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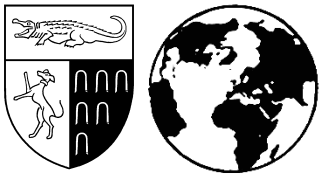

WHAT IS PATENTABLE UNDER THE TRANS-PACIFIC PARTNERSHIP?

AN ANALYSIS OF THE FREE TRADE AGREEMENT'S PATENTABILITY PROVISIONS FROM A PUBLIC HEALTH PERSPECTIVE

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On October 16, 2014,[1] WikiLeaks released a complete draft of the Intellectual Property Chapter of the proposed Trans-Pacific Partnership Agreement (TPP).[2] The TPP is a controversial[3] free trade agreement being negotiated behind closed doors[4] by officials from Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam. The commonly understood objective of the agreement, under negotiation since 2006,[5] is to lift trade tariffs and quotas between the negotiating

1. Previous versions of this chapter were leaked in 2010, 2011, 2012, and 2013. For a comprehensive collection of TPP documents and leaks, see *Trans Pacific Partnership Document Library*, INFOJUSTICE, http://infojustice.org/resource-library/tpp (last updated Sept. 9, 2012); and *Trans-Pacific Partnership*, INFOJUSTICE, http://infojustice.org/tpp (last visited Mar. 16, 2015).
2. *Secret TPP Treaty: Intellectual Property Chapter Working Document for all 12 Nations with Negotiating Positions*, WIKILEAKS (Oct. 16, 2014) [hereinafter *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*], http://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf.
3. *See, e.g.*, Paul Krugman, *TPP at the NABE*, N.Y. TIMES (Mar. 11, 2015, 8:43AM), http://krugman.blogs.nytimes.com/2015/03/11/tpp-at-the-nabe; Lawrence Summers, *A Trade Deal Must Work for America's Middle Class*, FIN. TIMES (Mar. 8, 2015, 3:49PM), http://www.ft.com/intl/cms/s/2/43920bae-c3f3-11e4-9019-00144feab7de.html; Letter from Elizabeth Warren, U.S. Senator, to Michael Froman, Assistant to the President (June 13, 2013), http://big.assets.huffingtonpost.com/EWFromanLetter.pdf.
4. Because this agreement is being negotiated in secret, the only way the public can gain access to the text is through leaks via sources such as WikiLeaks. *See generally*, Letter from Elizabeth Warren, *supra* note 3.
5. The TPP originates from a 2006 agreement between New Zealand, Singapore, Brunei, and Chile—a trade bloc known as the Pacific Four (P4)—aimed at eliminating tariffs. *Trans-Pacific Strategic Economic Partnership Agreement: Understanding the P4—The Original P4 Agreement*, N.Z. MINISTRY OF FOREIGN AFFS. AND TRADE, http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/0-history.php (last visited Mar. 8, 2015). In 2008, the United States, Australia, Peru, and Vietnam decided to join negotiations for an expanded Trans-Pacific Partnership. IAN F. FERGUSSON, MARK A.

parties. In reality, this agreement would set new rules for many non-trade issues, ranging from food safety to internet freedom, and rewrite important non-trade policy for all counties involved. In fact, only five of the TPP's twenty-nine chapters cover traditional trade matters, such as tariffs or quotas.[6]

One such non-trade chapter is the agreement's text on intellectual property (IP) protection—a section that actually restricts rather than frees competition. The United States' most recent proposals for the TPP's intellectual property chapter would require the majority of the negotiating parties to significantly alter the scope of their intellectual property laws[7]—changes that would raise drug and crop costs, therein restricting access to affordable medicines and foodstuffs.[8] For those nations that have already aligned their domestic laws with the TPP's intellectual property provisions, this agreement would further ossify detrimental standards. This feature examines only one small—but important—piece of the TPP's intellectual property chapter[9]: the text's provisions on patentability requirements. We argue that the patentability requirements set forth in the TPP could seriously harm public health and local farming practices in the negotiating countries.

Patentability requirements are the conditions that an invention must meet to qualify for patent protection. These requirements can be separated into two different categories: subject matter requirements and substantive patentability requirements. In a given country, certain types of inventions cannot be protected by patent *a priori* because they relate to a subject matter that the country has excluded from patentability. For example, in some countries, plants are *per se* excluded from patentability. Accordingly, a patent application on a breed of cactus would be rejected because such an invention (a plant) is excluded from patentability. If a patent applicant succeeds in showing that her invention meets the threshold subject matter eligibility requirements, she must then show that her application also satisfies certain substantive patentability requirements. For example, under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an invention must meet

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MCMINIMY & BROCK R. WILLIAMS, CONG. RESEARCH SERV., R42694, THE TRANS-PACIFIC PARTNERSHIP (TPP) NEGOTIATIONS AND ISSUES FOR CONGRESS 1 (2014). Malaysia joined these negotiations in 2010. WILLIAM KRIST, NEGOTIATIONS FOR TRANSPACIFIC PARTNERSHIP AGREEMENT 5 (2012).

