THE EFFECTS OF TRIPS-PLUS IP PROVISIONS ON ACCESS TO AFFORDABLE MEDICINES

Summary

This memo compiles a preliminary and non-exhaustive collection of analyses, reports and statements made by international experts, academics, international organizations and other stakeholders that demonstrate or project the impact TRIPS-plus intellectual property (IP) obligations have had or could have on access to affordable medicines. It provides examples of provisions such as secondary patents, data exclusivity and patent linkage – all under consideration in the Trans-Pacific Partnership (TPP) negotiations – that threaten to raise the cost of medicines.

These resources address the effects of TRIPS-plus provisions on any country. Resources were collected by requesting recommendations through listserves or from experts and stakeholders working on IP and access to medicines and through supplemental Google Scholar searches. Abstracts or excerpts were reviewed to determine the resources' relevance to this memo.

This memo begins with a summary of analyses of the projected effects of the TPP on access to medicines if adopted in its current proposed form. To date, at least four studies have assessed the impact the TPP is projected to have on access to medicines.

TRIPS-plus provisions have already been implemented by some countries. This memo compiles 12 studies or reports that have documented the effects of TRIPS-plus provisions restricting access to medicines and raising prices using case studies and empirical evidence. An additional 12 studies or reports provide projections or analyses of TRIPS-plus provisions' expected effects for access to medicines.

The second half of this memo summarizes the views of experts, public officials and health agencies. These include 24 public statements, reports or opinions by international institutions, experts and other stakeholders, 16 of which specifically warn of the TPP's effects on access to medicines, and an additional 25 letters or statements issued by several dozen U.S. Members of Congress in support of protections of access to medicines in the TPP.

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PART 1 - Publications

1.1: Analyses of the projected effects of the TPP on access to medicines

1. Gleeson D, Moir H, Lopert R. Costs to Australian taxpayers of pharmaceutical monopolies and proposals to extend them in the Trans Pacific Partnership Agreement [Online] Medical Journal of Australia, 2015; 202(6): 306-308 [Cited 2015 June 8]. Available from: https://www.mja.com.au/journal/2015/202/6/costs-australian-taxpayers-pharmaceutical-monopolies-and-proposals-extend-them.

Excerpt: "Data from the 2013 Pharmaceutical Patents Review, and from various submissions made to it, show that pharmaceutical monopoly protections already cost Australian taxpayers hundreds of millions of dollars each year. Provisions still being considered for the TPPA would further entrench and extend costly monopolies, with serious implications for the budget bottom line and the sustainability of the Pharmaceutical Benefits Scheme."

2. Gleeson D, Lopert R, Moir H. Proposals for extending data protection for biologics in the TPPA: Potential consequences for Australia [Online]. Submission to the Department of Foreign Affairs and Trade, 2014 December 15 [Cited 2015 June 8]. Available from: http://dfat.gov.au/trade/agreements/tpp/submissions/Documents/tpp_sub_gleeson_lopert_moir.pdf.

Excerpt: "Extending data protection for biologic drugs – even to eight years – could cost Australian taxpayers many hundreds of million dollars each year. If biosimilars had entered the market prior to July 2013 for each of the ten biologics accounting for the highest government expenditure, this would have resulted in over $205 million in savings through public subsidies alone in the year 2013-14. This figure illustrates the magnitude of the annual costs that would result for taxpayers from prolonging monopolies on biologic medicines. Once biosimilars have been listed on the PBS, all versions of the drug are subject to additional price reductions through price disclosure, which result in further savings over time. Not only should the TPPA text not distinguish between biologics and other pharmaceutical products, there should be no extension to test data protection agreed for any products. In both the US and Australia independent reviewers have concluded that there is no evidence to support such a change in policy. Unnecessary costs are inconsistent with government objectives to ensure sustainability of the PBS and to moderate growth in healthcare spending, and inconsistent with National Medicines Policy."

3. Moir H, Tenni B, Gleeson D, Lopert R. Assessing the Impact of Alternative Patent Systems on the Cost of Health Care: The TPPA and HIV Treatment in Vietnam. [Online] Asia-Pacific Innovation Conference, University of Technology Sydney, 2014 November 27-29 [Cited 2015 June 8]. Available from: http://ssrn.com/abstract=2536254.

Abstract: "In the Trans Pacific partnership Agreement (TPPA) negotiations, the United States has proposed expanded patent protections that will likely impact the affordability of medicines in TPPA partners. This includes antiretroviral (ARV) medicines used in the treatment of HIV/AIDS. Vietnam has the lowest GDP per capita of the 12 countries participating in the TPPA negotiations. Using the current Vietnamese patent regime as our base case, we analyse the potential impact of alternative patent regimes on access to ARVs in Vietnam. The two other scenarios investigated are a patent regime making full use of TRIPS flexibilities, and a regime based on the US proposals in the 2014 leaked draft of the TPPA intellectual property chapter. Using World Health Organization (WHO) treatment guidelines, we identified the most commonly used chemical entities and combinations used in the treatment of HIV. We examined patent data sets to discover patents that had been registered for these medicines and used information from examination of these patents to identify which might be granted under alternative patent

regimes. We then drew on the empirical literature to estimate prices under the three patent scenarios. The current ARV budget was used as a constraint, with the consequence that the results focus on the impact of alternative patent regimes on access to treatment. Our results indicate 82% of the HIV population eligible for treatment would receive ARVs under a full TRIPS flexibility scenario, while only 30% of Vietnam's eligible HIV patients would have access to ARVs under the US 2014 TPPA proposals – more than halving the proportion treated compared to the current 68% receiving treatment. Similar price impacts can be expected for other countries participating in the TPPA, though these are less economically vulnerable than Vietnam."

4. UNITAID. The Trans-Pacific Partnership Agreement: Implications for access to medicines and public health. [Online] 2014 March [Cited 2015 June 8]. Available from: http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf.

Excerpt: "In recent years, the number of bilateral and regional trade negotiations has been increasing. Many of these negotiations involve both developed and developing countries, and the ensuing free trade agreements often contain extensive provisions on the protection of intellectual property rights. These provisions usually impose a higher level of protection for intellectual property rights than is required under the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement. These so-called "TRIPS-plus" provisions delay generic market entry and competition. As such, they run counter to UNITAID's efforts to increase the affordability of, and access to, medicines and other medical products. ..

These concerns are particularly pertinent with regard to the negotiation of a Trans-Pacific Partnership Agreement, which has been positioned as a "model" for the 21st century—implying that the same or similar provisions are likely to appear in future trade agreements, including those involving developing countries…

The analysis in this report supports the view that the TPPA, if adopted, will have major implications for public health and access to medicines. The primary concern is that the implementation of the provisions proposed in the USA's TPPA proposal, as they currently stand, will restrict the adoption of policy options for developing countries to ensure that trade or commercial interests do not hinder the protection of health and human development."

