The Honorable Robert E. Lighthizer
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Ambassador Lighthizer:

In accordance with section 105(b)(4) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, and section 135(e) of the Trade Act of 1974, as amended, I am pleased to transmit the report of The International Trade Advisory Committee (ITAC) on Intellectual Property Rights regarding the Trade Agreement (ITAC-13), reflecting consensus advisory opinion on the proposed Trade Agreement with Mexico and potentially Canada (the "Trade Agreement" or "the Agreement").

It is the opinion of the Majority of the Committee that to a reasonable extent, the Trade Agreement promotes the economic interests of the United States and advances the overall and principal negotiating objectives with respect to intellectual property set forth in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 ("TPA"). While there are elements the Committee would prefer to have strengthened, clarified, or removed to conform better to TPA, the Trade Agreement intellectual property provisions generally improve standards of protection and enforcement and enhance U.S. economic interests.

We note the Minority views of the ITAC membership representing generic drug and biosimilar manufacturers, which believe that the Trade Agreement fails to achieve the principle trade objective "to ensure that trade agreements foster innovation and promote access to medicines" as set forth in section 102(b)(5)(C) of TPA 2015. Such ITAC membership believes that this failure will result in higher prescription drug prices for patients in the U.S. and therefore is not in the economic interest of the United States.

On balance we believe the Trade Agreement, with respect to Intellectual Property, does meet the requirements of TPA.

Sincerely,

Erin-Michael Gill
Chairman
ITAC-13, IPR

A Trade Agreement with Mexico and potentially Canada

Report of the
Industry Trade Advisory Committee on Intellectual Property Rights
(ITAC-13)

September 27, 2018

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The Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-13)

Advisory Committee Report to the President, the Congress, and the United States Trade Representative on a Trade Agreement With Mexico and potentially Canada

I. Purpose of the Committee Report

Section 105(b)(4) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, and section 135(e)(1) of the Trade Act of 1974, as amended, require that advisory committees provide the President, the Congress, and the U.S. Trade Representative with reports not later than 30 days after the President notifies Congress of his intent to enter into an agreement.

Under Section 135 (e) of the Trade Act of 1974, as amended, the report of the Advisory Committee for Trade Policy and Negotiations and each appropriate policy advisory committee must include an advisory opinion as to whether and to what extent the agreement promotes the economic interests of the United States and achieves the applicable overall and principal negotiating objectives set forth in the Bipartisan Congressional Trade Priorities and Accountability Act of 2015.

The report of the appropriate sectoral or functional committee must also include an advisory opinion as to whether the agreement provides for equity and reciprocity within the sectoral or functional area.

Pursuant to these requirements, the ITAC for Intellectual Property (ITAC-13) hereby submits the following report.

II. Executive Summary of Committee Report

It is the opinion of the majority of the Committee that to a reasonable extent, and with consideration of the broader impact of this agreement, the Trade Agreement promotes the economic interests of the United States and advances the overall and principal negotiating objectives with respect to intellectual property set forth in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015. While there are elements which the Committee would prefer to have strengthened, clarified or removed as detailed herein, the Trade Agreement does improve intellectual property provisions generally and does improve the IP environment for a broad range of U.S. stakeholders. The Committee notes that the proposed agreement will enhance the protection of innovator pharmaceuticals in parties to the trade agreement but also will create increased barriers to the export of generic and biosimilar medicines to those markets. ITAC membership representing generic drug and biosimilar manufacturers believes that the Trade Agreement fails to achieve the principle trade objective "to ensure that trade agreements foster innovation and promote access to medicines" as set forth in section 102(b)(5)(C) of TPA 2015. Such ITAC membership believes that this failure will result in higher prescription drug prices for patients in the U.S. and therefore is not in the economic interest of the United States.

The Committee expresses serious concerns that this report is being prepared without certainty relating to the inclusion of Canada in "NAFTA 2.0," and the implications for the agreement as reviewed by the Committee, regarding the outcome of those negotiations. The Committee underscores the very high commercial importance of Canada in this and other chapters, and urges robust negotiations with Canada to ensure that they also apply strong IP provisions such as those included in the IP chapter of this trade agreement and discussed in this report. Accordingly, the Committee believes this report must be supplemented with an addendum providing the Committee an opportunity to comment on the implications of the outcome of negotiations with Canada, thirty days after those negotiations are completed or otherwise terminated.

The Committee urges the United States not only to monitor very closely the implementation by Mexico of its new obligations, but also to ensure that it has in place, before entry into force of the new Trade Agreement, national legislation that faithfully reflects the new obligations.

Finally, this Committee would like to register its concern regarding the lack of sufficient substantive engagement by U.S. negotiators with ITAC-13 Committee members on the portions of the text relevant to their respective areas of expertise throughout the course of negotiations. The purpose of this Committee includes a charge to provide expert and detailed guidance to U.S. negotiators throughout the course of negotiations with our trading partners, not merely at the outset of trade discussions. Moving forward, we strongly recommend that USTR engage with members of this Committee in substantially greater detail on trade agreements' provisions as the U.S. considers text and approaches that may deviate substantially from initial U.S. proposals.

III. Brief Description of the Mandate of Industry Trade Advisory Committee on Intellectual Property Rights

The Committee shall perform such functions and duties and prepare such reports as may be required by section 135 of the Trade Act with respect to the industry trade advisory committees. The committee advises the US Secretary of Commerce and US Trade Representative concerning trade matters referred to in section 135(a)(1) of the Trade Act and is consulted regarding the matters referred to in section 135(a)(2) of the Trade Act.

In particular, the Committee provides detailed policy and technical advice, information, and recommendations to the Secretary and USTR regarding trade barriers, negotiation of trade agreements, and implementation of existing trade agreements affecting its subject area; and performs such other advisory functions relevant to US trade policy as may be requested by the Secretary and the USTR or their designees.

IV. Negotiating Objectives and Priorities of Industry Trade Advisory Committee on Intellectual Property Rights

Please find below the key objectives and priorities with respect to Trademarks, Geographical Indications, Domain Names, Copyrights and Related Rights, and Patents and Regulatory Data

Protection, Trade Secret, and IPR Enforcement. These objectives reflect the input the Committee provided to the Administration at the outset of the negotiations as to the types of provisions and level of protection that would satisfy the high standard for intellectual property set out in the TPA negotiating objectives.

Trademarks and Domain Name Objectives to Promote the Economic Interests of the United States

U.S. negotiators should seek to promote trademark systems in other countries that provide at least as much protection for trademarks as the U.S. system. Trademark owners should benefit from the broad scope of what may be registrable as a protected trademark. This includes expansion in order to protect sounds and scents in order to fully benefit from what may be used as a trademark and protected as such.

Trademark systems should provide easy and open access to each country's registry of existing trademarks, preferably through electronic means, to allow searches to be conducted quickly and inexpensively. This would help small businesses to register their marks and reduce the likelihood of filing applications that will be rejected.

Trademark enforceability is also a concern. Each U.S. trading Partner's trademark protection system should ensure that trademark owners may enforce exclusive rights to use a registered mark. The exclusive rights of use should include the ability to prevent third parties from using identical or similar marks and should protect the use of those marks from being appropriated or unduly restricted, including by regulation of geographical indications.

The ability to protect a registered mark should include a presumption of confusion for identical signs/marks for identical or similar goods or services.

The Trade Agreement should provide for the protection of well-known trademarks. In view of the level to which well-known marks are subject to counterfeiting and pirate registrations, the Trade Agreement should provide for appropriate measures to refuse the application or cancel the registration and prohibit the use of a trademark that is identical or similar to a well-known trademark, for identical or similar goods or services, if the use of that trademark is likely to cause confusion with the prior well-known trademark.

In addition, the Trade Agreement should state clearly that there is no administrative obligation to record trademark licenses and that the absence of a recorded license shall have no bearing on trademark validity. Moreover, recording a trademark license shall not be a condition for use of a trademark by a licensee to be deemed to constitute use by the holder in a proceeding that relates to the acquisition, maintenance or enforcement of trademarks.

The Trade Agreement should clearly require Parties to strongly defend full protection for trademarks in the context of industry regulation to avoid growing concerns about regulatory efforts to undermine trademark rights in various industries through regulation.

Finally, the Trade Agreement should provide that no country will require that a trademark holder be a domestic entity in order to secure certain economic advantages associated with use of the trademark.

Generally, the Domain Name Dispute Resolution language of a modernized NAFTA should not be the text of TPP. The TPP language at 18.28.2 is problematic and should be corrected. The TPP text was too narrowly written where it stated that appropriate remedies should be available "at least in cases in which a person registers or holds, with a bad faith intent to profit, a domain name that is identical or confusingly similar to a trademark". This language is inconsistent with the UDRP, being both narrower in some respects to the UDRP and broader than the UDRP in other respects.

This language appears to require "a bad faith intent to profit". The "profit" limitation is not found in the UDRP, and bad faith can be found under the UDRP for other reasons than a profit motive. For example, bad faith can be found under the UDRP when a domain registrant has engaged in a pattern of preventing trademark owners from reflecting their marks in corresponding domain names. The TPP standard for finding bad faith is too narrow.

