Oxfam Analysis of US Proposals for IP and Pharmaceutical Pricing Provisions in Trans-Pacific Partnership Agreement Negotiations

I. Introduction: New USTR Approach Threatens Health

The Office of the United States Trade Representative (USTR) has launched a "new strategic initiative" focused on trade, intellectual property, and access to medicines.[1] According to USTR, the initiative will be implemented through new intellectual property (IP) and pharmaceutical pricing rules in free trade agreements (FTAs), starting with the Trans-Pacific Partnership Agreement (TPPA). A paper released by USTR in September 2011 states that these proposals will not only improve access to medicines, they will actually *drive* access to medicines in US trading partners.[2]

Oxfam believes the above claim by USTR cannot be supported and that, to the contrary, the US proposals actually threaten public health in the TPPA countries. Now that the TPPA proposals have been leaked – despite US efforts to keep them confidential - it is possible to assess their potential impacts.

These US proposals 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, based on the addition of an "access window" mechanism. Specifically, the United States proposes that, in general, originator companies benefit from a broad range of TRIPS-plus IP protections. In addition, in connection with those applications involving registration by reliance (on prior approval elsewhere), originator companies would benefit from TRIPS-plus IP policies provided they commence the registration process within a given window of time.[3] As discussed in Section III, this proposal offers little discernible benefits to TPPA countries, it comes at too high a price, and it thus is a losing proposition for public health. It does not merit serious consideration in these or other FTA negotiations as a justification for TRIPS-plus concessions.

It is unfortunate that the United States is reverting to its earlier, heavy-handed negotiating positions on IP. The TPPA proposal includes various TRIPS-plus IP protections that have been demonstrated to undermine access when implemented in developing countries.[4] This shift reverses a somewhat positive evolution in US trade policy vis-à-vis developing countries in recent years, including the important "May 10th Agreement", which was a 2007 agreement between the US Congress and the Bush Administration to modify IP demands in FTA negotiations with developing countries, in recognition of the distinct health and resource challenges faced by them.[5] Moreover, this shift follows explicit recognition by the US Government, on a number of occasions, that extensive IP protection can undermine public health in low and middle-income countries.

In addition to having concerns about the substance of the US TPPA proposals, Oxfam is surprised and disappointed that USTR has chosen to market them as "pro-health". A USTR White Paper published in October states that the US IP proposal aims to "promote trade in, and reduce obstacles to, access to both innovative *and generic* medicines." [6] The US proposal even references the Doha Declaration, while inaccurately implying that its scope of application is limited to national emergencies.

Mention of the Doha Declaration is followed by a series of measures that would undermine and restrict its practical application, and which would delay and create new obstacles to access to affordable generic medicines. Analysis reveals that the US IP proposal is significantly worse for public health than the May 10th Agreement. In combination with the US proposal on pharmaceutical pricing, it is especially worrisome. Fortunately, at this point in time, these US proposals are only proposals. Oxfam trusts they will be rejected by negotiating partners, or that the United States will unilaterally scale back its ambitions.

Having tabled its October 2011 TPPA IP and pharmaceutical pricing proposals, Oxfam considers the United States has:

- Reneged on its commitment to prioritize health over IP rights for pharmaceuticals, delineated in the Doha Declaration on TRIPS and Public Health;
- Abandoned the May 10th Agreement between Congress and the Administration that certain TRIPS-plus IP rules are not appropriate for developing countries and should not be imposed on them through FTAs;
- Used public health to justify proposals that respond to the interests of its originator pharmaceutical companies, at the expense of patients; and
- Failed to provide even minimal transparency about its positions and objectives in the TPPA talks.

Oxfam has produced this analysis to provide clear guidance on the extent to which the US negotiating proposals will undermine access to medicines. Transparency, however obtained, does provide an opportunity to our organization, and to others, to offer our view of how this agreement will affect people living in poverty.

