedures, even when there is a good faith basis for their belief that they have a valid patent.

Assessment: Australia has a patent linkage system, but the inadequate mechanism for notifying patent holders of applications to market unauthorized copies of drugs, as well as the deterrent effect of unduly high damages on those seeking to enforce patent rights, are in tension with Australia’s FTA commitments.

Regulatory Data Protection

FTA Obligation: The AUSFTA obligates Australia to ensure that, for a period of five years, a third party applicant may not rely on an innovator’s undisclosed safety and efficacy data submitted in support of the innovator’s application for marketing approval of a new pharmaceutical product. This protection applies to products that do not contain a chemical entity that has been previously approved. The AUSFTA also specifies that this protection applies: (1) to information or evidence of prior marketing approval in other territories, where required (for a

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61 Harris, supra, at 143-44.

62 Id. at 143.

63 Id. at 144.

64 Australia Therapeutic Goods Act s 26D.

65 BIO Submission, at 44-45.
period of five years), and (2) to new clinical information required in certain circumstances (for a period of three years). 66

**Implementation**: Australian law provides that undisclosed information provided in relation to an application for approval of a drug may not be used in evaluating other drugs for a period of five years.67

**Assessment**: There do not appear to be significant concerns with Australia’s data protection law as implemented.

**Copyrights**

*Technological Protection Measures*

**FTA Obligation**: The AUSFTA requires Australia to provide for liability for any person who knowingly, or having reasonable grounds to know, circumvents TPMs; who manufactures, imports, distributes, or otherwise traffics in devices; or who provides services for the purpose of circumvention. It also sets out specific exceptions and limitations with respect to the TPM obligations.68 Australia was provided two years from entry-into-force to fully implement the TPM obligations in the Agreement.69

**Implementation**: The Copyright Amendment Act (2006) made it illegal to use devices that circumvent TPMs.70 Producing and selling devices for purposes of circumvention were already illegal, and continue to be.71 The Copyright Amendment Act also broadened the definition of TPMs to conform to the FTA. Previously, the definition referred only to measures that prevented copyright infringement, whereas the amended version includes any measure that prevents or restricts access to copyrighted content.72 Recent proposals to amend Australian law to permit consumer circumvention of TPMs in certain cases could undermine Australia’s implementation of its FTA obligations and will require further monitoring.73

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66 AUSFTA art. 17.10.1(a).
67 Australia Therapeutic Goods Act s 25A.
68 AUSFTA art. 17.4.7.
69 Id., art. 17.12.
72 Id.
**Assessment:** Australian’s implementation of the FTA’s anti-circumvention requirements do not appear to raise concerns.

**Frameworks for Cooperative Action Against Piracy**

**FTA Obligation:** The AUSFTA requires legal incentives for cooperation between OSPs and copyright-holders to permit effective action against copyright infringement, including by requiring that a safe harbor from liability be based in certain cases on “expeditiously removing or disabling access to the material . . . on obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement was apparent, such as through effective notifications of claimed infringement.”

**Implementation:** Australia maintains limitations on liability for OSPs that is conditioned on compliance, among other things, with notice and takedown requirements. We are not aware of any significant implementation concerns related to Australia’s notice and takedown system. However, Australia’s current review of its copyright laws should be monitored to ensure that the country’s strong copyright protection and enforcement regime is not weakened in this process.

**Assessment:** Australia appears to maintain an effective notice and takedown system and there do not appear to be implementation concerns with Australia’s current system.

**Government Legalization of Software**

**FTA Obligation:** The AUSFTA requires Australia to provide appropriate laws, orders, regulations, government issued guidelines, or administrative or executive decrees to provide that central government agencies not use infringing computer software and only use licensed computer software, and to provide for the regulation of the acquisition and management of software for government use.

**Implementation:** The Australian Government Intellectual Property Manual directs government agencies to obtain licenses when using third-party products. Relatively little data concerning implementation of this policy is publicly available, but audits of certain agencies reflect a practice of government use of licensed software.

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74 AUSFTA art. 17.11.29.
75 Australia Copyright Act ss 116AG-AH.
76 AUSFTA art. 17.4.9.
**Assessment:** Australia has issued government guidelines directing governments to use legal software, and there do not appear to be significant concerns with Australia’s enforcement of these guidelines.

