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What's New in the 2014 WikiLeaks TPP Intellectual Property Text?

Pharmaceuticals: Landing Zones and Issues for Ministerial Discussion[1]

Today, WikiLeaks released an updated draft of the Intellectual Property (IP) Chapter[2] of the proposed Trans-Pacific Partnership (TPP). The text includes U.S.-backed measures that would expand pharmaceutical monopoly power and compromise access to medicines in Pacific Rim countries. The deep resistance to these measures from many negotiating countries has endured for years. The U.S. has dropped some harmful proposals, but continues to insist on many others. Unable to agree, intellectual property negotiators have finally passed these controversies on to their countries' highest trade and commerce authorities, who will gather for a ministerial meeting later this month in Australia.

Addendums of the new leaked text include issues to be presented to ministers. Addendum I covers certain provisions specific to pharmaceuticals. The ministers will discuss "landing zones," not disclosed in this text but described in some detail in an Inside U.S. Trade article,[3] and known to close followers of the negotiation. A landing zone is a range of possibilities identified by the countries' chief TPP negotiators for possible agreement. In other words, countries are to choose from the several possible options either spelled out in Addendum I or listed as modifications to the Addendum I text in another undisclosed document. Not every country has a mandate to discuss every landing zone, and it is still possible that the ranges of possibilities may be adjusted or rejected entirely. It is also worth noting that the landing zone ranges are at times so wide as to encompass all possible options.

This paper analyzes Addendum I and discusses its provisions in light of what is known about the landing zones, and therefore the range of likely interpretations or applications of each provision. In several cases, the landing zones or bracketed options indicated in Addendum I make very important differences to the public interest. For example, countries are debating a range of possible monopoly periods for biotech drugs, ranging from zero years to twelve. That is the difference between life and death for many cancer patients.

More information and analysis is available at: www.citizen.org/tppa.

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[1] Public Citizen's Global Access to Medicines Program, October 2014, Dr. Burcu Kilic (bkilic@citizen.org) & Peter Maybarduk (pmaybarduk@citizen.org).

[2] Available at http http://wikileaks.org/tpp-ip2.

[3] Inside U.S. Trade, *Leaked TPP Paper On Drug IP Landing Zones Shows Extent Of Divisions*, INSIDE U.S. TRADE (Oct. 14, 2014).

Date of entry

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

The Trans-Pacific Partnership (TPP) Parties are discussing whether and how to mitigate the consequences for access to medicines and other public interests expected to arise from the text. Options under consideration include mere transition periods, in which countries would apply the full set of rules after a period of years, yet to be specified.[4]

The above provision applies to a second option under discussion. This provision would distinguish between 'low income' and 'high income' countries as defined by the International Bank for Reconstruction and Development. Accordingly, countries with per capita gross national income (GNI) under $12,616[5] would not have to apply the full set of more stringent intellectual property (IP) rules related to patent term adjustments for regulatory delays, data exclusivity and patent linkage rules until they cross that income threshold. Annex A would be applicable to those countries. Within one year of a country having maintained such 'high income' status for two years consecutively, it would have to implement fully the TPP IP provisions. The per capita GNIs of Malaysia, Peru, Mexico, and Vietnam would place them below the high-income threshold and thus allow differential treatment.

[4] For detailed analysis, see Public Citizen's paper on Addendum II Transition Periods Proposal for Implementation of Onerous Trans-Pacific Partnership Intellectual Property Rules http://www.citizen.org/documents/tpp-transition-periods.pdf.

[5] Based on 2012 GNI figures, countries with a per capita GNI of $12,616 or more are classified as high income by the World Bank.

Both options under consideration deal with only a few of the rules that affect access to medicines. It is important to note that many other proposed rules in the IP chapter have consequences for access to medicines and other public interests. No differential treatment, transition period or other mitigating term is under discussion for these provisions.

Patent Term Adjustment

The Parties are debating whether to require patent term adjustments in the context of perceived drug regulatory authority delays. Patent term adjustments (typically called extensions) significantly delay market entry of generic medicines and restrict access to affordable medicines.

Article QQ.E.14

1. Each Party shall make best efforts to process patent applications and applications for marketing approval[218] 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 adjustment[219] 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.5.[220], each Party may provide for conditions and limitations in implementing the obligations of this paragraph.

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

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

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

The first paragraph of this text follows the wording of the November 2013 WikiLeaks text[6] and encourages countries to process patent applications and applications for marketing approval of pharmaceutical products in an efficient and timely manner.

