

# Civil Society Comments on the Trans-Pacific Partnership Agreement

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## Introduction

We, the undersigned organizations, have serious concerns regarding the lack of transparency in the Trans-Pacific Partnership Agreement (TPPA) negotiations as well as the specific provisions contained in the US draft text for the TPPA's Intellectual Property Rights (IPR) chapter dated February 10, 2011.

It is expected that the norms that emerge from this negotiation will be extended to impact a much wider group of trading partners including both high income countries as well as developing countries in Latin America, Southeast Asia, and countries in the Pacific. Furthermore, the completed TPPA is likely to set precedents for other free trade agreements in the future, and thus it is very important that the precedents set in the TPPA are in harmony with the right to health and the agreed upon policy objective of access to medicine for all.

We have detailed our concerns and recommendations for the TPPA below, particularly those provisions that will impact public health. All citations to the US draft text refer to the draft dated February 10, 2011. Our recommendations apply specifically to the TPPA, but also to free trade agreements more generally.

### I. Transparency

#### **1. *Versions of the negotiating text for the intellectual property chapter, and any other sections of the text that will impact health and access to health treatments or technologies, should be made public once they have been widely circulated to the parties in the negotiation***

Transparency with regard to the negotiations and draft texts of the TPPA (as well as other free trade agreements) is critical in allowing stakeholders to evaluate the proposals and provide feedback. At present, the TPPA negotiations have excluded stakeholders from this process by not providing the proposed texts. The public, which will be affected by the outcome of the negotiations, is therefore denied the opportunity to effectively participate in the democratic process.

We note that the lack of access to information has been unequal. While some corporate interests, through advisory committees,<sup>1</sup> have special access to information about the negotiations, the general public has not been afforded the same opportunities. The general public has not been given any official access to the texts proposed by any country for the TPPA. While some texts have been leaked, including one on the US position, these texts are infrequently available and the leak of these documents or their publication may be subject to sanctions. They are therefore an unreliable source with regard to current US positions.

Without knowledge of the negotiating positions and the actual language contained within the draft text, it is extremely difficult to provide any meaningful input or to discern the effects it will have on various stakeholder groups. The precise wording of the provisions, the references to other documents and instruments, and the interplay of each provision with the rest of the text is crucial in understanding the full implications and consequences of the TPPA.

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<sup>1</sup> The advisory committee system in the US currently consists of 28 advisory committees, with a total membership of approximately 700 persons from the private sector. The Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) has 15 members, all of which represent large corporate holders of intellectual property rights.

Providing increased transparency legitimizes the entire process and allows public citizens to give feedback on the provisions that will ultimately affect them and will improve their ability to engage in the democratic political process. Ongoing public access to negotiating texts and other documents used in the negotiations is critical.

We recognize and acknowledge that concerns about the transparency of these texts are, of course, much broader than just these identified sections of the text. While the comments contained in this document concern access to medicines and the public health, we note that some of the signed groups have concerns extending to other issues in the TPPA.

**2. *Parties to the negotiations should invite public comment on the text of the agreement, including areas that could be extended to include positive measures to improve health***

The United States can benefit from the expertise of those in diverse fields by seeking public comments on the negotiating texts. Various individuals and civil society organizations have differing expertise and can offer their knowledge to create an improved agreement. Institutionalized public briefings to civil society and the general public after each negotiating round would provide further transparency to the negotiations and allow public participation in a more meaningful manner.

TPPA transparency can be improved by following the recent example of WIPO and USPTO concerning the proposed treaty on traditional cultural expression. WIPO created a “wiki” for this proposed treaty with the actual draft language, and invited the public to comment on each article. Anyone accessing the page could then see what comments had been made with regard to the articles, as well as what person or organization held these views. The day that comments were due on the wiki, the US Patent and Trademark Office held a stakeholder meeting on the existing language in the draft treaty, inviting a broad group of stakeholders to discuss the implications of each article. This session was extremely beneficial because the diversity of expertise allowed for collaboration to strengthen the document in a positive manner.