**Enforcement**

*Effective Border Measures*

**FTA Obligation:** The FTA requires Australia to provide border officers with *ex officio* authority to take measures against infringement.\(^{79}\)

**Implementation:** Australian border officers are authorized to seize infringing goods based on the lodging of a “Notice of Objection” by right holders. A single Notice can cover numerous registered marks and remains in force for four years. Thus, specific information about infringing shipments is not necessary.\(^{80}\)

**Assessment:** While the Notice of Objection procedure requires action on the part of a right holder to ensure protection, the burden it entails appears minimal and has not given rise to substantial criticisms of Australia’s compliance with its FTA obligation.

*Civil and Procedural Remedies*

**FTA Obligation:** The AUSFTA requires the availability of damages (including the infringer’s profits), injunctions, and the destruction of infringing goods as a remedy for infringement of intellectual property rights.\(^{81}\)

**Implementation:** Australian laws governing copyrights and patents make available the full range of civil remedies required: damages and injunctions with respect to patents and damages, injunctions, and destruction of infringing goods with respect to copyrights.\(^{82}\) However, while the

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\(^{79}\) AUSFTA art. 17.11.22.


\(^{81}\) AUSFTA arts. 17.11(6), (10), (14).

\(^{82}\) Australia Copyright Act ss 115, 133; Australia Patents Act s 122.
Trade-Marks Act provides for damages and injunctions, it does not appear to contain a provision for destruction of goods bearing an infringing mark as a remedy in civil judicial proceedings.\footnote{See Australia Trade Marks Act; Sharon C. Shockley, \textit{Trademark Infringement in Australia}, Creative Strategies (June 27, 2014), http://creative-strategies.be/trademark-infringement-australia/.

\footnote{AUSFTA art. 17.11.7.}

\footnote{Australia Copyright Act s 115(4); Australia Patents Act s 122(1A).}

**Assessment**: Australian law provides for most of the remedies contemplated by the AUSFTA, but the apparent absence of destruction of goods as a remedy for trademark infringement does not appear to be in line with Australia’s FTA commitments.

\textit{Pre-Established Damages}

**FTA Obligation**: The AUSFTA requires Australia to establish statutory damages as a remedy for copyright and trademark violations in civil judicial proceedings, or, as an alternative, to maintain a system of “additional damages” for copyright violations, as long as Australia ensures that such damages are “regularly awarded.”\footnote{AUSFTA art. 17.11.7.}

**Implementation**: Australia has not adopted a system of statutory damages, and instead has made “additional damages” available in both copyright and patent proceedings, at the court’s discretion and in the amount it considers appropriate.\footnote{Australia Copyright Act s 115(4); Australia Patents Act s 122(1A). We are not aware of any significant criticism that Australian courts do not in practice award additional damages on a regular basis, although a more in-depth assessment would be necessary to verify that this predicate for not providing for statutory damages is satisfied.

**Assessment**: Australian law provides an “additional damages” alternative that appears to satisfy its obligations under the AUSFTA, and there do not appear to be significant concerns with the availability of such damages in practice.
**CHILE**

**Patents**

*Criteria for Patentability*

**FTA Obligation:** The United States-Chile Free Trade Agreement (Chile FTA) requires Chile to make patents available for inventions that are new, involve an inventive step (are non-obvious), and are capable of industrial application (useful).\(^{86}\) Chile was provided a two-year transition period from entry-into-force for implementation of this provision.\(^{87}\)

**Implementation:** Chilean law sets out these three requirements for patentability.\(^{88}\) In practice, however, there are concerns that Chile has modified the standard required by the FTA by applying a heightened standard for non-obviousness. Specifically, in the area of pharmaceutical patents, Chile requires major structural differences between a claimed compound and previously existing compounds, even where the technical solution in the new compound is not part of the prior art.\(^{89}\) While other countries may treat structural similarities as presumptively indicating obviousness that requires some showing to overcome, Chilean law goes further in appearing to erect an absolute bar to patentability in the case of structural similarity.

Another practical obstacle to full implementation of Chile’s FTA commitments is the difficulty in obtaining a patent within a reasonable timeframe. Applicants for pharmaceutical patents have observed that wait times have averaged eight years; this delay has been improved, but is still approximately five years.\(^{90}\) Such significant delays indicate that patent protection may sometimes not be available in a meaningful sense.

