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22 March 2011

Anand Grover
The Special Rapporteur for the United Nations
on the right of everyone to the enjoyment
of the highest attainable standard of health

Re: Complaint about the Trans-Pacific Partnership Agreement Negotiation

Dear Mr. Grover:

In accordance with resolution 2002/31, we are writing to request that you issue an Urgent Appeal to the governments involved in the negotiation of the Trans Pacific Partnership (TPP), a regional free trade agreement being negotiated by the governments of Brunei, Chile, New Zealand, Singapore, Australia, Malaysia, Peru, Vietnam and the United States. The basis for the appeal is described in the attached memorandum.

Sincerely,

James Love, Thiru Balasubramaniam, Krista Cox and Manon Ress on behalf of Knowledge Ecology International
Edward Low on behalf of the Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
German Holguin Zamorano on behalf of Latin American and Caribbean(LAC)-Global Alliance for Access to Medicines
Roberto Lopez on behalf of Acción Internacional por la Salud (HAI) Peru
Dr Patricia Ranald on behalf of the Australian Fair Trade and Investment Network
Jose Teran on behalf of Acción Internacional por la Salud (HAI) Ecuador
Francisco Rossi on behalf of IFARMA Foundation - Colombia
German Holguin Zamorano on behalf of Mision Salud, Colombia
Alejandra Alayza on behalf of Peruvian Network for Fair Globalisation - RedGE
Health Action International (HAI) Europe
Acción Internacional por la Salud (HAI) Latin America and the Caribbean
Alberto Cerda Silva, Professor of Law, University of Chile Law School
Allen Black Jr., Adjunct Professor of Law, University of Pittsburgh
Jane Kelsey, Professor of Law, University of Auckland

Basis for Request that the Special Rapporteur for the United Nations on the right of everyone to the enjoyment of the highest attainable standard of health Issue an Urgent Appeal with Regard to the Trans-Pacific Partnership Agreement Negotiation

22 March 2011

Table of Contents

I. Introduction

In accordance with resolution 2002/31, we are writing to urge you to issue an Urgent Appeal in relation to the Trans Pacific Partnership (TPP), a regional free trade agreement being negotiated by the governments of Brunei, Chile, New Zealand, Singapore, Australia, Malaysia, Peru, Vietnam and the United States.

This communication is submitted by the following groups and individuals:

- James Love, Thiru Balasubramaniam, Krista Cox and Manon Ress on behalf of Knowledge Ecology International
- Edward Low on behalf of the Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
- German Holguin Zamorano on behalf of Latin American and Caribbean(LAC)-Global Alliance for Access to Medicines
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Since March 2010, there have been five rounds of negotiations on the text for the agreement.[1]

Among the topics that will be addressed in the TPP negotiation is a chapter on intellectual property rights, including provisions for patents and the protection of regulatory test data on medical inventions.

On 10 February 2011, KEI obtained the proposed United States text for an intellectual property chapter of the TPP, which is now available here: http://www.keionline.org/tpp. The chapter includes both specific plurilateral proposals for norms for intellectual property policies, and placeholders where text will be proposed at a later date.

It is extremely difficult to modify the text of such agreements, once the negotiators have reached an agreement. This difficulty extends to partial agreements on elements of the text.

The schedule of future rounds of TPP negotiations is as follows:

> Sixth round from 28 March – 2 April 2011, Singapore
> Seventh round from 20 – 24 June 2011, Viet Nam
> Eighth round from 6 – 11 September 2011, San Francisco, US
> Ninth round from 24 – 28 October 2011, Lima, Peru.

The parties to the negotiation are the governments of Brunei, Chile, New Zealand, Singapore, Australia, Malaysia, Peru, Vietnam and the United States. However, it is expected that the norms that emerge from this negotiation will soon afterwards be extended to impact a much wider group of trading partners, including the possibility of high income countries like Japan, Korea and Canada, as well as developing countries both within the Pacific region, and elsewhere, including, in particular, Latin America, South East Asia and countries in the Pacific, such as Indonesia, Thailand and the Philippines. Moreover, given economies of scale, any agreement that shrinks the market for legal generic medicines will have an adverse impact on consumers everywhere, particularly in developing countries where incomes are the lowest.

We allege that the TPP negotiations on intellectual property norms, as presently being conducted, threaten and violate the right of hundreds of millions of persons to the enjoyment of the highest attainable standard of health.

The bases for this complaint are grouped into the following areas:

1. The agreement is being negotiated in secret, without the opportunity for the persons who

1 A time-line of the negotiation is available here: http://keionline.org/node/1095

will be affected by the norms to participate effectively in democratic processes to influence the outcome of the negotiations. In this regard, we note that the lack of access to information is quite unequal, and some corporate interests have special access to information about the negotiations that is not available to the general public.

2. The agreement is taking place in an environment where one country, the United States, has far more power in the negotiation than other countries, and indeed, has deliberately designed this negotiation to maximize its unequal bargaining power, in part by avoiding more transparent and equal multilateral trade forums.

3. The United States has already made proposals that would require the parties to the negotiation to adopt levels of patent protection that exceed that which is required by the WTO TRIPS Agreement, and higher than the standards that developing countries "should" adopt, in order to promote access to medicine for all.

4. The United States is expected to propose, with possible support from Australia, a set of demands regarding the use of exclusive rights in regulatory test data, linkage between patent status and drug registration and the extension of patent terms, that will exceed WTO obligations for patent protection, and are counter to the obligation in Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health to implement TRIPS obligations in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicine for all.

5. The new obligations on intellectual property protection for medical technologies will make it less likely that developing countries will elect to provide legal guarantees of universal access to medical care, including new medicines, or that they can sustain and implement obligations they have already made.