II. Access to Medicines: Generics are Critical

Medicines play a critical role in health systems. Due to inadequate resources in both the public and private sector, affordable prices for medicines are an essential part of improving access to treatment. In particular, low-cost, quality generics play a key role – especially in developing countries. Though they are identical to them, generics cost a fraction of their originator counterparts, and the presence of multiple generic competitors in a market can reduce prices by as much as 80%[7] and sometimes by more than 99% as with anti-retroviral medicines to treat HIV and AIDS.[8]

Affordable prices are especially critical for households in developing countries that lack insurance and must therefore pay for medicines out-of-pocket. When a family member falls ill, difficult choices must be made between buying treatment, buying food, or paying school fees. For the poorest, even generics may not be affordable.

Ultimately, policies that strengthen or extend patent and data monopolies, which delay generic competition and the associated drop in medicines prices, negatively impact access to medicines and therefore public health. Extension of the patent and data monopoly keeps prices high. This prices medicines out of reach of poor patients and, in many cases, the public health system – without stimulating any additional innovation.[9]

In recent decades, the public health problems facing developing countries have evolved well beyond infectious diseases. In large part due to changing lifestyles, a range of non-communicable diseases is now *the* critical public health problem in low and middle-income countries, including those negotiating the TPPA. Countries will need to ensure access to affordable, quality medicines for a range of conditions, against the backdrop of rising expenditures on healthcare overall, a global economic crisis, and populations that are demanding more services.

III. The US IP Proposal: Severe Delays for Access to Generics

Despite efforts to keep its negotiating positions secret, US IP proposals were leaked to the public in February and October of this year. Together, they set out a range of TRIPS-plus IP protections that would delay the introduction of generics in TPPA markets.[10] Several of the provisions directly contradict the May 10th Agreement, and all of the TRIPS-plus proposals contravene the spirit of the Doha Declaration by imposing measures on developing countries that limit access to affordable medicines.

Specifically, Oxfam is concerned about the following elements of the US proposal on intellectual property:[11]

A. Expanded scope of patentability

The US proposes significantly expanding the scope of patentability, to allow for the patenting of new forms, uses, or methods of existing products even if there is no increase in efficacy.[12] This would enable companies to extend the term of patent protection for existing medicines that have already enjoyed a full term of patent protection by slightly modifying the product then applying for a new patent. This technique – known as "ever-greening" – may be used a number of times, delaying generic entry for lengthy periods of time.

In addition, the US TPPA proposal would prevent countries from excluding diagnostic, therapeutic, and surgical methods for the treatment of humans and animals from patentability. These exceptions, which are included in TRIPS and in previous US FTAs, are considered to be morally and ethically necessary. They are aimed at avoiding payment of royalties to medical professionals and hospitals for standard of care.

B. Mandatory patent term extensions

The US proposes that countries be obliged to grant patent term extensions as compensation for "unreasonable" delays in granting patents, and in the event the patent period is "unreasonably curtailed" as a result of delays in the marketing approval process.[13] The May 10th Agreement made the granting of such extensions,

which delay generic market entry, optional for developing countries. Fundamentally, this proposal conflates separate processes, with distinct purposes and objectives. Moreover, such extensions punish countries for not having the resources to effectively process increasing, and often overwhelming, volumes of patent applications and applications for marketing approval for new products. Pressed to approve patent applications in order to avoid having to grant extensions, patent examiners may approve low quality patent applications, allowing companies to obtain frivolous patents and extending the term of patent protection without justification.

The provisions providing for patent extension to compensate for delays in the granting of regulatory approval are subject to the access window proposal, described below – but only in connection with applications for registration that rely on evidence of prior registration in another country.[14] Other types of applications would benefit from patent extensions to compensate for delays in the patent prosecution as well as regulatory approval process, regardless of when registration is initiated.

C. Data exclusivity, including for secondary applications

The United States proposes that countries be required to grant at least five years of data monopoly for clinical data submitted for a new pharmaceutical product, as well as three years for clinical data submitted in connection with a secondary application involving the same chemical entity (*e.g.*, for new uses or new formulations or dosages), starting from the date on which the product or secondary product is granted approval in the relevant TPPA country.[15] There is no limit on the number of applications earning three years of exclusivity that can be filed. Data exclusivity constitutes a barrier to generic market entry that is separate from, and additional to, patent barriers. It delays generic entry by preventing generic medicines from obtaining marketing approval on the basis of data submitted for the (identical) proprietary product. Additional terms of data protection for secondary applications enable companies to "ever-green" in order to extend the initial period of data exclusivity.

