

Ambassador Michael Froman
United States Trade Representative
Executive Office of the President
600 17th Street, NW
Washington DC 20508

Dear Ambassador Froman:

In accordance with section 5(b)(4) of the Bipartisan 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 Intellectual Property Rights Industry-Trade Advisory Committee (ITAC-15) on the Trans-Pacific Partnership Agreement, reflecting our support of the Agreement.

Very truly yours,

Timothy P. Trainer

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The Trans-Pacific Partnership Agreement

**Report of the
Industry Trade Advisory Committee on Intellectual Property
Rights (ITAC-15)**

December 3, 2015

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**Prepared by the Industry Trade Advisory Committee on Intellectual
Property Rights (ITAC-15)**

**Advisory Committee Report to the President, the Congress and the U.S.
Trade Representative on the Trans-Pacific Partnership Trade Agreement**

I. Purpose of the Committee Report

In accordance with section 5(b)(4) of the Bipartisan Trade Priorities and Accountability Act of 2015, and section 135(e)(1) of the Trade Act of 1974, as amended, the statutory provisions require that advisory committees provide the President, the U.S. Trade Representative, and Congress 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 Trade Priorities and Accountability Act of 2015.

The report of the appropriate 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 Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) hereby submits the following report.

II. Executive Summary of Committee Report

It is the opinion of ITAC-15¹ that to a reasonable extent and with consideration of the broader impact of this agreement, the TPP 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 ITAC-15 would prefer to have strengthened, clarified or removed to conform better to the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 and previous bilateral free trade agreements (FTAs), the TPP intellectual property provisions generally modernize standards of protection and enforcement, with particular importance for the five TPP partners with which the United States does not have FTA's, and enhance US economic interests.

¹ ITAC Members representing BIO and PhRMA and those representing companies that are members of PhRMA or BIO reserve their position on this statement.

ITAC-15 urges the United States not only to monitor very closely the implementation by TPP partners of their FTA obligations, but also to ensure that they have in place, before the entry into force of the TPP Agreement, national legislation that faithfully reflects their FTA obligations.

III. Brief Description of the Mandate of ITAC-15

As part of its mandate to provide detailed policy and technical advice, information and recommendations on trade-related intellectual property matters, ITAC-15's predecessor committee, IFAC-3 advised U.S. negotiators on, and reviewed draft texts of, the Singapore FTA, the Chile FTA, CFTA-DR, the Australia FTA, and the Morocco FTA intellectual property chapters. In particular, IFAC-3 evaluated these FTA provisions in the context of the IP-related objectives contained in the Trade Act of 2002 and the objectives and achievements of other U.S. multilateral and bilateral initiatives on intellectual property. ITAC-15 continued this review with the Bahrain, Oman and South Korea FTAs and the Peru, Colombia and Panama TPAs and issued reports on those agreements as well.

IV. Negotiating Objectives and Priorities of ITAC-15

The negotiating objectives and priorities for ITAC-15 reflect those contained in the Bipartisan Trade Priorities and Accountability Act of 2015 (Pub. L. No. 114-26, 129 Stat. 319) (codified at 19 U.S.C. Sec. 4201 (2015)), trade promotion authority legislation which also provided the fast-track authority under which the TPP Agreement will be reviewed. Specifically, ITAC-15's objectives and priorities seek to ensure adequate and effective protection of intellectual property rights on a global basis with the aim of promoting the economic interests of the United States. Enforcement provisions are assuming increasing importance as countries improve their substantive standards of protection and especially in the context of increasing global trade in information and other innovative and creative products subject to intellectual property protection. The Committee also seeks to ensure that these standards of protection and enforcement keep pace with rapid changes in technology, including establishing that right holders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works. The Committee seeks to ensure the full range of protections for patented innovations, to eliminate any discrimination against U.S. right holders by any of our trading partners, and to secure deterrent enforcement against piracy, counterfeiting, cybersquatting and other infringements through significant improvements in civil and criminal remedies and penalties. Finally, the Committee seeks to establish strong precedents in these FTAs in order to raise the global level of protection and enforcement globally.

The FTA process has become the principal process through which the U.S. Government and IPR-based industries are able to ensure that the standards of protection and enforcement keep pace with new developments, and to provide for equity and reciprocity among the Parties to each FTA and within the sectoral or functional areas.

V. Advisory Committee Opinion on Agreement

Introduction

The TPP Agreement incorporates standards already in force in the TRIPS agreement, the NAFTA and earlier FTAs, and updates these standards to take into account the wealth of experience operating under those agreements since their coming into force from 1995 to 2007. It also takes into account the many years of experience gained from bilateral engagement with countries under the Special 301 trade process through which the U.S. Trade Representative has sought to leverage both legal and enforcement reforms in countries posing particular intellectual property problems for U.S. industry and for the U.S. economy. Additionally, the TPP Agreement takes into account the significant developments that have occurred since earlier agreements entered into force and largely mirrors earlier FTAs, though with some notable exceptions.

ITAC-15 recognizes that, to a large extent, the negotiation of FTAs has become the primary focus of the U.S. trade agenda and supports the use of all policy tools to gain worldwide improvement in intellectual property protection. ITAC-15 urges U.S. negotiators to ensure that FTAs remain part of a coordinated, multi-dimensional program that not only includes multilateral and regional initiatives but also focuses on substandard intellectual property protection and enforcement in countries that are not parties to FTA negotiations.

General Provisions

These provisions acknowledge that TPP Parties have already ratified or acceded to the major IPR treaties and contain the national treatment and other general provisions governing all of Chapter 18.

ITAC-15 notes that the TPP Agreement includes Objectives and Principles drawn from the General Principles of the WTO's TRIPS Agreement. Articles 18.2-18.4 address social and economic welfare, the balance of rights and obligations, the public interest (including public health and nutrition), abuse of intellectual property rights and promotion of competition. ITAC-15 was heavily divided on whether inclusion of these provisions advanced the U.S. national interest. While some members endorsed them without reservation, believing that they introduced a useful and productive sense of balance, there were significant concerns expressed within ITAC-15 that these provisions reflected skepticism of the very foundational role that intellectual property plays in promoting innovation in technology and creativity, in promoting dissemination of technology, knowledge, and creative works, in promoting public health through investments in new and better medical technologies, advancing the interests of users and consumers who benefit from the innovation and creativity and diversity of distribution models made possible by strong intellectual property systems.

ITAC-15 is pleased with the general breadth of the national treatment provision (Article 18.8). Nevertheless, it is particularly disappointing that the agreement carves back such

treatment and subjects to reciprocity the rights of phonogram producers and performers with regard to analog communications, including analog free over-the-air broadcasting and other analog broadcasting, and we express our hope that no future FTA will admit of such a derogation to national treatment. At the same time, we take note of, and appreciate, the express provisions of Footnote 4 requiring national treatment with respect to any form of remuneration for the use of protected works.

Cooperation

ITAC-15 welcomes the addition of this section that promotes greater cooperation between the relevant agencies of the various Parties. In view of the variance in the level of economic development among TPP Parties, it is critical to the future successful implementation of the Agreement's provisions to acknowledge that cooperation, information sharing, and training will be necessary for the effective operation of the intellectual property offices of the Parties as well as effective enforcement by the Parties' relevant agencies.