1.2: Documented effects of TRIPS-plus provisions - many of which are also proposed in the TPP - on access to medicines

1. Abud M, Hall B, Helmers C. An empirical analysis of primary and secondary patents in Chile. [Online] PLOS ONE 2015; DOI: 10.1371/journal.pone.0124257 [Cited 2015 June 8]. Available from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0124257

Abstract: "We analyze the patent filing strategies of foreign pharmaceutical companies in Chile distinguishing between "primary" (active ingredient) and "secondary" patents (patents on modified compounds, formulations, dosages, particular medical uses, etc.). There is prior evidence that secondary patents are used by pharmaceutical originator companies in the U.S. and Europe to extend patent protection on drugs in length and breadth. Using a novel dataset that comprises all drugs registered in Chile between 1991 and 2010 as well as the corresponding patents and trademarks, we find evidence that foreign originator companies pursue similar strategies in Chile. We find a primary to secondary patents ratio of 1:4 at the drug-level, which is comparable to the available evidence for Europe; most secondary patents are filed over several years following the original primary patent and after the protected active ingredient has obtained market approval in Chile. This points toward effective patent term extensions through secondary patents. Secondary patents dominate "older" therapeutic classes like anti-ulcer and

anti-depressants. In contrast, newer areas like anti-virals and anti-neoplastics (anti-cancer) have a much larger share of primary patents."

2. Bouchard R. I'm Still Your Baby: Canada's Continuing Support of U.S. Linkage Regulations for Pharmaceuticals. [Online] Marquette Intellectual Property Law Review 2010; 15(1) [Cited 2015 June 8] Available from: http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1166&context=iplr

Excerpt: "The data in Studies 1, 2, and 3 demonstrate that, when analyzed in its "real world" context, the Canadian linkage regulations are not working either as intended by Parliament at the time the law was passed or in a manner that is consistent with the goals and objectives of the federal government as articulated in later RIAS documents. Private firms are obtaining extended patent protection for weakly inventive products, while at the same time generic competition is markedly delayed. The result is that pharmaceutical firms are reaping the rewards of intellectual property protection at historically high levels in this country while the public (and institutional payers) is being deprived of reasonably priced pharmaceuticals."

3. Médecins Sans Frontières. Untangling the Web of Antiretroviral Price Reductions. [Online] 2001-2014 [Cited 2015 June 8]. Available from: http://www.msfaccess.org/content/untangling-web-antiretroviral-price-reductions

Over more than 10 years, MSF has been monitoring and reporting the prices and availability of ARVs in developing countries through the Untangling the Web report, including documenting the impact that patents and regulatory strategies have on prices and access to price-lowering generic competition.

See for example, Untangling the Web of Antiretroviral Price Reductions, 14th edition, in which MSF reports that in Malaysia, where GSK has been granted numerous patents for ABC, including for the "salt form" and pediatric variations of the drug, the public sector paid more than US $1,200 per person, per year for pediatric ABC, more than 8 times the price of the generic version in other countries, which sells for as low as US $139 per person, per year, even after the original patents on the drug had expired.

4. Kapczynski A, Park C, Sampat B. Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents. [Online] PLOS ONE 2012; DOI: 10.1371/journal.pone.0049470 [Cited 2015 June 8]. Available from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470.

Abstract: "We read the claims of the 1304 Orange Book listed patents on all new molecular entities approved in the U.S. between 1988 and 2005, and coded the patents as including chemical compound claims (claims covering the active molecule itself) and/or one of several types of secondary claims. We distinguish between patents with any secondary claims, and those with only secondary claims and no chemical compound claims ("independent" secondary patents). We find that secondary claims are common in the pharmaceutical industry. We also show that independent secondary patents tend to be filed and issued later than chemical compound patents, and are also more likely to be filed after the drug is approved. When present, independent formulation patents add an average of 6.5 years of patent life (95% C.I.: 5.9 to 7.3 years), independent method of use patents add 7.4 years (95% C.I.: 6.4 to 8.4 years), and independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years (95% C.I.: 5.3 to 7.3 years). We also provide evidence that late-filed independent secondary patents are more common for higher sales drugs."

Excerpt: "Our data also reveal the stakes of the decision that developing countries must make about the permissible scope of patents. Although the World Trade Organization's Trade-Related Aspects of

Intellectual Property Agreement does require member countries to adopt patent protection for medicines, its requirements are general, and do not clearly require countries to permit secondary patents [21]. We can quantify the stakes of such decisions: If the future looks like the past (and the patent landscape in other countries like that in the U.S.) a conservative estimate is that eliminating secondary patents could free up 36% of new medicines for generic production, since only 64% of drugs in our sample had patents with chemical compound claims. Additionally, for those drugs that still come under patent because a chemical compound claim exists, exclusions on secondary patents could limit the duration of patent protection by 4–5 years. The converse is that this study reveals the very substantial implications of new trade agreements. Negotiations are now underway for a new 'Trans-Pacific Partnership' treaty, and the U.S. has apparently proposed barring exactly the kind of limits on secondary patents adopted by India, and under consideration by other countries."

5. Cortés Gamba M, Rossi Buenaventura F, Vásquez Serrano M. Impacto de 10 Años de Proteccion de Datos en Medicamentos en Colombia. [Online] IFARMA and Fundación Misión Salud; Bogotá D.C., Colombia, 2012 [Cited 2015 June 8]. Available from: http://www.mision-salud.org/wp-content/uploads/2013/02/IMPACTO-DE-10-A%C3%91OS-DE-PROTECCION-DE-DATOS-EN-COLOMBIA.pdf

In Spanish: An evaluation of the impact of ten years of implementation of data-exclusivity rules, from 2003-2011, found that they resulted in an increase of more than US $396 million in additional expenses for the public health system of Colombia.

6. Kesselheim A, Solomon D. Incentives for drug development: the curious case of colchicines. [Online] New England Journal of Medicine 2010; 362:2045-2047 [Cited 2015 June 8]. Available from: http://www.nejm.org/doi/full/10.1056/NEJMp1003126.

This article documents how the price of colchicine, a treatment used mainly for gout increased by more than 5000% in the US after data exclusivity was enacted. Colchicine has been in use for thousands of years, costs almost nothing to produce, and cannot be patented. Therefore, generic formulations of the tablet have been widely available since the 19th century. However, a new monopoly on colchicine was created in 2009 when the FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma. URL Pharma subsequently sued to force other manufacturers off the market, and raised prices from $0.09 to $4.85 per pill. The article also highlights the effects this could have on US healthcare costs: "according to the Centers for Medicare and Medicaid Services, state Medicaid programs filled about 100,000 prescriptions of colchicine in 2007 and paid approximately $1 million for the drug. Use of the new brand-name colchicine could add as much as $50 million per year to these insurance programs' budgets at a time when they are addressing the rising costs of health care by reducing some services or raising eligibility thresholds."

7. WTO. European Union and a Member State – Seizure of Generic Drugs in Transit. May 19, 2010, *and* Zarocostas J. Brazil and India file complaint against EU over seizure of generic drugs. BMJ 2010; 340:c2672.