The May 10th Agreement provided for a "reasonable period" of data exclusivity, without specifying the number of years, and it required that it run concurrent to (or at least no longer than) data protection in the United States, rather than starting upon registration in the TPPA country. This limited the overall period of data exclusivity. The May 10th Agreement also enabled countries to institute public health exceptions to data exclusivity. In the section on data protection, the TPPA proposal references the Doha Declaration and Public Health but does not provide for any specific limitations on data exclusivity that would enable members to actually use flexibilities such as compulsory licensing.[16]

In connection with applications for marketing approval that rely on evidence of prior approval in another Party, the data exclusivity provisions are subject to the access window proposal.[17] For those applications for marketing approval that do not involve registration based on reliance, an automatic term of at least five years of data exclusivity is provided.

D. Patent-registration linkage

The United States proposes that countries institute patent-registration linkage, which prevents governments from granting marketing approval for any product alleged to infringe a patent.[18] Specifically, the US proposal provides for, among other things, "automatic delay in the granting of marketing approval" in cases where a patent exists and the applicant refuses to defer marketing of the product.[19] It also provides for a range of measures, including a system under which the patent owner would be alerted to any application for registration of a product that is the "same as, or similar to" the patented product.[20] Patent linkage can be a powerful tool for delaying generic competition, since the mere existence – not the quality, or legitimacy – of a patent on the relevant product delays approval.[21]

This US proposal ignores the fact that the determination that a product is safe, of the appropriate quality, and effective – and thus deserving of marketing approval – is distinct from the determination that the product is new, inventive, and industrially applicable – and thus deserving of patent protection. It would create incentives for originator companies to file additional patents (using "ever-greening" tactics, for instance) and then assert them against competitors in order to delay registration. Moreover, in countries with fewer resources, it is simply not feasible that drug regulatory authorities police patent status in addition to performing their own jobs. In recognition of the above, the May 10th Agreement made patent linkage optional for developing countries.

Patent linkage provisions are subject to the access window proposal, in connection with applications that rely on evidence of prior registration in another country. For applications that do not involve registration by reference, patent linkage provisions would automatically apply.[22]

E. Seizures of legitimate generics

The US proposal contains enhanced IP enforcement provisions, for instance allowing border measures against non-criminal products that happen to be "confusingly similar" to IP-protected products (with respect to trademarks and copyrights).[23] This could result in the seizure of lawfully available, quality generic medicines in addition to seizures of "counterfeits" which are products intended to deceive consumers. This is not a theoretical risk that legitimate medical supplies could be interrupted for no good reason. In Germany in 2009, customs officials detained a shipment of generic amoxicillin because the customs officials erroneously determined that the generic amoxicillin, which is named on the basis of the international non-proprietary name (INN), was confusingly similar to the GSK brand "Amoxil" (also based on the INN) – and thus should be seized under the European Union's border enforcement measures.

F. Elimination of pre-grant opposition

Pre-grant opposition systems, or third party observation systems, allow third parties to provide the patent office with evidence concerning the patentability or merits of a patent application. Such procedures, which have long been part of patent systems, currently exist in numerous jurisdictions including the EPO (European Patent Office) and several of the TPPA negotiating countries.

The US IP proposal would proscribe pre-grant opposition, thereby undermining the ability of developing countries to ensure that patents are granted only when the relevant patentability criteria are satisfied.

In many countries, especially those with fewer resources, poor quality or meritless patent applications are a recurring problem. Pre-grant opposition improves the quality and efficiency of patent examination process by assisting examiners in ferreting out unworthy patent applications, including applications that rely on weak or erroneous information.[24] Moreover, pre-grant opposition is more efficient and less costly than the alternative, which is post-grant litigation. Imposition of this proposal would require New Zealand, Australia, Vietnam, Peru, and Chile to amend their laws in order to eliminate pre-grant oppositions.[25]

G. Narrow interpretation of the Doha Declaration

The United States attempts in its proposal to narrow the scope of the Doha Declaration on TRIPS and Public Health. Specifically, it insinuates that the Doha Declaration and TRIPS flexibilities may only be relied upon in emergencies, stating that TPPA countries can take 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."[26] In fact, use of TRIPS flexibilities, including compulsory licensing, is not associated primarily with epidemics and emergencies (although the use of compulsory licensing is *facilitated* in the event of a national emergency). Rather, these tools may be used in connection with any public health problem. Any reference to the Doha Declaration in the final text must accurately reflect its scope of application, and must confirm that TRIPS flexibilities may be used to address any health problem.

