



## How the Trans-Pacific Partnership Agreement Threatens Access to Medicines

The eighth round of closed-door negotiations for the Trans-Pacific Partnership (TPP) agreement will be held in Chicago from September 6-15, 2011. Negotiations during this round are expected to be substantial, as the current nine negotiating countries, Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States and Vietnam, plan to present the outlines of an agreement at the Asia Pacific Economic Cooperation (APEC) Leaders' meeting in Honolulu, November 8-13 2011.<sup>1</sup>

According to the United States Trade Representative (USTR), "U.S. involvement in the TPP is predicated on the expansion of the agreement to include more economies across the Asia-Pacific region,"<sup>2</sup> and should "set the standard for 21st-century trade agreements going forward."<sup>3</sup> It is therefore expected that the norms that emerge from these negotiations will serve as a baseline for future trade agreements, potentially impacting a much wider group of countries, including developing countries where MSF has medical operations and beyond. For example, Japan and South Korea are reportedly currently considering joining the TPP.

TPP negotiating parties are under no obligation to subject their negotiating positions to public scrutiny; only the final agreed-upon text will be made publicly available. However, a leaked draft of the U.S. position, now available to the public,<sup>4</sup> indicates that the U.S. is demanding aggressive intellectual property provisions that go beyond what international trade law requires. Furthermore, the U.S. position represents a major retreat from previous U.S. commitments to global health, including the 2007 bipartisan New Trade Policy, in which Congress and the Bush administration agreed to abide by important public health safeguards in future trade agreements.

### 1. INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

#### Vital Importance of Affordable Medicines

Affordable, quality generic medicines are a critical component of treatment programs. About 80% of the HIV medicines that MSF uses are generics, and MSF routinely relies on generic drugs to treat TB, malaria, and a wide range of infectious diseases. In fact, all the major donors and leading international treatment providers, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, The U.S. President's Emergency Plan for AIDS Relief (PEPFAR), UNITAID and UNICEF, rely on quality affordable generic drugs for the programs they support. PEPFAR, which purchases 80-90 percent of its ARVs drugs from generic suppliers, has reported significant savings through the purchase of generic medicines.<sup>5</sup>

The first generation of HIV drugs have come down in price by 99 percent over the last decade, from U.S.\$10,000 per person per year in 2000 to roughly \$60 today, thanks to generic production in India, Brazil and Thailand, where these drugs were not patented. This dramatic price drop has been instrumental in helping scale up HIV/AIDS treatment for more than six million people in developing countries. About 80 percent of donor-funded anti-AIDS drugs and 92 percent of drugs to treat children with AIDS across the developing world comes from generic manufacturers.

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<sup>1</sup> <http://www.ustr.gov/tpp>

<sup>2</sup> <http://www.ustr.gov/about-us/press-office/press-releases/2010/june/ustr-ron-kirk-comments-trans-pacific-partnership-talk>

<sup>3</sup> <http://www.ustr.gov/about-us/press-office/press-releases/2009/november/ustr-news-kirk-comments-trans-pacific-partnership>

<sup>4</sup> Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>5</sup> <http://jama.ama-assn.org/content/304/3/313.short>

## **Public Health Safeguards Threatened**

Since the creation of the World Trade Organization (WTO) and the conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1995, the most comprehensive multilateral agreement on intellectual property to date, developing countries have struggled to strike a balance between protecting public health and making their patent laws TRIPS compliant. Patents and other intellectual property (IP) regulations pose significant barriers to access to life-saving medicines, and flexibilities in patent systems are recognized as important public policy tools in the fight to protect public health interests. Even developed countries like the U.S. have utilized TRIPS-compliant legal flexibilities to protect public health and other national interests.

The WTO 2001 Doha Declaration on TRIPS and Public Health was signed to reaffirm that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, and that it can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. These commitments were reaffirmed and strengthened in the 2008 World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

However, over the last decade, many developing countries have come under pressure in trade negotiations not to use TRIPS flexibilities and to implement even tougher rules than those set out in TRIPS – these are known as “TRIPS plus.” The U.S. and the European Union routinely use bilateral and regional trade agreements to limit or circumvent developing countries' abilities to implement the Doha Declaration and safeguard public health. The U.S. and the E.U. both have large pharmaceutical industries lobbying for stricter patent regulations, and these interests not only tip the balance away from public health protections and threaten access to medicines, but also work to counter the efforts of global health programs.

