

Without Prejudice

Cover Page

Intellectual Property [Rights] Chapter

Consolidated Text (Rebooted)

Clean version

11 May 2015

Notes on this document.

This is the first installment of text from the May 11, 2015 negotiating text for the TPP chapter on intellectual property. The whole IP chapter is 95 pages long, including the cover page.

This PDF includes: {Section E: Patents / Undisclosed Test or Other Data / Traditional Knowledge } , from pages 29 to 53 of the 11 May 2015 IP Chapter.

The next installments will include:

QQ.F. Industrial designs (page 54)
QQ.G. Copyright and Related Rights (pages 55 to 66),
QQ.H. Enforcement (pages 67 to 95), and
QQ.A-D, the front sections of the Agreement.

Given how fast negotiations are going on and how long it has been since anyone has leaked the IP Chapter we wanted to get the text out sooner rather than later. We might revise the document next week, after doing more proof reading.

We obtained the text in hard copy, and typed it into this document, preserving the formatting as best we can. The page numbers here refer to the May 11, 2015 consolidated text, rather than the page numbers of this PDF file.

Knowledge Ecology Staff, August 4, 2015.

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

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

1. Subject to paragraphs 3 and 4, 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. [58]

2. [US/NZ/SG/AU/JP/CA/PE/MX/BN/VN propose; CL oppose: Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit such processes to those that do not claim the use of the product as such.]

3. 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 or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Each Party may also exclude from patentability: diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; animals other than microorganisms; and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.

4. [59] Each Party may also exclude from patentability plants other than microorganisms. [US/JP/AU propose; CL oppose: However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants. [US/AU/JP propose; MY/NZ oppose: [60]]]

FN4 (based on TRIPs Art. 27.3): Each Party shall provide for the protection of plant varieties either by patents or by a sui generis system or by any combination thereof.

[58] For 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.

[59] Negotiators’ note: CL has a substantive issue with the second part of paragraph 4, and is exploring language that explicitly allow the application of national practices in respect to this part.

[60] US/AU/JP propose; MY/NZ oppose: Each Party affirms its commitment to the protection of plant varieties by, inter alia, an effective sui generis system, [CA oppose: Alt 1: consistent with UPOV ‘91] [Alt 2: through the obligation in QQ.A.8.2(c) (UPOV ‘91)]].

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Such a sui generis system shall, that at a minimum, adopts or maintains the standards regarding scope and conditions of protection, scope of rights, exceptions and duration of protection as set forth in UPOV '91.

Negotiator's Note: With respect to the second sentence of FN 4, Parties discussed the relationship between the UPOV '91 ratification provision in general provisions and the language of the FN. Some Parties commented that if a commitment to ratify/accede to UPOV '91 is agreed upon then the second sentence of the FN may not be necessary or may be necessary for an interim period only. One Party stated it is unlikely to accept the second sentence of the FN without further elaboration as to the provisions of UPOV '91 from which a Party may derogate.

Negotiator's Note: One Party is considering the placement of paragraph 2.

Negotiator's Note: CL has a fundamental issue with the content of paragraph 4, notwithstanding its support for the exception to patentability for plants.

Article QQ.E.2: {Grace Period}

Each Party shall disregard at least information contained in public disclosure used to determine if an invention is novel or has an inventive step if the public disclosure [61] [62]:

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

and

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

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

[62] For 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 application may be information contained in the public disclosure that was authorized by, or derived from, the patent applicant.

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Article QQ.E.3:

New Option

{Without prejudice to Article 5A of the Paris Convention, each Party shall provide that a patent may be cancelled, 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 cancelling, revoking or nullifying a patent or holding a patent unenforceable.[63]}

AU brainstorming on patents

Article QQ.E.3:

Option 2: Each Party shall provide that a patent may be cancelled, 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 cancelling, revoking or nullifying a patent or holding a patent unenforceable.[64] [AU/CL/MY/NZ/BN/CA/MX/VN/SG propose[65]; US/JP oppose: A Party may also provide that a patent may be cancelled, revoked or nullified on the basis that the patent is used in a manner determined to be anti-competitive {, or abusive,} in a judicial or administrative proceeding, {and} where the grant of a compulsory license would not have been sufficient to prevent the said anti-competitive use or abuse]. This Article is without prejudice to Article 5A 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.[AU propose: [66]]

[63] Negotiators' note: AU/US still need to resolve how to incorporate the issue of anti-competitive use as a basis for revoking a patent.