Trademarks and Domain Names

Generally, the trademarks section includes major provisions that should assist trademark owners in protecting trademarks.

Article 18.18 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 18.19 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 18.20 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. It is preferred that this presumption be included as it is in this FTA.

ITAC-15 is pleased with the scope of protection that will be required for well-known marks under Article 18.22. 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 18.22.4 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 18.20 in view of the fact that well-known marks is 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 18.23 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 18.24 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 18.27) 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 TPP Agreement addresses domain names in Article 18.28 and requires each Party to have a system of management of its country-code top-level domain (ccTLDs) names. Article 18.28.1 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 as approved by the Internet Corporation for Assigned Names and Numbers (ICANN) and providing public access to “reliable and accurate” database of contact information for each domain name registrant.

The Agreement’s Article 18.28.2 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-15 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-15 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-15 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.

Geographical Indications (GI)

The 2015 legislation providing Trade Promotion Authority requires U.S. international trade agreements to prevent the undermining of market access for U.S. products through improper use of a country’s system for protecting geographic indications, to seek transparency and procedural fairness in country geographic indication systems, and to protect generic terms. (19 USC § 4201(b)(3)(U)). USTR’s September 2015 statement of negotiating objectives for the IP Chapter of the TPP Agreement states that USTR will seek rules to promote “transparency and due process” with respect to geographic indications. The Committee recognized these standards in its evaluation of the IP Chapter provisions relating to Geographic Indications.

The TPP Agreement’s definition of “geographical indication” tracks the definition in the TRIPS agreement (TRIPS Article 22.1), but the Agreement does not include the additional explanation of a GI that is found in the KORUS FTA, which adds that any sign or combination of signs in any form whatsoever (not just limited to words or names) could be a geographical indication (Note 5 to KORUS Article 18.2.2). While an explanation similar to what is in the KORUS FTA might be helpful, the Committee does not view it as essential to interpretation of the TPP definition because of the generally accepted interpretation that the TRIPS definition applies to non-verbal indications of geographical origin.

Article 18.30 begins by recognizing that the TPP Parties have different approaches to regulating geographical indications. It states that geographical indications may be protected through a trademark system (reiterating what is stated in Article 18.19), a *sui*

generis system, or some other legal means.

ITAC-15 believes that Article 18.31 satisfies the basic U.S. objectives for ensuring transparency and procedural fairness in TPP Party systems for geographical indications. The Article requires administrative due process with regard to submission and processing of applications for new GIs, publication of and opportunity for comment on those applications, and procedures for opposing applications for new GIs and for cancelling existing GIs. Article 18.31 is similar to the equivalent provision in the KORUS FTA.

Article 18.32 provides additional procedural protections for existing trademarks or pending trademark registration and for customary common terms for goods against GI's that could cause confusion with those trademarks or common terms. TPP Parties must allow objections to GI's on those specific grounds and must allow them to be grounds for refusing protection for a proposed GI or for cancellation of an existing GI. These protections are generally favorable and desirable but ITAC-15 is concerned that the procedures in Article 18.32 could be interpreted as not requiring a Party to reject a GI on the grounds that the proposed GI is confusingly similar to an existing or pending trademark or to a common term.

ITAC-15 observed additional weak points in the notes to Article 18.32. Note 20 to Article 18.32 allows a TPP Party to "opt out" of applying the Article to wines and spirits. In addition, Note 22 allows a TPP Party to refuse cancellation of a GI on grounds specified in the Article if the GI was granted prior to ratification of the TPP Agreement and the Party did not otherwise recognize those grounds at the time of granting the geographical indication. These notes weaken the scope and application of Article 18.32. Since the notes do not apply to the requirements of Article 18.31, there is still an opportunity for interested parties to raise objections to or request cancellation of a GI under that Article. However, the Committee recommends that, once the TPP goes into effect, the U.S. government seek to encourage other TPP Parties to implement Article 18.32 for all geographical indications, subject as appropriate to Article 18.36.

Regarding the procedures outlined in Article 18.31 addressing recognition of a GI and the procedures for opposition and cancellation in Article 18.32, ITAC-15 would have preferred explicit language regarding the protection of earlier recognized well-known marks in the GI section. Although USTR has explained that both well-known marks and GIs are subsets of trademarks and, therefore, should be read in conjunction with the Trademark Section, this may not be the way some TPP Parties interpret the Agreement where GIs are not recognized through a trademark registration system.

ITAC-15 favors the inclusion of Article 18.33 and 18.34 as they add protection against GI over-reach. Article 18.33 provides guidelines that TPP Parties may use in determining whether a GI is a customary common name for the relevant good in that Party's territory. Article 18.34 states that if an individual component of a multi-component geographic indication is a customary common term for a good in a Party's territory, that individual component will not be protected in the Party's territory. Both of these Articles apply to all GIs subject to the procedures in Article 18.31. They are protections for generic and other common names for goods and, as such, are desirable conditions for the TPP Parties' regulation of geographical indications.

ITAC-15 commends the negotiators for inclusion of safeguard procedures in Article 18.36 regarding GIs. Article 18.36 sets forth the minimum procedures for GIs that are the subject of international agreements. The detailed procedures that are outlined in Article 18.36 cover situations when international agreements do not have precedence over the TPP Agreement (18.36.1) and situations when international agreements predate the TPP Agreement (18.36.2 and 18.36.6).

ITAC-15 considers the procedures provided for in Article 18.36.1 and the associated Notes to be relatively robust in terms of requiring transparency and procedural fairness. Those procedures would help to protect U.S. exporters against attempts by non-party countries to confiscate goodwill associated with U.S. goods through geographic indication agreements with TPP Parties after the TPP Agreement goes into effect.

The Committee does have concerns with regard to 18.36.6 because long delays in ratification of or entry into force of the TPP Agreement could lessen the Agreement's GI safeguards if international agreements between TPP members and non-Parties are ratified or go into effect first.

Finally regarding GIs and except for geographic indications specifically recognized pursuant to international agreements having precedence over the TPP Agreement, Article 18.36.3 provides that the TPP Parties must allow for protection of geographic indications to cease even though they have been recognized under another international agreement. The Committee considers this clause to be a desirable precedent.

Overall and subject to the above comments, the Committee supports the TPP Agreement's GI provisions as consistent with the Trade Promotion Authority requirements, as facilitating U.S. trade, and as a precedent for U.S. negotiation of other international trade agreements.

Patents

ITAC-15 supports adoption and maintenance of patent regimes that provide adequate and effective commercial protection for new technology, including vigorous enforcement provisions to protect against piracy and counterfeit products which are growing public safety and economic concerns. Effective patent regimes stimulate innovation and delivery to the market of new goods and services, thereby providing tangible benefits to consumers and the public at large. Innovation thrives in countries – whether developing or developed – which provide predictable and certain protection of innovation through the patent system, both by rewarding inventors for their inventive contributions, and by inducing early disclosure of technological information that can be used by others to stimulate further innovation. Effective patent systems also prompt early disclosure of new scientific and technological advances in exchange for the grant of patent exclusivity for limited periods of time. Effective patent systems necessarily include standards and practices that ensure that the rights granted are clearly defined so that others may design around valid patents, as well as measures that permit the revocation or invalidation of patents that do not meet the requirements of patentability. Effective patent regimes also promote competition by

providing safeguard provisions to discourage and prevent abuses of patent rights and eliminate erroneously granted or invalid patents.