6. There are also important errors of omission in the TPP. Based upon what is known about the text of the TPP so far, it does not include obligations for trading partners to act collectively to positively address well known development concerns. The parties negotiating the TPP have obligations under the UN Declaration on the Right to Development "to co-operate with each other in ensuring development and eliminating obstacles to development." Apparently missing from the TPP are obligations to support funding for global AIDS programs, to make investments in priority medical research and development, or to share access to government funded research – all topics that could and should be a subject of international cooperation and binding agreements.

The Urgent Appeal also includes at the end of this document suggestions for possible actions to remedy the violation of human rights.

II. Date and place of the incidents or the violation

If the United States proposal for an intellectual property chapter is accepted in full or in part by its TPP trading partners, the violation of the right of everyone to the enjoyment of the highest

attainable standard of health will take place at the date of entry into force of the Trans Pacific Partnership. Even before the conclusion of the agreement, there is a violation of the right of the affected parties to effectively influence the outcome of the negotiations, by the lack of access to information, and a general failure to consult with affected parties.

III. The specifics of the violation

The specifics of the violation are elaborated as follows:

1. The secrecy of the negotiation violates human rights

As noted, the TPP agreement is being negotiated in secret, without the opportunity for the persons who will be affected by the norms to participate effectively in democratic processes to influence the outcome of the negotiations.

The lack of access to information is quite unequal, and some corporate interests have special access to information about the negotiations that is not available to the general public. For example, the United States maintains a system of advisory bodies that have privileged access to information from trade negotiations. The advisory committee system was established by the Congress of the United States in 1974, and in practice is used to ensure that United States trade policy and trade negotiating objectives reflect certain private sector interests.

The advisory committee system 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. ITAC 15 includes officials from the trade associations PhRMA and BIO, as well as officials representing individual companies and several trade associations that represent publishers in the entertainment, software and book publishing industries. The Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health Science Products and Services (ITAC 3) has 22 members, including company representatives from the pharmaceutical companies Abbott Laboratories, Johnson & Johnson, and InterMune, medical device manufacturers such as Medtronic, AdvaMed, and North Coast Medical Equipment, and various other chemical and biotechnology interests, plus one seat for the United States Generic Pharmaceutical Association.

The 700 persons on the various advisory boards are given privileged access to information about trade negotiations, subject to signing confidentiality agreements.

The general public has not been given any official access to the texts proposed by any country for the TPP. Some texts have been leaked, including one paper by the United States that is on the keionline.org web site. However, the leaked texts are infrequently available, government officials are uncomfortable discussing their contents, and persons involving in leaking documents or publishing such leaks may be subject to a range of sanctions, including threats of losses of security clearances, losses of employment or employment opportunities, and even criminal sanctions including hefty fines and imprisonment.

The secrecy of the negotiating texts of the intellectual property agreements is completely inexcusable when the texts are circulated to all parties in the negotiations and large corporate right owners are privately briefed on the contents. Only the general public is kept behind a veil of ignorance. The secrecy is solely designed to insulate government officials from public accountability for tabling or endorsing or opposing specific proposals, and to give corporate right owners, including very large pharmaceutical companies, unequal influence on the outcome of the negotiations.

In the United States, the context for giving large corporate intellectual property right owners privileged access is a well established revolving door between trade negotiations and highly paid lobbyists who seek to influence trade policy.

This highly secretive, non-transparent behavior infringes upon the recognized rights to information and participation in public affairs. The right to access information, derived from Article 19 of the Universal Declaration on Human Rights[2] and Article 19 of the International Covenant on Civil and Political Rights (ICCPR)[3] has long been recognized as a "touchstone of all the freedoms to which the UN is consecrated."[4]

In particular, the right to access information held by the state is included in this basic human right and, in fact, is essential for political participation. The Special Rapporteur on the Promotion and Protection of Freedom of Opinion and Expression noted:

> The Human Rights Committee has emphasized the importance of the *right of citizens to be informed of the activities of public officials and to have access to information that will enable them to participate in political affairs*. In a democracy, the right of access to public information is fundamental in ensuring transparency. In order for democratic procedures to be effective, people must have access to public information, *defined as information related to all State activity*. *This allows them to take decisions; exercise their political right to elect and be elected; challenge or influence public policies; monitor the quality of public spending; and promote accountability*. All of this, in turn, makes it possible to establish controls to prevent the abuse of power.[5]

The Special Rapporteur in his 1998 Annual Report emphasized that this right to information "imposes a *positive obligation* on States to ensure access to information, particularly with regard

2 Universal Declaration of Human Rights, G.A. Res. 217A, art. 25, U.N. GAOR, 3rd Sess., 1st plen. Mtg., U.N. Doc A/810 (Dec. 12, 1948), Article 19 ("Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.").

3 International Covenant on Civil and Political Rights, art. 6(1), 16 Dec. 1966, 999 U.N.T.S. 171, Article 19. Stating that "1) Everyone shall have the right to hold opinions without interference; 2) Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writhing or in print, in the form of art, or through any other media of his choice."

4 UN General Assembly Resolution 59(1), 14 December 1946.

5 Report of the Special Rapporteur, Promotion and protection of the right to freedom of opinion and expression, UN Doc. A/HRC/14/23, 20 April 2010, para. 31 (emphasis added).

to information held by the Government in all types of storage and retrieval systems."[6]

By keeping the texts of these negotiations secret, the United States clearly violates this right to information as well as the recognized right to participate in the political process. The United States has not met its positive obligation of ensuring access and, in fact, has done the opposite through its secrecy. Without the text of its proposal, stakeholders do not have the opportunity to make informed opinions, challenge, and most effectively influence the policies expressed in the text.