In fact, studies have shown that U.S. bilateral and regional free trade agreements (FTAs) have already undermined access to medicines in developing countries. For example, Oxfam found in a 2007 study<sup>6</sup> that during the five-year period since Jordan implemented TRIPS plus measures included in the U.S.-Jordan FTA, medicines prices rose 20 percent, without any corresponding benefit in terms of domestic innovation or access to new products. In addition, the Center for Policy Analysis on Trade and Health (CPATH) found in a 2009 study<sup>7</sup> that once Guatemala enacted data exclusivity, on the basis of the Dominican Republic-Central America-United States (CAFTA-DR) FTA, prices for some medicines rose significantly – even though just a handful of medicines were under patent protection.

Recognizing the damaging effects that trade agreements have had on public health, the Bush administration and the U.S. Congress signed a bipartisan agreement on May 10th, 2007, known as the 2007 New Trade Policy,<sup>8</sup> to scale-back the harshest IP protections in order to strike a better balance between protection of IP and public health needs. The agreement specifies that the USTR should modify its intellectual property demands in trade agreement negotiations so that important public health safeguards are included. Yet in several meetings with U.S. civil society, the USTR has stated on the record that they are considering options in the TPP that would shift U.S. policy away from the 2007 New Trade Policy.

MSF is concerned that the U.S. demands for the TPP negotiations threaten to roll back vitally important public health safeguards in developing countries, creating a fundamental contradiction between U.S. trade policy and U.S. commitments and priorities on global health.

## **Medical Innovation Threatened**

MSF is also concerned about the effects that intellectual property norms have on innovation for essential medical technologies. The USTR presents its efforts to demand stronger regimes for intellectual property protection in developing countries as a tool to protect innovation. MSF recognizes the importance of innovation

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<sup>6</sup> [http://www.oxfam.org/en/policy/bp102\\_jordan\\_us\\_fta](http://www.oxfam.org/en/policy/bp102_jordan_us_fta)

<sup>7</sup> <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/cpathhaonline8-25-09.pdf>

<sup>8</sup> <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>

and the need to finance research and development. We are a humanitarian medical organization that needs and welcomes biomedical innovation to better treat our patients. However, the reality is that intellectual property protection in the medical field keeps prices high and limits access to treatment, and furthermore does not stimulate innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power. By seeking greater and higher intellectual property norms in developing countries, the U.S. government is perpetuating a failed business model that links innovation costs to high prices, and does not address the innovation needs of developing countries.

## **2. THE TRANS-PACIFIC PARTNERSHIP AND ACCESS TO MEDICINES**

The TPP negotiations are being conducted in secret, so MSF other interested stakeholders don't have access to the U.S. or other countries' demands. However, according to a leaked draft of the U.S. position, now available to the public at <http://keionline.org/node/1091>, as well as correspondence and discussions between Congress and the USTR, the U.S. is expected to demand the following TRIPS plus measures to be included in the Intellectual Property Chapter of the TPP:

### **a) Broadening the scope of patentability: the U.S. wants to make it easier to patent new forms of old medicines that offer no added therapeutic efficacy for patients**

The TRIPS agreement includes important flexibilities for governments to decide what type of "innovation" deserves to be protected by patents in a given country. Essential terms such as 'novelty,' 'inventive step,' and 'industrial applicability' are left undefined as standards to be best determined by individual governments within the context of existing national legislation and circumstances.

However, the U.S. is seeking to erode this flexibility by requesting that TPP partners introduce new rules that would severely limit the ability of each country to define what is 'patentable.'

For example, the U.S. proposal for the TPP requests the patenting of a "new form, use, or method of using" an existing product - even if there is no increase in efficacy.<sup>9</sup> This technique, known as "evergreening," allows pharmaceutical companies to obtain or extend monopoly protection for old drugs simply by making minor modifications to existing formulas. Evergreening significantly delays the arrival of more affordable generic medicines onto the market.