The positive experience of the United States and many other TPP Parties with effective patent systems reinforces the value of these important benefits to the public. Effective patent systems induce markets that create multiple levels of competition -- not only based on price when patent rights expire, but between innovators, who wish to compete by bringing to market better products and services. Both forms of competition advance the interests of consumers and the public. Effective patent protection has also proven essential to the viability of many private industries, particularly those facing difficult to predict, expensive and lengthy processes for commercializing innovations into tangible new products and services, as well as to the integrity and impact of public systems (including health systems) and to the health and security of consumers and public at large.

The TPP presents a unique opportunity to establish consistent and harmonized patent systems throughout the TPP region. Consistent, predictable and transparent patent standards and practices among TPP countries will enable greater cooperation between patent granting authorities in TPP countries which, in turn, will provide benefits to innovators and governments alike in the TPP countries by providing efficient and expeditious procedures for examining patent applications and granting patents.

As a general rule, the standards for securing and enforcing patent rights in industrialized economies, and especially the United States, establish the appropriate level of protection for innovation through the patent system. Subject to certain observations provided below, ITAC-15 believes the patent and regulatory data standards established by the TPP make significant progress toward establishing standards that are similar to those found in the United States, in keeping with the negotiating objectives of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015. The TPP thus should promote effective standards for protecting innovation - and facilitating competition - through patent and regulatory systems of TPP Members.

ITAC-15 notes that several Articles of the TPP will operate to reinforce or apply obligations already specified in the TRIPS Agreement (and acknowledges associated Declarations, including the Doha Declaration on the TRIPS Agreement and Public Health), the Paris Convention or other international agreements concerning patents (i.e., Articles 18.40, 18.41 and 18.43). ITAC-15 offers no additional observations on the pre-existing standards, which are important protections for patent owners. ITAC-15 offers the following observations on provisions within Section F of the TPP Agreement.

Article 18.37: Patentable Subject Matter

ITAC-15 notes that Article 18.37 expressly confirms obligations of Article 27.1 of the TRIPS Agreement to make patents available for innovations in all technology sectors. In particular, ITAC-15 notes that Article 18.37.2 confirms the existing obligations of Article 27.1 of TRIPS that require all TPP Parties to make patents available for any process that meets the requirements for patentability, including in particular new uses of a known product, new methods of using a known product or new processes of using a known product, provided that the standards for novelty, inventive step and industrial application are met.

ITAC-15 also notes that Article 18.37.4 requires TPP Parties to make effective patent protection available for plant innovations. The obligations set forth in this provision will ensure that processes, substances and articles that are used to impart improved characteristics into plants, as well as products derived from use of those processes, substances and articles, are eligible to be patented in all TPP Parties. Given the importance of continued innovation in plant technology, ITAC-15 urges U.S. negotiators to continue to press for inclusive standards of patent eligibility that make patents available for all plant technology, including for non-naturally occurring plants that incorporate inventive characteristics. ITAC-15 believes the objective of comprehensive patent protection for plant-related technology has been advanced by the TPP Agreement.

Articles 18.38 (Grace Period), 18.42 (Patent Filing), 18.44 (Publication of Patent Applications) and 18.45 (Information Relating to Published Patent Applications and Granted Patents)

ITAC-15 commends U.S. negotiators for securing inclusion in the TPP of several provisions that together will operate to promote (and hopefully, urge) harmonization of patent law, patent examination practices, and otherwise improve cooperation among TPP Parties in the examination and granting of patents. Harmonization of standards and cooperation will benefit governments of the TPP Parties, inventors and the public by reducing duplicative search and examination of patent applications, improving the quality of examination and expediting patent grants.

ITAC-15 specifically endorses Article 18.38 which requires Parties to provide a one-year grace period against patent-defeating disclosure that derive from the patent applicant. Article 18.38 corresponds to U.S. law adopted with passage of the America Invents Act (Pub. L. 112-29). *See* 35 U.S.C. § 102(b)(1). Under Article 18.38, all TPP Parties must exclude information in public disclosures from precluding a finding of novelty or lack of inventive step (non-obviousness) if the disclosure: (i) was derived from the patent applicant (i.e., the entity applying for the patent including its inventors), and (ii) occurred within 12 months of the effective filing date of the patent claim at issue. ITAC-15 believes establishment of the 12-month grace period according to Article 18.38 will promote harmonization of patent standards throughout the TPP.

ITAC-15 also specifically endorses Article 18.42, which, consistent with U.S. law, establishes that patents shall be granted to the first inventor to file an application for an invention, where two or more such inventors have independently developed the invention and filed separate applications. ITAC-15 encourages U.S. negotiators to promote implementation of this Article in a manner consistent with U.S. law, in order to protect the interests of legitimate inventors.

ITAC-15 also endorses inclusion of measures that will improve consistency in practices regarding the publication of applications and patent grants. The provisions of Articles 18.44 and 18.45 are examples of such measures, and are consistent with U.S. law and practices. The exchange among TPP Parties of search and examination information will promote the broader goals of patent harmonization within the TPP region.

Article 18.39: Patent Revocation

ITAC-15 notes that Article 18.39.1 affirms that patents may only be cancelled, revoked or nullified by any TPP Party for reasons that would have justified a refusal to grant the patent. Article 18.39.1 also permits TPP Parties to treat fraud, misrepresentation or inequitable conduct as the basis for cancelling, revoking or nullifying a patent, or holding the patent unenforceable. Such procedures may include post-grant procedures such as those recently adopted in the United States (American Invents Act), and protect the public interest and foster competition by permitting correction of mistakes in the granting process by eliminating invalid patents or those obtained improperly. However, there are safeguards for patent holders, including Article 18.39.2, which limits Article 18.39.1 by confirming it is subject to Article 5A of the Paris Convention, thereby confirming that actions causing an effective forfeiture of the patent (i.e., cancellation, revocation or nullification) must comply with the substantive and procedural restrictions on forfeiture of patents specified in Article 5A of the Paris Convention. In addition, ITAC-15 believes actions to revoke patents as specified in Article 18.39.1 remain subject to the obligations of Section I of the Agreement, as well as Part III, § 1 of the TRIPS Agreement. Those measures ensure transparency and equitable procedures to govern actions that may result in revocation of the patent. When taken collectively, ITAC-15 believes these measures represent important procedural protections for patent owners to prevent an unwarranted patent forfeiture. ITAC-15 urges the U.S. negotiators to ensure that measures adopted to implement Article 18.39 are appropriately constrained in their scope and application, as is the case under U.S. law, while assuring that patents may be cancelled, revoked or nullified when warranted.