The UN Convention Against Corruption, to which the United States is a party, similarly encourages Government transparency and public reporting. Article 10, for example, mandates that Parties take measures "as may be necessary to enhance transparency in its public administration, including with regard to its organization, functioning and decision-making processes . . ."[7] The Convention Against Corruption also requires Parties to promote civil society participation which can be strengthened by:

> (a) Enhancing the transparency of and promoting the contribution of the public to decision-making processes;
>
> (b) Ensuring that the public has effective access to information.[8]

Despite these international standards for transparency and access to information that promote an individual's right to participate in the political process, the United States has chosen to keep its TPP texts secret. The United States failure to make this information available to the public creates a significant obstacle to access to information on an important trade issue not only affecting those stakeholders within the US, but also those residing in other partner states to the negotiations and, potentially, other Asian, Pacific or Latin American states that may later sign onto the TPP.

Without access to this information, the right to participate in public affairs and the political process is also implicated. While each person has a right to participate in public affairs,[9] the United States insistence on limiting access to information threatens this essential freedom.

In particular, concerns exist for those that live in poverty, minority groups, and others who may lack a voice in the political process. The UN Secretary-General, acknowledged that, "From a

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6 Report of the Special Rapporteur, *Promotion and protection of the right to freedom of opinion and expression*, UN Doc. E/CN.4/1998/40, (28 Jan. 1998), para. 14 (noting also that the right to information is not only fundamentally important to freedom and democracy, but that concerns existed regarding "the tendency of Governments, and the institutions of Government, to withhold from the people information that is rightly theirs.")-.

7 UN General Assembly, United Nations Convention Against Corruption, 31 October 2003, A/58/422, Article 10.

8 UN General Assembly, United Nations Convention Against Corruption, 31 October 2003, A/58/422, Article 13(1).

9 *See e.g.*, International Covenant on Civil and Political Rights, art. 6(1), 16 Dec. 1966, 999 U.N.T.S. 171, Article 25 ("Every citizen shall have the right and the opportunity, without any of the distincitions metnioend in article 2 and without unreasonable restrictions: a) to take part in the conduct of public affairs, directly or through freely chosen representatives."); UN Secretary-General, Note on Human Rights and Extreme Poverty, UN Doc. A/65/259, 9 Aug. 2010, para. 88.

human rights perspective, the effective participation of the beneficiaries is not only desirable in terms of ownership and sustainability, but is in itself a human right: the right to take part in public affairs."[10] Furthermore,

> Participation must go beyond simple consultation. States should create an enabling environment for the effective participation of all vulnerable and disempowered groups, taking into account their constraints as well as asymmetries of power. Participation is also essential to ensure that the interventions aimed at the achievement of the Millenium Development Goals are empowering and transformative, rather than the result of technocratic, top-down State policies.[11]

Those living in extreme poverty often have inadequate resources to participate in the political process and failure to provide adequate access to information "leads to social exclusion and obstructs human development."[12] People who find themselves in poverty "find it difficult to make their voices heard" and access to information can be used as a "tool[ ] that can contribute to the eradication of poverty."[13] It is imperative for

> [e]ffective and meaningful participation by people living in poverty . . . that a broad set of rights are respected, protected and fulfilled . . . In practice, this requires the establishment of specific mechanisms and arrangements at different levels to ensure that . . . those living in poverty have a voice and play an effective part in the life of the community.[14]

Similar concerns arise for women who are often denied access to information or the ability to take part in public affairs.[15]

Additionally, the rights of a child—including a right to information[16]—would be highly impacted by the TPP provisions. The Committee on the Rights of a Child observed that:

> effective implementation of the Convention requires visible cross-sectoral coordination to recognize and realize children's rights across Government, between different levels of government and between Government and civil

10 UN Secretary-General, Note on Human Rights and Extreme Poverty, UN Doc. A/65/259, 9 Aug. 2010, para. 88.
11 UN Secretary-General, Note on Human Rights and Extreme Poverty, UN Doc. A/65/259, 9 Aug. 2010, para. 89.
12 Report of the Special Rapporteur, *Promotion and protection of the right to freedom of opinion and expression*, UN Doc. E/CN.4/1998/40, (28 Jan. 1998), para. 54.
13 Report of the Special Rapporteur, *Promotion and protection of the right to freedom of opinion and expression*, UN Doc. E/CN.4/1998/40, (28 Jan. 1998), para. 56.
14 Report of the Special Rapporteur, *Promotion and protection of the right to freedom of opinion and expression*, UN Doc. E/CN.4/1998/40, (28 Jan. 1998), para. 58.
15 Report of the Special Rapporteur, *Promotion and protection of the right to freedom of opinion and expression*, UN Doc. E/CN.4/1998/40, (28 Jan. 1998), para. 44 ("Everyone has the right to access the information needed to form opinions or to take decisions. However, women, in particular, have sometimes been denied full enjoyment of this right and, in extreme cases, this has led to them being denied information or the education they need. In cases where the State has failed to promote and ensure access to information and education, to means of expressing opinions, and to health and anti-violence programmes, this failure has had a negative impact on women's ability to make informed decisions freely."
16 Convention on the Rights of the Child, 20 November 1989, A/RES/44/25, art. 13.1.