**3. *Parties to the negotiations should provide access to the negotiating venue***

Notification of the dates and locations of the negotiating rounds is critical in allowing the public the opportunity to meet with negotiators and provide comments and feedback on the negotiations. Public notice of the venue location and dates of the negotiating round within seven days of the decision on this information would provide ample notice to the general public. We recommend the opportunity to participate in and view a public component of the negotiations to afford the public the ability to observe and comment on the norms that will affect them once an agreement is reached. At a minimum, the public needs physical access to the venue to ensure that civil society and the general public have the opportunity to share their views with the negotiators.

## **II. General Public Health Safeguards**

### **1. *The US should not propose norms requiring parties to the negotiation, particularly developing countries, to adopt levels of patent protection that exceed those required by the WTO TRIPS Agreement***

The TRIPS Agreement contains flexibilities that are crucial in protecting public health, particularly for those in low- and middle-income countries. The TRIPS Agreement reflects international standards for intellectual property protection while allowing states to balance protection for intellectual property and development concerns, such as public health policy. Any measures taken to adopt patent protection norms exceeding the requirements of TRIPS greatly erodes existing public health safeguards and endanger the lives of patients living in developing countries.

As will be discussed further, the US text of the TPPA contains numerous provisions that go well beyond that which is required internationally by TRIPS. Requiring TRIPS-plus measures, such as those found in the TPPA, prejudices access to medical treatment and care and is inappropriate for low- and middle-income countries, including several which are parties to the TPPA negotiations.

### **2. *The US should recognize the flexibilities and goals acknowledged in the Doha Declaration on the TRIPS Agreement and Public Health and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property***

The US should ensure that the TPPA and any free trade agreements with developing countries recognize the Doha Declaration on TRIPS and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property which recognize the importance of public health safeguards. These principles are crucial to the development of low and middle-income countries and are essential to the health of their citizens and residents who depend on the accessibility, availability and affordability of life-saving medicines and treatments.

Despite the importance of the flexibilities and principles contained in these international documents, the TPPA omits any reference to the Doha Declaration or WHO Global Strategy and Plan of Action.

### **3. *Norms that prejudice access to medical technology or care should not be part of a mandatory protocol***

The US should not require countries to accede to intellectual property norms that will prejudice access to medical technology or care. As will be discussed in further detail below, several of the provisions contained in the US draft of the TPPA's IPR chapter would severely limit access to medicines and treatment options. In general, such provisions should not be required by negotiating parties (“shall”), but should only be optional if they are to be included at all. Parties should not be bound by any provision conflicting with or undermining goals to provide access to medicines for all.

### III. Patent Provisions

#### 1. *The US should not seek to impose obligations concerning the subject matter or standards for granting of patents*

Patent eligible subject matter and standards for the grant of patents are best left to national legislation and the US should not seek to impose a set standard on other negotiating parties to free trade agreements such as the TPPA. Countries have the right to determine the scope of patentability, consistent with the TRIPS Agreement, which is a key public health flexibility. For example, TRIPS leaves essential terms such as novelty, inventive step, and industrial applicability undefined and these standards are best determined by the governments of each individual country within the context of existing national legislation and circumstances.

It should also be noted that the May 10, 2007 agreement between President George W. Bush and the leadership of the Democratic controlled House of Representatives on “Provisions on Patents/IPR and Access to Medicines” did not provide for mandatory provisions on the scope of patentability. The definition of these terms can greatly affect the scope of patent eligibility and by seeking to enforce a one-size-fits-all standard on other countries, the US prejudices the interests and unique considerations facing individuals in these countries.

