



1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

October 16, 2014

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

Highlights of Section E: Patents / Undisclosed Test or Other Data¹

Today, WikiLeaks released an updated complete draft Intellectual Property Chapter² of the proposed Trans-Pacific Partnership (TPP) free trade agreement (FTA). Prior leaks from 2010, 2011, 2012, and 2013 and analyses of many key issues are available at: www.citizen.org/tppa. The updated WikiLeaks text reveals new proposals and issues of interest. These include several helpful improvements, but also new dangers.

The 3(d) Provision

Patents / Patentable Subject Matter (Article QQ.E.1)

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

This provision first appeared in the prior version of the text obtained by WikiLeaks and released in November 2013. It is a US attack on Section 3(d) of the Indian Patent Act a famous rule which has helped protect access to affordable medicines worldwide, much to the chagrin of pharmaceutical industry and the U.S. Chamber of Commerce. It reflects the Office of the U.S. Trade Representative's (USTR) position that 3(d) is an impermissible "fourth criterion" for patentability. India is not among the countries negotiating the TPP. But the U.S. government has complained about India's patent rules and practices, and this TPP provision is a clear effort to curb India's influence and the spread of the rule.³

In the new text, the first part of the provision on new uses or methods of using a known product has been moved below as a separate section. In the prior version, this provision had

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://wikileaks.org/tpp-ip2>.

³ For more information, please see "What's new in the Wikileaks text November 2013" at: <http://www.citizen.org/documents/Whats%20New%20in%20the%20WikiLeaks%20TPP%20Text-11.pdf>.

been tied to language on new uses or methods of using known products. Two concepts have now been separated suggesting this very unpopular half may no longer be a priority for the U.S. and Japan, and that is likely to fail.

Patents on Plant and Plant-Related Inventions

Patents / Patentable Subject Matter (Article QQ.E.1.3)

3. [US/JP/SG proposes; AU/NZ/VN/BN/CL/PE/MY/ /CA/MX oppose: Consistent with paragraph 1, each Party shall make patents available for inventions for plants and animals.]

Alt.3: {Consistent with paragraph 1, each Party confirms that it makes available patents for plant-related inventions.⁵⁵}

FN55: For greater certainty, no Party shall be required to make patents available for plant varieties that are protectable in that Party under the International Convention for the protection of New Varieties of Plants [1991] (UPOV Convention).}

{Negotiator's note: AU would prefer this footnote to be in the main text.}

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

The text indicates that Parties will either have to make patents for plants available OR protect plant varieties under the 1991 UPOV and make patents available for plant-related inventions that are not protectable under the 1991 UPOV. The TPP language poses a threat to the livelihood of farmers and food security in developing countries.

Patents on New Uses and Methods of Using a Known Product

Patents / Patentable Subject Matter (Article QQ.E.1.4)

4. [US/AU/JP propose; CL/MY/PE/SG/VN/BN/NZ/CA/MX oppose : Consistent with paragraph 1, the Parties confirm that patents are available for⁵⁶:

(a) any new uses, or alternatively⁵⁷, new methods of using a known product.]

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

FN56: Negotiators' note: US/JP reconsidering the inclusion of subparagraph (b) (provision relating to diagnostic, therapeutic and surgical methods), subject to consensus on patent landing zone.

FN57: Negotiator's Note: AU is still considering inclusion of "alternatively".

The U.S., Australia, and Japan still seek patent protection for new uses or new methods of using a known product. Pharmaceutical companies commonly claim secondary patents on known products, which facilitates patent evergreening. These "evergreening" patents aim to effectively extend the life of existing patents through obtaining a new term of protection on minor changes in active pharmaceutical ingredients of existing products (polymorphs, salts, etc.), inert ingredients, formulations, dosages and combinations.

The language of this provision has been changed and arguably improved since last November. Negotiators changed the language from "patents shall be available," to "Parties confirm that patents are available." The Canadian proposal on "any new use . . . that is not otherwise excluded from patentability by the Party" is also new. This may provide some additional flexibility for countries seeking to maintain their existing rules and practices.

Patents on Diagnostic, Therapeutic, and Surgical Methods

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

4. [US/AU/JP propose; CL/MY/PE/SG/VN/BN/NZ/CA/MX oppose: Consistent with paragraph 1, the Parties confirm that patents are available for⁵⁶:

(a) any new uses, or alternatively⁵⁷, new methods of using a known product.]

