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International Trade Committee

Joint Trade/IP/Investment Panel

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Subject Matter Discussion Draft Outline

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- **IPBA Trade Committee Framework for Panel(s) Discussion:**

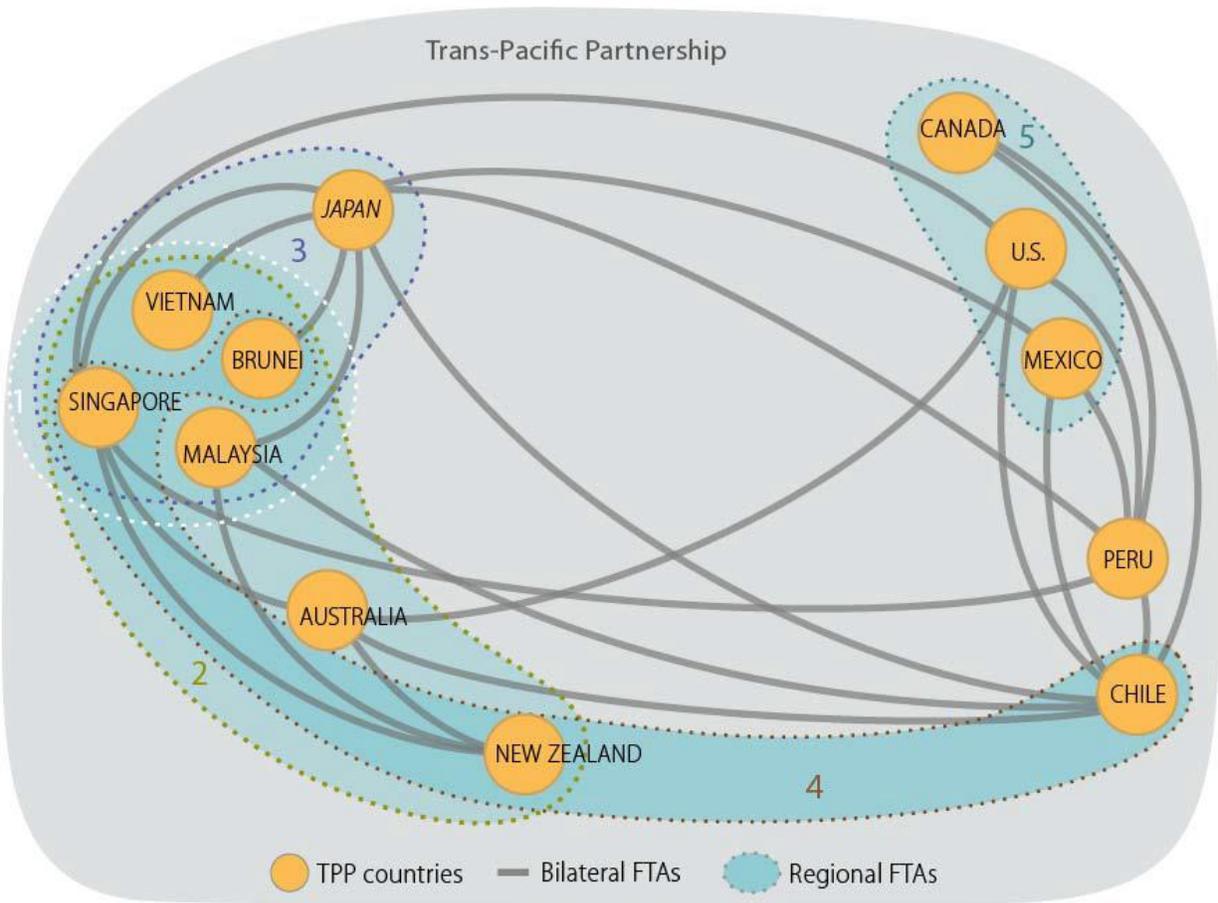
With IP - Sustainable Intellectual Property Rights in a Trans-Pacific Partnership World –

As the negotiations in the **Trans-Pacific Partnership (TPP)** progress, the **intellectual property provisions** being adopted are intended to bring greater harmonization between the IP laws of the various signatory countries. Such provisions are foreseen as **going beyond the harmonization already adopted under WIPO and the TRIPS agreement**. However, **some of those TPP provisions upon ratification in the individual countries may in turn have unintended consequences that could be inconsistent with or worse contrary to the current practices or traditions of certain signatory countries**. This panel session will explore the potential effects of the IP provisions in the TPP on various country jurisdictions with respect to each of the various types of intellectual property, namely patents, trademarks, copyrights and trade secrets. Among the issues that will be raised will be **whether the harmonization intended by the IP provisions of TPP can result in a sustainable IP regime consistent with the commercial, economic, health and environmental needs of the individual signatory countries**.

I. Overview/Background:

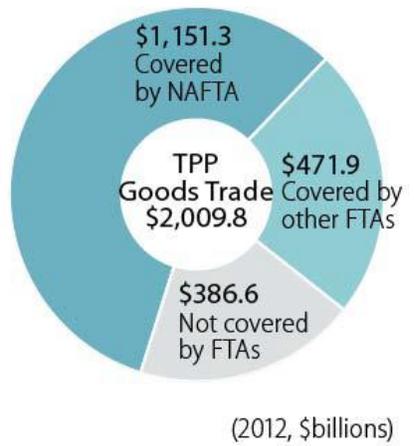
There are currently 12 TPP negotiating Parties, including the United States - Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. TPP Parties have bilateral and regional Free Trade Agreements (“FTAs”) in effect with other TPP negotiating partners, and are in the process of negotiating FTAs with other TPP Parties. The resulting ‘spaghetti bowl’ of agreements¹ appears as follows:

¹ See Ian F. Fergusson, William H. Cooper, Remy Jurenas, and Brock R. Williams, *The Trans-Pacific Partnership Negotiations and Issues For Congress*, Congressional Research Service Report R42694 (Aug. 21, 2013), at Figure 2, available at: <http://www.fas.org/sgp/crs/row/R42694.pdf>.



Encompassed Regional Trade Agreements

	1 ASEAN	2 ASEAN- Australia-NZ	3 ASEAN- Japan	4 P-4	5 NAFTA
Australia		●			
Brunei	●	●	●	●	
Canada					●
Chile				●	
Japan			●		
Malaysia	●	●	●		
Mexico					●
New Zealand		●		●	
Peru				●	
Singapore	●	●	●	●	
United States					●
Vietnam	●	●	●		



- U.S. - has FTAs with Australia, Canada, Chile, Mexico, Peru, and Singapore;
- Australia - has FTAs with Chile, Malaysia, New Zealand, Singapore, the U.S. and ANZ-ASEAN, and is currently negotiating FTAs with Japan;²
- New Zealand has FTAs with Australia, Malaysia and ANZ-ASEAN;³
- Canada has FTAs with Chile, Peru and the U.S., and is currently negotiating FTAs with Japan and Singapore;⁴
- Singapore has FTAs with Australia, Japan, New Zealand, Peru, U.S., ANZ-ASEAN and ASEAN, and is currently negotiating FTAs with Canada and Mexico;⁵
- Mexico has FTAs with Chile, Japan, Peru and the U.S., and has Investment and Promotion Agreements in place with Australia and Japan;⁶
- Chile has FTAs with Australia, Japan, Malaysia, Mexico, Peru, and the U.S.;⁷
- Japan has FTAs with Brunei Darussalam, Chile, Malaysia, Mexico, Singapore, Vietnam and ASEAN, and is currently negotiating an FTA with Canada;⁸
- Malaysia has FTAs with Australia, Chile, Japan, New Zealand, and ANZ-ASEAN;⁹
- Brunei Darussalam has FTAs with Japan, ANZ-ASEAN and ASEAN;¹⁰
- Peru has FTAs with Japan, Singapore and the U.S.;¹¹
- Vietnam has FTAs with Japan, ASEAN-Japan, ANZ-ASEAN and ASEAN.¹²

Furthermore, current TPP Parties include 4/10 members of the Association of Southeast Asian Nations (“ASEAN”) – Brunei Darussalam, Malaysia, Singapore, and Vietnam.¹³ And, ALL

² See Australian Government, *Australia’s Trade Agreements*, available at: <http://www.dfat.gov.au/fta/>.

³ See New Zealand Ministry of Foreign Affairs and Trade, *Trade Relationships and Agreements*, available at: <http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/index.php>.

⁴ See Government of Canada, Foreign Affairs, Trade and Development Canada, *Negotiations and Agreements*, available at: <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/fta-ale.aspx?lang=eng>.

⁵ See Singapore Government, *Singapore’s FTA Network: Expanding Markets, Connecting Partners*, available at: <http://www.fta.gov.sg/>.

⁶ See Government of Mexico, Secretary of the Economy, *International Trade Negotiations*, available at: <http://www.economia.gob.mx/trade-and-investment/foreign-trade/international-trade-negotiations>.

⁷ See Organization of American States, SICE – Foreign Trade Information System, *Trade Agreements in Force*, available at: http://www.sice.oas.org/agreements_e.asp.

⁸ See Government of Japan, Ministry of Foreign Affairs of Japan, *Free Trade Agreement (FTA) and Economic Partnership Agreement (EPA)*, available at: <http://www.mofa.go.jp/policy/economy/fta/index.html>.

⁹ See Government of Malaysia, Ministry of International Trade and Industry, *Free Trade Agreement – Malaysia’s FTA Involvement*, available at: http://www.miti.gov.my/cms/content.jsp?id=com.tms.cms.section.Section_8ab55693-7f000010-72f772f7-46d4f042.

¹⁰ See Government of Brunei Darussalam, Ministry of Foreign Affairs and Trade, *Brunei Darussalam’s FTA Policy*, available at: <http://www.mofat.gov.bn/index.php/free-trade-agreements-ftas/brunei-darussalam-s-fta-policy>.

¹¹ See Organization of American States, SICE – Foreign Trade Information System, *Trade Agreements in Force*, supra.

¹² See Socialist Republic of Vietnam, Ministry of Industry and Trade, *Free Trade Agreements*, available at: <http://webtr.vecita.gov.vn/>.

¹³ See Association of Southeast Asian Nations, *ASEAN Member States*, available at: <http://www.asean.org/asean/asean-member-states>.

current TPP Parties are members of the 21-country Asia-Pacific Economic Cooperation (“APEC”).¹⁴

Moreover, TPP Parties have entered into a number of bilateral investment treaties (“BITs”) with other TPP negotiating Parties, as follows:

- Australia has entered into BITs with Chile, Peru and Vietnam, but has signed but not ratified a BIT with New Zealand;¹⁵
- Canada has entered into BITs with Peru and Singapore;¹⁶
- Chile has entered into BITs with Australia, Malaysia and Peru, and has signed but not ratified BITs with New Zealand and Vietnam;¹⁷
- Japan has entered into BITs with Peru and Vietnam;¹⁸
- Malaysia has entered into BITs with Chile, Peru and Vietnam;¹⁹
- Mexico has entered into BITs with Australia and Singapore;²⁰
- New Zealand has signed but not ratified BITs with Australia and Chile;²¹
- Peru has entered into BITs with Australia, Canada, Chile, Japan, and Malaysia, and has signed but not ratified a BIT with Singapore;²²
- Singapore has entered into BITs with Canada and Mexico;²³
- Vietnam has entered into BITs with Australia, Japan, Malaysia and Singapore, but has signed and not ratified a BIT with Chile;²⁴
- The U.S. “typically includes investment provisions in its FTAs, as with each of the six existing FTAs between the United States and TPP participants.”²⁵

¹⁴ See Asia-Pacific Economic Cooperation, About APEC-Member Economies, available at: <http://www.apec.org/about-us/about-apec/member-economies.aspx>.

¹⁵ See United Nations Conference on Trade and Development, *Australia - Full List of Bilateral Investment Agreements Concluded 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_australia.pdf.

¹⁶ See United Nations Conference on Trade and Development, *Canada - Full List of Bilateral Investment Agreements Concluded 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_canada.pdf.

¹⁷ See United Nations Conference on Trade and Development, *Chile - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_chile.pdf.

¹⁸ See United Nations Conference on Trade and Development, *Japan - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_japan.pdf.

¹⁹ See United Nations Conference on Trade and Development, *Malaysia - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_malaysia.pdf.

²⁰ See United Nations Conference on Trade and Development, *Mexico - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_mexico.pdf.

²¹ See United Nations Conference on Trade and Development, *New Zealand - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_new_zealand.pdf.

²² See United Nations Conference on Trade and Development, *Peru - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_peru.pdf.

²³ See United Nations Conference on Trade and Development, *Singapore - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_singapore.pdf.

²⁴ See United Nations Conference on Trade and Development, *Vietnam - Full list of Bilateral Investment Agreements concluded, 1 June 2013*, available at: http://unctad.org/Sections/dite_pcbb/docs/bits_vietnam.pdf.

²⁵ See Brock R. Williams, *Trans-Pacific Partnership (TPP) Countries: Comparative Trade and Economic Analysis*, Congressional Research Service Report R42344 (June 10, 2013) at p. 12, available at: <http://www.fas.org/sgp/crs/row/R42344.pdf>.

