



## Health GAP Policy Analysis: U.S. Patent and Data Protection Proposals in Trans-Pacific Partnership Negotiations – A Grave Threat to Access-to-Medicines

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### 1. INTRODUCTION

This Policy Analysis critiques the access-to-medicines impact of two leaked U.S. proposals for an intellectual property chapter in the Trans Pacific Partnership (TPP) agreement and portions of a related transparency chapter for healthcare technologies.<sup>2</sup> In these leaked documents, the U.S. proposes the highest levels of patent and data protection of any free trade agreement to date and especially does so with respect to developing country Parties, Vietnam, Peru, Chile, and Malaysia. The proposed U.S. IP chapter greatly exceeds global IP standards codified in the 1994 WTO Trade-Related Aspects of Intellectual Property Rights Agreement [hereinafter TRIPS].<sup>3</sup> Instead, the proposals are primarily based on, but frequently exceed, the heretofore maximalist standards of the Korea-U.S. Free Trade Agreement (KORUS).<sup>4</sup> The proposals abandon previous flexibilities on access-to-medicines contained in the U.S. 2007 New Trade Deal<sup>5</sup> and included in the U.S.-Peru Trade Promotion Agreement and U.S.-Columbia Free Trade Agreement IP Chapters.<sup>6</sup>

Fundamentally, the U.S. TPP IP proposals seek to deepen, lengthen, and strengthen substantive patent and data exclusivities while simultaneously trying to help pharmaceutical companies gain quicker and easier monopoly access to lucrative markets through a so-called Access Window. Taken as a whole, the U.S. proposals poses a grave threat to access-to-medicines and to generic entry and competition, even though there is

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<sup>1</sup> This Analysis benefited of previous analyses, footnoting, editing and other suggestions from Public Citizen and the Program on Information Justice and Intellectual Property for which the author and Health GAP are

<sup>2</sup> Trans-Pacific Partnership, Intellectual Property Rights Chapter February Draft [hereinafter TPP], *available at* <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>; Trans-Pacific Partnership, Intellectual Property Rights Chapter September 2011 Draft (Selected Provisions) [hereinafter TPP-2], *available at* <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>; Transparency Chapter – Annex on Transparency and Procedural Fairness for Healthcare Technologies June 22, 2011 Draft [hereinafter Transparency Chapter] *available at* <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificTransparency.pdf>.

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 15, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round, 1869 U.N.T.S. 299 [hereinafter TRIPS].

<sup>4</sup> Free Trade Agreement between the United States of America and the Republic of Korea, U.S.-S. Korea, June 30, 2007 [hereinafter KORUS], *available at* [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Republic\\_of\\_Korea\\_FTA/Final\\_Text/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Final_Text/Section_Index.html).

<sup>5</sup> New Trade Policy for America, House Committee on Ways and Means, [hereinafter New Trade Policy], *available at* <http://waysandmeans.house.gov/media/pdf/NewTradePolicy.pdf>. An extended summary of the New Trade Policy provisions on patents/IPRs and access to medicines can be found in Mac Dressler, *American Trade Politics in 2007: Building Bipartisan Compromise*, Policy Brief, Peterson Institute for International Economics 25-26 (May 2007) *available at* <http://www.iie.com/publications/pb/pb07-5.pdf>.

<sup>6</sup> U.S.-Peru Trade Promotion Agreement, Chapter 16 Intellectual Property Rights (revised June 29, 2007) *available at* [http://www.ustr.gov/webfm\\_send/1031](http://www.ustr.gov/webfm_send/1031); U.S.-Columbia Free Trade Agreement, Chapter 16 Intellectual Property Rights, *available at* [http://www.ustr.gov/webfm\\_send/1336](http://www.ustr.gov/webfm_send/1336).

passing reference to the Doha Declaration on the TRIPS Agreement and Public Health [hereinafter Doha Declaration].<sup>7</sup> Although there are many troubling provisions in the U.S. TPP proposals, the most egregious involving access-to-medicines are: (1) a dramatic easing of patentability standards; (2) outlawing of pre-grant opposition procedures; (3) mandatory extensions of patent terms; (4) successive terms of data exclusivity; and (5) linkage of registration rights to patent status. A separate proposal threatening the use of pharmaceutical price controls and therapeutic formularies is not addressed in this paper.<sup>8</sup>

Even though the U.S. patent and data protection proposals would be disastrous if adopted by the nine TPP Parties, TPP itself is only the opening salvo in a U.S. IP/trade strategy of isolating India and reversing its more pro-access IP policies. The U.S. also has its sights on the entire ASEAN region and more particularly on China, where heightened IP rules and strengthened enforcement measures will accrue massively to the benefit of U.S. right holders. To preserve policy space to promote public health and access to medicines for all, parties to the TPP negotiations should at a minimum reject the U.S. proposals outright and insist that patent and data protection rights be no more stringent than that required by the TRIPS Agreement. An even more proactive policy would be for countries to acknowledge that medicines are a global public good, that the right to health requires differentiation in IP protection for medical technologies, and that the dysfunction patent and data protection regimes are neither incentivizing the medical innovation that we need nor ensuring affordable access of quality products for all patients, rich and poor.

In the discussion that follows, the Policy Analysis will initially address the patent provisions contained in the first leaked U.S. proposal. Next the Analysis will discuss the second leaked proposal both with respect to its patent and data-related provisions and with respect to its Doha Declaration and Access Window provisions.

## 2. TPP PATENT PROPOSALS

### A. Arts. 8.1, 8.12 FN 15 – Easing and Expanding Standards of Patentability

TPP art. 8.1 contains a controversial TRIPS-plus provision, most relevant to pharmaceutical patents, that the scope of patentability include “any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product . . . , even if such invention does not result in the enhancement of the known efficacy of that product”. This language goes far beyond definition of patentability contained in TRIPS art. 27.1, which merely states that “patents shall be 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 applicability.”<sup>9</sup>

Accordingly, art. 8.1 will require countries to open the flood gates to patent applications on minor modifications or variations of existing chemical entities; on new uses or methods of using existing medicines, e.g., tenofovir to treat hepatitis and HIV and to use for HIV and herpes simplex virus-2 prophylaxis;<sup>10</sup> or on new formulations, dosages, and combinations, e.g., heat-stable ritonavir/lopinavir or extended release formulations. Countries must do so

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<sup>7</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002).

<sup>8</sup> For a separate analysis of this threat, see Sean Flynn, Margot Kaminski, Brook Baker & Jimmy Koo, *supra*, 48-52 (Draft 2011), available at <http://infojustice.org/tpp-analysis-november2011>.

<sup>9</sup> TPP art. 8.1 also goes beyond KORUS art. 18.8.1, which altered that TRIPS standard by adding “each Party confirms that patents shall be available for any uses or methods of using a known product.”