> society—including, in particular, children and young people themselves. Invariably, many different government departments and other governmental or quasi-governmental bodies affect children's lives and children's enjoyment of their rights . . . Rigorous monitoring of implementation is required, which should be built into the process of government at all levels but also independent monitoring by national human rights institutions, NGOs and others.[17]

The Secretary-General also noted the importance of accountability and availability of redress in the case where individuals are denied the right to participate in public affairs and said, "Policymakers and others whose decisions and actions have a negative impact on the right to social security or the right to an adequate standard of living must be held accountable."[18]

At present, the TPP negotiations have completely excluded stakeholders that will be significantly affected by this agreement from this process and the United States behavior therefore infringes on the right of participation in the political process. By conducting negotiations in a secretive manner and refusing to share the text of the proposals, the United States has effectively denied individuals the right to access information and challenge or provide input on public policies. This secrecy is particularly concerning for marginalized groups, including women, children, and those living in poverty, who will be greatly affected by the outcome of the TPP.

What is particularly troubling for such groups is the fact that some corporate, industry parties have special access to the information that the United States refuses to make public. Such behavior only magnifies the issue of inequity and intensifies the problems for certain marginalized groups that will be affected by the TPP agreement. Such secrecy and lack of transparency violates human rights and cannot be tolerated.

Some argue that additional transparency will work against the weaker party or consumer interests in a trade negotiation. We do not believe this will be the case for negotiations involving intellectual property rights or policies regarding the prices of medical inventions. During the period of extreme secrecy, the norms reflected negotiating text of the Anti-Counterfeiting Trade Agreement (ACTA) was extremely hostile to privacy, civil rights and consumer concerns in general. Only after versions of the text were made public through a series of leaks and demands for transparency by the European Parliament was it possible to identify the harmful aspects of the agreement, and to modify the negotiating text so it was less harmful to access to medicine and access to knowledge. The negotiations at the World Intellectual Property Organization (WIPO) on the WIPO Development Agenda and at the World Health Organization (WHO) on Public Health, Innovation and Intellectual Property were both highly transparent with regard to the negotiating texts, as well as the ability of civil society to attend the public parts of the negotiating sessions and meet directly with negotiators. In all of these cases, the transparency had a positive impact on human rights, and the interests of the weaker parties.

We note that all governments party to the negotiation have agreed to the rules regarding secrecy of the negotiating text.

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17 UN Committee on the Rights of a Child, General Comment No. 5 (2003).
18 UN Secretary-General, Note on Human Rights and Extreme Poverty, UN Doc. A/65/259, 9 Aug. 2010, para. 90.

2. The negotiation is designed to exploit unequal bargaining power

All of the norms in the intellectual property chapter of the TPP could be negotiated in other fora, including multilateral institutions such as the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), or specialized agencies such as UNESCO or the World Health Organization (WHO). The decision to include intellectual property rights negotiations within a plurilateral FTA agreement is itself a violation of human rights, if, as in the present case, it pits nations and residents of very different incomes, interests and power into a situation where health is traded for market access in unrelated fields.

Consider the relative economic power and incomes of the countries in the negotiation. Tables 1 and 2 present the 2009 GDP, population and per capita incomes for the negotiating parties in absolute and relative terms.

Table 1: 2009 GDP, Population and Per capita incomes

Country	*2009 GDP (millions)*	*2009 Population (millions)*	*GDP/Pop*
USA	$14,119,000	307.0	$45,640
Australia	$924,843	21.9	$43,770
Brunei	$11,471	0.4	$27,050
Chile	$163,669	17.0	$9,470
Malaysia	$193,093	27.5	$7,350
New Zealand	$126,679	4.3	$27,260
Peru	$130,324	29.2	$4,200
Singapore	$182,232	5.0	$37,220
Vietnam	$90,090	87.3	$930
	$15,941,401	499.5	$31,917.27

Table 2: Shares of GDP, Population and Relative Income Per Capita

Country	*Share of GDP*	*Share of Population*	*Relative per capita income*
USA	88.6%	61.5%	143.0%
Australia	5.8%	4.4%	137.1%
Singapore	1.1%	1.0%	116.6%
New Zealand	0.8%	0.9%	85.4%
Brunei	0.1%	0.1%	84.8%
Chile	1.0%	3.4%	29.7%
Malaysia	1.2%	5.5%	23.0%
Peru	0.8%	5.8%	13.2%
Vietnam	0.6%	17.5%	2.9%

The TPP negotiation pits one economic superpower, the United States, against eight countries that collectively have only 11.4 percent of the GDP of the group. On a per capita basis, five of the nine countries have incomes between 84.8 and 143 percent of the population weighted average. Four of the countries have per capita incomes below 30 percent of the average. One country has a per capita income below 3 percent of the average.

It is difficult to imagine a single norm for intellectual property rights that would fit all of these countries. However, a review of the proposal by the United States shows that this is exactly what has been proposed, in the text that has been considered so far.

The concerns regarding the push by developed countries on developing countries to enact strict intellectual property regimes through Free Trade Agreements (FTA) have been well documented. Developed countries have negotiated these FTAs to reflect the standards of their own intellectual property regimes,[19] raising significant concerns for the right to health as will be discussed further in Section 3-5, *infra*. The behavior of the United States in this case is unconscionable, using its significant position of power in these negotiations to insert provisions in the TPP that fail to protect the public health and also lack public health safeguards and flexibilities that are allowed by international law.

While it is imperative that States consider the consequences for public health in negotiating FTAs,[20] the right to health and access to medicines issues have been clearly ignored in the TPP negotiations. The enforcement of an intellectual property regime that goes far beyond international standards and imposes norms that are US-based will greatly impact access to medicines and will have severe consequences on the right to health for citizens and residents of all parties to the TPP negotiations.

As the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health recommended in 2009, "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."[21] The United States has clearly ignored this recommendation, and as will be further discussed in Sections 3-5, *infra*, has violated its obligation to ensure the human right to health.