The proposed TPP seeks to build on the existing Trans-Pacific Strategic Economic Partnership (P-4), a free trade area among Brunei, Chile, New Zealand, and Singapore (not rising to the level of an FTA).

The IP chapter of the TPP has been quite controversial given its adherence to the USTR's previously expressed trade negotiating objectives incorporated into the last US trade promotion authority legislation passed by Congress. P.L. 107-210 (The Trade Act of 2002)²⁶ covered the five-year period spanning 2002-2007. These objectives included seeking:

- Accelerated implementation of the WTO TRIPS Agreement's enforcement provisions;²⁷
- Strong enforcement of IP rights, including through accessible, expeditious and effective civil, administrative and criminal enforcement mechanisms;²⁸
- Assurance that trade negotiations “reflect a standard of protection similar to that found in U.S. law”,²⁹ which objectives have since largely tracked the terms of the US-Korea FTA, which many governments and activists now refer to as “TRIPS-plus” standards;³⁰
- Application of existing IPR protection to digital media;³¹
- Strong protection for new and emerging technologies and new methods of transmitting and distributing IP-embodied products;³² and
- Respect for the Declaration on the TRIPS Agreement and Public Health.³³

Given the lack of transparency surrounding TPP negotiations since the U.S. formally joined them in 2008, several nongovernmental interest/activist groups have obtained, critiqued and posted on the web leaked copies of TPP Party negotiating texts. Such leaked texts, including those of the Government of New Zealand (Dec. 4, 2010³⁴) and the USTR (February 2011³⁵) and September 2011³⁶), have thus far reflected USTR's TRIPS+ objectives, which have triggered government

²⁶ See Public Law 107-210, *An Act to extend the Andean Trade Preference Act, to grant additional trade benefits under that Act, and for other purposes (“Trade Act of 2002”)*, § 2102, 116 Stat. 933, 995–996 (codified at 19 U.S.C. § 3802) available at: <http://www.gpo.gov/fdsys/pkg/PLAW-107publ210/html/PLAW-107publ210.htm>.

²⁷ Sec. 2102(b)(4)(A)(i)(I).

²⁸ Sec. 2102(b)(4)(A)(v).

²⁹ This negotiating objective, alone, has triggered protestations from legal academics and nongovernmental activist groups. See e.g., Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105, 106-107, available at: <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1775&context=auilr>

³⁰ P.L. 107-201, Sec. 2102(b)(4)(A)(i)(II).

³¹ Sec 2012(b)(4)(A)(iv).

³² Sec. 2102(b)(4)(A)(ii).

³³ Sec. 2102(b)(4)(C).

³⁴ See New Zealand, *Proposed Text for an Intellectual Property Chapter* <http://infojustice.org/download/tpp/tpp-texts/New%20Zealand%20Proposal%20for%20Intellectual%20Property%20Chapter.%20February%202011.pdf>.

³⁵ See United States, *Proposed Text for an Intellectual Property Chapter* at: <http://infojustice.org/download/tpp/tpp-texts/tpp%20IP%20chapter%20feb%20leak.pdf>.

³⁶ See United States, *Proposed Text on IP and Medicines*, at: <http://infojustice.org/download/tpp/tpp-texts/U.S.%20Proposed%20Text%20on%20IP%20and%20Medicines.%20dated%20September%202011.%20leakd%20October%202011.pdf>.

(e.g., Vietnam³⁷) and civil society stakeholder objections that have slowed down TPP negotiations.

The leaked TPP IP Chapter negotiating texts reveal that the TPP largely follows the terms of the Korea-U.S. Free Trade Agreement (“KORUS”),³⁸ the provisions of the Anti-Counterfeiting Trade Agreement (ACTA)³⁹ not yet in force, and the US Digital Millennium Copyright Act (DMCA).⁴⁰ Certain legal/academic commentators have alleged that, if successful, U.S. efforts to establish a TRIP+ TPP framework would impose an unbalanced view of IP rights throughout the Asia region which would adversely affect competing industries in other TPP Parties, the “public interest”, both in the U.S. and such TPP Parties, and would also severely impair access to health, information and technology in developing countries.

“Our ultimate conclusion is that the U.S. proposal, if adopted, would upset the current international framework balancing the interests of rights holders and the public. It would heighten standards of protection for rights holders well beyond that which the best available evidence or inclusive democratic processes support.[fn] It contains insufficient balancing provisions for users, consumers, and the public interest.[fn] The provisions would be particularly harmful for developing countries, where the risks and effects of exclusionary pricing by intellectual property monopolists are often most acute.[fn] The general thrust of the proposal conflicts with the ‘development agenda’ being debated in WIPO, which has a much stronger focus on the harmonization of limitations and flexibilities in international intellectual property law. The proposal also conflicts with the overwhelming trend in multilateral institutions toward protection of TRIPS flexibilities for developing countries to promote access to affordable medications.[fn] The proposal would make these changes in the context of a new and powerful dispute resolution system that would greatly expand the standing, venue, and causes of action that could be used to challenge domestic policies, including through actions by corporations directly against states.[fn]”⁴¹

II. Substantive Outline of Law & Policy Issues – Intellectual Property Chapter:

³⁷ See Hoang Phi, *Intellectual property a hindrance in TPP negotiations*, Saigon Times (Sept. 11, 2013), available at: <http://english.thesaigontimes.vn/Home/business/other/30978/Intellectual-property-a-hindrance-in-TPP-negotiations.html>.

³⁸ See Office of the United States Trade Representative, *Korea-U.S. Free Trade Agreement*, at: http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf.

³⁹ See Government of Japan, *Final Text of the Anti-Counterfeiting Trade Agreement* (May 2011), available at: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf; Government of Japan, *Joint Press Statement of the Anti-Counterfeiting Trade Agreement Negotiating Parties*, Press Release (Oct. 2011), available at: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1110.pdf.

⁴⁰ See Public Law 105–30, *Digital Millennium Copyright Act*, available at: <http://www.copyright.gov/legislation/pl105-304.pdf>.

⁴¹ See Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105, 119-120.

The leaked and critiqued TPP Intellectual Property Chapter negotiating texts address a number of substantive matters, including: copyright and related rights; patents; trade secrets; trademarks; civil and criminal enforcement. All TPP article references are to proposed TPP articles as revealed in the leaked texts of the proposed TPP Intellectual Property chapter.

1. ***Copyright and Related Rights***

a. TPP Art 4.1 – Right to Preclude Unauthorized Reproductions of Work – Commentators observe that this provision is identical to KORUS Art. 18.4.1 and resembles exclusive rights provided under US Copyright Act Sec. 106(1).⁴² However, since it prohibits unauthorized reproduction of “permanent or temporary including temporary storage in electronic form”, questions remain concerning what may be considered an unauthorized “copy” of a copyrighted work.

b. TPP Art. 4.5 – Term of Copyright – Commentators observe that while this provision resembles US Copyright Act Sec. 302, it sets the “life of the author and 70 years after the author’s death” as a minimum level of protection rather than as the standard. It has also been alleged that this provision’s addressing of the presumption of author death standard and the author’s failure to publish within 25 years of creating the work, closely resemble KORUS Art. 18.4.4.⁴³

c. TPP Art. 4.9(a) – Legal Protections for Circumvention of Technological Measures to Control Access to Works – Commentators observe that this provision closely resembles provisions found in the Anti-Counterfeiting Trade Agreement (ACTA), KORUS and the US Digital Millennium Copyright Act (DMCA). It also resembles KORUS Art. 18.4.7, but does not limit violation to ‘knowingly or having reasonable grounds to know’ – rather, goes beyond said language to resemble ACTA Art. 27.5. It also closely resembles DMCA Sec. 1201(a) and ACTA Art. 27.6, but applies to “any” effective technological measure. Unlike ACTA Art. 27.6, circumvention does not have to be carried out knowingly or with reasonable grounds to know that it will result in infringing activity. TPP Art 4.9 alleged to go beyond ACTA Art. 27.6 which covers only offering to the public. Allegedly, any act undertaken “for the purpose of circumvention of any effective technological measure” could be deemed infringing, not merely “use in circumventing under DMCA Sec. 1201(a) or “as means of circumventing under ACTA Art. 27.6(a) Other language goes beyond DMCA and ACTA.⁴⁴

⁴² See Jimmy Koo, *Trans-Pacific Partnership – Intellectual Property Rights Chapter February Draft – Section by Section Analysis* American University Washington College of Law Program on Information Justice and Intellectual Property (2011), at p. 10, available at: <http://infojustice.org/wp-content/uploads/2011/04/Koo-TPP-Section-by-Section-Analysis-April-2011.pdf>.

⁴³ *Id.*, at pp. 11-13.

⁴⁴ *Id.*, at pp. 14-16.

d. TPP Art. 4.9(d) – Exceptions to Implementing Legal Protections for Circumvention of Technological Measures to Control Access to Works – This provision directly reflects various exceptions and limitations in DMCA Sec. 1201, including ‘reverse engineering’, ‘encryption research’, ‘protection of minors’, ‘protection of personally identify information’, ‘government activities’ and ‘library’ exceptions.⁴⁵

e. TPP Art. 4.10 – How to Protect Rights Management Information – Commentators observe that this provision closely resembles substantively KORUS Art. 18.4.8, ACTA Art. 27.7 and DMCA Sec. 1202, except that no “knowing and intentional” infringement is required. While DMCA Sec. 1202(b)(7) prohibits a person from ‘distributing, importing for distribution, or publicly performing’, TPP alleged to go beyond DMCA by also prohibiting a person from ‘broadcasting, communicating or making available to the public’. TPP consists of civil remedies of DMCA Sec. 1203 combined with criminal procedures of DMCA Sec. 1204. TPP Art. 4.10(b)’s definition of ‘rights management information’, while identical to KORUS Art. 18.4.8(c), is broader than DMCA Sec. 1202(c).⁴⁶

f. TPP Art. 6 – Rights to Producers and Performers of Phonograms – Commentators observe that this provision incorporates various provisions from the WIPO Performances and Phonograms Treaty (WPPT) and KORUS Art. 18.6. However, it goes beyond same by adding that a performance or phonogram shall be considered first published in a Party’s territory within 30 days of its original publication there, and limits the WPPT’s definition of ‘broadcasting’ by excluding transmissions over computer networks and transmissions the time and place of which can be individually chosen by members of the public.⁴⁷

g. The Three-Step Test Circumscribing Copyright Limitations and Exceptions - During the San Diego Round of TPP negotiations that took place during July 2012, USTR proposed certain limitations on/exceptions to copyrights consistent with a ‘three-step test’. The exception must: 1) be consistent with domestic copyright law; 2) not conflict with the normal exploitation of the work; 3) not unreasonably prejudice the interest of the rights holder; and 4) be incorporated into domestic copyright law.⁴⁸

h) NGO Protestations - There are claims that treaty text would require significant changes in U.S. and/or other signatory’s copyright law.⁴⁹ For example, commentators have alleged that:

⁴⁵ Id., at pp. 17-18.

⁴⁶ Id., at pp. 19-20.

⁴⁷ Id., at pp. 21-22.

⁴⁸ CRS Report for Congress at p. 36.

