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TPP Agreement Documents (//wikileaks.org/Second-release-of-secret-Trans.html)
TPP Environment Consolidated Text (/tpp-enviro)
TPP Environment Chairs Report (/tpp-enviro-chairsreport)

Australia - Fairfax (http://www.theage.com.au/national/australians-may-pay-more-for-medicines-under-trade-deal-20141016-1175a2.html)

Chile - Derechos Digitales (https://www.derechosdigitales.org/8009/un-ano-despues-ha-cambiado-el-capitulo-de-propiedad-intelectual-del-tpp/)

Mexico - La Jornada (http://wikileaks.jornada.com.mx/notas/acuerdo-trans-pacifico-consolidacion-de-un-sistema-abusivo-de-patentes)

New Zealand - The NZ Herald (http://www.nzherald.co.nz)

US - Knowledge Ecology International (http://www.keionline.org/node/2108)

US - Public Citizen (http://www.citizen.org/tpp-ip-wikileaks)

US - Wall Street Journal (http://blogs.wsj.com/pharmalot/2014/10/16/trade-talk-documents-suggest-access-to-medicines-may-become-harder/)

(on 2014-10-16)

Updated Secret Trans-Pacific Partnership Agreement (TPP) - IP Chapter (second publication)

Today, Thursday 16 October 2014, WikiLeaks released a second updated version of the Trans-Pacific Partnership (TPP) Intellectual Property Rights Chapter. The TPP is the world's largest economic trade agreement that will, if it comes into force, encompass more than 40 per cent of the world's GDP. The IP Chapter covers topics from pharmaceuticals, patent registrations and copyright issues to digital rights. Experts say it will affect freedom of information, civil liberties and access to medicines globally. The WikiLeaks release comes ahead of a Chief Negotiators' meeting in Canberra on 19 October 2014, which is followed by what is meant to be a decisive Ministerial meeting in Sydney on 25-27 October.



Despite the wide-ranging effects on the global population, the TPP is currently being negotiated in total secrecy by 12 countries. Few people, even within the negotiating countries' governments, have access to the full text of the draft agreement and the public, who it will affect most, none at all. Large corporations, however, are able to see portions of the text, generating a powerful lobby to effect changes on behalf of these groups and bringing developing country members reduced force, while the public at large gets no say. Read the full press release here (/tpp-ip2/pressrelease/)

Read the WikiLeaks editorial on this Chapter - US and Japan Lead Attack on Affordable Cancer Treatments (/tpp-ip2/attack-on-affordable-cancer-treatments.html)

Download the Updated Secret Trans-Pacific Partnership Agreement - IP Chapter (second publication) as PDF here (/tpp-ip2/tpp-ip2-chapter.pdf).

WikiLeaks Release of Secret Trans-Pacific Partnership Agreement (TPP) - Second Release

Intellectual Property Chapter for All 12 Nations with Negotiating Positions (May 16 2014 consolidated bracketed negotiating text) Go to start of document

Show table of contents

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TPP Negotiations, Ho Chi Minh IP Group Intellectual Property [Rights] Chapter May 16, 2014

Without Prejudice

COVER PAGE

INTELLECTUAL PROPERTY [RIGHTS] CHAPTER

Consolidated Text

Ho Chi Minh Round – May 16, 2014

CHAPTER QQ1

{INTELLECTUAL PROPERY RIGHTS / INTELLECTUAL PROPERTY}

{Section A: General Provisions}

Article QQ.A.1: {Definitions}

For the purposes of this Chapter **intellectual property** refers to all categories of intellectual property that are the subject of Section 1 through 7 of Part II of the TRIPS Agreement.

Alt. - Article QQ.A.2²:

{[Confirming their commitment to] / [Each Party confirms its commitment to] // [Recognizing the importance of] / [Each Party recognizes the importance of] promoting innovation, creativity and deeper economic integration through:

effective and adequate creation, utilization, protection and enforcement of intellectual property rights, and

[achieving] a balance of {rights and} interests of [rights holders and interested parties/third parties/users],

[taking into account differences in levels of economic development and capacity]}

Article QQ.A.2: {Objectives}³

[Option: The Preamble, Article 7, and Article 8 of TRIPS is incorporated into and made part of this Chapter *mutatis mutandis.*]

[Option: [Replicating the TRIPS Preamble, Article 7, and Article 8 verbatim in the text.]

[Option: [Current Article QQ.A.2 and QQ.2bis]]

[NZ/CL/PE/VN/BN/MY/SG/CA⁴/MX⁵ propose; US/JP oppose: The objectives of this Chapter are:

- (a) enhance the role of intellectual property in promoting economic and social development, particularly in relation to the new digital economy, technological innovation, the [PE: generation,] transfer and dissemination of technology and trade;
- (b) reduce impediments to trade and investment by promoting deeper economic integration through effective and adequate creation, utilization, protection and enforcement of intellectual property rights, taking into account the different levels of economic development and capacity as well as differences in national legal systems;
- (c) maintain a balance between the rights of intellectual property holders and the legitimate interests of users and the community in subject matter protected by intellectual property;
- (d) protect the ability of Parties to identify, promote access to and preserve the public domain;
- (e) ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;
- (f) promote operational efficiency of intellectual property systems, in particular through quality examination procedures during the granting of intellectual property rights.]

[NZ/CA/SG/CL/MY/VN/BN/AU propose: (g) the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

(h) Support each Party's right to protect public health, including by facilitating timely access to affordable medicines.]

[AU: Each Party confirms its commitment to reducing impediments to trade and investment by promoting deeper economic integration through effective and adequate creation, utilization, protection and enforcement of intellectual property rights, and through greater quality, efficiency and transparency in its intellectual property administration and registration systems.]

Article QQ.A.2bis: {Principles}

[NZ/CA/SG/CL/MY/VN propose⁶: 1. Each Party may, in formulating or amending its laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to its socio-economic and technological development, provided that such measures are consistent with the provisions of this Chapter.

- 2. Each Party may adopt or maintain appropriate measures, provided that they are consistent with the provisions of this Chapter, to prevent the abuse of intellectual property rights by right holders or the resort of practices which unreasonably restrain trade or adversely affect the international transfer of technology.
- 3. Each Party may adopt or maintain, consistently with the other provisions of this Chapter, appropriate measures to prevent or control {licensing} practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.]

Article QQ.A.5: {General Provisions}

Each Party shall give effect to the provisions of this Chapter. A Party may, but shall not be obliged to, provide more extensive protection for, and enforcement of, intellectual property rights under its law than is required by this Chapter, provided that such protection and enforcement does not contravene the provisions of this Chapter. Each Party shall be free to determine the appropriate method of implementing the provisions of this Chapter within its own legal system and practice.

Article QQ.A.6: {Declaration on the TRIPS Agreement and Public Health}

The Parties affirm their commitment to the *Declaration on the TRIPS Agreement and Public Health* (WT/MIN(01)/DEC/2).

Note: Potential proposal to bracket the clause in first sentence.

Article QQ.A.7: {Understanding Regarding Certain Public Health Measures}

The Parties have reached the following understandings regarding this Chapter:

- (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health-{by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.} Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.
- (b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82), as well

as the Decision on the Amendment of the TRIPS Agreement, adopted by the General Council, 6 December 2005 and the WTO General Council Chairperson's statement accompanying the Decision (WT/GC/M/100) (collectively, the "TRIPS/health solution"), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.

(c) With respect to the aforementioned matters, if any waiver of any provision of the TRIPS Agreement, of any amendment of the TRIPS Agreement, enters into force with respect to the Parties, and a Party's application of a measure in conformity with that waiver or amendment is contrary to the obligations of this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the waiver or amendment.

Article QQ.A.8: {Existing Rights and Obligations / International Agreements}⁷

[NZ/MY/CA/MX/VN/BN/PE/CL oppose: 1. Each Party affirms that it has ratified or acceded to the following agreements, as revised and amended:

- (a) Patent Cooperation Treaty (1970), as amended in 1979;
- (b) Paris Convention for the Protection of Industrial Property (1967); and
- (c) Berne Convention for the Protection of Literary and Artistic Works (1971).

[JP oppose: 2. Each Party shall ratify or accede to each of the following agreements, where it is not already a Party to such agreement, {subject to the fulfillment of its necessary domestic requirements and in any event no later than 1 January 2015, or alternatively, by the date of entry into force of this Agreement.}:

- (a) Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989);
- (b) Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), as amended in 1980;
- (c) International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention);
- (d) {Singapore Treaty on the Law of Trademarks (2006) / the Trademark Law Treaty (1994)⁸};
- (e) WIPO Copyright Treaty (1996); and
- (f) WIPO Performances and Phonograms Treaty (1996).]
- 3. Each Party shall notify the WTO of its acceptance of the Protocol amending the TRIPS Agreement

done at Geneva on December 6, 2005.

- 4. Each Party shall undertake reasonable efforts to ratify or accede to the following agreements:
 - (a) [SG oppose: Patent Law Treaty (2000);]
 - (b) Hague Agreement Concerning the International Registration of Industrial Designs (1999)
 - (c) [JP oppose: Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974).]]

Article QQ.A.9: {National Treatment}

1. In respect of all categories of intellectual property covered in this Chapter,⁹ each Party shall accord to nationals¹⁰ of the other Party treatment no less favorable than it accords to its own nationals with regard to the protection¹¹ [MY/CA/VN/BN/NZ oppose: and enjoyment] of such intellectual property rights [MY/CA/VN/BN/NZ oppose: and any benefits derived from such rights¹²] [MY propose:, subject to the exceptions provided in the TRIPS Agreement and in those multilateral agreements concluded under the auspices of WIPO].

{With respect to secondary uses of phonograms¹³ by means of analog communications[,] free¹⁴ over-the-air [CL propose: radio]¹⁵ broadcasting [CA/JP propose; US oppose: and other non-interactive communications to the public], however, a Party may limit the rights of the performers and producers of the other Party to the rights its persons are accorded within the jurisdiction of the other Party.

[AU propose: Where a Party provides for the right of remuneration in a phonogram in respect of free over-the-air television broadcasting of a cinematographic film or other audio-visual work incorporating a phonogram, the Party may limit the rights of the performers and producers of the other Party in respect of the separate right of remuneration in the phonogram to the rights its persons are accorded within the jurisdiction of the other Party.]

ALTERNATIVE to previous 2 paras: [CA/JP/BN/MX propose; US oppose: With respect to secondary uses of phonograms, a Party may limit the rights of the performers [MX oppose: and producers] of the other Party to the rights its persons are accorded within the jurisdiction of the other Party.]}

- 2. A Party may derogate from paragraph 1 in relation to its judicial and administrative procedures, including requiring a national of the other Party to designate an address for service of process in its territory, or to appoint an agent in its territory, provided that such derogation is:
 - (a) necessary to secure compliance with laws and regulations that are not inconsistent with this Chapter, and
 - (b) not applied in a manner that would constitute a disguised restriction on trade.
- 3. Paragraph 1 does not apply to procedures provided in multilateral agreements concluded under the

auspices of WIPO relating to the acquisition of maintenance of intellectual property rights.

Original Article QQ.A.8: {Most-Favoured-Nation Treatment}

[VN propose: Article 4 and 5 of the TRIPS shall apply with necessary modifications to the protection of intellectual property in this Chapter.]

Article QQ.A.10: {Transparency}¹⁶

[NZ/AU/SG/MY/CA¹⁷/MX/CL/PE/VN propose: 2. Each Party shall endeavor to make available on the Internet

- (a) its laws, regulations, procedures, and administrative rulings of general application concerning the protection and enforcement of intellectual property rights; and
- (b) [JP/VN/US oppose: those details [JP propose:, where appropriate,] of patent, trademark, design, plant variety protection and geographical indication applications that are open to public inspection under national law.]]

{Article QQ.A.10bis: {Application of Agreement to Existing Subject Matter and Prior Acts}

- 1. Except as it otherwise provides, including in Article QQ.G8 (Berne 18/TRIPS 14.6), this Chapter gives rise to obligations in respect of all subject matter existing at the date of entry into force of this Agreement that is protected on that date in the territory of the Party where protection is claimed, or that meets or comes subsequently to meet the criteria for protection under this Chapter.
- 2. [CL/NZ/PE/MY/BN/VN/CA/MX oppose: Except as otherwise provided in this Chapter, including Article QQ.G.8 (Berne 18/TRIPS 14.6),] a Party shall not be required to restore protection to subject matter than on the date of entry into force of this Agreement has fallen into the public domain in its territory.¹⁸
- 3. This Chapter does not give rise to obligations in respect of acts that occurred before the date of entry into force of this Agreement.}

Article QQ.A.11: {Exhaustion of IP Rights}

Nothing in this Chapter shall be construed to address the issue of the exhaustion of intellectual property rights.

Article QQ.A.14: {Security Exceptions}

[Note: This Article is subject to further discussion pending outcome in the L&I group.]

Section B: Cooperation

Article QQ.B.1: {Contact Points for Cooperation}

Further to TT.3 [Contact Points for Cooperation and Capacity Building], each Party may designate one or more contact points for the purpose of cooperation under this section.

Article QQ.B.2: {Cooperation Activities and Initiatives}

The Parties shall endeavor to cooperate on the subject matter covered by this Chapter, such as through appropriate coordination, training and exchange of information between the intellectual property offices of the Parties, or other institutions as determined by each Party. Cooperation may cover such areas as:

- (a) developments in domestic and international intellectual property policy;
- (b) intellectual property administration and registration systems;
- (c) education and awareness relating to intellectual property;
- (d) intellectual property issues relevant to:
 - (a) small and medium-sized enterprises;
 - (b) science, technology & innovation activities; and
 - (c) the generation, transfer and dissemination of technology;
- (e) policies involving the use of intellectual property for research, innovation and economic growth;
- (f) implementation of multilateral intellectual property agreements, such as those concluded or administered under the auspices of WIPO; and
- (g) technical assistance for developing countries.

Article QQ.B.3: {Patent Cooperation/Work Sharing}

- 1. In order to improve quality and efficiency in the Parties' patent systems, the Parties shall endeavor to cooperate among their respective patent offices to facilitate the sharing and use of search and examination work of other Parties. This may include:
 - (a) making search and examination results available to the patent offices of other Parties¹⁹, and
 - (b) exchanges of information on quality assurance systems and quality standards relating to patent examination.
- In order to reduce the complexity and cost of obtaining the grant of a patent, the Parties shall endeavor to cooperate to reduce differences in the procedures and processes of their respective patent offices.

Article QQ.B.x: {Public Domain}

- 1. The Parties recognize the importance of a rich and accessible public domain.
- The Parties also acknowledge the importance of informational materials, such as publicly accessible databases of registered intellectual property rights that assist in the identification of subject matter that has fallen into the public domain.

Article QQ.B.4: {Cooperation on Request}

Cooperation activities and initiatives undertaken under this Chapter shall be subject to the availability of resources, and on request and on terms and conditions mutually agreed upon between the Parties involved.

{Section C: Trademarks}

Article QQ.C.1: {Types of Signs Registrable as Trademarks}

No Party may require, as a condition of registration, that a sign be visually perceptible, [²⁰] nor may a Party deny registration of a trademark solely on the ground that the sign of which it is composed is a sound [VN/BN/CA/JP oppose: or a scent] [²¹]. A Party may require a concise and accurate description, or graphical representation, or both, as applicable, of the trademark.

Article QQ.C.2: {Collective and Certification Marks}

1. Each Party shall provide that trademarks shall include collective marks and certification marks. A Party is not obligated to treat certification marks as a separate category in its domestic law, provided that such marks are protected. Each Party [MX oppose: shall] [MX propose: may] also provide that signs that may serve as geographical indications are capable of protection under its trademark system.²²

[US/PE/MX²³/SG propose; AU/NZ/VN/BN/MY/CA oppose: 2. Pursuant to Article 20 of the TRIPS Agreement, each Party shall ensure that its measures mandating the use of the term customary in common language as the common name for a good or service ("common name") including, *inter alia*, requirements concerning the relative size, placement or style of use of the trademark in relation to the common name, do not impair the use or effectiveness of trademarks used in relation to such good or service.[²⁴]]²⁵[²⁶]

Article QQ.C.3: {Use of Identical or Similar Signs}

Each Party shall provide that the owner of a registered trademark shall have the exclusive right to prevent third parties not having the owner's consent from using in the course of trade identical or similar signs, [PE/MY/VN/CA/MX oppose: including subsequent geographical indications,] for goods or services that are related to those goods or services in respect of which the owner's trademark is registered, where such use would result in a likelihood of confusion. In the case of the use of an identical sign, [PE/MY/SG/CL/CA/MX/VN oppose: including a geographical indication,] for identical goods or services, a likelihood of confusion shall be presumed.

Article QQ.C.4:

Each Party may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interest of the owner of the trademark and of third parties.

Article QQ.C.5: {Well Known Trademarks}

- 1. No Party may require as a condition for determining that a trademark is well-known that the trademark has been registered in the Party or in another jurisdiction, included on a list of well-known trademarks, or given prior recognition as a well-known trademark.
- 2. Article 6*bis* of the *Paris Convention for the Protection of Industrial Property* (1967) shall apply, *mutatis mutandis*, to goods or services that are not identical or similar to those identified by a well-known trademark,²⁷ whether registered or not, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the trademark, and provided that the interests of the owner of the trademark are likely to be damaged by such use.
- 3. Each Party recognizes the importance of the Joint Recommendation Concerning Provisions on the

Protection of Well-Known Marks (1999) as adopted by the Assembly of the Paris Union for the Protection of Industrial Property and the General Assembly of WIPO.

- 4. Each Party shall provide for appropriate measures to refuse the application or cancel the registration and prohibit the use of a trademark that is identical or similar to a well-known trademark, ²⁸ for identical or similar goods or services, if the use of that trademark is likely to cause confusion with the prior well known trademark. A Party may also provide such measures *inter alia* in cases in which the subsequent trademark²⁹:
 - (a) is likely to deceive or risk associating the trademark with the owner of the well-known trademark, or
 - (b) constitutes unfair exploitation of the reputation of the well-known trademark.

Article QQ.C.6: {Examination, Opposition and Cancellation / Procedural Aspects}

Each Party shall provide a system for the examination and registration of trademarks which shall include, inter alia:

- (a) providing to the applicant a communication in writing, which may be electronic, of the reasons for any refusal to register a trademark;
- (b) providing the opportunity for the applicant to respond to communications from the competent authorities, to contest an initial refusal, and to appeal judicially any final refusal to register a trademark;
- (c) providing an opportunity to oppose the registration of a trademark or to seek cancellation³⁰ of a trademark; and
- (d) requiring that administrative decisions in opposition and cancellation proceedings be reasoned and in writing. Written decisions may be provided electronically.