Novartis has been battling the Indian government on its implementation of this flexibility since 2006, when its patent for the cancer drug imatinib mesylate (Gleevec) was rejected on the grounds it was based on a drug compound that already existed. Having lost its case in 2007 and the patent appeal in 2009, Novartis is now attempting to ensure the words 'therapeutic efficacy' are interpreted in a way that allows even small changes to an old medicine - such as imatinib mesylate - to be patentable<sup>10</sup>.

Additionally, the US seeks to require that parties make patents available on plants and animals, as well as diagnostic, therapeutic and surgical methods for the treatment of humans or animals despite the fact that Article 27 of the TRIPS Agreement explicitly allows for the exclusion of these inventions from patent protection<sup>11</sup>. Aside from the serious ethical concerns for surgeons performing procedures on patients, this text is not even compatible with the U.S. policy not to enforce patents against medical professionals.<sup>12</sup>

### **b) Restrictions on pre-grant patent oppositions: the U.S. wants to make it harder to challenge unjustified patents**

The TRIPS agreement allows countries and third parties (including generic companies and civil society organizations such as patient groups) to file an opposition to the granting of a patent - either before it has been

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<sup>9</sup> Article 8.1, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>10</sup> <http://www.msfacecess.org/about-us/media-room/press-releases/drug-company-novartis-tries-weaken-indian-patent-law-protects>

<sup>11</sup> Article 8.2, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>12</sup> <http://keionline.org/node/1216>

granted (pre-grant opposition) or after (post-grant opposition). Patent opposition procedures have been successfully used in several countries to prevent patents being granted undeservedly.

For example, in June 2008 the Indian patent office rejected a patent for the hemihydrate (syrup) form of Nevirapine (NVP), a widely-used antiretroviral (ARV) treatment, based on pre-grant oppositions by civil society groups. The price of NVP has decreased dramatically over the past years as a result of generic competition. Similarly, the Indian patent office rejected the patent application for Tenofovir Disoproxil Fumarate (TDF), an important HIV drug highly recommended by the World Health Organization (WHO), and Darunavir (DRV), a third-line ARV, based on pre-grant oppositions.

Patent oppositions are an essential public health safeguard that can accelerate the entry of generic competition, improve the patent system through public participation, and help reduce over-patenting.

However, the U.S. government is now seeking to clamp down on this flexibility and prevent pre-grant oppositions in TPP partner countries,<sup>13</sup> making it more costly and cumbersome to oppose a patent. In addition, patent offices will not have the benefit of the expertise of opponents/competitors to the applicant who may be able to identify inaccuracies in the application before a patent is approved.

**c) Imposing new forms of IP enforcement: the U.S. wants to allow customs officials to seize shipments of drugs on mere suspicion of IP infringement and to increase damages for IP infringement**

The TRIPS agreement allows for governments to have a great amount of flexibility when designing the mechanisms that the country will allow for the enforcement of IP rights. However, the U.S., through the TPP and other tools (e.g. ACTA<sup>14</sup>), is demanding that countries enforce IP rights with new forms of enforcement beyond what TRIPS requires.

For example, the U.S. is requesting that TPP countries grant customs officials the ex officio right to detain shipments of medicines at the border, even in transit, if the goods are suspected of being counterfeits or if they are considered “confusingly similar” to trademarked goods.<sup>15</sup>

Under TRIPS, “counterfeit” products are defined as those resulting from criminal – and not civil – trademark infringement, which occurs knowingly and on a commercial scale.<sup>16</sup> The U.S.’s proposed TPP IP chapter allows border officials to rely on a different, more lenient standard – “confusingly similar” – in order to seize consignments. This standard conflates pure commercial trademark disputes, which do not represent a threat to public health or patent rights, with criminal offenses, such as production of counterfeit, falsified or substandard medicines.<sup>17</sup>

In fact, customs and border officials are often not fully trained or equipped to make accurate assessments with regard to intellectual property infringement and may be overzealous in the protection of brand name companies. For example, during 2008 and 2009, at least 19 shipments of generic medicines from India to other countries were impounded while in transit in Europe on grounds that the shipments were suspected of infringing patent rights.<sup>18</sup> In one instance, German customs authorities wrongfully seized a drug shipment of “Amoxicillin” on the suspicion that it infringed the brand name “Amoxil” – the cargo was detained for four weeks while further investigation took place, eventually revealing that there was no trademark infringement.<sup>19</sup> In another instance, the Dutch customs authorities seized a shipment of the AIDS drug abacavir sulfate while it was en route (via Europe) from India to a Clinton Foundation project in Nigeria.<sup>20</sup>

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<sup>13</sup> Article 8.7, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>14</sup> The Anti-Counterfeiting Trade Agreement (ACTA) would impose limits on price-reducing generic competition and jeopardize the free flow of legitimate medicines across borders.