Article 18.40: Exceptions

ITAC-15 observes that Article 18.40 corresponds to the limitations and exceptions authority of the TRIPS Agreement (i.e., TRIPS Article 30), and reinforces the principle that limitations or exceptions to the exclusive rights provided by a patent must not unreasonably conflict with normal exploitation of the patent and not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

Article 18.46: Patent Term Adjustment for Patent Office Delays

ITAC-15 applauds the inclusion of the protections specified in Article 18.46, pursuant to which all TPP Parties must adjust the term of patents to compensate patent owners for unreasonable delays incurred in the examination and grant of the patent. Article 18.46.2 also encourages TPP Parties to make available procedures to expedite the examination and grant of patents, which, in conjunction with the availability of patent term adjustments and appropriate revocation procedures, will help to ensure that valid patents have effective periods of patent term in all TPP Parties.

Importantly, Article 18.46 provides objective criteria to measure delays in the granting of patents, which, *inter alia*, will promote harmonization of practices among the patent granting authorities of TPP Parties. Pursuant to Article 18.46.4, a TPP Party must provide an adjustment to the term of the patent if it has not been granted within five years from the date filing of the application in the territory of the Party, or within three years after a

request for examination has been made in that territory, whichever is later. Article 18.46.4 confirms these periods may only exclude periods of delay that are directly attributable to the patent applicant (e.g., specific requests by the applicant to delay deadlines for response), are not directly attributable to the granting authority (e.g., unanticipated circumstances affecting operations of the patent granting authority that are outside the direction or control of the granting authority) or occur outside the processing and examination of the patent application by the granting authority.

ITAC-15 urges U.S. negotiators to promote implementation of Article 18.46 in a manner that results in equitable and transparent standards being adopted in TPP Parties that will govern the determination of periods of adjustment of patent terms. Although some ITAC-15 members would prefer to refrain from offering suggestions on implementation of this and other measures in the Agreement, certain members felt strongly that the committee should be in a position to provide expert guidance on the implementation of the TPP. For example, these members suggest that U.S. negotiators should work to discourage TPP Parties from adopting or maintaining systems that permit third parties to oppose the grant of a patent prior to its issuance, unless those Parties also provide for adjustments of patent term to compensate patent owners who have prevailed in such proceedings. These members further suggest that U.S. negotiators should ensure that TPP Parties implement their obligations under Article 18.46 in a manner that ensures that periods of delay in processing or examination of applications from any source (e.g., actions of another part of the government of a Party) are also included in the basis for term adjustments granted to the patent owner. Other ITAC-15 members believe that these suggestions for implementation cannot be reconciled with or inferred from the plain wording of Article 18.46, fall outside of the scope of the ITAC's statutory responsibilities and fail to recognize that there are other ways to achieve the goals of the Article which require consideration.

Article 18.47: Protection of Undisclosed Test or Other Data for Agricultural Chemical Products

ITAC-15 supports the adoption of measures to provide protection for regulatory test data submitted to support approval of new agricultural chemical products. Article 18.47.1 and 18.47.2 require TPP Parties to provide at least ten years of protection for regulatory data associated with a new agricultural product, both where the data is submitted to secure approval by the TPP Party (Article 18.47.1) or where the Party references prior approval of the product by another regulatory authority.

Measures Relating to Pharmaceutical Products

ITAC-15 commends U.S. negotiators for their efforts to secure improvements to patent and regulatory measures that provide important protections to pharmaceutical products, including pharmaceutical products that are human biological products, while at the same time endeavoring to strike a balance that permits timely competition, including requiring systems to design around or invalidate improperly issued patents.

Article 18.48: Patent Term Adjustment for Unreasonable Curtailment

ITAC-15 endorses the inclusion of Article 18.48 calling on TPP Parties to make available procedures enabling the expedited review of marketing approval applications and requiring TPP Parties to make available adjustments to the term of a patent to account for periods of regulatory review that operate as an unreasonable curtailment of the effective term of the patent. ITAC-15 endorses the structure of Article 18.48, including, *inter alia*, the inclusion of measures that impose reasonable and appropriate conditions on securing such extensions.

Article 18.48 does not set forth specific obligations concerning the features of systems that will govern the provision of extensions. In addition, Article 18.48 permits Parties to implement this provision by providing a *sui generis* mechanism (i.e., the provision can be interpreted to allow a mechanism other than an extension of the term of patent), provided that mechanism provides the same rights as would be provided through an extension of the patent.

ITAC-15 urges U.S. negotiators to promote implementation of appropriate standards to govern patent term adjustment determinations, consistent with U.S. law and practice. *See* 35 U.S.C. § 156. Such measures should be transparent, should provide reasonable procedural conditions, and should ensure that extensions are adequate to compensate patent owners for the loss of effective patent term that arises due to unreasonable delays caused by the requirement for regulatory review and approval of a product subject to the patent.

Article 18.49: Regulatory Review Exception

In order to prevent unnecessary delays to the entry of generic pharmaceutical products immediately after patent expiration, the TPP, importantly, requires all Parties to make available an exception from infringement of patents for actions taken to generate data to be submitted to a regulatory approval authority in connection with securing approval for a pharmaceutical product. As it is set forth in the Agreement, Article 18.49 provides discretion to TPP Parties as to the manner in which this exemption may be implemented. Such exemptions may include acts performed to generate data to support approval of the product in the same Party or in another country. Importantly, however, the scope of any regulatory review exemption provided in a TPP Party must remain consistent with the provisions of Article 18.40, which ensures that exceptions provided will not operate to prejudice the legitimate interests of the patent owner or conflict with the normal exploitation of the patent. ITAC-15 urges U.S. negotiators to carefully review implementation of regulatory review measures in the TPP Parties to ensure that those measures comply with the obligations of the TPP, and to ensure that those measures provide clarity with respect to the actions that are or are not permitted under this authority.

Article 18.50: Protection of Undisclosed Test or Other Data

Article 18.50.1 mandates an at least five-year minimum period of data protection for pharmaceutical products that contain a new chemical entity, while Article 18.50.2 mandates an at least three-year period for new indications of previously approved products. The provisions in Article 18.50 are generally consistent with earlier bilateral

agreements that require provision of this minimum term of protection for pharmaceutical products. In addition, Article 18.50.3 extends the protection provided by the Doha Declaration on the TRIPS Agreement and Public health.

Article 18.51: Measures Relating to the Marketing of Certain Pharmaceutical Products

Article 18.51 provides measures that permit entry of competition to patented pharmaceutical products, while mandating that Parties have systems to provide timely notice and procedures to enforce patents rights. These measures have proven important to ensuring the effective protection of patents relating to pharmaceutical products.

Under Article 18.51.1(a)², each TPP Party must provide a system to allow 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 product. Article 18.51.1(b) mandates that Parties provide adequate time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, remedies provided in Article 18.51.1(c). Article 18.51.1(c) indicates that Parties must provide procedures, such as judicial and administrative proceedings, and expeditious remedies for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use. Examples of remedies to be provided include preliminary injunctions or equivalent effective provisional measures. In combination, these provisions require TPP Parties to provide a transparent system that gives notice to patent owners in advance of marketing of the product, so as to enable the rights holder to initiate the appropriate actions to effectively enforce the patent rights.

ITAC-15 encourages U.S. negotiators to press for implementation of transparent, efficient and balanced measures that will prove effective in providing patent holders the opportunity to timely initiate proceedings to enforce the patent and to expeditiously resolve disputes over patents, while avoiding unnecessary constraints on competition.