[64] {For greater certainty, a Party may provide for forfeiture of a patent pursuant to Article 5A(3) of the Paris Convention.} Negotiators' note: Some Parties consider that this footnote may be necessary to ensure consistency with Article 5A(3) of the Paris Convention.

[65] Negotiators' Note: PE and SG are flexible with both options.

[66] [AU propose: For greater certainty, nothing in this Chapter shall prevent a Party from taking measures pursuant to Article 31 of the TRIPS Agreement, including any waivers or amendments thereto.]

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[AU: Insert new QQ.E.4.2

For greater certainty, nothing in this {Chapter} shall limit a Party's rights and obligations pursuant to Article 31 of the TRIPS Agreement, including any waivers or amendments thereto.]

Pharmaceutical regulatory review non paper 26 April 2015

OPTION 1

1. Consistent with, and without prejudice to {a Party's right to provide} limited exceptions under, QQ.E.4: [FN 1]

Each Party shall permit a third person to use the subject matter of a subsisting patent to support an application for marketing approval [FN 2] of a pharmaceutical product in that Party.

A Party may permit a third person to use the subject matter of a subsisting patent to support an application for marketing approval of a pharmaceutical product in another country.

ALT 1 (paragraph 3): A Party may also permit a third person to do {any} other acts that would infringe the exclusive rights of the patent owner {under that Party's law}.

ALT 2 [FN 1]: For greater certainty, nothing in this Article prevents a party from permitting a third person to do any other act that would otherwise infringe the exclusive rights of a patent for purposes of obtaining marketing approval in that Party or another country {provided that the Party acts in a manner consistent with QQ.E.4}.

[FN 2: For purposes of this Chapter, the term marketing approval is synonymous with sanitary approval {under a Party's Law}]

OPTION 2 (CA proposal)

Without limiting a Party's ability to provide regulatory review exceptions in any field of technology under, and consistent with, QQ.E.4 each Party shall permit a third person to use the subject matter of a subsisting patent to support an application for marketing approval [FN 1] of a pharmaceutical product in that Party. [FN2]

[FN 1: For greater certainty, nothing in this Article prevents a Party from permitting a third person to do any other act that would otherwise infringe the exclusive rights of a patent for purposes of obtaining marketing approval in that Party or another country.]

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[FN 2: For purposes of this Chapter, the term marketing approval is synonymous with sanitary approval {under a Party's law}]

OPTION 3: do nothing (CA proposal)

OPTION 4: Article QQ.*.** — Pharmaceutical Regulatory Review Exception

Consistent with and without prejudice to Article QQ.E.4, each party shall permit a third person to *perform an act that would otherwise infringe a patent, if such act is done for the purposes of supporting an application for marketing approval of a pharmaceutical*[FN]product in that Party and may permit such an act for the purposes of supporting an application for marketing approval of a pharmaceutical product in another territory.

[FN]: This article is without prejudice to a Party's right to provide for any other [CA: regulatory review] exception that {complies with/satisfies/meets the requirements of} Article QQ.E.4.

Article QQ.E.13[67][68]: {Exceptions / Regulatory Review Exception}

[CL 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 support an application for marketing approval of a pharmaceutical [CA/MY/BN propose; US oppose: or other] product [PE propose: and an agricultural chemical product], that Party shall provide that any product produced under such authority shall not be made, used, sold in, [AU/NZ considering: offered for sale,] [AU/NZ considering: or imported into,] the territory of that Party other than for purposes related to meeting requirements for marketing approval [US propose; AU/VN/NZ/MY/CA/BN oppose: of that Party] for the product [AU/VN/NZ/MY/CA/BN/MX propose; US oppose: , and each party may also permit such a product to be exported outside its territory for purposes related to support an application for marketing approval in the exporting party or another country.]] [69]

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

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

[69] Negotiators' 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 provisions makes it a limiting provision, rather than a more affirmative approach.