These sources document how between 2008 and 2009 at least 19 shipments of legal generic medicines from generics producing countries such as India were wrongfully seized while in transit in Europe. The shipments were suspected of infringing trademark and patent rights in Europe, even though they were en route to destination countries where the products would not infringe any patent rights. For example, German customs authorities seized and detained for a month a shipment of generic amoxicillin, wrongfully believing that 'amoxicillin' infringed the brand name 'Amoxil.' It was later determined that there was no trademark infringement. In another case, Dutch customs authorities seized the HIV drug

abacavir sulfate as it was shipped from India to a donor-funded treatment program in Nigeria, resulting in a disruption in the supply chain of legal generic versions of lifesaving drugs.

8. Bouchard R, Hawkins R, Clark R, et al. Empirical analysis of drug approval: Drug patenting linkage for high value pharmaceuticals. [Online] Northwestern Journal of Technology and Intellectual Property 2010:8(2) [Cited 2015 June 8]. Available from: http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1102&context=njtip

This study finds that patent linkage extends protections on patented medicines. Excerpt: "The linkage regulation regime in particular has proven to be an excellent vehicle for firms to obtain extended legal protection on drugs at all stages of development, including drugs about to come off patent protection, drugs moving through the regulatory approval stage, and drugs that are currently in development."

9. Shaffer E, Brenner J. A trade agreement's impact on access to generic drugs. [Online] Health Affairs 2009; 28(5):w957-w968 [Cited 2015 June 8]. Available from: http://content.healthaffairs.org/content/28/5/w957.full.pdf+html.

This study finds that implementation of the Central American Free Trade Agreement's intellectual property rules reduced access to some generic drugs already on the market and delayed new entry of other generics in Guatemala. In some cases CAFTA rules kept some generic drugs from entering the market in Guatemala, even after they were available in the U.S. Once Guatemala enacted data exclusivity, some medicine prices rose as much as 846 percent.

10. Bouchard R, Sawani J, McLelland C, Sawicka M. The pas de deux of pharmaceutical Regulation and Innovation: Who's Leading Whom. [Online] Berkeley Technology Law Journal 2009; 24(4): 1461-1522 [Cited 2015 June 8]. Available from: http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1812&context=btlj

Abstract: "Global drug development and regulation is undergoing a substantial transition, including redefinition of the roles of public and private actors responsible for developing, regulating, and paying for therapeutic products. This shift has been accompanied by growing debate over the validity of the claim that an efficiently functioning global public health system requires acceptance of models of drug development that promote early access to therapeutic products in exchange for strong intellectual property rights. Without these rights, advocates claim pioneering drug development will not occur. Here, we challenge this view, arguing that recent regulatory efforts designed to encourage the development of new and innovative drugs through the provision of strong patent and 'linkage' rights, which legally tie drug patenting and drug approval, have in fact had the opposite effect. We provide data to suggest that the pharmaceutical industry is leaning away from the development of new drugs and towards incremental changes in existing drugs as a result of firms locking in to discrete rights targets provided for by law."

11. Malpani, R. All costs, no benefits: how the US-Jordan free trade agreement affects access to medicines. [Online] Journal of Generic Medicines 2009, 6(3): 206-217 [Cited 2015 June 10]. Available from: http://jgm.sagepub.com/content/6/3/206.short.

This report commissioned by Oxfam finds that the impacts of the TRIPS-plus provisions of the Jordan-US trade agreement have negatively affected access to medicines in Jordan in just the first five years following implementation. Medicine prices increased 20% and more than a quarter of the Ministry of Health's budget was spent on medicine. Data exclusivity has delayed the introduction of cheaper generic versions of 79% of medicines between 2002 and 2006. Prices of medicines under data exclusivity were up to 800% higher than in neighboring Egypt.

12. Kesselheim A, Fischer M, Avorn J. Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending. [Online] Health Affairs 2006; 25(6): 1637-1647 [Cited 2015 June 9]. Available from: http://content.healthaffairs.org/content/25/6/1637.full

Excerpt: "Rising prescription drug costs present a critical policy issue for Medicaid. Generic substitution can reduce costs, but the effects are undercut by extensions of intellectual property (IP) protection, elevated generic prices, and low substitution rates. Using Medicaid prescription data for amoxicillin/clavulanate, metformin, and omeprazole, we calculated the savings that could have been realized if generic drugs had been available and fully substituted at their lowest cost when IP protection first expired (an average delay of twenty-six months). The delay in availability, elevated prices, and slow uptake of generic alternatives for these three drugs alone cost Medicaid $1.5 billion in 2000–2004."

1.3: Additional projections and analyses of the effects or expected effects of TRIPS-plus provisions on access to medicines

1. US Office of Management and Budget. The President's Budget for Fiscal Year 2016. [Online] 2015 [Cited 2015 June 8]. Available from: https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf

President Obama's Budget for Fiscal Year 2016 estimates cost savings of $4.53 billion dollars between 2016 and 2025 just for US federal programs as a result of decreasing data exclusivity for biologics by five years in the United States (from 12 to 7 years).

2. Lexchin J, Gagnon M. CETA and pharmaceuticals: impact of the trade agreement between Europe and Canada on the costs of prescription drugs. [Online] Globalization and Health 2014; 10(30): doi:10.1186/1744-8603-10-30 [Cited 2015 June 8]. Available from: http://www.globalizationandhealth.com/content/10/1/30

Abstract: "On a per capita basis, Canadian drug costs are already the second highest in the world after the United States and are among the fastest rising in the Organization for Economic Co-Operation and Development. The Comprehensive Economic and Trade Agreement (CETA) between the European Union (EU) and Canada will further exacerbate the rise in costs by: Committing Canada to creating a new system of patent term restoration thereby delaying entry of generic medicines by up to two years; Locking in Canada's current term of data protection, and creating barriers for future governments wanting to reverse it; Implementing a new right of appeal under the patent linkage system that will create further delays for the entry of generics.
CETA will only affect intellectual property rights in Canada—not the EU. This analysis estimates that CETA's provisions will increase Canadian drug costs by between 6.2% and 12.9% starting in 2023. The Canadian government committed to compensating provinces for the rise in costs for their public drug plans. Importantly, this means that people paying out-of-pocket for their drugs or receiving them through private insurance, will be charged twice: once through higher drug costs and once more through their federal taxes.
As drug costs continue to grow, there are limited options available for provincial/territorial governments: restrict the choice of medicines in public drug plans; transfer costs to patients who typically are either elderly or sick; or take money from other places in the health system, and threaten the viability of Canada's single payer system. CETA will therefore negatively impact the ability of Canada to offer quality health care."

3. Harris T, Nicol D, Gruen N. Pharmaceutical Patents Review Report. [Online] Commonwealth of Australia, Canberra 2013 [Cited 2015 June 8]. Available from: http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf

Excerpt: "At the time that the EOT [extension of term, or patent term extension] was introduced, the annual cost to the Pharmaceutical Benefit Scheme (PBS) was estimated to grow from $6 million in 2001-02 to $160 million in 2005-06. This cost arises because there is a delayed entry to the PBS of cheaper generic drugs. The estimate for 2012-13 is around $240 million in the medium term and, in today's dollars, around $480 million in the longer term. The total cost of the EOT to Australia is actually about 20 per cent more than this, because the PBS is only one source of revenue for the industry."