In other ways, the TPP language is too broad. The UDRP prohibits a finding for a complainant where the domain name registrant has legitimate rights or interests in the name subject to the domain registration. The TPP text does not exclude ruling against domain name registrants on that basis. The TPP language would improperly require a ruling against a domain registrant, even in some cases where that registrant has rights or legitimate interests to the name.

Mexico's domain name dispute policy is generally in line with the "Uniform Domain Name Dispute Resolution Policy". The Committee recommends that the U.S. obtain a commitment from Mexico that it will align its policy with the Uniform Domain Name Dispute Resolution Policy thereby eliminating any inconsistencies.

The fact that Canada and Mexico agreed to the TPP text is an insufficient reason to simply agree to the same text; a modernized NAFTA should improve upon the TPP text.

Geographical Indication (GI) Objectives to Promote the Economic Interests of the United States

The Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (the "TPA") requires U.S. international trade agreements to: (1) prevent the undermining of market access for U.S. agricultural products through improper use of a country's system for protecting geographic indications; (2) seek transparency and procedural fairness in country geographic indication systems; and (3) protect generic terms. (19 USC § 4201(b)(3)(U)).

In evaluating the measures needed to implement these objectives in the Trade Agreement negotiations, this ITAC recognizes that the challenges related to Geographic Indications (GIs) are different from those facing other forms of IPR. Among other things, GIs are the only area of IPR where a government that is not a Party to NAFTA has been actively and intentionally working to restrict market access rights for U.S. agricultural products while simultaneously strongly encouraging countries to abandon for GI purposes the genuine and robust due process procedures widely customary for other forms of IPR. As USTR noted in its 2017 Special 301 Report: "The EU GI agenda remains highly concerning, especially because of the significant extent to which it undermines the scope of trademarks and other IPR rights held by U.S. producers, and imposes barriers on market access for American-made goods and services that rely on the use of common names..."

This dynamic poses a particular challenge for U.S. companies exporting agricultural products that rely on commonly used names, including semi-generic, descriptive, and "traditional" terms. Some of those firms have largely built the markets for those products, including in our NAFTA partners, using names the EU seeks to confiscate.

This ITAC recognizes that U.S. trade partners may have different approaches to regulating GIs, such as through a trademark system, a sui generis system, or some other legal means. Regardless of the regulatory approach, this ITAC recommended that U.S. negotiators should seek to ensure that every country's process meets the TPA criteria of transparency, due process, generic name preservation, and maintenance of market access opportunities.

This ITAC also encouraged USTR to establish strong commitments and precedents on the GI issue for North America and for future trade agreements by using the Trans-Pacific Partnership (TPP) text on GIs as a starting point and working to improve upon that text in the NAFTA negotiations to effectively preserve U.S. market access opportunities for common name products and the integrity of U.S. trademark rights.

Copyrights and Related Right Objectives to Promote the Economic Interests of the United States

The United States is the world's largest producer and exporter of copyrighted materials and loses more revenue from piracy and other inadequate copyright protection than any other country in the world. High levels of copyright protection and enforcement mean more revenue and more higher-paying jobs benefiting all Americans. To illustrate, in 2015, the copyright industries accounted for 6.88% of U.S. GDP and employed over 5.5 million workers, who earned on average 38% higher wages than other U.S. employees.

Recent technological advances have allowed for the digital dissemination of all types of copyrighted works. As a result, every sector of the copyright industries is increasingly engaged in digital trade. Content industries and their licensed partners continue to explore new ways to deliver content to consumers, launching new legitimate businesses, services, and apps. The result: more movies, music, TV shows, video games, and published materials are available to more consumers in more countries and in more diversified and flexible ways than ever before. These innovative new services help drive the legitimate digital economy.

This explosion in digital dissemination of content is obviously thanks to the advent of the internet. The internet economy has grown from nothing when NAFTA was first implemented to one of the largest and fastest growing sectors of the United States economy.

For over two decades, U.S. free trade agreements have recognized the importance of copyright provisions, helping ensure a basic legal framework exists for this major U.S. export industry. With the growing importance of digital trade, any NAFTA modernization must address what many Committee members view as the single-most damaging barrier to digital trade faced by the creative industries: digital piracy. Content industries are forced to face unfair competition, including from those who engage in piracy as a high-profit, low-risk enterprise. Today, legitimate businesses built on copyrighted content are facing increased threats, as they must compete with the massive proliferation of illegal services unencumbered by costs associated with either producing copyrighted works or obtaining rights to use them (as well as other services that avoid fair licensing and claim no legal responsibility for the copyrighted works distributed on their sites). Mexico's copyright regime is woefully outdated, and meaningful reform of the Copyright Law and related laws have been long-stalled. In short, the Mexican legal regime is completely inadequate for the production and distribution of digital copyrighted works in Mexico, even as internet access in Mexico has grown exponentially in recent years.

The copyright provisions of the NAFTA are long overdue for updating to reflect the current international norms of protection and enforcement in the digital age. The marketplace for copyrighted works has changed dramatically since the NAFTA was first negotiated a quarter century ago, and important multilateral treaties and norms have developed since the NAFTA was completed to improve cross-border trade in copyrighted content. U.S. free trade agreements, culminating in the most recently negotiated KORUS FTA, have consistently expanded the level of reciprocity expected regarding protection and enforcement of IPR. The language and obligations in NAFTA fall far short of guaranteeing that the American creative industries can compete on a level playing field in Mexico and Canada today.

It is critical that NAFTA modernization include commitments for high standards of copyright protection and enforcement. These standards, today, include provisions that account for technological changes and reflect the global consensus on minimum standards of protection including the duration of protection, and effective legal protection of technological measures used by copyright owners to control access to and copying of their works; comprehensive obligations regarding copyright enforcement with a panoply of criminal penalties and civil remedies, including liability for aiding and abetting; and enforcement measures addressing online infringement that mandate deterrent civil and criminal remedies, and provide incentives for online service providers to cooperate with right holders. The copyright-related provisions of KORUS provide an excellent starting point for the U.S. to develop objectives. In addition to the obligations in KORUS, NAFTA should include obligations to provide: aiding and abetting liability; adequate legal incentives for ISPs to cooperate with right holders, including explicit principles of secondary liability; and specific recognition that civil and criminal enforcement procedures and remedies are available in the digital environment to the same extent that they are available in the physical environment.

Below is a description of specific concerns and recommended legal reforms regarding each country. It is critical for the NAFTA negotiations to address these important issues.

Mexico

There are two significant impediments stifling the development of a vibrant legal marketplace in Mexico for copyrighted materials. First, the Mexican IPR legal regime is antiquated for the digital age. For example, Mexico has not yet fully implemented the 1996 World Intellectual Property Organization (WIPO) Digital Treaties, much less the full panoply of legal provisions and procedures commonplace in most U.S. trading partners today. Second, Mexican enforcement authorities continue to focus on hard goods, not digital piracy. And, while some agencies have developed infrastructures for addressing Internet piracy, resources in key spots remain woefully short for effective enforcement.

To address these problems, a renegotiated NAFTA should obligate the Government of Mexico to undertake at least the following legal reforms and enforcement measures, which would significantly improve the market for U.S. copyrighted materials, and further create and support jobs in the United States:

- **Full Implementation of the WIPO Digital Treaties:** Amend the Copyright, Industrial Property, Criminal, and Criminal Procedural codes to fully implement the WIPO Digital Treaties. Implementation of these treaties is essential to provide a foundation for legitimate digital trade in copyrighted materials. These treaties provide the global minimum standards for healthy electronic commerce, including the right of copyright owners to control the distribution of copies of their works and the right to control the manner in which their works are communicated to the public.
- **Technical Protection Measures (TPMs):** Adequate protection for TPMs is critical because TPMs foster many of the innovative products and services available online by allowing creators to control and manage access to copyrighted works and to diversify products and services. Mexico should offer creators the same level of protection that the U.S. provides.
- **Criminal Liability:** Remove the proof of profit standard as a prerequisite to criminal liability. Provide criminal sanctions against commercial scale infringements “carried out for commercial advantage or financial gain” or that “have a substantial prejudicial impact” (current law applies only to infringement “for profit”). NAFTA, like other U.S. FTAs, should recognize that U.S. rights holders are harmed when illegal content is posted to the Internet with or without profit motive or commercial purpose, such as with peer-to-peer piracy. Add penalties for aiding and abetting criminal infringement (and, in addition, obligate the NAFTA Parties to implement Articles 10 and 11 of the Budapest Cybercrime Convention, which include commitments with respect to criminal copyright infringement and aiding and abetting).
- **ISP Liability:** Establish a legal regime that provides adequate legal incentives for ISPs to cooperate with rights holders to combat infringement, including through principles of secondary liability for copyright infringement, while providing conditional safe harbors from monetary damages to ISPs that do not control, initiate, or direct infringements, and take effective action when they become aware of infringing activity on their services. Mexico has no secondary liability regime nor a safe harbor regime. A modernized NAFTA should require all Parties to adopt an effective ISP liability/conditional safe

harbor regime based on the principles embodied in the U.S. system, including secondary liability for copyright infringement.