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Option 2:

[NZ/CA/SG/CL/MY/VN/BN/AU propose[70]: 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.][71]

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 date[72], unless that application has, prior to publication,[73] 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 applications[74].

Article QQ.E.8: [US/AU/PE/VN/JP propose; CL/MY/BN/CA/SG/MX[75] oppose: Each Party shall provide that a disclosure of a claimed invention shall be considered to be

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

[71] Negotiators' Note: Parties did not discuss Option 2 in detail as it some parties indicated that it was not a possible landing zone.

[72] A 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 make an application that contains or contained such a claim.

[73] For greater certainty, a Party may grant the patent to the subsequent application that is patentable, when an earlier application has been withdrawn, abandoned, or refused, or is not prior art against the subsequent application.

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

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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/MX 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; [76] 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

CL oppose[77] 1. Recognizing the benefits of transparency in the patent system, each Party shall endeavour to publish unpublished pending patent applications promptly after the expiry of 18 months from the filing date or, if priority is claimed, from the priority date.

2. Where a pending application is not published promptly under paragraph 1, Parties shall publish such application or the corresponding 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.}]

[75] Negotiator'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.

[76] Negotiators' Note: JP is considering this provision.

[77] Negotiator's Note: CL supports option 2 of the original proposal and see this as a CN issue.]

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Non-Paper

Patent Small Group Discussion on QQ.E.11 Publication of Applications
Jan. 30, 2015 (as of 11:45AM)
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[OPTION 2 [78]

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 publish [79] [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]].][80,81]

[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) [82] 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;

[78] Negotiators' note: CL sees this as a CN level issue and prefers option 2.

[79] [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.] Negotiators 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.] Negotiators' note: To drop this footnote if the larger package involving transparency and publication is resolved.

Negotiators' 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.

[80] Negotiators' note: US Support for this provision is contingent upon accommodating exceptions provided under U.S. law.

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

[82] Negotiators' note: AU is still considering (a).

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(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.]]]

Negotiator's Note: One Party indicated a preference for maintaining both Options for consideration at this time.

Article QQ.E.11bis

For published 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 the possession of the competent authorities and is generated on or after the date of entry into force of the Agreement for that Party:

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

[Secretariat's Note: Non-paper on QQ.E.12 dated 13 March 2015]

Article QQ.E.12

[AUS propose. 1. Each party shall make best efforts to process patent applications in an efficient and timely manner with a view to avoiding unreasonable or unnecessary delays.

2. Each Party may provide procedures for patent applications to request to expedite the examination of their patent application.

3.] [US/SG propose [83]; CA/NZ/MY/VN/CL/PE/MX/AU/BN [84] oppose:

[83] Negotiator's Note: JP can support this Article if JP proposals are accepted.

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{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 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 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 be included in the determination of such delay. }

[US propose: AU/NZ/VN 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: 85] [JP: 86] [87] [88]

[84] Negotiator's note: CA/PE cannot agree to including pharmaceuticals within the scope of this Article.

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

[86] JP propose: Notwithstanding Article QQ.A.10bis, this Article shall apply to all patent applications filed after the date of entry into force of this Agreement for a Party, or the date two years after the signing of this Agreement, whichever is later for that Party.]

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

[88] (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.

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[Secretariat's note: Non paper on Ag Chem, 13 March 2015]

Article QQ.E.13 {Agricultural Chemical Products}[89]

1. If a Party requires, as a condition for granting marketing approval [90] for a new agricultural chemical product, [91][1] the submission of undisclosed [92] 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 or a similar [93] product on the basis of that information of the marketing approval granted to the person who submitted such test or other data for at least ten years from the date of marketing approval of the new agricultural chemical product in the territory of the party.

[CL oppose: 2. If a party permits, as a condition of granting marketing approval for a new agricultural chemical 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 test or other data concerning the safety [US/JP propose: or] [CL Propose: and] efficacy of the product, to market a same or a similar product based on evidence relating to prior marketing approval in the other territory for at least ten years from the date of marketing approval of the new agricultural chemical product in the territory of the Party.]