- Draft Article 8.1 of the US text requires that parties to the negotiation make patents available for “any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.” This provision will require developing countries to provide eligibility of patents for new uses of older drugs, or new forms that do not have a significant impact on the efficacy of products but, nonetheless, extends the effective monopoly on products. Requiring second use patents will greatly impact the availability and affordability of new, life-saving treatments, even where the original product patent has expired.
- In draft Article 8.2, the US seeks to require that parties make patents available on plants and animals, as well as diagnostic, therapeutic and surgical methods despite the fact that Article 27 of the TRIPS Agreement explicitly allows for the exclusion of these inventions from patent protection. Aside from the serious ethical concerns for surgeons performing procedures on patients, this text is not even appropriate by US standards. The current free trade agreement between the US and Australia allows for the exclusion from patentability of “diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.”<sup>2</sup> Effectively, the US-proposed language in the TPPA eliminates the flexibility to not extend patents to these methods. Ironically, at present the United States does not even enforce patents against medical professionals,<sup>3</sup> following complaints from physicians that it was unethical to perform a surgery with anything less than the best standard of care. Not only does draft Article 8.2 seek to impose specific obligations regarding patent-eligible subject matter, but these standards do not even comport with existing US free trade agreements and US domestic standards.

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<sup>2</sup> United States-Australia Free Trade Agreement, 1 January 2005, Article 17.9(2).

<sup>3</sup> See 35 U.S.C. §287.

- Draft Article 8.3 contains only narrow limitations as to what a party may exclude from patent eligibility specifically that “which is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.”
- Draft Article 8.8 requires parties to disregard information contained in public disclosures used to determine novelty or inventive step if the disclosure was made or authorized by the patent applicant and if such disclosure occurred within twelve months prior to the patent application. This provision strongly favors the patent applicant, making it more difficult to rely on public documents to show that a patent application lacks novelty or an inventive step. This provision's blanket authorization of an additional twelve months of protection extends beyond non-prejudicial disclosures and should not be mandated in the TPPA. Grace periods should be conditioned on the type of disclosure; the length of the grace period is best determined by national legislation.
- Draft Article 8.12 requires parties to “provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.” As discussed with respect to Article 8.1, *supra*, it is inappropriate for the US to try to define specific patent law concepts such as “industrially applicable” that are left undefined by TRIPS. These definitions are best determined by the national legislation of individual countries. Further, this provision, when read in conjunction with Article 8.1, can be seen as defining the scope of patentability and expanding the obligation to grant patents.
- Draft Article 9 includes “placeholder” text for provisions that will define the terms “new pharmaceutical product” and “new agricultural product.” For the reasons detailed above, we have serious concerns about the US attempts to define these terms which could potentially expand the scope of patentability. These definitions should be determined in the context of the individual circumstances and existing legal regimes of each country party to the negotiations.

## **2. The US should not require TPPA members to create systems of exclusive rights to rely upon test data to register new drugs and vaccines**

Exclusive rights to rely upon information from clinical studies used to establish the safety and efficacy of new drugs reinforce monopolies for life-saving medicines, raising prices and creating barriers for access to essential medicines. The US draft text contains “placeholder” provisions for data protection for pharmaceutical products. Thus, the actual language of the text is still unknown, but based upon four existing US free trade agreements including the US-Singapore Free Trade Agreement, the US-Chile Free Trade Agreement, the US-Australia Free Trade Agreement and the US-Korea Free Trade Agreement, it is expected that the US will introduce language requiring an exclusive right to rely on certain evidence that products are safe and effective during the period of data protection. During this period of exclusive rights, it is impossible to register new medications without duplicating the clinical studies—representing not only an economically inefficient regime, but also ethically inappropriate. In the four aforementioned agreements, the US pressed for a minimum term of protection of 5 years for certain new drugs, but since these negotiations, the US has adopted new legislation creating a 12 year monopoly on the regulatory test data for biologic drugs.