<sup>10</sup> Graciela Andrei et al, *Topical Tenofovir, a Microbicide Effective against HIV, Inhibits Herpes Simplex Virus-2 Replication*, 10 CELL HOST & MICROBE, 379-89 (2011).

even if there is no enhancement of therapeutic efficacy – indeed there could be a decrease in therapeutic effect. Each new patent on new forms, uses, or formulation of an existing medical product will result in a new 20-year patent running from the date of patent application, thereby “evergreening” monopoly rights on the underlying medical product. For example, since the filing of the original patent application on ritonavir in 1980 there have been over 800 families of ever-greening patent applications, most first filed in the U.S. Those patent applications filed in 2009 will extend exclusivity period from the original 2000 date to 2029 – twenty-nine extra years and counting.<sup>11</sup>

TPP art. 8.1 is inconsistent with the laws of other TPP negotiating countries, including Australia, Malaysia, and Vietnam.<sup>12</sup> But the most direct target of the article is India, even though India is not a TPP party. The TPP proposal is clearly drafted to counter the policy embodied in the 2005 Amended India Patents Act section 3(d),<sup>13</sup> which prohibits the granting of patents for “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 process results in a new product or employs at least one new reactant.” India’s section 3(d) was enacted to reduce ever-greening of pharmaceutical patents, and is widely recognized as a pro-public health and TRIPS-compliant exception to patentability.<sup>14</sup> It has been offered as a model for other developing countries to follow.<sup>15</sup>

## **B. Art. 8.2 – Eliminating Exclusions from Scope of Patentable Subject Matter**

In direct contradiction to TRIPS art. 27.3, TPP art. 8.2 would require that “each party shall make patents available for . . . (a) plants and animals, and; (b) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.” The application of patents to these areas, mirrored in KORUS art. 18.8.2,<sup>16</sup> is expressly contrary to the right to exclude

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<sup>11</sup> See World Intellectual Property Organization, PATENT LANDSCAPE REPORT ON RITONAVIR (2011), available at [http://www.wipo.int/export/sites/www/patentscope/en/programs/patent\\_landscapes/reports/documents/ritonavir\\_plr\\_08112011\\_with\\_old\\_cover.pdf](http://www.wipo.int/export/sites/www/patentscope/en/programs/patent_landscapes/reports/documents/ritonavir_plr_08112011_with_old_cover.pdf). Note, some of the ritonavir patents filed are process rather than product patents.

<sup>12</sup> See Public Citizen, DANGERS FOR ACCESS TO MEDICINES IN THE TRANS-PACIFIC PARTNERSHIP AGREEMENT: COMPARATIVE ANALYSIS OF THE U.S. INTELLECTUAL PROPERTY PROPOSAL AND AUSTRALIAN LAW (2011) [hereinafter PUBLIC CITIZEN TPP-AUSTRALIAN LAW COMPARISON], available at <http://www.citizen.org/Page.aspx?pid=5025&frcrid=1>; Public Citizen, DANGERS FOR ACCESS TO MEDICINES IN THE TRANS-PACIFIC PARTNERSHIP AGREEMENT: COMPARATIVE ANALYSIS OF THE U.S. INTELLECTUAL PROPERTY PROPOSAL AND MALAYSIAN LAW (2011) [hereinafter PUBLIC CITIZEN TPP-MALAYSIAN LAW COMPARISON], available at <http://www.citizen.org/documents/Malaysia-chart.pdf>; Public Citizen & Health GAP, VIETNAM AND THE TRANS-PACIFIC PARTNERSHIP AGREEMENT: ACCESS TO MEDICINES RISK FOR A PEPFAR PARTNER (2011) [hereinafter, PUBLIC CITIZEN AND HEALTH GAP VIETNAM AND THE TPPA], available at <http://www.citizen.org/documents/Vietnam-and-the-Trans-Pacific-Partnership-Agreement.pdf>.

<sup>13</sup> The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 3, India Code (2005).

<sup>14</sup> Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007); Amy Kapczynski, *Harmonization and its Discontent: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CAL. L. REV. 1571-1650 (2009); Sudip Chaudhuri, Chan Park & K. M. Gopakumar, FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA’S RESPONSE (2010), available at [apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf](http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf).

<sup>15</sup> Carlos Correa, Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective 6–25 (Jan. 2007), available at [http://www.iprsonline.org/resources/docs/Correa\\_Patentability%20Guidelines.pdf](http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf) (drawing on sec. 3(d), and recommending that developing countries adopt comparable strict patentability standards, e.g., that they treat new formulations, compositions, salt patents, and enantiomers as obvious and/or as exceptions to patentability).

<sup>16</sup> KORUS art. 18.8.2 (preventing the exclusion of “diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals.”).

patents on such subject matter found in TRIPS art. 27.3.<sup>17</sup> TPP art. 8.2 is also contrary to the actual practice of U.S. law which allows patents on medical procedures but precludes use of such patents to seek remedies against medical practitioners.<sup>18</sup> The provision runs counter to the current law in several TPP member countries.<sup>19</sup>

### C. Art. 8.7 – Limiting Revocation and Eliminating Pre-Grant Opposition

TPP art. 8.7 contains TRIPS-plus restrictions on the grounds for patent revocation and on processes for permitting pre-grant opposition of patent applications. TRIPS art. 32 merely requires “An opportunity for judicial review of any decision to revoke or forfeit a patent.” The TPP proposal, modeled on KORUS art. 18.8.4, restricts the grounds upon which a patent may be revoked to “grounds that would have justified a refusal to grant the patent,” and specifies that such grounds include fraud, misrepresentation or inequitable conduct. Under TRIPS art. 32 there are no limitations on grounds for revocation, only a requirement of judicial review; likewise, under the earlier Paris Convention, countries have unlimited rights to revoke a patent, including specifically for any abuse of the patent that cannot be remedied through a compulsory license.<sup>20</sup>

TPP art. 8.7 additionally restricts the use of pre-grant oppositions. It provides that if proceedings permit a third party to oppose the grant of a patent, the “Party shall not make such proceedings available before the grant of the patent.” Pre-grant oppositions allow opportunities to contest a patent as it is filed, providing a potentially important source of information to patent examiners and generally improving patent quality.<sup>21</sup> The U.S. has justified this restriction (in a leaked Memorandum) as being in the interest of patent office efficiency and as protection against abusive oppositions.<sup>22</sup> The U.S. position and its reasoning was promptly criticized by public health advocates as removing an important tool for “preventing patent applicants from gaining patent monopolies based on weak or erroneous information, for improving the quality and efficiency of patent office examinations, and for safeguarding access to medicines.”<sup>23</sup>

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<sup>17</sup> TRIPS art. 27.3 (providing that “[m]embers 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” emphasis added). See generally Christopher Garrison, EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES (2006) available at [http://www.unctad.org/en/docs/iteipc200612\\_en.pdf](http://www.unctad.org/en/docs/iteipc200612_en.pdf).

<sup>18</sup> See 35 U.S.C. § 287(c).