**Assessment:** Implementation of the Chile FTA has been problematic. Chile has implemented the non-obviousness standard in a way that may restrict patentability in cases in which the three-part test, as ordinarily understood, is met. Moreover, the practical obstacles facing patent applicants are in tension with Chile’s obligation to make patents available as long as the prescribed standard is met.

\(^{86}\) Free Trade Agreement, U.S.-Chile, art. 17.9.1., June 6, 2003, 116 Stat. 933. (Hereinafter “Chile FTA”)

\(^{87}\) Id., art. 17.12.2(a).


\(^{90}\) See PhRMA Submission.
Discrimination Based on Field of Technology

FTA Obligation: The Chile FTA requires patents to be available for any invention under the patentability requirements “in all fields of technology,” creating a non-discrimination rule.91 Chile was provided a two-year transition period from entry-into-force for implementation of this provision.92

Implementation: Chile’s patent law specifically excludes from patent protection all “systems, methods, economic, financial, or commercial plans and principles.”93 While not explicitly addressed to software inventions, this exclusion has been interpreted as a categorical restriction on the patentability of computer-implemented inventions.94

The heightened requirements for establishing non-obviousness for a pharmaceutical patent, discussed above, also appear to discriminate against the pharmaceutical industry.

Assessment: Chilean law appears to discriminate against at least some technologies in the software and pharmaceutical industries with respect to the availability of patents, notwithstanding the FTA’s non-discrimination rule.

Patent Linkage

FTA Obligation: The Chile FTA requires Chile to implement a system of patent linkage. Specifically, Chile is obligated “to make available to the patent owner the identity of any third-party requesting marketing approval” during the term of a patent, and to “not grant marketing approval to any third party prior to expiration of the patent term” without consent of the patent owner.95

Implementation: In 2004, the Health Ministry adopted Resolution 5572 stating that it would publish a list twice a month of registrations being sought and indicating whether it is similar to another product.96 The resolution also provides for e-mail notification to patent holders.97 However, this Resolution as implemented has been widely regarded, including by USTR, as

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91 Chile FTA art. 17.9.1.
92 Id., art. 17.12.2(a).
93 Law 19,039, art. 37(c) (Chile).
95 Chile FTA art. 17.10.2.
96 Health Ministry Resolution 5572, Julio 15, 2004 §§ 1-2 (Chile).
97 Id. § 3.
failing to establish an effective patent linkage system. In addition to delays in notification in practice, the Resolution does not include any mechanism for ensuring that marketing approval is not granted when there is a valid patent in place. While Chile has claimed that the availability of ordinary infringement remedies satisfies this obligation, burdensome post-approval remedies are insufficient to satisfy Chile’s commitment not to grant marketing approval in the first place.

In recognition of the shortcomings of current regulations, the Chilean government has introduced a bill to create a new patent linkage system. The goal of the bill is to improve the transparency of the approval process and to provide better information on the patents affected by new applications for approval. Moreover, the bill would provide for a 12-month automatic stay of regulatory approval. The bill has survived a pre-enactment challenge in the Constitutional Court, but is not expected to pass in the near term.

Assessment: Current Chilean law and practice fails to provide adequate notice to patent holders of a manufacturer’s application for marketing approval, and does not contain a mechanism to prevent the granting of marketing approval for a non-innovative product when there is a valid patent. The law therefore falls short of the patent linkage commitments in the FTA.

Regulatory Data Protection

FTA Obligation: The Chile FTA obligates Chile to ensure that, for a period of five years, a third party applicant may not rely on an innovator’s undisclosed safety and efficacy data submitted in support of the innovator’s application for marketing approval of a pharmaceutical product. This protection applies to a product which utilizes a new chemical entity, which product has not been previously approved.

Implementation: Chilean law provides that “undisclosed test data or other information regarding the safety and efficacy of a pharmaceutical which utilizes a new chemical entity” may not be “disclose[d] or utilize[d]” to grant sanitary registration to a product without consent for a


100 See Message No. 414-359, Message of H.E. the President of the Republic that starts a draft law amending Law 19.039 Industrial property to strengthen the protection of drugs’ active ingredients (Jan. 20, 2012).

101 Id. (proposed art. 112 b).


103 Chile FTA art. 17.10.1.
period of five years. However, there is a potentially significant exception under which data protection can be denied based on “reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency,” or if the product is subject to a compulsory license.”