Requirements for exclusive rights in pharmaceutical test data raise serious implications for the availability of affordable drugs not only because of the high costs and ethics involved with regard to duplicating clinical trials, but also because of the lack of exceptions to these exclusive rights or mechanisms to challenge these monopolies. Furthermore, while patents have clear methods and procedures by which they can be challenged, rules governing exclusivity in pharmaceutical test data in some countries do not always provide the same exceptions. Thus, even where patients can overcome patent barriers and find generic suppliers, they will not be able to overcome drug registration barriers thereby greatly diminishing access to medicines.

The push for exclusive rights in test data without the possibility of exceptions would also override the May 10, 2007 agreement between President George W. Bush and the leadership of the Democratic controlled House of Representatives on “Provisions on Patents/IPR and Access to Medicines.” A portion of the agreement included “an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and subsequent protocols for its implementation.”

Furthermore we note that in several FTAs, the period for exclusive rights is based upon the date of the national rather than first global registration of the product. An older, expensive biologic that was later registered in a developing country will have a period of monopoly long after the monopoly ends in a country like the US where the drug was first registered. An extreme example occurs for products that are not registered at all by the originator in a developing country and for which the generic version is the only possible product that can be obtained.

### **3. *Patent linkage is not an appropriate intellectual property norm***

Linking drug registration and patent status can delay generic entry into the market and is an aggressive TRIPS-plus measure. The US draft text contains placeholder text for patent linkage for pharmaceutical products and, as a clear TRIPS-plus measure, is not appropriate as a mandatory provision for negotiating parties to the TPPA. Moreover, the May 10, 2007 agreement on “Provisions on Patents/IPR and Access to Medicine” provided for a less restrictive approach on linking patent status to drug legislation, making patent-linkage voluntary rather than mandatory; it is crucial for the US to recognize this agreement including, for example, in its negotiations and proposed language on the TPPA.

We note that most countries in Europe do not impose linkage between patent status and drug registration. If a linkage obligation is included in the TPPA, it will impose on developing countries more restrictive conditions for the registration of generic medicines than are found in Europe.

### **4. *The US should not require TPPA parties to enact patent terms beyond that which is required in TRIPS***

Patent extension beyond the twenty years patent term required by TRIPS is another area which is best determined by individual countries. Draft Article 8.6 contains a placeholder for provisions concerning patent term restoration or adjustment while draft Article 9.4 represents a placeholder for provisions related to the patent term and data protection relationship. Extension of patent duration will only strengthen monopolies while weakening access to essential medicines.

## **5. Procedures for addressing challenges to patentability should be left to each individual country**

Countries should preserve their ability to determine the best procedures to allow challenges to patentability given the circumstances, legislation, and administrative or court procedures of that country. It is often costly and difficult to challenge a patent once it has been granted; prohibition on methods to challenge patents before they have been granted will ultimately strengthen monopolies and restrict access to generics. Pre-grant opposition procedures have been successfully used in other countries to prevent the grant of patents on non-meritorious applications. These are fully compliant with TRIPS, which does not preclude pre- or post-grant opposition on patents.

Draft Article 8.7 of the US text provides that where a party allows third-party opposition to a patent, “a Party shall not make such proceedings available before the grant of the patent.” This prohibition on pre-grant opposition procedures will make it more costly and cumbersome to oppose a patent. Even where the patent should not have been granted in the first place, patent offices will not have the benefit of the expertise of competitors to the applicant who may be able to point to the application's flaws. Pre-grant oppositions can improve the patent system through public participation and help reduce over-patenting. It is highly inappropriate to dictate the manner in which patentability challenges are addressed and the US should remove this portion of Article 8.7.

## **6. Parties to the TPPA should not be required to ratify or accede to the Patent Cooperation Treaty of 1970**

Each country should determine for itself whether it is in its best interests to ratify or accede to the Patent Cooperation Treaty (PCT), particularly when these treaties have significant implications for the lives, safety and health of their citizens and residents. The PCT is more beneficial for countries that are net intellectual property exporters because the treaty's design is to make it easier to apply for patents in multiple countries.