<sup>19</sup> See PUBLIC CITIZEN & HEALTH GAP VIETNAM AND TPPA, *supra* note 12 (noting that the laws in “Vietnam and many other countries exclude diagnostic, therapeutic and surgical methods from patentability.”); PUBLIC CITIZEN TPP-AUSTRALIAN LAW COMPARISON, *supra* note 12 (noting that the proposed language would eliminate a flexibility recognized by art. 17.9.2 of AUSFTA); PUBLIC CITIZEN TPP-MALAYSIAN LAW COMPARISON, *supra* note 12 (explaining that Section 13(1) of Malaysia’s Patents Act of 291 of 1983 “expressly excludes treatment by surgery or therapy and diagnostic methods on the living human or animal body from patent protection.”).

<sup>20</sup> Paris Convention for the Protection of Industrial Property, Art. 5(A)(3).

<sup>21</sup> See Dietmar Harhoff, Frederic M. Scherer, Katrin Vopel, *Erratum to “Citations, family size, opposition and the value of patent rights,”* 33 RESEARCH POLICY 363-364 (March 2004) (noting that patents tested by opposition systems have greater value); Tahir Amin et al., *Expert Review of Drug Patent Applications: Improving Health in the Developing World*, 28:5 HEALTH AFFAIRS, 948, 951-52 (Aug. 25, 2009), available at <http://content.healthaffairs.org/content/28/5/w948.full.pdf+html> (arguing that pre-grant opposition systems lead to efficiency gains without causing problems of abuse of the system or rising costs of delay).

<sup>22</sup> See *Pre-Grant Opposition*, (“A lengthy or onerous pre-grant patent opposition system place undue burdens on patent applicants and create additional costs to patent offices, thereby causing uncertainty and deterring innovators and enterprises that would otherwise bring innovative products and services to TPP partners.”) available at <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

<sup>23</sup> Public Citizen, Health GAP, I-MAK & Third World Network, BRIEFING MEMO: ANALYSIS OF THE LEAKED U.S.

The U.S. TPP proposal would require change in Australia's law, which already includes a pre-grant opposition system.<sup>24</sup> As in other areas of the TPP, the clearest target of the proposal may be India, although it is not at the negotiating table. Adopting this proposal would prevent the countries of the TPP from adopting the kind of pre-grant opposition processes that India has found useful.<sup>25</sup>

#### **D. Art. 8.9 – Unlimited Amendments to Patent Applications**

Whereas art. 8.7 makes it harder to challenge and revoke patent rights, Art. 8.9 makes it much easier to successfully apply for them. Article 8.9 forces countries to allow patent applicants to make multiple amendments to their patent claims prior to approval on the merits. TRIPS does not require Members to allow amendment of patent applications. KORUS art. 18.8.8 includes a TRIPS-plus requirement to allow applicants at least one opportunity to make amendments, corrections, and observations in connection with their applications. Now the number of amendments is unlimited.

The interests of many patent offices will be best served by maximizing pre-grant oppositions and minimizing opportunities to amend patent claims after they are filed. In such a system, companies have incentives to only file their strongest claims, leading to a lower volume of weak applications and stronger overall patent value.<sup>26</sup> Under the US TPP proposal, applicants have more opportunities to game the system in their favor and can demand the elongation of processes. They can, for example, respond to a challenge or weakness in their application by adding new entirely new claims. They will lack an incentive to make all possible claims and arguments in an initial completed application.<sup>27</sup> Patent applicants will be rushed to file incomplete applications to gain priority dates over other potential inventors, and will not be penalized for filing incomplete or imperfect claims only to correct them after.

#### **E. Art. 8.10 and Art. 8.11– Minimize Required Disclosure**

TPP arts. 8.10 and 8.11 reduce flexibility that countries have under TRIPS to design domestic patent disclosure standards. TPP art. 8.10 and 8.11 require that a disclosure be considered sufficient if it “allows the invention to be made and used by a person skilled in the art, without undue experimentation.”<sup>28</sup> This provision may impede flexibility in

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PAPER ON ELIMINATING PATENT PRE-GRANT OPPOSITION (July 7, 2011), *available at* <http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf>; K.M. Gopakumar & Sanya R. Smith, *IPR Provisions in FTAs: Implications for Access to Medicines*, in *INTELLECTUAL PROP. & ACCESS TO MED: PAPERS & PERSPECTIVES*, WORLD HEALTH ORG. 141, 144 (2010) (criticizing the elimination of pre-grant opposition in U.S. FTAs).

<sup>24</sup> PUBLIC CITIZEN TPP-AUSTRALIAN LAW COMPARISON, *supra* note 12 (commenting that the TPP proposal would proscribe the “pre-grant opposition [process] in Australia [which] improves patent quality with minimal interference to well-drafted patent applications.”).

<sup>25</sup> See Shamnad Basheer, *India's Tryst With TRIPS: The Patents (Amendment) Act, 2005*, 1 *INDIAN J.L. & TECH.* 15, 26; Peter Drahos, *The Jewel in the Crown: India's Patent Office and Patent-Based Innovation*, in *INTELLECTUAL PROPERTY POLICY REFORM* 80, 95 (noting 150 pre-grant oppositions filed by Indian generic industry since 2005).

<sup>26</sup> Cf. Harhoff, Scherer & Vopel, *supra* note 15, at 363-364 (finding that patents which are upheld in opposition procedures are particularly valuable).

<sup>27</sup> A similar problem occurs as a result of TPP-2 Art. 9(8)(a), which makes the access window toll upon “commencement,” rather than completion, of the marketing approval process.

<sup>28</sup> TPP Art. 8.10. Without any TRIPS counterpart, TPP art. 8.11 specifies that “Each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date.” Cf. KORUS art. 18.8.10(a) (going further than TPP by requiring that a claim invention is sufficiently supported by its disclosure “if the disclosure allows a person skilled in the art to extend the teaching therein to the entire scope of the claim, thereby showing that the applicant does not claim subject matter which the applicant had not

implementing TRIPS art. 29.1's permission for a disclosure standard requiring disclosure of the best mode for carrying out the invention. In addition, there could be other disclosure requirements of interest to TPP members, including "information concerning the applicant's foreign applications and grants."<sup>29</sup> A country might also require, for example, that the description be sufficient to allow a person skilled in the art to be able to apply the technology in the country of the application. Or a country might want to condition approval of the application on disclosure of use of any traditional knowledge or genetic resources in order to facilitate access and benefit sharing. Finally, a country might require disclosure of the generic name of a pharmaceutical product that incorporates the subject matter of the patent application to ease patent searches on medicines.

#### **F. Art. 8.12 – Industrial Applicability/Utility**

TPP art. 8.12 imposes a weak, U.S.-centric definition of "industrial applicability" on TPP members. TRIPS art. 27.1 fn. 5 permits, but does not require, Members to define "industrial application" to be synonymous with the term "useful," and does not impose any further definition on the term. This was included to permit the U.S. to continue to implement its own very lax standard.<sup>30</sup> TPP art. 8.12 goes further, however, in exporting the lax U.S. standard, requiring that a claimed invention be considered industrially applicable "if it has a specific, substantial, and credible utility."<sup>31</sup> This weak standard, based on U.S. law, could be used by firms to press for the patenting of "useful" ideas such as diagnostic, surgical, and therapeutic methods, new uses of known medicines, business methods, and research tools – all of which are subject to frequent critique. This provision appears to be designed to foreclose adoption of stricter "industrial applicability" standards whereby some jurisdictions require a showing that the invention will result in an actual industrial product.<sup>32</sup>

### **3. TPP-2 PATENT AND DATA-RELATED RIGHTS**

#### **A. TPP-2 Art. 8.6 – Lengthening Patent Term to Compensate for Delays**

TPP-2 art. 8.6 would require TPP members to grant extensions of patent terms beyond the TRIPS 20-year minimum patent term to compensate both for delays in patenting and in granting marketing approval. Patent term extensions delay the introduction of generic products into a market, maintaining monopoly protections and higher prices during the extension.