⁴⁹ See David S. Levine, *The Most Important Trade Agreement That We Know Nothing About*, Slate (July 30, 2012), available at:

- i) the TPP “would force...adoption of the US DMCA Internet intermediaries copyright safe harbor regime”, thereby requiring countries such as Chile to rewrite their 2010 copyright law “that currently establishes a judicial notice-and-takedown regime which provides greater protection to Internet users’ expression and privacy than the DMCA.”⁵⁰
- ii) the TPP would “[t]reat temporary reproductions of copyrighted works [as found in temporary copies of programs found in computer files] without copyright holders’ authorization as copyright infringement”, expand copyright terms beyond the author’s life + 50 years term contained in TRIPS to author’s life + 70 years for individuals’ creations and to either 95 years after publication or 120 years after creation for corporate-owned works,⁵¹
- iii) the USTR’s three-step test would allegedly place ‘fair use’ at risk, and that TPP would “compel signatory nations to enact laws banning circumvention digital locks (technological protection measures or TPMs) that mirror the DMCA and treat violation of the TPM provisions as a separate offense even when no copyright infringement is involved.”⁵²

2. *Patents*

- a. TPP Art. 8.1 – Patentability – TPP expands KORUS Art. 18.8.1 which it closely resembles by adding that “any new forms, uses, or methods of using a known product” [and any] “new form, use or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.” Commentators have observed that such terminology “significantly lowers the standard of patentability for ‘new forms, uses, or methods of using a known product.’”⁵³
- b. TPP Art. 8.2 – Patentability of Life Forms – Unlike TRIPS Art. 27.3, which *permits* WTO Members to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals...plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”, TPP Art 8.2 obligates Parties to make patents available for such life

http://www.slate.com/articles/technology/future_tense/2012/07/trans_pacific_partnership_agreement_tpp_could_radically_alter_intellectual_property_law.html. “The owner of the copyright in a song or movie could use a “technological protection measure”—what are often called “digital locks”—to prevent your access to it, even for educational purposes, and regardless of whether the owner had the legal right to do so. Your very ability to read this article, with hyperlinks in it, could be affected by TPP. So, too, might your access to works currently in the public domain and available free of charge.” *Id.* See also Electronic Frontier Foundation, *Trans Pacific Partnership Agreement*, at:

⁵⁰ See Electronic Frontier Foundation, *Trans Pacific Partnership Agreement*, at: <https://www.eff.org/issues/tpp>.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*, at p. 23.

forms, methods and processes. TPP Art. 8.2 goes beyond even KORUS Art. 18.8.2, which goes beyond TRIPS Art. 27.3 by preventing exclusion of plants and animals from patentability. TPP Art. 8.2, also prevents Parties from excluding from patentability “diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals.”⁵⁴

c. TPP Art. 9 – Measures Related to Certain Regulated Products – Considerable debate continues over the IP protections to be accorded pharmaceuticals while ensuring access to medicines. In particular there is disagreement over whether the more IPR-protective provisions of KORUS should be adopted instead of “the somewhat looser ‘May 10th Agreement’ provisions the U.S. agreed to in the Colombia, Peru and Panama” US-FTAs. The May 10th Agreement relaxed provisions on patent term extensions, patent linkages and data exclusivity. In other words, difference of opinion remains among Parties concerning whether there should be different IPR standards for developed and developing country TPP Parties with respect to pharmaceuticals.

i. **USTR’s “TEAM” Proposal** - USTR tabled its proposal (“Trade Enhancing Access to Medicines” (TEAM)) at the September 2011 round of TPP negotiations in Chicago. It “reportedly would encourage companies to market innovations in TPP markets more quickly by making stronger patent term extensions, data exclusivity and patent linkage provision available to firms who apply for marketing approval for their products through a ‘TPP Access Window.’”⁵⁵ If pharma companies bring their drugs to market within this TPP Access Window, they would be entitled to “a KORUS standard of five years of data exclusivity, mandatory patent linkage and patent term extension provisions”. This would arguably undermine the May 10th Agreement commitments “that capped data exclusivity at five years *from US market approval*, had *optional* patent linkage and patent term extension provisions” (emphasis added).⁵⁶ USTR has represented that this would “allow for expedited introduction of generic medicines.”⁵⁷

USTR’s TEAM proposal incorporating a TPP Access Window has proved controversial and “text-based negotiations concerning pharmaceutical IPR reportedly have not occurred since the Melbourne round in March

⁵⁴ Id., at p. 24.

⁵⁵ CRS Report at pp. 36-37.

⁵⁶ Id., at p. 37.

⁵⁷ Id., citing USTR, *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, Whitepaper, available at: http://www.ustr.gov/webfm_send/3059. “[A] a ‘TPP access window’ [would p]romote the availability of life-saving and life-enhancing medicines in TPP markets and simultaneously establish a pathway for generics to enter those markets as quickly as possible by conditioning obligations to apply certain pharmaceutical-specific intellectual property protections on the requirement that innovators bring medicines to TPP markets within an agreed window of time.” Id., at p. 1.

2012.”⁵⁸ “The U.S. proposal, which focuses on the concept of an ‘access window,’ has been roundly rejected by many TPP partners. In response, the U.S. is now in a period of reviewing its proposal, and stakeholders are eager whether and how the U.S. opts to alter its proposal to make it more palatable to other TPP members.”⁵⁹ For example, “Peru, which ha[d] the ability to set the agenda for the May [2013] round [of negotiations], ha[d] refused to allow a discussion on a revised U.S. proposal at that round, and want[ed] to stick only to information exchange on this topic.”⁶⁰ More recently, “Peru publicly...indicated that it will not agree to proposed IPR provisions that go beyond the May 10, 2007 provisions that are enshrined in the U.S.- Peru FTA.”⁶¹

ii. **PhRMA Access Window Study** - PhRMA is alleged to have released a study calling for a six year [TPP Access Window] period,⁶² but has not generally expressed accord with the USTR Access Window objectives. The PhRMA study evaluated “896 marketing approval filings by large pharmaceutical companies in 15 emerging economies between 2000 and 2010 (Argentina, Brazil, China, Egypt, India, Indonesia, Malaysia, Mexico, Russia, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, and Turkey)”. It has been alleged that pharmaceutical companies’ delays in applying for marketing approval were based on various reasons including “country-specific regulatory reasons (presumably idiosyncratic registration procedures and practices), product-

⁵⁸ Id., at p. 38, citing *TPP Countries Slowly Restart Formal Talks On Pharmaceutical IP Protections*, Inside U.S. Trade, (March 15, 2013), available at: http://www.eatg.org/news/167875/TPP_countries_slowly_restart_formal_talks_on_pharmaceutical_ip_protections. (“After roughly a year hiatus, countries participating in the Trans-Pacific Partnership (TPP) talks here restarted formal 11-party talks on pharmaceutical intellectual property rights (IPR), although the nature of that conversation was fairly basic.”). Id.

⁵⁹ See *TPP Countries Slowly Restart Formal Talks On Pharmaceutical IP Protections*, Inside U.S. Trade, (March 15, 2013), supra. See also James Politi, Drug Groups Set for TPP Trade Clash, Financial Times (July 21, 2013), available at: <http://www.ft.com/intl/cms/s/0/606fcb32-efc7-11e2-8229-00144feabdc0.html#axzz2hQQZVIKz> (“The US tried to bridge the gap in the pharmaceutical debate two years ago with a plan that sought to establish a ‘TPP access window’, which would give greater legal certainty for generic manufacturers, and reduce customs obstacles and duties on medicines. But other TPP countries rebuffed the plan, with the poorest such as Vietnam seen to be most adversely affected. This issue is under discussion in Malaysia but the US has not submitted a revised offer.”). Id.

⁶⁰ Id.

⁶¹ CRS Report at p. 38. See also *Minister Silva: Do not Negotiate More About Intellectual Property in the FTA with U.S.*, La Republica (June 12, 2013) (english translation), available at: <http://www.larepublica.pe/12-06-2013/ministro-silva-no-se-negociara-mas-alla-de-lo-establecido-en-el-tlc-con-eeuu> (“The Ministry of Foreign Trade and Tourism (Mincetur) said today that there will be no more negotiations of those it has with the United States on the issue of intellectual property within the Free Trade Agreement (FTA) that you have with that country. This, after a group of organizations alerted that within the Trans-Pacific Partnership Agreement (TPP for its acronym in English), the United States wanted to tighten some rules that had already signed with Peru in that trade agreement, particularly on the issue of drugs and patents.”). Id.

⁶² Id., citing *USTR Plan to Table Full TPP IPR Proposal Spurs Pharmaceutical Lobbying*, Inside U.S. Trade, April 28, 2011.

specific characteristics (including the need to carry out additional clinical trials), and most importantly commercial considerations (including not having distribution systems for launching a product, low patient numbers or low purchasing power, and the like).”⁶³

iii. **NGO Protestations of Access Window** - Access to medicine activists have argued that PhRMA should have “propose[d] a 2-year window, which would have been sufficient...This long period of delay is even more unconscionable when taking into account that the US proposal on the access window allows applicants to initiate requests for marketing approval based on ‘any information available to the applicant,’ including evidence of prior approval of the product in another Party (country) (Art. 9.8(a)).”⁶⁴ There is also the “possibility of initiating requests for marketing approval without a complete dossier, [which] blows apart another excuse drug companies have used to justified delayed registration, namely the need to conduct in-country clinical trials. Companies can initiate applications and still proceed with the small clinical trials that are required in only a handful of countries.”⁶⁵ “PhRMA prefers to seek marketing approval when it is poised to exploit a [developed country] market and maximize its monopoly profits...[As a result, p]atients in poorer and smaller countries wait the longest for life-saving and life-enhancing medicines.”⁶⁶ In addition, activists have thus argued that a TPP Access Window “would delay the introduction of generic medicines” by putting “forth the fundamentally flawed premise that speeding up market entrance of brand-name monopoly-priced drugs will, in itself, solve the challenge of access to affordable medicines.”⁶⁷

iv. **USTR’s Non-Proposal on Biologics** - USTR has not tabled a proposal regarding the term of data protection for biologics. The US biotech industry has called for a 12-year data exclusivity provision, consistent with the Biologics Price Competition and Innovation Act of 2010 (“BPCIA”) (which is part of the 2010 Affordable Care Act). The industry argued that a 12-year data exclusivity period is justified because “the development and approval process[es] for large molecule biologics – as opposed to small molecule pharmaceuticals – are more complex and require longer exclusivity periods for a product to be commercially viable...It is not clear whether biologics will be dealt with separately

⁶³ See Brook Baker, *PhRMA's Sham Charm Campaign on TPP Access Window*, Essentialdrugs.org (May 7, 2012), available at: <http://www.essentialdrugs.org/edrug/archive/201205/msg00015.php>.

⁶⁴ Id.

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ CRS Report, at p. 37, citing Judit Rius Sanjuan, *Trans-Pacific Talks Move Forward at Chicago Meeting*, Bridges Weekly Trade News Digest (Sept. 21, 2011), available at: <http://ictsd.org/i/news/bridgesweekly/114215/>. See also

under the TPP,”⁶⁸ especially considering the opposing positions that various members of Congress have on the matter.⁶⁹

d. TPP Art. 9.5 - Patent Linkage Provisions - Consistent with many U.S. FTAs (including KORUS), the leaked U.S. TPP negotiating text for IPRs provides in Art. 9.5 for a U.S.-style patent registration linkage provision. WTO TRIPS does not contain such a provision; nor do the laws of some TPP negotiating countries, including Vietnam⁷⁰ and Malaysia.⁷¹ TPP Art. 9.5 would obligate TPP Parties to investigate and confirm that a generic drug seeking marketing approval does not infringe an existing patent claim. If a patent claim exists, the regulatory authority would have to deny marketing approval for that generic product until the patent term expires.

i. **Patent Linkage Concept** - The concept of patent linkage “refers to requirements that safety and efficacy marketing authorities (e.g., the U.S. Food and Drug Administration) do not register generic copies of medicines for which there is a patent claimed by another supplier...It permits them to use patent claims to block the marketing of products without the need to sue the alleged infringer in courts to enforce the patent rights. Generics will then be required to challenge the patent claims in court and wait until the completion of the challenge (for each claim) in order to reach the market, which may take many years.”⁷² Patent linkage

⁶⁸ CRS Report at p. 38. See also Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, 6 Global Trade and Customs Journal, Issues 11-2 at pp. 513, 536-538, available at: [http://www.itssd.org/GTCJ_6\(1112\)_Lawrence%20A%20Kogan%20-%20FINAL.pdf](http://www.itssd.org/GTCJ_6(1112)_Lawrence%20A%20Kogan%20-%20FINAL.pdf); BIO, *The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics* (July 2013), available at: http://www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf (“The existing standards found in agreements between the United States and its trading partners provide a good foundation to build upon, but must be updated to reflect the realities and challenges facing developers of new biological products. In particular, given the challenges of securing broad patent rights that can cover variations of an innovative biological product, and the need to ensure that investors see the potential to secure commercial success of these products, a period of data protection of not less than 12 years of duration is necessary. That was the period that the U.S. Congress found to be the minimum necessary to provide continued incentives to the biotechnology industry, and the investment communities upon which that industry depend, to develop new biological products.”) Id., at p. 38.

⁶⁹ See Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, 6 Global Trade and Customs Journal, Issues 11-2 at pp. 536-537.

⁷⁰ See Public Citizen, *Vietnam and the Trans-Pacific Partnership Agreement: Access to Medicines Risks for a PEPFAR Partner* (2011), available at: <http://www.citizen.org/documents/Vietnam-and-the-Trans-Pacific-Partnership-Agreement.pdf> (“The Vietnamese law contains no provision that links the patent system to the drug marketing approval process.”) Id., at p. 4.

⁷¹ See Burcu Kilic and Peter Maybarduk, *Dangers for Access to Medicines in the Trans-Pacific Free Trade Agreement: Comparative Analysis of the U.S. Intellectual Property Proposal and Malaysian Law*, Public Citizen (Sept. 2011), available at: <http://www.citizen.org/documents/Malaysia-chart.pdf> (“The Malaysian law contains no provision that links the patent system to marketing approval process.”) Id., at p. 11.