- **Rights Management Information (RMI):** Define RMI and provide civil and administrative sanctions for its unauthorized removal or alteration.
- **Camcording:** Outlaw camcording piracy, and eliminate the "for profit" and "intent to distribute" evidentiary requirements. Ninety (90) percent of infringing copies of film still in theatrical release can be traced to illegal camcords from theaters. Mexico must address this problem.
- **Statutory Damages:** Provide for pre-established (statutory) damages in civil enforcement proceedings for copyright infringement. Statutory damages are needed to compensate the copyright holder without the need to establish the infringer's profits or the rights holder's losses, which can be overly burdensome or even impossible. In many cases of infringement, especially online, the fact of harm – even massive harm – is certain, but the amount of harm is difficult to quantify. Statutory damages provide a deterrent remedy against infringers and ensure that running an infringement-based business does not pay.
- **Presumption of Copyright Ownership:** Provide clear presumptions of copyright ownership, and of the validity of copyright protections, in civil, criminal and administrative proceedings, absent proof to the contrary.
- **Satellite and Cable Signal Theft:** Outlaw cable signal theft (with both civil and criminal sanctions), and eliminate the "for profit" requirement for criminal enforcement against signal theft for decrypting cable or satellite signals.
- **Right of Communication to the Public:** Provide explicit clarification that the Mexican law protects the exclusive right to make works and sound recordings available to the public (a right of communication). This is critical in a digital, networked world in which copyright material can be fully exploited without a permanent copy ever being made by the user.
- **Reproduction Right for Electronic Copies:** Expressly protect the reproduction of electronic copies of sound recordings.
- **Criminal Enforcement:** Require materials and implements used to manufacture infringing goods to be destroyed at the request of rights holders without unwarranted delay or complex processes. Require formal notification to rights holders of seized pirated copyrighted goods.
- **Civil Enforcement:** Ensure reasonable cost of experts in civil infringement proceedings, and allow prevailing parties to recover costs and attorney's fees.
- **Border Enforcement:** Provide customs officers and authorities with *ex officio* authority as well as authority to take action at the border against TPM circumvention devices.

- **Exceptions and Limitations.** NAFTA should confine its exceptions and limitations provision to the three-step text, and ensure that all copyright exceptions are implemented in accordance with international obligations as codified in the three-step test.

- In addition to these legal reforms, Mexico needs to undertake significant improvements in its enforcement regime, including more criminal investigations, raids, and prosecutions; strengthened administrative enforcement; and improved prosecutions and adjudication of piracy cases, resulting in deterrent sentences.

Canada

Online infringement remains widespread in Canada, hampering the growth of the legitimate digital marketplace. Circumvention devices and services (and, increasingly, illicit streaming devices and apps) remain readily available, especially online. Canada's new Copyright Modernization Act clearly provides insufficient incentives for legitimate Internet intermediaries to cooperate with right holders to combat online infringement; nor has its "notice and notice" system changed consumer behavior with regards to infringement. Meanwhile, the greatly expanded exceptions to copyright protection that were the hallmark of the Copyright Modernization Act have already caused serious damage to Canada's educational publishing market. The ill-defined boundaries of Canada's limitations and exceptions, in combination with unfavorable decisions of Canadian courts and the Copyright Board, further ratchet up the level of uncertainty in the market for copyright materials in Canada. Making copyright enforcement a priority for police, prosecutors, and courts, and completing the task of harmonizing duration of Canadian copyright protection with that of its major trading partners, are other major pieces of unfinished business. Canada must recalibrate the course set by the Copyright Modernization Act in order to better confront the challenges of today's digital networked marketplace.

To address these problems, a renegotiated NAFTA should obligate the Government of Canada to undertake at least the following legal reforms and enforcement measures, which would significantly improve the market for U.S. copyrighted materials:

- **Exceptions and Limitations:** NAFTA should confine its exceptions and limitations provision to the three-step test, and ensure that all copyright exceptions are implemented in accordance with international obligations as codified in the three-step test. Canada, in particular, must commit to redressing the crisis in the educational publishing market (which has been decimated, in large measure, by the ambiguous "education" exception included in the fair dealing amendment adopted in the Copyright Modernization Act), and in similar fashion, to addressing the broad and globally unprecedented user-generated content exceptions, while taking care not to inhibit legitimate innovation.

- **ISP Liability:** Canada should establish a legal regime that provides adequate legal incentives for ISPs to cooperate with rights holders to combat infringement – e.g., through principles of secondary liability – while providing conditional safe harbors from monetary damages to certain ISPs that do not control, initiate, or direct infringements, and take effective action when they become aware of infringing activity on their services.

- **Global Consensus Term**: Complete the process of bringing Canada's duration of protection for copyright into conformance with the growing consensus minimum global standards. This consensus term of protection for copyrighted works has a direct benefit to the creators of these works, as well as consumers. The global consensus minimum term creates entrepreneurial opportunities, encouraging investment in new creative works, as well as the preservation, restoration and reissuing of older works in exciting new formats. This provides consumers more choice and preserves our cultural heritage. More than 90 countries around the world agree that copyright terms at or above the global minimum standard are necessary and appropriate in today's highly inter-connected world with simultaneous distribution of a wide variety of copyright-based products. U.S. FTAs after NAFTA have ensured that our trading partners move towards reciprocity for copyright term.

- **Collective Management**: Reform the Copyright Board's extremely slow and unpredictable tariff-setting process, especially regarding music royalties and payments.

- **Broadcasting**: Remove the cap on radio revenue in Canada. Radio stations pay an approved percentage tariff only for revenues in excess of C$1.25 million (US$951,000), which has resulted in broadcast revenues significantly lower than in similar economies. This limitation should be removed.

- **Open Digital Markets**: NAFTA contains a very broad "cultural" carve-out for Canada that enables it to impose restrictions on the provision of U.S content in Canada, potentially including various internet services. A modernized NAFTA should eliminate trade barriers resulting from this anachronistic carve-out. To the extent Canada maintains discriminatory policies, it should include them specifically in its schedules, preferably "Annex 1". At the very least, a modernized NAFTA should ensure that U.S. companies can provide internet services via all modes of supply and ensure the distribution of non-local content through the internet, without market access or national treatment restrictions. NAFTA should also prohibit discrimination against trade of digital products.

In addition to these legal reforms, Canada must improve its criminal enforcement regime, including by directing the Royal Canadian Mounted Police (RCMP) and Crown prosecutors to give high priority to intellectual property rights enforcement, particularly online piracy and the trafficking in illicit streaming devices and other circumvention tools; and by providing police, prosecutors and courts with the resources and training required to implement this priority and impose deterrent penalties on major violators.

Patents and Regulatory Data Protection Objectives to Promote the Economic Interests of the United States

Committee Members focused on these issues believed it was most useful to address the Committee objectives and analysis of the actual agreement together. Accordingly, please see the analysis section for a discussion of both.

<u>Trade Secret Objectives to Promote the Economic Interests of the United States</u>

The specific negotiating objectives for U.S. trade agreements in the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 include "*ensuring that the provisions of any trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law . . .*." (19 USC 4201(b)(5)(A)(i)(II)). Consequently, this ITAC appreciates and strongly supports specific provisions on trade secret protection in the renegotiated NAFTA that are consistent with both TPA and the Defend Trade Secrets Act (DTSA). This would build on the new language that U.S. negotiators included in Article 18.78 of the TPP, which predated the DTSA but set an important precedent for U.S. trade agreement negotiations, adding new language that implemented obligations of Article 39.2 of the TRIPS Agreement but that had not appeared in previous U.S. trade negotiations. This approach would mark a significant improvement over NAFTA's existing Chapter 1711, which provides basic rules for trade secrets but does not provide any clear language requiring all parties to make available strong civil and criminal penalties for trade secrets misappropriation.

This Committee's members encourage NAFTA negotiators to update TPP language – using template language from the DTSA – to ensure that NAFTA parties fully and consistently provide and implement civil and criminal procedures and penalties that are sufficient to deter unauthorized disclosure of trade secrets. Additionally, we encourage negotiators to press NAFTA Parties for increased harmonization of trade secret laws and jurisprudence consistent with evolving best practices and to ensure the fair and transparent application of trade secrets laws. This should include language matching U.S. law requiring liability or restrictions on a third party if they had a reason to know of the misappropriation.

Finally, the Committee members recommend that negotiators broaden language related to regulatory data protection to require NAFTA Parties to provide clear protection for any trade secrets or confidential business information collected as part of regulatory practices, including clear penalties for illegal disclosure. Businesses provide a wide variety of business data to government regulators to comply fully with local laws and regulations, some of which is highly sensitive and would impair their competitiveness if leaked to a competitor. Adding explicit language obligating NAFTA parties to protect such information would not only provide greater confidence that their data will be protected but would also guide regulatory decisions about what data should be required.

<u>IPR Enforcement Objectives to Promote the Economic Interests of the United States</u>

An effective enforcement system is critical to the protection of IPR assets. In the areas of border measures and criminal enforcement, NAFTA needs an overall rewrite. In addition, the impact of the internet requires more aggressive enforcement efforts.