TRIPS Art. 33 requires a patent term of twenty years. TRIPS does not require extensions beyond the 20-year life of a patent for delays in granting a patent or in obtaining marketing approval. The 20-year standard was developed in recognition of the known delays encountered through the patent examination process.

Mandatory patent term extensions have been a highly controversial aspect of the U.S.

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recognized and described or possessed on the filing date.”).

<sup>29</sup> TRIPS, *supra* note 3, art. 29.2.

<sup>30</sup> See PUBLIC CITIZEN & HEALTH GAP VIETNAM & TPPA, *supra* note 12 (commenting that the “U.S. patentability standard of specific, substantial and credible utility is more lenient than the industrial applicability standard used by Vietnam and many other countries.”); PUBLIC CITIZEN TPP-MALAYSIAN LAW COMPARISON, *supra* note 12 (pointing out that TPP art. 8.12 seeks to “impose the U.S. patentability test . . . [which is] broad enough to cover inventions without true industrial application.”).

<sup>31</sup> The language is similar to KORUS art. 18.8.10(b).

<sup>32</sup> See UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICE GUIDE TO THE TRIPS AGREEMENT, 361 (2005).

post-TRIPS trade agenda on pharmaceutical policy.<sup>33</sup> As part of the May 10<sup>th</sup> 2007 New Trade Deal, implemented in the Peru FTA, patent term extensions for any reason were made optional rather than mandatory. The Peru FTA allowed both countries to exempt pharmaceutical products from patent extension requirements. The U.S. TPP-2 proposal would require patent extensions for unreasonable delays in product registration or issuance of a patent without the May 10<sup>th</sup> exemption, thereby punishing patients for bureaucratic delays.

The TPP proposal is KORUS-plus. TPP-2 art. 8.6 requires an increase in patent terms beyond 20 years to compensate for “unreasonable” delay in the granting of a patent, defined as a delay of more than four years from the date of filing of the application – the same as KORUS – or two years after a request for examination – one year less than KORUS.<sup>34</sup> This requirement is broadly consistent with U.S. law, which has a three-year window.<sup>35</sup> In addition, TPP-2 art. 8.6 requires additional term extensions for regulatory delays in approving marketing of pharmaceutical products, including for patents that merely cover a new method of making or using a pharmaceutical product. As in other areas of TPP, although patent term extensions are mandatory, the limitation of patent term extensions, e.g. to a maximum of no more than five years and no more than one extension (both attributes of current U.S. law<sup>36</sup>) are permissive.<sup>37</sup>

The so-called Access Window features of TPP-2 art. 8.6(e) is subject to art. 9.2(b) or (d), which will be discussed further below.

The predictable impact of patent term extensions is to lengthen monopolies and thereby raise the medicines bill for member countries. Moreover, the time pressure of early patent examination and early marketing approval might result in over-extended patent offices granting invalid patents and in hurried, drug regulatory registering unsafe or inefficacious medicines. This is especially a problem as the international volume of pharmaceutical patent applications and marketing approval applications grows overwhelming countries, especially developing countries, with weak regulatory capacity.

## **B. TPP-2 Art. 9.2 – Expanded Data Exclusivity**

TPP-2 art. 9.2 requires data exclusivity, a very strict form of data protection that is in excess of TRIPS requirements and negates the pro-development flexibilities of the 2007 New Trade Deal. The U.S. proposal on data exclusivity is a “TRIPS-plus provision that restricts access to essential clinical trial data . . . [and] prevent[s] generic manufacturers from using existing clinical research to gain regulatory approval of their medicines, forcing them to perform duplicate clinical trials or wait for the ‘data monopoly’ period to end.”<sup>38</sup> In essence, data exclusivity prevents a drug regulatory agency from referencing regulatory data submitted by a prior registrant and from relying on the fact of prior registration

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<sup>33</sup> See UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM – MINORITY STAFF SPECIAL INVESTIGATIONS DIVISION, TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION (June 2005).

<sup>34</sup> KORUS art. 18.8.6.

<sup>35</sup> If the USPTO fails to issue a patent within three years from the actual U.S. filing date, it must extend the patent term one day for each day beyond the three-year period. 35 U.S.C. §154(b)(1)(B).

<sup>36</sup> See 35 U.S.C. §156. The period of restoration extends from the original expiration date of the patent; however, the total patent term, with restoration, following FDA market approval may not exceed fourteen years. §156(c)(3).

<sup>37</sup> TPP-2 art. 8.6(d) (permitting regulatory-delay patent term extensions to be limited to a single adjustment for each new pharmaceutical product and for the basis of the adjustment to be the first marketing approval granted to a new pharmaceutical product).

<sup>38</sup> MSF Campaign for Access to Essential Medicines, TPP ISSUE BRIEF (September 2011), available at <http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf>.

anywhere else. Introducing data exclusivity threatens the registration of generic versions of medicines and creates a system conducive to creating monopolies

Data exclusivity is not required by TRIPS. In fact, during the negotiation of TRIPS Art. 39.3, the U.S. proposal that TRIPS incorporate a data exclusivity standard was flatly rejected by the negotiating parties. Instead, TRIPS Art. 39.3 merely requires protection against the “unfair commercial use” of “undisclosed” data that was required to be submitted in order to obtain marketing approval of a “new chemical entity.”<sup>39</sup> TPP-2 art. 9.2(a) and (b), patterned on KORUS art. 18.9.1, abandons the inherent flexibilities in TRIPS Art. 39.3 and imposes U.S.-style data monopolies.

- Rather than banning only the unfair commercial use of information, which could allow for registration authorities to use registration-related information to grant marketing approval of generic drugs, the TPP-2 data exclusivity proposal bans reference and reliance registration of any new product “based on” safety and efficacy information submitted to it or to another country for an originator product.<sup>40</sup>
- The TPP-2 data exclusivity provision abandons the TRIPS provision that protection is only required for “undisclosed” information and now requires protection for all data whether previously disclosed or not. Often clinical trial data is made public in various ways, including by funders, registration authorities, and academic publication. Thus, TPP-2 would require granting of exclusive rights for information that is already in the public domain and is in no sense a trade secret.
- The TPP-2 data exclusivity proposal also abandons the TRIPS rule that requires protection only for “new chemical entities” and instead requires protection of new pharmaceutical product that might incorporate existing chemical entities.
- In addition, TPP-2 art. 9.2(c) and (d) both require an additional three-year term of exclusivity for data submitted for approval of a new use or form of a previously approved chemical entity.<sup>41</sup> Moreover, as in U.S. law, there can be successive three-year data exclusivity extensions, meaning that data exclusivity, like patents, can be evergreened.