[89] CL's negotiator's note: If there is going to be an explicit mention to the possibility of implementing flexibilities to encourage early entry, then CL will need to have a high level language such as the one in QQ.E.14.3(*For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article*) and also to apply it to undisclosed test or other data protection for agricultural chemical products, pharmaceutical products (small molecules) and biologics.

[90] For purposes of this Chapter, the term "marketing approval" is synonymous with "sanitary approval" {under a Party's law}.

[91] For 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.]

[92] Negotiator's note: Issues under discussion between JP/CA/US/AU.

[93] For greater certainty, for purposes of this Section, an agricultural chemical product is "similar" to a previously approved agricultural chemical product if the marketing approval of that similar agricultural chemical products is based upon the information concerning the safety [US/JP propose: or] [CL propose: and] efficacy of the previously approved agricultural chemical product, or the prior approval of that previously approved product.

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3. For the purposes of this Article, a new agricultural chemical product [CL propose; US oppose: Means a product that does not contain or utilize a chemical entity that has been previously approved in the Party.] [CL oppose; US propose: 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.][2][AU propose:[94]]

[Note: One Party sees “considerable efforts” as part of the overall package.]

Article QQ.E.23[95]: {Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources}

[PE/NZ/VN/BN/MX/SG/CL/MY propose[96]: 1. The parties recognise the importance and contribution of traditional knowledge, traditional cultural expressions, and biological diversity to cultural, economic and social development.]

[[97]PE/MY/MXBN 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: [98] 3. Where national legislation [MY/BN propose: or policies] establishes such requirements, the parties recognise that users of genetic resources [NZ/CA oppose: and their derivatives][99] or traditional knowledge associated with genetic resources [NZ/CA oppose: and their derivatives] and [NZ propose: may] [PE/MY propose: shall]:

[94][AU propose: For greater certainty and for the purposes of this Article, a Party may require a chemical entity to {ALT 1: include an active component that has not been previously approved} {ALT 2: be primarily responsible for the product’s intended effect} {ALT 3: be an active component}.]

[95]Negotiators’ Note: CA/US position is that QQ.E.23 provisions should be addressed in the Environment Chapter. The US/JP opposes the inclusion of the Article in this Chapter.

[96]Negotiator’s Note: AU is considering this paragraph in light of the rest of the Article.

[97]Negotiators Note: Appropriate placement within the Agreement of paragraphs 2, 3 and 7 is under consideration

[98] Negotiator’s Note: NZ/CA prefer the issues included in this paragraph to be discussed in the Environment Chapter.

[99][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.]

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- (a) obtain prior informed consent to access genetic resources [NZ/CA oppose: and their derivatives];
- (b) access traditional knowledge associated with genetic 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 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 patent examination including applications concerning genetic resources and traditional knowledge associated with genetic resources. This may include:

- (a) in determining prior art, publicly available documented information related to genetic resources or traditional knowledge associated with genetic resources 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 database 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 with genetic resources.]

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

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[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[101].]

[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/VL propose: 8. The Parties shall endeavour 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 resources[102].

[Secretariat's note: Non paper dated 31 Jan 2015] [3]

[Article OO.B.xx {Cooperation in the Areas of Traditional Knowledge}]

XX.1. The Parties recognise the importance and contribution of traditional knowledge, traditional knowledge associated with genetic resources and traditional cultural expressions to cultural, economics and social development.

XX.2. The Parties recognize the relevance of IP systems to {the respect, preservation and promotion of} {respecting, preserving and maintaining}[103] the traditional knowledge associated with genetic resources.

XX.3. The Parties shall endeavor to cooperate through their respective agencies responsible for intellectual property or other relevant institutions to enhance the understanding of issues connected with traditional knowledge associated with genetic resources, and genetic resources.

XX.4. The Parties shall endeavor to pursue quality patent examination, [in relation to applications that may involve the subject matter of paragraph x above]. This may include:

[101] Negotiators' Note: Proponents of this provision could be flexible to move this provision to Chapter AA {Initial Provisions} in order to drive consensus.