Additionally, a modernized NAFTA should include strong language committing parties to make online enforcement of IP rights a priority for cooperation and enforcement and setting common standards and approaches for how NAFTA parties should work together and separately to enforce IP in the digital environment.

1. Border Measures

Neither Canada nor Mexico have demonstrated a commitment to interdict shipments of trademark or copyright infringing goods. The Committee believes that in order to protect U.S. IPR owners doing business in either country, it is incumbent upon the U.S. to obtain strong commitments for protection of IPR at the border. While we are not advocating for expanding border measures to forms of IPR not covered by TRIPS, the Committee believes that our NAFTA Parties should provide the level of border enforcement that U.S. CBP and ICE provide to IPR owners.

a. IPR owners should be able to apply for border measures without onerous and overly burdensome information requirements. Generally, IPR owners should not be required to provide detailed information about infringing goods as a condition for applying for border measures.
b. Applications for border measures, upon acceptance, should be effective for a period similar to the effective terms of recordation in the U.S. A longer effective period for accepted applications for border measures would decrease the administrative burdens on both IPR owners and the government agencies responsible for processing applications.
c. Mexico and Canada should be required to enforce against the movement of goods intended for export, goods moving in-transit (and goods being transshipped) and against infringing goods entering or exiting a free trade zone in cases where such actions involve an infringing use of the IPR within the country where the movement of goods occurs. U.S. authorities should not bear the burden of enforcement. There is no reason for the U.S. to accept from Canada and Mexico a standard of enforcement that is lower than the standards the U.S. negotiated in CAFTA.
d. Mexico and Canada should provide its authorities with ex officio authority to take enforcement actions even where an IPR owner has not applied for border measures as there is no reason to be aware of the movement of infringing goods and allow such movement to occur simply because an administrative requirement has not been met.
e. Enforcement to stop the flow of small consignments should be required in view of the impact of the internet. Today's online activity has resulted in significant volume of shipments of small packages through the international mail system and via express couriers that enable producers of counterfeit and pirate product to ship direct to customers. The personal exemption should not be allowed to become a basis for facilitating illegal activity (production and distribution of infringing goods).
f. Expand the scope of border measures to include enforcement against circumvention devices, which is consistent with developments under U.S. law.
g. Require border enforcement authorities to share information with IPR owners.

2. Criminal Procedures and Penalties

The inclusion of criminal procedures and penalties for knowing violations is essential for NAFTA. Canada and Mexico have not been aggressive in IPR enforcement. The Committee, therefore, supports strong provisions in a modernized NAFTA. Some of the provisions we propose have been included in previous agreements concluded by the U.S., including TPP.

a. Enact criminal penalties for the willful importation and exportation of counterfeit and pirate goods, including subjecting such goods in free trade zones to criminal penalties thereby eliminating FTZs as a safe haven for infringing activity.
b. Enact criminal penalties for aiding and abetting (implementing Articles 10 and 11 of the Budapest Cybercrime Convention, which include commitments with respect to criminal copyright infringement and aiding and abetting).
c. Enact criminal penalties for online infringement.
d. Remove the proof of profit standard as a prerequisite to criminal liability.
e. Provide criminal sanctions against commercial scale infringements "carried out for commercial advantage or financial gain" or that "have a substantial prejudicial impact".
f. Require materials and implements used to manufacture infringing goods to be destroyed at the request of rights holders without unwarranted delay or complex processes and the seizure of assets and documentary evidence without qualification.
g. Enact criminal laws subjecting a person to criminal liability for the act of unauthorized copying of a motion picture from a performance in a movie theatre.

V. Advisory Committee Opinion on Agreement

The Committee notes that the analysis that follows of necessity relates only to the extent to which the objectives have been advanced with respect to Mexico. As noted above, at the time of this report, the Trade Agreement did not include Canada, so it is not possible to evaluate the Trade Agreement IP provisions with respect to Canada. The Committee re-iterates that it believes this report must be supplemented with an addendum on the implications of the outcome of negotiations with Canada, thirty days after those negotiations are completed or otherwise terminated.

It is the opinion of the Committee that to a reasonable extent, the Trade Agreement promotes the economic interests of the United States and advances the overall and principal negotiating objectives with respect to intellectual property set forth in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 ("TPA"). While there are elements the Committee would prefer to have strengthened, clarified, or removed to conform better to TPA, the Trade Agreement intellectual property provisions generally improve standards of protection and enforcement and enhance U.S. economic interests.

The Trade Agreement incorporates standards already in force in the TRIPs agreement and other U.S. FTAs and in many cases updates these standards to take into account developments in technology, law, and implementation of similar provisions in existing FTAs. The Trade Agreement borrows from the terms of the agreement formerly known as the Trans Pacific Partnership (TPP). In some areas, this was useful, reflecting a gold standard. In others, however, that decision was regrettable as TPP reflected a step back from higher standards in prior U.S. FTAs.

Please find below more in-depth analysis of the text with respect to significant areas of IP.

Trademarks and Domain Names

Generally, the trademarks and domain names sections include major provisions that should assist trademark owners in protecting trademarks and help prevent abusive domain name practices.

Article 18.C.1 provides that marks need not be visually perceptible to be registered. This provision indicates clearly that Parties cannot deny registration of a trademark only on the ground that the proposed mark is a sound. It would be preferred if scent marks were mandated as protectable rather than subject to best efforts of a Party that does not currently permit scents to be registered. Nevertheless, removing the barrier to protection of sound marks is a step forward.

Article 18.C.2 states clearly that trademarks include certification marks and collective marks. The language also provides that geographical indications be eligible for protection as trademarks. This language lends itself to a system of protection for geographical indications similar to the preferred U.S. system where geographical indications are eligible for protection through the trademark system of protection.

Article 18.C.3 reaffirms the TRIPS requirement that the registered trademark owner's rights are exclusive rights—that is, the trademark owner can prevent third parties who do not have the owner's consent from confusing uses of identical or similar signs, including geographic indications. This is a favorable provision and its inclusion is commended. This Article also includes the presumption of confusion for identical signs for identical goods or services as has been included in prior FTA's.

ITAC-13 is pleased with the scope of protection that will be required for well-known marks under Article 18.C.5. This Agreement extends protection of well-known marks to dissimilar goods and services, whether registered or not, with the proviso that the expanded protection is based on an association between the goods/services and the owner of the well-known mark and when the interests of the trademark owner are likely to be damaged. The explicit language of this Article also prevents Parties from requiring a well-known mark to be on a list before receiving protection as a well-known mark or having been recognized previously as a well-known mark as a condition for protection as a well-known mark. In view of the frequency of infringements of well-known marks, the ability of well-known trademark owners to protect their marks on unregistered and dissimilar goods and services is critical to protecting these valuable assets.

Article 18.C.5.4 requires Parties to provide for measures to refuse applications or cancel registrations and prohibit use of a trademark identical or similar to a well-known mark. This protection extends not only to registration of conflicting marks but also to the *use* of the conflicting mark. This provision does *not* explicitly state that a well-known mark is protected against a geographical indication that is subsequently the subject of an application or causes confusion, mistake or deceives as in the KORUS FTA.

Well-known mark owners will have to rely upon the protection of such marks against subsequent geographical indications as provided for in Article 18.E in view of the fact that well-known marks are a subset of trademarks generally. We are concerned that this may lead to obstacles to effective protection of well-known marks because of the absence of the explicit language as found in the KORUS FTA. Despite the concern, this provides a heightened level of protection for well-known marks and should be applauded.

Article 18.C.6 gives trademark owners greater assurances regarding the ability to communicate with and receive communications from the relevant trademark officials regarding the registration process. The imposition of the procedural obligations on all Parties makes positive strides toward modernization and transparency of the process. Overall, these procedural elements should protect trademark owners from arbitrary and unreasonable actions of trademark agencies.

Article 18.C.7 makes strides toward office automation and greater use of electronic means to interact with trademark officials and the establishment of accessible trademark databases.
The elimination of the requirement of trademark license recordals (Article 18.C.10) is a positive development. This change means that trademark owners and licensees can take steps to protect and enforce trademarks without unnecessary administrative hurdles.

The Agreement addresses domain names in Article 18.C.11 and requires each Party to have a system of management of its country-code top-level domain (ccTLDs) names. Article 18.C.11.1 requires that each Party shall have available an appropriate procedure for the settlement of disputes modelled along the lines of the Uniform Domain Name Dispute Resolution Policy providing public access to "reliable and accurate" database of contact information for each domain name registrant.

The Agreement's Article 18.C.11.2 improves on past FTAs by requiring Parties to have a ccTLD management system that must have remedies for trademark owners at least in cases involving persons who register or hold a domain name with a bad faith intent to profit from the domain name that is identical or confusingly similar to a trademark.

These provisions combine to combat the problems of copyright and trademark cyber-piracy and are welcome. ITAC-13 prefers, however, (and mentioned this in its Colombia, Oman, Chile and Morocco FTAs, the Peru TPA and CAFTA-DR reports) that there be a direct reference to the "Whois" database and any additional contact information elements as available in the gTLDs namespace. Inclusion of this direct reference would clarify the type of information this database must contain. Reference to "Whois" was included in the Singapore FTA.