The U.S. TPP-2 data exclusivity proposal expressly abandons data-exclusivity flexibilities adopted in the 2007 New Trade Policy and thereafter granted to Peru and Columbia in their FTAs with the U.S. Like TRIPS Art. 39.3, the Peru and Columbia FTAs’ data exclusivity provisions were limited to new chemical entities. Contrary to U.S. law imposing strict exclusivity periods and the TPP-2 draft which requires “at least” five years of exclusivity, the Peru and Columbia FTAs required data exclusivity for an undefined “reasonable period.” The Peru and Columbia FTAs also included a use-or-lose it restriction on data exclusivity whereby if a Party relied on marketing approval granted by the U.S. Food and Drug Administration and if the Party granted approval within six months of an

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<sup>39</sup> See Carlos Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES (2006) (explaining that, under TRIPS, the reliance on prior reviewed data by a regulation authority to approve a generic version of the same drug need not be considered a “commercial use” of the data); Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity And Patent/Registration Linkage*, 34 AM. J. LAW & MEDICINE 303-44(2008).

<sup>40</sup> See TPP-2 art. 9.2(b) (stipulating that the drug regulatory authority may neither reference previously submitted clinical trial data nor rely on evidence that the product was previously approved either domestically or in another territory).

<sup>41</sup> See also KORUS art. 18.9.2.

application for marketing approval, the five-year data exclusivity period began when the drug was first approved in the U.S.<sup>42</sup> Finally, the Peru and Columbia data exclusivity provisions provided for an express public health exception to data exclusivity allowing reference or reliance registration when either a compulsory licensing had been issued on the underlying patent(s) or even when there was no patent(s) if public health needs so required. All of these data exclusivity flexibilities are missing from the U.S. TPP-2 proposal.

Commentators are virtually unanimous in concluding that data exclusivity is not required by TRIPS art. 39.3.<sup>43</sup> Moreover, commentators express alarm that the adoption of data exclusivity would require a generic producer to reproduce clinical trial evidence in order to obtain marketing approval during the period of exclusivity. Not only would such evidence be duplicative, costly, and time-consuming, its collection would violate human subject protections in clinical trials, as trial participants would be required to submit to double-blind clinical trials even though evidence of efficacy and safety had been previously established.

### **C. TPP-2 Art. [X] and Art. 9.3 – Mere Reference to the Doha Declaration, Public Health Protections**

The U.S. proposal mentions the Doha Declaration on the TRIPS Agreement and Public Health in TPP-2 Article [X] and Article 9.3. But the provisions fail to protect the core of the Doha Declaration's object – ensuring that all WTO members remain free to exercise “to the full” TRIPS flexibilities that promote access to affordable medicines for all. Notably, the provisions fail to incorporate the public health exceptions to data exclusivity and patent/registration linkage from the 2007 New Trade Policy.

#### **1. TPP-2 Art. [x].1**

Article [X].1 starts with the now standard affirmance of the Parties' prior commitment to the Doha Declaration. Although it is boilerplate to acknowledge a unanimous WTO commitment made over ten years ago, and although acknowledgement is superior to exclusion or rejection, the boilerplate does not make up for an absence of specific clarifying commitments about how countries can operationalize Doha to overcome the many TRIPS-plus provisions in the TPP and TPP-2 proposals.

#### **2. TPP-2 Art. [x].2**

Article [X].2 articulates Doha-related “understandings.” Subsection (a) states that “The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.”<sup>44</sup> This statement has at least two problems.

First, it is important that any affirmation of the Doha Declaration not be limited to certain infectious disease epidemics and to a narrow subset of public health needs that can be classified as matters of extreme urgency or national emergency. The burden of non-communicable chronic diseases (NCDs) is escalating throughout the world, particularly in

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<sup>42</sup> U.S.-Colombia FTA, *supra* note 6, art. 16.10.2(c); U.S.-Peru TPA, art. 16.10.2(c). This early filing requirement applied only if Peru or Columbia granted marketing approval based in whole or in part on evidence of marketing approval in the U.S.

<sup>43</sup> See *e.g.* note 39, *supra* and sources cited.

<sup>44</sup> TPP-2 art. [X].2(a) (noting that subsection (a) ends with Doha-consistent boilerplate that the “[c]hapter can and should be interpreted and implemented in a manner supportive of each Party’s right to protect public health and, in particular, to promote access to medicines for all.”).

low- and middle-income countries<sup>45</sup> where the cost of many chronic disease medicines, including those for cancers, psychiatric illnesses and other illnesses is too expensive for individual patients, insurers, and governments.<sup>46</sup> Likewise, many developing countries face a persistent crisis with respect to neglected tropical diseases<sup>47</sup> where newer, more expensive medicines might again be priced at unaffordable levels. The U.S.'s intent to purposefully exclude non-infectious chronic disease can be inferred from its efforts at the UN High Level Meeting on NCDs to ensure that they were not described as an "epidemic" nor as an "emergency" and that no mention of IP flexibilities the Doha Declaration appeared in the meeting's outcome.<sup>48</sup>

Second, the affirmation that the U.S. TPP proposals "do not" prevent a Party from taking measures to promote access to medicines may set a dangerous precedent for the interpretation of the Doha Declaration. As described throughout this note, there are numerous TRIPS-plus standards in the TPP proposal that will predictably lead to higher prices and lower availability of pharmaceutical products, especially in developing countries.<sup>49</sup> Implicitly defining these standards as compliant with the Doha Declaration significantly limits the express statement in the Declaration that TRIPS flexibilities can and should be available "to the full." Doha should be read to prevent the proposal or adoption of any TRIPS-plus measure that may negatively impact public health and access to medicines for all.<sup>50</sup> A better provision fully embracing Doha would create an explicit and operational exception for any TPP provision on the basis that the member country concludes that the provision would impede access to affordable medicines or the promotion of public health objectives.

### **3. TPP-2 Art. [X].2(b)**

Article. [X].2(b) appears as an attempt to narrow the interpretation of TRIPS- and Doha-compliant compulsory licenses to the procedurally labyrinth contours of what the U.S. calls

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<sup>45</sup> World Health Organization, NON-COMMUNICABLE DISEASES: COUNTRY PROFILES 2011, *available at* [http://whqlibdoc.who.int/publications/2011/9789241502283\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241502283_eng.pdf).

<sup>46</sup> See e.g. Felicia Marie Knaul, Julio Frenk & Lawrence Shulman for the Global Task Force on Expanded Access to Cancer Care and Control in Developing Countries, CLOSING THE CANCER DIVIDE: A BLUEPRINT TO EXPAND ACCESS IN LOW AND MIDDLE INCOME COUNTRIES, Section 7 (2011), *available at* [http://ghsm.hms.harvard.edu/uploads/pdf/ccd\\_report\\_111027.pdf](http://ghsm.hms.harvard.edu/uploads/pdf/ccd_report_111027.pdf).