3. The current proposals for intellectual property rights norms are inappropriate for both developed and developing countries

As noted above, the United States has made proposals for intellectual property norms that would require the parties to the negotiation to adopt levels of patent protection that exceed those

19 Human Rights Council, Report of the Special Rapporteur n the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,A/HRC/11/12, 31 March 2009, para. 94. (citing United States Trade Promotion Authority Act (2002), 116 STAT. 933, s. 2102(b)(4)(A)(II).

20 *See* Human Rights Council, Report of the Special Rapporteur n the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,A/HRC/11/12, 31 March 2009, para.70.

21 Human Rights Council, Report of the Special Rapporteur n the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,A/HRC/11/12, 31 March 2009, para. 108.

required by the WTO TRIPS Agreement, and higher than the standards that developing countries "should" adopt, in order to promote access to medicine for all.

The following are examples of provisions that are included in the February 2011 proposal for the chapter on intellectual property by the United States:

1. The first is an error of omission. The proposal by the United States makes no mention of the Doha Declaration on the TRIPS Agreement and Public Health or the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

2. The United States proposes that patents shall be 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. (art. 8.1) This provision is designed to prevent developing countries from eliminating patents for new uses of older drugs, or new forms that do not have a significant impact on the efficacy of the products, but which can be used to extend the effective monopoly on products. This standard is certainly not appropriate for a trade agreement that includes developing countries,[22] and in our opinion, it is not appropriate as a global standard even for higher income countries.

3. In civil and administrative proceedings involving patents, the United States has proposed that each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.

4. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, the United States proposal would prevent countries from making such proceeding available before the grant of the patent. (art 8.7)

5. The United States has proposed that "Each Party may only exclude from patentability inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law. (art. 8.3). The proposed text would also *require* Parties to make patents available on plants and animals, as well as diagnostic therapeutic, and surgical methods. (art. 8.2) This is more

22 The March 15, 2011 UNAIDS/WHO/UNDP Policy brief on "Using TRIPS flexibilities to improve access to HIV treatment" states: "High-income governments should ensure that free trade agreements with middle-or low-income countries comply with the principles of the Doha Declaration." Noting also that " . . . certain key terms relating to TRIPS obligations are not defined in the Agreement itself, including such essential patent law concepts as 'invention', 'new/novel' and 'involve an inventive step/non-obvious', which leaves considerable discretion to WTO Members as to how to apply the three criteria of patentability – novelty, inventive step and industrial applicability – within their national laws. The use of these policy options and other flexibilities can directly or indirectly help to increase the supply and availability of necessary medicines. This should enable low- and middle-income countries to achieve a balance between intellectual property protection and specific developmental priorities, including the attainment of national public health objectives." Finally, the brief says "The decision on whether a new form of a known substance can be patented has major implications for many drugs used in HIV care, now and in the future."

restrictive than the text of AUSFTA, which reads:

> Each Party may only exclude from patentability: (a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and *(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals*.[23]

The effect of the proposal by the United States is to eliminate the flexibility to not extend patents or the enforcement of patents to diagnostic, therapeutic, and surgical methods for the treatment of humans and animals. Ironically, at present the United States does not enforce patents against medical professionals, following complaints from physicians that it was unethical to perform a surgery with anything less than the best standard of care.

6. The TPP text proposes that parties shall provide *ex officio* border measures with respect to **in-transit**[24] merchandise that is suspected of using "confusingly similar" trademarks. This is a separate category in the TPP from counterfeit products. Recently, in several well publicized cases, legitimate medicines that were not considered infringing in the exporting or importing markets were seized in European Airports, in route from India to Africa or Latin America. In the opinion of many public health and development groups, in-transit seizures of medicines should be limited to cases of counterfeit products, and not to products where there is a mere allegation that trademarks are confusingly similar. This is because the standards for determining what constitutes a "confusingly similar" mark differs from country to country, trademark registrations are not the same in every market, and border authorities are often poorly trained and overzealous protectors of big brand name companies. In terms of the standards for trademark infringement involving medicines, some countries permit products to have similar colors and shapes, in order to help patient identify the proper medicines and doses to taken, in cases where patients switch suppliers for the same drug. Some countries also permit references on packages that say things like "compare to" a trademarked name of branded product. In other countries, this may be considered an infringement. These differences in national policies, as well as geographically diverse trademark registrations, create problems for legitimate generic manufacturers, when products are seized in-transit, and have made the global supply of generic medicines more risky and costly, and less reliable.[25]

Collectively, the above provisions significantly erode the public health safeguards and

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23 Australia-United States Free Trade Agreement, 1 January 2005, Article 17.9(2) (emphasis added).

24 Article 51 of the TRIPS requires measures regarding the import and export of counterfeit trademark or pirated copyright goods, but allows the extension of the procedures to "other infringements of intellectual property rights." The extension beyond the narrower cases set out in Article 51 of the TRIPS may be subject to other WTO Agreements, such as the GATT provisions on the free movement of goods. Footnote 13 to Article 51 of the TRIPS says "It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit."

25 See the February 18, 2009 NGO letters to WHO & WTO on Dutch seizures of generic medicines in-transit from India to Brazil, Colombia & Peru. http://keionline.org/blogs/2009/02/19/ngo-letters-to-who-wto-on-dutch-seizure.

flexibilities contained in international documents such as TRIPS or the WHO Global Strategy on Public Health, Innovation and Intellectual Property, and also infringe upon the human right to health. The right to health has been derived from, or affirmed in, numerous international documents including, the Universal Declaration of Human Rights;[26] the International Covenant on Economic, Social and Cultural Rights;[27] the International Covenant on Civil and Political Rights;[28] the Convention on the Rights of the Child;[29] and the Declaration on the Right to Development.[30]

This right to health includes access to medicines[31] and medical treatment, and imposes a positive obligation on the State. The Human Rights Council has determined that States hold a responsibility "to ensure access to all, without discrimination, of medicines, in particular essential medicines that are affordable and of good quality."[32] Additionally,

> Current health inequalities regarding access to medicines demonstrate the need for States to respect their obligations under international law to protect the right to health. This includes ensuring that their laws and practices, including those related to IP, take into consideration the right to health and the need to ensure access to affordable medicines to all.