⁷² See Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105, 179-180, supra.

effectively “shifts burdens of early patent enforcement to drug regulatory authorities”, and “could interfere with the marketing of generics produced pursuant to a compulsory license or to meet a public health need.”⁷³ Legal commentators have argued that, “[l]inkage systems might interfere with the effective use of compulsory licenses...because licensees could be prevented from marketing their generic equivalents after receiving a license on some patent claims, by virtue of the linkage provisions preventing product registration.”⁷⁴

ii. **KORUS Delayed Implementation** - Under the KORUS, the U.S. had first given South Korea 18 months to implement such a system, and later, in response to political pressure, provided South Korea with 36 months to implement such a system. The 18 and 36 month moratoria applied only to KORUS Art. 18.9.5(b)’s obligation to deny marketing approval for a generic product found to infringe an existing patent claim; it did not apply to KORUS Art. 18.9.5(a)’s obligation to disclose the identity of the generic applicant that seeks marketing approval to enter the market during the patent term.⁷⁵

3. *Trade Secrets*

a. **USTR Special 301 Report** - USTR’s 2013 Special 301 Report reflects greater emphasis on trade secret theft among companies in a wide variety of industry sectors, including information and communication technologies, services, biopharmaceuticals, manufacturing and environmental technologies. It expressly recognizes how “trade secrets are often among a company’s core business assets and a company’s competitiveness may depend on its capacity to protect such assets.”⁷⁶ In this regard, the U.S. has “urge[d] its trading partners to ensure that they have robust systems for protecting trade secrets, including deterrent penalties for criminal trade secret theft.”⁷⁷ For example, the US has enacted “the *Theft of Trade Secrets Clarification Act of 2012*, which clarified provisions in the *Economic Espionage Act* with respect to the theft of trade secret source code, and

⁷³ See Public Citizen, *Vietnam and the Trans-Pacific Partnership Agreement: Access to Medicines Risks for a PEPFAR Partner* (2011), supra at pp. 4-5.

⁷⁴ See Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105, at 180-181.

⁷⁵ See *Exchange of Letters Between The Honorable Susan C. Schwab, United States Trade Representative and The Honorable Hyun Chong Kim, Minister for Trade, Republic of South Korea* (Jun. 30, 2007), available at: http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file941_12967.pdf; *U.S. Agrees to Lengthen Patent Linkage Implementation for Korea in FTA*, Inside US Trade Daily News (Dec. 6, 2010), http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2010-December/000555.html.

⁷⁶ See Office of the United States Trade Representative, *2013 Special 301 Report*, at p. 13, available at: <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf>.

⁷⁷ Id. For example, the USG has been “[f]ocusing diplomatic efforts to protect trade secrets overseas, which include sustained and coordinated engagement with trading partners, the use of trade policy tools (including through the use of the Special 301 Report), cooperation, and training, among others.” Id., at p. 14.

the *Foreign and Economic Espionage Penalty Enhancement Act of 2012*, which increased criminal penalties for economic espionage.”⁷⁸

The USTR’s 2013 Special 301 Report also recognizes that “threat of trade secret theft is not the only way that foreign actors may seek to undermine U.S. commercial advantages. In addition to protecting against theft of trade secrets, the United States continues to urge trading partners to reject trade-distortive policies which are sometimes designed to promote ‘indigenous innovation’ by forcing U.S. companies to hand over valuable commercial information.”⁷⁹ Such policies include *inter alia* “[f]ailing to effectively enforce IPR, including patents, trademarks, trade secrets, and copyrights, thereby allowing firms to gain competitive advantages from their misappropriation or infringement of another’s IPR[. r]equiring use of, or providing preferences to, products or services in which IPR is either developed or owned locally, including with respect to government procurement...manipulating the standards development process to create unfair advantages for domestic firms, including with respect to the terms on which IPR is licensed [and r]equiring unnecessary disclosure of confidential business information for regulatory approval, or failing to protect such information.”⁸⁰

b. TPP Art. 9.2 – Data Exclusivity Provisions – Prohibit the use of clinical trial data submitted to the government to approve marketing of an initial applicant pharmaceutical product for the subsequent expedited approval of a subsequent product. U.S. law provides for the establishment of a form of proprietary rights that are distinct from patent rights. These “consist of a period of time during which the FDA affords an approved drug protection from competing applications for marketing approval” **and** restricts competitors’ (e.g., generic competitors) ability “to reference the data generated by the manufacturers of brand-name drugs.” Such rights are “sometimes termed ‘data exclusivity’ or ‘data protection.’”⁸¹

i. **Data Exclusivity Concept** - Data exclusivity is, in part, “an affirmative common law property right of trade secret,” which may be protected only by means of nondisclosure, which is “legally defined as ‘anything that gives a competitor an advantage [edge] or head start’ that is

⁷⁸ Id.

⁷⁹ Id.

⁸⁰ Id., at pp. 14-15.

⁸¹ See *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), cited in Wendy H. Schacht & John R. Thomas, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984* (“The Hatch-Waxman Act”), Congressional Research Service (CRS) Report for Congress (RL30756) (Jan. 10, 2005), 18–19, available at: <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf>; John R. Thomas, *Proprietary Rights in Pharmaceutical Innovation: Issues at the Intersection of Patents and Marketing Exclusivities*, Congressional Research Service (CRS 2006) Report for Congress (RL 33288) (Feb. 28, 2006), 1 and 7, available at: http://assets.opencrs.com/rpts/RL33288_20060228.pdf.

not in the public domain.” It is also, in part, “an affirmative common law right of prospective economic advantage the unlawful and willful interference with which gave rise to a legal action in tort.”⁸²

ii. **TPP Data Exclusivity Provisions Compared to KORUS** – TPP Articles 9.2(a)-(b) resemble KORUS Article 18.9.1(a)-(b). KORUS Art. 18.9.1(a) “imposes an obligation of ‘non-reliance’ on either the originator’s approval or the originator’s data package itself for a period of at least five years from the date of approval for a pharmaceutical product...in Korea”⁸³ KORUS Art. 18.9.1(b) provides “protection in cases where regulatory approval is conditioned on the demonstration of prior marketing approval in another territory by requiring the deferral of the date of any marketing approval to third parties not having the consent of the party providing the information in the other territory for a period of at least five years from the date of approval for a pharmaceutical product.”⁸⁴

TPP Articles 9.2(c)-(d) resemble KORUS Articles 18.9.2(a)-(b) which go beyond the May 10 Agreement applicable to the U.S. FTAs with Colombia, Panama, and Peru.⁸⁵ They also are ‘TRIPS+. These KORUS provisions require Korea to provide additional periods of non-reliance of three years from the date of marketing approval in Korea for new clinical information (other than information related to bioequivalency) or evidence of prior approval of the product in another territory that requires such new information, which is essential for the approval of a pharmaceutical product that uses a previously approved chemical component.

iii. **TPP Data Exclusivity Provisions Compared to TRIPS** - TPP Art. 9.2 also arguably goes beyond TRIPS Art. 39. “Rather than banning only the unfair commercial use of information, the data exclusivity proposal bans reference and reliance registration of any new product ‘based on’ safety and efficacy information submitted to it or to another country for an originator product. This language would appear to

⁸² See Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, 6 *Global Trade and Customs Journal*, Issues 11-2 at p. 521. “In the context of chemically synthesized drugs, such property right entitles originator pharmaceutical companies [to] obtain a period of time, ranging from three- to ten years, during which would-be generic producers of existing drugs cannot themselves obtain regulatory approval for a competing drug if they rely—directly or indirectly— on the results of the originator’s own undisclosed test data, which will have been provided to governments under strict conditions of trade secrecy.” *Id.*, at pp. 521-522.

⁸³ See *Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) on The U.S.-Korea Free Trade Agreement (FTA)*, The Intellectual Property Provisions (Apr. 27, 2007) at p. 16, available at: <http://www.iipa.com/pdf/ITAC15FinalReportKoreaApril272007.pdf>.

⁸⁴ *Id.*

⁸⁵ See Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 *AM. U. INT’L L. REV.* 105, 171-172.

foreclose the flexibility in TRIPS that would allow traditional uses of registration data to approve generic medicines as not being an ‘unfair commercial use’ of that data.”⁸⁶ In addition, the “data exclusivity provision abandons the TRIPS provision that protection only be required for ‘undisclosed’ information, instead requiring protection for all data.”⁸⁷

TRIPS Art. 39.1 generally requires WTO Member States to ensure effective protection against unfair competition [by] ‘protect[ing] undisclosed information.’ TRIPS Art. 39.2 generally requires WTO Member States to enable natural and legal persons to prevent the disclosure, acquisition or use of “information lawfully within their control...by others...without their consent in a manner contrary to honest commercial practices.” This latter obligation applies to the extent such information is “secret⁸⁸ has commercial value because it is secret,⁸⁹ and [has remained] secret because of reasonable steps taken by the person(s) lawfully in control of such information to maintain its secrecy.”⁹⁰

TRIPS Art. 39.3 imposes two specific obligations on WTO Member States to protect information they require to be submitted as a condition of securing the marketing approval of pharmaceutical or agricultural chemical products utilizing new chemical entities. The first obligation is to protect against unfair commercial use information that is submitted to governments or governmental agencies as undisclosed test or other data, the origination of which involves a considerable effort.⁹¹ The second obligation is to protect ‘such data’ against disclosure (to the public or even within the government⁹²), except where necessary to protect the public, or

⁸⁶ Id., at 170.

⁸⁷ Id., at p. 171.

⁸⁸ TRIPS Art. 39.2(a).

⁸⁹ TRIPS Art. 39.2(b).

⁹⁰ TRIPS Art 39.2(c).

⁹¹ See Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, 6 *Global Trade and Customs Journal*, Issues 11-2 at p. 529.

⁹² See Office of the General Counsel, U.S. Trade Representative, *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3*, unattributed paper for submission in bilateral discussions with Australia, May 1995, cited in International Federation of Pharmaceutical Manufacturers Associations, *Encouragement of New Clinical Drug Development: The Role of Data Exclusivity* (2000) at Annex III—Nature of Obligations under TRIPS Art. 39.3, at p.15 and accompanying fn. 7, available at: http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf. See also Government of New Zealand, *Protection of Undisclosed Information and Control of Anti-competitive Practices* (APEC TRIPS Seminar 1995), cited in European Commission, *Questions on TRIPS and Data Exclusivity: An EU Contribution, Compulsory Licensing and Data Protection* (2001), at p.19 and accompanying n. 20, http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf.

unless the government or governmental agency can ensure that the data, if it were disclosed, would be protected against unfair commercial use.⁹³

4. *Trademarks/Geographical Indications*

a. TPP Art. 2.1 – Scope of Trademark – This provision, which is identical to KORUS Art. 18.2.1, incorporates the scope of trademark subject matter under Sec. 45 of the Lanham Act. Trademarks include *inter alia* colors per se, 2D/3D designs, motion marks, sound, scent, and non-visual marks as well,⁹⁴ if they can fulfill the legal requirements of graphic representation.⁹⁵ Legal commentators have alleged that this provision conflicts with TRIPS Art. 15 which provides that “[m]embers may require as a condition of registration that signs be visually perceptible,” and also goes beyond TRIPS Art. 15 by providing “a non-exclusive list of what can be a protectable trademark, by explicitly requiring recognition of sound and scent.”⁹⁶

b. TPP Art. 2.2 & Accompanying FN 4 – Geographical Indications Defined – TPP Art. 2.2 provides that “geographical indications are eligible for protection as trademarks.” TPP Art. 2.2 and FN 4, which are identical to KORUS Art. 18.2.2 and FN 5, together contain a broader definition of the term “geographical indication” than does TRIPS Art. 22.1. In addition to requiring protection of “geographical indications” as defined in TRIPS Art. 22.1, which is included in FN 4’s first sentence, FN 4 also defines protectable “geographical indications” via a non-exhaustive list as including “[a]ny sign or combination of signs (such as words, including geographical and personal names, as well as letters, numerals, figurative elements and colors, including single colors), in any form whatsoever.” It also leaves undefined the term “originating” “in the context of GIs, thereby leaving the possibility that that ‘originating in the territory of a Party’ may not necessarily mean actually originating from the territory of a Party”, which

⁹³ See Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, 6 Global Trade and Customs Journal, Issues 11-2 at pp. 529-530.

⁹⁴ See United States Patent and Trademark Office, *Trademark “Sound Mark” Examples*, at: <http://www.uspto.gov/trademarks/soundmarks/index.jsp>; Cynthia Henderson, *Overview of Trademarks*, The U.S. Patent and Trademark Office, Office of Intellectual Property Policy and Enforcement (Aug. 27, 2007), available at: http://www.uspto.gov/web/offices/dcom/olia/conf_gipa2007aug27/agenda/southafrica_2007aug07tmv2.pdf.

⁹⁵ See Alex Butler, *The Smell of Ripe Strawberries: Representing Non-visual Trademarks*, Intellectual Asset Management (April-May 2008), at p. 7, available at: <http://www.iam-magazine.com/Issues/Article.aspx?g=4339d6d7-b7f6-4d57-9823-d4c55de588ff>; Vasheharan Kanesarajah, *The Taste of Ripe Strawberries: Representing Non-visual Trademarks*, KnowledgeLink (March 2008), available at: <http://ip-science.thomsonreuters.com/m/pdfs/klnl/2008-03/taste.pdf>.