Article QQ.C.7: {Electronic Trademarks System}

Each Party shall provide:

- (a) a system for the electronic application for, and maintenance of, trademarks; and
- (b) a publicly available electronic information system, including an online database, of trademark applications and of registered trademarks.

Article QQ.C.8: {Classification of Goods and Services}

Each Party shall adopt or maintain a trademark classification system that is consistent with the *Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks* (Nice Classification) of June 15, 1957, as revised and amended. Each Party shall provide that:

[CA oppose: (a) registrations and the publications of applications indicate the goods and services by their names grouped according to the classes established by the Nice Classification³¹; and]

(b) goods or services may not be considered as being similar to each other on the ground that, in any registration or publication, they are classified in the same class of the Nice Classification. Conversely, each Party shall provide that goods or services may not be considered as being dissimilar from each other on the ground that, in any registration or publication, they are classified in different classes of the Nice Classification.

Article QQ.C.9: {Term of the Protection for Trademarks}

Each Party shall provide that initial registration and each renewal of registration of a trademark shall be for a term of no less than 10 years.

Article QQ.C.10:

No Party may require recordal of trademark licenses: to establish the validity of the license; [VN/MX oppose: [CL/BN/MY oppose: as a condition for any right that a licensee may have under that Party's law to join infringement proceedings initiated by the holder, or to obtain by way of civil infringement proceedings damages resulting from an infringement of the trademark which is subject to the license]; or as a condition for use of a trademark by a licensee, to be deemed to constitute use by the holder in proceedings relating to the acquisition, maintenance and enforcement of trademarks].

Article QQ.C.12: {Domain Name Cybersquatting}

- 1. In connection with each Party's system for the management of its country-code top-level domain (ccTLD) domain names, the following shall be available:
 - (a) an appropriate procedure for the settlement of disputes, based on, or modeled along the same lines as, the principles established in the Uniform Domain-Name Dispute-Resolution Policy, or that is: (i) designed to resolve disputes expeditiously and at low cost, (ii) fair and equitable, (iii) not overly burdensome, and (iv) does not preclude resort to court litigation; and

- (b) online public access to a reliable and accurate database of contact information concerning domain-name registrants;
- in accordance with each Party's laws and, or relevant administrator policies regarding protection of privacy and personal data.
- 2. In connection with each Party's system for the management of ccTLD domain names, appropriate remedies,³² shall be available, at least in cases where a person registers or holds, with a bad faith intent to profit, a domain name that is identical or confusingly similar to a trademark.

{Section D: Geographical Indications}

Note: As a result of further changes, Parties may need to re-attribute to provisions not previously closed below.

Article QQ.D.1: {Recognition of Geographical Indications}

The Parties recognize that geographical indications may be protected through a trademark or *sui generis* system or other legal means.

Article QQ.D.2:

Where a Party provides administrative procedures for the protection or recognition of geographical indications, whether through a trademark or a *sui generis* system, the Party shall with respect to applications for such protection or petitions for such recognition:

- (a) accept those applications or petitions without requiring intercession by a Party on behalf of its nationals³³;
- (b) process those applications or petitions without imposition of overly burdensome formalities;
- (c) ensure that its regulations governing the filing of those applications or petitions are readily available to the public and clearly set out the procedures for these actions;
- (d) make available information sufficient to allow the general public to obtain guidance concerning the procedures for filing applications or petitions and the processing of those applications or petitions in general; and allow applicants, petitioners, or their representatives to ascertain the status of specific applications and petitions;
- (e) ensure that those applications or petitions are published for opposition and provide procedures for opposing geographical indications that are the subject of applications or petitions; and
- (f) provide for cancellation³⁴ of the protection or recognition afforded to a geographical indication.

Article QQ.D.3: {Grounds of Opposition and Cancellation}³⁵

- 1. Where a Party protects or recognizes a geographical indication through the procedures referred to in Article QQ.D.2, that Party shall provide procedures that allow interested persons to object to the protection or recognition of a geographical indication, and that allow for any such protection or recognition to be refused or otherwise not afforded, [MX oppose: at least on the following grounds:
 - (a) [MY/VN oppose: the geographical indication is likely to cause confusion with a trademark or geographical indication that is the subject of a pre-existing good faith pending application or registration in the territory of the Party;]
 - (b) [MY/VN oppose: the geographical indication is likely to cause confusion with a pre-existing trademark or geographical indication, the rights to which have been acquired in accordance with Party's law; and]
 - (c) the geographical indication is a term customary in common language as the common name for such goods in that Party's territory.]

[NZ/CL/US/AU/SG/MY/MX/VN/BN propose; 2. [JP propose: As an alternative to paragraph 1,] Where a Party has protected or recognized a geographical indication through the procedures referred to in Article QQ.D.2, that Party shall provide procedures that allow for interested persons to seek the cancellation of a geographical indication, and that allow for the protection or recognition to be canceled [MX oppose at least on the grounds listed in paragraph 1 [MY/VN propose: (c)]]. A Party may provide that such grounds shall apply as of the time of filing the request for protection or recognition of a geographical indication in the territory of the Party³⁶.³⁷

[NZ/US/AU/JP³⁸ propose; MY/CL/MX/VN/SG/BN oppose: 2*bis*. Each Party [NZ/AU/US: shall] [JP propose: need not] apply procedures that are equivalent to, and grounds that are the same as, those set forth in {paragraph 1 and 2} with respect to geographical indications for goods protected pursuant to an agreement with another government or government entity, where those geographical indications are not protected pursuant to the procedures in Article QQ.D.2]

3. Where a Party has in place a *sui generis* system for protecting unregistered geographical indications by means of judicial procedures, a Party shall provide that its judicial authorities have the authority to deny the protection or recognition of a geographical indication where any of the circumstances identified in paragraph 1(i), paragraph 1(ii) and paragraph 1(iii) have been established³⁹. A Party shall also provide a process that allows {interested persons} to commence a proceeding on such grounds.

OPTION to replace Article QQ.D.3bis:

[4. Where a Party extends protection or recognition of any geographical indication, whether pursuant to the procedures referred to in Article QQ.D.2 or pursuant to an agreement with another government or government entity, to the translation or transliteration of such geographical indication, the Party shall make available procedures that are equivalent to, and grounds that are the same as, those set forth in paragraphs 1 and 2 with respect to such translation or transliteration.]

Article QQ.D.3bis: {Grounds of Opposition and Cancellation for translations and transliterations}

[NZ/US/AU/SG/BN/JP propose; MX/MY/PE oppose: 1. If a Party provides for protection or recognition of a translation or transliteration of a geographical indication, that Party shall also make available procedures that are equivalent to, and grounds that are the same as, those set forth in {Article QQ.D.3.1 and QQ.D.3.2} with respect to such translation or transliteration.]

[NZ/US/AU/JP propose; MX/MY/PE/SG/CL/BN oppose: 2. Each Party [shall] [JP propose: need not] apply the procedures that are equivalent to, and grounds that are the same as, those set forth in {Article QQ.D.3.1 and QQ.D.3.2} with respect to translations and transliterations of geographical indications for goods other than wines and spirits protected pursuant to an agreement with another government or government entity, where those geographical indications are not pursuant to the procedures in Article QQ.D.2].⁴⁰

Article QQ.D.4: {Opposition and Cancellation (wines and spirits pursuant to agreements)}

{Each Party {shall apply} {need not apply} procedures equivalent to those set forth in {Article QQ.D.2(e) – (f)} with respect to geographical indications for wines and spirits protected pursuant to an agreement with another government or government entity, where those geographical indications are not protected pursuant to the procedures in Article QQ.D.2.}

Note: Parties will need to consider their attributions for QQ.D.4

Article QQ.D.5: {Existing International Agreements}

[NZ/US/SG/AU/CA⁴¹ propose: No Party shall be required to apply [Section D] [Article QQ.D.3] [CA propose: QQ.D.3, QQ.D.4, QQ.D.X and QQ.D.9] to geographical indications that [have been specifically identified in] [are protected pursuant to] an agreement between that Party and another government, government entity {or international organization}[.] [provided that such an agreement was concluded or agreed in principle prior to 31 December 2013] [provided that such agreement was concluded or agreed prior to the date of entry into force of this Agreement]⁴². [VN propose: provided that such an agreement was concluded or agreed prior to the expiry of three years after entry into force of this Agreement]. [CA propose: For the purpose of this Article, "agreed in principle" refers to an agreement with another government or government entity or international organization in respect of which a political understanding has been reached and the negotiated outcomes of the agreement have been publicly notified/announced].]

[MX propose: No Party shall be required to apply (Section D) to geographical indications that are protected pursuant to an international agreement between that Party and another government, government entity or international organization, provided that the geographical indications are specifically identified and that such an agreement was concluded or agreed in principle prior to the date of entry into force of this Agreement.⁴³]

Article QQ.D.X:

NZ/US/AU/SG/BN propose;⁴⁴ No Party shall preclude the possibility that the protection or recognition of a geographical indication may be canceled⁴⁵ or otherwise cease on the grounds that the protected or recognized term has ceased meeting the conditions upon which the protection was originally granted.⁴⁶ ⁴⁷

Article QQ.D.6: {Date of Protection of a Geographical Indication}

- 1. Where a Party grants protection or recognition to a geographical indication through the procedures referred to in Article QQ.D.2, such protection or recognition shall commence no earlier than the filing date⁴⁸ in the Party or the registration date in the Party, as applicable.
- [2. NZ/SG/CA/AU/US/CL/PE/VN/JP/BN propose; MX oppose: Where a Party grants protection or recognition to a geographical indication through an agreement with another government or government entity, [and those geographical indications are not protected pursuant to the procedures in Article QQ.D.2,] such protection or recognition shall commence no earlier than the date on which such agreement enters into force, or if that Party implements such protection or recognition on a date after entry into force of the agreement, on that later date.] [MY propose:⁴⁹]

Article QQ.D.8: {Guidelines for Determining whether a term is the term customary in the common language as the common name for the relevant goods in a Party's territory}

In determining whether a term is the term customary in the common language as the common name for the relevant goods in a Party's territory, a Party's authorities shall have the authority to take into account how consumers understand the term in that Party's territory. Factors relevant to such consumer understanding may include:

- (a) whether the term is used to refer to the type of product in question, as indicated by competent sources such as dictionaries, newspapers, and relevant websites; and
- (b) how the product referenced by the term is marketed and used in trade in the territory of that Party.⁵⁰

Article QQ.D.9: {Multi-Component Terms}

An individual component of a multi-component term that is protected as a geographical indication in a Party shall not be protected in that Party where the individual component is a term customary in the common language as the common name for the associated goods.

Article QQ.D.11:[CL/SG/BN/VN/MX propose⁵¹; AU/PE/US/NZ/CA/JP oppose: **List of Geographical Indications**

The terms listed in Annex [...] are recognized as geographical indications of the respective Party, within the meaning of paragraph 1 of Article 22 of the TRIPS Agreement. Subject to domestic laws [⁵²], in a manner that is consistent with the TRIPS Agreement, such terms will be protected as geographical indications in the territories of the other Parties.]

Article QQ.D.12: {Homonymous Geographical Indications}

[PE oppose: Where a Party provides protection for homonymous geographical indications for spirits, that Party shall determine the practical conditions under which such indications will be differentiated from each other in its territory, taking into account the need to ensure equitable treatment of the procedures concerned and that consumers are not misled.]

[CL propose; AU/US/PE/NZ/VN/SG/MY/BN/MX/CA/JP oppose: 2. The Parties recognize the geographical indication *Pisco* for the exclusive use for products from Chile and Peru.]

[CL/SG/BN/MX propose; AU/PE/US/NZ/CA/JP/VN/MY oppose: **Annex [...] Lists of Geographical Indications**]

Article QQ.D.13: {Country Names}⁵³

Each Party shall provide the legal means for interested parties to prevent commercial use of countries names of the Parties in relation to goods in a manner which misleads consumers as to the origin of such goods.

{Section E: Patents / Undisclosed Test or Other Data / Traditional Knowledge}

Article QQ.E.1: {Patents / Patentable Subject Matter}

1. Subject to the provisions of paragraph 2 and 3, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.⁵⁴

2. Each Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature of the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

[US/JP propose; CL/MY/PE/SG/VN/BN/AU/NZ/CA/MX oppose: 2bis. For greater certainty, a Party may not deny a patent solely on the basis that the product did not result in an enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.]

- 3. [US/JP/SG propose; AU/NZ/VN/BN/CL/PE/MY/CA/MX oppose: Consistent with paragraph 1, each Party shall make patents available for inventions for plants and animals.]
- Alt. 3: {Consistent with paragraph 1, each Party confirms that it makes available patents for plant-related inventions.⁵⁵}
- 4. [US/AU/JP propose; CL/MY/PE/SG/VN/BN/NZ/CA/MX oppose: Consistent with paragraph 1, the Parties confirm that patents are available for⁵⁶:
 - (a) any new uses, or alternatively⁵⁷, new methods of using a known product.]

[CA propose: Alt (a) any new use, or new method of using a known product that is not otherwise excluded from patentability by the Party.]

[NZ/CA/CL/MY/VN/MX/BN/PE/AU propose: ALT 3. Each Party may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Parties shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.]

[MX propose: (c) and the diagrams, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods as such; software as such, methods to present information as such; and aesthetic creations and artistic or literary works.]

Article QQ.E.2: {Grace Period}

Each Party shall disregard at least information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure⁵⁸ ⁵⁹:

(a) was made by the patent applicant or by a person who obtained the information directly or indirectly from the patent applicant,

and

(b) occurred within 12 months prior to the date of filing of the application in the territory of the Party.

Article QQ.E.3:

Option 1: [US/JP propose; CA/CL/MX/BN/MY/AU/VN/NZ/SG oppose: Without prejudice to Article 5A(3) of the Paris Convention,] each Party shall provide that a patent may be canceled, revoked, or nullified only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for canceling, revoking or nullifying a patent or holding a patent unenforceable.

Option 2: Each Party shall provide that a patent may be canceled, revoked or nullified only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for canceling, revoking or nullifying a patent or holding a patent unenforceable.⁶⁰

[AU/CL/MY/NZ/BN/CA/MX/VN/SG/PE propose⁶¹; US/JP oppose: A Party may also provide that a patent may be canceled, revoked or nullified on the basis that the patent is used in a manner determined to be anti-competitive in a judicial or administrative proceeding] [AU/CL/CA/MX/NZ/MY/BN/VN/SG/PE propose: consistent with Article 5A(3) of the Paris Convention.]

Article QQ.E.4: {Exceptions}

Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article QQ.E.13⁶² 63: {Exceptions / Regulatory Review Exception}

[CL/MY oppose: Consistent with Article QQ.E.4 (Exceptions),] if a Party permits a third person to use the subject matter of a subsisting patent to [CL oppose: generate information necessary] to support an application for marketing approval of a pharmaceutical [CA/MY/BN: or other] product [PE: and an agricultural chemical product], that Party shall provide that any product produced under such authority shall not be made, used, sold in, [PE: offered for sale,] {or imported into,} the territory of that Party other than for

purposes related to [CL oppose: generating information to meet] [CL: meeting] requirements for marketing approval {of that Party} for the product {, and each Party may also {also} permit {such} {a} product{s} to be exported outside its territory for purposes related [CL oppose: to generating information] to support an application for marketing approval in the [CL: exporting] Party or another country.}]⁶⁴

Option 2:

[NZ/CA/SG/CL/MY/VN/BN/AU propose⁶⁵: Consistent with [Article QQ.E.5 (Exceptions)], each Party may provide that a third person may do an act that would otherwise infringe a patent if the act is done for purposes connected with [AU oppose: the collection and submission of data in order to comply with the regulatory requirements of that Party or another country, including for purposes connected with marketing or sanitary approval.] [AU propose: obtaining marketing or regulatory approval or meeting sanitary permit requirements of that Party or another country.]]⁶⁶

Article QQ.E.6: {Patent Filing}

Each Party shall provide that where an invention is made independently by more than one inventor, and separate applications claiming that invention are filed with or for the relevant authority of the Party, that Party shall grant the patent on the application that is patentable and that has the earliest filing, or if applicable, priority date⁶⁷, unless that application has, prior to publication, [⁶⁸]been withdrawn, abandoned or refused.

Article QQ.E.7:

Each Party shall provide patent applicants with at least one opportunity to make amendments, corrections, and observations in connection with their applications⁶⁹.

Article QQ.E.8:

[US/AU/PE/VN/JP propose; CL/MY/BN/CA/SG/MX oppose: Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.]

Article QQ.E.9:

[US/PE/AU/JP/SG/VN propose; CL/MY/BN/NZ/CA/MX⁷⁰ oppose: Each Party shall provide that a claimed invention [AU/VN oppose: is] [AU/VN propose: shall be] sufficiently supported by its disclosure [AU/JP/SG/VN oppose: if the disclosure reasonably conveys to a person skilled in the art that the applicant

was in possession of the claimed invention] [JP propose; VN oppose: if the disclosure allows a person skilled in the art to extend the teaching therein to the entire scope of the claim] as of the filing date.]

Article QQ.E.10:

[US/AU/MX/SG propose;⁷¹ CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU/SG propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.]

Article QQ.E.11: {Publication of Patent Applications}

[AU/PE/NZ/MY/CL/VN/US/CA/MX/BN/JP/SG propose: 1. Each Party shall publish⁷² [US/MX oppose: or make available for public inspection] any patent application promptly after the expiry of 18 months from its filing date or, if priority is claimed, from its priority date, unless the application has been published earlier or has been withdrawn, abandoned or refused [CA/CL/BN/PE propose:, without leaving any rights outstanding [PE propose:, where applicable]].]⁷³ ⁷⁴

[US/JP/MY/SG/CA/PE/BN/CL/MX/NZ/VN propose: 2. A Party may provide that the obligation in paragraph 1 does not apply where the patent application:

(a)⁷⁵ implicates national security, [VN oppose: public safety, or public order [JP/MY/SG/PE/BN/CL propose: or morality]];

[US propose; JP/MY/SG/CA/PE/BN/CL/MX/AU/NZ/VN oppose: (b) has been issued as a patent;

- (c) contains or comprises disparaging or offensive subject matter;
- (d) was filed with a non-publication request, accompanied by the applicant's certification that the invention has not been and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications; or
- (e) involves other exceptional cases under the Party's law.]]

[AU propose: ALT to paras 1 and 2

- 1. Recognizing the benefits of transparency to the patent system, including by promoting innovation, each Party shall endeavor to publish⁷⁶ [US/MX oppose: or make available for public inspection] any unpublished pending patent application promptly after the expiry of 18 months from its filing date or, if priority is claimed, from its priority date. Where an application is not published promptly, Parties shall make best efforts to publish such applications or the relevant patent as soon as practicable.]
- 3. Each Party shall provide that an applicant may request the early publication of an application prior to the expiry of the period mentioned in paragraph 1.