<sup>47</sup> World Health Organization, WORKING TO OVERCOME THE GLOBAL IMPACT OF NEGLECTED TROPICAL DISEASES, UPDATE 2011, *available at* [http://www.who.int/neglected\\_diseases/2010report/WHO\\_NTD\\_report\\_update\\_2011.pdf](http://www.who.int/neglected_diseases/2010report/WHO_NTD_report_update_2011.pdf).

<sup>48</sup> William New, *Questions Arise over UN Policy on Non-Communicable Diseases and IP Rights*, IP-WATCH (Sept. 16, 2011), *available at* <http://www.ip-watch.org/weblog/2011/09/16/questions-arise-over-un-policy-on-non-communicable-diseases-and-ip-rights/>. These efforts were ultimately successful, though there were two references to countries' need to use intellectual property flexibilities to access NCD medicines. See, *Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases*, A/66/L1 (Sept. 19-20, 2011), *available at* <http://www.un.org/en/ga/ncdmeeting2011/>.

<sup>49</sup> Chief among them may be: (1) lowered patent standards, presumptions of valid patent status, and express obligations to grant patents for new uses and new forms of existing products, (2) elimination of rights of pre-grant opposition, (3) extension of patent terms beyond the TRIPS requirement of 20 years to compensate for delays in granting patents and/or in granting marketing approval, (4) five-year data exclusivity following the first registration of a new pharmaceutical product with rights to evergreen data exclusivity for an additional three years whenever new clinical trial data is submitted, (5) mandatory patent/registration linkage giving patent holders a right to prevent registration of alleged patent infringing products no matter how weak the patent claim is, (6) unconscionable restrictions on government price control and therapeutic formulary policies, and (7) multiple TRIPS-plus enforcement measures.

<sup>50</sup> TRIPS flexibilities thus include, for example, the adoption of strict patentability criteria under TRIPS Art. 27, the avoidance of patent extensions beyond 20 years in implementing TRIPS art. 33, the avoidance of data exclusivity in the implementation of TRIPS art. 39.3, and the avoidance of any other TRIPS-plus protection or enforcement measure that will increase market power of brand name pharmaceutical companies.

the “TRIPS/Health solution.” The TRIPS/Health solution is a current waiver and a proposal to amend the TRIPS agreement to allow export/import of medicines produced under special compulsory licenses to a country with little or no manufacturing capacity.<sup>51</sup> The proposed TRIPS art. 31bis amendment on export licenses should not be called a “solution” to anything – it is labyrinth and virtually unworkable.<sup>52</sup> It has been used only once, as a trial run between two countries that have not used it again.<sup>53</sup> There is no evidence that the proposed TRIPS amendment will in fact promote global access to medicines, a fact articulated by Ecuador at the most recent TRIPS council meeting.<sup>54</sup> Countries should maintain flexibilities to explore other options for meeting the particular challenges of supplying non-producing countries, including: (1) export of unlimited quantities through compulsory licenses issued on competition grounds (TRIPS Art. 31(k); (2) exporting non-predominant quantities pursuant to an ordinary TRIPS Art. 31 license; or (3) export to non-producing countries through an easy-to-use TRIPS Art. 30 limited exception.<sup>55</sup>

#### **4. TPP-2 Art. 9.3**

TPP-2 Art. 9.3, which deals with “measures relating to certain regulated products,” and more particularly with U.S. proposals for data exclusivity and patent-registration linkage, also contains boilerplate references to the Doha Declaration.<sup>56</sup> The 2007 New Trade Policy, which led to revisions in the U.S.-Peru and U.S.-Columbia free trade agreements, provided express guidance on how to operationalize a text-based public health exception to data exclusivity and patent/registration linkage which is lacking from the current proposal. Specifically, TPP art. 9.3 fails to provide for rights to override data exclusivity and patent/registration linkage either (1) to ensure rights to obtain marketing approval when a compulsory license or government use license is issued or (2) to have a compulsory-license-like exception to data exclusivity and patent/registration linkage even if no patent bar is in place.

#### **D. TPP-2 Art. 9.5 – Mandatory Adoption of Patent/Registration Linkage**

TPP-2 art. 9.5 contains a TRIPS-plus proposal on what is called patent/registration linkage. Although patent/registration linkage is not mentioned in TRIPS and is not required in many countries, including most TPP negotiating countries,<sup>57</sup> it has become a common and

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<sup>51</sup> Paragraph 6 of the Doha Declaration required the development of a quick and expeditious mechanism allowing export/import of medicines to countries that had insufficient pharmaceutical capacity locally to either produce medicines that were not patented or those authorized pursuant to a properly issued compulsory license or government use order. Article 31(f) of the TRIPS Agreement had created a major barrier for these non-producing importers because it restricted the quantity of medicines produced pursuant to a compulsory license that could be exported to other countries to “non-predominant” amounts, presumably less than 50% of output. Unfortunately, the TRIPS/Health solution that was adopted on 30 August 2003 is painfully complex. See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L 317 (2005).

<sup>52</sup> Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT’L & COMP. L. REV. 613-715 (2004).

<sup>53</sup> The TRIPS/Health Solution has only been used once in eight years by a generic company, Apotex, that says it will never use it again unless the procedures are simplified. See Goldis Chami and Samuel Wasswa-Kintu, *Compulsory licensing of generic drugs remains mired in quagmires*, 183 CAN. MED. ASS’N J. E705-706 (2011).

<sup>54</sup> See TWN, *Review of “Para 6” system, ACTA feature at TRIPS Council*, SUNS #7252 (2 November 2011), available at [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/2011/ipr.info.111101.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/2011/ipr.info.111101.htm).

<sup>55</sup> Baker, *supra* note 52.

<sup>56</sup> See TPP-2 art. 9.3 (reiterating that “a Party may take measures to protect public health in accordance with” the Doha Declaration, any current waiver (including presumably the TRIPS/Health solution) and any eventual amendment based on implementing the Doha Declaration (presumably referring indirectly to proposed amended Art. 31bis).

<sup>57</sup> See PUBLIC CITIZEN & HEALTH GAP, *supra* note 9 (explaining that “Vietnamese law contains no provision that

contested feature of U.S. free trade agreements.<sup>58</sup> Linking marketing approval to patent status gives patent owners a powerful and cost-effective tool to block generic entry. Any company claiming a patent on a drug may halt the regulatory approval of a competing product without any private enforcement action and without a determination as to the validity of the underlying patent claim. This provides strong incentives for the filing of numerous, even if weak or invalid, patent claims, which can then be used to halt marketing approval of potential competitors through the linkage system. Generics will then be required to wait until the completion of a patent challenge (for each patent claim) in order to reach the market, which may take many years. The costs of litigation and delay may so high as to provide an effective deterrent to generic companies entering the market via patent challenges – even where underlying patents are patently invalid.