Article 18.52: Biologics

The TPP Agreement is the first U.S. trade agreement to include provisions expressly directed to new pharmaceutical products that are or contain a biologic. The inclusion of such provisions is consistent with U.S. law. *See* 42 U.S.C. §262(k)(7).

Pursuant to Article 18.52.1, a TPP Party must provide either (a) eight years of “effective market protection” in the manner by which five years of data protection is provided in Article 18.50.1 and 18.50.3 of the Agreement, or (b) a “comparable outcome” that includes at least five years of data protection in compliance with Article 18.50.1 and 18.50.2 in combination with “other measures.” Article 18.52.2 requires TPP Parties to provide the protection period of Article 18.52.1 to at least those human biological products that are or which contain a protein produced by biotechnology processes. Finally, in recognition of the nascent stage of development of the biologic market and its regulatory framework, Article 18.52.3 provides for the TPP Parties to consult after 10 years from the date of this

² U.S. negotiators have informed ITAC-15 Members that Article 18.51.1 applies to all TPP Parties other than Japan and Mexico, to which Article 18.51.2 applies.

Agreement, or as otherwise decided by the Commission to review the period of exclusivity and scope of application.

Certain of the ITAC-15 Members had differing views on Article 18.52 and the perspective that U.S. negotiators might take toward its implementation in TPP Parties.

Certain ITAC-15 Members had the following views on Article 18.52:

A major negotiating objective for the U.S. was to establish in the TPP a uniform standard requiring TPP Parties to provide a period of regulatory data protection for pharmaceutical products that are biologicals of at least 12 years from the date of the approval of the product in each TPP Party. The existing U.S. standard is supported by a broad, bipartisan majority of Members of Congress, and is an articulated negotiating objective for the TPP.

The certainty of a 12-year regulatory data protection period for pharmaceutical products that are biologics has been recognized as being essential to encourage the continued clinical development of biological products. The 12-year period is supported by extensive economic analyses and policy considerations. Unfortunately, the standard established in the TPP falls short of this clear negotiating objective in several important respects.

First, the period of protection that must be provided by TPP Parties under Article 18.52.1 is defined to be only at least eight (rather than at least twelve years) in duration from the date of approval of the product in the Party. Specifically, pursuant to Article 18.52.1, a TPP Party must provide either (a) eight years of test data protection in the manner by which five years of test data protection are provided in Article 18.50.1 and 18.50.3 of the Agreement, or (b) eight years of effective market protection that includes at least five years of test data protection in compliance with Article 18.50.1 and 18.50.2 in combination with “other measures.” The eight-year term of protection is a substantially shorter period of protection than has been recognized in the U.S. as being essential to encourage continued clinical development of biological products.

Second, while each TPP Party must provide measures that provide at least eight years of effective market protection for new biological products, the manner by which the TPP requires the Parties to provide this at least eight-year period of protection is not defined in objective or transparent terms in the Agreement. Instead, the TPP appears to provide discretion for a TPP Member to combine various types of measures that, in the aggregate, operate to provide the at least eight-year period of effective market protection. While Article 18.52.1 obliges TPP Parties to adopt government-applied measures, rather than point to the effect of patents or natural market forces, the lack of clarity in the nature of measures other than test data protection consistent with Article 18.50 may undesirably create uncertainty for developers of innovative biological products and other market participants. Article 18.52.1(b)(ii) and (iii), in particular, may be used by TPP Parties as a basis for adopting non-transparent or ineffective mechanisms for providing the required effective market protection for new biological products of at least 8 years.

Third, the Agreement provides extended periods for TPP Parties to implement the obligations specified in Article 18.52, ranging from four to ten years. Compounding this problem is that footnote 47 of the Agreement specifies that TPP Parties may apply the provisions of Article 18.52 to applications for marketing approval that are filed after the

date of entry into force of Article 18.52 in that Party. The effect of extended delays for implementation of Article 18.52, in combination with an application of its provisions only to applications for marketing approval filed after those provisions apply to the Party may function to discourage developers of new biological products from pursuing prompt approval of such products in those Parties.

The scope of biological products required to be subject to the obligation of Article 18.52.2 also falls short of U.S. objectives. In Article 18.52.2, TPP Parties are required to provide the at least 8-year protection period of Article 18.52.1 to at least those human biological products that are or which contain a protein produced by biotechnology processes. While the scope of the obligation for protein-based biological products is clear (i.e., it encompasses any protein-based product made in whole or in part by use of technologies recognized to be within the field of biotechnology), the Agreement does not require TPP Parties to make the period of protection specified in Article 18.52.1 available for other pharmaceutical products that are generally recognized to be human biological products. Consequently, TPP Parties may choose to extend to such non-protein based biological products the term of data protection required by Articles 18.50.1 and 18.50.3.

These ITAC-15 Members urge U.S. negotiators to address the lack of transparency and certainty in Article 18.52 during implementation of the Agreement, including, *inter alia*, by pressing for implementation of the protections specified in Article 18.52.1 entirely through test data protection consistent with the structure of Article 18.50. ITAC-15 also urges U.S. negotiators to press for early implementation of the protections specified in Article 18.52, and to extend the protections to all pharmaceutical products that are biologicals which are the subject of applications for marketing approval that, as of the date of application of the Agreement to the Party, have not been approved. Finally, ITAC-15 urges U.S. negotiators to advance the objectives specified in Article 18.52.3 to press for enhancement of the measures specified in Article 18.52 through cooperation and coordination with other TPP Parties.

Other ITAC-15 Members had the following views on Article 18.52:

These ITAC-15 Members would have preferred not to express an opinion or otherwise advocate within this report that the U.S. negotiators press for a specific data protection period, and simply commended the U.S. negotiators for reaching a balanced and equitable agreement in the context of a highly contentious and sensitive, but critically important, substantive area for which a widely divergent set of positions exist.

However, despite their misgivings about entering into a policy debate in this Report regarding what might have been agreed to in TPP – but was not – these Members feel compelled to briefly address some of the above statements by the other Members.

These Members agree that a major negotiating objective for the U.S. was to establish in the TPP at least 12 years of exclusivity for biologics. These Members also know that U.S. negotiators did their utmost to achieve that objective. However, the odds of achieving it were always slim. U.S. negotiators were candid with Members of the ITAC, as well as Members of Congress, in expressing their doubt that they could impose 12 years of biologic exclusivity on the eleven other TPP Parties, four of which have no exclusivity for

biologics in their domestic law, five of which have 5 years and two of which have 8 years. Given the diversity of policies on biologic exclusivity among the TPP Parties, the outcome reached by the negotiators is significant. These Members also note that this is the first time biologic exclusivity has been included in any U.S. trade agreement.

These Members disagree with the other Members' interpretation of the term of the exclusivity provided in Article 18.52.1(b): "*eight years* of effective market protection that includes at least five years of test data protection in compliance with Article 18.50.1 and 18.50.2 in combination with 'other measures'" (emphasis added). The number eight appears nowhere in Article 18.52.1(b). The provision, rather, uses the phrase "a comparable outcome in the market" to represent the sum of "at least five years" plus "other measures."