Article QQ.E.11bis:

For published⁷⁷ patent applications and issued patents, and in accordance with the Party's requirements for prosecution of such applications and patents, each Party shall make available to the public at least the following information, to the extent that such information is in possession of the competent authorities and is generated on or after the date of entry into force of the Agreement for that Party:

- (a) search and examination results, including details of, or information related to, relevant prior art searches;
- (b) non confidential communications from applicants, where appropriate; and
- (c) patent and non-patent related literature citations submitted by applicants, and relevant third parties.

Article QQ.E.12:

[US/SG propose⁷⁸; CA/NZ/MY/VN/CL/PE/MX/AU/BN oppose:

{Option 1: Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in the granting of the patent.} {Option 2: If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of the patent owner, shall, adjust the term of the patent to compensate for such delays.} For purposes of this {subparagraph/Article}, an unreasonable delay at least shall include a delay in the issuance of {the} / {a} patent of more than four [CL/PE propose: five] years from the date of filing of the application in the territory of the Party, or two [JP/CL/PE propose: three] years after a request for examination of the application has been made, whichever is later. {Option 1: Periods attributable to actions of the patent applicant [JP propose: and to judicial or quasi-judicial actions on the patent application] need not to be included in the determination of such delays.} / {Option 2: For the purposes of this Article, any delays that occur in the issuance of a patent due to periods attributable to actions of the patent applicant or any opposing third person need not to be included in the determination of such delay.} [AU/NZ oppose: Any patent term

adjustment under this Article shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions that would otherwise apply to the patent absent any adjustment of the patent term.]] [SG:⁷⁹] [JP:⁸⁰]⁸¹ 82

Article QQ.E.13: {Agricultural Chemical Products}⁸³

[MX oppose: 1. If a Party requires, as a condition of approving the marketing {or sanitary permit} of a new agricultural chemical product, ⁸⁴ [JP/US propose; CL/PE/SG/CA/NZ/BN/MY/VN oppose: including certain new uses of the same product,] the submission of undisclosed {information}/{test or other data} concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same [CL oppose: or a similar] product on the basis of {that information, [CL oppose: or} the {marketing} approval granted to the person who submitted such {information}/{test or other data}], for at least [ten] [five] years from the date of the marketing approval {of the new agricultural chemical product} by the Party.]

[MX/CL oppose: 2. If a Party permits as a condition of approving the marketing of a new agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously submitted {undisclosed} {information}/{test or other data} concerning safety or efficacy, to market the same or a similar product on the basis of evidence of prior marketing approval in another country, or {undisclosed} {information}/{test or other data} that has not been made publicly available⁸⁵ concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory, for at least [ten] [five] years for agricultural chemical products, from the date of {first} marketing approval {relied on}/{by the Party, or the other territory, whichever is later.}]

[CL propose: Alt 2. A Party may provide for the possibility of granting marketing approval or sanitary permit for a new agricultural chemical product based on a prior marketing approval in another territory. If a Party provides for such possibility, the Party may also require consent or acquiescence of a person previously submitting the undisclosed test or other data to obtain marketing approval in the other territory, in order to authorize a third person to market a same or similar product in the territory of the Party for at least 10 years from the date of the first marketing approval of the new agricultural chemical product.]

3. For the purposes of this Article, a new agricultural product [CL propose: means a product that does not contain or utilize a chemical entity that as been previously approved in the Party.] [CL oppose: is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product.]

[MX/CL oppose: 4. Where a Party provides protection under paragraphs 1 and 2, a Party may require in conjunction with paragraph 2 that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.]

[MX propose:

- 1. If a Party requires, as a condition of approving the marketing for a new agricultural chemical product that utilizes a new chemical entity, the submission of undisclosed test or other data concerning safety or efficacy of that product, the Party shall protect against disclosure of such data for at least five years from the date of the marketing approval, where the origination of such data involve considerable effort, ⁸⁶ of the new agricultural chemical product by the Party, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.
- 2. Each Party shall provide that for data subject to paragraph 1 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.
- 3. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.]

Article QQ.E.23⁸⁷: {Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources}

[PE/NZ/VN/BN/MX/SG/CL/MY propose⁸⁸: 1. The Parties recognize the importance and contribution of traditional knowledge, traditional cultural expressions, and biological diversity to cultural, economic and social development.]

[89PE/MY/MX/BN propose; NZ/AU/SG/CL oppose: 2. Each Party exercises sovereignty over their biological [MY/BN oppose: diversity] [MY/BN propose: resources] and shall determine the access conditions to their genetic resources and their derivatives in accordance to their domestic legislation.]

[PE/BN/MY/MX/VN propose; AU/SG/CL oppose:⁹⁰ 3. Where national legislation [MY/BN propose: or policies] establishes such requirements, the Parties recognize that users of genetic resources [NZ/CA oppose: and their derivatives] [⁹¹] or traditional knowledge associated with generic resources [NZ/CA oppose: and their derivatives] [NZ propose: may] [PE/MY propose: shall]:

- (a) obtain prior informed consent to access genetic resources [NZ/CA oppose: and their derivatives];
- (b) access traditional knowledge associated with generic resources [NZ/CA oppose: and their

- derivatives] with the prior informed consent or approval and involvement of the indigenous or local community holding such knowledge; and
- (c) [BN/MY propose: fairly and] equitably share the benefits arising from the use of the genetic resources [NZ/CA oppose: and its derivatives] and traditional knowledge associated with genetic resources [NZ/CA oppose: and their derivatives] on mutually agreed terms.]

[PE/NZ/MX/CL/VN/BN/MY propose: 4. The Parties recognize that the intellectual property system may be one possible means to protect the traditional knowledge associated with genetic resources and traditional cultural expressions of indigenous and local communities.]]

[PE/NZ/MX/CL/SG/BN/VN/MY/AU propose: 5. The Parties shall endeavor to {pursue} quality patent examination including applications concerning genetic resources and traditional knowledge associated with generic resources. This may include:

- (a) in determining prior art, publicly available documented information related to genetic resources or traditional knowledge associated with genetic resources⁹² may be taken into account;
- (b) an opportunity for third parties to cite, in writing, to the competent examining authority prior art that may have a bearing on patentability;
- (c) where applicable and appropriate, the use of databases or digital libraries containing traditional knowledge associated genetic resources; and
- (d) cooperation in the training of patent examiners in the examination of patent applications related to genetic resources and traditional knowledge associated genetic resources.]

[PE/NZ/AU/MX/MY/BN/VN/CL/SG propose: 6. Subject to each Party's international obligations each Party may establish appropriate measures to {respect, preserve and promote} {protect} traditional knowledge and traditional cultural expressions. ⁹³]

[PE/MX/BN propose; NZ/AU/SG/CL oppose: 7. Each Party will take appropriate, effective and proportionate measures to address situations of non-compliance with provisions established in paragraph 3.]

[PE/NZ/MX/SG/MY/BN/VN/CL propose: 8. The Parties shall endeavor to cooperate through their respective agencies responsible for intellectual property or other relevant institutions to enhance understanding of how the intellectual property system can deal with issues associated with traditional knowledge, traditional cultural expressions and genetic resources⁹⁴.

Note: Pharmaceutical Provisions Are in Addendum I.

Section F: Industrial Designs

Article QQ.F.1: {Industrial Designs}⁹⁵

{Subject to} / {Without prejudice to a Party's rights and obligations under} Articles 25 and 26 of the TRIPS Agreement, each Party shall ensure adequate and effective protection of industrial designs. The Parties

also confirm that protection for industrial designs is available for designs:

(a) embodied in a part of an Article, or alternatively,

(b) of a part of an Article, where appropriate, having regard to the part in the context of the Article as

a whole.

[Alternative text below – for confirmation by Parties]

Article QQ.F.1: {Industrial Designs}⁹⁶

Subject to Articles 25 and 26 of the TRIPS Agreement, each Party shall ensure adequate and effective protection of industrial designs. The Parties also confirm that protection for industrial designs is available for

designs:

(a) embodied in a part of an Article, or alternatively,

(b) of a [VN propose: component] part of an Article, where appropriate, having regard to the part in

the context of the Article as whole.

{Section G: Copyright and Related Rights}

Article QQ.G.1: {Copyright and Related Rights / Right of Reproduction}

Each Party shall provide⁹⁷ that authors, performers, and producers of phonograms⁹⁸ have the right⁹⁹ to authorize or prohibit all reproductions of their works, performances 100, and phonograms in any manner of

form, including in electronic form.

Article QQ.G.2: {Copyright / Right of Communication to the Public}

Without prejudice to Articles 11(1)(ii), 11bis(1)(i) and (ii), 11ter(1)(ii), 14(1)(ii), and 14bis(1) of the Berne Convention, each Party shall provide to authors the exclusive right to authorize or prohibit the communication to the public of their works, by wire or wireless means, including the making available to the public of their works in such a way that members of the public may access these works from a place and a time individually chosen by them.¹⁰¹

Article QQ.G.4: {Right of Distribution}

Each Party shall provide to authors, performers, and producers of phonograms the right to authorize or prohibit the making available to the public of the original and copies¹⁰² of their works, performances, and phonograms through sale or other transfer of ownership.¹⁰³ ¹⁰⁴

Article QQ.G.5: {No Hierarchy}

Each Party shall provide that in cases where authorization is needed from both the author of a work embodied in a phonogram and a performer or producer owning rights in the phonogram, the need for the authorization of the author does not cease to exist because the authorization of the performer or producer is also required. Likewise, each Party shall provide that in cases where authorization is needed from both the author of a work embodied in a phonogram and a performer or producer owning rights in the phonogram, the need for the authorization of the performer or producer does not cease to exist because the authorization of the author is also required.

Article QQ.G.14: {Related Rights}

- 1. Each Party shall accord the rights provided for in this Chapter with respect to performers and producers of phonograms to the performers and producers of phonograms who are nationals of another Party and to performances or phonograms first published or first fixed in the territory of another Party.¹⁰⁵ A performance or phonogram shall be considered first published in the territory of a Party in which it is published within 30 days of its original publication.¹⁰⁶
- 2. Each Party shall provide to performers right to authorize or prohibit:
 - (a) broadcasting and communication to the public of their unfixed performances, except where the performance is already a broadcast performance; and
 - (b) fixation of their unfixed performances.

[CA oppose:

3.

- (a) Each Party shall provide to performers and producers of phonograms the right to authorize or prohibit the broadcasting or any communication to the public of their performances or phonograms, by wire or wireless means. 107 108 [JP/US propose:109], and the making available to the public of those performances and phonograms in such a way that members of the public may access them from a place and at a time individually chosen by them.
- (b) Notwithstanding subparagraph (a) an Article [QQ.G.16] [three step test], the application of this right to analog transmissions and non-interactive free over-the-air broadcasts. [CA propose: and to the retransmission of phonograms] and exceptions or limitations to this right for such activities, shall be a matter of each Party's law.]

[CA propose: Alt 3. Each Party shall provide to performers and producers of phonograms the rights to authorize or prohibit:

- (a) the broadcasting or any communication to the public of their performances or phonograms; and
- (b) the making available to the public, by wire or wireless means, of their performances and phonograms in such a way that members of the public may access them from a place and at a time individually chosen by them.

Where, upon the data of signature of this Agreement, the right in subparagraph (a) has not been implemented by a Party, the requirement may be satisfied by providing a right to a single equitable remuneration for the direct or indirect use of phonograms published for commercial purposes for broadcasting or for any communication to the public. 111

Article QQ.G.15: For purposes of this [Article QQ.G.1 and Article QQ.G.3 – 18], the following definitions apply with respect to performers and producers of phonograms:

- (a) "broadcasting" means the transmission by wireless means for public reception of sounds or of images and sounds or of the representations thereof; such transmission by satellite is also "broadcasting"; transmission of encrypted signals is "broadcasting" where the means for decrypting are provided to the public by the broadcasting organization or with its consent;
- (b) "communication to the public" of a performance or a phonogram means the transmission to the public by any medium, other than by broadcasting, of sounds of a performance or the sounds or the representations of sounds fixed in a phonogram. For purposes of paragraph [3][QQ.G.14.3], "communication to the public" includes making the sounds or representations of sounds fixed in a phonogram audible to the public;
- (c) "fixation" means the embodiment of sounds, or of the representations thereof, from which they can be perceived, reproduced, or communicated through a device;

- (d) "performers" means actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore;
- (e) "phonogram" means the fixation of the sounds of a performance or of other sounds, or of a representation of sounds, other than in the form of a fixation incorporated in a cinematographic or other audiovisual work;
- (f) "producer of a phonogram" means the person who, or the legal entity which, takes the initiative and has the responsibility for the first fixation of the sounds of a performance or other sounds, or the representations of sounds; and
- (g) "publication of a performance or a phonogram" means the offering of copies of the performance or the phonogram to the public, with the consent of the rightholder, and provided that copies are offered to the public in reasonable quantity.

Article QQ.G.6:

Each Party shall provide that, where the term of protection of a work (including a photographic work), performance, or phonogram is to be calculated 112:

- (a) on the basis of the life of a natural person, the term shall not be less than the life of the author and [50] [70] [100] after the author's death; and
- (b) on a basis other than the life of a natural person, the term shall be:
 - i. not less than [50] [70] [75] [95] years from the end of the calendar year of the first authorized publication of the work, performance, or phonogram, or
 - ii. failing such authorized publication within [25] [50] years from the creation of the work, performance, or phonogram, not less than [50] [70] [100] [120] years from the end of the calendar year of the creation of the work, performance, or phonogram.¹¹³

[JP propose: Notwithstanding Article QQ.A.7.1, a Party may limit the term provided to authors of another Party [MY propose: or country] to the term provided to authors under the legislation of the other Party [MY propose: or country.]]

Article QQ.G.8: {Berne 18}

Each Party shall apply Article 18 of the Berne Convention for the Protection of Literary and Artistic Works (1971) (Berne Convention) and Article 14.6 of the TRIPS Agreement, *mutatis mutandis*, to works, performances and phonograms, and the rights in and protections afforded to that subject matter as required by Section G.¹¹⁴

Article QQ.G.16: {Limitations and Exceptions}

- (a) With respect to Section G, each Party shall confine limitations or exceptions to exclusive rights to certain special cases that do not conflict with a normal exploitation of the work, performance, or phonogram, and do not unreasonably prejudice the legitimate interests of the right holder.
- (b) Article QQ.G.16(a) neither reduces nor extends the scope of applicability of the limitations and exceptions permitted by the TRIPS Agreement, the Berne Convention, [VN propose; US/SG oppose: the Rome Convention,] the WIPO Copyright Treaty, and the WIPO Performances and Phonograms Treaty. 115

Article QQ.G.Y: {Limitations and Exceptions}

Each Party shall endeavor to achieve an appropriate balance in its copyright and related rights system, *inter alia* by means of limitations or exceptions that are consistent with Article QQ.G.16.1, including those for the digital environment, giving due consideration to legitimate purposes such as, but not limited to: criticism, comment, news reporting, teaching, scholarship, research, and other similar purposes; and facilitating access to [AU oppose: published] works for persons who are blind, visually impaired, or otherwise print [AU propose: or perceptually] disabled.¹¹⁶ ¹¹⁷

Article QQ.G.ZZ: {Internet Retransmission}

[US/SG/PE propose: CL/VN/MY/NZ/MX/CA/BN/JP oppose: No Party may permit the retransmission of television signals (whether terrestrial, cable, or satellite) on the Internet without the authorization of the right holder or right holders of the content of the signal [SG oppose: and, if any, of the signal]. 118] 119

[ALTERNATE: 120

FN attached to QQ.G.2: A Party may not limit this right in order to provide for a compulsory remuneration regime in cases where an over the air signal containing an audiovisual work is transmitted on the Internet.]

Article QQ.G.9: {Contractual Transfers}

Each Party shall provide that for copyright and related rights, any person acquiring or holding any economic right¹²¹ in a work, [SG/BN/MY/VN oppose: performance,] or phonogram:

- (a) may freely and separately transfer that right by contract; and
- (b) by virtue of a contract, including contracts of employment underlying the creation of works, [SG/BN/MY/VN oppose: performances,] and phonograms, shall be able to exercise that right in

that person's own name and enjoy fully the benefits derived from that right. 122

Article QQ.G.X: {No Formalities Rule}

No Party may subject the enjoyment and exercise of the rights of authors, performers and producers of phonograms provided for in this Chapter to any formality.

Article QQ.G.10: {Technological Protection Measures}¹²³ 124

- (a) In order to provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that authors, performers, and producers of phonograms use in connection with the exercise of their rights and that restrict unauthorized acts in respect of their works, performances, and phonograms, ¹²⁵ each Party shall provide that any person who:
 - i. knowingly [MX propose:, or with respect to civil remedies] [CL oppose:, or having reasonable grounds to know,] circumvents without authority any [MY propose: such] effective technological measure [MY oppose: that controls access to a protected work, 126 performance, or phonogram]; 127 or
 - ii. manufactures, imports, distributes¹²⁸, offers for sale or rental to the public, or otherwise provides devices, products, or components, or offer to the public or providers services, that:
 - A) are promoted, advertised, or otherwise marketed by that person¹²⁹ for the purpose of circumventing any effective technological measure,
 - B) have only a limited commercially significant purpose or use other than to circumvent any effective technological measure¹³⁰, or
 - C) are primarily designed, produced, or performed for the purpose of circumventing any effective technological measure, shall be liable and subject to the remedies set out in [Article QQ.H.4.17 (Civil Judicial Proceedings relating to TPMs and RMIs)¹³¹].

Each Party [US/CA/SG/NZ/MX/PE/AU/BN/JP/CL propose: shall] [VN/MY propose: may] provide for criminal procedures and penalties to be applied where any person is found to have engaged willfully¹³² and for the purposes of commercial advantage or financial gain¹³³ in any of the above activities.¹³⁴

Each Party may provide that such criminal procedures and penalties do not apply to a non-profit library, museum archive, educational institution, or public non-commercial broadcasting entity. A Party may also provide that the remedies set out in Article QQ.H.4.17 (Civil Judicial Proceedings relating to TPMs and RMIs) do not apply to those same entities provided that the above activities are carried out in good faith without knowledge that the conduct is prohibited.

(b) In implementing subparagraph (a), no Party shall be obligated to require that the design of, or the design and selection of parts and components for, a consumer electronics, telecommunications, or computing product provide for a response to any particular technological measure, so long as the product does not

otherwise violate any measure implementing subparagraph (a).

[CL oppose: (c) Each Party shall provide that a violation of a measure implementing this paragraph is independent of any infringement that might occur under the Party's law on copyright and related rights.]