Although most of the TPPA negotiating parties have already ratified or acceded to the PCT, it should not be a requirement of the TPPA. By making ratification or accession a requirement, it could result in difficulty in later withdrawing if the PCT is found to be cumbersome or threatening to public health. These concerns are particularly relevant given that the US has been trying to reform the PCT<sup>4</sup> into a substantive patent law treaty, drastically decreasing TRIPS flexibilities that are essential to the health of those living in developing countries.

## **7. Parties to the TPPA should not be required to “make all reasonable efforts” to ratify or accede to the Patent Law Treaty of 2000**

The PLT sets a maximum set of requirements that seek to reduce or eliminate formalities of patent applications, making it easier to obtain a patent. The PLT will result in more registered patents and decrease the ability to produce generic versions of these medicines. Generic production will become more heavily dependent on a country's administrative systems and willingness to issue compulsory

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<sup>4</sup> See WIPO Patent Cooperation Treaty (PCT) Working Group, *Comprehensive Proposal for PCT Reform* (Document prepared by the United States of America), PCT/WG/2/12, 24 April 2009. For example, this proposal would result in any applications receiving a positive Patentability Report (which, in brief, would occur when three international search authorities find a patent valid) automatically issuing as national patents.

licenses, as well as the domestic manufacturing capacity to produce generic medicines. Ratification or accession to the Patent Law Treaty will ultimately harm the public health by severely limiting access to affordable generics, particularly in the developing world.

In addition to the PLT's impact on access to medicines, ratification or accession to the treaty would place heavy burdens on developing countries which would be required to invest resources into the amendment of national legislation and training of IP offices and enforcement officials to comply with the revisions. The PLT's language requirements create further obstacles and increased costs for developing countries. The lack of flexibility allowed by the PLT hampers developing countries and the US should not seek to impose ratification or accession to the PLT through the TPPA negotiations.

## **IV. Enforcement Provisions**

### **1. *Ex-officio border measures, particularly those concerning in-transit merchandise are inappropriate enforcement mechanisms***

Ex-officio border measures, particularly when applied outside of cases dealing with willful, commercial scale counterfeiting, raise due process concerns as customs and border officials are often not fully trained or equipped to make accurate assessments and determinations with regard to intellectual property infringement or may be overzealous in the protection of brand name companies. Furthermore, in-transit seizures are particularly inappropriate because the exporting and importing countries may have different standards of patentability and the alleged infringing goods may actually be valid, legitimate products in the country of origin and country of ultimate destination.

Draft Article 14.4 provides for ex-officio border measures with respect to imported, exported or *in-transit* merchandise that is “suspected of being counterfeit or confusingly similar.” This provision should be removed from the US proposed language on the TPPA because of the issues with regard to ex-officio measures, the application to in-transit merchandise, and the unworkable standard set by the term “confusingly similar.”

In several recent, well-publicized cases, legitimate medicines that were not considered infringing in the countries of export or import were nonetheless seized in transit through Europe, from India to Africa or Latin America. Many public health and development groups believe that in-transit seizures of medicines should be limited to actual cases of counterfeit products, not to products where there is a mere allegation of confusingly similar trademarks. Moreover, the “confusingly similar” standard differs from country to country and trademark registrations are not the same in every market. In terms of standards for trademark infringement with respect to medicines, some countries permit products to have similar colors and shapes to help patients identify the proper medicines and doses to take, including where the patient switches suppliers for the drug. Some countries may also permit references on packaging such as “compare to,” with reference to a branded product, while other countries may consider these references to be infringements. The differences in national policies and geographically diverse trademark registrations create problems for legitimate generic manufacturers when products are seized in transit. At a minimum, these seizures will delay generics from reaching their country of destination, thereby also delaying access to essential medicines. More likely, however, this provision will result in making the global supply of generic medicines more risky, costly and less reliable and should therefore be removed from the US proposed language on the TPPA.