4. Georgetown University Law Center. Prescription for failure: health and intellectual property in the Dominican Republic [Online] Georgetown Human Rights Action/Human Rights Institute Fact-Finding Mission 2010 [Cited 2015 June 9]. Available from: http://www.law.georgetown.edu/academics/centers-institutes/human-rights-institute/fact-finding/upload/FinalDRReport.pdf

Excerpt: "The Dominican government's ability to address these public health challenges may be limited by the promotion of stringent intellectual property protections by the U.S. government and the multinational pharmaceutical industry. Further, concern was expressed that U.S. technical assistance to the Dominican Republic provides information about DR-CAFTA obligations without equal information about public health safeguards that could be implemented. Without information about public health safeguards, DR-CAFTA could be implemented in a manner that is potentially devastating for Dominican patients."

5. El-Said M. Public health-related TRIPS-plus provisions in bilateral trade agreements. [Online] World Health Organization and International Center for Trade and Sustainable Development 2010 [Cited 2015 June 9]. Available from: http://applications.emro.who.int/dsaf/dsa1081.pdf

Excerpt: "One of the primary effects of data exclusivity will be on medicines that are not patented, particularly for those countries that are not members of the WTO and are not yet bound by TRIPS. Data exclusivity will also significantly affect those member states that did not recognize pharmaceutical product patents prior to TRIPS, as many products that are off-patent may be protected under test data protection. Accordingly, generic producers will have to wait for at least five years from the date of approval of the original medicine before obtaining registration for their own generics. This explains the rationale behind multinational pharmaceutical companies' aggressive support for data exclusivity provisions under these bilateral agreements."

6. Kessomboon N, Limpanonont J, Kulsomboon V, et al. Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-US FTA. [Online] Southeast Asian Journal of Tropical Medicine and Public Health 2010; 41(3): 667-677 [Cited 2015 June 8]. Available from: http://www.tm.mahidol.ac.th/seameo/2010-41-3/23-4785.pdf.

Abstract: "This study assessed the impact of the Thai-US Free Trade Agreement (FTA) on access to medicines in Thailand. We first interpreted the text of the sixth round of Thai-US negotiations in 2006 on intellectual property rights (IPR). The impact was estimated using a macroeconomic model of the impact of changes in IPR. The estimated impact is based on a comparison between the current IPR situation and the proposed changes to IPR. The FTA text involves the period of patent extension from the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). The provisions involve the period of patent extension, which have to do with compensation for delays in patent registration

and/or drug registration, data exclusivity that would result in a delay in generic drug entry, and the enforcing role of the Thai Food and Drug Administration of patent linkages. As a worst case scenario for this single provision, a 10 year patent extension would be given to compensate for delays in patent registration and/or drug registration. The impact on access to medicine, in the year 2027, would be: 1) A 32% increase in the medicine price index, 2) spending on medicines would increase to approximately USD 11,191 million, (USD1= THB 33.9 on September 2, 2009), and 3) the domestic industry could loss USD 3.3 million. These results suggest there would be a severe restriction on the access to medicines under the TRIPS-Plus proposal. IPR protection of pharmaceuticals per the TRIPS-Plus proposal should be excluded from FTA negotiations."

7. Rathe M, Minaya R, Cuzco L, Guzman D. Medicamentos y propiedad intelectual: Evaluación del impacto de los nuevos estándares de derechos de propiedad intelectual en el precio de los medicamentos: el caso de la República Dominicana. [Online] ICTSD 2009 [Cited 2015 June 8]. Available from: http://www.ictsd.org/downloads/ip/Medicamentos_y_Propiedad%20Intelectual-re_co_columns.pdf

In Spanish. This study for the Dominican Republic by Fundación Plenitud and the Pan-American Health Organization predicted medicine prices will increase by 9 to 15 percent by 2027 as a result of DR-CAFTA implementation.

8. Hernandez-Gonzalez G, Valverde M. Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica. [Online] ICTSD 2009 [Cited 2015 June 8]. Available from: http://www.ictsd.org/themes/innovation-and-ip/research/evaluaci%C3%B3n-del-impacto-de-las-disposiciones-de-adpic-en-el-mercado

In Spanish. This study for Costa Rica with the Pan-American Health Organization predicted medicine prices will increase between 17 and 31 percent by 2030, with a resulting estimated increase in costs to public health budgets between US $176 million to $331 million, as a result of DR- CAFTA implementation.

9. Akaleephan C, Wibulpolprasert S, Sakulbumrungsil R, et al. Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: analysis of the effect of TRIPS-plus proposal. [Online] Health Policy 2009; 91: DOI: 10.1016/j.healthpol.2008.12.009 [Cited 2015 June 8]. Available from: http://www.healthpolicyjrnl.com/article/S0168-8510(08)00286-8/abstract

Abstract: "Background: In Thailand and the US negotiating FTA, the 'TRIPs-Plus' is one of the US proposal which would result in an extension of market exclusivity of innovative drugs. In addition, it would foreseeably lead to high and unaffordable medicine prices and inaccessibility to essential medicines.

Objective: To quantify the impact on medicine expense and medicine accessibility.
Methods: Based on 2000 to 2003 Thai Food and Drug Administration (FDA)'s and the Drug & Medical Supply Information Center (DMSIC), costs and accessibility were estimated upon the price and quantity costing between innovative drugs and their generics plus some parameters found from their competitive behaviour. Thereafter, we simulated the 10-year potential additional expense on the 2003 unit price of the patented and monopolized non-patented medicines.
Results: In 2003, the availability of generics helped to save 104.5% of actual expense and the accessibility would increase by 53.6%. By extension of market exclusivity, given that there were 60 new items approved annually, the cumulative potential expense was projected to be $US 6.2 million for the first year to $US 5215.8 million in tenth year.
Conclusion: The TRIPs-Plus proposal would result in a significant increase in the medicine expense; and a delay in the increase in drug accessibility via generics. Several options as well as other related mechanisms to help reduce the negative impact are proposed."

10. IFARMA. Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru. [Online] Health Action International Europe and IFARMA Foundation 2009 [Cited 2015 June 8]. Available from: http://www.haiweb.org/11112009/ReportIFARMAImpactStudyPeru%28EN%29.pdf

Excerpt: "It is estimated that the introduction of the two measures on data exclusivity and supplementary patent protection would lead to an increase of 459 million USD in Peru's total pharmaceutical expenditure in 2025 and a cumulative increase in expenditure of 1267 million dollars (at present value, PV) for the same year."