- (d) (i) Each Party may provide MY/MX/PE oppose: certain] exceptions and limitations to the measures implementing subparagraphs (a)(i) and (ii) in order to enable non-infringing uses where there is an actual or likely adverse impact of those measures on those non-infringing uses, as determined through a legislative, regulatory, or administrative process in accordance with the Party's law, giving due consideration to evidence when presented in that process, including with respect to whether appropriate and effective measures have been taken by rights holders to enable the beneficiaries to enjoy the limitation s and exceptions under that Party's law [in accordance with Article QQ.G.16] [CL propose:, as well as the evidence presented by the beneficiaries with respect to the necessity of the creation of such exception and limitation] ¹³⁵. ¹³⁶
- (ii) Any exceptions and limitations to the measures implementing subparagraph [CL propose: a(i) and] (a)(ii) shall be permitted solely to enable the legitimate use of an exception or limitation permissible under Article QQ.G.10 (TPMs) by its intended beneficiaries [CA propose: ¹³⁷] and [CL propose: in the case of subparagraph (a)(ii)] shall not authorize the making available of devices, products, components, or services beyond such intended beneficiaries. ¹³⁸
- (iii) [NZ/CA/BN propose: Paragraph (d)(i) and (ii) shall not be used by a Party to undermine] [US propose: By providing exceptions and limitations under paragraph d(i) and (ii) a Party shall not {impair}/{undermine}] the adequacy of that Party's [MY propose: overall] legal {framework} / {system} / {regime} for the protection of effective technological measures, or the effectiveness of legal remedies against the circumvention of such measures, that authors, performers, or producers of phonograms use in connection with the exercise of their rights, or that restrict unauthorized acts in respect of their works, performances or phonograms, as provided for in this Chapter. [CL propose: 139]

[MY oppose: (e) "Effective technological measure" means any effective technology, device or component that, in the normal course of its operation, controls access to a protected work, performance or phonogram, or protects [CA propose: copyright or related] rights related to a work, performance or phonogram [CL propose, CA oppose:, and cannot, in a usual case, be circumvented accidentally].]

Article QQ.G.13: {Copyright and Related Rights / Rights Management Information}

In order to provide adequate and effective legal remedies to protect rights management information: 140

(a) each Party shall provide that any person who without authority, and knowing, or, with respect to civil remedies, having reasonable grounds to know, that it would induce, enable, facilitate or conceal an infringement of the copyright or related right of authors, performers, or producers of

phonograms,

(i) knowingly¹⁴¹ removes or alters any rights management information;

[US/BN/SG/NZ/PE/CL/JP/AU/MX propose; CA/MY/VN oppose: (ii) knowingly distributes or imports for distribution rights management information knowing that the rights management information has been altered without authority¹⁴²;] or

(iii) knowingly distributes, imports for distribution, broadcasts, communicates or makes available to the public copies of works, performances, or phonograms, knowing that rights management information has been removed or altered without authority,

shall be liable and subject to the remedies set out in [Article QQ.H.4(17).]¹⁴³

Each Party [US/SG/MX/NZ/PE/JP/BN/AU/CL/MY propose: shall] [VN/CA propose: may] provide for criminal procedures and penalties to be applied where any person is found to have engaged willfully and for purposes of commercial advantage or financial gain in any of the above activities.

Each Party may provide that such criminal procedures and penalties do not apply to a non-profit library, museum, archive, educational institution, or public non- commercial broadcasting entity.¹⁴⁴

- b. For greater certainty, nothing prevents a Party from excluding lawfully authorized activities carried out for the purpose of law enforcement, essential security interests, [MY propose: performing statutory functions,] or other governmental purposes, from measures implementing subparagraph (a).
- c. "Rights management information" means:
 - i. information that identifies a work, performance, or phonogram, the author of the work, the performer of the performance, or the producer of the phonogram; or the owner of any right in the work, performance, or phonogram;
 - ii. information about the terms and conditions of the use of the work, performance, or phonogram; or
 - iii. any numbers or codes that represent such information,

when any of these items of information is attached to a copy of the work, performance, or phonogram or appears in connection with the communication or making available of a work, performance or phonogram, to the public.

d. For greater certainty, nothing in this Article shall obligate a Party to require the owner of any right in the work, performance, or phonogram to attach rights management information to copies of the work, performance, or phonogram, or to cause rights management information to appear in connection with a communication of the work, performance, or phonogram to the public.

Article QQ.G.18: {Collective Management}

The Parties recognize the important role of collective management societies for copyright and related rights in collecting and distributing royalties¹⁴⁵ based on practices that are fair, efficient, transparent and accountable, and which may include appropriate record keeping and reporting mechanisms.

{Section H: Enforcement}

Article QQ.H.1: {General Enforcement / General Obligations Relating to the Enforcement of Law of Intellectual Property Rights}

- 1. Each Party shall ensure that enforcement procedures are specified in this section, are available under its law¹⁴⁶ so as to permit effective action against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to future infringements [PE/CL propose:¹⁴⁷]. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.
- 2. [US/NZ/MY/BN/SG/AU/CA/PE/MX/JP propose; CL/VN¹⁴⁸ oppose: Each Party confirms that the enforcement procedures set forth in Articles {QQ.H.4 and QQ.H.5 (civil and provisional measures) and QQ.H.7 (criminal measures)} shall be available [to the same extent] with respect to acts of [PE oppose: trademark,] copyright or related infringement in the digital environment.
- 3. Each Party shall ensure that its procedures concerning the enforcement of intellectual property rights shall be fair and equitable. These procedures shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.
- 4. This section does not create any obligation:
 - (a) 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 each Party to enforce law in general, or
 - (b) with respect to the distribution as between the enforcement of intellectual property rights and the enforcement of law in general.
- 5. [US/JP propose; NZ/VN/MX/PE/AU/MY/BN oppose: The Parties understand that the distribution of enforcement resources does not excuse that Party from complying with this section.

Article QQ.H.2: {Presumptions}

- 1. In civil, criminal, and if applicable, administrative proceedings involving copyright or related rights, each Party shall provide:
 - (a) for a presumption¹⁴⁹ that, in the absence of proof to the contrary, the person whose name is indicated in the usual manner¹⁵⁰ as the author, performer, producer of the work, performance, or phonogram, or as applicable, the publisher is the designated right holder in such work, performance, or phonogram; and
 - (b) for a presumption that, in the absence of proof to the contrary, the copyright or related right subsists in such subject matter.
- In connection with the commencement of a civil, administrative or criminal enforcement proceeding involving a registered trademark that has been substantively examined by the competent authority, each Party shall provide that such a trademark be considered *prima facie* valid.
- 3. In connection with the commencement of a civil or administrative enforcement proceeding involving a patent that has been substantively examined and granted¹⁵¹ by the competent authority, each Party shall provide that each claim in the patent be considered *prima facie* to satisfy the applicable criteria of patentability in the territory of the Party¹⁵² 153.

Article QQ.H.3: {Enforcement Practices With Respect to Intellectual Property Rights}

- 1. Each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights shall preferably be in writing and state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based. Each Party shall also provide that such decisions and rulings shall be published 154 or, where publication is not practicable, otherwise made available to the public, in a national language in such a manner as to enable interested persons and Parties to become acquainted with them.
- 2. Each Party recognizes the importance of collecting and analyzing statistical data and other relevant information concerning intellectual property rights infringements as well as collecting information on best practices to prevent and combat infringements.
- 3. Each Party shall publish or otherwise make available to the public information on its efforts to provide effective enforcement of intellectual property rights in its civil, administrative and criminal systems, such as statistical information that the Party may collect for such purposes.

Article QQ.H.4: {Civil Procedures and Remedies / Civil and Administrative Procedures and Remedies}

1. Each Party shall make available to right holders¹⁵⁵ civil judicial procedures concerning the enforcement of any intellectual property right covered in this Chapter.

- 2. Each Party shall provide¹⁵⁶ that in civil judicial proceedings its judicial authorities have at least the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.¹⁵⁷
- 3. At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the infringer, at least as described in paragraph 2, to pay the right holder the infringer's profits that are attributable to the infringement. 158
- 4. In determining the amount of damages under paragraph 2, its judicial authorities shall have the authority to consider, *inter alia*, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or service measured by the market price, or the suggested retail price.
- 5. Each Party shall provide that its judicial authorities have the authority to order injunctive relief that conforms to the provisions of Article 44 of the TRIPS Agreement, *inter alia*, to prevent goods that involve the infringement of an intellectual property right [MY propose: in that Party's jurisdiction] from entering into the channels of commerce [VN propose: pursuant to that Party's law].

- 6. [US oppose: Each Party shall ensure that its judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide the party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.]
- 7. In civil judicial proceedings, with respect to infringement of copyright or related rights protecting works, phonograms, and performances, each Party shall establish or maintain a system that provides for one or more of the following:
 - (a) pre-established damages, which shall be available upon the election of the right holder; or
 - (b) additional damages. 159
- 8. In civil judicial proceedings, with respect to trademark counterfeiting, each Party [US propose: shall] [NZ/JP/MX/AU/BN/MY propose: may] also establish or maintain a system that provides for one or more of the following:
 - (a) pre-established damages, which shall be available upon the election of the right holder; or
 - (b) additional damages. 160
- 9. Pre-established damages under paragraphs (7) and (8) shall be set out in an amount that would be sufficient to compensate the right holder for the harm caused by the infringement, and with a view to deterring future infringements.
- 10. In awarding additional damages under paragraphs (7) and (8), judicial authorities shall have the authority to award such additional damages as they consider appropriate, having regard to all relevant matters, including the nature of the infringing conduct and the need to deter similar infringements in the future. ¹⁶¹
- 11. Each Party shall provide that its judicial authorities, where appropriate ¹⁶², have the authority to order, at the conclusion of civil judicial proceedings concerning infringement of at least copyright or related rights, [US oppose: patents,] and trademarks, that the prevailing party be awarded payment by the losing party of court costs or fees and appropriate attorney's fees, or any other expenses as provided for under that Party's law.

- 12. Each Party shall provide that in civil judicial proceedings:
 - (a) At least with respect to pirated copyright goods and counterfeit trademark goods, each Party shall provide that, in civil judicial proceedings, at the right holder's request, its judicial authorities have the authority to order that such infringing goods [VN propose; US/JP oppose: disposed of outside the channels of commerce in such a manner to avoid any harm caused to the right holder, or] destroyed, except in exceptional circumstances, without compensation of any sort.
 - (b) Each Party shall further provide that its judicial authorities have the authority to order that materials and implements that have been [VN propose; US oppose: predominantly] used in the manufacture or creation of such infringing goods, be, without undue delay and without compensation of any sort, destroyed or disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.¹⁶³
 - (c) In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional circumstances, to permit the release of goods into the channels of commerce.
- 13. Without prejudice to its law governing privilege, the protection of confidentiality of information sources, or the processing of personal data, each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority, upon a justified request of the right holder, to order the infringer or, in the alternative, the alleged infringer, to provide to the right holder or to the judicial authorities, at least for the purpose of collecting evidence, relevant information as provided for in its applicable laws and regulations that the infringer or alleged infringer possesses or controls. Such information may include information regarding any person involved in any aspect of the infringement or alleged infringement and regarding the means of production or the channels of distribution of the infringing or allegedly infringing goods or services, including the identification of third persons alleged to be involved in the production and distribution of such goods or services and of their channels of distribution.
- 14. Each Party shall provide that in relation to a civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial or other authorities have the authority to impose sanctions on a party, counsel, experts or other persons subject to the court's jurisdiction, for violation of judicial orders concerning the protection of confidential information produced or exchanged in that proceeding.
- 15. To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that such procedures conform to principles equivalent in substance to those set out in this Article (civil and administrative proceedings).
- 16. In the event that a Party's judicial or other authorities appoint technical or other experts in civil proceedings concerning the enforcement of intellectual property rights and require that the parties to the litigation bear the costs of such experts, that Party should seek to ensure that such costs are reasonable and related appropriately, *inter alia*, to the quantity and nature of work to be performed and do not unreasonably deter recourse to such proceedings.
- 17. In civil judicial proceedings concerning the acts described in Article QQ.G.10 (TPMs) and Article

QQ.G.12 (RMI)¹⁶⁴, each Party shall provide that its judicial authorities shall, at least, have the authority to¹⁶⁵:

- (a) impose provisional measures, including seizure or other taking into custody of devices and products suspected of being involved in the prohibited activity;
- (b) order the type of damages available for copyright infringement, as provided under its regime in accordance with Article QQ.H.4;¹⁶⁶
- (c) Order court costs, fees, or expenses as provided for under Article QQ.H.4.11; and
- (d) order [CL propose:, at their discretion,] the destruction [CL propose:, except in exceptional cases,] of devices and products found to be involved in the prohibited activity.¹⁶⁷

A Party may provide that damages shall not be available against a nonprofit library, archives, educational institution, museum, or public [PE oppose: noncommercial] broadcasting entity that sustains the burden of proving that such entity was not aware or had no reason to believe that its acts constituted a prohibited activity.

Article QQ.H.5: {Provisional Measures}

- 1. Each Party's authorities shall act on requests for relief *inaudita altera parte* expeditiously in accordance with the Party's judicial rules.
- 2. Each Party shall provide that its judicial authorities have the authority to require the applicant, with respect to provisional measures, to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to such procedures.
- 3. In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities shall have the authority to order the seizure or other taking into custody of suspected infringing goods, material and implements relevant to the infringement, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement.

Article QQ.H.6: {Special Requirements Related to Border Enforcement / Special Requirements related to Border Measures}¹⁶⁸

1. Each Party shall provide for applications to suspend the release of, or to detain, any suspect

counterfeit [US/JP/NZ/AU/MX/PE propose; CA/MY/SG/BN/VN/CL oppose: or confusingly similar] trademark, or pirated copyright goods that are imported [CA propose: 169] into [MY/VN/NZ/AU/BN/MX oppose:, or [SG oppose: about to be] exported from,] the territory of the Party.

- 2. [US/AU/JP/NZ/BN propose; CL/SG/PE/MY/MX oppose: Each Party shall provide that such applications remain in force for a period of not less than one year from the date of application, ¹⁷⁰ or the period that the good is protected by copyright or the relevant trademark registration is valid, whichever is shorter. A Party may provide that its competent authorities have the authority to suspend or invalidate an application when there is due cause, including when the applicant has abused the procedures described in this Article.]
- 3. Each Party shall provide that any right holder initiating procedures for its competent authorities to suspend release of suspected counterfeit {or confusingly similar} trademark goods, or pirated copyright goods¹⁷¹ into free circulation is required to provide adequate evidence to satisfy the competent authorities that under the law of the Party providing the procedures there is *prima facile* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable by its competent authorities. The requirement to provide such information shall not unreasonably deter recourse to these procedures.
- 4. Each Party shall provide that its competent authorities have the authority to require a right holder initiating procedures to suspend the release of suspected counterfeit {or confusingly similar} trademark goods, or pirated copyright goods, to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that such security or equivalent assurance shall not unreasonably deter recourse to these procedures. A Party may provide that such security may be in the form of a bond conditioned to hold the defendant harmless from any loss or damage resulting from any suspension of the release of goods in the event the competent authorities determine that the Article is not an infringing good.
- 5. Without prejudice to a Party's laws pertaining to privacy or the confidentiality of information, where its competent authorities have detained or suspended the release of goods that are suspected of being counterfeit or pirated, a Party may provide that its competent authorities have the authority to inform the right holder without undue delay of the names and addresses of the consignor, exporter, consignee, or importer, a description of the goods, quantity of the goods, and, if known, the country of origin of the goods. Where a Party does not provide such authority to its competent authorities when suspect goods are detained or suspended from release, it shall provide at least in cases of imported goods, its competent authorities with the authority to provide the foregoing information to the right holder normally within 30 days 173 of the seizure or determination that the goods are counterfeited or pirated.
- 6. [VN/NZ/MX oppose¹⁷⁴: Each Party shall provide that its competent authorities may initiate border measures ex officio¹⁷⁵ with respect to goods {subject to customs procedures}/{under customs control} that are:

- (a) imported,
- (b) [MY/BN/SG oppose: {about to be exported/destined for export}] // [New Alt. Text: {destined for export}/{exported}], or
- (c) [SG/CA/MY/BN/AU oppose: in-transit] [US propose: 176],

that are suspected of being counterfeit {or confusingly similar} trademark goods, or pirated copyright goods.]¹⁷⁷ [CL propose: In the case of paragraph (c), each Party, in conformity with other international agreements subscribed to by it, may provide that *ex officio* authority shall be exercised prior to sealing the container, or other means of conveyance, with the customers seals, as applicable.]

7. Each Party shall adopt or maintain a procedure by which its competent authorities may determine, within a reasonable period of time after the initiation of the procedures described under Article QQ.H.6(1) [AU/BN oppose: and (6)]¹⁷⁸ whether the suspect goods infringe an intellectual property right. Where a Party provides administrative procedures for the determination of an infringement it may also provide its authorities with the authority to impose administrative penalties or sanctions, which may include fines or the seizure of the infringing goods, following a determination that the goods are infringing.

- 8. Each Party shall provide that its competent authorities have the authority to order the destruction of good following a determination that the goods are infringing. In cases where such goods are not destroyed, each Party shall ensure that, except in exceptional circumstances, such goods are disposed of outside the channels of commerce in such a manner as to avoid any harm to the right holder. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit the release of the goods into the channels of commerce.
- 9. Where a Party establishes or assesses, in connection with the procedures described in this Article, an application fee, storage fee, or destruction fee, such fee shall not be set at an amount that unreasonably deters recourse to these procedures.
- 10. Each Party shall include in the application of this Article goods of a commercial nature sent in small consignments. A Party may exclude from the application of this Article small quantities of goods of a non-commercial nature contained in travelers' personal luggage.¹⁷⁹

Article QQ.H.7: {Criminal Procedures and Remedies / Criminal Enforcement} 180

- 1. Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. {For the purposes of this Article, [US propose, CA/MY oppose: such acts of [NZ: willful] copyright or related rights piracy {on a commercial scale} include at least:] [CA/MY propose: In respect of copyright or related rights piracy, acts carried out on a commercial scale include at least:] [CL propose: 181] [182]
 - (a) acts carried out for commercial advantage or financial gain[CA propose: 183]; and
 - (b) significant acts [CA oppose: of copyright or related rights piracy], not carried out for commercial advantage or financial gain, that have a substantial prejudicial impact on the interests of the copyright or related rights owner in relation to the marketplace.} [AU propose: 184]

[The following paragraph is to be deleted and replaced with subparagraph (a): 2. Each Party shall provide that criminal procedures and penalties are available against willful infringement of copyright or related rights carried out for commercial advantage or {financial gain 185}.]