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

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

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

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

One very significant development in the new text is the removal of the highly unpopular U.S. proposal on diagnostic, therapeutic, and surgical methods patents, also known as medical procedure patents. Every negotiating country aside from the U.S. opposed this proposal. Footnote 56 explains that the U.S. and Japan are "reconsidering the inclusion" of this proposal subject to consensus in the patent landing zone. This may refer to a deal between Parties on

patents for new uses/new methods of use in exchange for the revocation of proposals on medical procedures.

Grace Periods

Article QQ.E.2: {Grace Period}

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

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

and

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

A grace period is a period of time before the date of filing a patent application during which certain kinds of disclosures would not undermine the novelty of the invention. In other words, under a grace period system, an invention may still be considered new (and therefore patentable) even if it has been described publicly, before the patent application was filed.

New in this text, TPP countries have agreed on broad grace periods for any public disclosure that is authorized by or derived from the patent applicant. The duration of the TPP grace period is 12 months, which would double the grace periods in most TPP negotiating countries, prolong uncertainty, make it easier to get patents, and delay entry of inventions into the public domain.

The grace period system was originally designed as a special relief measure under the first-to-file system. The majority of patent systems do not provide general grace periods. At the international level, there is no harmonization of grace periods. However, grace period language is a standard provision of U.S. free trade agreements (FTAs) and one of the priorities of the U.S. in the Transatlantic Trade and Investment Partnership (TTIP) negotiations.

Patent Oppositions (ex-Article QQ.E.4)

The U.S. has withdrawn its highly controversial proposal to eliminate pre-grant opposition, a key mechanism used in TPP countries and many others to prevent patent abuse. A footnote referencing the proposal in last year's text has been removed. This too can be seen as a modest but important victory for health.

Exception/Regulatory Review Exceptions (Article QQ.E.13)

Article QQ.E.13^{62 63}: {Exceptions / Regulatory Review Exception}

[CL/MY oppose: Consistent with Article QQ.E.4 (Exceptions),] if a Party permits a third person to use the subject matter of a subsisting patent to [CL oppose: generate information necessary] to support an application for marketing approval of a pharmaceutical [CA/MY/BN: or other] product [PE: and an agricultural chemical product], that Party shall provide that any product produced under such authority shall not be made, used, sold in, [PE: offered for sale,] {or imported into,} the territory of that Party other than for purposes related to [CL oppose: generating information to meet] [CL: meeting] requirements for marketing approval {of that Party} for the product {, and each Party may also {also} permit {such} {a} product{s} to be exported outside its territory for purposes related [CL oppose: to generating information] to support an application for marketing approval in the [CL: exporting] Party or another country.}]⁶⁴

FN62: Negotiator's Note: CA/MX/AU is still considering the options in this provision.

FN63: [MX propose: For greater clarity, the duration of the regulatory review exception will be subject to each Party's national legislation.]

FN64: Negotiator's Note: 1. Parties focused discussion on Option 1, as a possible landing zone, rather than Option 2; 2. Consider moving Option 1 (Bolar for pharmaceuticals) to the Other Regulated Products provisions. For some countries, that might potentially remove the need to include reference to "other products" in the section.; 3. Would it be possible to remove "generating information necessary" if the reference to QQ.E.4 remained?; 4. Given length and complexity of paragraph, could we break this out into two subparagraphs?; 5. Comment that the drafting/structure of the provision makes it a limiting provision rather than a more affirmative approach.

Option 2:

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

FN65: Negotiator's Note: MX supports in principle, pending the discussion on QQ.E.13.

FN66: Negotiator's Note: Parties did not discuss Option 2 in detail as some Parties indicated that it was not a possible landing zone.

The regulatory review exception, widely known as the Bolar exception in the United States, helps accelerate the introduction of generic drugs to market. It is a safe harbor provision that permits the use of patented subject matter without risk of liability for infringement. In other words, companies can use a patented invention for regulatory review in preparation for marketing generic versions of the patented invention.

New this year, several negotiating countries have helpfully proposed expanding the scope of the Bolar provision, which would benefit competition.

There are two options included in the Article above, but option 1 is favored by the parties. The negotiating countries specifically address three main issues in this provision.

Scope of product coverage: The current provision only applies to pharmaceutical products. Canada, Malaysia and Brunei want to extend its scope to other regulated products (for example, medical devices), and Peru suggests including agricultural chemical products.

Acts covered by the exemption: It appears countries favor expanding the TPP Bolar exemption to encompass a wider range of acts. By way of reference, the U.S. Bolar exemption is said to include acts committed in determining how the patented invention works, determining the scope of the patented invention, determining the validity of the claims and attempts to improve the patented invention. It appears the TPP countries are moving in this direction.

