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NOVEMBER 13, 2013

What's New in the WikiLeaks TPP Text?¹

Today, WikiLeaks published the complete draft Intellectual Property Chapter² of the proposed Trans-Pacific Partnership (TPP) free trade agreement (FTA). Prior leaks from 2010, 2011 and 2012³ had provided insights into the proposals of several countries, especially the United States. The WikiLeaks text reveals new issues of interest and changes in the state of play. These include a few, but not many, helpful changes to the U.S. position. More importantly, the Wikileaks publication reveals unanimous or nearly unanimous opposition to many harmful U.S. proposals, and indeed heroic efforts by some countries to advance the public interest and public domain.

This is a sampling of what is new and other highlights in the WikiLeaks publication, since the prior leaks. Public Citizen will add to this sampling in the coming days and weeks. Detailed analyses of the longstanding problems in the U.S. proposal can be found at www.citizen.org/tppa.

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

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

US/AU propose – (Japan is considering this provision)
CL/MX/PE/SG/VN/BN/NZ/CA/MX oppose

(a) Patents shall be available for any new uses or methods of using a known product

¹ Public Citizen's Global Access to Medicines Program, for more information please contact pmaybarduk@citizen.org or bkilic@citizen.org.

² Available at: <http://wikileaks.org/tpp>. Further analysis available at: <http://citizen.org/access>.

³ Available at <http://www.citizen.org/leaked-trade-negotiation-documents-and-analysis>.

The U.S. has dropped patents for “new forms” of known substances from its original proposal⁴. This is a positive change.

The U.S. still aims to impose patents for new uses or methods of using old medicines. These can facilitate patent ‘evergreening,’ a form of abuse leading to long drug monopolies. Nine countries oppose this proposal.

The new provision mirrors AUSFTA (The Australia-U.S. Free Trade Agreement), which may suggest an explanation for the change.

US & Japan propose
CL/MX/PE/SG/VN/BN/AU/NZ/CA/MX oppose

(b) 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 attacks Section 3(d) of Indian Patent Act⁵, a famous rule which has helped protect access to affordable medicines worldwide, much to the chagrin of Big Pharma and the U.S. Chamber of Commerce.⁶ While the U.S. proposal against a limited efficacy requirement was included in earlier versions of the TPP text⁷, it has been revised here to reflect USTR’s 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.

According to Section 3(d), a new form of a known chemical substance is not considered an invention if it “does not result in the enhancement of the known efficacy of that [known] substance.”

⁴ Article 8.1 of the leaked U.S. TPP Proposal (February 2011): The Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product

⁵ The Section (d) of Indian Patent Act “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant”.

⁶ For information on U.S. Chamber interference in public interest regulation, see Public Citizen’s Chamber Watch: <http://www.fixthechamber.org/>.

⁷ Article 8.1. and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.

However, a derivative of a known substance can overcome this presumption against subject matter eligibility if it demonstrates a significant difference in its properties with regard to efficacy⁸.

According to USTR, India's law creates a special, additional patentability criterion for select technologies like pharmaceuticals⁹, which might be prohibited by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO's TRIPS).

Yet Section 3(d) is structured as a subject matter eligibility threshold, not as a patentability test.¹⁰ Under WTO rules, countries are free to define what qualifies as an invention (patent eligible subject matter). Like the U.S. – see the recent *Myriad* U.S. Supreme Court case limiting gene patents -- India excludes certain categories from patent eligible subject matter.

For example, In India, combinations and derivatives of known substances are “considered to be the same substance,” and therefore do not qualify as inventions, “unless they differ significantly in properties with regard to efficacy.” While this standard is most relevant to chemical and pharmaceutical inventions--and, as the Indian Supreme Court noted, may indeed have been inspired by a concern for “evergreening” of chemical and pharmaceutical compounds--it applies uniformly to all known substances. This is in full compliance with WTO rules.

- **Patentable Subject Matter (Article QQ.E.2)**

[US: Consistent with paragraph 1] each Party [US proposes; AU/NZ/VN/BN/CL/PE/MY/SG/CA/MX oppose: shall make patents available for inventions for the following]

[NZ/CL/PE/MY/AU/VN/BN/SG/CA/MX propose: may also exclude from patentability]:

- (a) plants and animals, [NZ/CL/PE/MY/AU/VN/BN/SG/CA/MX propose: other than microorganisms];
- (b) [JP opposes: (b)diagnostic, therapeutic, and surgical methods for the treatment of humans or animals [US proposes; AU/SG/MY/NZ/CL/PE/VN/BN/CA/MX oppose: if they cover a method of using a machine, manufacture, or composition of matter]; [NZ/CL/PE/MY/AU/VN/BN/SG/CA/MX propose:] and

The U.S. still insists countries should make patents available for:

- Plants and animals – reversing the TRIPS presumption against such a requirement; and
- Diagnostic, therapeutic and surgical methods, also known as medical procedure patents.