TPP-2 goes even further than KORUS in specifying linkage requirements. TPP-2 proposes that members be required to provide: (1) a transparent and effective mechanism to identify patent(s) covering an approved pharmaceutical product or its approved method of use; (2) notice to a patent holder of the identity of another person who intends to market the same or "similar" products during the term of the identified patent or patents; (3) automatic stays of marketing approval activity for the follow-on product sufficient to allow an opportunity to adjudicate disputes concerning patent validity or infringement; (4) expeditious judicial or administrative procedures to allow timely adjudication of patent disputes, including rights to issue provisional orders; and (5) for the denial of registration for infringing products for the duration of the patent. On the other hand, consistent with U.S. law, where a challenged party successfully challenges the validity or applicability of the patent, it is required to be provided with an effective reward, which might include a period of marketing exclusivity.

Patent/registration linkage turns drug regulatory authorities into patent policing agents who aid patent holders in the enforcement of their private rights. Moreover, automatic stays can be abusive. In response to the experience of the use of linkage to evergreen patents through the filing of subsequent (often invalid) claims to halt generic entry, U.S. law now limits patent holders to one automatic stay to litigate any patent claims.<sup>59</sup> Furthermore, there are still concerns that strict forms of patent/registration linkage might interfere with effective use of compulsory licenses. This is because licensees could be prevented from marketing their generic equivalents after receiving a license on some patent claims by virtue of subsequent claims being filed on the same product.

#### **E. TPP-2 Arts. 9.4, 9.6, 9.7, and 9.8 – TEAM Access Window Mainly Benefits Innovator Registration**

Well before the new leak of TPP-2, the U.S. released a memo on its Trade-Enhancing Access to Medicines proposal (TEAM Access Window).<sup>60</sup> The memo stated that the Access

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links the patent system to the drug marketing approval process” and that many U.S. FTAs require patent linkage which “shifts burdens of early patent enforcement to drug regulatory authorities.”); *see also* PUBLIC CITIZEN TPP-MALAYSIAN LAW COMPARISON, *supra* note 9 (noting that “Malaysian law contains no provision that links the patent system to marketing approval process.”); *cf.* PUBLIC CITIZEN TPP-AUSTRALIAN LAW COMPARISON, *supra* note 9 (explaining that although “AUSFTA introduced patent linkage in Australia, Australia sought to limit its effect through statutory measures imposing penalties for linkage evergreening” and subsequently, the USTR attacked these safeguards and therefore, the TPP proposal “raises a serious concern that the [U.S.] may seek to limit or eliminate Australian safeguards.”).

<sup>58</sup> *See* KORUS art. 18.9.5.

<sup>59</sup> 21 U.S.C. 355(j)(2) and (5).

<sup>60</sup> *See Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, USTR, available at [http://www.ustr.gov/webfm\\_send/3059](http://www.ustr.gov/webfm_send/3059).

Window was “designed to deploy the tools of trade policy to promote trade in, and reduce obstacles to, access to both innovative and generic medicines, while supporting the innovation and intellectual property protection that is vital to developing new medicines and achieving other medical breakthroughs.” The memo immediately became the subject of criticism for both its obscuration of substance and its non-transparent process by public health advocates.<sup>61</sup> Now that the actual text of the Access Window has been leaked, it is clear that its main impact will be to potentially ease registration for innovators with no real benefit for access to generics.

As discussed above, the general rule under TPP-2 is that members must grant patent extension for regulatory delays, 5/3-year data exclusivity, and patent/registration linkage. These requirements will apply to the vast majority of marketing requests where the Access Window does not apply either because a country has not changed its law to utilize Access Window provisions (see discussion below) or because the marketing-approval applicant has chosen not to utilize the Access Window mechanism<sup>62</sup>.

The U.S. Access Window provides countries with the option of having marketing approval procedures that rely in whole or in part on the fact of marketing approval/registration in another country.<sup>63</sup> If countries have such a fast-track, reliance mechanisms, they can limit patent term extensions related to regulatory delays (not patenting delays),<sup>64</sup> data protection, and patent/registration linkage for applicants who use the reliance mechanism to applicants who file reliance-applications within a yet to be specified number of years – the access window.<sup>65</sup> If the reliance registrant delays filing a reliance-application until after the access window, the applicant loses rights to these three, TRIPS-plus, registration-related IP benefits.

It is important to remember that the applicant would always have the option to apply for marketing approval by submitting a full registration dossier that does not rely in whole or in part on the fact or prior registration elsewhere. The silver lining for pharmaceutical companies, even where the Access Window does apply, is contained in Article 9.8(a), which requires the TPP country to allow initiation of marketing registration in that country based on any information available to the applicant, including “evidence of prior approval of the product in another Party [country].” This easy-to-meet standard makes it easier to file early for marketing approval, but it does not necessarily ensure quicker final approval of drugs. More importantly, speedier registration will not necessarily result in lower prices – generics will still have to wait until patent terms and/or data exclusivity periods expire.

Pharmaceutical companies have long chafed over the lack of harmonization of drug regulatory authorities' marketing approval requirements, standards, and processes. The

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<sup>61</sup> <http://www.citizenstrade.org/ctc/blog/2011/10/22/leaked-trans-pacific-fta-texts-reveal-u-s-undermining-access-to-medicine/>

<sup>62</sup> TPP-2 art. 9.8(b) confirms that “a Party may not refuse to grant approval of a new pharmaceutical product on the basis of a failure of an applicant for marketing approval to satisfy the [Access Window] requirements of subparagraphs 6(e) of Article 8 or paragraph 4 and 6 of this Article.”

<sup>63</sup> See TPP-2 arts. 9.4, 9.6, 8-6(e) (noting that countries are not required to create the TEAM Access Window, but they “may” do so in a narrow subset of cases - where the party “requires or permits an applicant to obtain approval for marketing a new pharmaceutical product in its territory by relying, in whole or in part, on the prior approval of the pharmaceutical product by the regulatory authority in another county.”).

<sup>64</sup> See TPP-2 art. 8.6(e) (applying Access Window restrictions only with respect to art. 8.6(c) extensions – those caused by unreasonable delays in the marketing approval process).

<sup>65</sup> See TPP-2 FN 2 (claiming that the length of the TEAM Access Window should enhance certainty, provide incentive for the diffusion of pharmaceutical products, respect commercial consideration, and account for challenges faced by smaller or lesser experienced applicants or the time needed to assess country-specific safety and efficacy issues).

multinational pharmaceutical industry would like a registration process that is very like what is provided by the WIPO Patent Cooperation Treaty, an easy-to-use, standardized mechanism to initiate marketing approval applications before national drug regulatory authorities. Indeed, there is a separate annex on pharmaceutical regulatory harmonization in the US TPP proposals.<sup>66</sup> Article 9.8(a) provides the industry with the easy-to-use, fast-track mechanism it has desired. Moreover, pharmaceutical companies can even choose which information and format they want to submit as applicants do not have to submit complete dossiers in order to cross the start-line for the Access Window.<sup>67</sup>

Based on having satisfied minimal Access-Window information and timing prerequisites, right-holders will potentially be entitled to multi-year patent-term extensions for marketing approval delays, to successive data exclusivity periods that will run from the time final marketing approval (not from the time of the simplified initiation of the registration request), and patent-registration linkage -- all without benefit of the flexibilities called for in the 2007 New Trade Deal.