Assessment: Chilean law provides for a 5-year period of data protection, however, the expansive set of exceptions are not contemplated by the FTA and, depending on how they are implemented, provide the potential for circumventing its requirements.

Copyrights

Technological Protection Measures

FTA Obligation: The Chile FTA requires Chile to provide for liability for any person who knowingly circumvents TPMs, or who manufactures, imports, distributes, sells, or rents devices or provides services for the purpose of circumvention. It also sets out specific exceptions and limitations with respect to the TPM obligations. Chile was provided a five-year transition period from entry-into-force for implementation of these obligations.

Implementation: Chilean law lacks specific protections against circumvention of TPMs, including with respect to the acts of circumventing access controls and trafficking in devices. Companies report, moreover, that circumvention devices are sold freely in online and physical marketplaces in Chile.

Assessment: Chile’s lack of anti-circumvention legislation is inconsistent with its FTA obligations.

Frameworks for Cooperative Action Against Piracy

FTA Obligation: The Chile FTA requires legal incentives for cooperation between OSPs and copyright-holders to permit effective action against copyright infringement, including by requiring that a safe harbor from liability be based in certain cases on “expeditiously removing or

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104 Law 19,039 (Chile) art. 89; Supreme Decree No. 107/08, Diciembre 1, 2010 (Chile).
105 Law 19,039 (Chile) art. 91; Supreme Decree No. 107/08, Diciembre 1, 2010 (Chile).
106 Chile FTA art. 17.7.5(a) n. 18 states that for purposes of this paragraph, “knowledge may be demonstrated through reasonable evidence taking into account the facts and circumstances surrounding the alleged illegal act.”
107 Chile FTA art. 17.7.5(a)(b).
108 Id., art. 17.12.2(c).
109 USTR Special Report, at 44.
disabling access to the material . . . upon obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement was apparent, including through effective notifications of claimed infringement." Chile was provided a four-year transition period from entry-into-force for implementation of its enforcement provisions.  

**Implementation:** In 2010, Chile amended its Copyright Law to create a “notice plus notice” system. The amendment creates a safe harbor from liability where the service provider lacks “actual knowledge” of the infringing nature of the material. However, the law provides an extremely narrow definition of “actual knowledge” limited to “when a competent court of justice . . . has ordered that the data be removed.” Similarly, the law requires service providers to maintain a policy that it may terminate agreements with repeat infringers, but they must be declared repeat infringers “by court resolutions.” While these amendments create a mechanism for the eventual takedown of infringing material by judicial order, they do not create a meaningful incentive for OSPs to remove infringing material in an expeditious and efficient manner.

**Assessment:** Chile’s “notice plus notice” system does not promote the expeditious takedown of infringing material, and thus does not fully satisfy the FTA’s requirements for effective incentives for cooperative action against piracy.

**Government Legalization of Software**

**FTA Obligation:** The Chile FTA requires Chile to issue appropriate laws, orders, regulations, or decrees to “actively regulate” the acquisition and management of software for government use, in order to confirm that agencies only use properly licensed software.

**Implementation:** A Presidential Directive from 2001 requires government agencies to maintain licenses for all software products that they use. However, neither this order nor any additional order post-dating the FTA provides additional guidance or measures in order to “actively regulate” agencies’ use of software. Moreover, industry reports suggest that while some agencies regularly license their software and government expenditure on software licenses has increased, piracy continues to be a problem in government agencies.

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111 Chile FTA art. 17.11.23.
112 Id., art. 17.12.2(b). Obligations related to frameworks for cooperative action against piracy are included in the enforcement section.
114 Id.
115 Id. art. 85O.
116 Chile FTA art. 17.7.4.
117 Presidential Directive No. 905 (Chile).
118 GIPC Index, at 54; IIPA Submission, at 20.
Assessment: While Chile has promulgated a directive concerning government legalization of software, its regulations are not sufficiently detailed and do not appear to be enforced uniformly in practice despite this FTA commitment.

Enforcement

Effective Border Measures

FTA Obligation: The Chile FTA requires Chile to provide border officers with *ex officio* authority to take measures against infringement.\(^{119}\) Chile was provided a four-year transition period from entry-into-force for implementation of this and other enforcement provisions.\(^{120}\)

Implementation: Chilean law has provided *ex officio* authority to initiate border measures since 2003.\(^{121}\) Moreover, some industry groups have noted that customs officials regularly exercise their enforcement authority.\(^{122}\)

Assessment: We are not aware of significant implementation concerns of Chile’s FTA commitments regarding *ex officio* authority.