[102] Negotiators' Note: Proponents of this paragraph could be flexible to move to Section B {Cooperation} in order to drive consensus.

[103] Negotiator's note: Parties will reflect on the formulation of wording on this and consistency with para 6.

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(a) in determining prior art, relevant publicly available documented information related to traditional knowledge associated with genetic resources 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 with genetic resources; and

(d) cooperation in the training of patent examiners in the examination of patent applications related to traditional knowledge associated with genetic resources.

(Note: Paragraph 6 in consolidated text, as amended, placed in Chapter AA.)

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

1. Each Party shall make best efforts to process {patent applications and} [104] applications for marketing approval [105] of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.

[106,107] [US/JP/CL/SG propose; MX/PE/VN/MY oppose [108]: 2. With respect to a pharmaceutical product [AU propose: [109]] that is subject to a patent, each Party shall make

[104] Negotiators' note: Parties agree that this may be removed if the language in QQ.E.12 is accepted.

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

[106] Negotiators' note: NZ is considering its position on paragraphs 2 and 3.

[107] Negotiators' note: MY may consider this if the ~~provision is redrafted in a similar manner as patent term extension~~ and Parties establish cooperation between drug approval authorities to facilitate processing applications of marketing approval. MY/MX are also considering inclusion of a footnote similar to that proposed by JP in QQ.E.12 to clarify that this provision only applies to marketing approval applications filed after entry into force of this Agreement for that Party. BN also supports MY's proposal for this provision to be redrafted in a similar manner as a patent term extension.

[108] Negotiators' note: MX/PE can accept if this is a "may" provision. VN can accept these paragraphs only if an adequate transition period for VN based on a development indicator is agreed.

[109] [AU/SG propose: A Party may comply with the obligations of this paragraph with respect to a pharmaceutical product or, alternatively, with respect to a pharmaceutical substance.]

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available an adjustment[110] of the patent term to compensate the patent owner for unreasonable curtailment [MX propose; US/JP oppose;[111] of the effective patent term as a result of the marketing approval process.

3. For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article.

Article QQ.E.16: {Pharmaceutical Data Protection}[112]

[113] 1. (a) If a Party requires, as a condition for granting marketing approval for a [US propose; PE/MX oppose: new pharmaceutical product], the submission of undisclosed test or other data concerning the safety [US/JP propose; PE/CL/MX/CA oppose: or][PE/CL/MX/CA propose; US/JP oppose: and] efficacy of the product, the Party shall not permit third persons; without the consent of the person who previously submitted such information [MX/PE propose; US/JP oppose:; if the origination of such information involves considerable effort], to market the same [US propose; MY/PE/VN/BN/MX oppose: or a similar[114]] product on the basis of:

- (i) that information; or
- [PE oppose: (ii) the marketing approval granted to the person who submitted such information]

[110] For greater certainty, a Party may alternatively make available a period of additional sui generis protection to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process. The sui generis protection shall confer the rights conferred by the patent subject to any conditions and limitations pursuant to Paragraph 3.

[111] [MX propose: For greater certainty, the definition of “unreasonable curtailment” is subject to each Party’s domestic legislation.] Negotiator’s note: PE/MY/BN/CL/SG neutral on this footnote.

[112] Negotiator’s note: VN can give consideration to these paragraphs only if an adequate transition period for VN based on a development indicator is agreed.

[113] Negotiator’s note: CL position on this paragraph is pending outcome on the discussion of the definition of “similar.”

[114] For 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.

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for [PE oppose: at least][PE propose: normally] five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party [MY/PE/VN/Bn propose; JP/US oppose: , or an other country where marketing approval is first granted]. [115]

[US/JP propose; CL oppose: (b) If a Party permits, as a condition of granting marketing approval for a [US/JP propose; PE/MX oppose: 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 [MX/PE propos; US/JP oppose: , if the origination of such information involves considerable effort] concerning the safety [PE/ME oppose: or] [PE/MX propose: and] efficacy of the product, to market a same [MY/PE/VN/BN/MX oppose: or a similar] product based on evidence relating to prior marketing approval in the other territory for [PE oppose: at least] [PE propose: normally] five years from the date of marketing approval of the new pharmaceutical product in the territory of the party [MY/PE/VN/BN propose; JP/US oppose: , or any other country where marketing approval is first granted].]