6. Lori Wallach & Ben Beachy, *Obama's Covert Trade Deal*, N.Y. TIMES (June 2, 2013), http://www.nytimes.com/2013/06/03/opinion/obamas-covert-trade-deal.html.
7. *See, e.g.*, *TPP Country Resource Page*, PUB. CITIZEN, http://www.citizen.org/TPP-country-resource-page (last visited Mar. 16, 2015) (providing resources that explain how the TPP would affect the domestic laws of individual TPP negotiating parties); *Transpacific Trade Partnership*, ELECTRONIC FRONTIER FOUND., https://www.eff.org/issues/tpp (last visited Mar. 16, 2015) (same).
8. *See, e.g.*, *Trans-Pacific Partnership Agreement*, MEDICINS SANS FRONTIERES ACCESS CAMPAIGN, http://www.msfaccess.org/spotlight-on/trans-pacific-partnership-agreement (last visited Mar. 16, 2015); PUBLIC CITIZEN'S GLOBAL ACCESS TO MEDICINES PROGRAM, HOW THE TPP ENDANGERS ACCESS TO AFFORDABLE MEDICINE (Nov. 2013), http://www.citizen.org/documents/TPPonepagerfinalnovember2013.pdf; Special Rapporteur on the Right to Food, *Report on Seed Policies and the Right to Food*, ¶ 24, U.N. Doc. A/64/170 (July 23, 2009) [hereinafter *Report on Seed Policies*].
9. All the of the IP chapter's provisions will significantly impact public interests such as access to affordable medications, access to improved crops, and internet freedom and privacy.

the substantive requirements of newness, inventive step, and industrial application.[10]

The negotiating parties to the TPP have vigorously debated the scope of patentability requirements.[11] The most recent draft indicates that the United States has retreated from its position that patents should be available for medical procedures,[12] but might succeed in obtaining patent protection for plant-related inventions. The proposal to provide flexibility to exclude medical procedures from patentability will help ensure that the populations of the negotiating parties have access to all useful diagnostic, therapeutic, and surgical methods.[13] However, if implemented, the new plant patent provisions could seriously disrupt traditional farming practices in the Pacific Rim and threaten food security in poorer farming communities.[14] The text also shows that the parties are still debating how they should define utility—a substantive requirement that all inventions must be useful.[15] Furthermore, a provision relating to the practice of drug-evergreening (when drug manufacturers obtain a second term of patent protection on a new form, use, or method of using a known substance) still remains in the agreement.[16] Accordingly, despite some improvements, we contend that the text of the TPP's intellectual property chapter remains a bad bargain for participating countries from a public health perspective. As government officials indicate that the agreement is nearing completion,[17] careful consideration of the TPP's patentability provisions becomes imperative.

I. TRIPS

The TRIPS Agreement sets forth the minimum standards for intellectual property protection among WTO members. Because every negotiating party to the TPP is a member of the WTO, the patent provisions of the TRIPS Agreement can be considered a floor. Any provisions that require more stringent patent protection than those set forth in the TRIPS Agreement are known as TRIPS-plus (TRIPS+) measures.

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10. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter Agreement on Trade-Related Aspects of Intellectual Property Rights], http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
11. *See, e.g.*, William New, *Leaked Documents Show Tough Road to Completion of TPP*, INTELL. PROP. WATCH (Dec. 10, 2013), http://www.ip-watch.org/2013/12/10/new-leaked-documents-show-tough-road-to-completion-of-tpp; William New, *USTR: IPRs Among "Most Challenging" Issues as TPP Talks Accelerate*, INTELL. PROP. WATCH (Mar. 14, 2013), http://www.ip-watch.org/2013/03/14/ustr-iprs-among-most-challenging-issues-as-tpp-talks-accelerate.
12. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.4 (there is no longer a stand-alone provision making patents on medical procedures available).
13. *See infra* Section II.D.
14. *See infra* Section II.C.
15. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.10.
16. *Id.* art. QQ.E.1.4.
17. Shawn Donnan, *US Trade Chief Says Pacific Deal is Close*, FIN. TIMES (Jan. 27, 2015), http://www.ft.com/intl/cms/s/0/780076d2-a62f-11e4-abe9-00144feab7de.html.

At a minimum, the TRIPS Agreement requires WTO members to make patents available "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[18] A footnote to this provision clarifies that "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively."[19] The requirements that any invention be "new," "involve an inventive step," and be "capable of industrial application" are substantive eligibility requirements. After describing the substantive requirements, the TRIPS Agreement carves out certain categories of inventions from patentability:

> 2. Members 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 the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.[20]

Any requirement that nations offer patents on plants, animals, or diagnostic, therapeutic, and surgical methods for the treatment of humans or animals therefore constitutes a TRIPS+ measure.

II. THE TPP

A. *Patent Evergreening: Patents on New Uses or Methods of Using a Known Substance*

The TPP requires negotiating parties to make patents available for a greater range of inventions than the TRIPS agreement through a number of different sections. First, the TPP contains provisions that limit the ability of governments to curb the practice of patent evergreening.[21] As previously described, patent evergreening occurs when a company or individual obtains successive patents on a product or process to extend its term of exclusive control.[22] Patent evergreening is controversial from a public health perspective because it enables

18. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 10, art. 27.
19. *Id*. art. 27 n.5.
20. *Id*. art. 27.
21. *See Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.1.2 & 1.4(a).
22. *See* Burcu Kilic & Luigi Palombi, *The Question of Patent Eligible Subject Matter and Evergreening Practices*, INFOJUSTICE (July 27, 2013), http://infojustice.org/archives/30314.

pharmaceutical companies to delay generic competition and maintain monopolistic prices.