ITAC-13 wishes to underscore that the provisions regarding the establishment of Uniform Domain Name Dispute Resolution Procedures for ccTLDs in this FTA address only ***trademark*** cyber-piracy, and not other *alleged* abuses such as the use of geographic terms in domain names. ITAC-13 commends the fact that challenges based upon the use of geographic terms as, or as part of, a domain name are **not** included as a basis of challenge pursuant to the Uniform Domain Name Dispute Resolution Procedures.

This Agreement, like the KORUS, Colombia, Oman, Chile, Singapore, Morocco and Bahrain FTAs and the Peru TPA does not include a sentence providing that "due regard may be given to the Parties' legislation protecting the privacy of its nationals" as it relates to domain name contact information because such a provision could be used to limit or restrict right holders access to an accurate Whois database.

Geographic Indications

The Trade Agreement includes a number of elements that help to further build upon transparency and due process disciplines in the geographical indications arena. However, it regrettably does not fully preserve U.S. market access opportunities. Therefore, important work remains to be achieved outside of the text of this agreement in order for the U.S. to preserve the maximum range of market access opportunities possible.

The GI Section of the intellectual property chapter establishes a framework for beginning to introduce more transparency and due process procedures to the area of GI consideration. In doing so, it draws strongly upon the text negotiated under the Trans-Pacific Partnership agreement. The obligations in the GI Section should help to mitigate against the inappropriate future registration of unwarranted GIs. The GI Section also provides a basic structure on the topic of GIs from which the U.S. can build further in FTA negotiations to come.

Some examples of the Agreement's notable positive features include:

- A requirement for governments to review GI applications, not merely publish them without independent government analysis;
- Objection procedures to avoid situations seen in the EU-Canada agreement and in Mexico's prior process for handling WIPO Lisbon Agreement GIs wherein GIs are registered without the opportunity for public comment;
- Various illustrative, non-exhaustive criteria that are relevant to the determination of the generic status of a term;
- Greater clarity requirements regarding protection sought for translations/transliterations to ensure the public is fully informed of the scope of the proposed GI's restrictions.

In practice, as the Agreement's commitments are implemented, the U.S. will need to strongly guard against the approval of GIs that may result from compliance with the letter of the process requirements outlined in the GI Section yet fail to reflect the intent of the Article to prevent the registration of GIs that restrict the use of commonly used terms. This is of particular priority with regard to Mexico given that country's 2018 decision to register numerous EU GIs despite clear evidence of common usage of those terms in Mexico.

This ITAC has some concerns with the interpretation and application of certain provisions in Article 18.E.7, International Agreements.

First, this ITAC understands that the provisions of Article 18.E.7 apply only to GI registrations under international agreements that preceded this Trade Agreement, as defined in clause 6 of that Article. GI registrations under international agreements that come after this Trade Agreement would not come under Article 18.E.7 and would be fully subject to the other provisions in the GI Section. This ITAC also understands that clause 6 only applies to GI's specifically identified in prior international agreements. New GI registrations under those agreements are subject to the procedures specified in Article 18.E.7, particularly clauses 1 and 2. These interpretations are vital to prevent undermining of the GI Section's protections and to make the GI Section a strong precedent for future FTA negotiations.

Second, even assuming that the above ITAC interpretations are correct, clause 4 in Article 18.E.7 exempts applications for GI's for wine and spirits under pre-existing international agreements from the requirements in Article 18.E.3 (Grounds of Denial, Opposition, and Cancellation). The ITAC questions why wine and spirits GI applications should be exempt from the requirements applicable to other GI applications. In particular, the ITAC notes that footnote 19 in clause 1 of Article 18.E.3 is intended to prevent GI registrations for wine from essentially confiscating a common grape varietal name. This protection should apply to all GI registrations for wine that do not precede the Trade Agreement.

Third, the scope of the GI Section text does not address those registrations that have to date posed the greatest commercial concerns to the U.S. in light of the fact that clause 6 in Article 18.E.7 effectively grandfathers terms covered by the EU-Mexico 2018 agreement and those WIPO Lisbon Agreement terms registered before implementation of this agreement. In doing so, it foregoes the opportunity to preserve export opportunity rights for the U.S. companies relying on those common terms in Mexico and reduces the commercial benefit of the GI provisions for the Mexico market.

On the whole, this ITAC welcomes the establishment of new disciplines for an area of IP that has too often lacked the type of transparency and basic checks and balances already established for other forms of IP. These building block due process elements are expected to help to establish greater "transparency and procedural fairness", as required by TPA language. However, we have some concerns and regret that the provisions do not appear to fully meet the TPA charge regarding "eliminating…the undermining of market access for United States products" given the exclusion of GI decisions made during 2018 from the agreement's scope.

On a related matter, the committee strongly welcomes the Trade Agreement's text on Traditional Descriptive Terms and Related Concerns. As recommended by this ITAC, the Distilled Spirits, Wine, Beer and Other Alcoholic Beverages Annex 3B to the Agriculture Chapter included clause 18 a provision to help address an area of the GI-related restrictions that the U.S. wine industry has experienced: limits on the use of terms typically used to describe wine. Clause 18 commits the Parties to not reject imports solely because they use certain "traditional" descriptive terms and adjectives related to wine or winemaking (see Section C-18.). This ITAC commends USTR for the inclusion of this provision in the Trade Agreement. It will help preserve market access opportunities for U.S. wine exports and serves an important precedent for future FTA negotiations.

<u>Copyright and Related Rights</u>

In the copyright and related rights text, the Trade Agreement in many ways continues important provisions from and builds upon prior FTAs. Many of the Committee's negotiating objectives with respect to Mexico were fully satisfied. In other areas, the Committee believes that the text is missing important elements (e.g., explicit principles of secondary liability for infringement) or uses text that should not be the model moving forward (e.g., ISP safe harbors).

The Agreement includes obligations that would fully implement the WIPO Internet Treaties, including rights of distribution and communication to the public and explicit coverage of electronic copies. The Trade Agreement also meets the objectives relating to criminal liability, RMI, camcording, presumption of ownership, criminal enforcement (authority to destroy only), civil enforcement, and border enforcement discussed under Mexico above. For a discussion of the Committee's views on statutory damages, please see the Enforcement section below.

The Trade Agreement also includes rigorous protections relating to technological protection measures that are an improvement over the flawed TPP model. Article 18.H.11 prohibits acts of circumvention of TPMs that control access to copyrighted works as well as trafficking in tools, devices, components, or services that can be used to circumvent TPMs. We expect that Mexico, in implementing this Article, finally updates its law to close the importation loophole with regard to circumvention devices and that acts of circumvention applies to all copyrighted works, not just computer software. Although exceptions to this provision are confined to those listed, which is very helpful, the lack of an explicit requirement for regular review of additional exceptions does cause concern. This provision was included in the KORUS FTA and is a key aspect of U.S. law needed to ensure that additional exceptions remain appropriate for changing technologies and the evolving marketplace. In implementation, ITAC-13 expects that USTR will ensure a regular review process for additional exceptions.

Article 18.A.7—ITAC-13 is pleased with the general breadth of the national treatment provision, particularly that the agreement does not include any derogation regarding the rights of phonogram producers and performers with regard to analog communications.

Article 18.H.7—The Committee commends continuation of the precedents established in every prior FTA this century to require a term of protection closer to that provided to works created in the U.S. (life + 70/95 years from date of publication), which helps ensure reciprocity of protection for creative works. ITAC-13 is very pleased that the Trade Agreement improves upon the standard of protection of the KORUS FTA, requiring a term of protection of at least life of the author plus 70 years/75 years from publication for most works.

Article 18.H.9—ITAC-13 is pleased that this Agreement follows longstanding precedent from prior FTAs and provides a clean repetition of the three-step test for circumscribing the scope of exceptions to copyright protection found in the TRIPS Agreement and the WCT and WPPT. This is critical to ensure that our FTA partners do not undermine important protections in the Agreement.

Article 18.J.8—ITAC-13 is pleased that this Agreement requires criminal remedies for signal theft and forward distribution of unauthorized encrypted program-carrying satellite signals, and for receiving or assisting another to receive unauthorized encrypted program-carrying cable signals. ITAC-13 encourages USTR to continue to work with stakeholders on cable theft language for future FTAs.

18.J.10 and 18.J.11—ITAC-13 does not support the text in Articles 18.J.10 and 18.J.11, and does not recommend using this text as a model for any future agreement. ITAC-13 is concerned by the inclusion of detailed prescriptive provisions on copyright safe harbors for online service providers that incorporate highly-contentious issues into this Agreement. Effective safe harbors are necessary for a legitimate online ecosystem, but the proper interpretation and application of those safe harbors is very complex with many different and strongly-held views on all sides. The operation of the system for safe harbors in the United States, which dates back two decades, is constantly changing due to rapid changes in technology, judicial evolution, and shifting business conditions. At the same time, increasing questions are being raised whether such detailed provisions reflect the "state of the art" in this complicated area.