- 2. Each Party shall treat willful importation [VN oppose: or exportation] of counterfeit trademark goods or pirated copyright goods on a commercial scale as unlawful activities subject to criminal penalties. 186
- 3. Each Party shall provide for criminal [VN propose: or administrative] procedures and penalties to be applied in cases of willful importation¹⁸⁷ and domestic use, in the course of trade and on a commercial scale, of labels or packaging¹⁸⁸:
 - (a) to which a mark has been applied without authorization which is identical to, [PE oppose: or

- cannot be distinguished from 189, a trademark registered in its territory; and
- (b) which are intended to be used in the course of trade on goods or in relation to services which are identical to goods or services for which such trademark is registered. 190
- 4. [US/CA/JP/MY propose: [MX/PE oppose: Each Party [NZ/SG/AU/CL/BN/VN propose: may] [NZ/SG/AU/CL/BN/VN oppose: shall] provide criminal procedures and penalties for the knowing and unauthorized copying¹⁹¹, or [CA oppose: {transmittal¹⁹²}] of a cinematographic work, or any part thereof, from a performance in a movie theater.¹⁹³ ¹⁹⁴]

Possible Alternative to Para. 4

{Each Party shall {provide}/{ensure that} criminal procedures and penalties, or administrative procedures and penalties of sufficient severity to provide a deterrent¹⁹⁵, {are available} for the [SG: willful and] unauthorized copying [CA oppose: or transmittal,¹⁹⁶] of cinematographic work, or [MX propose: a significant] [MX oppose: any] part thereof, [MX propose: for purposes of financial gain] [AU propose: or commercial advantage, or on a commercial scale] from a performance in a movie theater.¹⁹⁷} [CL/MX/PE propose:¹⁹⁸]

- 5. With respect to the offenses for which this Article requires the Parties to provide for criminal procedures and penalties, Parties shall ensure that criminal liability for aiding and abetting is available under its law.
- 6. With respect to the offenses described in Article QQ.H.7 (1)(5) above, each Party shall provide:
 - (a) penalties that include sentences of imprisonment as well as monetary fines sufficiently high to provide a deterrent to future acts of infringement, consistently with the level of penalties applied for crimes of a corresponding gravity; 199
 - (b) that its judicial authorities shall have the authority, when determining penalties, to account for the seriousness of the circumstances, which may include those that involve threats to, or effects on, health or safety;²⁰⁰
 - (c) that its judicial or other competent authorities shall have the authority to order the seizure of suspected counterfeit trademark goods or pirated copyright goods, any related materials and implements used in the commission of the alleged offense, documentary evidence relevant to the alleged offense [MY oppose: and assets derived from²⁰¹, or obtained through the alleged infringing activity].
 - Where a Party requires the identification of items to subject to seizure as a prerequisite for issuing any such judicial order, that Party shall not require the items to be described in greater detail than necessary to identify them for the purpose of seizure;
 - (d) [MY oppose: that its judicial authorities shall have the authority to order the forfeiture, at least for serious offenses, of any assets [PE oppose: derived from, or] obtained through the infringing activity;

- (e) that its judicial authorities shall have the authority to order the forfeiture or destruction of
 - i. all counterfeit trademark goods or pirated copyright goods; and
 - ii. material and implements that have been [CA propose: predominantly²⁰²] used in the creation of pirated copyright goods or counterfeit trademark goods; and
 - iii. any other labels or packaging to which a counterfeit trademark has been applied and that have been used in the commission of the offense.

 In cases where counterfeit trademark goods and pirated copyright goods are not destroyed, the competent authorities shall ensure that, except in exceptional circumstances, such goods shall be disposed of outside of channels of commerce in such a manner as to avoid causing any harm to the right holder. Each Party shall further provide that forfeiture or destruction under this subparagraph and subparagraph (c) shall occur without compensation of any kind to the defendant;
 - g. that its judicial or other competent authorities shall have the authority to release or, in the alternative, provide access to, goods, material, implements, and other evidence held by the authority to a right holder for civil²⁰³ infringement proceedings.
 - h. [VN oppose: that its competent authorities may act upon their own initiative to initiate a legal action without the need for a formal complaint by a private party or right holder. [JP propose:²⁰⁴]]
- 7. With respect to the offenses described in Article QQ.H.7 [(1)] [(5)] above, a Party may provide that its judicial authorities have the authority to order the seizure or forfeiture of assets, or alternatively, a fine, the value of which corresponds to that of the assets derived from, or obtained directly or indirectly through, the infringing activity.

Article QQ.H.8: {Trade Secrets}

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention, each Party shall ensure that natural and legal persons have the legal means to prevent trade secrets lawfully in their control from being disclosed to, acquired by, or used by others (including state commercial enterprises) without their consent in a manner contrary to honest commercial practices.²⁰⁵ As used in this Chapter, trade secrets encompass, at a minimum, undisclosed information as provided for in Article 39.2 of the TRIPS Agreement.

Note: Parties are still reflecting on the new formulation for paragraphs 2 and 3.

2. Each Party shall provide for criminal [VN propose: or administrative] procedures and penalties for one or more of the following:

- (a) the unauthorized, willful access to a trade secret held in a computer system;
- (b) the unauthorized, willful misappropriation of a trade secret, including by means of a computer system; or
- (c) the fraudulent {or unauthorized} disclosure of a trade secret, including by means of a computer system.
- 3. A Party may, where appropriate, limit the availability of such criminal procedures or limit the level of penalties available in respect of the aforementioned activity to one or more of the following conditions:
 - (a) for purposes of commercial advantage or financial gain;
 - (b) related to a product or service in national or international commerce;
 - (c) intended to injure the owner of such trade secret;
 - (d) directed by or for the benefit of or in association with a foreign economic entity; or
 - (e) detrimental to a Party's economic interests, international relations, or national defense or national security²⁰⁶.²⁰⁷

Article QQ.H.9: {Protection of Encrypted Program-Carrying Satellite Signals / Protection of Encrypted Program-Carrying Satellite and Cable Signals}

- 1. Each party shall make it a [CL propose: civil or] [VN propose: administrative or] criminal offense:
 - (a) manufacture, assemble, modify, import, export, sell, lease, or otherwise distribute a tangible or intangible device or system, knowing²⁰⁸ [CL/MX/JP oppose: or having reason to know]²⁰⁹ that the device or system is primarily of assistance or alternatively, that the system's principal function is solely to assist, in decoding an encrypted program-carrying satellite signal without the authorization of the lawful distributor of such signal²¹⁰; and
 - (b) willfully receive²¹¹ [VN/CL oppose: and make use of,²¹² ²¹³] or willfully further distribute [CA/MX/BN propose: to the public], a program-carrying signal that originated as an encrypted satellite signal knowing that it has been decoded without the authorization of the lawful distributor of the signal [CL/PE/CA/SG/VN/MX/BN/JP oppose: {or if the signal has been decoded with the authorization of the lawful distributor of the signal, willfully to further distribute the signal for purposes of commercial advantage knowing that the signal originated as an encrypted program-carrying signal and that such further distribution is without the authorization of the lawful signal distributor.}]
- 2. Each Party [MY/BN oppose: shall] [MY/BN propose: may] provide for civil remedies for any person injured by any activity described in paragraph [1], including any person that holds an interest in the encrypted programming signal [CA propose:, as determined by that Party's law,] or its content.²¹⁴
- 3. [CL/PE/VN/MY/MX oppose: Each Party shall provide for criminal [CA/SG/BN/ oppose: [and] civil] penalties for willfully:

- (a) {manufacturing or distributing equipment knowing that the equipment is intended to be used in the unauthorized reception} of any program-carrying cable signal; and
- (b) [BN oppose: {receiving, or assisting another to receive}²¹⁵, a program-carrying cable signal without authorization of the lawful distributor of the signal.²¹⁶]]

Article QQ.H.11: {Government Use of Software / Government Use of Software and Other Materials Protected by Copyright or Related Rights}

Each Party shall adopt or maintain appropriate laws, regulations, policies, orders, government-issued guidelines, or administrative or executive decrees providing that its [SG/CL/BN/NZ/PE oppose: central²¹⁷] government agencies use only non-infringing computer software [CL/VN/JP/PE/BN oppose:, and [CA propose: make use of] other [CA propose: works, phonograms, and performances] [US propose: materials] protected by copyright or related rights] in a manner authorized by law and by the relevant license. These measures shall apply to the acquisition and management [CL/VN/JP/PE/BN oppose: of such materials] for government use.

Note: ISP Provisions are in Addendum III.

Addendum I

NON-PAPER

(As of March 13, 2014)

{FINAL PROVISIONS}

Article QQ.J.X:

- 1. Except as otherwise provided in paragraph 2 below, each Party shall give effect to this Chapter on the date of entry into force of this Agreement.
- 2. As specified below, a Party may delay giving effect to certain provisions of this Chapter as set forth in this paragraph, beginning on the data of entry into force of the Agreement.
 - (a) Except as provided in **Annex A**, Articles QQ.E.14, QQ.E.16, QQ.E.17, QQ.E.20, and QQ.E.22 apply to all Parties.
 - (b) If a country specified in **Annex A** becomes a "high income" country, as defined by the official statistics of the International Bank for Reconstruction and Development, such country shall fully implement the obligations of Articles QQ.E.14, QQ.E.16, and QQ.E.22 within one year after it has maintained such "high income" country status for two years consecutively.

{PATENTS/UNDISCLOSED TEST OR OTHER DATA/TRADITIONAL KNOWLEDGE}

{Section E: Patents / Undisclosed Test or Other Data / Traditional Knowledge}

Article QQ.E.14: {Patent Term Adjustment / Marketing Approval}

- 1. Each Party shall make best efforts to process patent applications and applications for marketing approval²¹⁸ of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.
- 2. With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment²¹⁹ of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
- 3. For greater certainty, further to/consistent with Article QQ.A.5²²⁰, each Party may provide for conditions and limitations in implementing the obligations of this paragraph.

Article QQ.E.16: {Pharmaceutical Data Protection}

1.

- (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who previously submitted such information, to market the same [MY oppose: or a similar²²¹] product on the basis of:
 - i. that information; or
 - ii. the marketing approval granted to the person who submitted such information

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party [MY propose:, or any other country where marketing approval is first granted].

(b) If a Party permits, as condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, the Party shall not permit third persons, without the consent of a person who previously submitted such information concerning the safety or efficacy of the product, to market a same [MY oppose: or a similar] product based on evidence relating to prior marketing approval in the other territory for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party [MY propose:, or any other country where marketing approval is first granted].

[CL propose: Alt (b) A Party may provide for the possibility of granting marketing approval or sanitary permit for a new pharmaceutical product based on a prior marketing approval in another territory. If a Party provides for such possibility, it may also require consent or acquiescence of a person previously submitting the undisclosed test or other data to obtain marketing approval in the other territory in order to authorize a third person to market a same or similar product (in the territory of the Party) for at least 5 years from the date of the first/prior marketing approval of the new pharmaceutical product.]

- 2. With respect to previously approved pharmaceutical products, if a Party requires the submission of:
 - (a) new clinical information (other than information related to bioequivalency), or
 - (b) evidence of prior approval of the product in another territory that requires such new information,

which is essential to the subsequent approval of a pharmaceutical product, the Party shall not permit a third person not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the marketing approval granted to a person submitting the information for a period of at least three years from the date of marketing approval by the Party [MY oppose: or the other territory, as applicable, whichever is later] [MY propose: or any other country where marketing approval is first granted].²²²

- 3. Notwithstanding paragraphs 1 and 2 above, a Party may take measures to protect public health in accordance with:
 - (a) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");
 - (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
 - (c) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.

[MY propose: 4. A Party may for the purpose of granting protection under subparagraph (1)(a) and (1)(b), require an applicant to commence the process of obtaining marketing approval for that pharmaceutical product within 18 months from the date the product is first registered or granted marketing approval, and granted protection for such information in any country.]

[MY propose: 5. A Party may for the purpose of granting protection under paragraph 2 require an applicant to commence the process of obtaining marketing approval for that pharmaceutical product within 12 months from the date the product is first registered or granted marketing approval, and granted protection for such information in any country.]

[MY propose: 6. Notwithstanding paragraphs 1 and 2 above, a Party may waive the protection under paragraphs 1 and 2 above, where it has taken measures

- (a) in accordance with:
 - (i) Article 31 of the TRIPS Agreement;
 - (ii) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");
 - (ii) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and/or
 - (iii) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.

(b) necessary to protect public health, national security, non-commercial public use, national emergency or other urgent circumstances as determined by the Party.]

Article QQ.E.17: {TPP Patent Linkage}

- 1. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:
 - (a) that Party shall provide measures in its marketing approval process to prevent those other persons from:²²³
 - i. marketing a product, where that product is claimed in a patent; or
 - ii. marketing a product for an approved use, where that approved use is claimed in a patent,

during the term of that patent, unless by consent or acquiescence of the patent owner²²⁴ [CA propose:²²⁵]; and

- (b) if the Party permits a third person to request marketing approval to enter the market with:
 - i. a product during the term of a patent identified as claiming the product; or
 - ii. a product for an approved use, during the term of a patent identified as claiming that approved use,

the Party shall provide for the patent owner to be notified of such request and the identify of any such other person.

- 2. Where a Party chooses not to implement paragraph 1, such Party shall provide that with respect to any pharmaceutical product that is subject to a patent²²⁶ [MX propose:²²⁷]:
 - (a) the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner [CL propose:²²⁸]; and
 - (b) the Party shall provide for the patent owner to be notified of, or make available to the patent owner, the identify of any third party requesting marketing approval effective during the term of the patent.²²⁹ ²³⁰

Article QQ.E.20: With respect to the first marketing approval of a pharmaceutical product that is biologic, ²³¹ each Party shall provide the protection afforded under Article QQ.E.16.1(a)-(b), *mutatis mutandis* for a period of [0] / [5] / [8] / [12] years from the date of marketing approval of such pharmaceutical product in that Party.²³²

Article QQ.E.21: For the purpose of Article QQ.E.16, a new pharmaceutical product means a product that does not contain [CL propose: or utilize] a chemical entity that has been previously approved by the Party. {In the alternative, a} A Party may {also} provide that a new pharmaceutical product means a pharmaceutical product that utilizes a chemical entity that has not been previously approved in the Party.²³³

Article QQ.E.22: Subject to Article QQ.E.16.3 (*protection of public health*), when a product is subject to a system of marketing approval in the territory of a Party pursuant to Articles QQ.E.16, QQ.E.20, or QQ.E.XXX (*agricultural chemical products*), and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to Articles QQ.E.16, QQ.E.20, or QQ.E.XXX (*agricultural chemical products*) in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in Articles QQ.E.16, QQ.E.20, or QQ.E.XXX (*agricultural chemical products*).

ANNEX A

I. For {<u>specified countries</u>}, the following subparagraph shall apply in lieu of Article QQ.E.14 (2)-(3) (patent term restoration) as set out in Article QQ.A.X (general provisions):

With respect to any pharmaceutical product that is covered by a patent, each Party may make available a restoration of the patent term or patent rights to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party. Any restoration under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent.

II. For {<u>specified countries</u>}, the following subparagraphs shall apply in lieu of Article QQ.E.17 (*TPP patent linkage*) as set out in Article QQ.X.A (*general provisions*):

Each Party shall provide:

- (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use;
- (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use; and

- (c) sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product.
- III. For {<u>specified countries</u>}, the following paragraphs shall apply in lieu of Article QQ.E.16 and Article QQ.E.22 as set out in Article QQ.A.X:

1.

- (a) If a Party requires, as a condition for approving the marketing of a pharmaceutical product that utilizes a new chemical entity,²³⁴ the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.
- (b) Each Party shall provide that for data subject to paragraph 1(a) that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies.
- (c) Where a Party relies on a marketing approval granted by another Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.
- (d) A Party need not apply the provisions of subparagraphs (a), (b), and (c) with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product.
- (e) Notwithstanding subparagraphs (a), (b), and (c), a Party may take measures to protect public health in accordance with:
 - I. the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");
 - II. any waiver of any provision of the TRIPS Agreement granted by WTO Members in

- accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
- III. any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.
- 2. Subject to paragraph 1(e), when a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1, Article QQ.E.20, or Article QQ.E.XXX (agricultural chemical products) and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1, Article QQ.E.20, or Article QQ.E.XXX (agricultural chemical products) in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1, Article QQ.E.20, or Article QQ.E.XXX (agricultural chemical products).

Addendum II

INTELLECTUAL PROPERTY [RIGHTS] CHAPTER

Non-Paper on Transitional Periods and Obligation for Patents Pharma

(as of February 22, 2014)

Proposal on Patent Pharmaceuticals Transition Periods

Article QQ.A.X:

- 1. For the purposes of these Articles, the Parties to this Agreement shall be divided into Category A, Category B, or Category C as follows:
 - (a) Category A: United States, Japan, Singapore, [other countries to be confirmed]
 - (b) Category B: Mexico, Brunei, [other countries to be confirmed]
 - (c) Category C: Peru and Vietnam
- 2. In implementing Articles QQ.E.14 (Patent Term Adjustment/Marketing Approval), and QQ.E.17 (Patent Linkage), Parties shall comply with the implementation schedule stated in <u>Table 1</u>.

Table 1

Category A	2 years after entry into force of the Agreement
Category B	2 + [X ₁] years after entry into force of the Agreement
Category C	2 + [X ₁] + [X ₂] years after entry into force of the Agreement

3. For the purposes of Article QQ.E.16.1(a) and (b), the period of protection to be accorded (from the date of marketing approval of the new pharmaceutical product in the territory of the Party) shall be no less than that specified in Table 2.

Table 2

	2 years after entry into force of the Agreement	2 years after entry into force of the Agreement + [X ₁] years	2 years after entry into force of the Agreement + [X ₁] + [X ₂] years		
Category A	5 years				
Category B	3 years	5 years			
Category C	0 years	3 years	5 years		

4. For the purposes of Article QQ.E.20, the period of protection to be accorded (from the date of marketing approval of the pharmaceutical product that is biologic in that Party) shall be no less than that specified in Table 3.

Table 3

	2 years after entry into force of the Agreement	2 years after entry into force of the Agreement + [X ₁] years	2 years after entry into force of the Agreement + [X ₁] + [X ₂] years		
Category A	[Ω] years				
Category B	[Ω-3] years	[Ω] years			
Category C	0 years	[Ω-3] years	[Ω] years		

5. Article QQ.E.22 shall apply to all Parties, with the exception of Parties falling within Category C prior

to the period of 2 years after entry into force of the Agreement + $[X_1]$ years. For greater certainty, upon 2 years after entry into force of the Agreement + $[X_1]$ years, Article QQ.E.22 shall thereafter apply to such Parties falling within Category C.

