Trans-Pacific Partnership Agreement:
Harmful provisions for access to medicines

The Trans-Pacific Partnership (TPP) is a proposed free trade agreement between 12 countries in the Asia-Pacific including the United States. According to leaked texts, the U.S. seeks to expand pharmaceutical monopolies at the expense of consumers' health despite significant opposition from negotiation partners. In 2001, all World Trade Organization (WTO) members—including the U.S.—agreed that patent rights should not block access to affordable medicines and that IP rules should not interfere with countries' public health agenda. In the TPP, however, the United States Trade Representative (USTR) is proposing measures that would limit generic competition, raise drug prices for consumers, and constrain future innovation in the Asia-Pacific. Almost all TPP countries oppose these proposals and some countries have heroically championed pro-competition and pro-health alternative measures. This chart provides an explanation of harmful provisions for access to medicines and their potential impact. It also reflects country positions as revealed by the Wikileaks publication of the proposed intellectual property chapter. For a more detailed explanation of the differences between the Wikileaks text and previously leaked texts, please see What's New in Wikileaks Text?. Available at: http://bit.ly/1aEpdBA.

AU=Australia BN=Brunei Darussalam CA=Canada CL=Chile JP=Japan MY=Malaysia MX=Mexico NZ=New Zealand PE=Peru SG=Singapore PE=Peru US=United States VN=Vietnam

Item	Explanation	Impact	Examples
Patent protection for new uses or methods	Under international standards—the *Trade-Related Aspects of Intellectual Property Agreement* (TRIPS)—World Trade Organization (WTO) members must grant 20-year patents for inventions such as pharmaceuticals, that are new and non-obvious. The U.S. proposal requires countries to go beyond TRIPS and grant patents for minor variations of old medicines even if these changes do not provide additional therapeutic benefits for patients. CL/MY/PE/SG/VN/BN/NZ/CA/MX have opposed this proposal.	Patents for new uses or methods of already known drugs promote evergreening, a strategy used by pharmaceutical companies to maintain control of the market after the primary patent expires. Such patents promote widespread prevalence of "me-too" drugs — slightly-modified top-selling products that are re-sold as new treatments. Thus, new use/method patents fail to contribute significantly to innovation, greatly increase healthcare costs, and delay access to more affordable treatments.	 In Australia, evergreening patents have enabled pharmaceutical companies to prevent cost-cutting generic competition for nearly 50 years on some products.  In 2001, the cost of Gleevec, a breakthrough drug against leukemia, was $30,000 in the U.S. After the patent holder obtained new form patents for the drug, the price rose to $92,000 per year.
Patent protection for diagnostic, therapeutic, and surgical methods	The U.S. proposal eliminates an exception in TRIPS that allows countries to exclude therapeutic, surgical, or diagnostic methods from patentable subject matter. TRIPS provides this exclusion to ensure that medical professionals can meet the standard of care. AU/NZ/VN/BN/CL/PE/MY/SG/CA/MX have opposed the U.S. proposal. Instead, NZ/CA/SG/CL/MY have proposed an alternative provision that would preserve the TRIPS exception.	Medical procedure patents raise healthcare costs. Health providers, including surgeons, could be liable for the methods they use to treat patients. Essentially, except for when a surgeon uses her bare hands, surgical methods would be patentable. While U.S. law immunizes certain care providers from infringement liability, the U.S. TPP proposal fails to include these safeguards, risking yet more serious consequences for TPP negotiating countries.	 The risk of liability can discourage doctors from selecting the best available treatments for their patients. More than 80 countries have excluded medical procedures from patent protection. The United States and Australia are the only countries to allow medical methods patents.