11. IFARMA. Impact of the EU–Andean Trade Agreement on access to medicines in Colombia. [Online] IFARMA 2009 [Cited 2015 June 8]. Available from: http://www.haiweb.org/04102010/29_Mar_2010_Report_IFARMA_Impact_Study_Colombia_EN_.pdf

Excerpt: "It is estimated that the introduction of the two measures on data exclusivity and supplementary patent protection would lead to an increase of 756 million USD in Colombia's total pharmaceutical expenditure (at present value, PV) in 2025, and at the same time, a decrease in consumption of 10%. The consumption decrease is caused by an 8% increase in the number of IPR protected products, which in turn would produce a 16% price increase."

12. El-Said H, El-Said M. TRIPS-plus implications for access to medicines in developing countries: lessons from Jordan-United States Free Trade Agreement. [Online] Journal of World Intellectual Property 2007: 10(6): 438-475 [Cited 2015 June 9]. Available from: http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2007.00330.x/abstract

Abstract: "Since the establishment of the World Trade Organization (WTO) in 1995 and implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a result, the United States (US) sought to impose still higher levels of intellectual property rights on developing countries, a phenomenon that is commonly known today as TRIPS-Plus. The Jordan–US FTA, signed in 2001, contains several TRIPS-Plus rules that restrict the poor's access to medicines, and is today touted by US officials and the US Trade Representative (USTR) as a success, and providing a wide range of benefits. These benefits not only include a higher growth rate, but also more specific benefits to the pharmaceutical sector in particular, such as an improved ability to develop generic medicine and engage in new innovative research, as well as increasing the presence of and collaboration with multinational drug makers. This article analyzes in detail the TRIPS-Plus provisions of the Jordan–US FTA. It challenges the claims that the FTA brings general and specific benefits to developing countries, and

provides fresh evidence which strongly suggests that benefits from the Jordan–US FTA have been largely exaggerated while the costs underestimated."

PART 2 - Commentary on the effects of restrictive IP provisions on access to medicines

2.1: Notable quotes on restrictive IP provisions and impact to access to medicines

United Nations Office of the High Commissioner for Human Rights, 2015

Ten UN experts, Special Rapporteurs, "draw attention to the potential detrimental impact these treaties and agreements [trade and investment agreements] may have on the enjoyment of human rights as enshrined in legally binding instruments, whether civil, cultural, economic, political or social. Our concerns relate to the rights to life, food, water and sanitation, health, housing, education, science and culture, improved labour standards, an independent judiciary, a clean environment and the right not to be subjected to forced resettlement …. We believe the problem has been aggravated by the "chilling effect" that intrusive ISDS awards have had, when States have been penalized for adopting regulations, for example to protect the environment, food security, access to generic and essential medicines, and reduction of smoking, as required under the WHO Framework Convention on Tobacco Control, or raising the minimum wage."[1]

The UN MDG Gap Task Force, 2012

In a report prepared with input from more than 20 UN agencies and the World Trade Organization, the MDG Gap Task Force, a task force established by the UN Secretary-General to improve monitoring of MDG 8 by leveraging coordination, recommends taking the following actions to increase the accessibility and affordability of essential medicines: … "Developing countries should carefully assess possible adverse impacts on access to medicines when adopting TRIPS-plus provisions."[2]

Joint statements of United Nations Development Programme and UNAIDS, 2012

"Assertions are often made about the advantages of TRIPS-plus protection but there has been little evidence of the beneficial effects of TRIPS-plus measures either in the form of increased foreign investment or increased innovation.

To retain the benefits of TRIPS Agreement flexibilities, countries, at minimum should avoid entering into FTAs that contain TRIPS-plus obligations that can impact on pharmaceuticals' price or availability."[3]

Joint statements of UNAIDS, United Nations Development Programme and WHO, 2011

In a joint policy brief the bodies reiterate the WHO Global Strategy and Plan of Action recommendation that Member States "take into account… the impact on public health when considering adoption or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights."

The document cites a number of TRIPS-plus provisions "that may have an impact on public health or may hamper the use of TRIPS flexibilities, including: test data protection [data exclusivity]; requiring countries to loosen the criteria for patentability; providing for the possibility of extensions of terms for individual patents … to compensate for delays in … approval processes; and limiting the grounds under which a patent may be revoked."

The document recommends that "high-income governments should ensure that free trade agreements with middle- or low-income countries comply with the principles of the Doha Declaration."[4]

Global Fund to Fight AIDS, Tuberculosis and Malaria, 2011

In a report the organization expresses concern about the potential impact of the proposed EU-India FTA on prices of, and access to, HIV treatment. The report emphasized that countries should use TRIPS flexibilities to achieve the lowest possible prices for products of assured quality.[5]

UNAIDS, 2010
"In this current economic climate, resources for AIDS have already flattened and need for treatment continues to outstrip supply. Trade agreements that place additional burdens on the manufacture, import or export lifesaving medicines—so-called 'TRIPS plus' measures such as 'data exclusivity'—and incorrect interpretations of the term 'counterfeit' should be avoided." [6]

UN Special Rapporteur on the Right to Health, 2009
"These agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPS. Studies indicate that TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition."
Some of the UN Special Rapporteur report recommendations included:
"100. Developing countries and LDCs should establish high patentability standards and provide for exclusions from patentability, such as new forms and new or second uses, and combinations, in order to address evergreening and facilitate generic entry of medicines.
105. Developing countries and LDCs should establish liberal pre-grant, post-grant opposition and revocation procedures, which can be taken advantage of by all concerned stakeholders, including patients' groups.
108. Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health." [7]

World Health Organization, 2006
"From the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection" … "TRIPS plus' requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not 'trade away' their people's right to have access to medicines." [8]

2.2: Notable quotes/reports/letters on the TPP and access to medicines

Brookings Institute, 2015
In an issue brief Brookings warns that "imposing US standards [of data exclusivity for biologics] on the 11 member countries would inevitably restrict competition at the global level, and many patient advocacy and international humanitarian organizations have argued that doing so would undermine the efforts of US global health initiatives like the Vaccine Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria, which rely on price competition to manage program costs."[9]

World Medical Association, 2015
"The World Medical Association (WMA) calls on national governments and national members associations to "oppose any trade agreement provisions which would compromise access to health care services or medicines including but not limited to: Patenting (or patent enforcement) of diagnostic, therapeutic and surgical techniques; 'Evergreening', or patent protection for minor modifications of existing drugs; Patent linkage or other patent term adjustments that serve to as a barrier to generic entry into the market; Data exclusivity for biologics; Any effort to undermine TRIPS safeguards or restrict TRIPS flexibilities including compulsory licensing; Limits on clinical trial data transparency."[10]

Oxfam, 2015

"These US proposals [for the TPP] are not, in fact, new. They consist of IP protection and other provisions that originator pharmaceutical companies have been seeking for years. What is new is the way these provisions are being repackaged and marketed by USTR as supportive of access to medicines."[11]

"In particular, Oxfam and the other development groups warn that intellectual property and pharmaceutical pricing provisions are a step backward for public health, by unduly expanding monopoly power, limiting generic competition and restricting the policy space available to governments to promote access to medicines for all. Additionally, investment rules privilege the interests of foreign investors over the rights of local communities, limiting governments' ability to regulate in the public interest. And provisions on agricultural market access and government procurement fail to take into account the legitimate interest of governments to protect national food security. Trade has the potential to lift millions of people out of poverty, but as we've seen with the US's bilateral trade agreements, the most vulnerable get a raw deal."[12]