This positive obligation is particularly relevant in the context of the protection of children where states are required to take the best interests of the child as its primary consideration in any

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26 Universal Declaration of Human Rights, G.A. Res. 217A, art. 25, U.N. GAOR, 3rd Sess., 1st plen. Mtg., U.N. Doc A/810 (Dec. 12, 1948), Article 25(1) ("Everyone has the right to a standard of living adequate for the necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.")

27 International Covenant on Economic, Social and Cultural Rights, art. 11, 16 Dec. 1966, 993 U.N.T.S. 3, Article 12 ("The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.")

28 International Covenant on Civil and Political Rights, art. 6(1), 16 Dec. 1966, 999 U.N.T.S. 171, Article 6 ("Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.")

29 Convention on the Rights of a Child, 2 September 1990, Article 24 ("State Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and facilities for the treatment of illness and rehabilitation of health. State Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services . . . State Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries."

30 Declaration on the Right to Development, A/RES/41/128, 4 December 1986, Article 8 (States should undertake, at the national level, all necessary measures for the realization of the right to development and shall ensure, inter alia, equality of opportunity for all in their access to basic resources, education, health services, food, housing, employment and distribution of income. Effective measures should be undertaken to ensure that women have an active role in the development process. Appropriate economic and social reforms should be carried out with a view to eradicating all social injustices.")

31 We note that this right to access to medicines is generally considered as stemming from the essential right to health. On a related note, human rights documents also provide for the human right to the benefits of science. Article 15 of the ICESCR, for example, provides that everyone has the right "To enjoy the benefits of scientific progress and its applications," and further imposes on State Parties an obligation to take steps to provide for the "conservation, the development and the diffusion of science and culture."

32 Human Rights Council, Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/12/24, 12 October 2009.

decision.[33] This positive obligation has been interpreted as requiring the State to consider "how children's rights and interests are or will be affected by their decisions and actions—by, for example, a proposed or existing law or policy or administrative action . . . including those which are not directly concerned with children, but indirectly affect children."[34]

States, bound by their obligation to protect the human right to health, must take steps to ensure, for example, that medicines are available, affordable and accessible. These factors often depend on intellectual property and trade rules and it is the State's responsibility to ensure that their policies consider the right to health.

Ensuring this human right requires states to be aware "of the primacy of human rights obligations under international law over economic policies and agreements."[35] Furthermore, in order to promote human rights in accordance with international standards, states should, "in national, regional and international economic policy forums . . . take international human rights obligations and principles fully into account in international economic policy formulation."[36]The United States seeks to violate these mandates, placing intellectual property and economic policy above human rights in its draft text. These provisions have strong implications for the human right to health.

By significantly eroding the flexibilities now available in the TRIPS Agreement, States have fewer options to protect the public health and ensure the highest attainable standard of health. Knowing that FTAs have demonstrated an "adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfill the right to health,"[37] it is important to influence these negotiations in a way to assure greater adherence to human rights obligations.

4. New text for TPP intellectual property rights norms are expected to undermine access to medicine

As noted above, the United States is expected to propose, with possible support from Australia, a set of demands regarding the use of exclusive rights in regulatory test data, linkage between patent status and drug registration and the extension of patent terms, that will exceed WTO obligations for patent protection, and are counter to the obligation in Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health to implement TRIPS obligations in a manner to promote access to medicine for all. For example, in the February 2011 proposed intellectual property rights chapter, the United States listed the following provisions:

[Placeholder for provisions related to data protection for pharmaceutical products]

33 Convention on the Rights of the Child, 20 November 1989, A/RES/44/25, art. 3.1.
34 United Nations Committee on the Rights of the Child., General Comment No. 5 (2003).
35 Commission on Human Rights resolution 2001/33. Access to medication in the context of pandemics such as HIV/AIDS, UN Doc. E/CN.4/RES/2001/33, 20 April 2001, para. 1).
36 The Sub-Commission on the Promotion and Protection of Human Rights, Intellectual Property Rights and Human Rights, resolution 2001/21, UN Doc. E/CN.4/SUB.2/RES/2001/21, 16 August 2001, para. 3.
37 Human Rights Council, Report of the Special Rapporteur n the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,A/HRC/11/12, 31 March 2009, para. 94.

[Placeholder for provisions related to patent linkage]
[Placeholder for provisions related to patent term/data protection relationship]
[Placeholder for definitions of "new pharmaceutical product" and "new agricultural product"]

It is anticipated that each of these areas will include provisions that either extend the life of the patent beyond the 20 years mandated by the WTO TRIPS Agreement, or create special enforcement rights in regulatory forums that are likely to be abused by patent owners (as has been the case repeatedly in the United States, and is well documented by the United States Federal Trade Commission[38]), or create an ethically inappropriate[39] and economically inefficient regime of exclusive rights to rely upon information from clinical studies used to establish the safety and efficacy of new drugs.

None of these provisions are required by the WTO. All will predictably strengthen monopolies for life saving medicines, raise prices and create barriers for access to medicines.