Civil and Procedural Remedies

FTA Obligation: The Chile FTA requires the availability of damages (including the infringer’s profits) and the destruction of infringing goods as a remedy for infringement of intellectual property rights.\(^{123}\) Chile was provided a four-year transition period from entry-into-force for implementation of this and other enforcement provisions.\(^{124}\)

Implementation: Chilean laws governing trademarks, copyrights, and patents make available a range of civil remedies required by the FTA, including damages, injunctions, and the destruction of infringing goods.\(^{125}\) However, industry groups have reported that enforcing intellectual property rights in Chile is hindered by procedural obstacles, delays, and a lack of judicial capacity regarding complex intellectual property matters.\(^{126}\) Patent holders report difficulties in patent enforcement related to a lack of technical expertise.\(^{127}\) Software companies have

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\(^{119}\) Chile FTA art. 17.11.20.

\(^{120}\) *Id.*, art. 17.12.2(b).

\(^{121}\) Law 19,912 (Chile).

\(^{122}\) IIPA Submission, at 21 (2014).

\(^{123}\) Chile FTA arts. 17.11(8), (12).

\(^{124}\) *Id.*, art. 17.12.2(b).

\(^{125}\) Law No. 17,336 (Chile) art. 85B; Law No. 19,039 (Chile) art. 106.

\(^{126}\) IIPA Submission, at 21 (2014).

\(^{127}\) BIO Submission, at 27 (2014).
expressed concern that *ex parte* search requests, intended to discover and destroy infringing goods, are made publicly available, providing advance notice of a search and thwarting the ability to secure a remedy.\textsuperscript{128}

**Assessment**: Chile has laws on the books providing remedies for intellectual property infringement. In practice, however, right holders have experienced difficulties that call into question Chile’s full implementation of its commitments in a meaningful and effective way.

*Pre-Established Damages*

**FTA Obligation**: The Chile FTA requires Chile to make statutory damages available at least in copyright and trademark infringement actions.\textsuperscript{129} Chile was provided a four-year transition period from entry-into-force for implementation of this and other enforcement provisions.\textsuperscript{130}

**Implementation**: Chile has not amended its laws to provide for statutory damages.

**Assessment**: The failure to provide pre-established damages as a remedy for right holders is inconsistent with Chile’s FTA commitments.

\textsuperscript{128} IIPA Submission, at 21 (2014).
\textsuperscript{129} Chile FTA, art. 17.11.9.
\textsuperscript{130} Id., art. 17.12.2(b).
Criteria for Patentability

**FTA Obligation:** NAFTA requires Canada to make patents available for inventions that are new, result from an inventive step (are non-obvious), and are capable of industrial application (useful).

**Implementation:** Canada’s patent act requires that patents will be granted to inventions that meet “the statutory requirements of novelty, ingenuity and utility.” However, over the past decade, Canada has applied a burdensome and unpredictable utility standard that has led to the revocation of patents found useful in jurisdictions around the world. Under this judicially created “promise doctrine,” Canadian courts are subjectively construing the “promise of the patent” and applying heightened evidentiary standards and disclosure requirements with respect to utility. Applying this new utility standard, since 2005 Canadian courts have revoked approximately 20 pharmaceutical patents as allegedly not “useful,” even though the patents have in fact been deemed safe and effective by health regulators and “industrially applied” in products (e.g., been used by countless patients). The doctrine has also been incorporated into the Canadian Patent Office’s Manual of Patent Office Practice (MOPOP).

**Assessment:** Canada is denying patent protection for useful inventions in a manner inconsistent with its FTA commitments.

Discrimination Based on Field of Technology

**FTA Obligation:** NAFTA requires patents to be available for any invention under the patentability requirements “in all fields of technology,” creating a non-discrimination rule.

**Implementation:** As discussed above, the “promise doctrine” has resulted in the invalidation of approximately 20 patents for lack of utility. All invalidations have occurred with respect to pharmaceutical patents. No patents in any other sector have been revoked on the basis of utility.

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134 MOPOP, § 12.08.