⁸ See Burcu Kilic & Luigi Palombi, “The Question of Patent Eligible Subject Matter and Evergreening Practices”, July 2013, <http://infojustice.org/archives/30314#more-30314>

⁹ See USTR's 2013 Special 301 Report.

¹⁰ See Public Citizen, “India's Patent System Plays by WTO Rules and Supports Global Health,” June 27, 2013, available at: <http://www.citizen.org/documents/India%20and%20patents%20by%20Public%20Citizen%20final.pdf>.

The U.S. has added the proviso that medical procedure patents should be available “if they cover a method of using a machine, manufacture or composition matter.”

In one sense, this is progress, a modest limitation on a bad rule. However the proposed rule still:

- Fails to include safeguards in U.S. law which immunize medical practitioners from suit, particularly when the machine, manufacture or composition of matter itself is not patented;
- Flouts international norms – eighty countries have excluded such methods from patent eligible subject matter, only one other country permits them (Australia, which nevertheless opposes the U.S. proposal), and medical societies worldwide are outraged by the idea.

For detailed analysis, see Public Citizen’s memo, “Medical Procedure Patents in the TPP: A Comparative Perspective on the Highly Unpopular U.S. Proposal,” available at www.citizen.org/access.

NZ/CA/SG/CL/MY propose: ALT 3. Each Party may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non- biological and microbiological processes.
However, Parties shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.]

A new competing five-country proposal (NZ/CA/SG/CL/MY) offers language similar to the TRIPS Agreement; presuming members may exclude such objectionable subject matter from patents.

- **Patent Oppositions (Pre- and Post-Grant; Article QQ.E.4)**

Footnote 94: US withdraws
Article QQ E.4 ad referendum pending confirmation from capital
NZ/CA/SG/CL/MY propose: Each Party shall provide a procedure for third persons to oppose the grant of a patent, either before or after the grant of a patent, or both.

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 paper on this U.S.

proposal was leaked in 2011,¹¹ to significant international criticism.¹² This too can be seen as a modest but important victory for health.

The new five-country proposal would require countries to provide a procedure for third persons to formally oppose the grant of a patent, but leaves it to their discretion whether it should be before or after a decision on the application or available at any time. This is a superior, pro-health alternative to the original U.S. proposal.

- **Utility (Article QQ.E.10)**

US/AU/MX propose SG/CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.]
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Eli Lilly recently sued Canada for \$500 million under investor-state dispute mechanisms, due to appropriate Canadian decisions invalidating a Lilly patent. Canada’s decisions are based in its “promise doctrine,” a patent rule which requires patents claiming a future usefulness to demonstrate or soundly predict that usefulness at the time of filing.

The United States has proposed a rule for the Trans-Pacific Partnership (TPP) negotiations that could undermine Canada’s promise doctrine. Whether purposeful or not, this would support Big Pharma’s plans to transform Canadian practice and even, seemingly, some of the goals of Lilly’s outrageous suit.

The U.S has seemingly actually softened its proposal somewhat (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 standard¹³. Now it appears only countries (including Canada) that employ utility standards would necessarily be bound by the weak U.S. version. Amazingly, Mexico would prefer to require not even 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: www.citizen.org/access.

¹¹ Available at: <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

¹² E.g., <http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf>.

¹³ Article 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.

- **Patent Term Adjustments (for patent prosecution periods) (Article QQ.E.XX)**

[US proposes; CA/NZ/JP oppose: 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. For purposes of this subparagraph, an unreasonable delay at least shall include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application has been made, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays. 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.]

This widely criticized U.S. proposal would delay market entry of generic drugs, thereby restricting access to affordable medicines.

Now Canada, New Zealand and Japan are taking the lead in opposition.

- **Patent Term Adjustments (for regulatory approval periods) (Article QQ.E.14)**

[US proposes (Japan is considering);
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.
- (c) 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 product or a patent that covers a method of making or using a pharmaceutical product, to compensate the patent owner of unreasonable curtailment of the effective patent term as a result of the marketing approval process.
- (d) 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.

This, too, would delay generic market entry. Patent extensions also constrain incremental innovation by keeping inventions out of the public domain. Ten countries have announced their opposition.

The U.S. proposal would require countries to make patent term extensions available when regulatory review exceeds a certain period of time. The measure would introduce patent extensions not only for new pharmaceutical products but also for methods of making or using pharmaceutical products.

- **Data Exclusivity** (Article QQ.E.16 - *Submission of Information or Evidence Concerning the Safety or Efficacy of a New Pharmaceutical Product*)

[US proposes;

AU/PE/VN/NZ/CL/MY/SG/BN oppose:

1. (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.

Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic market entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.

The U.S. is still insisting on its proposal, even though eight other negotiating parties oppose it. In a footnote, Canada “reserves its position” and Japan states that it is still considering its position.

The U.S. proposal is more aggressive than data exclusivity provisions in prior FTAs. The provision provides at least five years of data exclusivity for safety and efficacy information submitted in support of marketing approval and at least three years additional data exclusivity for submission of new clinical information on new uses or indications for existing pharmaceutical products, even if it is disclosed and in the public domain. Products that are considered the same as or similar to the reference product are also prevented from relying on its protected data.

- **Patent Linkage (Article QQ.E.17)**

Where a Party requires or permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence concerning safety or efficacy information for a product that was previously approved, such as evidence of prior marketing approval in another territory, each Party shall:

- (a) provide a transparent and effective system to:
 - (i) identify a patent or patents covering an approved pharmaceutical product or its approved method of use; and
 - (ii) provide notice to a patent holder of the identity of another person who intends to market, during the term of the identified patent or patents, a product that is the same as, or similar to, the approved pharmaceutical product referenced in subparagraph 5(a)(i).
- (b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by providing:
 - (i) an automatic delay of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate¹¹⁵ disputes concerning the validity or infringement of allegedly infringed patents; and
 - (ii) judicial or administrative procedures, including effective provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent.
- (c) If such other person's product has been found to infringe a valid patent identified pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent.
- (d) when a Party delays the grant of marketing approval consistent with subparagraph 5(b)(i), provide an effective reward, consistent with the provisions of this Agreement, for the successful challenge of the validity or applicability of the patent.

The US proposal links drug marketing approval to patent status and shifts the burden of early patent enforcement to drug regulatory authorities. This “linkage” provision is more aggressive than comparable measures in past FTAs, and it has not changed. The provision would require countries to provide a mechanism to identify patents covering an approved pharmaceutical product or its approved method of use. The US draft introduces a notification system for patent holders, an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of the patent.

Interestingly, no comments seem to have been recorded related to this measure. Patent linkage may be the most unpopular proposal in the text.

It is not clear from the wording of the provision under what conditions a product would be considered 'similar' to an pharmaceutical product and trigger an obligation to notify a patent holder. However, this provision could facilitate patent holder harassment of potential competitors. Under patent linkage, even spurious patents may function as barriers to generic drug registration.

Biologics (Article QQ. E.20)

Placeholder for specific provision applying to biologics

Biologics, including many new cancer drugs, are exceptionally expensive and constitute one of the main drivers of rising healthcare costs. The U.S. has included a placeholder for automatic monopolies on such biotech medicines in its TPP proposal for two years now.

Imposing biologics exclusivity would constitute a major change to countries' laws with potentially dramatic financial consequences for patients, medical providers, and governments.

Since the Affordable Care Act, U.S. law has required 12 years of biologics exclusivity (4 years data and 8 years market). But the White House aims to reduce this period to seven years, and has pledged to consumers and federal programs the resultant savings in its recent annual budgets¹⁴. Any TPP provision on biologics exclusivity would lock Americans into the TPP rule, potentially costing billions of dollars.

Protection of Undisclosed Data (Article QQ.E.XX.4)

¹⁴ Office of Management and Budget, "Fiscal Year 2014 Budget of the U.S. Government," Executive Office of the President of the United States. Available at: <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf>.

[NZ/CA/SG/CL/MY/VN propose: 1. Where a Party requires, as a condition of marketing, regulatory or sanitary approval for pharmaceutical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, that Party shall protect such data against unfair commercial use. In addition, each Party shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

2. Each Party may provide that the protection of data under paragraph 1, inter alia:
 - (a) is limited to undisclosed test or other data, the origination of which involves a considerable effort;
 - (b) is limited to pharmaceutical products that do not contain a new chemical entity that has been previously approved for marketing in the Party;
 - (c) is limited to pharmaceutical products which utilize a new chemical entity;
 - (d) is available only once per pharmaceutical product;
 - (e) is not available for new uses or indications, new dosage forms or methods of making a pharmaceutical product;
 - (f) is limited to a period of time as determined by the Party; or
 - (g) may be waived to facilitate the marketing, regulatory or sanitary approval of a pharmaceutical product that is the subject of a voluntary or compulsory license, or a licence otherwise issued pursuant to the TRIPS Agreement.
3. Each 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");

Half the TPP countries have advanced an alternative, superior vision to the U.S. data exclusivity proposal. This provision mirrors the language of TRIPS Article 39.3 on the protection of undisclosed information, and comes without imposing the burden of pharmaceutical monopolies.