One significant problem with prior FTA text on legal remedies and safe harbors is that the text does not adequately reflect important aspects of U.S. law that are necessary for adequate and effective protection and enforcement. This problem is also present in the text of this Agreement, and in some important respects this Agreement exacerbates this shortcoming. For example, regarding the obligation to provide "legal incentives . . . to cooperate with copyright owners to deter the unauthorized storage and transmission of infringing materials," an important feature of U.S. law is the set of secondary liability doctrines under which service providers could be held responsible for infringements carried out by third parties using their services or networks. Secondary liability is what provides the legal incentives for cooperation in the U.S. system, and any text that includes detailed obligations on safe harbors should explicitly spell out obligations regarding secondary liability.

Not only is secondary liability not explicitly stated in this agreement, but this Article includes a number of new provisions that could undercut USTR's efforts to ensure U.S. trading partners provide adequate legal incentives through secondary liability principles. For example, unlike in prior FTAs, the text includes an option to "take other action to deter the unauthorized storage and transmission of copyrighted materials." While the intent of this language is not clear, one interpretation is that it provides broad flexibility in additional measures Parties may choose to take to address online piracy and frame limitations on liability, undercutting the "legal incentives" obligation.

Also exacerbating the "secondary liability" concern -- the text introduces a new provision, not found in prior United States FTAs, stating that "the failure of an Internet Service Provider to qualify for the limitations in paragraph 1(b) does not itself result in liability." First, this provision is arguably inconsistent with U.S. law since violation of one of the safe harbor conditions (right and ability to control; direct financial benefit) is itself a basis for infringement liability. Second, the provision highlights the absence of an explicit secondary liability obligation – many ISPs face no threat of liability without secondary liability concepts, meaning in that context that the conditions imposed on the safe harbors are essentially voluntary.

Furthermore, this agreement for the first time authorizes Parties to "prescribe in its law conditions for ISPs to qualify" for safe harbors, or, "alternatively, shall provide for circumstances under which ISPs do not qualify" for safe harbors. Thus, Parties appear to have flexibility to shift the burden such that, rather than requiring ISPs to affirmatively meet certain conditions to qualify for the safe harbor, Parties may provide ISPs a blanket entitlement to a safe harbor, and the rights holder would have the burden of proving the ISP did not qualify. The impact of these new provisions is unclear, but it does not appear that they reflect the standards found in U.S. law. The Agreement does include a qualification on this burden-shifting provision that the system must "facilitate effective action to address infringement." USTR should work closely with rights holders on implementation to ensure this qualification is satisfied.

This Article also falls short of prior FTA language in a number of other ways. For example, although prior FTAs required that safe harbors "shall be confined" to the four functions listed, NAFTA does not explicitly include this limit. This raises the potential for Parties to provide additional safe harbors for additional functions, which again would not be consistent with U.S. law. USTR should ensure this provision is implemented consistent with U.S. law, and ensures effective action against online piracy.

In addition, prior FTAs more robustly spelled out the conditions for safe harbors. For example, prior FTAs required that the safe harbors are conditioned on the service provider publicly designating a representative to receive notifications. In addition, prior FTAs conditioned eligibility for the caching safe harbor on compliance with industry standard technology or refreshing rules and a requirement to expeditiously remove or disable access to cached material upon notice that the original source of the material has been taken down (although the Agreement text includes this condition as a permissive option that a Party may adopt). We expect that USTR will work to ensure conditions for safe harbors that are at least as robust as those provided in prior FTAs and in U.S. law, and ensure effective action against online piracy.

Questions remain about footnote 108 and exactly what type of system requiring a governmental role would not end up impeding the effectiveness of the prescribed enforcement procedures. The Committee is doubtful that any such system could work in practice. In any event, Mexico's implementation of a system consistent with the entirety of the ISP safe harbor text must be closely monitored.

As illustrated by the comments above, a granular approach to FTA language on legal remedies and safe harbors is fraught and made it nearly impossible for negotiators to reflect the standards found in U.S. law. On this highly technical issue, a high-level approach that is general and articulates key principles, while providing flexibility for Congress, would have been most appropriate. The Internet has changed dramatically and will do so again. This Article should have reflected this reality, rather than exporting in detail, albeit not in its entirety, what is now widely agreed to be a flawed model. As noted above, ITAC-13 expects that the many shortcomings of this provision will be addressed in implementation.

ITAC-13 is concerned that Articles 9.17 and 9.18 in the Digital Trade chapter, which are new Articles that do not appear in prior FTAs, will be implemented by Mexico or Canada in a manner that could interfere with effective protection and enforcement of intellectual property rights. For example, it is critical that implementation of any limitation of liability contemplated by Article 9.17 should not diminish adequate and effective protection and enforcement of copyright or trademark rights, particularly regarding the implementation of Articles 18.J.10 and 18.J.11. In addition, implementation of Article 9.18 on Open Government Data should not diminish adequate and effective protection and enforcement of copyright holders. ITAC-13 expects that USTR will ensure that implementation of Articles 9.17 and 9.18 does not impede the full implementation of any article in the Intellectual Property chapter regarding protection and enforcement of intellectual property.

<u>Patents and Regulatory Data Protection</u>

This ITAC supports modernizing NAFTA to ensure broad, effective and balanced patent and regulatory data protection regimes that reflect U.S. standards. Modernizing NAFTA presents a unique opportunity to establish more consistent and harmonized patent systems between Canada, Mexico and the United States. Consistent, predictable and transparent patentability standards among these three countries will enable greater cooperation between patent granting authorities and provide benefits to innovators and governments through reliable, efficient application of agreed standards. In general, the standards for securing and enforcing patent rights and regulatory data protection standards in the United States should be adopted in a modernized NAFTA.

Consistent with TPA,-ITAC Members generally support provisions that balance innovation and competition in the pharmaceutical sector.[1] This sector, which includes the innovator pharmaceutical sector, which develops new drugs and biological products as well new uses of those products, as well the generic/biosimilar pharmaceutical sector, which develops generic drugs and biosimilar products, has thrived in the United States under schemes established by the Hatch-Waxman Act of 1984 and the Biosimilar Price Competition and Innovation Act of 2009, to the great benefit of patients. ITAC Members support inclusion of provisions in trade agreements that implement the incentives and mechanisms in these acts, including measures that promote innovation (e.g., patent term adjustments, data protection and measures to facilitate patent enforcement) as well as those which facilitate market entry for generic drugs and biosimilars (e.g., exemptions from infringement to generate test data to support generic drug and biosimilar approvals, provision of generic exclusivity periods and measures that provide transparency in patent status for drug products).

ITAC offers the following observations on specific provisions that should be considered.

<u>1. Patentable Subject Matter</u>

ITAC Members generally support the terms of Article 18.F.1, which confirm that within the NAFTA countries, all inventions that are new, useful and non-obvious are eligible to be patented. Article 1709(1) of NAFTA, like Article 27.1 of the TRIPS Agreement, provides a solid foundation but should be updated to reflect developments in technology and in patent law practices in the NAFTA countries and around the world.

ITAC Members support Article 18.F.1(2) as it confirms that patents will be made available by NAFTA countries for inventions claimed as new uses of a known product, new methods of using a known product, or new processes of using a known product

[1] Bipartisan Congressional Trade Priorities and Accountability Act of 2015, Pub .L. No. 114-26, Sec. 102(b)(5)(C) (creating a principle trade objective "to ensure that trade agreements foster innovation and promote access to medicines.")

ITAC Members also generally support the clarifications in Article 18.F.1(4) that effective patent protection is to be provided for innovations involving plants within the NAFTA countries. The biotechnology industry in the United States relies on technological innovation to compete effectively in the global agricultural industry, and clarifications providing assured patent eligibility for plant-based innovations are therefore welcomed. The language in Article 18.F.1.4 is favorable because it confirms that patents will be made available for plant-based innovations, and ITAC Members encourage the NAFTA countries to implement make such protections broadly available.[2]

ITAC Members also support Article 18.F.4, which affirms that limited exceptions (including the one specified in Article 18.F.12) should not prejudice the legitimate interests of the patent owner or conflict with the normal exploitation of the patent.

2. Patent Harmonization Changes

ITAC Members support provisions in NAFTA 2.0 that will facilitate greater harmonization of the patent systems of the United States, Canada and Mexico to thereby enable closer coordination in patent examination and grant practices. ITAC Members support additional provisions that would define common standards for, *inter alia*, prior art, patent application disclosure requirements and inventorship/ownership of patent applications and patents. Regarding disclosure requirements, ITAC Members would support additional provisions specifying, among other things, that a patent disclosure provide an adequate written description of the claimed invention and that it enable a skilled person to practice the claimed invention without undue experimentation.

ITAC Members support inclusion of Article 18.F.2 providing a grace period consistent with U.S. law. This provision will ensure that the public disclosure of the invention made by the inventor or patent applicant, within 12 months of the priority date claimed by the applicant, is not considered for patentability purposes. ITAC Members also support Articles 18.F.7 and 8 establishing standards governing the publication of patent applications and information relating to such applications.

ITAC Members also would support inclusion of common rules concerning inventorship and ownership of patent applications, reflecting current practices followed in the United States.