6. Unless the Parties agree otherwise, any Party acceding to this Agreement after its entry into force shall likewise be assigned to Category A, B, or C, but the implementation schedules in subparagraphs 2 to 5 applicable to such a Party shall be deemed to have commenced from the time of entry into force of the Agreement.

Addendum III

INTELLECTUAL PROPERTY [RIGHTS] CHAPTER

Non-Paper on Internet Service Provider Safe Harbors [CL propose: 235]

[AU propose: Consistent with Article 41 of the TRIPS Agreement,] In order to facilitate the continued development of entities engaged in providing [AU oppose: legitimate] online services, while also [AU oppose: ensuring the availability of] [AU: providing] enforcement procedures that permit effective action against copyright infringement²³⁶ [CL/PE propose: covered under this Chapter] [AU oppose:, each Party shall establish or maintain a framework that provides legal] [AU propose: including] remedies for right holders to address copyright infringement in the online environment [AU oppose: and] [AU propose:, each Party shall establish or maintain a framework] that provides safe harbors with respect to copyright infringement limiting the {liability of, or the availability or remedies against}, online service providers²³⁷ that [AU oppose: meet [CA oppose: appropriate] [CA propose: certain] requirements. Such a framework shall include] [AU propose: includes] the following elements:

- 1. Each Party shall provide legal incentives [CA propose:²³⁸] for online service providers to cooperate with [MX propose: authorities or] copyright owners or [AU/NZ/ oppose: otherwise] [AU/NZ propose: in the alternative to] {help} / {take action} to deter the unauthorized storage and transmission of copyrighted materials [MX propose: in accordance to the national legislation of each Party].
- 2. Each Party shall provide limitations in its law on the {liability of ²³⁹, or [AU oppose: the {availability of {[CA/CL oppose: monetary]] [AU propose: scope of] remedies [CL propose: ²⁴⁰]} against, online service providers [CA oppose: {acting as [AU oppose: neutral] intermediaries}²⁴¹] for copyright infringements that they do not control, initiate, or direct, and that take place through systems or networks controlled or operated by them or on their behalf. [PE propose: ²⁴³] [CA propose: ²⁴⁴]
- 3. The limitations described in paragraph 2 shall cover [CA propose: at least] the following functions:
 - i. transmitting, routing, or providing connections for material without modification of its content²⁴⁵, or the intermediate and transient storage of such material done automatically in the

- course of such a technical process;
- ii. caching carried out through an automated process;
- iii. storage²⁴⁶, at the direction of a user, of material residing on a system or network controlled or operated by or for the service provider²⁴⁷; and
- iv. referring or linking users to an online location by using information location tools, including hyperlinks and directories.
- 4. Each Party shall prescribe in its law conditions for online service providers to quality for the limitations described in paragraph 2 [CA oppose:, or shall otherwise provide for their fulfillment, to incentivize online service providers to take effective action] [CA propose: to participate in a system for sending notices of alleged infringement] with respect to infringements that take place through systems or networks controlled or operated by them or on their behalf [CA propose:, or otherwise ensure participation in such a system]. With respect to infringing material residing on online service providers' networks [CL propose: or systems] under [CL propose: functions referred to in] paragraph 3(iii) and 3(iv) above, [CL oppose: online service providers shall be required] [CL propose: limitations shall be conditioned on the service provider] expeditiously to remove or disable access to such material upon [MX oppose: obtaining] [MX propose: receiving a notification from the authority or person authorized to do so, in accordance to the national legislation of each Party] [MX oppose: actual knowledge of the infringement or awareness of facts or circumstances from which the infringement is apparent [AU propose:, such as] [CL propose: 248] [AU oppose:, or upon] receiving a legally sufficient notice²⁴⁹ of alleged infringement from the rights holder or a person authorized to act on its behalf], and in the absence of [AU oppose: legally sufficient statement] [AU propose: counternotice] from the person whose material is [AU oppose: removed or disabled] [AU propose: subject to a notice for removal or disabling] indicating that the notice was the result of mistake or misidentification.²⁵⁰ An online service provider that removes or disables access to material in good faith pursuant to and consistent with this paragraph shall be exempted from any liability for having done so [NZ propose:²⁵¹], provided that it takes reasonable steps [JP propose: in advance or] promptly to notify the person whose material is removed or disabled.²⁵² [JP propose:²⁵³]

[AU propose: The limitations in paragraph 2 shall not be conditioned on the service provider undertaking measures that impose substantial costs or substantial burdens on their systems or networks.]

[MX propose: Where a person, whose material is removed or disabled, claims that the notice was the result of mistake or misidentification, online service providers shall be required expeditiously to upload or enable access to such material upon receiving a notification from the authority or the person authorized to do so, in accordance to the national legislation of each Party.]

- 5. Eligibility for the limitations in paragraph 2 may not be conditioned on the service provider monitoring its service or affirmatively seeking facts indicating infringing activity.
- 6. Each Party shall provide procedures, whether judicial or administrative, in accordance with that Party's legal system, and consistent with principles [JP propose:²⁵⁴] of due process and privacy, enabling a copyright owner who has made a legally sufficient claim of copyright infringement to obtain expeditiously from an online service provider information in the provider's possession identifying the

alleged infringer, where such information is sought for the purpose of protecting or enforcing such copyright.

[AU propose: Each Party shall provide for monetary remedies against any person who makes a knowing material misrepresentation in a notification or counter-notification that causes injury to any interested party as a result of a service provider relying on the misinterpretation.]

7. This Article is without prejudice to the availability in a Party's law of [JP oppose: other defenses,] limitations, and exceptions to the infringement of copyright [JP propose: or any other defenses].

ANNEX TO IP CHAPTER

[Placeholder for grandfather provision.]

Addendum IV

INTELLECTUAL PROPERTY [RIGHTS] CHAPTER

Non-Paper on State-Owned Enterprises and IPS

(as of February 22, 2014)

Article QQ.H.1: {General Enforcement / General Obligations Relating to the Enforcement of Law of Intellectual Property Rights}

1. Each Party shall ensure that enforcement procedures as specified in this section are available under its law²⁵⁵ so as to permit effective action against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to future infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. [FN]

FN For greater certainty, each Party confirms that it makes such enforcement procedures available consistent with the provisions of this Agreement, with respect to state-owned enterprises.²⁵⁶

Addendum V

INTELLECTUAL PROPERTY [RIGHTS] CHAPTER

Non-Paper on National Treatment

Article QQ.A.9: {National Treatment}

In respect of all categories of intellectual property covered in this Chapter,²⁵⁷ each Party shall accord
to nationals²⁵⁸ of the other Party treatment no less favorable than it accords to its own nationals with
regards to the protection²⁵⁹ [MY/CA/VN/BN/NZ oppose: and enjoyment] of such intellectual property
rights

[MY/CA/VN/BN/NZ oppose: and any benefits derived from such rights²⁶⁰].

With respect to secondary uses of phonograms²⁶¹ by means of analog communications [CA propose:,] [CA oppose: and] free²⁶² over-the-air broadcasting [CA/JP propose; US oppose: and other non-interactive communications to the public], however, a Party may limit the rights of the performers and producers of the other Party [CA oppose: to the rights its persons] [CA propose: to the extent to which the rights] are accorded [CA propose: to its persons] within the jurisdiction of the other Party.

ALTERNATIVE to previous 2 paras: [CA/JP/BN/MX propose; US oppose: With respect to secondary uses of phonograms, a Party may limit the rights of the performers [MX oppose: and producers] of the other Party to the rights its persons are accorded within the jurisdiction of the other Party.]

- 2. A Party may derogate form paragraph 1 in relation to its judicial and administrative procedures, including requiring a national of the other Party to designate an address for service of process in its territory, or to appoint an agent in its territory, provided that such derogation is:
 - (a) necessary to secure compliance with laws and regulations that are not inconsistent with this Chapter; and
 - (b) not applied in a manner that would constitute a disguised restriction on trade.
- 3. Paragraph 1 does not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Addendum VI

INTELLECTUAL PROPERTY [RIGHTS] CHAPTER

Non-Paper on QQ.A.10 {Transparency}

(as of May 16, 2014)

Current Provision

Article QQ.A.10: {Transparency}

[NZ/AU/SG/MY/CA²⁶³/MX/CL/PE/VN propose: 2. Each Party shall endeavor to make available on the Internet:

- (a) its laws, regulations, procedures, and administrative rulings of general application concerning the protection and enforcement of intellectual property rights; and
- (b) [JP/VN/US oppose: those details [JP propose:, where appropriate,] of patent, trademark design, plant variety protection and geographical indication applications that are open to public inspection under national law.]

Alternative Option for Parties Consideration

- [1. Further to Article ZZ.2 {Publication} and QQ.H.3.1 {Enforcement practices with Respect to Intellectual Property Rights}, each Party shall endeavor to make available on the Internet its laws, regulations, procedures and administrative rulings of general application concerning the protection and enforcement of intellectual property rights.
- 2. Without prejudice to QQ.C.7 {Electronic Trademarks System}, each Party shall endeavor to make available on the Internet the content of {applications for} patent, trademark, design, plant variety and geographical indication {applications} that are open to public inspection under their national law, ²⁶⁴
- 3. Without prejudice to QQ.C.7 {Electronic Trademarks System}, each Party shall make available on the Internet the registered or granted patents, trademarks, designs, plant variety rights and geographical indications that are open to public inspection under their national law.]²⁶⁵

Note: Some Parties will confer with the legal working group to check the reference to Article ZZ.2 {Publication}.

1Section and Article titles and headings appear in this text on a without prejudice basis. Parties have agreed to defer consideration of the need for, and drafting of, Section and Article titles and headings. Such titles or headings that appear in braces (i.e., "{ }") are included for general reference and information purposes only. **Chair has also used braces in the text to indicate issues needing technical work.**

2{U.S. Negotiator's Note: Delegations worked on this text during the Singapore Round to reflect a possible alternative to approaches appearing in Non-Paper from Salt Lake City Round. Delegations discussed whether this text should be preambular text or objectives text. Delegations also discussed the possibility of including concepts from TRIPS Art. 40 in this text or elsewhere.}

3Negotiator's Note: AU supports including objectives but is still considering the drafting and scope of this Article.

4Negotiator's Note: CA supports this provision in principle, but is reviewing the proposal.

5Negotiator's Note: MX will reflect further on the additional subparagraphs (g) and (h).

6Negotiator's Note: BN can support in principle but is considering discussion on QQ.A.9.

7Parties reserve right to revisit in light of outcome of AA.2 and QQ.C.2.2.

8A Party may satisfy the obligation in Article QQ.A.8.2(d) by ratifying or acceding to the *Singapore Treaty on the Law of Trademarks* (2006).

9For greater certainty, nothing in this Agreement limits Parties from taking otherwise permissible derogations from national treatment with respect to {copyright and related rights} not covered under Section G (Copyright and Related Rights) of this Chapter.

10For purposes of Articles [QQ.A.7.1-2 (National Treatment and Judicial/Admin Procedures), QQ.D.2.a (GIs/Nationals), and QQ.G.14.1 (Performers/Phonograms/Related Rights),] a "national of a Party" shall mean, in respect of the relevant right, an entity of that Party that would meet the criteria for eligibility for protection provided for in the agreements listed in [Article QQ.A.6.A – must include WPPT (Article 3)] and the TRIPS Agreement.

11For purposes of this paragraph [Article QQ.A.7.1], "protection" shall include matters affecting the availability, acquisition, scope, maintenance, and enforcement of intellectual property rights as well as matters affecting the use of intellectual property rights specifically covered by this Chapter. Further, for purposes of paragraphs {1 and 2}, "protection" also includes the prohibition on circumvention of effective technological measures set out in Article QQ.G.10 and the rights and obligations concerning rights management information set out in Article QQ.G.13.]

12For greater certainty, "benefits derived from such rights" refers to benefits such as copyright levies.

13[JP propose: For greater certainty, it is understood that secondary uses of phonograms by means of television programs are outside of the scope of this Article.]

14[JP propose: For greater certainty, it is understood that public and non-commercial broadcasting with a mandatory receiving fee under a Party's national law is included in "free over-the-air broadcasting" in the context of Article QQ.A.7.1.]

15Negotiator's Note: Technical work is ongoing on the scope of the broadcasting exclusion.

16Chair's Note: As of May 16, 2014, discussions on Article QQ.A.10 Transparency are reflected in Addendum VI – Non Paper on Transparency.

17Negotiator's Note: CA supports in principle pending clarification of what is meant to "open to public inspection" in subparagraph (b).

18Negotiator's Note: AU/NZ/CL/SG/PE/MY/BN/VN/JP/MX/CA/US reserve positions {on paragraphs 1 and 2} pending final

outcome of Chapter. All Parties agree to revisit this provision at the conclusion of this Chapter.

19Parties recognize the importance of multilateral efforts to promote the sharing and use of search and examination results, with a view to improving the quality of search and examination processes and to reducing the costs for both applicants and patent offices.

20VN can accept the protection of sound but only if it is given an adequate transitional period.

21[MX propose: For greater certainty, nothing in this Article shall be construed to obligate a Party to grant protection for non-visually perceptible trademarks other than sounds and scents.]

22For purposes of this Chapter, **geographical indication** means indications that identify a good as originating in the territory of a Party, or a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin. Consistent with this definition, any sign or combination of signs shall be eligible for protection under one or more of the legal means for protecting GIs, or a combination of such means.

23Negotiator's Note: PE/MX/SG will go with consensus on this paragraph.

24[PE/US propose: For greater certainty, the existence of such measures does not per se, amount to impairment.]

25Negotiator's Note: JP is considering this provision.

26[SG propose: This provision is not intended to affect the use of common names of pharmaceutical products in prescribing medicine.]

27Where a Party determines whether a mark is well-known in the Party, the Party need to not require that the reputation of the trademark extend beyond the sector of the public that normally deals with the relevant goods or services.

28It is understood that such well-known trademark is one that was already well-known before the registration or use of the first-mentioned trademark.

29Negotiator's Note: AU opposes the last sentence of this chapeau, but is in discussion with NZ and US as to language that could resolve this.

30For greater certainty, cancellation for purposes of this Section may be implemented through nullity or revocation proceedings.

31Parties that rely on translations of the Nice Classification are required to follow updated versions of the Nice Classification to the extent that official translations have been issued and published.

32It is understood that such remedies may but need not include, for example, revocation, cancellation, transfer, damages, or injunctive relief.

33Subparagraph (a) shall also apply to judicial procedures that protect or recognize a geographical indication.

34For greater certainty, cancellation for purposes of this Section may be implemented through nullity or revocation proceedings, {small group to discuss making this also applicable to GI cancellation.}

35A Party is not required to apply Article QQ.D.3 and Article QQ.D.3bis to geographical indications for wines and spirits or applications for such geographical indications.

36{Option 1: For greater certainty, where the grounds listed in paragraph 1 did not exist as of the time of the filing of the request for protection or recognition of a geographical indication under Article QQ.D.2, a Party is not required to apply such grounds for the purposes of paragraph 2 or Article QQ.D.3*bis* in relation to such geographical indication.} {Option 2: No Party shall be required to apply paragraph 2 in respect of geographical indications that are protected or recognized in that Party before this Agreement comes into force.} Negotiator's Note: Parties are still considering the two Options for this footnote.

37[JP/PE propose: This paragraph does not prevent a Party from limiting the availability of the procedures for cancellation to a certain period after registration.]

38Negotiator's Note: JP support is contingent upon rendering the provision inapplicable to geographical indications protected pursuant to agreements.

39[MY/SG propose: As an alternative to paragraph 3, where a Party has in place a *sui generis* system of the type referred to in paragraph 3 as of [*date x- already in place pre-TPP*], that Party shall at least provide that its judicial authorities have the authority to deny the protection or recognition of a geographical indication where the circumstances identified in paragraph 1(iii) have been established.]

40Negotiator's Note: JP support is contingent upon rendering the provision inapplicable to geographical indications protected pursuant to agreements.

41Negotiator's Note: AU/CA to confirm.

42[CL propose: For greater certainty, this provision applies to any modification made to an existing agreement.]

43[MX propose: For greater certainty, the protection of geographical indications in accordance with this provision may take place after the entry into force of this Agreement.]

44Negotiator's Note: MX/PE is still reflecting on the application of this provision with regards to its national geographical indications.

45Negotiator's Note: VN would like to use the word "termination" instead of "cancellation".

46A Party need not apply Article QQ.D.X to geographical indications for wines and spirits.

47[JP/VN propose: For greater certainty, this Article does not apply to cases where a GI becomes {generic} after protection or recognition is given.]

48For greater certainty, the filing date referenced in this paragraph includes the priority filing date under the Paris Convention, where applicable.

49[MY propose: This paragraph shall not apply to protection or recognition of unregistered geographical indications by means of juridical procedures.]

50[CL/SG/MX/US/NZ/MY/CA/BN/JP/AU/VN propose: For purposes of subparagraph (b), a Party's authorities may take into account, where appropriate, whether the term is used in relevant international standards recognized by all the Parties to refer to a type or class of product in the Party's territory.]

Negotiator's Note: PE is considering.

51Negotiator's Note: VN supports subject to the list of GIs in the Annex.

52[CL/BN/SG propose: For greater certainty, the Parties acknowledge that geographical indications will be recognized and protected in the Parties only to the extent permitted by and according to the terms and conditions set out in their respective domestic laws.]

53Negotiator's Note: Legal scrub to determine placement in TM vs GI vs standalone.

54For purposes of this Section, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art having regard to the prior art.

55{For greater certainty, no Party shall be required to make patents available for plant varieties that are protectable in that Party under the International Convention for the Protection of New Varieties of Plants [1991](UPOV Convention).} {Negotiator's Note: AU would prefer this footnote to be in the main text}.

[Note: This formulation is premised upon the understanding that TPP Parties will make a commitment to accede to UPOV 1991].

56Negotiator's Note: US/JP reconsidering the inclusion of subparagraph (b) (provision relating to diagnostic, therapeutic and surgical methods), subject to consensus on patent landing zone.

57Negotiator's Note: AU is still considering inclusion of "alternatively".

58A Party shall not be required to disregard information contained in applications for, or registrations of, intellectual property rights {made available to the public}/{published} by a patent office unless erroneously published or unless the application was filed without the consent of the inventor or their successor in title by a third party who obtained the information directly or indirectly from the inventor.

Negotiator's Note: Parties to consult on whether "published" is needed.

59For greater certainty, a Party may limit application of this provision to disclosures made by or obtained directly or indirectly from the inventor or joint inventor. For greater certainty, a Party may provide that, for purposes of this Article information obtained directly or indirectly from the patent applicant may be information contained in the public disclosure that was authorized by, or derived from, the patent applicant.