A number of different countries have enacted laws aimed at curbing the practice of patent evergreening.[23] Section 3(d) of India's Patent Act[24] is a well-known example of such a law. Under Section 3(d), "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" is not patentable.[25] Although this standard applies uniformly to all known substances, it is most relevant to chemical and pharmaceutical inventions. In practice, Section 3(d) prevents pharmaceutical companies from obtaining an additional term of protection on known drugs simply because the company can describe a new use, property, or non-therapeutically important form of the drug.[26]

Unsurprisingly, the pharmaceutical industry[27] and governments that protect their interests, such as the United States,[28] have opposed these anti-evergreening standards. In response, the United States has begun inserting clauses into its free trade agreements that prevent trading partners from enacting laws that would prevent patent-evergreening.[29] The TPP represents one such example: the United States has repeatedly attempted to add two clauses that would prevent negotiating

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23. Argentina and the Philippines have provisions echoing India's Section 3(d) in their patent laws. Brazil, China, Indonesia, Malaysia, and Thailand are contemplating amending their patent laws with flexible provisions to include enhanced efficacy requirements that make it harder for pharmaceutical company to engage in patent evergreening. *See* Lisa Kilday, *Global IP Reaction to India's Rejection of the Novartis Drug Patent*, IP WATCHDOG (May 28, 2013), http://www.ipwatchdog.com/2013/05/28/global-ip-reaction-to-indias-rejection-of-the-novartis-drug-patent; *see also* CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES 79 (2009); Laurence R. Helfer, Karen J. Alter & M. Florencia Guerzovich, *Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community*, 103 AM. J. INT'L L. 1, 30 (2009).
24. The Patent Amendment Act, No. 15 of 2005, § 3, INDIA CODE (2005).
25. *Id.*
26. Bhaven N. Sampat & Tahir Amin, *How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?*, http://www.columbia.edu/~bns3/trips_april.pdf.
27. *See* Patralekha Chatterjee, *Novartis Loses Patent Bid: Lessons From India's 3(d) Experience*, INTELL. PROP. WATCH (Jan. 4, 2013), http://www.ip-watch.org/2013/04/01/novartis-loses-patent-bid-lessons-from-indias-3d-experience.
28. *See* OFFICE OF THE U.S. TRADE REPRESENTATIVE, SPECIAL 301 REPORT 2014, at 37, 39-41 (Apr. 2014), https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.
29. Both the Australia-U.S. and the Korea-U.S. free trade agreements require the parties to offer patents on new uses or methods of using a known product. U.S.-Korea Free Trade Agreement, Intellectual Property Chapter, art. 18.8.1 (2012), https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf; U.S.-Australia Free Trade Agreement, Intellectual Property Chapter, art. 17.9.1 (2005), https://ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file469_5141.pdf; *see also* Kilday, *supra* note 23.

parties from implementing patentability criteria that help curb the practice of patent-evergreening.[30]

First, the United States, Australia, and Japan seek patent protection for new uses or new methods of using a known product.[31] Pharmaceutical companies usually seek patent protection on both a particular drug's active ingredient as well as its use—i.e., what conditions or patient populations the medication can be used to treat. In countries that permit patents on new uses or methods of using known substances, a pharmaceutical company can obtain a second patent on a drug if the company can show, for example, that the drug can be used to treat a different class of patients than the group claimed in the original patent or that the drug can be administered through a new method.[32] If enacted, the TPP's provision on new uses would impede the ability of the negotiating parties to prevent the practice of patent evergreening based on new uses.

Despite the problematic nature of this new use provision, its language has been slightly softened since the TPP draft leaked in November 2013. Negotiators have changed the language "patents shall be available"[33] to "[p]arties confirm that patents are available."[34] This change may provide the negotiating parties with greater leeway to address the issue of patents on new uses in patent examination guidelines.

Second, the United States and Japan have proposed language that would preclude parties from denying a new patent on a known substance "solely on the basis that the product did not result in an enhanced efficacy of the known product."[35] If implemented, pharmaceutical companies may attempt to rely on such a provision to obtain new patents on small tweaks to previously patented drugs even when the changes to these drugs have not enhanced the efficacy of the medications. Thus, this provision would again hinder the ability of the TPP parties to curb patent evergreening.