⁹⁶ See Jimmy Koo, *Trans-Pacific Partnership – Intellectual Property Rights Chapter February Draft – Section by Section Analysis* American University Washington College of Law Program on Information Justice and Intellectual Property (2011), *supra* at p. 1.

suggests FN 4 endeavors to weaken GI protections “by lowering the standards of eligibility while broadening the scope of protectable subject matter.”⁹⁷

Furthermore, “[t]he non-exhaustive list of examples of “sign or combination of signs” contains many elements similar to a protectable trademark than a traditional GI.”⁹⁸ Moreover, since both TPP Art. 2.8 and KORUS Art. 18.2.8 are rooted in trademark law and provide for the refusal, opposition or cancellation of GI protection or recognition if the “use of that trademark or geographical indication is likely to cause confusion, or to cause mistake, or to deceive or risk associating the trademark or geographical indication with the owner of the well-known trademark, or constitutes unfair exploitation of the reputation of the well-known trademark”, it is arguable that these provisions “demonstrate that the focus of GI protection in KORUS and the TPP is not the protection of traditional origin but rather previously existing trademarks.”⁹⁹

c. TPP Art. 2.4 – Rights Conferred by a Trademark – TPP Art. 2.4 goes beyond TRIPS Art. 16.1, which confers upon the trademark owner the “exclusive right to prevent” all unauthorized third parties “from using... identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered”, and even KORUS Art. 18.2.4, which confers upon the trademark owner the “exclusive right to prevent” all unauthorized third parties “from using in the course of trade identical or similar signs, **including geographical indications, at least for** goods or services that are identical or similar to those goods or services in respect of which the owner’s trademark is registered.” Unlike these provisions, TPP Art. 2.4 confers upon trademark owners “the exclusive right to prevent” all unauthorized third parties “from using... identical or similar signs, including geographical indications, for goods or services that are related to those goods or services in respect of which the owner’s trademark is registered”. According to one commentator, “[r]elated to’ is a much broader standard than ‘identical or similar to’ [and is also broader than “at least for”] and may be interpreted much more flexibly thereby leading to a flood of frivolous infringement claims against parties in the trade of ‘related goods or services’.”¹⁰⁰ In addition, TPP Art. 2.4 includes geographical indications “within the purview of this provision.”¹⁰¹

⁹⁷ Id., at p. 2.

⁹⁸ Id.

⁹⁹ See Bernard O’Connor, *The European Union and the United States Conflicting agendas on Geographical Indications - What’s happening in Asia?*, NCTM Association d’avocats and O’Connor European Lawyers (Oct. 7, 2013) at p. 3, available at: <http://www.lexology.com/library/detail.aspx?g=19b3a3b9-f55e-4485-83dd-60e387a9c4b3>.

¹⁰⁰ See Jimmy Koo, *Trans-Pacific Partnership – Intellectual Property Rights Chapter February Draft – Section by Section Analysis* American University Washington College of Law Program on Information Justice and Intellectual Property (2011), supra at p. 3.

¹⁰¹ Id.

d. TPP Articles 2.6 and 2.7 – Well-Known Marks Protection Based on Registration and/or Use – Articles 2.6(a) and 2.7, which are identical to KORUS Articles 18.2.6 and 18.2.7, reflect an effort to export the U.S. Lanham Act (Sec. 1) basis for trademark protection (“use in commerce”) into the TPP, where many other jurisdictions simply require “registration” as “a condition precedent for trademark protection.”¹⁰² In other words, the sole lack of a registration may not serve as grounds for a Party to deny remedies or relief with respect to “well-known marks”, particularly, where likely damages to a well-known mark can be shown. TPP Art. 2.7, reaffirms this by requiring the application of Article 6bis of the Paris Convention¹⁰³ whether or not the well-known mark has been registered.

TPP Art. 2.6(c) ensures “the basis for remedies or relief for alleged ‘well-known’ marks even though the mark may not have been recognized as well-known. Art. 2.6(c)...could provide “well-known mark protection” for non-well-known marks.”¹⁰⁴ TPP Art. 2.7 and accompanying FN 5’s use of terminology contained in TRIPS Art. 16.2 potentially make it easier to identify a well-known mark by narrowing the scope of the analysis to only the sector in which the goods or services to which the mark relates normally appears. Unlike TRIPS Art. 16.2 “which requires but does not limit the analysis to the consideration of “the knowledge of the trademark in the relevant sector of the public”, FN 5 mandates, for purposes of determining well-known mark status, that “No Party shall require that the reputation of the trademark extend beyond the sector of the public that normally deals with the relevant goods or services” – i.e., that the “parties shall only require that the reputation of the well-known mark extend to the ‘sector of the public that normally deals with the relevant goods or services’.”¹⁰⁵

e. TPP Art. 2.15 – Grounds for Refusing Recognition or Protection of Geographical Indications – TPP Articles 2.15(a)(i)-(iii) and (b)(i)-(ii) are identical to KORUS Articles 18.2.15(a)(i)-(iii) and 18.2.15(b)(i)-(ii). TPP Art. 2.15(a)-(b) goes beyond TRIPS Art. 22(a)-(b), which require Parties to provide legal means to prevent the use of a GI that “misleads the public as to the geographical origin of the good” or “which constitutes an act of unfair competition.” TPP Art. 2.15(a)(i) “prohibits the use of a GI that is “likely to cause confusion with a trademark or geographical indication.” According to one commentator, the “TPP alters the fundamental focus of GI protection from the protection of goods from a specific place of origin to the protection of goods with specific trademark or geographical indication,” especially when read together with the expansive definition of GI which leaves the term “originating” undefined.¹⁰⁶

¹⁰² Id., at p. 4.

¹⁰³ See *WIPO Paris Convention for the Protection of Industrial Property*, Art. 6bis Marks: Well-Known Marks, available at: http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P151_21198.

¹⁰⁴ Id., at p. 5.

¹⁰⁵ Id.

¹⁰⁶ Id., at p. 6.

TPP Art. 2.15(a)(ii)'s terminology – “rights...acquired in the territory of the Party through use in good faith” reflects efforts “to export the U.S.’s ‘use in commerce’ standard” to GIs.¹⁰⁷ In addition, TPP Art. 2.15(b)(ii)'s terminology – “the date of protection of the geographical indication in a territory of a Party shall be...in the case of...recognition provided through other means [i.e., other than through recognition provided as a result of an application or petition”, “leaves open the possibility that ‘use in commerce’ may also be sufficient to provide for a date of protection or recognition.”¹⁰⁸

TPP Art. 2.15(a)(iv) goes beyond KORUS Art. 18.2.15(a) to prohibit the protection and recognition of a GI that constitutes a ‘generic term’ for the goods or services associated with the GI. TPP Art. 2.18 goes beyond the KORUS (there is no such provision in KORUS) and provides that “a term is generic if it is the term customary in common language as the common name for the goods or services associated with the trademark or geographical indication.” While TPP Art. 2.18 “closely follows the definition of ‘generic’ under TRIPS Art. 24.6...which focuses on the generic nature of the indicator in the territory of the Member, [TPP Art. 2.18] omits the phrase ‘in the territory of the Member’” Therefore, TPP leaves open the possibility that a term may be generic in the territory of a 3rd party member while it’s not generic in the territory of the GI’s origin.”¹⁰⁹ FN 7 accompanying TPP Art. 2.18 also suggests that a term that a Party recognizes as a trademark or GI at one point may, over time, “become a generic designation for the associated goods or services.”

f. TPP Art. 2.22 – GIs for Products *Other than Wine and Spirits that Reference a Geographical Area Not the True Place of Origin* – This provision prohibits the use and registration of wines or spirits that reference a geographical area that is not the true place of origin. TPP Art. 2.22(a)-(b) permit the use and registration of a GI for products other than wine or spirits that reference a geographical area not the true place of origin provided, the public is not misled by the GI as to the geographical origin of the goods or services, and the GI does not constitute an act of unfair competition. TPP Art. 2.22(c) “exten[ds] the ‘likelihood of confusion’ standard of trademark protection to GIs.”¹¹⁰ TPP Art. 2.22(d) permits protection of GIs for products other than wine or spirits that reference a geographical area not the true place of origin if the term is not a generic term. However, TPP Art. 2.18 “leaves open the possibility that a term may be generic in the territory of a 3rd party member while it’s not generic in the territory of the GI’s origin.”¹¹¹

¹⁰⁷ Id., at p. 7.

¹⁰⁸ Id.

¹⁰⁹ Id.

¹¹⁰ Id., at p. 9.

¹¹¹ Id.

5. *Civil and Administrative Enforcement of IP Rights*

a. TPP Art. 12.3 – Civil and Administrative Enforcement Provisions – Compensatory Damages – TPP Art. 12.3(a)-(b) are virtually identical to KORUS Art. 18.10.5(a)-(b). “TPP [A]rt. 12.3 does not presume the [IPR] infringer’s profits to be the amount of damages suffered as the result of infringement. Instead, TPP separates the compensatory damages for the injury caused by the infringement from the profits of the infringer that were not taken into account in computing the compensatory damages.”¹¹² Consistent with TPP Art. 12.3(a)-(b), a civil tribunal may authorize the payment of compensatory damages “adequate to compensate for the injury”¹¹³ to a rightsholder, including an “exclusive licensee” and any “federation[] and association[] having the legal standing and authority to assert such rights”.¹¹⁴ In the case of patent infringement, adequate compensation “shall not be less than a reasonable royalty.”¹¹⁵ “In the case of copyright or related rights infringement and trademark counterfeiting” adequate compensation shall be “at least...the profits of the infringer that are attributable to the infringement and that are not taken into account in computing the amount of the damages.”¹¹⁶ In other words, adequate compensation is the lesser of actual damages or lost profits.

In general, TPP Art. 12.3(b) provides that, for purposes of determining compensatory damages, “judicial authorities shall consider, *inter alia*, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder. By comparison, KORUS Art. 18.10.5(b) provides that the value of the infringed good or service could be measured more broadly, by reference to “the market price, the suggested retail price, or other legitimate measure of value...”¹¹⁷ Unlike ACTA Art. 9.1, “TPP [A]rt. 12.3 does not require the infringer to ‘knowingly or with reasonable grounds to know, engage in infringing activity’.”¹¹⁸

b. TPP Art. 12.4 – Pre-established Damages and Treble Damages – TPP Art. 12.4 goes beyond both ACTA Art. 9.3 and KORUS Art. 18.10.6, each of which require that Parties, in civil infringement proceedings, provide for pre-established damages sufficient to compensate the rightsholder. Instead, TPP Art. 12.4 requires, in cases of copyright or related rights and trademark counterfeiting, for tribunals to provide pre-established damages “in an amount sufficiently high to constitute a deterrent to future infringements and to compensate fully the right

¹¹² Id., at p. 26.

¹¹³ TPP Art. 12.3(a)(i).

¹¹⁴ Id., at FN 17.

¹¹⁵ Id., at FN 18.

¹¹⁶ TPP Art. 12.3(a)(ii).

¹¹⁷ KORUS Art. 18.10.5(b).

¹¹⁸ Id., at p. 26.

holder for the harm caused by the infringement.”¹¹⁹ In addition, it goes beyond KORUS Art. 10.8.6, with which it is virtually identical, by providing tribunals with the authority, in civil proceedings involving patent infringement, to impose treble damages – “to increase damages to an amount that is up to three times the amount of the injury found or assessed.”¹²⁰

c. TPP Art. 12.7 – Destruction and Disposal of Pirated Copyright and Trademarked Goods – TPP Art. 12.7(a)-(c) is identical to KORUS Art. 18.10.7 (a)-(c). TPP Art. 12.7(a) does not go as far as ACTA Art. 10.1, which confers authority on judicial tribunals to require, at the request of the rights holder, the destruction of pirated copyright or counterfeit trademark goods be carried out without compensation of any sort. TPP Art. 12.7(b) authorizes judicial tribunals to require the destruction of only the materials and implements “used in the manufacture or creation of such pirated or counterfeit goods”, without compensation.¹²¹ TPP Art. 12.7(b) goes beyond ACTA Art. 10.2, which authorizes destruction or disposal of “materials and implements, the predominant use of which has been in the manufacture or creation of such infringing goods”. By comparison, TPP Art. 12.7 “simply refers to materials and implements and does not require them to have been predominantly used in manufacture or creation of the infringing goods.”¹²²

Like KORUS Art. 18.10.7(b), TPP Art. 12.7(b) provides for either destruction or disposal of materials and implements “outside the channels of commerce” without compensation. In lieu of destruction, TPP Art. 12.7(b) permits materials and implements to be disposed of “outside channels of commerce”, however, only in exceptional circumstances, as where disposal is undertaken in such a manner as to minimize the risks of further infringements.¹²³ TPP Art. 12.7(c) goes beyond ACTA Art. 20.2, which permits, “except in exceptional cases”, the disposal of counterfeit trademark goods into the channels of commerce once the trademark has been removed. Like KORUS Art. 18.7.10(b), TPP Art. 12.7(b) provides, however, in the case of trademark infringement, that “the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce”, under ANY circumstances/ in ANY cases.¹²⁴

d. TPP Art. 12.8 – Provision of Third Party Information Relating to Infringement – TPP Art. 12.8 goes beyond both ACTA Art. 11 and KORUS Art. 18.10.10 Unlike ACTA Art. 11, which provides safeguards to the provision of

¹¹⁹ Id; TPP Art. 12.4.