The relevant provision in the November 2013 WikiLeaks text provided patent term adjustments not only for patents covering new pharmaceutical products, but also for patents that cover methods of making or using pharmaceutical products. The scope of this provision is now narrower regarding which pharmaceutical patents would be subject to a patent term adjustment. It does not apply to patents covering methods of making or using pharmaceutical products. This is an important development in the sense that it is more limited than the relevant provision in Korea-US Free Trade agreement.

The earlier version of the provision provided limitations on the period and applicability of patent term extensions. These limitations were similar to, though not entirely the same as, those found in the U.S. Patent Act, *i.e.*, a party may limit extensions to one per pharmaceutical product. The current version of the text does not prescribe limitations, but rather allows Parties to provide for conditions and limitations within their own legal system and practice.[7]

Landing zones related to patent term adjustments

Option 1 – Countries offer a patent term extension
Option 2 - No obligation for Parties to offer a patent term extension

[6] Article QQ.E.14 read:

> [US propose;110 AU/NZ/CL/PE/MY/SG/BN/VN/CA/MX oppose:
> (a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable or unnecessary delays.
> (b) Each Party, at the request of the patent owner, shall make available an adjustment of the patent term of a patent which covers a new pharmaceutical product111 or a patent that covers a method of making or unreasonable curtailment of the effective patent term as a result of the marketing approval process.
> (c) In implementing subparagraph 6(c), a Party may:
> (i) limit the applicability of subparagraph 6(c) to a single patent term adjustment for each new pharmaceutical product that is being reviewed for marketing approval;
> (ii) require the basis for the adjustment to be the first marketing approval granted to the pharmaceutical product in that Party; and
> (iii) limit the period of the adjustment to no more than 5 years."

[7] Article QQ.A.5 reads: "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."

Pharmaceutical 'Data Exclusivity' (Market exclusivity)

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

(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 similar[221]] 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].

FN221: 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.

The new version of this provision mirrors the language in the Australia-U.S. Free Trade Agreement (AUSFTA). The provision allows for "at least five years" of "data exclusivity" (technically this appears to be market exclusivity) for new pharmaceutical products, and "at least three years" of data exclusivity for previously approved pharmaceutical products containing a "new clinical information (other than information related to bioequivalency)" or "evidence of prior approval of the product in another territory" running from the date of marketing approval for that product in the Party's territory.

Distinct from the WikiLeaks text of November 2013,[8] the provision distinguishes between the information required and permitted. If a Party requires the submission of an undisclosed test or

[8] The previous text read:

[US propose; AU/PE/VN/NZ/CL/MY/SG/BN oppose:

other data prior to granting marketing approval, paragraph (a) applies. If a Party relies on the marketing approval conferred in a foreign country, paragraph (b) applies.[9]

(a) If a Party requires or permits, as a condition for granting marketing approval for a new pharmaceutical product, the submission of information concerning the safety or efficacy of the product, the origination of which involves a considerable effort, the Party shall not, without the consent of a person previously submitting such safety or efficacy information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on:
    (i) the safety or efficacy information previously submitted in support of the marketing approval; or
    (ii) evidence of the existence of the marketing approval, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

(b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person previously submitting the safety or efficacy information to obtain marketing approval in the other territory, authorize a third person to market a same or a similar product based on:
    (i) the safety or efficacy information submitted in support of a prior marketing approval in the other territory; or
    (ii) evidence of the existence of a 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.

[9] The previous text of paragraph (b) reads:

(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.]

The WikiLeaks text of November 2013 provided data exclusivity for any "information" submitted in support of marketing approval, even if it was disclosed and in the public domain. The scope of exclusivity is more limited now; data exclusivity is only provided for "undisclosed test or other data."

Products that are considered to be the same as or similar to their reference product cannot rely on the reference product's protected data. Footnote 221 clarifies that a pharmaceutical product can be a "similar" to a previously approved pharmaceutical product if the marketing approval of that similar pharmaceutical product is based upon the information concerning the safety or efficacy of the previously approved pharmaceutical product, or the prior approval of the reference product. Malaysia is the only country opposing the application of data exclusivity for similar products.