Nevertheless, there may be reason to be less concerned about this enhanced efficacy provision. The previously leaked version of the TPP's intellectual property chapter (the November 2013 version) linked the text's "enhanced

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30. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2.
31. *Id.* art. QQ.E.1.4 ("4. [United States / Australia / Japan propose; Chile / Malaysia / Peru / Singapore / Vietnam / Brunei / New Zealand / Canada / Mexico oppose: Consistent with paragraph 1, the Parties confirm that patents are available for: (a) any new uses, or alternatively, 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.]") (footnotes omitted).
32. New therapeutic applications of known substances may still fall within a category of inventions excluded from patentability.
33. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, art. QQ.E.1.1(a), WIKILEAKS (Nov. 13, 2013) [hereinafter *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter* (November 13, 2013)], http://wikileaks.org/tpp/static/pdf/Wikileaks-secret-TPP-treaty-IP-chapter.pdf.
34. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.1.4.
35. *Id.* art. QQ.E.1.2 ("For greater certainty, a Party may not deny a patent solely on the basis that the product did not result in an enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.").

efficacy" clause to the chapter's requirement that "patents shall be available for any new uses or methods of using a known product."[36] The most recent TPP text decouples these provisions: the TPP's "enhanced efficacy" provision no longer follows the requirement that patents be made available for "any new uses, or alternatively, new methods of using a known product."[37] The separation of the two provisions suggests the "enhanced efficacy" clause may no longer be a priority for the United States and Japan and may be removed from the text entirely.

B. *Utility*

The practice of patent evergreening can also be prevented through the utility standards a country sets. As previously discussed, utility (usefulness) is a substantive requirement that all inventions must meet to qualify for protection.[38] The TPP's current language would preclude signatories from enacting or maintaining strict utility requirements, allowing inventors to more easily obtain patents on products or processes. Article 1.1 of the TPP's intellectual property chapter requires each negotiating party to make patents available for "any invention, whether a product or process . . . provided that . . . [it] is capable of industrial application."[39] A footnote in the text, after the phrase "industrial application," clarifies that this term is "synonymous with the term[] . . . 'useful.'"[40] Although this language is uncontroversial, a later article defining the word "useful" is.[41] According to the leaked text, the majority of the negotiating parties oppose the addition of language whereby any invention that has a specific, substantial, and credible utility could qualify as useful and, therein, become eligible for patent protection.

This proposed definition of utility could have significant consequences for access to affordable medicines and one prominent investor-state dispute illustrates why. Currently, the pharmaceutical company Eli Lilly & Company is suing the government of Canada for $500 million in front of a North American Free Trade Agreement (NAFTA) arbitration tribunal.[42] In this lawsuit, Eli Lilly challenges

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36. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter* (Nov. 13, 2013), *supra* note 33, art. QQ.E.1.1(a).
37. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.1.1 & 1.4(a). In the new text, the language on new uses or methods of using a known product has been moved below as a separate section.
38. *See supra* note 15 and accompanying text.
39. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.1.1.
40. *Id.* art. QQ.E.1.1 n.54.
41. *Id.* art. QQ.E.10 ("[United States/Australia/Mexico/Singapore propose; Chile/Malaysia /Vietnam/Peru/Brunei Darussalam/New Zealand/Canada oppose: Each Party shall provide that a Claimed invention is [United States/Australia/Singapore propose: useful] [Mexico propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility."]; *id.* at n.71 ("Negotiator's Note: JP is considering this provision.").
42. *See* Jeff Gray, *Eli Lilly NAFTA Challenge 'Without Merit,' Ottawa Says*, GLOBE & DAILY MAIL (July 14, 2014), http://www.theglobeandmail.com/report-on-business/industry-news/the-law-page/lilly-nafta-challenge-without-merit-ottawa-says/article19602896; Burcu Kilic, Mikyoeng Kim & Peter Maybarduk, *U.S. Proposal Could Undermine Canadian Law;*

Canada's substantive utility requirement that a patent applicant must either demonstrate or soundly predict the utility of her invention at the time she files her patent application.[43] Canada implemented this patentability standard to discourage inventors from racing to the patent office based on inadequate data.[44] Because a successful patent filing reduces the incentives of competing researchers to finish their own studies, Canada's requirement helps ensure that only demonstrated or soundly predicted utility will pass the test.

Eli Lilly initiated this suit after Canadian courts invalidated Lilly's patents on the company's attention deficit hyperactivity disorder drug called Strattera and antipsychotic drug called Zyprexa.[45] In the Strattera case, a trial court found that the evidence of utility that Lilly presented when it filed its patent application—a single study involving twenty-two patients—was insufficient to soundly predict that its drug would be "clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted."[46] Another trial court invalidated Lilly's Zyprexa patent because the evidence available to Lilly at the time it filed its patent application did not demonstrate that Lilly's drug "could meet the [patent's claimed] promise . . . that it would provide markedly superior clinical treatment of schizophrenia with a better side effects profile than other known antipsychotics."[47] In response, Lilly mounted a facial and as-applied challenge to Canada's utility standard.

Article 10 of the TPP's intellectual property chapter is most likely aimed at undermining Canada's utility requirements. The article states: "Each Party shall provide that a claimed invention is . . . useful . . . if it has a specific, substantial, and credible utility."[48] If implemented, pharmaceutical companies may argue that Canada's rule that patent applicants demonstrate or soundly predict the utility of their inventions at the time of filing is an impermissible elevation of the TPP's utility definition. In other words, they might contend that sound prediction of an invention's utility at the time of filing is not necessary to showing specific, substantial, and credible utility.