As noted in Section 3, *supra*, the human right to health includes a positive obligation on the State to ensure access to medicines. These placeholder provisions have the potential to severely infringe upon the human right to health by restricting access to essential medicines.

We are particularly concerned about the proposal to introduce into the TPP obligations to create new intellectual property rights in regulatory test data. We anticipate that the provisions on regulatory test data that will be proposed for the TPP text will be based upon four existing FTA texts

- The United States-Singapore Free Trade Agreement that has been in force since January 1, 2004.
- The United States-Chile Free Trade Agreement that entered into force on January 1, 2004.
- The United States-Australia Free Trade Agreement that entered into force on January 1, 2005.
- The United States-Korea Free Trade Agreement that was signed on June 30, 2007 (but is not yet in force).

In each of these texts, the parties have agreed to create an exclusive right to rely on certain evidence that products are safe and effective, during the period of protection of the data. During the period of exclusive rights, it is impossible to register new medicines with drug regulatory agencies without undertaking time consuming, costly, wasteful and ethically inappropriate duplicate clinical studies.[40] In these earlier FTA agreements, the United States pressed for a minimum term of protection of 5 years for certain new drugs. Since then, the United States has adopted new legislation to create a 12 year monopoly on the regulatory test data for biologic

38 Federal Trade Commission. Generic Drug Entry Prior to Patent Expiration: An FTC Study. July 2002.

39 See: Ska Keller tables MEP question on ethical aspects of pharmaceutical test data protection. http://keionline.org/node/1061, and Senator Sanders' summary of Ethical Pathway Act of 2010 – S. 3921, http://keionline.org/node/965.

40 James Love, "The production of generic drugs in India: A new trade agreement with the EU would hinder access to drugs in developing countries," BMJ 2011;342:d1694 .

drugs, such as the important cancer drug trastuzumab (sold by Roche under the trade name Herceptin), or agalsidase beta (sold by Genzyme under the trade name Fabrazyme), a treatment for Fabry disease.

The 12 year period of test data protection was recently cited by Francis Collins, the head of the United States National Institutes of Health (NIH), when he denied a request for a compulsory license for patents on NIH funded inventions involving Fabrazyme.[41] In the Fabrazyme case, the patent holder was unable to manufacture sufficient supplies of the drugs for patients suffering from Fabry's disease, including some patients who required kidney dialysis as a result of the shortage of the drugs. Collins noted that even if the patients overcome the patent barrier, they would not be allowed to obtain FDA registration for the product, due to the data exclusivity regime for biologic drugs, because the United States does not provide for exceptions in the exclusive rights, even when patients are facing a life threatening shortage of drugs.

Trastuzumab is another example to consider, when evaluating the impact of exclusive rights in regulatory data and access to medicines. For persons with HER2+ type of cancer, trastuzumab is an extremely effective drug that dramatically decreases the probability of a rapid and painful death. The price of Roche's Hereceptin is as high as $100,000 for a year of treatment. It may be possible to obtain a similar biosimilar version for for less than $500 per patient. At present, there is effectively no access to trastuzumab for many breast cancer patients living in developing countries.

If cancer patients can overcome patent monopolies and find generic suppliers of the drug, they will still have to overcome drug registration barriers. As implemented in the four FTA agreements cited above, the test data intellectual property regimen would be more restrictive than patents. An absolute monopoly right provides no safeguards against abuses, and nor does it allow any possibility for the state to order licensing of the rights in the test data, as can be done for a patent. As noted, it is costly and time consuming to duplicate clinical trials and doing so often violates ethical standards relating to the unnecessary repetition of scientific tests on humans. In the absence of regulatory pathways that permit manufacturers to rely on existing evidence of safety and efficacy, no new generic drug could be sold without the permission of the company that owns the data that was used to register the originator's product.

We also note that in several FTA agreements, the period for the exclusive rights is based upon the date of the national rather than the first global registration of the product. Thus, an older, expensive biologic drug, than was registered later in a developing country (due to lack of demand associated with the extremely high price) will have a period of a monopoly long after the monopoly ends in a country like the United States, where the drug was first registered. An extreme example of this will be 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. Note that in some cases, the lack of registration by the originator may even be a retaliatory measure for issuing compulsory licenses, and was threatened recently by Abbott Laboratories, in a case involving Thailand. In particular, consider the following quote from a March 2007 United States Department of State cable written by Ralph L. Boyce, then the United

41 Francis S. Collins, Director, National Institutes of Health, Determination in the Case of Fabrzyme Manufactured by Genzyme Corporation, December 1, 2010. For background on this dispute, see: http://www.keionline.org/fabrazyme.

States Ambassador to Thailand. [42]

> Abbott Labs, the recent target of a compulsory license on their patented antiretroviral Kaletra, confirmed to Embassy that the company had withdrawn applications for registration of seven new pharmaceutical products in Thailand, and had no plans to introduce new products until its intellectual property was property respected. The seven drugs include Aluvia, a new heat-stable version of Kaletra. Although the two drugs are identical in effect, the new version is considered ideal for tropical environments such as Thailand. Other drug applications pulled include treatments for hypertension, kidney disease, auto-immune disease and congestive heart failure. . . Comment: Abbott's actions will certainly be controversial. However, the action may strengthen the hand of Abbott and the rest of industry in future dealings with the RTG. Abbott's move puts the RTG on notice that there are visible consequences for its actions, rather than solely a vague weakening of the investment environment. Whether this focuses the minds of RTG officials at upcoming negotiations remains to be seen. End comment.