Footnote 222[10] allows Parties to retain their current system if they provide data exclusivity for previously approved pharmaceutical products containing "new clinical information (other than information related to bioequivalency)" or "evidence of prior approval of the product in another territory" on the date of entry into force of this Agreement. The footnote further clarifies that additional data exclusivity protection on the submission of new chemical information does not extend to biologics and/or pharmaceutical products that receive eight years of data exclusivity (as in the case of Japan).

Malaysia proposes[11] that data exclusivity periods begin at the first marketing approval of the product in any country. This reflects the May 10th Agreement principle that generics should be available in developing countries no later than in wealthy countries. After the first marketing approval, it usually takes between six to eight years (sometimes even longer) for

[10] Footnote 222 reads:

> 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 {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.]

[11] Malaysia's proposal reads: "[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.]"

pharmaceutical companies to apply for marketing approval in developing countries. There is no time limit on when applicants must submit their request for marketing approval; a pharmaceutical company can delay finalization of its application as long as it wants. The Malaysian proposal would shorten this waiting time in developing countries and provide a more balanced 'access window.' A pharmaceutical company seeking to receive exclusivity over undisclosed data would have to file its application for marketing approval as soon as possible in that country in order to get five years of exclusivity.

The provision also includes safeguards for Parties to take measures to protect public health in accordance with the TRIPS Agreement and Doha Declaration. These safeguards are new, and they are borrowed from the previous FTAs (Peru US FTA, Korea-US FTA).[12] Malaysia's proposal adds clarity and certainty to the public health safeguards mentioned above: it includes a flexible clause that would enable Parties to waive data exclusivity for the protection of public health, non-commercial public use, national emergency, or other urgent circumstances as determined by the party.[13]

Malaysia proposes the creation of a window within which a pharmaceutical company should file a marketing approval request after the data on the product is first registered. This so-called 'access window' is eighteen months for pharmaceutical products and twelve months for previously approved pharmaceutical products.[14]

[12] The text of the safeguard reads:

> 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.

[13] The text of this provision reads:

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

[14] The text of this provision reads: "[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.]"

Landing Zones to Data Exclusivity

There are six options for data exclusivity, all of which involve an obligation to provide some type of data exclusivity. But important questions regarding its breadth are before the Ministers for discussion. For example, whether data exclusivity will be extended to new uses of known products is an extremely important issue.

Option 1—A hybrid model based on the U.S. FTAs with Australia and Singapore, with modifications as discussed above.
Option 2—No data exclusivity for new clinical information.

Patent Linkage

Patent linkage is a regulatory mechanism that links medicine marketing approval to patent status. Under patent linkage, even spurious patents may function as barriers to generic medicine registration. Patent linkage can facilitate abuse, since the financial benefits to patent holders of deterring generic market entry may outweigh risks of penalties. The draft TPP provides countries with two options: the first is modelled on AUSFTA and the second is modelled on Chilean-U.S. FTA. The AUSFTA option is much more onerous and anti-competitive.

Article QQ.E.17 {TPP Patent Linkage}

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 owner[224] [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.

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

FN 224: Negotiator'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.

FN 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.]

The provision mirrors the language in the AUSFTA creating a patent linkage mechanism. A Party is required to include measures in its regulatory process to prevent the applicant from marketing a product, or a product for an approved use, that is claimed under a patent. This obligation extends to cover the entire term of the patent, unless the patent owner has consented to, or acquiesced in, the use of the information.

Footnote 223 clarifies that these measures may be implemented in conjunction with the Party's marketing approval process.

Article QQ.E.17 {TPP Patent Linkage}

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 patent FN226 [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 identity of any third party requesting marketing approval effective during the term of the patent.[229] [230]

FN226: For greater certainty, a Party may limit the obligation of paragraph 2 to the types of patents described in paragraphs 1(a)(i) and (ii).

FN227: [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).]

FN 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.]

FN229: {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.}

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

The provision provides another option to the Parties. If a Party chooses not to implement paragraph 1, a Party can provide a system where marketing approval is linked to "consent or acquiescence" of a patentee. This language mirrors the U.S.-Chile FTA. Under this system, a Party shall not grant marketing approval to any third Party prior to expiration of the patent term, unless by "consent and acquiescence" of the patent owner. The identity of the any third party requesting marketing approval will be available to the patent owner during the term of the patent.

Footnote 228 is a proposal by Chile, which allows Parties to use injunctions or other judicial proceedings within their infringement proceedings.