Lawrence Summers, former U.S. Treasury Secretary, 2015

"Some matters pushed by the business community have little or nothing to do with the interests of the vast majority of U.S. workers and should not be emphasized. These include [efforts to] extend and strengthen patent protections."[13]

27 health practitioners featured in The Lancet, 2015

"Serious concerns about the health effects of the TPPA have been highlighted in medical journals and by civil society. The concerns include unprecedented expansion of intellectual property rights that would prolong monopolies on pharmaceuticals and reduce access to affordable and lifesaving generic medicines. Effective price regulation of medicines could also be undermined. Rising medicine costs would disproportionately affect already vulnerable populations, obstructing efforts to improve health equity within and between countries."[14]

Robert Reich, former U.S. Labor Secretary, 2015

"What's been leaked about it so far reveals, for example, that the pharmaceutical industry gets stronger patent protections, delaying cheaper generic versions of drugs. That will be a good deal for Big Pharma but not necessarily for the inhabitants of developing nations who won't get certain life-saving drugs at a cost they can afford."[15]

Joseph Stiglitz, recipient of the Nobel Prize for economics, 2014

"There are other noxious provisions [in the TPP]. America has been fighting to lower the cost of health care. But the TPP would make the introduction of generic drugs more difficult, and thus raise the price of medicines. In the poorest countries, this is not just about moving money into corporate coffers: thousands would die unnecessarily."[16]

UNITAID, 2014

UNITAID, a global health initiative hosted by the World Health Organization (WHO) that raises funds for and purchases treatments against HIV, tuberculosis, and malaria at low-cost for distribution by implementer organizations, warns policy-makers to "be wary of the effect of the USA's TPPA proposal on the gains achieved in global public health. For example, the massive investment of effort and funds in the global battle against HIV/AIDS has resulted in tremendous gains towards meeting treatment goals in developing countries, but the implementation of proposed TPPA provisions may well undermine these gains and prevent further progress. The strategies and tools that have been so successfully employed to enhance competition and reduce the prices of ARV medicines—to the extent that universal access to such medicines is finally a reachable aim—may no longer be available. At a time when financing needs are threatened by funding cuts, the need for the widest range of options to reduce costs is paramount."[17]

Paul Krugman, recipient of the Nobel Prize for economics, 2014

"What the T.P.P. would do ... is increase the ability of certain corporations to assert control over intellectual property. Again, think drug patents and movie rights.

Is this a good thing from a global point of view? Doubtful. The kind of property rights we're talking about here can alternatively be described as legal monopolies. True, temporary monopolies are, in fact, how we reward new ideas; but arguing that we need even more monopolization is very dubious."[18]

The American Foundation for AIDS Research (AmfAR), 2014

"Despite the huge advances that have been made in the variety and efficacy of ART over the last decade, newer and better-tolerated treatment options will be needed to fight the epidemic effectively," says Chris Collins, amfAR vice president and director of public policy. "The TPP could delay the entrance of generic competition for these much-needed medicines and keep prices high."[19]

The Holy See, 2013

"Currently there is a clear tendency to further enlarge these RTAs to form mega-regional trade agreements such as the Transatlantic Trade and Investment Partnership, or the Trans-Pacific Partnership…

Among the most damaging concessions developing countries make in regional and bilateral agreements are those enhancing the monopolies on life-saving medicines, which reduce access and affordability and those that provide excessive legal rights to foreign investors, limiting the policy space for nations to promote sustainable and inclusive development."[20]

Médecins Sans Frontières / Doctors Without Borders, 2013

In an open letter to the heads of government of all TPP negotiating countries, MSF writes, "We are writing to express serious concern over provisions under negotiation in the Trans-Pacific Partnership Agreement (TPP) that threaten to restrict access to affordable medicines for millions of people, especially in low- and middle-income countries. Unless certain damaging provisions are removed, the TPP has the potential to become the most harmful trade pact ever for access to medicines."[21]

International HIV/AIDS Society, 2013

"The United States have suggested new Intellectual Property (IP) provisions that would make medicines less affordable and accessible to people living in TPP countries, especially in their generic form...We call for a Public Health exception that will allow all countries to sustain their current access to life-saving drugs and even extend it. We also call for more transparency in the TPP negotiation processes and for inclusion of all stakeholders in the discussions, including, but not limited to, HIV/AIDS and other health organizations."[22]

AARP, 2013

This association for American retirees writes in a letter to US Trade Representative Michael Froman, "AARP strongly believes the [Trans-Pacific Partnership] should not bind the U.S. to a 12-year market exclusivity period for brand-name biologic drugs....

Should the U.S. agree to the TPP with a provision requiring a 12-year market exclusivity period for brand-name biologics, U.S. policymakers would be prevented from taking action to reduce the costs associated with biologic drugs for U.S. consumers."[23]

Rodrigo Contreras, former Chilean chief negotiator for the TPP, 2013

"Our countries need the flexibility that has been recognized by multilateral trade negotiations on issues such as intellectual property,…and the proper balance between the rights of private investors and the State...[we] have a long way to go to advance access to knowledge, quality education, health care coverage, and the strengthening of their economies....

The extension of drug patent protections beyond the current terms, or the restriction of challenges to frivolous patent applications, would delay the availability of generic drugs and increase the cost of medicines. Public health budgets and access to health services for the most vulnerable would be affected in our countries....
It is critical to reject the imposition of a model designed according to realities of high-income countries, which are very different from the other participating countries."[24]

UNDP Global Commission on HIV and the Law: Risks, Rights and Health, 2012
"Free trade agreements (FTAs) and economic partnership agreements (EPAs) containing TRIPS-plus standards also threaten access to medicines. A case in point is the United States–promoted Transpacific Partnership Agreement (TPPA). Among other terms friendly to the United States pharmaceutical industry, the proposed patenting standards would allow patenting of new forms, new uses and new formulation of existing medicine; extend patent terms; and restrict the use of price control mechanisms. In another example, the proposed EU-India FTA would shrink the latitude of countries to adopt policies promoting the production and distribution of generic medicines. The United States trade stance, which threatens access to affordable medicines for millions of the world's poorest people, is egregious given President Barack Obama's professed commitments to increased economic equality and access to health care in the United States." [25]

2.3: Letters and statements by U.S. Members of Congress on the TPP and access to medicines

May 28, 2015 – Representative Sander Levin (D-MI): Op-ed in Huffington Post[26]
In an op-ed titled "Is TPP the Most Progressive Trade Agreement in History? Not If You Need Access to Affordable Medicines," Congressman Levin warned that the TPP threatens access to affordable medicines.
"The May 10th Agreement struck the right balance between the need to promote innovation and the need to protect public health. TPP must meet the standards set in the May 10th Agreement. Right now it does not. It should not be loaded up with new anticompetitive provisions when governments struggle to manage health care costs."