¹²⁰ TPP Art. 12.4.

¹²¹ TPP Art. 12.7.

¹²² See Jimmy Koo, *Trans-Pacific Partnership – Intellectual Property Rights Chapter February Draft – Section by Section Analysis* American University Washington College of Law Program on Information Justice and Intellectual Property (2011), supra at p. 29.

¹²³ Id.

¹²⁴ Id., at pp. 29-30.

such information – i.e., “access to such information shall be without prejudice to” a Party’s law governing privilege, the protection of confidential[] information sources or [the] processing of personal data”, and shall be provided only “upon a justified request of the right holder”. TPP Art. 12.8 does not contain any such safeguards – there is no privilege accorded to such disclosures – and does not impose as a precondition for gaining access to such information a “justified request of the right holder”.¹²⁵ In addition, whereas both ACTA Art. 11 and KORUS Art. 18.10.10 call for such information to be provided by “the infringer or alleged infringer” “to the right holder or to the judicial authorities”, TPP Art. 12.8 calls for such information to be provided only to the right holder, and omits the word “alleged” when referring to the infringer and the infringement. Furthermore, unlike ACTA Art. 11, which provides judicial tribunals with the authority to order the production of such information “at least for the purpose of collecting evidence”, TPP Art. 12.8, like KORUS Art. 18.10.10 imposes no such limitation on the use of such information.¹²⁶

e. TPP Art. 12.9 – Civil Remedies in Case of Violation of Judicial Orders – TPP Art. 12.9, which is virtually identical to KORUS Art. 18.10.11, empowers judicial tribunals to impose “fines and imprisonment [on a party to a civil proceeding] as [a] means of punishing those who fail to abide by valid orders issued” by such tribunals. KORUS Art. 18.1.11(a) provides also for a Party to detain a party to a civil proceeding. Such fines and imprisonment can also be imposed on a party’s “counsel, experts, or other persons subject to the court’s jurisdiction, for violation of judicial orders regarding the protection of confidential information produced or exchanged in a proceeding.”¹²⁷ At least one legal commentator has argued that such provision “reaches into the subject matter of contempt of court”, and therefore, “does not belong in an agreement concerning intellectual property.”¹²⁸

f. TPP Art. 13.1 – Acting on Requests for Adoption of Provisions Measures – TPP Art. 13.1, which is similar to both ACTA Art. 12.2 and KORUS Art. 18.10.17, calls for each Party to empower its judiciary to adopt provisional measures at the request of one party and without prior hearing of the other side *inaudita altera parte*, as appropriate, and to ensure that such requests are acted on (executed) expeditiously within 10 days. Neither KORUS Art. 18.10.17 nor ACTA Art. 12.2 impose a ten day limit. Although TPP Art. 13.1 requires, prior to issuing a provisional measure, that the judicial tribunal possess, based on any reasonable information provided by the applicant, “a sufficient degree of certainty that the applicant’s right is being infringed or that such infringement is

¹²⁵ Id., at p. 31.

¹²⁶ Id.

¹²⁷ TPP Art. 12.9(a)-(b).

¹²⁸ See Jimmy Koo, *Trans-Pacific Partnership – Intellectual Property Rights Chapter February Draft – Section by Section Analysis* American University Washington College of Law Program on Information Justice and Intellectual Property (2011), *supra* at p. 32.

imminent”, TPP Art. 13.1 does not contain the safeguard in ACTA Art. 12.2. ACTA Art. 12.2 conditions the tribunal’s adoption of a provisional measure on an applicant’s showing of “any delay...likely to cause irreparable harm to the right holder, or...a demonstrable risk of evidence being destroyed.”¹²⁹

g. TPP Art. 14.1 – Jurisdictional Law Applicable for Purposes of Border Authority Determining Counterfeit Trademark Goods and Pirated Copyright Goods Subject to Suspension of Release – TPP Art. 14.1 FN 30 (which is identical to KORUS Art. 18.10.19) defines “counterfeit trademark goods” and “pirated copyright goods” by reference to a determination that such trademark or copyright or related right was infringed or would be deemed infringed “under the law of the country of importation.” ACTA Art. 5(d) defines “counterfeit trademark goods” and ACTA Art. 5(k) defines “pirated copyright goods” by reference to a determination of infringement “under the law of the country in which the...Enforcement of Intellectual Property Rights...procedures are invoked.”¹³⁰

h. TPP Art. 14.6 – Destruction of Counterfeit or Pirated Goods; No Release of Trademark Goods into Noncommercial Channels; No Exportation of Counterfeit or Pirated Goods – Like TPP Art. 12.7(a), TPP Art. 14.6 requires each Party to provide for competent authority-determined counterfeit or pirated goods to be destroyed, except in exceptional circumstances. Like TPP Art. 12.7(c), TPP Art. 14.6 prohibits the disposal of counterfeit trademark goods into the channels of commerce upon simple removal of the trademark. In addition, TPP Art. 14.6 prohibits each Party from authorizing competent authorities, except in exceptional circumstances, to “permit the exportation of counterfeit or pirated goods or to permit such goods to be subject to other customs procedures.” TPP Art. 14.6 is quite similar to KORUS Art. 18.10.23, except that the latter applies to goods “that have been suspended from release by its customs authorities and that have been forfeited as pirated or counterfeit.”¹³¹

i. TPP Art. 14.8 – De minimis Quantities of Noncommercial Infringing Goods in Travelers’ Personal Luggage – Virtually identical to ACTA Art. 14.

6. *Criminal Enforcement Provisions*

a. TPP Art. 15 Criminal Enforcement Provisions – TPP Art. 15.2 (applicable to trademark counterfeiting and copyright or related rights piracy) is similar to ACTA Art. 23.2 and KORUS Art. 18.10.28. However, unlike ACTA, said provision “alters the standard for criminal procedures and penalties in cases of infringements of labels or packaging or any type or nature of the product” from

¹²⁹ Id., at p. 33.

¹³⁰ Id., at p. 34.

¹³¹ KORUS Art. 18.10.23.

“willfull importation and domestic use in the course of trade and on a commercial scale” to “knowing trafficking in”. It also “changes the threshold for infringement [in ACTA] from authorized use of identical/undistinguishable trademark to a use of a trademark” “which is likely to cause confusion, to cause mistake, or to deceive.”¹³² And, unlike ACTA, it does “not require the use of the ‘confusing’ label “on goods or in relation to services which are identical to goods or services for which such trademark is registered.” It also “protects against counterfeit or illicit labels affixed to, enclosed in, or accompanying a phonogram, a computer program, a copy of a movie, [or] documentation or packaging for such items.”¹³³

b. TPP Art. 15.5(a) – Criminal Penalties – This provision closely resembles ACTA Art. 24 and is identical to KORUS Art. 18.10.27(a). In addition to prescribing “imprisonment and monetary fines sufficiently high to provide a deterrent to future” infringements, said provision “also adds that such penalties should be “consistent with a policy of removing the infringer’s monetary incentive.”¹³⁴ There is no safeguard as in ACTA to limit such penalties to those consistent with “the level of penalties applied for crimes of a corresponding gravity.”¹³⁵ TPP Parties are also required to “establish policies or guidelines that encourage judicial authorities to impose those penalties...”

c. TPP Articles 15.5(b) and (d) – Seizure, Forfeiture and Destruction – Although substantially similar to ACTA Art. 25.1, which requires seizure of “assets derived from, or obtained directly or indirectly through the alleged infringing activity”, TPP Art. 15.5(b) imposes a broader standard - it requires seizure of “any assets traceable to the infringing activity”.¹³⁶ Although substantially similar to ACTA 25.3, which requires “forfeiture OR destruction of all counterfeit or pirated goods, TPP Art. 15.5(d) requires “forfeiture AND destruction”.

III. Substantive Outline of Law & Policy Issues – Investment Chapter:

In addition, there is also a leaked TPP Investment chapter¹³⁷ covering intellectual property rights which legal/academic commentators and nongovernmental activist groups deem controversial.¹³⁸

¹³² See Jimmy Koo, *Trans-Pacific Partnership – Intellectual Property Rights Chapter February Draft – Section by Section Analysis* American University Washington College of Law Program on Information Justice and Intellectual Property (2011), supra at p. 37.

¹³³ Id., at pp. 37-38.

¹³⁴ Id., at p. 38.

¹³⁵ Id.

¹³⁶ Id., at p. 39.

¹³⁷ See *Newly Leaked TPP Investment Chapter Contains Special Rights for Corporations*, Citizens Trade Campaign (June 13, 2012), available at: <http://www.citizenstrade.org/ctc/blog/2012/06/13/newly-leaked-tpp-investment-chapter-contains-special-rights-for-corporations/>; Jane Kelsey, *National Says ‘Yes’ to Investor Rights to Sue*, Scoop Independent News New Zealand (June 12, 2012), available at: <http://www.scoop.co.nz/stories/PO1206/S00186/national-says-yes-to-investor-rights-to-sue.htm>. See also *Leaked*

According to certain legal/academic commentators, “[t]he United States is also proposing to introduce new mechanisms of enforcement that are not present in the multilateral system [, but which are present in NAFTA and KORUS]. These include ‘investor-state’ dispute proceedings, where corporations can sue member states directly for alleged infringements.”¹³⁹ At least one TPP Party, Australia, is reported to have objected to such provisions.¹⁴⁰ All TPP article references are to proposed TPP articles as revealed in the leaked text of the proposed TPP Investment chapter.

Several of these controversial investment chapter provisions relate to intellectual property rights. They closely track KORUS and include the following:

1. ***Investor Rights and Intellectual Property Rights***

- a. TPP Art. 12.2 - Covered ‘Investments’ Defined – “Forms that investments may take include... (g) **intellectual property rights** [which are conferred pursuant to domestic laws of each Party]; (h) **licenses**... conferred pursuant to domestic law.”¹⁴¹ According to accompanying footnote 3, “[w]hether a particular type of license... has the characteristics of an investment depends on such factors as the nature and extent of the rights that the holder has under the law of the Party”. This arguably applies to exclusive licenses to commercialize intellectual property which typically require significant capital and/or other investments.
 - i. This TPP article is virtually identical to KORUS, Chap. 11, Art. 11.28.
 - ii. Presumably, the coverage of intellectual property rights includes both ‘positive’ **rights to use** intellectual property assets and ‘negative’ **rights to exclude** unauthorized third parties from using intellectual property assets, consistent with the TRIPS Agreement.

TPP Investment Chapter, available at: <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf>.

¹³⁸ See *Public Interest Analysis of Leaked Trans-Pacific Partnership (TPP) Investment Text*, Public Citizen (June 13, 2012), available at: <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/gtwtpinvestmentanalysis.pdf> (“The definition of “investment” in the leaked text would allow attacks on a vast array of nondiscriminatory domestic policies before foreign tribunals. This includes health and land use policies, government procurement decisions, regulatory permits, intellectual property rights...”) Id., at p. 3.

¹³⁹ Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105, 122, supra.

¹⁴⁰ See *Leaked TPPA Trade Chapter: Australia Says No to Investor Rights to Sue, Fair Trade Groups Demand Release of All Text*, Australia Fair Trade and Investment Network, Ltd. (2012), available at: <http://aftinet.org.au/cms/trans-pacific-partnership-agreement/leaked-tppa-trade-chapter-australia-says-no-investor-rights-sue->.