These Members also disagree with the following statements: "The certainty of a 12-year regulatory data protection period for pharmaceutical products that are biologics has been recognized as being essential to encourage the continued clinical development of biological products. The 12-year period is supported by extensive economic analyses and policy considerations. The eight-year term of protection is a substantially shorter period of protection than has been recognized in the U.S. as being essential to encourage continued clinical development of biological products." These Members note that the Federal Trade Commission (FTC) has concluded that it was not necessary for the U.S. to provide *any* exclusivity period for biologic products, while the President has, for each of the past five years, recommended in his budget proposals that the U.S. reduce the period of exclusivity from 12 years to 7 years. The excessiveness of 12 years of exclusivity (in addition to patent protection) for biologic products, which would have resulted in increased costs for and reduced access to medicines, was also recognized by the eleven other TPP Parties, resulting in a shorter period of protection.

Article 18.54: Alteration of Period of Protection

ITAC-15 notes that U.S. negotiators incorporated Article 18.54, which ensures that the expiration of a patent on a pharmaceutical product shall not alter the period of data protection for the product. This provision ensures the independent nature of the rights provided by patents and by regulatory data protection in a pharmaceutical product.

Copyright and Related Rights and the Protection of Certain Satellite Signals

As ITAC-15 noted in its report relating to the KORUS, it is the goal of ITAC to "ensur[e] that the model FTA intellectual property text, which has been carefully developed through the course of negotiation of eleven prior FTAs, continues to form the basis for" future FTAs. The KORUS standards in many important areas improved on the standards in TRIPS and NAFTA and, in others, clarified provisions in those agreements, in light of the industries' evolving business models and the U.S. copyright industries' wide experience with copyright enforcement globally. ITAC 15 notes that in a number of important areas TPP is less robust than the KORUS standard, and updates to KORUS standards to take into account developments since the negotiation of KORUS were not in every case achieved.

While the text repeats some obligations already contained in the TRIPS agreement without change, other language has been clarified, particularly in the enforcement text. The TPP text also contains detailed provisions that require implementation of the obligations provided in the WCT and WPPT. Additionally, the TPP carries forward provisions or principles from the standards articulated in the KORUS FTA. These include:

- An obligation to ratify or accede to the WCT and the WPPT;
- Providing protection for a range of core rights in copyright, including reproduction, public performance/making available, and right of distribution so that rights holders have the right to control any technological manner of transmitting works, including transmissions over electronic networks like the Internet, with only minor exceptions;
- The protection for technological protection measures (TPMs) used by right holders to protect against unauthorized access and exploitation of their works, including restrictions on trafficking in circumvention technologies and services, in a manner compatible with and mostly reflecting the approach of U.S. in the DMCA in 1998;
- Implementation of the WCT and WPPT provisions on prohibiting the removal or alteration of electronic rights management information similar to the approach in the DMCA; and
- A 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. TPP is different from prior FTAs in its treatment of exceptions, but ITAC-15 believes that, provided that USTR is vigilant during implementation and thereafter, this difference in approach should not undermine the core protections in the Agreement.

Other key provisions include:

- Continuing the precedents established in every prior FTA this century to extend term of protection closer to that provided to works created in the U.S.—to at least life of the author plus 70 years/70 years from publication for most works. This is the standard already in place throughout a majority of OECD countries, and in roughly 100 countries worldwide.
- Inclusion of a provision that makes clear that there is no hierarchy of rights between those of authors on the one hand, and those of record producers and performers on the other.
- Incorporation of the “contractual rights” provision requiring Parties to give effect to transfers of rights and the treatment of monetary benefits resulting from such transfers that are contained in U.S contracts. This provision is intended to safeguard the freedom of contract and to ensure that a country may not pass laws that undermine the intent of the parties to such contracts.
- Presumption that named authors and producers own the relevant copyright and of a subsistence of copyright, which have proven important to enable rights holders, as a practical matter, to enforce their rights in legal and administrative proceedings.
- Recognition of the importance of collective management societies for copyrights and related rights, and noting they should be managed according to principles of fairness, transparency and accountability in their operations
- Inclusion of provisions similar to KORUS and other prior FTAs protecting against the theft of encrypted program-carrying satellite signals and the manufacture of and

trafficking in tools to steal those signals. Under the TPP, Parties are required to provide criminal remedies for the manufacture and trade in these tools and to “receive or further distribute” such encrypted signals. The TPP also includes protection for encrypted cable signals, requiring TPP Parties to provide criminal or civil remedies with respect to theft of cable signals. These provisions bring TPP closer into line with protections found in the U.S Communications Act. ITAC 15 notes that the KORUS FTA required criminal remedies for signal theft and forward distribution for both types of encrypted program-carrying signals and hopes future FTAs will return to this approach.

- The substantive text adds a provision requiring criminal penalties for unauthorized camcording. Unauthorized camcords account for over 90% of all movie piracy and experience has demonstrated that effective criminal laws can significantly reduce this criminal activity. The TPP language is not identical to the standards articulated in KORUS, but ITAC 15 fully expects USTR to ensure enactment of substantively equivalent provisions during implementation.

Copyright and Related Rights: Additional Comments

Reflecting the diversity of ITAC 15’s membership there were differing views on aspects of the TPP Agreement, including in particular with regard to the value of including specific language calling for “balance” in copyright systems. All ITAC-15 members believe that copyright systems should be balanced, but different sectors have different views on how that balance should be struck. Apart from the concept of balance in the abstract, there is disagreement over whether inclusion of specific language on this issue in a trade agreement advances or prejudices US economic interests, particularly in light of the state of intellectual property systems in many of our trading partners. Notwithstanding any disagreement on this point, as well as the sensitivities and differing viewpoints on issues such as proportionality of remedies, all ITAC-15 members involved in the copyright space endorse the TPP IP Chapter as a whole and commend the negotiators for doing their best to navigate complicated waters.

Enforcement

ITAC-15 wishes to underscore the importance that it attaches to the effective enforcement of the full panoply of intellectual property rights afforded in this agreement, which build upon the enforcement obligations in the TRIPS agreement and previously negotiated free trade agreements. The updated protections afforded in this agreement will be of little value to U.S. companies without the capability and willingness of the TPP Parties to enforce those standards, particularly against commercial piracy and counterfeiting (and other infringements) that cause such a drain on the TPP economies.

Today, almost two decades after the WTO TRIPS enforcement obligations came into effect, U.S. companies and workers continue to suffer billions of dollars in losses due to global piracy, counterfeiting and other infringements of the rights provided in TRIPS and in this agreement – primarily due to ineffective enforcement by our trading partners.

While, for the most part, the substantive provisions of the TRIPS Agreement have been implemented in these countries, the enforcement obligations are not being met by many

countries. The continued development and importance of new technologies, such as the Internet, and the accompanying greater ease with which piracy and counterfeiting can be accomplished, have made this situation even more acute. In addition, the alarming increase in the international trade in counterfeit pharmaceutical products is a serious public health concern, especially in developing and least developed countries. It was the objective of the U.S. government, of ITAC-15 and of the entire U.S. intellectual property community to use the opportunity offered by the FTA process to use our enforcement experience over this period to improve and strengthen these enforcement obligations, with the goal of having them adopted on a global basis.