Geographical scope: The broadening TPP provision would provide a regulatory review exception not only for products intended for domestic use, but also those destined for export. Broad regulatory exemptions that are not limited in scope most strongly support competition for generics, biosimilar, and medical device manufacturers. Canada and New Zealand's springboarding provisions, for instance, go above and beyond those of the U.S. in promoting competition for generics, biosimilar, and medical device manufacturers because they are not limited to testing conducted with the intent of seeking domestic regulatory review only. Springboarding provides exemption for foreign regulatory reviews.

Utility/ Usefulness (Article QQ.E.10)

Article QQ.E.10

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

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

In light of the *Eli Lilly v. Canada* North American Free Trade Agreement (NAFTA) arbitration case, this provision continues to be a source of considerable controversy. Canada's patent decisions are based on a requirement that patent applicants that claim a future usefulness must demonstrate or soundly predict that usefulness at the time of filing. The reasons for this rule include discouraging races to the patent office based on inadequate data. After all, patent filing and successful applications may cut off competing research efforts that might yield better results.

This TPP provision could undermine Canada's utility requirements. The U.S. has softened its proposal somewhat since the November 2013 text (though not in a way that helps Canada). The prior U.S. proposal would have replaced TPP countries' industrial applicability requirements with the weak U.S. utility standard. The current provision would require only countries (including Canada) that employ utility standards to be bound by the weak U.S. standard. Amazingly, Mexico would prefer not even to require 'credibility'.

For more information on utility standards, and the suggested improvement of adding a timing requirement, see Public Citizen's memo "Patents in the TPP: Proof of Utility at the Time of Filing" available at:

<http://www.citizen.org/documents/Memo%20on%20the%20timing%20of%20utility.pdf>

Patent term adjustments (For Patent Examination Period) (Article QQ.E.12)

Article QQ.E.12

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

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

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

FN78: Negotiator's Note: JP can support this Article if JP proposals are accepted.

FN79: [SG propose: Periods attributable to actions of the patent applicant shall include such periods of time taken to file prescribed documents relating to the examination as provided in the laws of the Party.]

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

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

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

This widely criticized U.S. and Singapore proposal would grant additional patent terms for pharmaceutical products that experienced delays in patent examination process. This provision would further postpone market entry of generic drugs, thereby restricting access to affordable medicines.

There are two options for countries included in the Article above:

- (1) **Option 1**- Adjustment of patent term
- (2) **Option 2**- Means to adjust the term

Option 2 provides more flexibility to countries. Even in the U.S., patent term adjustment time is calculated using a complex set of rules that, in general, involves adding up the days of delay attributable to the patent office and then subtracting the days of delays that the patent applicant himself caused.

Another conflicting issue is how to define unreasonable delays. The initial U.S. proposal defined an unreasonable delay as the later of four years from the date of filing or two years after an examination request. In alignment with their prior FTA commitments, Chile and Peru proposed the later of five years from the date of filing and three years after the examination request. Japan supports the three years proposal.

Subtraction of delays attributable to actions of the patent applicant is another area where Parties have two options from which to choose.

Option 1: Periods attributable to actions of the patent applicant

Japan proposes to include “judicial or quasi-judicial actions on the patent application” in the calculation of time to be subtracted when determining a patent term extension period. Parties disagree over the meaning of “quasi-judicial,” which is intended to cover primarily processes by patent appeal boards. Some Parties want to include administrative proceedings in the definition of “quasi-judicial.” However, according to the footnote “at least one Party” is concerned whether this provision goes beyond existing FTAs.

Option 2: Periods attributable to actions of the patent applicant or any opposing third party

The U.S. has withdrawn its highly controversial proposal to eliminate pre-grant opposition, a key mechanism used in TPP countries and many others to prevent patent abuse. The TPP is no longer prescriptive on this: it is up to Parties to decide what is best for their interests. Option 2 would allow authorities to subtract from the calculation of a patent term extension the time taken to consider a third party’s pre-grant patent opposition. For countries offering a pre-grant opposition system, Option 2 seems to be more beneficial, as time taken to consider the opposition would not extend the monopoly period in the event that such an opposition was unsuccessful. An absence of this flexibility might have implications for effective operation of pre-grant opposition systems in countries that allow them.

According to footnote 80, the U.S. & Japan will work on an appropriate transition period for Parties who don’t currently provide such a system for patent term extensions, namely Japan, Australia, New Zealand, Malaysia, Vietnam, Canada, and Mexico.