III. The Access Window: A Bad Deal for Health

The "access window" mechanism, embedded in the US IP proposal, is a bad deal for public health. On the basis of this proposal, under limited circumstances, TPPA countries would require originator companies to register medicines within a specified timeframe, in order to benefit from certain TRIPS-plus IP policies. It would function as described below.

Essentially, the TPPA country would be required to apply TRIPS-plus IP policies that delay generic market entry across the board; the country would be able to restrict application of data exclusivity, patent linkage, and patent extensions (to compensate for delays in the regulatory process) only in certain, limited circumstances (see below).[27] The country would be required to amend its regulatory process to enable or require pharmaceutical companies to obtain regulatory approval by reliance prior registration in another country. In return, the country would benefit from originator companies beginning the registration process within a specified access window timeframe, in cases where registration by reliance is sought.

A critical detail is that the access window only applies to one type of application for registration: those that rely on evidence of prior registration in another country. In

connection with such applications, if registration is not initiated during the window, that product cannot benefit from the abovementioned TRIPS-plus provisions *on the basis of that application*.[28] In other words, for a product to benefit from the full range of TRIPS-plus IP provisions in the US proposal, the originator company would have to submit a complete application directly to national authorities (without relying on evidence of prior approval in another country); in this case, the registration process would not have to commence within a specified time period.

The duration of the access window is not specified in the proposal. Importantly, whether registration would have been initiated *anyway* within the (to be determined) timeframe is impossible to determine.[29] While it is therefore highly difficult to evaluate the benefits associated with this proposal, we nonetheless provide some analysis below.

At first glance, this proposition may seem beneficial to access to medicines, since earlier registration of the originator product means that a new medicine may become available sooner than without such inducements.[30] Beginning the registration process earlier could mean that the period of data exclusivity, which the United States proposes should commence upon granting of marketing approval in the TPPA country, would begin – and expire – sooner.[31] Once the period of data exclusivity expires, generics are able to obtain registration on the basis of originator test data (though registration may be affected by patent linkage and the assertion of new patents, or in the event a company seeks an additional term of data exclusivity for a new use).

In reality, however, it is not clear that *any* benefit would actually be obtained under the access window proposal. The proposal suffers from the following, serious shortcomings:

First, the access window relates to a limited set of applications that rely on evidence of prior approval in another country. All other applications could benefit from the full range of TRIPS-plus IP provisions in the US proposal, with no time constraints imposed on the timing of registration. As noted above, to implement the access window, countries would have to modify their laws to enable (or require) applicants to register a medicine by reliance, an important concession to originator pharmaceutical companies.

Second, it's not possible to know whether the registration process would actually commence any earlier – due to incentives provided by the access window – than would otherwise be the case. It is not possible to predict when a company would seek to register a medicine in a given market. This makes it highly difficult to assess whether this proposal provides value in terms of early registration. Decisions to register medicines in low-income countries are not determined by any one factor. For example, GSK registered its medicines and competed on the Indian pharmaceutical market in the decades prior to full implementation of TRIPS in India. During that time, India only offered process patent protection for medicines, which did not serve to prevent copying of pharmaceutical products by generic producers based in India.

Third, even if one could demonstrate that registration would be initiated earlier, registration does not necessarily translate into access. Once registration has been

granted, companies are not under any obligation to actually market the medicine. A company may delay commercialization of a product due to factors such as lack of commercial interest, or lack of scientific expertise, or health infrastructure in the country. Moreover, new products are often expensive, especially if they are patent-protected and there is no generic competition. Under such circumstances, a medicine may be registered and sold in a market without actually being accessible to most people – even through the public health system.

Fourth, even if it could be established that registration would be initiated earlier, one of the benefits associated with earlier registration – earlier expiry of the data protection period, and thus the possibility of earlier generic approval – may not materialize. The combined term of the "access window", the registration process, and the term of data exclusivity that is implemented upon completion of registration could be very lengthy. A company has to merely *commence* the process of marketing approval to satisfy the obligations under the access window; it does not have to actually actively participate in or even complete the registration process until some period of time thereafter. And the monopoly term generated by data exclusivity can be extended through additional, three-year terms of data exclusivity for secondary applications.