On May 10, 2007, President George Bush and the leadership of the Democratic controlled House of Representatives reached an agreement on "Provisions on Patents/IPR and Access to Medicine." This agreement included a poorly written and confusing statement that was open to different interpretations, but which did include "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." The Bush Administration never clarified what exactly this language meant. More clear were two other elements of the May 10, 2007 agreement: one would change "shall" to "may" for patent extensions, and the other would provide a less restrictive approach on linking patent status to drug legislation. Unfortunately, the Bush Administration never clarified which countries would benefit from the new policy to accommodate the obligations in the Doha Declaration to permit policies that promoted access to medicine.

The Obama Administration has not remedied the confusion created earlier by the Bush Administration, and recently declared the May 10, 2007 concessions to access to medicine to be no longer relevant, and completely abandoned by the White House.

The placeholders in the text concerning regulatory test data, patent extensions, linkage between patents and drug registration suggest that the United States expects these provisions to be addressed in the TPP. If such agreements follow the contours of the Chile, Singapore, Australia and Korea FTA agreements, or are even more aggressive following new United States legislation creating a 12 year period of protection for biologic drugs, they will significantly impact the human right to health, for those who would otherwise benefit from access to generic medicines. It will also make it more difficult to reform shortcomings in the United States legislation, such as to shrink or eliminate the period of exclusivity, create exceptions to address abuses of the exclusive rights, or to replace exclusivity with different approaches, such as cost sharing approaches, which may be appropriate for higher income countries such as the United States, Singapore, Australia, New Zealand and Brunei.

42 See: FOIA document: In 2007, United States Ambassador Ralph Boyce was pleased that Abbott withdrew life saving drugs from market in Thailand, http://keionline.org/node/799.

5. The new intellectual property rights norms will undermine efforts to create, sustain or develop legal guarantees of universal access to medical care, including new medicines

It is obvious that these new obligations regarding intellectual property protection for medical technologies will make it less likely for developing countries to elect to provide legal guarantees of universal access to medical care, including new medicines, or that they can sustain and implement obligations they have already made. Thus, not only will the IPR norms create barriers through high prices for products, they will lead to less insurance coverage and risk sharing, creating even more harsh barriers for persons who are sick.

Although States have a positive obligation to protect the right to health and need to ensure access to affordable medicines, as discussed in Section 3, *supra*, the standards pushed by the United States in the TPP agreement will greatly impact the ability of developing countries to take the positive steps necessary to protect the health of its citizens.

6. The TPP does not include positive measures to address development needs in the area of health

There are also important errors of omission in the TPP. Based upon what is known about the text of the TPP so far, it does not include obligations for trading partners to collectively act to positively address well known development concerns. The parties negotiating the TPP have obligations under the UN Declaration on the Right to Development "to co-operate with each other in ensuring development and eliminating obstacles to development."[43] Apparently missing from the TPP are obligations to support funding for global AIDS programs, to make investments in priority medical research and development, or to share access to government funded research – all topics that could and should be a subject of international cooperation and binding agreements.

The Human Rights Council called upon states:

> To take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of their available resources, with a view to achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.[44]

Not only do States have an obligation to co-operate in ensuring development and the realization of human rights, including the right to health,[45] but they should take into consideration

43 UN General Assembly, Declaration on the Right to Development, A/RES/41/128, 4 December 1986, para. 3.

44 Human Rights Council, Resolution on the Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/15/22, para. 4(d).

45 *See* Section 3, *supra*. *See also* Human Rights Council, Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/12/24, 12 October 2009 (States have a responsibility "to ensure access to all, without discrimination, of medicines, in particular

marginalized groups. The Human Rights Council called upon states to guarantee the human right, and

> To pay special attention to the situation of the poor and other vulnerable and marginalized groups, including by the adoption of positive measures, in order to safeguard the full realization of everyone to the enjoyment of the highest attainable standard of physical and mental health.[46]

The United States has clearly ignored marginalized groups and those living in extreme poverty by pushing for a strict intellectual property regime that fails to incorporate the flexibilities provided for in TRIPS. The TPP proposal contains no mechanisms to fulfill the obligation on States to cooperatively promote the rights to development and health.

IV. Possible actions to remedy the violation of human rights

Without prejudice to any other actions that may be considered appropriate, we respectfully suggest some possible actions to remedy the violations of human rights.

1. The versions of the negotiating text for the intellectual property chapter, and any other sections of the text that concern the right to obtain the highest standard of health, should be made public, once they have been widely circulated to the parties in the negotiation, and there is no longer any reason to withhold information from the public.

2. In general, norms that concern measures that prejudice access to medical technology or care should not be part of a mandatory protocol.

3. In general, no party should be bound by any provision that is in conflict with providing access to medicine for all, or which undermines the creation, implementation or sustainability of programs to extend access to medical care to all. This could be included in a trade agreement, as a special provision, just as the TRIPS has special provisions on the exhaustion of rights (Article 6) and the control of anticompetitive practices (Article 40), which override other sections of the agreement.

4. In particular, no developing country should be obligated to implement intellectual property obligations concerning the duration of patent, the subject matter or standards for granting patents, procedures for addressing challenges to patenability, the linkage of patents to drug registration, or the protection of drug registration data. In each of these cases, the WTO standards are more than sufficient, and indeed, excessive in some areas, even for higher income countries. Also, border measures should not be used to stop in-transit movements of drugs, when the products are not considered infringing products in the importing country.

5. The parties to the TPP negotiation should invite public comment on areas where the

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essential medicines, that are affordable and of good quality.")

46 Human Rights Council, Resolution on the Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/15/22, para. 4(f).

agreement could be extended to address positive measures to improve health, including for example, commitments to fund humanitarian programs to support treatments for AIDS, investments in medical R&D for neglected diseases, or by providing open access to government funded research findings.