3. Patent Revocation

ITAC Members support Article 18.F.8 which confirms that patents may only be cancelled, revoked or nullified by any member Party for reasons that would have justified a refusal to grant the patent and recognize that fraud, misrepresentation or inequitable conduct may also be bases for cancelling, revoking or nullifying a patent, or holding the patent unenforceable. The

[2] ITAC Members supporting the innovator pharmaceutical sector believe the new provisions of this trade agreement and longstanding international obligations will help to remedy the negative effects of decisions of the Canadian judiciary that have imposed an unwarranted standard for patent "utility," referred to as the "promise" doctrine. This doctrine has resulted in the improper invalidation of at least 25 biopharmaceutical patents. It has also been applied in a facially discriminatory manner: since 2005, not a single non-biopharmaceutical patent has been revoked for lack of "promise." No other country has a patent utility test like Canada's – none of the patents revoked in Canadian courts have been found to lack utility in any other country.

Agreement also confirm that procedures for revoking should be consistent with Article 5A of the Paris Convention and TRIPS Agreement.

4. Patent Term Adjustment for Patent Office Delays

ITAC Members[3] support Article 18.F.9, which provides patent term adjustment for unreasonable delays in the examination and grant of patents, consistent with the standards adopted in the United States. The articulation of standards for what constitutes an unreasonable delay is also welcomed, as it will help to ensure consistent practices by NAFTA countries to ensure that such delays do not function to diminish the effective duration of patent exclusivity for patentable inventions.

5. Patent Term Adjustment for Curtailment of Patent Term

ITAC Members from the innovator pharmaceutical sector support Article 18.F.11, which requires NAFTA countries to make available procedures for the expedited review of marketing approval applications, and which require such countries to make available adjustments to the term of a patent to account for periods of regulatory review. These measures will ensure that Parties have incentives to expeditiously approve new drug and biological products, and to likewise ensure that periods of time necessary to secure those approvals do not prejudice the legitimate exclusive rights in such products provided by patents. Patent term restoration measures have been an integral feature of the U.S. systems for approving new drugs and biologics, and have served an important role in encouraging the development and clinical testing of such products.

6. Regulatory Review Exception

ITAC Members generally support Article 18.F.12, which provides that each Party shall adopt or maintain a regulatory review exception for pharmaceutical products. ITAC Members, however, would support clarifications to this provision that make it conform more closely to U.S. law. ITAC Members, in particular, would support clarifications to Article 18.F.12 that specify that it shall not be an act of infringement of a patent to make, use, offer to sell, or sell within the territory of a Party or import into the territory of a Party a patented invention solely for uses reasonably related to the development and submission of information required to comply with a law or regulation governing the manufacture, use, or sale of drugs or biological products in the country of the trade agreement. Such measures would be consistent with provisions of U.S. law, in particular 35 U.S.C. § 271(e).[4]

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[3] ITAC members representing manufacturers of generic drugs and biosimilars support a trade agreement that balances incentivizing innovation while ensuring access to medicines. They believe that the current trade agreement does not meet this objective of balance. Accordingly, manufacturers of generic drugs and biosimilars are unable to support inclusion of provisions that delay generic or biosimilar competition among the Parties, including articles pertaining to: patent term adjustment (18.F.11), protection of undisclosed test data (18.F.13), and Biologics (18.F.14).

[4] 35 U.S.C. 271(e) provides "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the

7. Protection of Regulatory Data for Drug and Biological Products

The NAFTA was the first trade agreement to integrate protections for regulatory data submitted to support approval of new pharmaceutical products – including both new drugs and new biologics.

ITAC Members representing the innovator pharmaceutical sector generally support the inclusion of Article 18.F.13 as it provides at least five years of regulatory data protection for new drug products and at least three years of such protection for new clinical information associated with drug products.

ITAC membership representing the interests of the biosimilar and generic medicines industry do not believe that this provision is appropriately balanced consistent with U.S. law. In the U.S., innovator regulatory data protection is balanced in the Hatch-Waxman amendments with an incentive for the first generic filer to challenge weak patents (e.g., 180-day exclusivity). If the Trade Agreement includes regulatory data protection, there should also be an incentive for the first generic filer consistent with the Hatch-Waxman amendments.

ITAC-13 members representing the interests of innovative biopharmaceutical companies also generally support Article 18.F.14, which specifies an enforceable period of at least ten years regulatory data protection of undisclosed test or other data for biological products. While this measure will remedy deficiencies in Mexico, which does not provide any protection for such products, these ITAC-13 Members continue to believe a twelve-year period of regulatory data protection for biologics, such as is provided under U.S. law, is the appropriate standard internationally.

ITAC-13 membership representing the interests of biosimilar manufacturers believes that the ten year period of protection will harm their ability to export to Mexico and Canada and therefore will slow the growth of the biosimilar industry. We believe that this provision contradicts other Administration policies to enhance biosimilar uptake in the U.S. in order to lower drug prices for patients and taxpayers in the U.S. Consequently, they believe that Article 18F.14 should be omitted. Moreover, if the provision is maintained, it should be made clear that it is a ten-year period of *market* exclusivity and does not prohibit biosimilar companies from submitting regulatory applications during the ten-year period.

8. Measures Relating to the Marketing of Drug and Biological Products

ITAC Members generally support Article 18.F.16, which specifies measures that facilitate competition concerning patented pharmaceutical products while ensuring that sponsors of innovative pharmaceutical products are provided timely notice and procedures to enforce patent rights. ITAC-13 Members believe such measures are an important feature of a modernized NAFTA Agreement – they have proven important to ensuring the effective protection of patents relating to pharmaceutical products while simultaneously encouraging the market entry of generic drugs and biosimilar products within the United States (i.e., via the Hatch-Waxman Act for drug products and the Biologics Price Competition and Innovation Act (BPCIA) for biological products).

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development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

ITAC-13 members representing the interests of innovative biopharmaceutical companies welcome, in particular, the inclusion of provisions requiring parties to provide notice to a patent holder prior to the marketing of products that rely on evidence or information concerning the safety and efficacy of a patented pharmaceutical product. In addition, such Members welcome provisions allowing for adequate time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, the initiation and timely resolution of disputes concerning patents relating to an approved pharmaceutical product, and procedures such as judicial or administrative proceedings and expeditious remedies such as preliminary injunctions or equivalent effective provisional measures

ITAC membership representing biosimilar and generic pharmaceutical interests believe that this provision should be balanced by including the requirement of a publicly available registry of each approved pharmaceutical product and all applicable patent claims that cover such pharmaceutical product as well as relevant periods of exclusivity relating to such pharmaceutical product. Enhancing the transparency of pharmaceutical and biologic patents and exclusivity is fully consistent with the regulatory requirements of the U.S., and is achieved, for example, via the Orange Book maintained by the FDA and required under U.S. law.

9. Protection of Undisclosed Test or Other Data for Agricultural Chemical Products

ITAC-13 supports the adoption in NAFTA of measures to provide protection for regulatory test data submitted to support approval of new agricultural chemical products. Those measures should be consistent with standards and practices followed in the United States.

Annex 12b Comments

Annex 12b on Transparency and Procedural Fairness for Pharmaceutical and Medical Devices includes welcome principles recognizing the importance of research and development (R&D), including innovation associated with R&D related to pharmaceutical products and medical devices. In addition, the annex includes welcome provisions recognizing the value of pharmaceutical products and medical devices through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical product or medical device. Overall, a competitive global marketplace is the best way to ensure that innovation is appropriately recognized and reimbursed for the benefit of patients and society.

While we support procedural fairness provisions including an appeal and review process, as drafted, provisions which note that “the same expert or group of experts that made the recommendation or determination” may review and reconsider an application may not provide as meaningful and objective a review as an independent body would.

Trade Secrets

Section I of the proposed chapter on intellectual property mirrors important language that U.S. negotiators included in Article 18.78 of the TPP, requiring each Party to implement obligations of Article 39.2 of the TRIPS Agreement. This approach would mark a significant improvement over NAFTA’s existing Chapter 1711, which provides basic rules for trade secrets but does not provide any clear language requiring all parties to make available strong civil and criminal penalties for trade secrets misappropriation.

Article 18.I.1 and 18.I.2 also build on template language from the DTSA to ensure that each Party fully and consistently provides and implements civil and criminal procedures and penalties that are sufficient to deter unauthorized disclosure of trade secrets. Article 18.I also raises procedural standards jurisprudence among all parties in areas such as effective provisional measures, greater confidentiality for trade secrets in civil proceedings, stronger standards for injunctive relief and damages. Such rules are consistent with evolving best practices and better ensure the fair and transparent application of trade secrets laws. The definition of trade secret misappropriation has also been expanded to state that misappropriation also includes the acquisition, use, or disclosure of a trade secret a third party if they knew or had reason to know of the misappropriation, an improvement that matches existing U.S. law.