<sup>15</sup> Article 14.4, Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>16</sup> [http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF\\_Final.pdf](http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF_Final.pdf)

<sup>17</sup> [http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF\\_Final.pdf](http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF_Final.pdf)

<sup>18</sup> <http://www.bmj.com/content/340/bmj.c2672.extract>

<sup>19</sup> <http://www.twinside.org.sg/title2/IPR/pdf/ipr13.pdf>

<sup>20</sup> <http://www.safemedicines.org/nigeriabound-hivaids-drugs-seized-in-netherlands.html>

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In addition, under the U.S.'s proposed TPP regulations, shipments that are legitimate in the country of origin and the country of ultimate destination would still be subject to detention in the transit country. Unwarranted interception of legitimate in-transit pharmaceutical supplies can undermine legitimate trade in generic medicines.

Furthermore, the U.S. is requesting TPP countries to mandate that judicial authorities consider valuing damages based on "the suggested retail price or other legitimate measure of value submitted by the right holder" in cases of infringement of intellectual property rights,"<sup>21</sup> a mechanism that strongly favors the rights holder and increases damage amounts. Each country should have the flexibility to individually determine the appropriate measure for damages for IP infringement.

**d) Expanding data exclusivity: the U.S. is seeking to expand a backdoor way to grant monopoly status**

Data exclusivity is a TRIPS plus provision that restricts access to essential clinical trial data pertaining to the safety and efficacy of drugs. Data exclusivity measures prevent generic manufacturers from using existing clinical research to gain regulatory approval of their medicines, forcing them to perform duplicate clinical trials or wait for the "data monopoly" period to end.

In the absence of data exclusivity measures, when a generic manufacturer applies to register and sell a version of a previously-registered medicine, they only have to provide data showing that their product is equivalent to the original.<sup>22</sup> The drug regulatory authority relies on the clinical trial data provided by the original manufacturer to evaluate the safety and efficacy of the generic drug.

The introduction of data exclusivity provisions essentially creates a new system for granting monopolies by blocking registration of generic medicines until the data exclusivity period ends, even if the patent monopoly has already ended or been overcome, for example with the use of a compulsory license. Under these terms, generic competition is stifled not only for old medicines no longer under patent protection, but also for new medicines that don't warrant patent protection.

Data exclusivity prevents the registration of generic versions of a medicine for many years (the U.S. is asking for up to 12 years of data exclusivity for some classes of drugs), unless the generic manufacturer repeats the necessary clinical trials. This is not only extremely costly, but also arguably unethical, as it forces duplication of clinical trials for patients and animals in order to prove something that is already known.

In addition, while there are clear methods and procedures by which patents can be challenged and overcome – such as patent oppositions and compulsory licenses – rules governing data exclusivity for pharmaceutical test data do not always provide the same public health safeguards.

Although it is not yet clear what the U.S. demands for data exclusivity will be for the TPP, the U.S. has traditionally pressed for a minimum term of five years, similar to U.S. law for certain products. However, Pharmaceutical Research and Manufacturers of America (PhRMA) has been aggressively lobbying for the TPP to require 12 years of data exclusivity for a subset of pharmaceutical drugs, called biologic (also called biosimilar or biopharmaceutical) drugs.<sup>23</sup> In August 2011, several members of the House of Representatives, led by Rep. Henry Waxman, urged president Obama to refrain from negotiating any provisions on exclusivity for biologics in the TPP, noting that a 12-year exclusivity period would impede the ability of Congress to achieve the administration's proposal that the exclusivity period for biologics be reduced to seven years, as reflected in the FY2012 budget proposal, without running afoul of U.S. trade obligations.<sup>24</sup> It is also unclear if the U.S will allow the public health safeguards for data exclusivity specified in the 2007 New Trade Policy.