Despite this issue, Article 10's language has been softened in the most recent iteration of the TPP. As previously discussed, TRIPS requires all WTO members to offer patents on inventions that are that are new, involve an inventive step, and are capable of industrial application.[49] The "capable of industrial application" requirement is commonly referred to as the "usefulness" condition. Some countries have enacted more exacting standards for useful than others; for

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Support Eli Lilly Attacks, PUB. CITIZEN (Nov. 13, 2013), http://www.citizen.org/documents/Memo%20on%20the%20timing%20of%20utility.pdf.

43. Apotex, Inc. v. Wellcome Found. Ltd., [2002] 4 S.C.R. 153 (Can.); CANADIAN INTELL. PROP. OFFICE, PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE § 12.08.03 (1998 ed., rev. Dec. 2010).
44. Gray, *supra* note 42.
45. Adam Behsudi, *Eli Lilly Sues Canada on Drug Patents*, POLITICO (Sept. 12, 2013), http://www.politico.com/story/2013/09/eli-lilly-sues-canada-over-drug-patents-96743.html.
46. Novopharm Ltd. v. Eli Lilly & Company, 2010 FC 915, ¶ 93 (C-160).
47. Eli Lilly Canada Inc. v. Novopharm Ltd., 2011 FC 1288, ¶¶ 209 & 210 (C-146).
48. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.9.
49. *Id*. art. QQ.E.1.2.

example, the United States uses a utility standard that is weaker than the "capable of industrial application" standard that other countries employ.[50] The 2011 version of the leaked TPP IP chapter contained a U.S. proposal that would have required all negotiating parties that currently use a "capable of industrial application" standard to adopt the United States' weaker utility requirements.[51] The more recent versions of the TPP (both the November 2013 and October 2014 versions) only require countries that already employ utility standards, such as the United States and Canada, to be bound by the TPP's definition of utility.[52]

C. *Patents on Plants and Plant-Related Inventions*

Another critical change to the TPP's provisions on patentability is its new language regarding the patentability of plants. Under the new draft, negotiating parties must accede to the 1991 International Convention for the Protection of New Varieties of Plants (UPOV), if they have not done so already, and make patents available for either plants or plant-related inventions.[53] These measures have the potential to disrupt traditional farming practices in many of the negotiating parties.[54]

The 1991 UPOV is the most recent version of an international agreement that gives plant breeders the exclusive right to sell the propagating materials of plants on which they have obtained a term of exclusivity.[55] Known as a breeder's right or plant variety protection, these exclusive rights extend to the harvests of the protected plant varieties in certain circumstances, enabling breeders to prevent farmers from selling the crops or fruits of protected plants. Currently, only fifty-two nations have signed onto the 1991 UPOV, the vast majority of which are high-income countries.[56]

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50. 35 U.S.C. § 101 (2012); *see also In re* '318 Patent Infringement Litigation, 583 F.3d 1317, 1324 (Fed. Cir. 2009).
51. *Trans-Pacific Partnership – Intellectual Property Rights*, art. 8, KNOWLEDGE ECOLOGY INT'L (Feb. 10, 2011), http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf.
52. *Secret Trans-Pacific Partnership Agreement (TPP) – Intellectual Property Chapter*, *supra* note 2, art. QQ.E.10; *Secret Trans-Pacific Partnership Agreement (TPP) – Intellectual Property Chapter* (Nov. 13, 2013), *supra* note 33, art. QQ.E.10.
53. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.1 ("3. [US/JP/SG propose; AU/NZ/VN/BN/CL/PE/MY/CA/MX oppose: Consistent with paragraph 1, each Party shall make patents available for inventions for plants and animals.] Alt. 3: {Consistent with paragraph 1, each Party confirms that it makes available patents for plant-related inventions.}. . . . [NZ/CA/CL/MY/VN/MX/BN/PE/AU propose: *ALT* 3. Each Party may also exclude from patentability: . . . (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.]") (footnote omitted).
54. *See Report on Seed Policies*, *supra* note 8, at ¶ 42-51.
55. International Convention for the Protection of New Varieties of Plants, art. 14(1)(a), Mar. 19, 1991, http://www.upov.int/en/publications/conventions/1991/act1991.htm.
56. *Members of the International Union for the Protection of New Varieties of Plants*, INT'L UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (June 10, 2014), http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf.

Nevertheless, because the UPOV was specifically designed to protect the propagating materials of plant varieties, the UPOV's grant of protection does not extend to "technical processes for the production of those varieties."[57] In other words, breeders cannot obtain exclusive rights over particular breeding methods, such as techniques for genetically engineering or conventionally breeding new plants. Moreover, the 1991 UPOV provides for certain exceptions and limitations to the exclusive rights it confers. For example, the 1991 UPOV allows any individual to experiment with a protected plant breed to create new varieties or to market those new varieties.[58] It also grants farmers the right to use the seeds (and other propagating materials) of protected plant varieties for noncommercial purposes, such as personal consumption.[59] However, the 1991 UPOV prohibits farmers from selling protected seeds to other farmers.[60]

Patent protection on plants or plant-related materials provides breeders with a more complete set of exclusive rights than the 1991 UPOV. Under the TRIPS agreement, a patent must, at minimum, confer upon the patent holder the exclusive right to make, use, offer for sale, sell, or import the patented product or process.[61] Critically, patent protection does not provide for research and/or development exemptions nor allow certain populations, such as farmers, to make use of patented products for personal consumption.