135 NAFTA art. 1709.1.
Canada is thus applying its heightened utility standard in a manner that discriminates against one field of technology – pharmaceuticals. We are not aware of any other fields of technology being treated differently under Canada’s patent laws. For example, Canadian law does not exclude computer-implemented inventions from patentability. Intellectual Property Office, Examination Practice Respecting Computer-Implemented Inventions, at 1 (2013), available at http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopпись.nsf/vwapj/PN2013-03-eng.pdf/$file/PN2013-03-eng.pdf.

Assessment: Canada’s application of its patent laws appears to discriminate against pharmaceuticals as a field of technology.

Patent Linkage

FTA Obligation: NAFTA does not impose a patent linkage obligation on Canada.

Implementation: Despite the absence of such a requirement, Canada’s Patented Medicines (Notice of Compliance) Regulations (PM (NOC) Regulations) establish a system to prevent copies of patented medicines from being sold before the expiration of the patent. Patents are listed in a Patent Register, and a generic drug applicant seeking to enter the market cannot obtain marketing approval prior to expiration of the patent without submitting, and serving on the patent holder, a Notice of Allegation (“NOA”) that the patent is expired, invalid, or not infringed. The patent holder is then permitted to seek an order blocking marketing approval of the generic product, triggering an automatic 24-month stay.

However, significant concerns exist with respect to the ability of patent holders to enforce their patents, thereby undermining the effectiveness of Canada’s patent linkage system. For example, the PM NOC Regulations establish asymmetrical rights to appeal an adverse decision. If the patent holder’s claim is accepted and regulatory approval of the generic is blocked, the party seeking to introduce the generic has a right of appeal. However, if regulatory approval is granted, the patent holder has no right of appeal and is limited to pursuing patent infringement remedies. In the context of its Comprehensive Economic and Trade Agreement (CETA) with the European Union, Canada has acknowledged this deficiency by agreeing to ensure all litigants “have equal appeal rights.” It remains to be seen how this commitment will be implemented.

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137 Id. § 5(3)(a)-(b).

138 Id. §§ 6(1), 7(1)(e), 7(2)(a)-(b), 7(4).

139 Id. § 6.

Assessment: Canada is not out of compliance with NAFTA on this issue given that there is no patent linkage requirement in the agreement. However, using more modern U.S. FTA standards as a benchmark, Canada’s practice of asymmetrically denying appeal rights to patent holders hinders effective enforcement of its patent linkage system.\textsuperscript{141}

Regulatory Data Protection

FTA Obligation: NAFTA obligates Canada to ensure that, for a period of five years, a third party applicant may not rely on an innovator’s undisclosed safety and efficacy data submitted in support of the innovator’s application for marketing approval of a pharmaceutical product. This protection applies to products that utilize new chemical entities.\textsuperscript{142}

Implementation: Prior to 2006, Canada’s regulations implementing data protection were weak in practice. While the regulations prevented the Health Ministry from actually examining data submitted by an innovator in granting regulatory approval to a similar product, in practice the Ministry would grant approval based on bioequivalence nevertheless.\textsuperscript{143} This functional limitation on data protection was in tension with NAFTA since the safety and efficacy determination made based on bioequivalence relied implicitly, if not explicitly, on the initial review of the innovator’s data.

In 2006, however, Canada amended its Food and Drug Regulations to provide data protection whenever marketing approval is sought based on any comparison, direct or indirect, to an innovative drug.\textsuperscript{144} In such cases, the manufacturer is prohibited from seeking approval for a period of six years and from obtaining marketing approval for a period of eight years.\textsuperscript{145} However, this protection applies only if the innovative drug is “being marketed in Canada.”\textsuperscript{146}

Assessment: As a result of the 2006 amendments, Canada’s current regulations significantly improved Canada’s data protection regime; however, concerns remain about whether Canada’s requirement that drugs be marketed in Canada to receive this protection is consistent with NAFTA.

\textsuperscript{141} See KORUS FTA art. 18.9.5(b).
\textsuperscript{142} NAFTA arts. 1711.5-6.
\textsuperscript{144} Food and Drugs Act, C.R.C c. 870 (Canada) § C.08.004.1.
\textsuperscript{145} Id.
\textsuperscript{146} Id. § C.08.004.1(5).
Technological Protection Measures

**FTA Obligation:** NAFTA does not include provisions requiring action against circumvention of technological protection measures.