TPP-2 art. 9.7 contains another new-to-U.S. FTAs provision encouraging even longer periods of data exclusivity. The provision states that parties would be exempted from the three-year data protection terms for submission of new clinical information, automatic delays of marketing approval in their patent/registration linkage mechanisms, and rewards for successful challenges to patent rights if they adopt periods of data exclusivity for new pharmaceutical products for an undefined duration (“Y”) in excess of five years. If pharmaceutical companies can get substantially longer data exclusivity, especially if it contains mechanisms for evergreening exclusivity such as that involving biologics, they won’t have to rely on patent protections to obtain marketing monopolies. Data monopolies of sufficient length will be superior to patents from the perspective of pharmaceutical firms because data monopolies give the same or higher level of monopoly protection without the need and expenses of proving that a product meets the relatively high standards for patentability.

Admittedly, there is some potential benefit to countries that want to provide inducements to pharmaceutical companies to bring their new medicines to market more quickly. To the extent that differential registration standards and processes have disincentivized innovators from quickly launching new products, simplification might speed up market entry. However, pharmaceutical companies should be motivated to introduce new life-saving medicines more quickly in developing country markets without gaining new

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<sup>66</sup> See Trans-Pacific Partnership, U.S. Introduction to Proposed TBT Annexes on Medical Devices, Pharmaceutical Products and Cosmetic Products [hereinafter TPP U.S. Intro to TBT Annexes], available at [http://www.bilaterals.org/IMG/pdf\\_TransPacificTBTwMedicalAnnexes.pdf](http://www.bilaterals.org/IMG/pdf_TransPacificTBTwMedicalAnnexes.pdf) (extending the industry’s intentions and interests); Trans-Pacific Partnership, U.S. Textual Proposal for the TBT Chapter: Annex on Pharmaceutical Products, Annex IV [hereinafter TPP Annex IV], available at [http://www.bilaterals.org/IMG/pdf\\_TransPacificTBTwMedicalAnnexes.pdf](http://www.bilaterals.org/IMG/pdf_TransPacificTBTwMedicalAnnexes.pdf) (noting that in paras. 8 and 9, the U.S. seeks TPP partners’ agreement to use the ICD Common Technical Document as the standardized harmonized form to initiate marketing approval requests.)

<sup>67</sup> TPP-2 article 9-8 (providing that “[w]here a party chooses to apply subparagraph 6(e) of Article 8 and paragraphs 4 and 6 of this Article [Article 9], the following provisions shall apply: (a) a Party shall permit an applicant to commence the process of obtaining marketing approval by providing the regulatory authority of the Party information supporting approval of the new pharmaceutical product in the Party **that is available to the person at the time the request is made**, such as evidence of the prior approval of the product in another Party. It is understood, that, while a Party may impose reasonable additional requirements or deadlines as a condition of authorizing the person to market to market the pharmaceutical product in its territory, satisfaction of those additional requirements or deadlines or the granting of approval shall be recognized by the Party as necessarily occurring after the commencement of the marketing approval process within the meaning of subparagraph 6(e) of Article 8 or paragraphs 4 and 6 of this Article.”) (emphasis added).

data-related monopolies and patent term extensions. Drug regulatory systems should be made more transparent, efficient, and even harmonized, but only so long as high, country-specific standards for assuring quality, safety, and efficacy are maintained. The desirability of earlier product introduction should have nothing to do with a trade off involving greater IP protections that extend and strengthen drug company patent and data-related monopolies. The Access Window is promoted as benefitting TPP parties, but it is clear that the true beneficiaries are innovator companies.<sup>68</sup>

#### 4. CONCLUSION

The U.S. IP proposals in TPP negotiations pose unprecedented threats to access to affordable medicines. There is a crisis looming with respect to the affordability of second- and third-generation AIDS medicines at the same time that new science shows that we must greatly expand treatment in order to reap the benefit both of saved and extended lives and of a 96% reduction in the risk of transmission.<sup>69</sup> Twenty-seven million people living with HIV remain untreated and face the risk of more expensive medicines at the very time that donor resources for global AIDS are stagnating and even falling.<sup>70</sup> Although earlier investments in expanded treatment access are ultimately cost-saving,<sup>71</sup> we face unprecedented risks as the Global Fund cancels new funding rounds in the face of donors' failure to honor funding commitments.<sup>72</sup> Yet the threat of the U.S.'s TPP proposals is not merely to HIV/AIDS and the success of the U.S.'s own PEPFAR program – there is an equal threat to the affordability of medicines for other infectious diseases, for non-communicable, chronic diseases, and for neglected tropical diseases. In the case of IP, more is less – stronger, deeper, and broader patent and data monopolies may make more profits for Big Pharma but the cost to poor patients is failed prevention, increased illness, and ultimately death. The IP maximalist proposals that the U.S. has put forward for the TPPA must be rejected at all costs.

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<sup>68</sup> The problem is not simply making a big deal out of very minor process, the Access Window provisions are also likely to result in pressure from the US and Big Pharma for what is essentially a harmonized global registration system, such as those proposed in the Proposed TBT Chapter Annex on Pharmaceutical Products. We can now see that US is arguing with trade partners that they should vicariously grant registration in their countries based on prior marketing approval by drug regulators in the US, Europe, or Japan. If countries are tempted to adopt full-scale reliance registration, there is a risk that they will have reduced ability to assess medicines in light of the particular patient risks and benefits in their country. Although reliance registration may have certain advantages for countries with weak regulatory authorities and although lack of procedural harmonization adversely impacts both innovator companies and generics, countries are being asked to give up far too much TRIPS-plus territory for a quick-registration Access Window that doesn't require fast completion and prosecution of registration applications and that results in greater and longer monopoly protections that will inevitably lead to higher prices and reduced generic competition.

<sup>69</sup> Cohen MS, Chen YQ, McCauley M, et al., *Prevention of HIV-1 infection with early antiretroviral therapy*, 365 N.E.J. MED. 493-505 (2011), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1105243>.

<sup>70</sup> Jennifer Kates et al., FINANCING THE RESPONSE TO AIDS IN LOW- AND MIDDLE-INCOME COUNTRIES: INTERNATIONAL ASSISTANCE FOR DONOR COUNTRIES IN 2010 (Kaiser 2011), available at <http://www.kff.org/hiv/aids/upload/7347-07.pdf>.

<sup>71</sup> Jan A.C. Hontelez et al., *The Impact of the New WHO Antiretroviral Treatment Guidelines on HIV Epidemic Dynamics and Cost in South Africa*, 6 PLoS ONE e21919 (July 2011), available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0021919>.

<sup>72</sup> Aidspan, Board Cancels Round 11 and Introduces Tough New Rules for Grant Renewals, 167 GLOBAL FUND OBSERVER (Nov. 23, 2011), available at <http://www.aidspan.org/index.php?issue=167&article=1>.