60{For greater certainty, a Party may provide for forfeiture of a patent pursuant to Article 5A(3) of the Paris Convention.}

Negotiator's Note: Some Parties consider that this footnote may be necessary to ensure consistency with Article 5A(3) of the Paris Convention.

61Negotiator's Note: PE and SG are flexible with both options.

62Negotiator's Note: CA/MX/AU is still considering the options in this provision.

63[MX propose: For greater clarity, the duration of the regulatory review exception will be subject to each Party's national legislation.]

64Negotiator's Note: 1. Parties focused discussion on Option 1, as a possible landing zone, rather than Option 2; 2. Consider moving Option 1 (Bolar for pharmaceuticals) to the Other Regulated Products provisions. For some countries, that might potentially remove the need to include reference to "other products" in the section.; 3. Would it be possible to remove "generating information necessary" if the reference to QQ.E.4 remained?; 4. Given length and complexity of paragraph, could we break this out into two subparagraphs?; 5. Comment that the drafting/structure of the provision makes it a limiting provision rather than a more affirmative approach.

65Negotiator's Note: MX supports in principle, pending the discussion on QQ.E.13.

66Negotiator's Note: Parties did not discuss Option 2 in detail as some Parties indicated that it was not a possible landing zone.

67A Party shall not be required to apply this provision in cases involving derivation or in situations involving any application that has or had at any time at least one claim having an effective filing date before this Agreement comes into force or any application that has or had at any time a priority claim to an application that contains or contained such a claim.

68[VN propose: For greater certainty, a Party may grant the patent to the subsequent application that is patentable and that has a filling or priority date which is prior to the publication of the earlier application in cases where the earlier application has been withdrawn, abandoned, or refused, either prior to or after its publication.]

69Each Party may provide that such amendments do not go beyond the scope of the disclosure of the invention as of the filing date.

70Negotiator's Note: MX/SG are willing to accept the Article provided that the sentence "without undue experimentation" is deleted. NZ can go along with consensus.

71Negotiator's Note: JP is considering this provision.

72[CA/SG/MY/JP/PE/MX/BN/VN/CL propose; US oppose: For the purposes of this Section [*Patents*], "publish" or "publication" includes making available for public inspection, which may include making available on the Internet.] *Negotiator's Note: AU support for this FN is linked to resolution of Article QQ.A.10(2) and subject to clarification of the use of the word Internet.*Alt. [US propose; VN oppose: For the purposes of this Section [*Patents*], "publish" or "publication" means making available on the Internet.]

Negotiator's Note: Other relevant provisions in QQ.E (Patents) are QQ.E.6 (priority date re where publication of patent application has occurred) and QQ.E.12 (other information in respect of published patents to be made publicly available). CA/SG propose to move this FN to be attached to QQ.E.6.

73Negotiator's Note: US support for this provision is contingent upon accommodating exceptions provided under U.S. Law.

74[US propose; AU oppose: For greater certainty, this Article does not apply to industrial designs.]

75Negotiator's Note: AU is still considering (a).

76[CA/SG/MY/JP/PE/MX/BN/VN/CL propose; US oppose: For the purposes of this Section [*Patents*], "publish" or "publication" includes making available for public inspection, which may include making available on the Internet.] *Negotiator's Note: AU support for this FN is linked to resolution of Article QQ.A.10(2) and subject to clarification of the use of the word Internet.*Alt. [US propose; VN oppose: For the purposes of this Section [*Patents*], "publish" or "publications" means making available on the Internet.]

Negotiator's Note: Other relevant provisions in QQ.E (Patents) QQ.E.6 (priority date re where publication of patent application has occurred) and QQ.E.12 (other information in respect of published patents to be made publicly available), CA/SG propose to move this FN to be attached to QQ.E.6.

77Negotiator's Note: The word "published" is subject to larger discussions in this section concerning its scope.

78Negotiator's Note: JP can support this Article if JP proposals are accepted.

79[SG propose: Periods attributable to actions of the patent applicant shall include such periods of time taken to file prescribed documents relating to the examination as provided in the laws of the Party.]

80[JP propose: Notwithstanding Article QQ.A.11, this Article shall apply to all patent applications filed on or after [January 1, 2016].]

81Negotiator's Note: JP and US to lead work on an appropriate transition period for Parties who do not currently provide such a system.

82(a) "Quasi-judicial" is intended to cover primarily processes by patent appeal boards; (b) One Party suggested using the phrase, "or any opposing third person" within the scope of provision; (c) One Party suggested including provision on "judicial or quasi-judicial" proceedings in a footnote; (d) Some Parties suggested including "administrative" proceedings, in addition to, or in lieu of "quasi-judicial."; (e) At least one Party expressed a concern that this provision goes beyond existing FTAs.

83VN can support only based on provision of transitional period based on factors including living standard of farmers. BN would also require a transition period. Parties are still considering certain technical issues on this provision.

84For purposes of this Article, a new agrochemical product is one that either (i) does not contain a chemical entity that has been previously approved for marketing in the Party, or for which a sanitary permit has been obtained (in the Party) or (ii) which utilizes a new chemical entity that has not been previously approved in the territory of the Party.

85For greater certainty, information available through subscription services that are open to the public to subscribe are considered to be publicly available.

86For greater certainty, to determine whether the applicant of a marketing approval made a "considerable effort" a Party may consider the time length to obtain the test data, the number of persons subjected to the relevant tests, the amount of financial and any other type of resource utilized to obtain the data and that a significant part of such data was generated by the applicant.

87Negotiator's Note: CA/US position is that QQ.E.23 provisions should be addressed in the Environment Chapter. The US/JP opposes the inclusion of this Article in this Chapter.

88Negotiator's Note: AU is considering this paragraph in light of the rest of the Article.

89Negotiator's Note: Appropriate placement within the Agreement of paragraphs 2, 3 and 7 is under consideration.

90Negotiator's Note: NZ/CA prefer the issues included in this paragraph to be discussed in the Environment Chapter.

91[MX/PE propose; CL/MY/SG/AU/NZ oppose: For greater certainty "derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, without human manipulation, even if does not contain functional units of heredity.]

92[PE/MY/BN/VN propose; NZ/CL/AU/SG/CA oppose: For greater certainty, the term "genetic resources" may also encompass its derivatives.]

93Negotiator's Note: Proponents of this provision could be flexible to move this provision to Chapter AA {*Initial Provisions*} in order to drive consensus.

94Negotiator's Note: Proponents of this paragraph could be flexible to move to Section B (Cooperation) in order to drive consensus.

95Negotiator's Note: NZ is still considering.

96Negotiator's Note: NZ is still considering.

97The Parties reaffirm that it is a matter for each Party's law to prescribe that works in general or any specified categories of works, performances and phonograms shall not be protected by copyright or related rights unless they have been fixed in some material form.

98References to "authors, performers, and producers of phonograms" refer also to any successors in interest.

99With respect to copyrights and related rights in this Chapter, the "right to authorize or prohibit" and the "right to authorize" refer to exclusive rights.

100With respect to this Chapter, a "performance" means a performance fixed in a phonogram unless otherwise specified.

101It is understood that the mere provision of physical facilities for enabling or making a communication does not in itself amount to communication within the meaning of this Chapter of the Berne Convention. It is further understood that nothing in this Article precludes a Party from applying Article 11bis(2) of the Berne Convention.

102The expressions "copies" and "original and copies" subject to the right of distribution in this paragraph refer exclusively to fixed copies that can be put into circulation as tangible objects.

103Nothing in this Agreement shall affect a Party's right to determine the conditions, if any, under which the exhaustion of this right applies after the first sale or other transfer of ownership of the original or a copy of their works, performances, or phonograms with the authorization of the author, performer, or producer.

104Negotiator's Note: AU's support for this provision may be contingent on how the exhaustion issue is dealt with in General Provisions.

105For greater certainty, in this paragraph with respect to performances or phonograms first published or first fixed in the territory of a Party, a Party may apply the criterion of publication, or alternatively, the criterion of fixation, or both. [JP propose: A Party may also comply with its obligation under this Paragraph by legislating that performers are protected to the extent provided for in Article 3 of the WPPT.]

106For purposes of this Article, fixation means the finalization of the master tape or its equivalent.

107With respect to broadcasting and communication to the public, a Party may satisfy the obligation by applying Article 15(1) and 15(4) of the WPPT [and may also apply Article 15(2)] of the WPPT, as long as it is done in a manner consistent with that Party's obligations under Article QQ.A.7 (National Treatment).

108[CA/US/AU/SG/NZ/MX propose: For greater certainty, making the sounds or representation of sounds fixed in a phonogram audible to the public is not included in this right, except where done by wire or wireless means.] // [Possible Alt. Text: For greater certainty, the mere act of making the sounds or representations of sounds fixed in a phonogram audible to the public is not included in this right.] Negotiator's Note: CA proposes to do away with this footnote entirely if the 2nd sentence in QQ.G.15(b) is also dropped.

109[JP/US propose: For greater certainty, broadcasting or communicating to the public the sounds or representation of sounds incorporated in a cinematographic or other audiovisual work by wire or wireless means is not included in this right.]

110The term published in this paragraph includes phonograms that are made available in accordance with Article 15(4) of the WPPT.

111Where a Party has availed itself of an option contained in Article 15(3) of the WPPT, the obligation contained in [QQ.A.7 – national treatment] does not apply to the extent that a Party makes use of a reservation taken under that Article.

- 112Negotiator's Note: CA to propose footnote on conditions.
- 113[CA propose: Articles 7 and 7*bis* of the Berne Convention apply *mutatis mutandis*, with the exception of the provisions of Article 7(4), in respect to photographic works.]
- 114Negotiator's Note: MY agrees but reserves the right to revisit where there are changes to certain positions on substantive obligations in the Copyright Section, if required.
- 115Negotiator's Note: Delegations are considering the relationship between Article QQ.G.16(b) and new multilateral agreements concluded under the auspices of WIPO and the agreements listed in Article QQ.G.16(b). Delegations will work to resolve this issue in Article QQ.A.6 (General Provisions relationship to other agreements) or elsewhere.
- 116{In particular,} As recognized by the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled (June 27, 2013).
- 117For purposes of greater clarity, a use that has commercial aspects may in appropriate circumstances be considered to have a legitimate purpose under Article QQ.G.16.3.
- 118For purposes of this Article and for greater certainty, retransmission within a Party's territory over a closed, defined, subscriber network that is not accessible from outside the Party's territory does not constitute retransmission on the Internet.
- 119Negotiator's Note: PE is considering the use of the work "emissions" in addition to "signals" as an alternative.
- 120Negotiator's Note: If this alternative is used, it is understood that there may be changes required in this language.
- 121For greater certainty, this provision does not affect the exercise of moral rights.
- 122Nothing in this Article affects a Party's ability to establish: (i) which specific contracts underlying the creation of works or phonograms shall, in the absence of a written agreement, result in a transfer of economic rights by operation of law; and (ii) reasonable limits to protect the interests of the original right holders, taking into account the legitimate interests of the transferees.
- 123Nothing in this Agreement shall require any Party to restrict the importation or domestic sale of a device that does not render effective a technological measure the sole purpose of which is to control market segmentation for legitimate physical copies of cinematographic film, and is not otherwise a violation of law.
- 124Negotiator's Note: MY and VN oppose mandatory application of this Article to access control TPMs. NZ/CA's agreement to this Article is subject to securing sufficient flexibility to adopt exceptions and limitations to the prohibition on circumvention for non infringing uses. CL reserves its position on the approach set out in paragraph (d) pending national consultations and may support the approach in the consolidated text.
- 125{AU/NZ propose: For greater certainty, nothing shall prevent a Party from limiting "unauthorized acts in respect of their works, performances, and phonograms" to infringing acts, where appropriate, subject to any other {remedies/liability} available under the Party's law.}
- 126For greater certainty, in this Chapter, cinematographic works and computer programs are included in the term "work". Chair's Note: Ultimate placement of this FN to be determined based on when the word "works" first appears in this Chapter as this is a cross-section issue.
- 127For greater certainty, no Party is required to impose civil or criminal liability under subparagraph (a)(i) for a person who circumvents any effective technological measure that [MY oppose: protects any of the exclusive rights of copyright or related rights in a protected work, performance or phonogram, but that does not control access to such work, performance or phonogram.]
- 128[MY propose: A Party may provide that the obligations described in paragraph (ii) in respect to manufacturing, importation, and distribution apply only where such activities are undertaken for sale or rental, or to such an extent as to affect prejudicially the owner of the copyright.]
- 129It is understood that this provision still applies where the person promotes, advertises, or markets through the services of a third party.

- 130A Party may comply with this paragraph if the conduct referred to in (ii) does not have a commercially significant purpose or use other than to circumvent any effective technological measure.
- 131Negotiator's Note: Parties' position on this reference is pending resolution of the discussion on QQ.H.4.17 (Civil Judicial Proceedings relating to TPMs and RMIs).
- 132For great certainty, for purposes of Articles QQ.G.10 and QQ.G.13, it is understood that willfulness contains a knowledge element.
- 133For greater certainty, for purposes of Articles QQ.G.10 and QQ.G.13, it is understood that a Party may treat "financial gain" as "commercial purposes" in its law.
- 134For purposes of greater certainty, no Party is required to impose liability under Articles [QQ.G.10 (TPMs)] and [QQ.G.13 (RMIs)] for actions taken by that Party or a third party acting with the authorization or consent of that Party.
- 135Negotiator's Note: Agreement ad referendum on bracketed text; further technical work required.
- 136For greater certainty, nothing in this provision requires Parties to make a new determination via the legislative, regulatory, or administrative process with respect to exceptions and limitations to the legal protection of effective technological measures previously [established in trade agreements in force between Parties or] implemented by the Parties, [provided that such exceptions and limitations are otherwise consistent with Article QQ.G.10(d).] (ref QQ.A.11(3)) (agreement ad referendum; further technical work required).
- 137[CA propose: For greater certainty, a Party may provide an exception to a(ii) without having to provide a corresponding exception to a(i), provided that the exception to a(ii) is limited to enabling an act that is within the scope for exceptions to a(i) under d(i).]
- 138For the purposes of interpreting subparagraph d(ii) only, subparagraph a(i) should be read to apply to all effective technological measures as defined in paragraph (e), *mutatis mutandis*. Negotiator's Note: agreement ad referendum on this footnote; further technical work required.
- 139[CL propose: It is understood that the circumvention of a technological protection measure may be permitted solely to enable the legitimate use of an exception or limitation under each Party's domestic law.]
- 140Each Party may comply with the obligations in this Article by providing legal protection only to electronic rights management information.
- 141Each Party may extend the protections afforded by this paragraph to circumstances in which a person engages without knowledge in the acts in subparagraph (i), (ii), and (iii), and to other related rights holders.
- 142A Party may comply with its obligations under this sub-paragraph by providing for civil judicial proceedings concerning the enforcement of moral rights under the Party's copyright law.
- 143Negotiator's Note: Parties' position on this reference is pending resolution of the discussion on QQ.H.4(17).
- 144For greater certainty, a Party may treat a broadcasting entity established without a profit-making purpose under its law as a public non-commercial broadcasting entity.
- 145For greater certainty, royalties may include equitable remuneration.
- 146For greater certainty, "law" is not limited to legislation.
- 147[PE/CL propose: Nothing in this Chapter shall affect the discretion that the competent authorities may exercise when enforcing intellectual property rights.]
- 148Negotiator's Note: VN can accept this on the condition that VN's proposal on administrative measures as an alternative to criminal measures is accepted.
- 149For greater certainty, a Party may implement this Article on the basis of sworn statements or documents having evidentiary value, such as statutory declarations. A Party may also provide that such presumptions are rebuttable presumptions that may be rebutted by evidence to the contrary.

150Each Party may establish the means by which it shall determine what constitutes the "usual manner" for a particular physical support.

151For greater certainty, nothing prevents a Party from making available third party procedures in connection with its fulfillment of Paragraphs 2 and 3.

152For greater certainty, where a Party provides its administrative authorities with the exclusive [VN propose: or non-exclusive] authority to determine the validity of a registered trademark or patent, nothing in paragraphs 2 and 3 shall prevent that Party's competent authority from suspending the enforcement procedures until the validity of the registered trademark or patent is determined by the administrative authority. In such validity procedures, the party challenging the validity of the registered trademark or patent is not valid. Notwithstanding the foregoing sentence, a Party may require the trademark holder to provide evidence of first use.

153A Party may provide that this provision applies only to those patents that have been applied for, examined and granted after the entry into force of this Agreement.

154A Party may satisfy the requirement for publication by making the decision or ruling available to the public on the Internet.

155For the purposes of this Article, the term "right holder" shall include those authorized licensees, federations and associations that have the legal standing and authority to assert such rights. The term "authorized licensee" shall include the exclusive licensee of any one or more of the exclusive intellectual property rights encompassed in a given intellectual property.

156A Party may also provide that the right holder may not be entitled to [AU oppose: either] [AU propose: any] of the remedies set out in [AU oppose: 2 and 3] [AU propose 2, 3 and 8] in the case of a finding of non-use of a trademark. It is understood that there is no obligation for a Party to provide for the possibility of the [AU: any of the] remedies in 2, 3, 7 and 8 to be ordered in parallel.

157Negotiator's Note: US is withdrawing reasonable royalties for patent infringement ad ref pending outcome.

158A Party may comply with this paragraph through presuming those profits to be the damages referred to in paragraph 2.

159For greater certainty, additional damages may include exemplary or punitive damages.

160For greater certainty, additional damages may include exemplary or punitive damages.

161US withdraws ad ref Article QQ.H.4.Y on patents/treble damages pending outcome.

162[CA propose: For the purposes of this Article, "where appropriate" shall not be limited to cases where a Party acted in bad faith.]

163Negotiator's Note: This subparagraph was previously closed, but VN would like to insert "predominantly" before "used in the manufacture" in subparagraph b.

164Negotiator's Note: CL support depends on content of RMI and TPM provisions.

165For greater certainty, a Party may, but is not required to, put in place separate remedies in respect of Article QQ.G.10 (TPMs) and Article QQ.G.12 (RMI), if such remedies are available under its copyright law.

166Where a Party's copyright regime provides for both pre-established damages and additional damages, it may comply with the requirements of this subparagraph by providing for only one of these forms of damages.

167Negotiator's Note: PE/CL have introduced a footnote 139 to accommodate judicial discretion and are working with the US to finalize language and placement.

168[CA propose: It is understood that there shall be no obligation to apply the procedures set forth in this Article to goods put on the market in another country by or with the consent of the right holder.]

169[CA propose: For greater certainty, reference to "imported" need not include goods moving "in transit".]

170[For purposes of this Article, a Party may also provide that the applicant may designate a shorter period.]

171For purposes of Article QQ.H.6:

- (a) counterfeit trademark goods means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the Party providing the procedures under this section; and
- (b) pirated copyright goods means that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and that are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the Party providing the procedures under this section.