Article 18.I.8 also marks an important step forward to strengthen requirements for government officials to protect any trade secrets or confidential business information collected as part of regulatory practices, and prohibiting any disclosure outside of the scope of their official duties. Article 18.I.8 requires each Party to prohibit such unauthorized disclosure, as well as to provide in its law deterrent level penalties. This language will aid U.S. businesses, as they provide a wide variety of business data to government regulators to comply fully with local laws and regulations, some of which is highly sensitive and would impair their competitiveness if leaked to a competitor. Explicit obligations and penalties for government officials raises regional standards in line with U.S. law and helps to guide regulatory decisions about what data should be required.

We note that the revised trade secrets section still contains some unclear language that does not reflect updates in the DTSA. For example, language included in the introductory paragraph to Section 18.I does not adequately define the “legal means” that parties must provide to allow rights holders to prevent unauthorized trade secret disclosure. Similarly, Article 18.I.2 on criminal enforcement does not specify the severity of available criminal penalties and include allowances (albeit a list narrowed from TPP) for a Party to limit the availability or level of criminal penalties. These features could prevent the ability of criminal penalties from serving as an adequate deterrent.

<u>IPR Enforcement</u>

The Trade Agreement includes an extensive set of enforcement obligations. The Committee wishes to underscore the importance that it attaches to the effective enforcement of the full panoply of intellectual property rights afforded in this agreement. The updated protections in this agreement will be of little value to U.S. companies without the capability and willingness of the Parties to enforce those standards, including the availability of effective civil remedies.

U.S. companies and workers continue to suffer billions of dollars in losses due to global piracy, counterfeiting, and other IPR violations, often due to a lack of effective enforcement. This agreement makes some significant advances toward the broader goal of setting high standards, but the proof will lie in the implementation by police, prosecutors, administrative authorities, judges, Customs, and other entities involved with enforcement. Among the positive provisions of the agreement –

- Express application of the enforcement procedures and obligations to the digital environment. While prior IP provisions have been technology neutral and therefore apply to the Internet, and the WCT and WPPT require effective enforcement for online copyright infringement, this language provides a clear requirement that the full application of enforcement obligations apply with respect to online infringement.
- The provisions relating to presumptions concerning the subsistence and ownership of copyright in all protected subject matter. The absence of such presumptions imposes significant costs and delays on enforcement and in some cases can be so onerous or formalistic as to be an effective bar to enforcement.
- The Agreement makes mandatory many discretionary remedies from the TRIPs Agreement, including provisions requiring courts to have the authority to order payments of court costs and fees, and to order the seizure and destruction of goods, implements, and other materials in the case of infringement.
- The Agreement extends the panoply of civil remedies to the TPMs and RMI provisions, including the option of statutory damages and device destruction.
- The Agreement requires judicial authorities have the power to order injunctive relief
- The Agreement requires availability of expeditious *ex parte* provisional relief in civil cases and ensures that any security required be "reasonable" and not "deter" recourse to the procedures.
- With respect to copyright, related rights, and trademark industries, the provision requires criminal penalties for all infringements on a "commercial scale," clarified to include infringing acts without a profit motive or commercial purpose, but that have a substantial prejudicial impact on the interests of the rights holder in relation to the marketplace.
- Provides a potentially useful new requirement requiring Parties to provide criminal procedures and remedies for aiding and abetting infringement.
- Provides a provision similar to that in the KORUS FTA, requiring Parties to have criminal procedures subjecting a person to criminal liability for unauthorized "camcording" -- recording or transmitting a motion picture from a performance in a movie theater or other exhibition venue.

<u>IPR Enforcement: Border Measures</u>

The Border Measures provisions are, in general, positive developments, but also includes deficiencies. The Committee provides the following regarding these provisions.

The Agreement requires border enforcement procedures, particularly for owners of trademarks, copyrights, and related rights, and includes provisions to streamline the availability of those procedures. The Committee notes that expanding border measures to allow for enforcement against goods bearing confusingly similar marks (18.J.6 (1)) is a positive step forward.

18.J.6 (4)—It is unfortunate that the agreement does not impose a requirement on Mexico that it must amend its law to allow its competent authorities to disclose the information that is in subparagraph (a). The proliferation of cross border trade in infringing goods demands that governments share more information with stakeholders as soon as possible in the enforcement procedures. The US has amended its laws and customs regulations allowing for greater information sharing with stakeholders. The disclosure of more information about those involved in the production, distribution and sale of infringing goods would allow stakeholders to use the information to track back to foreign sources involved in the production and distribution of infringing goods. Subparagraph (b) delays the disclosure of information until after a proceeding on the merits that determines that goods are counterfeit or pirate goods. Under the best circumstances, these proceedings may be months after the detection of the goods and during the pendency of the proceedings more infringing goods may be produced and distributed, delaying possible efforts to target manufacturers and distributors.

The Agreement requires that Parties' Custom authorities have *ex officio* enforcement authority. 18.J.6 (5). This provision is a major step forward as it requires Mexico's customs authorities to act against counterfeit and pirate goods in situations where a trademark or copyright owner has not filed an application for border measures, including imports, goods destined for exports, goods in transit, and goods entering or exiting free trade zones or bonded warehouses. These requirements exceed the minimum requirements of the WTO TRIPS text. Given these expanded enforcement requirements and the lack of experience by Mexican authorities to take enforcement actions in these situations, the Committee supports expanded cooperation and technical assistance to help Mexico effectively implement its new obligations. Accordingly, and as discussed below, the Committee believes that the areas identified in Article 18.B.3(3) should be expanded.

Regarding Article 18.B.3(3), the Committee supports technical assistance and cooperation between Customs authorities of the Parties to the Trade Agreement. The Committee believes the current provision is too narrow, however, in referencing only trade secrets as subjects for capacity building. Mexico's IP enforcement regime suffers from deficiencies in other areas, for example, lack of experience in border enforcement. Therefore ITAC-13 believes that this subsection is too narrow in scope and may cause the U.S. Government to inadequately provide the assistance to Mexico necessary for U.S. rights holders to fully benefit from the effective implementation of the enforcement requirements of this agreement.

18.J.6 (10). While the text instructs that the border measure provisions apply to goods of a commercial nature sent in small consignments, it permits exclusion from enforcement of small quantities of goods of a non-commercial nature in a traveler's personal luggage. In view of the growth of small consignments in international trade, including their use to distribute infringing products, this authority is important. While the language in the body of the text is acceptable as written, Footnote 93 significantly undercuts it and opens up opportunities for great abuse that undermines effective enforcement. The Footnote states that "a Party may exclude from the application of this Article small quantities of goods of a non-commercial nature sent in small consignments". The internet-related trade involves massive amounts of small consignments that contain infringing goods that exploit express couriers and the international postal system to evade detection. The exception should have been limited to non-commercial quantities in a traveler's personal luggage. ITAC-13 advises the U.S. to prevent the inclusion of the footnote language in future agreements and, to the extent possible, remove the language from this Agreement.

IPR Enforcement: Criminal Procedures & Penalties

Several provisions in this section should provide higher levels of protection for IP owners.

18.J.7(2) will require criminal penalties for importing, exporting, infringing products and extends these penalties to cover the entry into and out of FTZs of infringing products.

The requirement that competent authorities be able to act on their own initiative, *ex officio*, to initiate legal action without a formal complaint is a positive development (18.J.7 (6)(g)).

The Committee would have preferred greater clarity in 18.J.7 (6)(d) that refers to forfeitures of assets "at least for serious offenses". The term is ambiguous and is likely to lead to arbitrary application of the language and weaken the intended penalties arising from illegal infringing conduct.

IPR Enforcement—Additional Comments

While the above bullet points highlighted positive developments, we also comment on provisions that we believe continue to be problematic.

18.J.3(1)(a)—The Committee regrets that the Trade Agreement misses an opportunity to require an important concept from transparency and due process -- requiring that judicial decisions and administrative rulings state relevant findings of fact and the legal reasoning for the decision, at least as to the parties involved in a proceeding.

18.J.4(6)—Unfortunately the Trade Agreement diverged from the KORUS FTA, and almost all prior FTA's with new language from TPP relating to statutory (pre-established) damages. Instead of the clean and clear language from prior FTAs, with respect to copyright infringement and trademark counterfeiting, Parties are required to provide statutory damages, or a system of additional damages designed to have a similar effect (i.e. to provide compensation to the right holder without the need to establish the infringer's profits or the right owner's losses). The Committee does not support this new language and hopes that prior statutory damages provisions will be the model for future FTAs, because certainty about the availability of statutory damages "sufficient to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by the infringement" is critical for effective enforcement.

18.J.5(3)—This provision obligating Parties' to provide to their judicial authorities the authority to order the seizure of documentary evidence does not specifically highlight the need for such authority in copyright or related rights infringement cases. Such authority is in fact needed in both trademark counterfeiting and copyright or related rights infringement cases for effective enforcement. ITAC-13 expects that in implementation USTR will ensure that this authority is available in Mexico and in Canada for at least trademark counterfeiting and copyright or related rights infringement cases.

Other Comments

ITAC-13 expresses serious concerns about changes to the investor state dispute settlement provisions of the Agreement. Many foreign investments have a significant intellectual property component and many IP-intensive industries must make foreign investments in order to compete effectively in those markets. ITAC-13 believes it is not beneficial to the U.S. economic interest to curtail rights for U.S. companies to protect their IP investments in overseas markets.

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