This agreement makes some significant advances toward the broader goal of setting high standards and good precedents for the future and for other FTAs. But again, the proof will lie in the implementation of these new standards on the ground in the country, by police, prosecutors, judges and administrative agencies responsible for enforcement and implementation of intellectual property rights. Some of these advances (clarifying or building upon existing TRIPS standards) include:

General Obligations

- These general provisions clarify and expand, for the most part, existing TRIPS obligations, including avoiding barriers to legitimate trade.
- One particularly important change made in the TPP is the express application of the enforcement procedures and remedies to the digital environment. While TRIPS is technology neutral and therefore applies to the Internet, and whereas the WPPT and WCT require parties to provide effective enforcement for online copyright infringement, this is the clearest articulation to date of the full application of enforcement obligations with respect to infringements taking place online.
- The provisions relating to presumptions represent a significant advance, and address a serious problem in many enforcement systems. This provision lays out detailed presumptions that must be implemented in national law concerning the subsistence and ownership of copyright in all protected subject matter. Proving these preliminary issues in court, without the benefit of presumptions, makes enforcement difficult, expensive and causes long and unnecessary delays. ITAC-15 notes with approval that the TPP text improves on earlier FTA's that only required a defendant to provide "evidence" to rebut the presumption by now providing that the presumption will remain in place "in the absence of proof to the contrary."

Civil and Administrative Procedures and Remedies

- With respect to copyright infringement and trademark counterfeiting, TPP Parties are required to provide statutory (pre-established) 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). Statutory damages must be "sufficient to compensate the right holder for the harm caused by the infringement, with a view to deterring future infringements."
- Article 18.74 elaborates on and makes mandatory many discretionary remedies from the TRIPS Agreement. Article 18.74 provides that judicial authorities must have the

authority to order payment of court costs, fees and appropriate attorney's fees in cases involving infringements of copyright and related rights, trademarks, and patents. Article 18.74 also makes clear the right of judicial authorities to order the seizure and destruction of infringing goods, implements and other materials.

- Article 18.74 extends the panoply of civil remedies to circumventing technological protection measures and tampering with rights management information including the use of statutory damages at the election of the right holder. Authority to order the destruction of devices is mandatory, an improvement over some earlier FTA formulations.
- Article 18.74.2 requires that judicial authorities have the power to order injunctive relief that conforms to Article 44 of TRIPS, including in particular to prevent infringing goods from "entering into the channels of commerce."
- With respect to patent infringement cases and the determination of damages in such cases, judicial authorities should consider the proportionate economic value of the patented invention.
- Article 18.74.15 requires Parties to give the judicial authorities the authority to impose measures on a party at whose request enforcement measure are taken as a result of the abuse of the enforcement procedures. The provision attempts to deter a party from abusing the procedures to wrongfully enjoin or restrain another party. The inclusion of this provision injects some balance in the enforcement procedures.

Provisional Measures

- Article 18.75 reflects the TRIPS requirement for *ex parte* provisional relief in civil cases and requires that such orders be issued "expeditiously." Quick *ex parte* search orders are critical to meaningful civil enforcement against infringements.
- Article 18.75.2 has a dual purpose. First, it builds upon TRIPS by providing that any security required of the plaintiff be "reasonable" and not "deter" recourse to these procedures (experience in many countries is that the right to require bonds and security has been abused). Second, the provision exists in order to protect the defendant who is the subject of the provisional measure.

Special Requirements Related to Border Measures

The provisions relating to enforcement at the border include improvements over the TRIPS text.

- This Article streamlines the border enforcement measures and clarifies and expands TRIPS border enforcement powers, providing owners of trademarks, copyrights and related rights with broader protection at the border than is expressly set out in TRIPS. In addition to border measures to stop counterfeits, trademark owners can seek protection against goods bearing confusingly similar marks. Article 18.76 states that right holders must provide sufficient information to identify goods to establish a *prima facie* case, but it attempts to limit the information that can be required by stating that the information should be reasonably expected to be in the right holder's knowledge. Moreover, the requirement to provide such information must not unreasonably deter recourse to these procedures. These are welcome clarifications. This Article also

provides that Parties may require right holders to provide a reasonable security, but that the amount of such security be reasonable and not unreasonably deter recourse to the procedures.

- Article 18.76 raises the border measures above the TRIPS minimum. As TRIPS does not expressly require that the competent authorities have *ex officio* enforcement authority, the requirement for such authority at the border is a welcome addition in that customs should have the authority to take action without a right holder complaint. Moreover, the Article requires that the competent authorities have authority to take action against imports, goods destined for exports, and goods in-transit.
- Article 18.76 improves upon TRIPS by requiring that Parties give its competent authorities the authority to provide right holders information once infringing goods have been seized.
- Article 18.76 recognizes that competent authorities should be able to take enforcement actions against small consignments of a commercial nature, distinguishing those from small quantities of goods of a non-commercial nature contained in travelers' personal luggage that may be exempt from border measures. In view of the growth in international commercial transactions involving small consignments imported through international mail facilities and express courier hubs, this provision should be included in all future FTAs in order to eliminate a loophole in enforcement.
- ITAC-15 members support the Article 18.76.5(c) obligation for TPP Parties to apply border measures to suspected infringing goods moving in-transit, which is consistent with recent FTAs. ITAC-15 hopes that all future FTAs will eliminate the possibility of trading partners opting out of border measures that apply to suspected infringing goods moving in-transit. ITAC-15 also believes that TPP Parties should exercise care regarding enforcement against goods moving in-transit in order to minimize any disruption to legitimate trade due to undue inspection delays or enforcement actions against goods that are in compliance with laws of the destination/country of importation.

Criminal Procedures and Remedies

- Article 18.77 again builds on the TRIPS provisions in this area. For the copyright or related rights and trademark industries, criminal remedies are key to reducing losses globally. The critical concept of piracy or counterfeiting “on a commercial scale” is clarified to include infringing acts without a profit-motive or commercial purpose but that “have a substantial prejudicial impact on the interests of the copyright or related rights owner in relation to the marketplace.”
- Article 18.77.2, in addition to requiring criminal penalties for the willful importation and exportation of counterfeit and pirate goods, subjects such goods in free trade zones to criminal penalties (Note 127), thereby eliminating FTZs as a safe haven for infringing activity.
- Article 18.77.5 provides an important and new requirement under FTA's requiring TPP Parties to provide criminal procedures and remedies for aiding and abetting infringement, which should prove to be very useful; however, some members of ITAC-15 hope for greater clarity in future FTAs in order to avoid possible misinterpretation of this provision.

- Article 18.77.6 seeks to reach one of the most serious problems for right holders globally—the failure of judges or other enforcement authorities to actually impose penalties at a real deterrent level. The text is more specific with respect to the remedies that must be available and includes reference to penalties being sufficiently high to provide a deterrent and consistent with “the level of penalties applied for crimes of corresponding gravity”.
- Article 18.77.6 also deals with the oft-encountered problem of the seizure by authorities of only products and implements named in a search order even though other clearly infringing products are at the search site. The provision also requires the seizure of implements used in committing an offense, and the seizure of assets and documentary evidence without qualification.
- Article 18.77.6.d raises the enforcement bar by requiring judicial authorities to have the authority to order forfeiture of assets derived from, or obtained through, the infringing activity.
- Article 18.77.4 requires each Party to have criminal procedures subjecting a person to criminal liability for unauthorized copying of a motion picture from a performance in a movie theatre. This provision, which was a key objective of the U.S. motion picture industry, is essential to combat the global piracy of motion pictures and audiovisual works.