According to the footnote 229, in the absence of legal action by a right holder (the state of acquiescence), if a Party delays the issuance of marketing approval to a third party until the expiration of the patent term, the Party is not required to provide notification or make available information about third parties applying for marketing approval.

Footnote 230 clarifies that the patent linkage provision should not interpreted to mean that the marketing approval authority makes validity or infringement determinations.

Landing Zones to Patent Linkage

Option 1—A "hybrid" approach based on the U.S. free trade agreements with Australia, Singapore, and Chile, with "modifications as discussed," such as the footnote proposed by New Zealand.
Option 2—Limit coverage to product patents
Option 3—Peru-U.S. FTA model with optional linkage (but the provision still requires an administrative system in place).

Exclusivity on Biologics (Article QQ.E.20)

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]

FN 231: Negotiator'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.

FN 232: 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 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.

This new and dangerous provision provides exclusivity for biologics, including for many new cancer drugs. The provision makes direct reference to Article QQ.E.16 on data exclusivity. There are two issues where Parties have disagreements.

The period of protection

Zero years: No special and differential protection for biologics. It will be up to the countries to decide whether they provide protection for biologics under the definition of pharmaceutical products or not.

Five years: Under Article QQ.E.16, the Parties will provide five years of protection for pharmaceutical products. The term "pharmaceutical product" includes biologics. Thus, this language provides five years of exclusivity to biologics.

Eight years: If Parties agree on eight years of data protection, they need to provide special and differential treatment to biologics and set a special system for them. This is not ideal for countries which are not distinguishing between biologics and other chemical products. Japan is the only country providing eight years of exclusivity for pharmaceutical products (for chemical entities and biologics).

Twelve years: This is an US proposal. The current U.S. law provides for twelve years of exclusivity. Nevertheless, the White House has called for a roll back to seven years of exclusivity.

The Definition of 'Biologic'

The definition of "biologic" is yet another matter of controversy among Parties because it will determine which products may receive the special and longer exclusivity periods under discussion in this Article. According to Footnote 231, the delegations discussed two approaches and have different views and preferences regarding these two approaches. Approach 2 is the better approach: it allows for self-definition and provides flexibility to each country to implement the standards that work best for them. Biotechnology is a fast moving field; Parties would like to have flexibility to update their definitions in the future.

Approach 1 provides a definition for a biological product. If Approach 1 is selected, a narrower definition be better for access and future innovation. Approach 1 reads:

> {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]}

This language establishes an extremely broad definition of biologics, with the proposed language by the U.S. and Japan establishing the most expansive limits. Though the language proposed by the U.S. (the second sentence) may seem to provide parties flexibility to determine the definition established in the sentence preceding it, the potential limitations of scope suggested by the U.S. would likely not narrow the suggested range of products covered. In fact, the proposed language could be interpreted to reinforce the broad language established by the initial terms.

> **Language proposed by the U.S.**: 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 recombinant DNA technology.
>
> **Language opposed by the U.S.**: A Party may limit the scope of such pharmaceutical products to products that are produced by biotechnology [such as]/ [including]] recombinant DNA technology.

While the proposed U.S. language establishes an extremely broad definition of biologics potentially protected by data exclusivity, the language opposed by the U.S. still covers a wide range of potential biologics. Specifically, the inclusion of "produced by" in the opposed language could extend data exclusivity protection to products made via methods such as recombinant DNA technology, even if those products are synthetic versions of naturally-occurring substances, including substances naturally produced by the human body. This could extend data exclusivity protection to notable examples such as synthetic versions of insulin and human growth hormone.

Footnote 232 is a grandfathering clause. Countries in which biologics can already receive exclusivity under the general data or marketing exclusivity rules have a five-year transitional period before they must provide the TPP's special terms for biologics.

Landing Zones for exclusivity on biologics
Term of protection: 0 or 5 or 8 or 12 years
Definition: Define the scope or leave it to individual countries to define.

Data Exclusivity & Term of Patent

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 shallnot 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).

Some countries end the data exclusivity period when the patent term ends. In other words, data exclusivity should not outlast patent protection. USTR aims to defeat this practice with Article QQ.E.22. The Article provides that data exclusivity and patent terms are independent. In some cases, this may lead to longer monopoly protection for originator companies. Nevertheless, this Article will be subject to the WTO's TRIPS flexibilities (compulsory licenses). The best interpretation would hold that compulsory licenses may be used to introduce competition even when data exclusivity is in effect. However, this point is not as clear as it should be and is open to the different interpretations.