[JP/US propose; PE/NZ/VN/BN/CL/MX/AU/SG/CA oppose: 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 [JP/US propose; MY oppose: or the other

[115] Negotiators' note: MX/PE support for this paragraph is contingent on the inclusion of the concept of "considerable effort."

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territory, as applicable, whichever is later [116] [MY propose; JP/US oppose: or any other country where marketing approval is first granted].[117]]

3. Notwithstanding paragraphs 1 and 2 above, a Party may take measures to protect public health in accordance with: [118]

(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/VN/BN/MX propose; JP/US oppose: 4. A Party may for the purpose of granting protection under subparagraph (1)(s) 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.][119]

[116] Negotiators’ note: Parties need to discuss the interpretation of the phrase “whichever is later.”

[117] As 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 [NZ/SG oppose: chemical] [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 is not required to apply Article QQ.E.16.2.]

[118]Negotiators’ note: the applicability of this para 3 to other parts of this sections needs to be discussed in a small group.

[119] CL’s Negotiators’ note: If there is going to be an explicit mention to the possibility of implementing flexibilities to encourage early entry, then CL will need to have a high level language such as the one in QQ.E.14.3 (*For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article*) and also apply it to undisclosed test or other data protection for agricultural chemical products, pharmaceutical products (small molecules) and biologics.

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[MY propose; CL/MX/US/JP/BN/PE/SG oppose: [120] 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.]

[121][MY/VN/MX propose; US/JP oppose: 6. Notwithstanding paragraphs 1 and 2 above, a Party may waive the protection under paragraphs 1 and 2 above, where it has take 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: [122,123, 124, 125]

[120] Negotiators’ note:CL/MX/BN/PE opposition here is linked to their opposition to paragraph 2.

[121] Negotiators’ note:MY proposal will be discussed in tandem with paragraph 3.

[122] Negotiators’ note: VN can give consideration to these paragraphs only if an adequate transition period for VN based on a development indicator is agreed.

[123] Negotiators’ note: MX/CL support for this Article is contingent on acceptance of their respective footnotes.

[124] Negotiators’ note: NZ is considering this Article as a whole, but needs to see its footnote on “in conjunction with” included.

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[J{/US propose; PE/BN oppose: 1. {As an alternative to paragraph 1} {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 patent[130][MX propose; US oppose:[131]]:

(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; JP?US oppose: [132]]; and

(b) the Party shall provide for the patent owner to be notified of, or make available to the patent owner, the identity of any third party requesting marketing approval effective during the term of the patent.[133/134]]

Peru' alternative proposal on patent linkage QQ.E.17[4]

[As an alternative to paragraphs 1 and 2, A Party shall provide the following measures with respect to any pharmaceutical product that is subject to a patent:

a) sufficient time and opportunity for a patent holder to get the expeditious adjudication of disputes concerning the infringement of the patent, prior to the marketing of an allegedly infringing product through procedures, such as judicial or administrative proceedings, and available remedies, such as preliminary injunctions or equivalent effective provisional measures; and

[130] For greater certainty, a Party may limit the obligation of paragraph 2 to the types of patents described in paragraphs 1(a)(i) [US/JP propose; SG/MX oppose: and (ii).]

[131] [MX/SG 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).]

[132] [CL propose; JP.US oppose: For greater certainty, Parties may comply with this obligation by providing expeditious, efficient and transparent judicial proceedings, with include injunctions, and criminal sanctions in the case of patent infringement.]

[133] For greater certainty, a Party is not required to provide [JP propose: for] the [JP propose: system of] notification or to make available the information set forth in paragraph 2(b), if that Party [JP propose: has a system to preclude] [JP oppose: 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 rightholder.

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

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(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 the protection of a patent.]