The TPP's text indicates that the majority of countries prefer the language "makes available patents for plant-related inventions" to the phrase "make patents available for inventions for plants."[62] Unfortunately, the latter option can be interpreted in a way that renders its practical difference from the former non-existent.

Today, new plants can either be created through conventional breeding techniques or genetic engineering. While traditional breeding practices employ selection to achieve expression of genetic material already present within a plant species, genetic engineering enables scientists to insert carefully selected genetic material into the genome of a particular plant and precisely control the expression of certain genes.[63] For example, researchers once introduced an antifreeze gene from Arctic flounder into tobacco and tomato plants.[64]

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57. Claudio Chiarolla, *Commodifying Agricultural Biodiversity and Development-Related Issues*, 9 J. WORLD INTELL. PROP. 25, 28 (2006).
58. International Convention for the Protection of New Varieties of Plants, *supra* note 55, arts. 14(5)(a), 15(1)(ii).
59. LAURENCE R. HELFER, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTELLECTUAL PROPERTY RIGHTS IN PLANT VARIETIES: INTERNATIONAL LEGAL REGIMES AND POLICY OPTIONS FOR NATIONAL GOVERNMENTS 26 (2004), http://www.fao.org/3/a-y5714e.pdf.
60. *Id.* art. 14(1)(a)(iv).
61. Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 10, art. 28.
62. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art. QQ.E.1 (demonstrating that only the United States, Japan, and Singapore propose, and nine nations oppose, "each Party shall make patents available for intentions for plants and animals").
63. Charles S. Gasser & Robert T. Fraley, *Genetically Engineering Plants for Crop Improvement*, 244 SCI. 1293, 1293 (1989).
64. *See generally* Robin Hightower et al., *Expression of Antifreeze Proteins in Transgenic Plants*, 17 PLANT MOLECULAR BIOLOGY 1013, 1014-15 (1991) (describing an experiment which produced transgenic tobacco and tomato plants expressing genes encoding antifreeze

The rise of genetically engineered crops has spawned a corresponding patent term: plant-related invention. The term plant-related invention covers the features or characteristics of a plant, such as the process used to create that plant or genetic information inserted into the plant's genome. Patents on plant-related inventions enable individuals to obtain exclusive rights over these features. Accordingly, any unauthorized use or sale of plants containing these features constitutes infringement.

Although the term "plant-related invention" would seem to cover only inventions relating to plants, these patents can provide their holders with the functional equivalent of a patent on the plant itself. For example, when Monsanto inserted an herbicide-resistant gene into soybeans, the company was able to obtain patent protection on both the herbicide-resistant gene and the plant cell into which the gene was inserted in countries such as Canada,[65] which makes patents on biotechnology such as plant genes, but not plants, available. When Monsanto sued a Canadian farmer for replanting the seeds of a Monsanto soybean crop that had blown onto his field as seedlings, the Canadian Supreme Court ruled in favor of the corporation, holding that the farmer had infringed Monsanto's patent.[66] Thus, even if a nation does not make patents on plants available, a seed manufacturer can obtain the practical equivalent of patent protection for its plants if that nation makes patents on plant-related inventions available.

Currently, half of the TPP signatories have not acceded to the 1991 UPOV, and only three parties make plant patents available. As the table below demonstrates, signing the current U.S.-proposed text of the TPP would require nine nations to significantly alter their plant-related intellectual property laws and policies (six nations must sign onto the 1991 UPOV and an additional 3 must clarify that patents are available for plants).

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proteins). These products were not commercially successful. *See, e.g.*, Jeffrey Smith, *Throwing Biotech Lies at Tomatoes – Part 1: Killer Tomatoes*, HUFFINGTON POST (May 25, 2011, 6:20 PM), http://www.huffingtonpost.com/jeffrey-smith/throwing-biotech-lies-at_b_803139.html ("The tomato that did make it to market was called the Flavr Savr, engineered for longer shelf life. Fortunately, it was removed from the shelves soon after it was introduced.").

65. Glyphosate-Resistant Plants, Canadian Patent No. 1,313,830 (issued Feb. 23, 1993), http://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/patent/1313830/summary.html.
66. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.).

The Current Membership Status of TPP Parties to International Agreements that Provide for Plant-Related Intellectual Property Protection			
TPP Party	**TRIPS Signatory[67]**	**UPOV 1991 Signatory[68]**	**Patent Protection for Plants**
Australia	✔	✔	✔
Brunei	✔	✕[69]	Unclear[70]
Canada	✔	✕	Does not grant patents on "higher life forms," a term that includes plants, but will grant patents on plant cells and genes.[71]
Chile	✔	✕	✕
Japan	✔	✔	✔
Malaysia	✔	✕	✕
Mexico	✔	✕	✕
New Zealand	✔	✕	No patents on plant varieties
Peru	✔	✔	✕[72]
Singapore	✔	✔	Unclear[73]
United States	✔	✔	✔
Vietnam	✔	✔	No patents on plant varieties[74]