¹⁴¹ There appears to be a transposition error in the proposed text. Subparagraph (g) should be redesignated as subparagraph (f), and subparagraph (h) should be redesignated as subparagraph (g).

iii. Legal/academic commentators have noted that “[t]he Article 12.2 definition of “investment” is broad enough to cover medicines-related intellectual property rights (patents, data and other trade secrets) as an investment”. They also note how “the proposed definition of investment[’s]...further...direct[] reference [to] ‘intellectual property rights’...protecting any and all intellectual property rights is problematic [because it] could be interpreted over broadly to include all of the IPRs codified in the loose language of the TRIPS Agreement. For example, TRIPS...Art. 39.3 currently provides data protection against “unfair commercial use” for undisclosed data compiled at consideration expense and submitted to regulatory authorities. Big Pharma and EU and US trade negotiators have consistently interpreted this language as requiring **data exclusivity** – monopoly control over the data so as to prevent regulatory reliance on or reference to the data when considering a generic company’s attempt to register an equivalent product. Many other countries and leading expert commentators believe that Art. 39.3 does not require data exclusivity, a protection explicitly rejected during the negotiation of the TRIPS Agreement.”¹⁴²

A. Data Exclusivity Claims Rarely Initiated By USTR, Would Be Available to Private Investors Under TPP and Could Deter Implementation of TRIPS Public Health Flexibilities – “At present, the only way that this interpretive battle can be decided multilaterally is for an aggrieved WTO Member to bring a WTO complaint against another Member... However, despite intense industry lobbying on this issue, the Office of the United States Trade Representative (USTR) has initiated only one such complaint against Argentina and subsequently abandoned it because of concerns that it would lose and because of other complex political calculations that structure a Member’s decision to fully prosecute a WTO complaint or not. However, if the Investment Chapter is adopted, even if the US proposal for data exclusivity in its IP Chapter were to be rejected, a pharmaceutical company could bring an extra-judicial arbitral claim (e.g. violation of reasonable expectations covered by the minimum standard of treatment) against a TPP Party based on a judicial dispute over whether TRIPS requires data exclusivity... the mere threat of such a lawsuit could deter Parties from adopting lawful public health

¹⁴² See Brook Baker, *Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines* (Sept. 2012) at p. 4, available at: http://works.bepress.com/cgi/viewcontent.cgi?article=1007&context=brook_baker.

flexibilities that they might otherwise believe exist in the TPP because of the prohibitive costs of arbitral hearings and the risk of excessive judgments should they lose.”¹⁴³

- B. TPP Would Allow for Ever-greening of Patents – “[I]f the TPP IP chapter requires countries to allow patents on new forms of existing medicines, a patent office might still conclude that a particular new polymorph form lacks an inventive step. The pharmaceutical company could argue that the TPP-compliant national law actually creates a presumption in favor of patentability of new forms and thus that it has an expectation of profit from exclusive rights on an evergreened patent.”¹⁴⁴
- C. TPP Would Go Beyond TRIPS by Allowing for Private Claims of Inadequate Enforcement of IP Rights – “Although TRIPS mainly relies upon ‘private enforcement’ e.g., the creation of a procedurally fair judicial system for the private prosecution of IP infringement claims, the proposed IP Chapter creates multiple new enforcement rights with respect to civil remedies, criminal sanctions, and border measures.”¹⁴⁵
- I. “[A]n IP rightholder might bring claims because of what it considers to be inadequate enforcement, e.g., the failure to criminally prosecute a trademark counterfeiter because of scarce prosecutorial and judicial resources or a failure to impose the level of damages that the IP rightholder proposes.”¹⁴⁶ – FAILURE TO PROVIDE ‘FAIR & EQUITABLE TREATMENT’.
- II. Paradoxically, a government could face investor claims for failure to unilaterally enforce what are fundamentally private rights – no longer could Parties use their TRIPS-compliant right not to give priority to publicly funded and initiated IP enforcement.” For example, TRIPS Article 41.5 provides that “[i]t is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in

¹⁴³ Id., at pp. 4-5.

¹⁴⁴ Id., at p. 5.

¹⁴⁵ Id., at p. 6.

¹⁴⁶ Id.

this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.”¹⁴⁷

III. “[T]here is a risk that an IP rightholder might bring a claim because of a failure to intercept alleged IP-infringing, in transit medicines via stringent border measures. This too might violate the right to ‘fair and equitable treatment’ in administrative border measures...[D]rug companies have initiated seizures of medicines-in-transit on multiple occasions in Europe, not because they violated IP rights in the countries of origin or destination, but because they interfered with fictional patent rights in the transit country. [Although] the TPP border measures Art. 14.1 instructs customs official to apply the law of the importing country, as required by TRIPS...trademark-related IP rights might be enforced through ISDS proceedings based on misunderstanding of the governing law and of trademark status in the importing country.”¹⁴⁸

- b. TPP Art. 12.3 – Scope and Coverage – “This Chapter applies to measures adopted or maintained by a Party relating to: (a) investors of another Party; (b) covered investments; and (c) [with respect to Articles 12.7 (Performance Requirements) [and 12.15 (Investment and Environment)], all investments in the territory of the Party.]”
- i. This TPP article is virtually identical to KORUS, Chap. 11, Art. 11.1.1(a)-(c).
- c. TPP Art. 12.7.1 – ‘Performance Requirements’ – “No Party may, in connection with the establishment, acquisition, expansion, management, conduct, operation, or sale or other disposition of an investment of an investor of a Party [or of a non-Party] in its territory, impose or enforce any requirement or enforce any commitment or undertaking... (b) to achieve a given level or percentage of domestic content... (f) to transfer a particular technology, a production process or other proprietary knowledge to a person in its territory;... (h) (i) to purchase, use, or accord a preference to, in its territory, technology of the Party or persons of the Party; or (ii) that prevents the purchase or use of, or the according of a preference to, in its territory, particular technology, so as to afford

¹⁴⁷ Id., citing TRIPS Art. 41.5.

¹⁴⁸ Id.

protection on the basis of nationality to its own investors or investments or to technology of the Party or of persons of the Party].”

i. TPP Articles 12.7.1(a)-(g) are virtually identical to KORUS Articles 11.8.1(a)-(g).

A. Subsection (f) is likely intended to address government-issued compulsory licenses for pharmaceuticals to ensure universal access to healthcare, or some other form of compulsory technology transfer designed to satisfy a Party’s indigenous innovation policy.

B. Subsection (h) is likely intended to address governmental preferences for proprietary rather than open source/open standards-based technologies (e.g., interoperable software) to ensure universal access to knowledge, or some other form of compulsory technology transfer designed to satisfy a Party’s indigenous innovation policy.

d. TPP Art. 12.7.2 – ‘Performance Requirements’ – “No Party may condition the receipt or continued receipt of an advantage, in connection with the establishment, acquisition, expansion, management, conduct, operation, or sale or other disposition of an investment in its territory of an investor of a Party [or of a non-Party,] on compliance with any requirement: (a) to achieve a given level or percentage of domestic content; (b) to purchase, use, or accord a preference to goods produced in its territory, or to purchase goods from persons in its territory.

i. TPP Articles 12.7.2(a)-(b) are virtually identical to KORUS Articles 11.8.2(a)-(b).

e. TPP Art. 12.7.3 – ‘Performance Requirements’ – No Required Transfer of Technology, Production Process or Other Proprietary Knowledge Incident to Local Work and R&D Efforts – (a) “Nothing in paragraph 2 shall be construed to prevent a Party from conditioning the receipt or continued receipt of an advantage, in connection with an investment in its territory of an investor of a Party [or of a non-Party,] on compliance with a requirement to locate production, supply a service, train or employ workers, construct or expand particular facilities, or carry out research and development, in its territory.”

i. TPP Art. 12.7.3(a) is virtually identical to KORUS Art. 11.8.3(a), except for its footnote 5. KORUS footnote 5 provides that “[f]or greater certainty, nothing in paragraph 1 shall be construed to prevent a Party...from imposing or enforcing a requirement or enforcing a commitment or undertaking to locate production,

supply a service, train or employ workers, construct or expand particular facilities, or carry out research and development, in its territory, provided that such activity is consistent with paragraph 1(f).” – i.e., it does not compel the “transfer of a particular technology, a production process or other proprietary knowledge to a person in its territory.”

ii. TPP Art. 12.7.3bis is virtually identical to combined KORUS Art. 11.8.3(a) and FN 5 – “For greater certainty, nothing in paragraph 1 shall be construed to prevent a Party...from imposing or enforcing a requirement or enforcing a commitment or undertaking to employ or train workers in its territory [**provided that such employment or training does not require the transfer of a particular technology, production process, or other proprietary knowledge to a person in its territory.**] In other words, like KORUS footnote 5, this provision apparently distinguishes between joint R&D efforts and forced technology transfers.

f. TPP Art. 12.7.3(b)(i) – Exception to Prohibition of Compelled Technology Transfer – “**Paragraph 1(f) does not apply** when a Party authorizes use of an intellectual property right in accordance with [Article 31 of the TRIPS Agreement] [Article ___ (Intellectual Property Rights Chapter; Patents Article; Paragraph on use of the subject matter of a patent without the authorization of the right holder)], or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement”.

i. TPP Art. 12.7.3(b)(1) is identical to KORUS Art. 11.8.3(b)(i).

A. This provision addresses government-issued compulsory licenses with respect to patented technologies (e.g., pharmaceuticals, energy-related, etc.) that comply with the requirements of TRIPS Art. 31.

B. Legal/academic commentators have alleged that “TRIPS Article 31, referenced in the bracketed language of TPP Art. 12.7.3(b)(i) and Art. 12.12.5, covers only a portion of legally issued licenses under TRIPS. Specifically, the referenced TRIPS-CL language does not directly reference proposed TRIPS Article 31bis or the current waiver of Article 31(f) found in the WTO Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Likewise, the bracketed TPP compulsory licensing language in subparagraph 3(b)(i) and the unbracketed TRIPS-CL language in Art. 12.12.5 do not allow the possibility of judicially authorized [de facto]

compulsory licenses such as those granted in the U.S. in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 126 S. Ct. 1837 (2006) and its progeny and in *India in Roche v. Cipla*, CS (OS) No.89/2008. Such judicial licenses are directly authorized by Article 44.2 of the TRIPS Agreement.”¹⁴⁹

- C. This provision also addresses government-required submissions of clinical testing and other proprietary data for purposes of securing regulatory marketing approval for pharmaceutical and/or agricultural chemical products, consistent with TRIPS Art. 39.
- g. TPP Art. 12.7.3(b)(ii) – Exception to Prohibition of Compelled Technology Transfer – “**Paragraph 1(f) does not apply** when the requirement is imposed or the commitment or undertaking is enforced by a court, administrative tribunal, or competition authority to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party’s competition laws.”
- i. This provision is identical to KORUS Art. 11.8.3(b)(ii).
- ii. This provision is likely intended to address administrative agency and court-issued consent-decrees (*de facto* compulsory licenses) ordering patent litigants to enter into commercial licensing arrangements to avoid patent hold-ups and resolve what would otherwise constitute antitrust activities – e.g., upon a change in corporate control; a bad faith withholding by patent owners of information about patent-essential standards from standards development organization (“SDO”) members; patent tying agreements between branded and generic pharmaceutical companies, etc.
- h. TPP Art. 12.7.3(c) – Nondiscriminatory and Non-protectionist Application of TPP Articles 12.7.1(b),(c), [and (f)] [and (h)] and 12.7.2(a) and (b) – “[S]hall not be construed to prevent a Party from adopting or maintaining measures, including environmental measures (i) necessary to secure compliance with laws and regulations that are not inconsistent with this Agreement; (ii) necessary to protect human, animal, or plant life or health; or (iii) related to the conservation of living or non-living exhaustible natural resources.”
- i. This provision is virtually identical to KORUS Art. 11.8.3(c).

¹⁴⁹ See Brook Baker, *Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines* (Sept. 2012), *supra* at p. 7.

- ii. This provision is likely intended to allow measures providing for compulsory licenses of technologies and/or preferences for certain technologies provided such measures are not designed to discriminate against foreign nationals and/or to impose unnecessary obstacles to trade on foreign nationals.
- i. TPP Art. 12.7.3(e) – Inapplicability of TPP Articles 12.7.1(f) [and (h)] to Government Procurement – Governments may require “transfer of a particular technology, a production process or other proprietary knowledge to a person in its territory,” as a condition to a government procurement contract. Governments may also “accord a preference to, in its territory, technology of the Party or persons of the Party”, as a condition to a government procurement contract.
 - i. This provision is virtually identical to KORUS Art. 11.8.3(e).
 - j. TPP Art. 12.12.1(a)-(d) – General Prohibition Against Direct and Indirect Expropriation – “No Party may expropriate or nationalize a covered investment either directly or indirectly through measures equivalent to expropriation or nationalization (‘expropriation’), **except**: (a) for a **public purpose** [FN 19]; (b) in a non-discriminatory manner; (c) on payment of prompt, adequate, and effective compensation in accordance with paragraphs 2 through 4; **and** (d) in accordance with due process of law.”
 - i. This provision is virtually identical to KORUS Art. 11.6.1(a)-(d).
 - ii. TPP Art. 12.12 – Title: Expropriations and Compensation – Footnote 18 accompanying TPP Art. 12.12 indicates that the phrase ‘expropriations and compensation’ “shall be interpreted in accordance with” two annexes – TPP Annexes 12-B and 12-C. KORUS Art. 11.6 contains an identical definition and accompanying footnote 2, and refers to Annexes 11-A and 11-B, which are virtually identical to TPP Annexes 12-B and 12-C. Both TPP Annex 12-B and KORUS Annex 11-A generally indicate that “the Parties understand that customary international law...results from a general and consistent practice of States that they follow from a sense of legal obligation.”¹⁵⁰ Both TPP Annex 12-C(1) and KORUS Annex 11-B(1) provide that “Article...[Expropriation and Compensation](1) is intended to reflect customary international law concerning the obligation of States with respect to expropriation.”¹⁵¹

¹⁵⁰ KORUS Annex 11-A.

¹⁵¹ Id., at Annex 11-B(1).

iii. TPP Art. 12.12(2), like identical KORUS Art. 11.6(2) provides that “[c]ompensation shall (a) be paid without delay (b) be equivalent to the **fair market value** of the expropriated investment immediately before the expropriation took place (‘the date of expropriation’); (c) not reflect any change in value occurring because the intended expropriation had become known earlier; and (d) be fully realizable and freely transferable.” TPP Art. 12.12(3) (and identical KORUS Art. 11.6(3)) provide that compensation “shall be **no less than the fair market value** on the date of expropriation, **plus interest** at a commercially reasonable rate...accrued from the date of expropriation until the date of payment.”