**Implementation:** Under the Copyright Modernization Act of 2012, Canada prohibited circumvention of TPMs, including criminal liability for those who provide services or technology to enable others to circumvent TPMs.\(^{147}\)

**Assessment:** While NAFTA does not contain a TPM anti-circumvention requirement, using more modern U.S. FTA standards as a benchmark, Canada’s recent enactment of anti-circumvention measures appears to be in line with those standards. Effective enforcement of this law will be critical to ensuring adequate and effective implementation of these new prohibitions.

Frameworks for Cooperative Action Against Piracy

**FTA Obligation:** NAFTA, which came into effect prior to passage of the DMCA, does not include provisions to encourage cooperative action against online piracy.

**Implementation:** The Copyright Modernization Act of 2012 formalizes a “notice and notice” regime under which copyright owners provide notice of alleged infringement to OSPs, and the OSP is required to forward that notice to the allegedly infringing customer. This was previously a voluntary industry practice, and the 2012 law, effective January 2015, codifies this practice. However, there is no mechanism for the “takedown” of infringing material by the OSP.\(^{148}\)

**Assessment:** NAFTA does not include OSP liability limitation requirements, including an effective notice and takedown system. Using more modern U.S. FTA standards as a benchmark, however, it remains to be seen whether Canada’s copyright amendments, including the codification of its “notice and notice” regime will provide the incentives necessary to promote cooperative action against copyright infringement.

Government Legalization of Software

**FTA Obligation:** NAFTA lacks a requirement concerning government legalization of software.

**Implementation:** Canada’s communications policy requires government respect for copyright ownership rights, although it does not appear to contain the level of detail concerning acquisition of rights.

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\(^{147}\) Copyright Act, R.S.C. 1985, c. C-42 (Canada) §§ 41.1(1), 42(3.1). (Hereinafter “Canada Copyright Act”)

and management of software contemplated by more modern FTAs. However, we have not identified concerns that government use of unlicensed software is a significant problem in Canada.

**Assessment:** NAFTA does not include a requirement concerning government legalization of software. Using more modern U.S. FTA standards as a benchmark, however, while as a formal matter Canada’s communication policy may be lacking in detailed guidance, we are not aware of concerns that this policy has proved inadequate in practice.

**Enforcement**

**Effective Border Measures**

**FTA Obligation:** NAFTA does not require that border officials be granted *ex officio* authority to initiate border measures.

**Implementation:** Under Canadian law, border officials have not had *ex officio* authority to seize or detain suspected infringing goods on their own initiative. On December 9, 2014, however, Bill C-8, the Combating Counterfeit Products Act, received Royal Assent. Once fully implemented, C-8 will provide customs officials authority to take some border measures on their own initiative. While this authority would apply to imports and exports, the bill explicitly carves out goods in transit through Canada.

**Assessment:** NAFTA does not explicitly require the granting of *ex officio* authority for border officials. Using more modern U.S. FTA standards as a benchmark, Bill C-8, once fully implemented, would constitute an improvement but would still fall short, particularly in light of the lack of *ex officio* authority over in-transit goods.

**Civil and Procedural Remedies**

**FTA Obligation:** NAFTA requires the availability of damages, injunctions, and the destruction of infringing goods as remedies for infringement of intellectual property rights.

**Implementation:** Canada’s Trade-marks Act provides for injunctions, recovery of damages or profits, and the destruction of offending materials. Its Copyright Act provides for injunctions, damages, accounts, and “delivery up” of offending materials. The Patent Act provides for

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150 Bill C-8 (Canada).
151 See KORUS FTA art. 18.10.22.
152 NAFTA arts. 1715(2)(c), (2)(d), & (5).
153 Canada Trade-marks Act § 53.2
154 Canada Copyright Act § 34(1).
damages and injunctions, and while the statute does not specifically address destruction of patent-infringing goods, it appears to be available in practice.

Assessment: Canadian laws governing trademarks, copyrights, and patents appear to make available a range of civil remedies anticipated under NAFTA.

Pre-Established Damages

FTA Obligation: NAFTA does not require that statutory damages be made available; it simply provides that a party “may” make such damages available “at least” with respect to copyright.

Implementation: Canada does make statutory damages available, at the election of the right holder, in cases of copyright infringement. However, in 2012 Canada substantially reduced the effectiveness of statutory damages for cases of “non-commercial” infringement; since that statutory term is undefined, it is not yet clear how broadly it will be invoked to limit liability for infringers. In such cases, rather than the $5,000-$20,000 fine range per infringed work, a defendant will face only a $100-$5,000 fine range for all infringed works.