March 25, 2015 – Senator Sherrod Brown (D-OH): Statement to New York Times[27]
In a March 2015 New York Times article on the WikiLeaks leak of the TPP Investment Chapter, the Senator was quoted characterizing the TPP as troubling, in part due to the fact that corporations were influencing the trade agreement text, at the expense of public health.
"Senator Brown contended that the overall accord, not just the investment provisions, was troubling. 'This continues the great American tradition of corporations writing trade agreements, sharing them with almost nobody, so often at the expense of consumers, public health and workers,' he said."

March 17, 2015 – Representative Sander Levin (D-MI): Op-ed in Politico[28]
In his op-ed with Simon Johnson, the former Chief Economist for the IMF, the Ranking Member of the House Committee on Way and Means called for the TPP to uphold the May 10 New Trade Policy protections for access to medicines.
"We must provide the appropriate balance between fostering innovation and providing access to medicines…The May 10th Agreement of 2007 got this balance right, and we must not retreat."

January 22, 2015 – Representative Sander Levin (D-MI): The Trans-Pacific Partnership: A Path Forward to an Effective Agreement[29]
In his proposal the Ranking Member of the House Ways & Means Committee calls for the TPP to respect the Doha Declaration and the May 10 Agreement.

"The TPP Agreement should respect both the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at Doha, Qatar, and the May 10 Agreement which fosters innovation and promotes access to medicines for all."

September 27, 2014 – Representative Sander Levin (D-MI): Statement on the TPP[30]
In a statement following the September 2014 Australia round of negotiations, House Ways and Means Committee Ranking Member Levin called for the TPP to build upon, not weaken access to medicines as compared to the May 10 Agreement.
"The May 10 structure, which I helped negotiate, was a major breakthrough on the rights of workers, environmental protections, and access to medicines, and it is vital that TPP build on them, not weaken them."

September 18, 2014 – Representative Sander Levin (D-MI): Report to the Council on Foreign Relations[31]
House Ways & Means Ranking Member Levin in his report to the Council on Foreign Relations, "The Trans-Pacific Partnership Negotiations: The Need for Congress to Get Fully in the Game," called for May 10 provisions to be upheld in the TPP. Levin noted that "transition periods," after which May 10 provisions would not apply, were inconsistent with the May 10 Agreement.
"TPP also must incorporate the May 10 provisions on access to medicines, which seek to better ensure that developing countries have access to affordable medicines, while still strengthening intellectual property rights over what is required under WTO rules."

April 21, 2014 – Representatives George Miller (D-CA), Louise Slaughter (D-NY) and Rosa DeLauro (D-CT): Op-ed in LA Times[32]
The 3 representatives co-author an op-ed published in the LA Times, "Free Trade on Steroids: The threat of the Trans-Pacific Partnership" which names among other concerns, that intellectual property provisions could limit access to affordable medicines.
"There are other unresolved issues — such as intellectual property concerns that could limit access to affordable medicines — that have deadlocked the 12-nation pact."

April 8, 2014 - Representative Raúl Grijalva (D-AZ): Blog post on Huffington Post[33]
Representative Grijalva coauthors a blog post titled, "The Trans-Pacific Partnership is Terrible for Public Health" with Peter Maybarduck of Public Citizen.
"Despite the damage it would do to global health, U.S. officials are advancing special rules that expand drug giants' power under TPP, blocking generic drug competition that could save the lives of people suffering from cancer, HIV and other diseases."

March 14, 2014 – 16 Members of Congress:[34] Letter to Ambassador Froman[35]
Sixteen Members of Congress write to United States Trade Representative (USTR) Michael Froman, expressing concern that the Trans-Pacific Partnership Agreement (TPP) proposed provisions go beyond what is required of TRIPS and what is required of the Bipartisan Agreement of May 10, 2007.
"We are concerned that the provisions under discussion- such as those asking countries to enact patent linkage and patent term extension policies- would tip the balance represented in the TRIPS and May 10 compromises away from public health needs in order to further the interests of the pharmaceutical industry."

February 25, 2014 – Congressman Jim McDermott (D-WA): MSF and O'Neill Institute of Georgetown Law panel on challenges and opportunities for access to medicines[36]
Congressman McDermott participates in a panel on access to medicines and speaks to his role as a Congressional advocate for access to medicines for developing countries. McDermott is critical of TPP

proposals tabled that "back Big Pharma" and threaten to undo gains made in treatment funding programs like PEPFAR in recent years.

January 17, 2014 – Representatives Sander Levin (D-MI), Henry Waxman (D-CA), John Conyers, Jr. (D-MI), Charles Rangel (D-NY) and Jim McDermott (D-WA): Letter to Ambassador Froman[37]
The five ranking members of Congress write a letter to Froman urging the USTR to uphold the U.S.'s commitment to the 2007 New Trade Policy (May 10 Agreement).
"There would be significant concern if action through TPP could delay access to generic medicines, which may result in higher costs to the U.S. government to reach PEPFAR treatment goals or could result in removing patients from treatment."

December 10, 2013 – Representative Sandy Levin (D-MI): Statement **following the TPP Singapore Ministerial Meeting of December 2013**[38]
Representative Levin issues a statement noting that critical work lay ahead on TPP negotiations on the issue of access to medicines, among others and called for transparency.

December 9, 2013 – Representatives Jan Schakowsky (D-IL), Michael Michaud (D-ME), Rosa DeLauro (D- CT), George Miller (D-CA), Barbara Lee (D-CA) and Peter Welch (D-MA): Letter to President Obama[39]
Six Members of Congress write to Obama to ensure that the TPP not undermine the goals of improving access to affordable healthcare in the U.S. around the world and called for transparency.
"The effect of data exclusivity, patent registration and procedure, enforcement and other provisions would be to delay generic competition and increase the price of medicines…Again, we want to express our strong opposition to action that would create new barriers to generic competition or remove pricing and formulary options that would allow the United States and other countries to lower the prices of medicines."

December 6, 2013 – Representative Henry Waxman (D-CA): Letter to Froman[40]
Waxman expresses opposition to 12 years of data exclusivity for biologics in the TPP and stated that it was critical that "USTR ensure that developing countries are not left behind in this agreement…In addition, the patent flexibilities available to developing nations in the Doha Declaration on Public Health should not be denied or weakened in the agreement."

December 5, 2013 – Representative Rosa DeLauro (D-CT): Congressional TPP "Red Lines" Teleconference[41]
DeLauro expresses concern for access to medicines in the TPP, among other concerns during a Congressional teleconference coordinated by Sierra Club.

December 5, 2013 – Representative DeLauro (D-CT): Special Order Statement on the House floor[42]
DeLauro warns of threats to public health and lack of transparency of the negotiations in the TPP on the House Floor as part of the Congressional Progressive Caucus' "Special Order Time" on the dangers of the TPP. DeLauro noted that leaked texts show proposals of "unbalanced intellectual property provisions that hinder our trading partners' access to safe and more affordable drugs," and highlighted the discrepancy of the Administration's proposal to reduce data exclusivity for biologics to 7 years as the USTR is pushing for 12 years in the TPP.