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<sup>21</sup> Article 12.3 (b), Leaked TPP IPR chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)

<sup>22</sup> [http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04\\_093Rev4\\_final.pdf](http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_093Rev4_final.pdf)

<sup>23</sup> <http://www.pharmalot.com/2011/05/phrma-wants-12-years-data-protection-in-tpp-talks>

<sup>24</sup> [http://www.waxman.house.gov/UploadedFiles/TPP\\_Biologics\\_Letter\\_08-04-11.pdf](http://www.waxman.house.gov/UploadedFiles/TPP_Biologics_Letter_08-04-11.pdf)

**e) Requesting patent term extensions: the U.S. is seeking to keep generic competitors out of the market, for longer**

The TRIPS Agreement requires patents to last 20 years. Although it is not yet clear what the U.S. demands for patent term extensions in the TPP will be, the U.S. is expected to seek to extend the monopoly patent period in order to compensate for administrative delays in the regulatory process, even though the 2007 New Trade Policy made patent extensions optional for countries negotiating trade agreements with the U.S. Such extensions delay the entry of generic medicines, punishing patients for bureaucratic delays.

**f) Requesting patent linkage: the U.S. is seeking to turn drug regulatory authorities into ‘patent police’**

Patent linkage provisions prevent drug regulatory authorities from approving new drugs if they could potentially infringe existing patents. Such provisions effectively require drug regulatory authorities, which are responsible for evaluating the safety, quality, and efficacy of medicines, to take on the responsibility of policing patents, an area normally under the purview of separate patent authorities. Linking drug registration and patent status can delay generic entry into the market and is an aggressive TRIPS plus measure.

The 2007 New Trade Policy made patent linkage optional for countries negotiating trade agreements with the U.S. Most countries in Europe do not impose linkage between patent status and drug registration. If a linkage obligation is included in the TPP, it will impose on developing countries more restrictive conditions for the registration of generic medicines than are found in Europe

### **3. OBAMA ADMINISTRATION BACKTRACKING ON U.S. COMMITMENTS TO ACCESS TO MEDICINES**

The TPP is the first trade agreement negotiated under the Obama administration. Leaked U.S. positions and correspondence and discussions between Congress and the USTR indicate that the U.S. is prepared to walk away from its previous public health commitments, including the 2007 New Trade Policy.

The bipartisan May 10th, 2007 New Trade Policy,<sup>25</sup> signed by the Bush administration and U.S. Congress, specified that the USTR should modify its intellectual property demands in trade agreement negotiations so that important public health safeguards are included. The 2007 New Trade Policy aims to scale-back the harshest IP protections for developing countries in order to strike a better balance between protection of IP and public health needs. Although it did not go far enough, it was a step in the right direction. In particular:<sup>26</sup>

- Patent linkage provisions were made voluntary (whereas they had been mandatory in previous US trade agreements).
- Patent term extension provisions were made voluntary (whereas they had been mandatory in previous US trade agreements).
- Data exclusivity was limited to five years for new chemical entities; concurrent periods of exclusivity were mandated, and public health exceptions were allowed to ensure governments could still implement public health safeguards such as compulsory licenses.

When the 2007 New Trade Policy was announced, the House Ways and Means Committee called it “a fundamental shift in U.S. trade policy.”<sup>27</sup> However, the U.S. pharmaceutical industry has been aggressively lobbying against the 2007 New Trade Policy being applied to the TPP negotiation countries. USTR has stated that they are considering options in the TPP that would shift U.S. policy away from the 2007 New Trade Policy and toward greater protection of intellectual property rights for brand-name pharmaceutical companies in the

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<sup>25</sup> <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>

<sup>26</sup> For an analysis of the May 10 agreement, see: Fabiana Jorge. New U.S. trade policy: A turning point?. *Journal of Generic Medicines* (2007) 5, 5–8. doi:10.1057/palgrave.jgm.4950093. Available at: <http://www.palgrave-journals.com/jgm/journal/v5/n1/abs/4950093a.html>

<sup>27</sup> <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>

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developing world. Several Members of US Congress have also warned against this possibility and written to the Obama administration to demand that it uphold the 2007 New Trade Policy<sup>28</sup>.