## **2. Presumptions regarding patent validity are best determined by the national legislation of each individual country rather than imposition of a one-size-fits-all regime**

Each country has a unique patent system, court system and administrative procedures with regard to intellectual property. As a result, imposing a one-size-fits-all regime whereby specific presumptions on patent validity apply in all countries party to the negotiation is inadvisable. Draft Article 10.2 provides for a “rebuttable presumption that a patent is valid” and requires parties to “provide that each claim of a patent is presumed valid independently of the validity of the other claims.” We believe that the creation of presumptions surrounding validity should be set at the national level, with each country determining the most appropriate standards to evaluate patent validity.

## **3. The use of suggested retail price or “other legitimate measure of value submitted by the right holder” may not be the most appropriate mechanism to determine damages for IP infringement**

Each country should individually determine the appropriate measure for damages for IP infringement. Damages may vary by type of infringement, conduct of the infringer, and other factors. We therefore recommend that Draft Article 12.3(b), which provides that “in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder,” be removed from the US proposed TPPA text.

## **V. Pharmaceutical Pricing Provisions**

### **1. The US should not seek to include pharmaceutical pricing provisions in the TPPA**

The pharmaceutical industry has reportedly lobbied for pharmaceutical pricing provisions or a separate pharmaceutical pricing chapter in the TPPA, modeled after Chapter 5 of the Korea-US (KORUS) and Annex 2(c) of the Australia-US (AUSFTA) FTAs. Pharmaceutical pricing provisions raise serious concerns for the public health and should not be included in the TPPA.

The US and many other countries, as well as private insurers, use formularies to restrain pharmaceutical prices. Brand name pharmaceutical companies have long objected to the use of government formularies because they are effective at restraining prices. Provisions in both KORUS and AUSFTA require that government reimbursement formularies “recognize the value” of patented medicines and provide appeals and other administrative processes to increase the influence of pharmaceutical companies over formulary decisions. The US is pushing for a double standard in its advocacy for restrictions on foreign pharmaceutical programs. Drug reimbursement programs in the US, such as the largest program, Medicaid, have price restraining formularies and achieve prices on par with, and often lower than, those operated by foreign country reimbursement programs. These programs also generally do not provide listing appeals or other procedures required by KORUS. The KORUS FTA responded to this fact by attempting to carve out all US pharmaceutical pricing programs from its coverage. Most federal pharmaceutical programs in the US, such as the Veterans Administration hospitals, and through GSA, are direct purchase programs, but the KORUS agreement

only covers “reimbursements.” Medicaid is the largest government drug reimbursement program in the US, but it is specifically carved out in a footnote to the KORUS agreement that clarifies that KORUS does not cover “regional level of government” programs. The USTR is advocating a standard that restrains other TPPA members' programs, but is drawn to place no restraints on similar programs operating in the US.

One problem with attempting to negotiate an agreement that only applies abroad, especially with minimal public consultation on the applicable language in the agreement, is that it may not succeed in efforts to carve out US programs, thereby putting US consumers at risk. For example, the Medicaid carve out in KORUS does not similarly exempt the federal 340(b) program of providing discounts for pharmaceutical reimbursements by health facilities that serve poor and disabled persons in the US.

Another major problem with attempts to negotiate double standards into international agreements is that they are bound to fail. Furthermore, as former Vermont Governor James Douglas wrote in a letter to Secretary Sebelius last year, the US should not “promote policies abroad that it is not prepared to require governments to abide by at home.”

Finally, there is an immense difference between the TPPA and KORUS and the AUSFTA in that the TPPA includes developing countries where the impact of restrictions on pharmaceutical price restraints is likely to be much more severe.

Respectfully Submitted,

Doctors Without Borders/Médecins Sans Frontières (MSF)

Health Action International—Global

Health GAP

Knowledge Ecology International

National Legislative Association on Prescription Drug Price\*

Oxfam America

Public Citizen

Universities Allied for Essential Medicines

\*National Legislative Association on Prescription Drug Prices has signed on to Part V of these comments which cover Pharmaceutical Pricing Provisions.