A. Legal/academic commentators have alleged that “[a]lthough there is an exception in subsection 5 [of TPP Art. 12.12] with respect to ‘compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement,’ this exception would not appear to cover exceptions to data exclusivity or patent-registration linkage rights...Even the broader bracketed portion of subsection 5, which includes ‘the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter __ (Intellectual Property Rights),’ does not give rights to create novel exceptions to intellectual property rights in the absence of full remuneration. Pursuant to the indirect expropriation rule, it would become unlawful, arguably, to create a new public health exception to data exclusivity or to require disclosure of the international proprietary name of active pharmaceutical ingredients on medicines-related patents.”¹⁵²

iv. Determining Whether a Direct or Indirect Expropriation (of IP Rights (or IP Assets) Has Occurred – TPP Annex 12-C and KORUS Annex 11-B, which are virtually identical to each other and to Annex B(4) of the U.S. Model BIT (2004)¹⁵³ and (2012),¹⁵⁴ are relevant for such purposes.

¹⁵² See Brook Baker, *Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines* (Sept. 2012), *supra* at p. 3.

¹⁵³ See Office of the United States Trade Representative, *U.S. Model Bilateral Investment Treaty (2004)*, Annex B(4) (hereinafter referred to as “U.S. Model BIT (2004)”), available at: <http://www.state.gov/documents/organization/117601.pdf>.

- A. TPP Annex 12-C(2), KORUS Annex 11-B(2), and U.S. Model BITs (2004/2012) Annex B(2) provide that “[a]n action or a series of actions by a Party cannot constitute an expropriation unless it interferes with a tangible or intangible property right or property interest in an investment.”
- B. TPP Annex 12-C(3), KORUS Annex 11-B(3), and U.S. Model BITs (2004/2012) Annex B(3) provide that “**direct expropriation**...[occurs] where an investment is nationalized or otherwise directly expropriated through formal transfer of title or outright seizure.”¹⁵⁵ ACTUAL LOSS OF TITLE, POSSESSION OR CONTROL.
- C. TPP Annex 12-C(4), KORUS Annex 11-B(4), and U.S. Model BITs (2004/2012) Annex B(4) provide that “**indirect expropriation**...[occurs] where an action or series of actions by a Party has an effect equivalent to direct expropriation without formal transfer of title or outright seizure.”¹⁵⁶ EFFECTIVE LOSS OF TITLE, POSSESSION, CONTROL OR IMPLIED LOSS OF USE.
- D. **TPP Annex 12-D** is set forth as a possible alternative to TPP Annex 12-C. TPP Annex 12-D(2)(a) provides that, “**direct expropriation** occurs when a state takes an investor's property outright, including by nationalization, compulsion of law or seizure.” ACTUAL LOSS OF TITLE, POSSESSION OR CONTROL. TPP Annex 12-D(2)(b) provides that “**indirect expropriation** occurs when a state takes an investor's property in a manner equivalent to direct expropriation, in that it **deprives the investor in substance of the use of the investor's property**, although the means used fall short of those specified in subparagraph (a) above. EFFECTIVE LOSS OF TITLE, POSSESSION, OR CONTROL OR EXPRESS LOSS OF USE.
- E. TPP Annex 12-C(4)(a), KORUS Annex 11-B(4)(a), and U.S. Model BITs (2004/2012) Annex B(4)(a) further provides that whether “a specific fact situation, constitutes an indirect expropriation, requires a case-by-case, fact-based inquiry that considers, among other factors:”¹⁵⁷

¹⁵⁴ See Office of the United States Trade Representative, *U.S. Model Bilateral Investment Treaty (2012)*, Annex B(4) (hereinafter referred to as “U.S. Model BIT (2012)”), available at: <http://www.state.gov/documents/organization/188371.pdf>.

¹⁵⁵ U.S. Model BIT (2004) and U.S. Model BIT (2012), Annex B(3).

¹⁵⁶ *Id.*, at Annex B(4).

¹⁵⁷ *Id.*, at Annex B(4)(a).

- I. “the economic impact of the government action...or series of actions;”¹⁵⁸
 - II. “the extent to which the government action interferes with distinct, reasonable investment-backed expectations; and”¹⁵⁹
 - III. “the character of the government action.”¹⁶⁰
 - IV. KORUS Annex 11-B(3)(a)(iii) elaborates on the third factor. It provides that, “the character of the government action, includ[es] its objectives and context. Relevant considerations could include whether the government action imposes a special sacrifice on the particular investor or investment that exceeds what the investor or investment should be expected to endure for the public interest.”¹⁶¹
- F. **TPP Annex 12-D(3)** alternatively provides that “[i]n order to constitute indirect expropriation, the state's deprivation of the investor's property must be: (a) either severe or for an indefinite period; and (b) **disproportionate to the public purpose.**” **DEPENDS ON FACTS AND CIRCUMSTANCES – “NECESSARY” TO ACHIEVE LEGITIMATE OBJECTIVES” AS DETERMINED UNDER BIT ARBITRATION AND WTO CASE LAW.**
- G. **TPP Annex 12-D(4)** alternatively provides that “[a] deprivation of property shall be particularly likely to constitute indirect expropriation where it is either: (a) discriminatory in its effect, either as against the particular investor or against a class of which the investor forms part; or (b) in breach of the state's prior binding written commitment to the investor, whether by contract, license or other legal document.”
- H. TPP Annex 12-C(4)(b), KORUS Annex 11-B(3)(b), and U.S. Model BITs (2004/2012) Annex B(4)(b) set forth a **presumption of non-expropriation**. It provides that, “[e]xcept in rare circumstances, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, do not constitute indirect expropriations.” Accompanying FN 23 states that, “for greater certainty, the list of legitimate public welfare objective in this subparagraph is not exhaustive.”]

¹⁵⁸ Id., at Annex B(4)(a)(i).

¹⁵⁹ Id., at Annex B(4)(a)(ii).

¹⁶⁰ Id., at Annex B(4)(a)(iii).

¹⁶¹ KORUS Annex 11-B(3)(a)(iii).

- I. TPP Annex 12-D provides two alternative formulations of TPP Annex 12-C(5)'s presumption of non-expropriation.
 - I. **Formulation #1 – Less Permissive:** “Except in rare circumstances to which paragraph 4 applies, such measures taken in the exercise of a state's regulatory powers as may be reasonably justified in the protection of the public welfare, including public health, safety and the environment, shall not constitute and indirect expropriation.]”
 - II. **Formulation #2 – More Permissive:** “Non-discriminatory regulatory actions by a Party that are designed and applied to achieve legitimate public welfare objectives, such as the protection of public health, safety, and the environment do not constitute indirect expropriation.])”
 - J. Legal/academic commentators have alleged that, of “[t]he possible meanings of indirect expropriation...addressed further in proposed Annexes 12-B, C, and D [which] also include the likelihood of protecting investor expectations...Annex 12-C is the most far reaching clarification and requires a case-by-case, fact-based inquiry...Investors can claim: (1) that their cases are the rare ones where even non-discriminatory regulation is not permitted, (2) that the regulatory actions are discriminatory, e.g., targeted solely at or disproportionately applied to pharmaceutical investors, or (3) that the interests being protected are not legitimate. To give concrete examples, if a compulsory licensing regime were to have a local capacity building option, a pharmaceutical investor might claim this objective was a rare, challengeable circumstance. Likewise, if facially neutral compulsory licensing rights were used more routinely to grant pharmaceutical-related licenses, the pharmaceutical investor might claim ‘discrimination.’ Finally, if a price-control or formulary measure did not adequately ‘respect’ innovation according to a drug company’s perspective, the control measure’s purpose might be deemed not legitimate.”¹⁶²
- v. TPP Art. 12.12.1(a) and accompanying Footnote 19 (in brackets) – Reflect that “the term ‘public purpose’ refers to a concept in customary international law”, which may be expressed in domestic

¹⁶² See Brook Baker, *Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines* (Sept. 2012), supra at p. 3.

law in similar terms “as ‘public necessity’, ‘public interest’ or ‘public use’.”]

- vi. Determining Whether a Governmental Activity Was Undertaken for a ‘Public Purpose’ is Facts-Intensive and Often Subject to Debate - Some commentators argue that “that as long as a regulation is passed for a public purpose, the enacting government need not pay compensation to the foreign investor even if the regulation results in a total deprivation of value...[,while other commentators argue] “that even if a regulation is enacted for a public purpose, [it] does not trump the requirement that compensation be rendered to foreign investors where government regulation has damaged or totally destroyed the value of their investments.”¹⁶³
- A. Section 712(1)(a) of the Restatement (Third) of the Foreign Relations Law of the United States (1987) states that “[a] state is responsible under international law for injury resulting from: (1) a taking by the state of the property of a national of another state that (a) is not for a public purpose.”¹⁶⁴ Comment (g) to Section 712 provides that “[a] state is not responsible for loss of property or for other economic disadvantage resulting from bona fide general taxation, regulation, forfeiture for crime, or other action of the kind that is commonly accepted as within the police power of states...”¹⁶⁵
- B. TPP Art. 12.12(5) states that “[t]his Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement [, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter (Intellectual Property Rights)].”¹⁶⁶ A CASE-BY-

¹⁶³ See Justin R. Marlles, *Public Purpose, Private Losses: Regulatory Expropriation and Environmental Regulation in International Investment Law*, 16 J. Transnational Law & Policy 275, 308 (2007), available at: http://www.law.fsu.edu/journals/transnational/vol16_2/Marlles.pdf.

¹⁶⁴ See *Restatement (Third) of the Foreign Relations Law of the United States*, American Law Institute, Vol. 1 (1987), Sec. 712(1)(a), available at: <http://translex.uni-koeln.de/output.php?docid=450400&markid=965000>.

¹⁶⁵ “A state is responsible as for an expropriation of property when it subjects alien property to taxation, regulation or other action that is confiscatory, or that prevents, unreasonably interferes with, or unduly delays, effective enjoyment of an alien’s property or its removal from the state’s territory....A state is not responsible for loss of property or for other economic disadvantage resulting from bona fide general taxation, regulation, forfeiture for crime, or other action of the kind that is commonly accepted as within the police power of states, if it is not discriminatory...” *Id.*, at Comment g.

¹⁶⁶ See also US-Uruguay Bilateral Investment Treaty (Nov. 2005), Art. 6(5), available at: http://www.ustr.gov/sites/default/files/uploads/agreements/bit/asset_upload_file748_9005.pdf.

CASE INQUIRY IS LIKELY NECESSARY TO DETERMINE WHETHER STATE ACTIONS WERE TRIPS (ARTICLE 31)-COMPLIANT.

2. *Investor-State Dispute Settlement* – TPP Section B

The investor-state dispute settlement procedures contained in the TPP leaked Investment Chapter draft are substantially similar to those contained in the KORUS. A brief description of the pre-arbitration procedures follows.

- a. TPP Art. 12.16bis – Scope and Application Where There is a Dispute – Dispute settlement procedures apply “where there is a dispute between a Party and an investor of another Party related to a covered investment made in the territory of a Party in accordance with its laws, regulations and investment policies”, except where a dispute is “related to government procurement or the provision of a subsidy or grant.”
- b. TPP Art. 12.17(1) – Consultation and Negotiation Required Prior to Commencing Arbitration – TPP Art. 12.17(1) requires [...a Party and the investor of another Party...in the event of...an alleged breach of an obligation of the former under Section A of this Chapter [which causes loss or damage to the investor or its investment]] [to] “initially seek to resolve the dispute through consultation and negotiation, which may include the use of non-binding, third-party procedures, such as good offices, conciliation and mediation. [Such consultations shall be initiated by written request for consultations delivered by the claimant to the respondent [, and shall state the nature of the dispute].”
 - i. TPP Art. 12.17(3) provides that “[t]he disputing parties shall endeavor to commence consultations within 30 days” of respondent’s receipt of such notice, “unless the disputing parties otherwise agree.”
 - ii. TPP Art. 12.17(2) provides that, upon receipt of said notice, “the state Party may require the investor concerned to pursue any applicable domestic administrative review procedures specified by the laws and regulations of the state Party, which may not exceed three months before the submission of the claim to arbitration under Article 12.18...”
 - A. The required administrative review procedures would presumably be those relating to the IP rights and assets alleged to have been indirectly expropriated.

- iii. TPP Art. 12.17(4) provides that, “[w]ith the objective of resolving an investment dispute through consultations, a claimant shall make all reasonable efforts to provide the respondent, prior to the commencement of the consultations, with information regarding the legal and factual basis for the investment dispute.”

- c. TPP Art. 12.17 goes beyond KORUS Section B, Art. 11.15. The latter merely states that “In the event of an investment dispute, the claimant and the respondent should initially seek to resolve the dispute through consultation and negotiation, which may include the use of non-binding, third-party procedures.”