October 3, 2013 – Representative Jim McDermott (D-WA): Public Citizen TPP Teleconference[43]
McDermott supports ensuring access to medicines in the TPP during a teleconference hosted by Public Citizen, noting that the TPP was a long way from finished. The Congressman characterized the current U.S. proposal as "totally unacceptable" in its retreat from previous U.S. commitments to access to medicines.

May 31, 2013- Representative Jim McDermott (D-WA): Commentary piece published in Roll Call[44]
McDermott describes the TRIPS-plus provisions proposed by the U.S. and describes them thusly: "But the U.S.' current TPP proposal on medicines upends the present well-structured balance by extending monopoly protections much further. It would force people in developing countries to wait longer for affordable medicines, if they can access them at all…Global health, innovation and access to medicines are top priorities for many members of Congress and should be for this administration."

July 24, 2012 – Representative Henry Waxman (D-CA): Op-Ed on AIDS[45]
Representative Waxman calls for the U.S. to negotiate IP rules in the TPP that protect generic drug competition. He also calls for increased use of the Medicines Patent Pool and for "creative" mechanisms for bringing more partners on board.

December 1, 2011 - Senator Bernie Sanders (I-VT): Letter to Ambassador Kirk[46]
Senator Sanders objects to USTR's position with regard to access to medicines in the TPP and the apparent retreat from the May 10th Agreement. Senator Sanders also objects to the secrecy of the negotiations and calls for the public release of the TPP negotiating texts.
"I join other members of Congress in calling for improvement of the USTR's position in this negotiation, including the incorporation of the May 10 Agreement provisions."
The Senator notes that the USTR's Trade Enhancing Access to Medicines (TEAM) approach is a "disingenuously named initiative [that] does not balance trade with access to medicines. Rather, it would erect even higher intellectual property barriers to affordable generic medicines for millions."

October 19, 2011 - Representative Henry Waxman (D-CA), Representative Sander Levin (D-MI), Representative John Conyers Jr. (D-MI), Representative Jim McDermott (D-WA): Letter to Ambassador Kirk[47]
Members of Congress ask the USTR to ensure that the TPP upholds U.S. commitments to safeguard access to medicines in the developing world.
"We are concerned that some of the goals and approaches described as part of the new strategic initiative Trade Enhancing Access to Medicines (TEAM) could limit, rather than expand, access to medicines in poor countries… The best way to preserve our developing country trade partners' access to medicines is to incorporate in the TPP the Bipartisan Agreement on Trade Policy of May 10, 2007."
"There would be significant concern if action through TPP could delay access to generic medicines which may result in higher costs to the U.S. government to reach PEPFAR treatment goals or could result in removing patients from treatment."

September 8, 2011 - Representative John Lewis (D-GA), Representative Pete Stark (D-CA), Representative Charles Rangel (D-NY), Representative Earl Blumenauer (D-OR), Representative Lloyd Doggett (D-TX): Letter to Ambassador Kirk[48]
Members of Congress advocate for improved public health standards in TPP negotiations, especially relating to global health and access to medicines.
"The standards established by this agreement should reflect our shared goals to improve global health and access to medicines. The terms agreed to by Congress and President Bush on May 10, 2007 should be considered a non-negotiable starting point for the TPP negotiations."
"…we have long urged an improved and transparent interagency process and structured consultations with public health interests regarding the potential impact of IP and pharmaceutical provisions on U.S. and global public health efforts."

August 4, 2011 - Representative Henry Waxman (D-CA), Representative Jim McDermott (D-WA), Representative Pete Stark (D-CA), Representative Peter Welch (D-VT), Representative Rosa

DeLauro (D-CT), Representative Raul Grijalva (D-AZ) and Representative Jan Schakowsky (D-IL): Letter to President Obama[49]
Members of Congress advocate against 12 years of exclusivity for biologics included in TPP.
"As the United States prepares to propose text on intellectual property right concerning pharmaceuticals in the negotiations of the Trans-Pacific Partnership (TPP, we strongly recommend that the Unites States refrain from negotiating any provisions related to exclusivity for biosimilar medicines."
"Proposing 12 years of exclusivity in the context of TPP negotiations would conflict with stated Administration policy, as reflected in the FY 2012 budget proposal, recommending that the exclusivity period for biologics be reduced to 7 years. According to the Administration's budget, a term of 7 years of exclusivity instead of 12 years would achieve an estimated $2.34 billion in savings over the decade."

August 2, 2011 - Representative Jan Schakowsky (D-IL), Representative John Conyers (D-MI), Representative Donald Payne (D-NJ), Representative Rosa DeLauro (D-CT), Representative Maxine Waters (D-CA), Representative Lynn Woolsey (D-CA), Representative Jesse Jackson, Jr. (D-IL), Representative Barbara Lee (D-CA), Representative Raul Grijalva (D-AR), and Representative Michael Michaud (D-ME): Letter to Ambassador Kirk[50]
Members of Congress express concerns that the public health interests of developing countries are not being effectively addressed.
"We are concerned… that the balance is once again shifting away from… access to affordable medicines and towards the greater protection of intellectual property rights for brand-name pharmaceutical companies in the developing world, a move that would jeopardize treatment goals and millions of lives."
"TRIPS-plus provisions in FTAs have been demonstrated to dramatically increase the cost of medicines in developing countries, pricing medicines out of reach of the poor and straining public health budgets."

July 26, 2011 - Representative Sander M. Levin (D-MI), Representative Jim McDermott (D-WA), Representative Charles Rangel (D-NY), Representative Pete Stark (D-CA), Representative John Lewis (D-GA), Representative Richard E. Neal (D-MA), Representative Xavier Becerra (D-CA), Representative Mike Thompson (D-CA), Representative John Larson (D-CT), Representative Earl Blumenauer (D-OR), Representative Ron Kind (D-WI), Representative Bill Pascrell, Jr. (D-NJ), Representative Shelley Berkley (D-NV), Representative Joseph Crowley (D-NY) : Letter to Ambassador Kirk[51]
Members call on the USTR to incorporate and defend the "May 10 Agreement" Provisions.
"The consensus that was reached between Congress and the Bush Administration on May 10, 2007 was an historic first step in that direction, laying out key obligations to help raise living standards at home and abroad. We urge you to incorporate and defend the May 10 Agreement as you develop the U.S. position in the TPP negotiations."

January 20, 2010 – 30 Members of Congress: Letter to Ambassador Kirk[52]
Members of Congress identify some of the key provisions included in previous trade agreements from which they expect additional progress in TPP negotiations.
"It is imperative that TPP patent rules do not undermine the flexibilities and rights included in the access to medicine policies that were agreed in the 2001 WTO Doha Declaration on the Trade Related Intellectual Property Agreement (TRIPS) and Public Health, a standard which the 2002 U.S. Trade Promotion Authority bill formally identified as a policy goal."

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