67. *Members and Observers*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Sept. 30, 2014).
68. *Members of the International Union for the Protection of New Varieties of Plants*, INT'L UNION FOR PROTECTION NEW VARIANTS PLANTS (June 10, 2014), http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf.
69. However, Brunei will join the UPOV by 2015. Intell. Prop. Office of Brunei Darussalam, *Intellectual Property Regime*, BRUNEI-PATENTS, http://www.brunei-patents.com.bn/index.php/about-us/ip-regime (last visited Mar. 16, 2015).
70. Brunei's current patent law neither explicitly includes nor excludes plants from its provision on patentable subject matter. *See* Brunei Darussalam Patents Order 2011, Part III (Oct. 17, 2011), http://www.wipo.int/edocs/lexdocs/laws/en/bn/bn027en.pdf.
71. *See* Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.) (explaining that patents on plant genes and cells are valid but patents on plants are not); Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 48 ("Since patenting higher life forms would involve a radical departure from the traditional patent regime, and since the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues, clear and unequivocal legislation is required for higher life forms to be patentable. The current Act does not clearly indicate that higher life forms are patentable.").
72. The Andean Pact countries, which include Peru, have chosen not to grant patents on plants. Decision 486: Common Intellectual Property Regime, art. 20 (Sept. 14, 2000), http://www.wipo.int/edocs/lexdocs/laws/en/can/can012en.pdf.
73. *What is a Patent?*, INTELL. PROP. OFFICE OF SINGAPORE, http://www.ipos.gov.sg/AboutIP/TypesofIPWhatisIntellectualProperty/Whatisapatent.aspx (last updated Dec. 12, 2013).
74. Vietnam Intellectual Property Law 50/2005, Art. 59(5); *see also* Nguyen Nguyet Dzung, *Vietnam Patent Law Substantive Law Provisions and Existing Uncertainties*, 6 CHI.-KENT J. INTELL. PROP. 138, 142 (2007).

Such changes to the parties' plant-related intellectual property provisions have the potential to harm traditional farming practices in Pacific Rim nations. Worldwide, at least 1.5 billion individuals depend on small-scale farming for their livelihoods, and in developing countries, informal seed systems often account for 98% of seed supply.[75] For such farmers, saving, selling, and exchanging seeds in informal markets is pervasive and essential to the viability of their farming practices.[76] Because the 1991 UPOV as well as plant patents prevent farmers from selling and exchanging protected seeds, such laws disrupt the traditional exchange of seeds in informal seed markets.[77] As the Special Rapporteur on the Right to Food warns, "The oligopolistic structure of [the breeders'] market may result in poor farmers being deprived of access to seeds productive resources essential for their livelihoods, and it could raise the price of food, thus making food less affordable for the poorest."[78]

One common response to this criticism posits that, without patent protection, many corporations would not create improved seeds. But this argument starts from a false premise. The vast majority of nations worldwide does not currently offer patents on plants or plant-related inventions, nor protects breeders' rights under the 1991 UPOV.[79] In spite of this lack of protection, many corporations have found seed development and sale to be a highly profitable field.[80] Accordingly, the argument that seed manufacturers would stop innovating without increased patent protection is not only implausible, but contrary to the current reality. Moreover, seed manufacturers can profit from selling their seeds without patent protection: before a farmer can trade an improved seed strain, he must purchase it or obtain it through a bartering process. Patent protection serves to exponentially augment the profits of an already lucrative industry through preventing resale of later generations of protected seeds. The farmers in many of the TPP nations are too poor to continually pay the monopolistic prices that seed manufacturers would extract should those nations begin to offer plant and plant-related patents.[81] Heightened intellectual property protection of plant-related

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75. *Report on Seed Policies*, *supra* note 8, ¶ 24.
76. BERNE DECLARATION, OWNING SEEDS, ACCESSING FOOD: A HUMAN RIGHTS IMPACT ASSESSMENT OF UPOV 1991 BASED ON CASE STUDIES IN KENYA, PERU, AND THE PHILIPPINES 7 (Oct. 9, 2014), http://www.bernedeclaration.ch/media/press-release/stronger_plant_variety_protection_may_threaten_the_right_to_food.
77. *See id.* at 7, 14; *see also* GEOFF TANSEY, THE FUTURE CONTROL OF FOOD 41 (2008).
78. *Report on Seed Policies*, *supra* note 8, ¶ 27; *see also* BERNE DECLARATION, *supra* note 76, ("From a human rights perspective, restrictions on the use, exchange and sale of protected seeds could adversely affect the right to food, as seeds might become either more costly or harder to access. These restrictions could also affect other human rights, by reducing the amount of household income which is available for food, healthcare or education.").
79. International Convention for the Protection of New Varieties of Plants, *supra* note 55.
80. *The World's Top Ten Seed Companies: Who Owns Nature*, GM WATCH, http://www.gmwatch.org/gm-firms/10558-the-worlds-top-ten-seed-companies-who-owns-nature (last visited Mar. 16, 2015).
81. *See* Hossein Azadi, *Genetically Modified and Organic Crops in Developing Countries: A Review of Options for Food Security*, 28 BIOTECHNOLOGY ADVANCES 160, 164 (2010); *Report on Seed Policies*, *supra* note 8, ¶ 27.

materials would simply deprive poor farmers of access to improved seeds instead of expanding the market of seed manufacturers.