Trade Secrets

ITAC-15 commends the negotiators for including specific provisions for trade secret protection in Article 18.78. This Article implements the obligations of Article 39.2 of the TRIPS Agreement, but is new to U.S. free trade agreements. It supplements existing FTA’s with the TPP Parties (Australia, for example) and represents an important precedent for future FTA negotiations. Furthermore, the explicit reference that this Article applies to state owned enterprises is helpful.

ITAC-15 notes that Article 18.78 has weaknesses due in part to the lack of sufficiently strong U.S. domestic law. Article 18.78.1 does not specify or contain any requirements for the “legal means” that must be provided to allow persons to prevent the unauthorized disclosure of their trade secret information. Similarly, Article 18.78.2 does not specify the severity of criminal penalties that should be imposed for the specific acts listed there. In addition, Article 18.78.3 allows the availability or severity of criminal penalties to be limited to specific circumstances that do not necessarily relate to the extent of the unauthorized disclosure or the harm to the possessor of the trade secrets. Consequently, a TPP Party could provide for legal means and limit criminal penalties in a manner that does not provide an effective deterrent to unauthorized disclosures of trade secrets.

The increased threats to government and commercially owned trade secrets warrant this provision in the TPP Agreement. ITAC-15 is concerned with the implementation of this provision in view of the weaknesses in its current form. ITAC-15 recommends that once the TPP Agreement is in effect, the U.S. government should encourage other TPP Parties to implement civil and criminal procedures and penalties that are sufficient to deter unauthorized disclosures of trade secrets. ITAC-15 encourages negotiators of future FTA’s to obtain stronger protection for trade secrets. ITAC-15 also encourages

negotiators to press 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.

Internet Service Providers: Legal Remedies and Safe Harbors

ITAC-15 supports the text in Article 18.82, though there are some differences of viewpoint on specific provisions.

Article 18.82 governs the issue of the liability, and limitations on the liability, of service providers that are involved in the hosting and transmission of infringing material over their facilities. ITAC-15 notes with approval that for the first time that we are aware of in an FTA, this section properly places any limitations on liability within the broader context of “facilitating the continuing development of legitimate online services operating as intermediaries,” and Article 41 of TRIPS which requires WTO members to ensure that enforcement procedures “are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.”

The TRIPS Article 41 context for consideration of limitations on liability has been a feature of prior FTA’s by reference to the need to ensure that any limitations do not impair effective action against acts of infringement, but we welcome the express reference to Article 41 of TRIPS. Similarly, the TPP for the first time explicitly requires FTA partners to provide “enforcement procedures that permit effective action by right holders against copyright infringement covered under this Chapter that occurs in the online environment.” This too is a welcome clarification, even if prior FTA’s were similarly intended.

This Section requires Parties to provide legal incentives for ISP’s to cooperate with copyright owners to deter the unauthorized storage and transmission of infringing materials. As ITAC reports for prior FTAs have noted, this language is an important part of the balance of an effective ISP liability/safe harbor regime.

TPP also introduces a concept previously unknown in TPA’s—namely that Parties may “take other action to deter the unauthorized storage and transmission of copyrighted materials,” thereby manifesting flexibility in additional measures Parties may choose to take to address online piracy and frame limitations on liability, subject to the overarching legal requirement that any system of incentives, measures and limitations on liability must permit effective action against online piracy. ITAC-15 believes that properly implemented, these new provisions will help ensure that the object of any system of limitations on liability is to safeguard responsible actors, foster cooperation, and ensure effective remedies and responses to infringement.

Article 18.82.8 contains the language from prior FTA’s that “the failure of an Internet Service Provider to qualify for the limitations in paragraph 1 does not by itself result in liability.” It also provides that the safe harbor “is without prejudice to the availability of other limitations and exceptions to copyright, or any other defenses under a Party’s legal

system.” This language is an important part of the balance of an effective ISP liability/safe harbor regime.

Article 18.82.1.b of this Section sets out the basic framework for limitations on liability for Internet service providers, requiring Parties to exempt certain ISP’s from monetary relief for copyright infringements that they “do not control, initiate or direct, and that take place through systems or networks controlled or operated by them or on their behalf.” Article 18.82.3 gives flexibility to TPP Parties to establish conditions that must be met for ISP’s to qualify for limitations on liability permitted under the Agreement, provided further that such conditions for limitations on liability with respect to storage or linking must, at a minimum, require ISP’s to “expeditiously remove or disable access to material residing on their networks or systems upon obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement is apparent.” This knowledge/red flag knowledge requirement is critical. A Party may not condition eligibility for limitations on liability under this Section on an ISP monitoring its service or affirmatively seeking facts indicating infringing activity. ITAC-15 takes note, however, that this provision only precludes Parties from conditioning safe harbors from monetary remedies on such affirmative acts, but does not constrain Parties in determining the proper scope of judicial relief in cases of infringement, or otherwise requiring the use of available tools to prevent infringement.

ITAC-15 is concerned, for a variety of reasons, that the TPP does not spell out the conditions for safe harbors as robustly as in KORUS and other FTA’s, but understands that multilateral agreements do not always admit of the same granularity. We do understand, however, that the TPP is designed to have the same or similar effect as prior FTA’s and expect USTR will work to ensure this outcome during implementation. We also express our concerns with Footnote 154 and Annex 18-E which set out detailed requirements for alternative arrangements. While we support the requirement set out in 18-E.1.b, and believe that it should form a part of the core substantive text of any future FTA—namely, that FTA’s should require Parties to establish liability for services that are designed or operated for the purpose of enabling infringement, we do not support the notion that this should serve as an alternative to other conditions on limitations on liability. In a similar vein, while we support appropriately structured “notice plus notice” regimes, they are an adjunct to notice and takedown, not a substitute for it.

Finally, we take note of another new provision contained in Paragraph 9—namely that Parties “recognize the importance, in implementing their obligations under this Article, of taking into account the impacts on rights holders and Internet Service Providers.” This is a very important principle that properly takes account of the fact that technological changes may require constant readjustments of the structure of incentives established under national law, bearing in mind the objectives of enhancing tools to address online infringement and to protect responsible Internet service providers from facing liability for monetary relief. Reasonable cooperation between copyright owners on the one hand and Internet service providers on the other may take quite a different form in ten years from what it looks like today, and this provision reminds TPP Parties to examine relative impacts on the key players as they seek to enhance legitimate online commerce and incentivize reasonable cooperation in addressing infringement.

Final Provisions

ITAC-15 is very pleased that for the most part, TPP Parties shall give effect to their obligations under the Agreement as of the date of entry into force. There are of course some unfortunate exceptions, including Mexico with respect to ISP liability; New Zealand with its highly detailed and byzantine provisions related to term of protection for copyright and related rights; and Vietnam for a variety of obligations, including camcording.

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