[US/JP propose; CL/MX/BN/PE/MY/VN/AU/NZ oppose [135]: **Article QQ.E.20:** With respect to the first marketing approval of a pharmaceutical product that [contains/is] [136] a [new] biologic [137,138], each Party shall provide the protection afforded under Article

[135] Negotiators' note: CL/MX/NZ/BN considering this proposal subject to definition of biologics, length of protection and QQ.E.16.

[136]Negotiators' note: Some Parties need to discuss "contains/is" after the discussion on "new pharmaceutical product" in QQ.E.21 is settled.

[137]Negotiators' note: CA needs to discuss the formulation of "pharmaceutical product that is biologic."

[138]Negotiators' note: Delegations discussed two approaches to a footnote on biologics, which are set forth below. Delegations different views and preferences regarding these two approaches.

Approach 1: {For purposes of this Chapter, a pharmaceutical product that is a biologic means [at least] a vaccine, a protein, or a [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 that are produced [US propose: at least in part, through biological processes involving living organisms, tissues, or cells, such as those involving][US oppos: 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, 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 provision [are subject to]/[shall be evaluated under] Article QQ.E.16]

Approach 1bis: For the purposes of this [Article][Section][Chapter], a pharmaceutical product that is a biologic means a peptide or protein produced using biotechnology [FN] processes for use in human beings for the prevention, treatment, or cure of a disease or condition.

FN: Biotechnology means any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses.

Approach 1ter: For the purposes of this [Article][Section][Chapter], a pharmaceutical products that [contains/is] a biologic means a product produced using biotechnology processes for use in human beings for the prevention, treatment, or cure of a disease or condition. At a minimum, such products include polypeptides, proteins [,blood derivatives, and vaccines] produced using biotechnology [FN] processes.

[Option 1: FN: Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses.]

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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.[139]][140]

{Option 1: Article QQ.E.21: For the purposes of Article QQ.E.16, a new pharmaceutical product means a product that does not contain [CI propose: or utilize] [FN[a chemical entity that has been previously approved in the Party. [CA propose: In the alternative, a][CA oppose: A] Party may provide that a new pharmaceutical product means a

- pharmaceutical product that utilizes a chemical entity that has not been previously approved in the Party.[141]

[FN: For purposes of this [Article][Section], the term “utilize” may be deemed by a Party to be synonymous with the term “contain.”}]

{Option 2: Article QQ.E.21

For the purposes of Article QQ.E.16, a new pharmaceutical product means a product that does not utilize [FN] a chemical entity that has been previously approved in the Party.

[FN: For purposes of this [Article][Section], the term “utilize” may be deemed by a Party to be synonymous with the term “contain.”}]

[Option 2: FN: Biotechnology process means a biological processes involving living organisms, tissues, or cells.]

Negotiators’ note: Consistent with QQ.A.5, the Parties may, but shall not be obliged to, implement in their laws more extensive protection than is required by this Article, provided such protection does not contravene the provisions of this Agreement.

Approach 2: Self-defining/according to national law. [NZ/AU propose: For the purposes of this Chapter, each Party is free to determine the scope of the pharmaceutical products that constitute biologics under its domestic law.] CL supports this approach.

[139] Each 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 the 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.

[140] CL negotiators’ note: If there is going to be an explicit mention to the possibility of implementing flexibilities to encourage early entry, then CL will need to have a high level language such as the one in QQ.E.14.3 (*For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article*) and also to apply it to undisclosed test or other data protection for agricultural chemical products, pharmaceutical products (small molecules) and biologics.

[141] Negotiators’ note: CL does not consider the 2nd sentence necessary given the 1st sentence.

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Category A	Upon entry into force of the Agreement
Category B	X years after entry into force of the Agreement for that Party
Category C	Y years after entry into force of the Agreement for that Party
Category D	Z years after entry into force of the Agreement for that Party

3. A Party in Category B, C, or D shall provide periodic updates to the Joint Commission, at least annually, regarding the progress of its implementation schedule for the provisions contained in paragraph 1, C. until those provisions come into force for that Party.

4. A Party may seek an extension of the time applicable to that Party for the implementation of the Section on Patent Pharmaceuticals from the Joint Commission if there has been any significant change in a Party's social or economic circumstances.