Patent term extensions	The U.S. proposal requires patent term extensions, also known as "adjustments," if patent prosecution or drug regulatory review exceeds a certain period. Patent term extensions allow pharmaceutical companies to extend their patents beyond 20 years. Under the 2007 U.S. New Trade Policy,[1] countries can choose whether to provide patent term extensions. The U.S. proposal eliminates this flexibility. CA/NZ/JP are leading the opposition to the U.S. proposal for patent term extensions for perceived delays at the patent office. AU/NZ/CL/PE/MY/SG/BN/VN/CA/MX have opposed longer patent terms for perceived delays during regulatory approval.	Longer pharmaceutical patent terms increase cost burdens on patients and government health programs by delaying market entry for low-cost generic alternatives. These extensions also constrain incremental innovation by delaying inventions from being available in the public domain.	 The New Zealand Ministry of Economic Development found that such extensions further delayed market entry of generic drugs, caused higher drug costs, and failed to result in increased levels of foreign pharmaceutical investment.
Patent linkage	The U.S. proposal introduces a patent linkage system. Under this system, drug regulatory authorities would be required to delay approval for generics applicants until patents claimed to protect the original product are determined invalid or expire. The 2007 U.S. New Trade Policy relaxes requirements for patent linkage *per se* for developing countries. However, the U.S. proposal requires developing countries to go beyond the New Trade Policy. TRIPS does not provide a system for patent linkage.	Under linkage, patents, even overly broad or bad patents that should not have been granted, block generic market entry. This system delays access to low-cost alternatives and can incentivize patent abuse since the financial benefits of deterring generic market entry may outweigh risks or penalties. Linking the drug regulatory process and the patent system shifts the burden of early patent enforcement to drug regulatory authorities, which are not competent to assess patent validity.	 The European Commission strictly prohibits patent linkage systems. The Commission found that linkage created unnecessary delays in generics market entry and unjustifiably blocked access to affordable medicines, especially during a time of economic crisis.
Expanded data exclusivity protection for pharmaceutical products	The U.S. proposal requires countries to provide automatic data exclusivity protection for new pharmaceutical products for *at least* five years and *at least* three more years in cases of new uses of existing medicines. TRIPS does not provide data exclusivity protection. Under data exclusivity, drug regulatory bodies cannot rely upon a brand-name company's clinical trial data to grant market approval for a generic drug. Under the TPP, brand-name companies are granted exclusive commercial control over the use of this information, even if it is in the public domain. The U.S. has insisted on its proposal, even though eight other negotiating parties oppose it.	Data exclusivity protection requires the duplication of costly and time-consuming clinical trials for which the outcome is already known. Since a generics applicant is unable to rely upon the test data from the original clinical trials, it must replicate these tests or wait until the end of the exclusivity period to submit an application for approval. Thus, data exclusivity creates patent-like monopolies, chokes access to more affordable medicines, and is inconsistent with medical ethical standards against trials duplication. The U.S. proposal would introduce automatic data exclusivity where countries do not provide such measures, expand existing requirements, and limit	 Following the US-Peru FTA, Peru was obliged to grant data exclusivity for a "reasonable period"—five years from the date of market approval for the originator product. The protection only applies to undisclosed information related to new pharmaceutical products. The Peruvian system includes important safeguards for public health. Under the TPP, Peru may have to extend the protection of data

[1] On May 10, 2007, the Bush Administration and Congress reached a trade deal known as the U.S. New Trade Policy or the "May 10" Agreement that began to reduce the harmful effects of U.S. trade agreements on access to medicines in developing countries. Members of Congress have stated that the terms in the agreement "should be considered a non-negotiable starting point for the TPP negotiations." However, the Obama Administration is rolling back on these modest achievements in the TPP.

		TPP countries' ability to define national standards for clinical trial data protection that are both compliant with international rules and effective safeguards for access to medicines.	exclusivity beyond five years even if the information is in the public domain. Peru may also have to provide an additional three years of exclusivity for new clinical information related to new uses of existing products.
Data exclusivity for biologics	PhRMA and the biotech industry are urging the USTR to propose a special 12-year exclusivity period for biotech medicines.	Biologics are exceptionally expensive and constitute one of the main drivers of rising healthcare costs. Imposing this system on parties to the TPP would constitute a major expansion of each country's laws with potentially dramatic financial consequences for patients, medical providers, and governments. Current U.S. law requires 12 years of exclusivity for biologics. Locking a special exclusivity period for biologics in the TPP could constrain Congress' ability to shorten this period and control healthcare costs in the future.	 Biologics are prohibitively expensive. In 2012, 11 of the 12 cancer drugs approved by the FDA cost more than $100,000. The White House Budget has repeatedly proposed reducing the length of exclusivity to 7 years to contain costs. Such changes could save $3 billion for federal health programs including Medicare and Medicaid over 10 years and save consumers tens of billions.
Presumption of patent validity	The U.S. proposal provides for a rebuttable presumption that a patent and each of its claims are valid. TRIPS does not provide for this presumption.	The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures and renders challenges to even weak patents more burdensome.	 Data from the U.S. Patent Office suggests that 78% of re-examined patents have serious problems with their original claims. U.S. law could change if the Supreme Court hears two cases that involve this presumption this year.