Moreover, the proposal provides for patent-registration linkage, in addition to data exclusivity. Thus, even if data is no longer protected, a generic could still be blocked from registering on the basis of frivolous patents. Linkage could delay registration.

Finally, and most importantly, **in exchange for virtually no benefits, the US proposal requires payment of a high price**. The TPPA country must provide data exclusivity, patent linkage, and, depending on the circumstances, also patent term extensions to products for which originator companies submit applications that rely on prior approval. In connection with all other products, the country must apply these and various other TRIPS-plus IP policies. The country must also modify its regulatory approval process to enable or require companies to register medicines by reference.

The access window, together with the rest of the US IP proposal, is a bad deal for public health, particularly for low- and middle-income TPPA countries.

The May 10th Agreement represented a better and more balanced deal for developing countries, as, fundamentally, it applied to all products – not just those for which registration by reliance is sought. Also, it required that data exclusivity run concurrently with data protection in the US (provided certain conditions were present), thus curbing the total period of exclusivity. It made patent linkage, as well as the granting of patent extensions to compensate for delays in regulatory approval, optional for developing countries. And it provided for public health exceptions to data exclusivity, something that is referenced but not actually incorporated meaningfully into the US proposal. Countries should insist that, at least with respect to low- and middle-income TPPA countries, the United States uphold the May 10th Agreement.

IV. US Pharmaceutical Pricing Proposal: Compounding the Risk to Health

The United States has proposed enhancing the "transparency" of government programs through which the price of pharmaceuticals and other healthcare technologies is reimbursed.[32] Specifically, it has tabled a draft Annex of rules on "Transparency and Procedural Fairness for Healthcare Technologies". This proposal, which was leaked to the public in October 2011, requires more than transparency and would restrict TPPA countries' ability to broaden access to new medicines.

Competition is considered the best strategy for reducing medicines prices, and health experts routinely advise countries to have a robust generics strategy in place. However, generic competition is not always possible, for instance due to patent barriers. Under such circumstances, governments must find other ways to manage the cost of new products, whether they are purchased on the open market or provided through public healthcare schemes. Governments regularly manage the price of disbursing and/or reimbursing new medicines under public health programs, using approaches that include, among others, external reference pricing (ERP) and pharmaco-economic analysis.[33]

The US pharmaceuticals pricing proposal would restrict countries' ability to manage reimbursement prices using these policy tools. The proposal, which does not differentiate between developed and developing countries, sets forth the following:

- Imposes a series of "procedural fairness" requirements that provide companies with greater opportunities to participate in government implementation of drug reimbursement schemes, including the possibility of commenting on – and even appealing – drug listing and reimbursement price decisions;[34]
- Requires governments to provide full information, including justifications for pricing decisions, to manufacturers;[35] and
- Mandates that countries set prices based on "market derived prices" in their own territory (in other words, forego the use of external reference pricing) – or else ensure that reimbursement prices "appropriately recognize" the value of patented and generic products.[36]

In addition to establishing procedural barriers to the use by governments of important policy tools such as external reference pricing and pharmaco-economics, this US proposal would create opportunities for originator companies to intervene, appeal, and otherwise influence the implementation of drug reimbursement under public health programs. At the least, this could result in wasted resources as governments are forced to engage more intensely with these stakeholders. At the most, it could lead to enactment of policies that are sub-optimal from a public health perspective.

This proposal is controversial even within the United States, where state legislators are warning that a TPPA pharmaceuticals chapter could jeopardize efforts by Medicaid and other federal and state health care programs to manage medicine costs.[37] Other negotiating countries, with less resources, growing demand for health services, and rising health costs – for instance, Vietnam, which has struggled for years to contain rising medicines prices of new medicines – can certainly not afford to sign up to the US proposal.[38] The TPPA should not contain the pharmaceutical pricing ("transparency") provisions proposed by the United States.