Increased intellectual property protection of plant varieties may also skew incentives in the seed industry in ways that reduce genetic diversity among plants, further harming developing nations.[82] Plant variety protection does not encourage breeding related to minor crops with small markets "because the likelihood of good returns on breeders' research investment is small even with the legal protection provided by [plant variety protection]."[83] Instead, intellectual property protection of plant varieties encourages breeding targeted at major crops with significant commercial potential. Plant variety protection "may contribute to a trend whereby traditional diverse agro-ecosystems, containing a wide range of traditional crop varieties, are replaced with monocultures of single agrochemical-dependent varieties."[84] Indeed, most of "mankind now lives off no more than twelve plant species, with the four biggest staple crops (wheat, rice, maize and potato) taking the lion's share."[85] Furthermore, because private multinational corporations are the primary beneficiaries of increased intellectual property protection of plants,[86] implementation of the 1991 UPOV or a system of plant patents may orientate research and development towards the needs of farmers in rich countries, while neglecting poor farmers in developing countries.[87] For example, very little research has been directed towards developing new varieties of tropical maize, sorghum, millet, banana, cassava, groundnut, oilseed, potato, or sweet potato.[88] This reduction in biodiversity and crop availability has the potential to threaten food security in developing nations and narrow the range of nutritious foods available in local markets.[89]

D. *Patents on Diagnostic, Therapeutic, and Surgical Methods*

One very significant and positive development in the new TPP text is the withdrawal of the highly unpopular U.S. proposal on diagnostic, therapeutic, and surgical methods patents, also known as medical procedure patents. In the

82. *Report on Seed Policies*, *supra* note 8, ¶ 24 ("[T]he expansion of surfaces cultivated with commercial seeds accelerates crop diversity erosion, as an increasing number of farmers grow the same crops, using the same, 'improved' varieties on their fields."); *see also* TANSEY, *supra* note 77, at 41; S. Ragavan, *To Sow or Not to Sow: Dilemmas in Creating New Rights in Food*, *in* AGRICULTURAL AND BIOTECHNOLOGY AND INTELLECTUAL PROPERTY: SEEDS OF CHANGE 320, 323-24 (Jay P. Kesan ed., 2007).

83. TANSEY, *supra* note 77, at 41.

84. *Id.*

85. *Report on Seed Policies*, *supra* note 8, ¶ 38; *see also* TIMOTHY SWANSON, GLOBAL ACTION FOR BIODIVERSITY 52 (2005); *see generally* José Esquinas-Alcázar, *Protecting Crop Genetic Diversity for Food Security: Political, Ethical and Technical challenges*, 5 NATURE 946 (2005).

86. Harbir Singh, *Plant Variety Protection and Food Security: Lessons for Developing Countries*, 12 J. INTELL. PROP. RTS. 391, 395-96 (2007) ("Data on the North American seed market revealed that in case of hybrid corn and soybean, top five companies account for 69% and 51% share, respectively. In case of cottonseed, Monsanto alone controls 84% of the market on account of its purchase of Delta and Pine Land.").

87. *Report on Seed Policies*, *supra* note 8, ¶ 34.

88. *Id.*

89. *Id.*, ¶¶ 26-27; TANSEY, *supra* note 77, at 41; Ragavan, *supra* note 82, at 322-24.

previous drafts of the IP chapter, the United States proposed that patents on "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals be made available."[90] Every negotiating country aside from the United States opposed this proposal.[91] Footnote 56 of the new text explains that the United States and Japan are "reconsidering the inclusion" of this proposal subject to consensus in the patent landing zones.[92] This may refer to a deal between negotiating parties wherein patents for new uses and new methods of use of known substances are allowed in exchange for the revocation of patents on medical procedures.

III. CONCLUSION

The patentability provisions of the TPP's IP chapter are a bad bargain from a public health perspective. These patent standards are significantly more detrimental than those set forth in the TRIPS Agreement: The TRIPS+ standards of the TPP would impede access to affordable medications and potential threaten the livelihood of communities that rely on traditional farming practices. For these reasons, the TPP negotiators should to push for IP provisions that go no further than those mandated by the TRIPS agreement.

90. *Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter* (November 13, 2013), *supra* note 33, art. QQ.E.1.3(a).

91. *See id.*; *see also* Burcu Kilic & Tiffany Jang, *Medical Procedure Patents in the TPP: A Comparative Perspective on the Highly Unpopular U.S. Proposal*, PUB. CITIZEN (Nov. 13, 2013), http://www.citizen.org/documents/MEDICAL%20PROCEDURE%20PATENTS%20IN%20THE%20TPP.pdf.

92. *See Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter*, *supra* note 2, art.QQ.E.1.4. The deep resistance of many negotiating countries to some measures included in the IP chapter of TPP has prompted the intellectual property negotiators to pass these controversies on to their countries' highest trade and commerce authorities, who gathered for a ministerial meeting in late October. There, the ministers discussed "landing zones": a range of possible options identified by the countries' chief TPP negotiators for possible agreement. Emma Woolacott, *US Fails to Close TPP as Wikileaks Exposes Discord*, FORBES (Dec. 10, 2013 9:28 AM), http://www.forbes.com/sites/emmawoollacott/2013/12/10/us-fails-to-close-tpp-deal-as-wikileaks-exposes-discord.