172For greater certainty, a Party may establish reasonable procedures to receive or access such information.

173For purposes of this Article, "days" shall mean "business days".

174[Negotiator's Note: AU is still considering this Article.]

175For greater certainty, the Parties understand that *ex officio* action does not require a formal complaint from a private party or right holder.

176[US propose: Subparagraph (c) applies to suspect goods which are in-transit from one customs office to another customs office in the Party's territory from which the goods will be exported. As an alternative to subparagraph (c), a Party shall endeavor upon request to examine such suspect goods not consigned to a local party and transshipped through its territory and destined for the territory of another Party, and shall cooperate {upon request} to provide all available information to the other Party to enable effective enforcement against such suspect goods.]

[CA propose: Alt second sentence to footnote 176: As a alternative to subparagraph (c), if upon conducting an examination of goods in transit, a Party suspects such goods are counterfeit trademark or pirated copyright, it shall provide its competent authorities the authority to provide information to other Party to identify those goods upon arrival in the other Party's territory.]

177Negotiator's Note: Further technical work is needed on terminology used in this Article.

178Negotiator's Note: There may not be a procedure to be invoked in respect of H.6(6), if the obligation is as defined in footnote for H.6(6) covering "in transit".

179For greater certainty, a Party may also exclude from the application of this Article small quantities of goods of a non-commercial nature sent in small consignments.

180In conjunction with Article QQ.H.7, nothing prevents a Party from exercising any discretion that it may have to also provide for administrative enforcement procedures and penalties. [VN propose: A Party that provides for administrative procedures and penalties as an alternative to criminal procedures and penalties under [this Chapter]/[paragraphs QQ.G.10(a), QQ.G.13(a), QQ.H.7.3, QQ.H.7.4, QQ.H.8.2, QQ.H.9.1] shall ensure that: (i) such administrative penalties shall be [of sufficient severity to provide a deterrent]/[substantially equivalent to criminal penalties as required by this Chapter and may not include imprisonment]; and (ii) its administrative authorities may initiate a legal action without a formal complaint.

181[CL propose: It is understood that a Party may comply with this paragraph where acts on a commercial scale include the willful infringing reproduction or distribution, including by electronic means, of copies with a significant aggregate monetary value, calculated based on the legitimate retail value of the infringed good.]

182Negotiator's Note: VN will need to propose a footnote to address "commercial scale".

183[CA propose: For greater certainty, for the purposes of this subparagraph, it is understood that a Party may treat "financial gain" as "commercial purposes".]

184[AU propose: A Party may provide that the volume and value of any infringing articles may be taken into account in determining whether the act has a substantial prejudicial impact on the interests of the copyright or related rights owner in relation to the marketplace.]

185{For greater certainty, "financial gain" does not obligate a Party to provide criminal procedures and penalties in cases of *de minimis* infringements.}

186For greater certainty, it is understood that a Party may comply with its obligation relating to importation and exportation of counterfeit trademark goods or pirated copyright goods by providing that distribution or sale of such goods on a commercial scale is an unlawful activity subject to criminal penalties.

187A Party may comply with its obligation relating to importation of labels or packaging through its measures concerning distribution.

188A Party may comply with its obligation under this paragraph by providing for criminal procedures and penalties to be applied to attempts to commit a trademark offense.

189Negotiator's Note: PE to confirm whether it can go along with this language.

190Negotiator's Note: US is prepared to drop illicit labels chausette ad ref pending outcome.

191For greater certainty, for purposes of Article QQ.H.7.4 it is understood that a Party may treat copying as recording in its law.

192[JP/MY/VN propose: For greater certainty, a Party may comply with this paragraph by providing criminal procedures and penalties for the act of transmittal that makes the cinematographic work available to the public.]

193A Party may limit application of this provision to first-run cinematographic works.

194[SG/NZ/AU/CL/MY/BN/VN propose: A Party may meet the requirements of this obligation by providing criminal procedures and penalties for the willful copying of a significant part of the cinematographic work for the purposes of commercial advantage {or alternatively on a commercial scale}.]

195{A Party that provides for administrative procedures and penalties under this paragraph [MX oppose: shall] also ensure that its administrative authorities may initiate a legal action without a formal complaint.}

196{A Party may comply with this paragraph by providing criminal procedures and penalties for the act of transmittal that makes the cinematographic work available to the public. A Party may also treat copying [CA: and transmittal] as recording to its law.}

197{A Party may limit application of this paragraph to first-run cinematographic works. [MX oppose: A Party may also exclude *de minimis* recordings from application of this paragraph.]}

198[CL/MX/PE propose: For grater certainty, a Party may comply with this provision where it provides for criminal procedures and penalties for the willful and unauthorized reproduction and/or communication to the public for purposes of financial gain of cinematographic works.]

199It is understood that there is no obligation for a Party to provide for the possibility of the imprisonment and monetary fines to be imposed in parallel.

200A Party may also account for such circumstances through a separate criminal offense.

201Negotiator's Note: PE is considering language to address its concerns with "derived from".

202Negotiator's Note: CA is interested in knowing whether "primarily" might be acceptable to the group in lieu of "predominantly".

203A Party may also provide such authority in connection with administrative infringement proceedings.

204[JP propose: With regard to copyright and related rights piracy, a Party may limit application of this provision to the cases where there is an impact on the right holder's ability to exploit the work in the market.] Negotiator's Note: JP's support of this provision is conditioned upon acceptance of this footnote.

205For the purposes of this paragraph "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

206A Party may deem the term "misappropriation" to be synonymous with "unlawful acquisition."

207Negotiator's Note: PE needs to clarify whether it can meet the requirements of paragraphs 2 and 3.

208For purposes of paragraph 1, it is understood that knowledge may be demonstrated through reasonable evidence, taking into account the facts and circumstances surrounding the alleged illegal act.

209[JP propose: A Party may implement this paragraph, by applying it to the cases where such acts are committed willfully or in willful negligence.] Negotiator's Note: JP can support "or having reasons to know" with this footnote.

210The obligation regarding export may be met by making it a criminal offense to possess and distribute such a device or system. [CA/US/SG/NZ/MY/AU propose: For the purposes of this provision, a Party may provide that a "lawful distributor" means a person who has the lawful right in that Party's territory to distribute the signal and authorize its decoding.]

211For greater certainty, a Party may provide that "willfully receiving" may mean operating a radio apparatus so as to receive an encrypted signal.

212[CA propose: For greater certainty, a Party may provide that "receive and make use of" includes [MX oppose: viewing] [MX propose: displaying] of the signal, whether such activity is private or commercial.]

213[CA/MX/BM/AU propose: A Party need not apply the [criminal] offense in paragraph b in circumstances where [a person receives and makes use of such signal and where] the lawful distributor has not made the signal available to persons in the area where the decoding occurs.]

214Negotiator's Note: CL position will depend on the outcome of paragraph 1.

215[NZ propose: For greater certainty, a Party may limit "assisting another to receive" to mean publishing information.

216For purposes of Articles QQ.H.9.1 – QQ.H.9.3, each Party may provide that receipt of a program-carrying satellite or cable signal without authorization includes receipt of the signal with intent to avoid payment, or alternatively receipt of the signal without payment.

217Negotiator's Note: This is pending the outcome of horizontal discussions on the issue of levels of government covered by the Agreement.

218For greater certainty, the term "marketing approval" is synonymous with "sanitary approval" under a Party's law.

219[CA propose: For greater certainty a Party may alternatively provide for a period of additional *sui generis* protection to compensate for unreasonable curtailment.]

220Negotiator's Note: Parties to further discuss and consider need for reference to QQ.A.5.

221For greater certainty, for purposes of this Section, a pharmaceutical product is "similar" to a previously approved pharmaceutical product if the marketing approval of that similar pharmaceutical products is based upon the information concerning the safety or efficacy of the previously approved pharmaceutical product, or the prior approval of that previously approved product.

222As an alternative to this paragraph, where a Party, on the date of entry into force of this Agreement for that Party, has in place a system for protecting information submitted in connection with the approval of a pharmaceutical product that utilizes a previously approved {AU/NZ/SG oppose: chemical} {AU/NZ/SG propose: active} component from unfair commercial use, the Party may retain that system, notwithstanding the obligations of this paragraph. Additionally, a Party is not required to apply Article QQ.E.16.2 with respect to pharmaceutical products covered by Article QQ.E.20 [CA oppose: or to pharmaceutical products that receive a period of at least 8 years of protection pursuant to subparagraph 1(a) and 1(b) of Article QQ.E.16.] [CA propose: A Party that provides a period of at least 8 years of protection pursuant to QQ.E.16.1 is not required to apply Article QQ.E.16.2.]

223For greater certainty, the measures referred to in this subparagraph may be in conjunction with a Party's marketing approval process.

224Negotiator's Note: Some Parties are considering possibility of a negotiator's note to address questions surrounding the application of this [paragraph/Article], that could be relied upon for the purposes of supplementary legal interpretation. This is without prejudice to CA's position regarding its prior FN 6.

225[CA propose: For greater certainty, the consent or acquiescence is with respect of those other persons bypassing the measures in the Party's marketing approval process that would prevent the marketing of a product and not with respect to preventing the marketing of the product.]

226For greater certainty, a Party may limit the obligation of paragraph 2 to the types of patents described in paragraphs 1(a)(i) and (ii).

227[MX propose: Where a Party has in place a system with the requirements set forth in paragraph 2(a) on the date of entry into force of this Agreement for that Party, it may retain that system as an alternative to paragraphs 1(a)(i) and (ii).]

228[CL propose: For greater certainty, Parties may comply with this obligation by providing for injunctions or other judicial proceedings within their patent infringement procedures.]

229{For greater certainty, a Party is not required to provide the notification or to make available the information set forth in paragraph 2(b), if that Party precludes the issuance of marketing approval or sanitary permit to a third party prior to the expiration of the patent term in the absence of legal enforcement action by a right holder.}

230For greater certainty, the Parties recognize that this Article does not imply that the marketing approval authority should make patent validity or infringement determinations.

231Negotiator's Note: Delegations discussed two approaches to a footnote on biologics, which are set forth below. Delegations had different views and preferences regarding these two approaches.

Approach 1: {For purposes of this Chapter, a pharmaceutical product that is biological means [at least] a vaccine, a protein, or a [AU propose: plasma-derived product, US propose: blood-derivative, JP propose: blood-derived product] for use in human beings for the prevention, treatment, or, cure of a disease or condition. A Party may limit the scope of such pharmaceutical products to products that are produced [US propose: at least in part, through biological processes involving living organisms, tissues, or cells, such as those involving] [US oppose: by biotechnology [such as]/[including]] recombinant DNA technology. [CA propose: Products that] a Party may exclude [CA oppose: the following] from the scope of such pharmaceutical products, [CA: include:] blood and blood components, chemically synthesized polypeptides, and [US propose: naturally occurring] animal-derived polypeptides that are derived wholly by means of extraction and purification from animal organs and tissues [CA propose: or from plants]} *Note: Delegations also to consider necessity and potential drafting of the following text:* [CA oppose: For greater certainty, each Party confirms that pharmaceutical products that are not defined as biologics under this provisions [are subject to]/[shall be evaluated under] Article QQ.E.16.]

Approach 2: Self-defining / according to national law.

232Each Party may provide that an applicant may request approval of a pharmaceutical product that is a biologic under the procedures set forth in Article QQ.E.16(1)(a)-(b) within 5 years of entry into force of this Agreement, provided that other pharmaceutical products in the same class of products have been approved by the Party under the procedures set forth in Article QQ.E.16(1)(a)-(b) before entry into force of this Agreement.

233Negotiator's Note: CL does not consider the 2nd sentence necessary given the 1st sentence.

234For greater certainty, the Parties understand that the definition in QQ.E.21 for "new pharmaceutical product" is applicable to subparagraph C.

235Negotiator's Note: CL is still considering this proposal and reserves its position to the entire section.

236For the purposes of this Article, "copyright" includes related rights.

237For purposes of this Article, "online service provider" and "provider" mean a provider of online services or network access, or the operators of facilities therefore, and includes [CL oppose: an entity] [CL propose: any person] offering the transmission, routing, or providing of connections for digital online communications, between or among points specified by a user, of material of the user's choosing, without modification to the content of the material as sent or received [CA propose: other than modifications made as part of a technical process or for solely technical reasons]. A Party may provide that network access includes cases in which network access is provided by another provider. [NZ propose: A Party may limit the application of this Article to entities offering the transmission, routing, or providing of connections for digital online communications, between or

among points specified by a user, of material of the user's choosing, without modification to the content of the material as sent or received, or offering the hosting of material on websites or other electronic retrieval systems that can be accessed by a user.]

238[CA propose: Legal incentives may be understood as exposure to potential liability under that Party's domestic copyright law.]

239{[CA oppose: Where a Party chooses to limit liability, appropriate court-ordered relief] [CA propose: Limitation in law on the liability of online service providers shall not affect any judicial authority, in accordance with a Party's legal system,] to compel or restrain certain actions [CA propose: where appropriate and] [CA oppose: shall be available,] subject to reasonable restrictions with due regard to the relative burdens to the service provider and harm to the copyright owner, the technical feasibility and effectiveness of the relief and whether less burdensome, comparably effective enforcement methods are available.}

240[CL propose: For greater certainty, these limitations may preclude monetary relief and provide reasonable limitations on court order relief to compel or restrain certain actions for the functions referred to in paragraph 3 and shall be confined to those functions.]

241[CA oppose: {Placeholder for further elaboration on what factors may determine what is a neutral intermediary, with focus on separating out non legitimate ISPs that promote infringement}.]

242It is understood that, to the extent that a Party determines, consistent with its international legal obligations, that a particular act does not constitute copyright infringement, there is no obligation to provide for a limitation in relation to the act.

243[PE propose: For greater certainty, the failure of a service provider to quality for the limitations in paragraph 2 does not itself result in liability. Furthermore, paragraph 2 is without prejudice to the availability of defenses to copyright infringement that are of general applicability.]

244[CA propose: It is understood that online service providers may control, initiate, or direct various acts of reproduction or communication that may involve infringing acts solely for technical reasons in carrying out the functions in paragraph 3 and as part of providing their services.]

245Such modification does not include modifications made as part of a technical process or for solely technical reasons [CL propose:, such as division in to packages.]

246For greater certainty, Parties may interpret "storage" as "hosting".

247For greater certainty, such storage of material may include e-mails and their attachments stored in the provider's server and web pages residing on the provider's server.

248[CL propose: A Party may require judicial intervention for purpose of obtaining actual knowledge of the infringement or awareness of facts or circumstances from which the infringement is apparent.]

249Each Party understands that a legally sufficient notice or statement, as defined under a Party's law, must contain information that is reasonably sufficient to enable the online service provider to identify the work, performance, or phonogram claimed to be infringed, the alleged infringing material, and the online location of the alleged infringement and that has a sufficient indicia of reliability with respect to the authority of the party sending the notice.

250A Party may comply with [JP oppose: its] [JP propose: the] obligations under [JP propose: the second sentence of] [JP oppose: sub] paragraph 4 by [JP propose: (1)] having a [JP oppose: multi-]stakeholder organization [JP propose:, which includes representatives of both online service providers and rights holders, with the government involved,] to develop and maintain [JP oppose: adequacy of institutional] [JP propose: adequate] procedures to verify [JP oppose: or underwrite] the validity of [JP oppose: a notice on] [JP propose: notices of] copyright infringement [JP oppose:, and by providing that a provider shall be exempted from any liability for removing or disabling access to material, (a) upon receiving the notice underwritten or verified through such procedures; or (b) upon receiving other notice after informing of such notice and not receiving objections within a reasonable period from the person.] [JP propose:, and (2) taking appropriate measures to limit the liability of online service providers for copyright infringement where the online service providers expeditiously remove or disable access to the material, upon obtaining actual knowledge of the infringement or awareness of facts or circumstances from which the infringement is apparent, including through receiving a verified notice.]

251[NZ propose: for greater certainty, where no such liability exists under a Party's law, a Party need not provide any further exemption.]

252With respect to the function in subparagraph 3(ii), a Party may limit the requirements of paragraph 4 related to removing or disabling access to infringing material to circumstances in which the service provider becomes aware or receives notification that the cached material has been removed or access to it has been disabled at the originating site.

253[JP propose: A Party need not require such notification in circumstances in which the online service provider has reasonable grounds to believe that infringement is occurring.]

254[Negotiator's Note: JP would like to invite Parties' views on including other principles.]

255For greater certainty, "law" is not limited by legislation.

256Negotiator's Note: The definition of SOEs will be subject to resolution by the SOE Chapter working group.

257For greater certainty, nothing in this Agreement limits Parties from taking an otherwise permissible derogation from national treatment with respect to {copyrights and related rights} that are not covered under Section G (Copyright and Related Rights) of this Chapter. Negotiator's Note: Chile will confirm.

258For purposes of Articles [QQ.A.9.1-2 (National Treatment and Judicial/Admin Procedures), QQ.D.2.a (GIs/Nationals), and QQ.G.14.1 (Performers/Phonograms/Related Rights),] [CA propose: subject to the flexibilities in QQ.G.14.1] a "national of a Party" shall mean, in respect of the relevant right, a person of that Party that would meet the criteria for eligibility for protection provided for in the agreements listed in [Article QQ.A.6.4] and the TRIPS Agreement. Negotiator's Note: Parties to remember to insert correct cross references to other treaties including WPPT (Article 3) depending on whether Chapter includes an obligation to accede to a list of treaties.

259For purposes of this paragraph (Article QQ.A.9.1), "protection" shall include matters affecting the availability, acquisition, scope, maintenance, and enforcement of intellectual property rights as well as matters affecting the use of intellectual property rights specifically covered by this Chapter. Further, for purposes of paragraph 1, "protection" also includes the prohibition on circumvention of effective technological measures set out in Article QQ.G.10 and the provisions concerning rights management information set in Article QQ.G.13.

260For greater certainty, "benefits derived from such rights" refers to benefits such as copyright levies.

261[JP propose: For greater certainty, it is understood that secondary uses of phonograms by means of television programs are outside of the scope of this Article.]

262[JP propose: For greater certainty, a Party may define "free" to include the imposition through legislation of a mandatory fee on the general public for reception of broadcast from a public and non-commercial entity specifically chartered by a Party's law, where that Party is responsible for the appointment or approval of the members of the entity's governing board.]

263Negotiator's Note: CA supports in principle pending clarification of what is meant by "open to public inspection" in subparagraph (b).

264Placeholder for footnote, indicating that this provision is without prejudice to the manner in which each Party provides for these rights under its law.

265Placeholder for language clarifying that the obligation does not extend to making the whole dossier open to public inspection.

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