#### **4. RECOMMENDATIONS**

The U.S. government should:

- a) **Withdraw TRIPS plus requests:** The U.S. should not seek to impose TRIPS plus provisions (e.g. broader scope of patentability, limits on patent oppositions, new forms of enforcement, data exclusivity, patent extensions and patent linkage) on TPP partners. At a minimum, the Obama administration should not walk away from public health protections agreed between Congress and the Bush administration in the 2007 New Trade Policy.
- b) **Increase transparency:** The TPP is being negotiated entirely in secret. Trade agreement negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, both with respect to the actual negotiating texts under discussion and the relevant negotiating position and demands of each country.
- c) **Recognize previous commitments to access to medicines and innovation:** The U.S. should ensure that the final text of the TPP agreement is aligned with the US global health priorities and specifically mentions and honors the commitments made in the 2001 WTO Doha Declaration on TRIPS and Public Health, the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and its own 2007 New Trade Policy.

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<sup>28</sup> <http://democrats.waysandmeans.house.gov/press/PRArticle.aspx?NewsID=11756>

**APPENDIX: Summary of TRIPS, 2007 New Trade Policy and TRIPS plus policies**

Policy	TRIPS flexibilities for public health	2007 New Trade Policy	U.S. “TRIPS plus” proposals for TPP
<b>Scope of patentability</b>	Countries have the right to define patentability criteria; for example, to only grant patents for truly innovative products and to exclude certain products from patentability	No mention	USTR leaked position expands scope of patentability to include: <ul style="list-style-type: none"> <li>– New forms &amp; uses, even if no increase in efficacy</li> <li>– “Evergreening” of old drugs</li> <li>– Patenting of plants &amp; animals, and diagnostic, therapeutic &amp; surgical methods</li> </ul>
<b>Patent challenges</b>	Countries have the right to create patent challenge mechanisms. The TRIPS agreement contains no limits on the possibility of pre- or post-grant patent challenges	No mention	USTR leaked position does not allow pre-grant patent oppositions
<b>Enforcement</b>	Countries can define intellectual property enforcement mechanisms within broad confines of TRIPS agreement	No mention	USTR leaked position imposes new mechanisms of enforcement: <ul style="list-style-type: none"> <li>– More lenient standards for seizures</li> <li>– Allows seizures in transit countries even if products are legal in origin &amp; destination countries</li> <li>– Defines IP damages based on retail price of drugs</li> <li>– Patent validity presumed until proven otherwise</li> </ul>
<b>Data exclusivity</b>	Countries have the right to define data protection provisions that do not grant market exclusivity or monopolies; data exclusivity is not included in the TRIPS agreement	Mandated, but for a maximum of five years; exceptions allowed for public health, including the granting of patent compulsory licenses	<ul style="list-style-type: none"> <li>- USTR position not public but the U.S. will reportedly require data exclusivity and extension of term to 12 years for biologic products</li> <li>- Unclear if public health exceptions will be allowed</li> <li>- Prevents generic drug registration during period of data exclusivity unless generic firm conducts duplicate clinical trials (expensive, unethical)</li> </ul>
<b>Patent Term Extensions</b>	TRIPS agreement only requires 20-year patent terms; term extensions beyond 20 years are not in the TRIPS agreement	Term extensions for regulatory delays are optional	USTR position not public but the U.S. will reportedly require countries to extend 20-year patents to compensate for regulatory delays
<b>Patent Linkage</b>	Countries have the right to grant regulatory approval of generic medicines independent from patent status; patent linkage is not in the TRIPS agreement	The implementation of patent-linkage optional	USTR position not public the U.S. will reportedly require countries to implement patent linkage
<b>Compulsory Licenses</b>	Countries can issue compulsory licenses and can authorize the use of a patented product without the authorization of the patent holder for a variety of reasons, including public health	Recognizing that data exclusivity can eliminate effectiveness of compulsory licenses by delaying entry of generics, a public health exception to data exclusivity is allowed (see Data exclusivity)	No mention in leaked USTR position
<b>Parallel Importation</b>	Countries have the right to define their patent exhaustion regime and to allow for parallel importation of cheaper medicines	No mention	No mention in leaked USTR position