Canada also does not provide statutory damages for cases of trademark infringement; while Bill C-8 clarifies that punitive damages may be available, it does not establish statutory damages.

Assessment: NAFTA does not have a statutory damages requirement. Using more modern U.S. FTA standards as a benchmark, however, Canadian law provides statutory damages but seems to dilute their effectiveness against “non-commercial” infringement. Canada also falls short of the modern standard by failing to provide such damages for trademark infringement.

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157 NAFTA art. 1715(4).
158 Canada Copyright Act § 38.1.
159 Id. § 38.1(b).
160 Bill C-8 § 45 (amending Trade-marks Act § 53.2(1)).
Appendix II: Table Comparing Certain FTA IP Obligations across Four FTAs

Select Examples Below* (emphasis added)

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Discrimination Based on Field of Technology: to make patents available in all fields of technology

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<td>Requires that the identity shall be made available of any third party requesting marketing approval during patent term</td>
<td>Requires that the identity shall be notified of the identity of any other person requesting marketing approval during the patent term</td>
<td>Requires that the patent owner shall be notified of the identity of any other person requesting marketing approval during the patent term</td>
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Regulatory Data Protection: to prohibit third parties from using data submitted in support of an innovator’s application for marketing approval of a new pharmaceutical product for a period of five years

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<td>Specifies that this protection applies: (1) to information or evidence of prior marketing approval in other territories, where required (for a period of five years) and (2) to new clinical information required in certain circumstances (for a period of three years)</td>
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Technological Protection Measures: to implement protections against the circumvention of technological protection measures

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<td><strong>Technological Protection Measures (con’t):</strong> to implement protections against the circumvention of technological protection measures</td>
<td><strong>Canada (NAFTA, 1994)</strong></td>
<td><strong>Chile (2004)</strong></td>
<td><strong>Australia (2005)</strong></td>
<td><strong>Korea (2012)</strong></td>
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<td>Prohibits the provision of services which <strong>do not have a commercially significant purpose or use</strong> other than to circumvent any effective TPM</td>
<td>Prohibits the provision of services which <strong>have only a limited commercially significant purpose or use</strong> other than to circumvent any effective TPM</td>
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| **Frameworks for Cooperative Action Against Piracy:** to provide legal incentives for cooperation between online service providers (OSPs) and copyright-holders to permit effective action against copyright infringement | N/A | A side letter to the agreement provides more detail about implementation of an effective “notice and takedown” system modeled on the DMCA. | A side letter to the agreement provides more detail about implementation of an effective “notice and takedown” system modeled on the DMCA. |

| **Government Legalization of Software:** to issue appropriate laws, regulations, decrees, or other orders requiring that government agencies use only properly licensed software | N/A | | Includes broader mandate by also covering government agency use of materials protected by copyright and related rights |

<p>| <strong>Effective Border Measures:</strong> to authorize border officials to act <strong>ex officio</strong>, without the need for a request from a right holder, to take measures against infringement | N/A | <strong>Ex officio</strong> border measures may be initiated with respect to goods <strong>imported, destined for export, or moving in transit</strong> [that] are counterfeit or pirated | <strong>Ex officio</strong> border measures may be initiated with respect to <strong>imported merchandise, suspected of being counterfeit trademark or pirated copyright goods</strong> | <strong>Ex officio</strong> border measures may be initiated with respect to <strong>imported, exported, or in-transit merchandise, or merchandise in free trade zones; suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods</strong> |</p>
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<td>Each Party’s judicial authorities shall have the authority to order that goods that they have found to be infringing be disposed of outside the channels of commerce or, unless this would be contrary to existing constitutional requirements, destroyed</td>
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<td>N/A</td>
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<td><strong>Chile</strong> <em>(2004)</em></td>
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<td>Requires pre-established damages that the judicial authorities deem reasonable in light of the goals of the intellectual property system and the objectives set forth in the IP Chapter</td>
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* Note: This chart is intended to be illustrative only rather than a comprehensive analysis of all differences between the ten obligations assessed for the four selected FTAs. Examples of distinctions between trade agreements for particular provisions are highlighted in the relevant country column above.