V. Conclusions and Recommendations

Contrary to USTR rhetoric about seeking to improve access to treatment, the United States has submitted IP and pharmaceutical pricing proposals that will undermine access to medicines in TPPA countries. Oxfam urges TPPA negotiators to reject these proposals, and would advocate the elimination of all TRIPS-plus provisions on patents, data, pricing, and enforcement. If this cannot be achieved, Oxfam recommends that at the very least the following elements be included in the TPPA, to limit the negative impact of the Agreement on access to medicines.

- **Transparency**: The negotiating text should be available for public commentary and scrutiny, and the positions of each negotiating party should be made public at the completion of each negotiating round.

- **May 10th Agreement**: The agreement reached between the Bush Administration and Congress in 2007 must, at a minimum, be upheld. Specifically, the IP chapter should include more flexible provisions, in line with public health concerns, patent term extensions, test data protection (data exclusivity), and patent-registration linkage. The TEAM access window, an ineffective policy tool to enhance access to medicines, should be abandoned.

- **Scope of Patentability**: Provisions in the IP chapter regarding the scope of patentability should be voluntary (whereas they are currently mandatory).

- **Enforcement provisions**: These should not target any products that do not criminally infringe IP, including products that may be considered "confusingly similar" to IP-protected products.

- **Pre-grant opposition**: Such systems are an important safeguard against patent abuse and should not be restricted or eliminated in the TPPA.

- **Pharmaceutical pricing**: There should be no pharmaceuticals chapter in the TPP. The US should not be negotiating programs that curb the ability of developing countries to enact international best practices in health and medicines policy.

In addition, Oxfam calls on the US Government to stop using public health to justify negotiating proposals that threaten access to affordable medicines, especially for the poor. If the USTR wishes to pursue TRIPS-plus IP provisions, together with restrictions on pharmaceutical reimbursement policies, it should acknowledge that it is doing so in the name of mercantilism – not the public good.

[1] USTR Press Release, *available at* <http://www.ustr.gov/about-us/press-office/press-releases/2011/september/trade-enhancing-access-medicines>.

[2] *See* "TPPA Trade Goals to Enhance Access to Medicines (TEAM)" White Paper, *available at* <http://www.ustr.gov/webfm_send/3059>.

[3] *See* USTR TEAM White Paper, and US IP proposal from October 2011, *available at* <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>.

[4] *See* Oxfam briefing paper, "All Costs, No Benefits" (finding that, during the 6-year period following implementation by Jordan of its TRIPS-plus FTA with the United States, medicines prices rose 20%, putting government health programs at risk – without any corresponding benefit in terms of domestic innovation or access to new products), *available at* <http://www.oxfam.org/en/policy/bp102_jordan_us_fta>. *See also* CPATH briefing paper, "A Trade Agreement's Impact on Access to Generic Medicines" (finding that once Guatemala enacted data protection, on the basis of CAFTA, some medicines prices rose as much as 846% – even though just a handful of medicines were under patent protection. In this case, test data protection provided a distinct monopoly from patent rights, resulting in high prices that poor people and the government cannot afford), *available at* <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/cpathhaonline8-25-09.pdf>.

[5] The May 10th Agreement provides for optional (not mandatory) provisions on patent extensions and patent linkage, in addition to more flexible data exclusivity provisions. *See* USTR Fact Sheet on May 10th Agreement, at <http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf>. *See also* <http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf>.

[6] *See* "TPPA Trade Goals to Enhance Access to Medicines (TEAM)" White Paper, *available at* <http://www.ustr.gov/webfm_send/3059>. *Emphasis added*.

[7] *See* "Generic Competition and Drug Prices," FDA website, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm>.

[8] *See* "Untangling the web of anti-retroviral price reductions", *available at* http://www.doctorswithoutborders.org/publications/reports/2011/MSF_Access_Report_13th_edition.pdf.

[9] For instance, the granting of patent extensions to compensate for delays in the regulatory approval process is one example of a monopoly-extending policy that does not stimulate innovation. An expanded scope of patentability, which may facilitate the practice of "ever-greening" by originator companies, is another.

[10] The leaked US IP proposal from October 2011 is available at <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>. It must be read together with the leaked US IP proposal from February 2011, available at <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>. The leaked US proposal for pharmaceutical pricing provisions (October 2011) is available at <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificTBTwMedicalAnnexes.pdf>.

[11] Concerns regarding the proposed provisions on pharmaceutical prices are outlined below, under Section IV.

[12] Article 8(1), US IP proposal February 2011.

[13] Article 8(6)(b-d), US IP proposal October 2011.

[14] Article 8(6)(e) of the US IP proposal October 2011.

[15] Article 9(2)(a) – (d), US IP proposal October 2011.

[16] Article 9(3), US IP proposal October 2011.

[17] Article 9(4), US IP proposal October 2011.

[18] Article 9(5), US IP proposal October 2011.

[19] Article 9(5)(b)(i), US IP proposal October 2011.

[20] Article 9(5)(a)(ii), US IP proposal October 2011.

[21] Generic producers often seek marketing approval prior to patent expiry, so they can enter the market immediately upon expiry.

[22] Article 9(6), US IP proposal October 2011.

[23] Article 14(1), US IP proposal February 2011.
[24] US paper on pre-grant opposition, *available at* <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

[25] US paper on pre-grant opposition, *available at* <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

[26] Article 2(a), US IP proposal October 2011.

[27] Articles 8(6)(e) contains the access window in connection with patent term extensions, Article 9(4) in connection with data exclusivity, and Article 9(6) in connection with patent linkage. Note that these TRIPS-plus policies are applied automatically in all cases, but are restricted (timeframe) in the case of applications involving registration based on reliance on prior approval elsewhere.

[28] The access window applies in cases where applications for marketing approval rely on prior granting of marketing approval in a different Party (for instance, approval by the US FDA). For other applications, under the US proposal, data exclusivity and other TRIPS-plus benefits would be provided regardless of the timing of registration. In connection with the access window and data exclusivity, see Article 9(4), US IP proposal October 2011.

[29] The access window language in Articles 8(6)(e), 9(4), and 9(6) stipulates that a Party "may require an applicant that has submitted an application for marketing approval consistent with Article 9.2(b) or Article 9.2(d) to *commence* the process of obtaining marketing approval for that new pharmaceutical product in the Party within [X] years of the date of first marketing approval of the same pharmaceutical product in another Party". *Emphasis added*.

[30] With regard to use of the word "may": first, it is difficult to assess whether the terms of the access window induce registration earlier than would have happened in their absence; second,,registration of a new product does not necessarily mean the product is also placed on the market, and actual commercialization of a product may be delayed.

[31] It is important to note that under the May 10th Agreement, data exclusivity would expire at the same time as in the United States, in cases where the application for marketing approval relies on approval by the US FDA and the Party grants marketing approval within six months of application. The analysis in this section is based on the US TPPA IP proposal from October 2011, based on which data protection would not run concurrently – a step backwards for public health, as this would delay generic entry longer. Oxfam opposes the imposition of data exclusivity on developing countries.

[32] The US TPPA proposal on Transparency and Healthcare Technologies, *available at* <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificTBTwMedicalAnnexes.pdf>.

[33] *See* Espin J. Rovera J., Review Series of Pharmaceutical Pricing Policies and Interventions: "Working Paper 1: External reference pricing." WHO/HAI May 2011. *See also* Faden L, Vialle-Valentin C, Ross-Degnan D, Wagner A., Review Series on Pharmaceutical Pricing Policies and Interventions: "Working Paper 2: The Role of Health Insurance in the Cost-Effective Use of Medicines." WHO/HAI May 2011.

[34] Article X.3(c), (i), US TPPA proposed Annex on Transparency and Procedural Fairness, October 2011.

[35] Article X.3(g), US TPPA proposed Annex on Transparency and Procedural Fairness, October 2011.

[36] Article X.3(d), US TPPA proposed Annex on Transparency and Procedural Fairness, October 2011.

[37] *See* analysis and statements by State officials, *available* at <http://www.forumdemocracy.net/section.php?id=322>.

[38] *See* Nguyen AT, Knight R, Mant A, Cao QM, Brooks G., "Medicine pricing policies: Lessons from Vietnam," Southern Med Review (2010) 3; 2:12-19; Nguyen AT, Knight R, Mant A, Cao QM, Auton M., " Medicine prices, availability, and affordability in Vietnam," Southern Med Review (2009) 2; 2:2-9.