



Briefing Memo

Vietnam and the Trans-Pacific Partnership Agreement

Access to Medicines Risks for a PEPFAR Partner

Vietnam and the United States are currently negotiating the Trans-Pacific Partnership free trade agreement (TPPA) with seven other countries. The leaked U.S. proposal for the intellectual property chapter of the TPPA would require significant changes to Vietnamese law, including changes that would limit generic competition and raise drug prices, thereby restricting access to affordable medicines.

The U.S. TPPA proposal could undermine U.S. commitments to Vietnam in the fight against HIV/AIDS. The two countries are partners under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). But the U.S. TPPA proposal would increase the cost of new and forthcoming AIDS medicines, at a time when AIDS funding is being flat-lined and the U.S. is seeking greater efficiencies (not higher costs) in its PEPFAR programming.

On the eve of the Vietnam round of TPPA negotiations (June 20-24), Public Citizen and Health GAP have released a new resource analyzing in detail the changes that the U.S. proposal would require to Vietnam laws on patents and access to medicines, available at: <http://www.citizen.org/tpa-access-chart>.

The U.S. proposal would:

- Expand pharmaceutical patenting and create new drug monopolies, by lowering Vietnam's patentability standards and requiring patentability of new uses and minor variations of older, known drugs.
- Eliminate safeguards against undeserved patents, including the right to challenge a patent before it is granted.
- Favor big pharmaceutical companies in court, by requiring Vietnamese courts to presume any challenged patent valid and weigh the patent holder's measure of the value of damages.

The U.S. proposal also leaves placeholders for several controversial provisions to come that may require changes to Vietnam's law while forsaking prior U.S.

commitments to reduce the negative impact of trade agreements on global access to medicines.

Vietnam, PEPFAR and HIV/AIDS

Vietnam (population 90.5 million) ranks 166th worldwide in GDP per capita. Fifty percent of Vietnam's people have a daily income below \$2, and about twenty-four percent of the population lives below the International Poverty Line of \$115 per year.¹ The number of people living with HIV in 2009 was 280,000². However, the actual number could be much higher.³

In Vietnam's fight against HIV/AIDS, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) is a close partner of the Vietnamese government. Between 2004 and 2009, Vietnam received \$323.6 million for HIV/AIDS prevention, treatment and care programs. A significant portion of that money is spent to purchase antiretroviral medicines and medicines for opportunistic infections. Currently, over ninety percent of PEPFAR purchases are off-patent generic medicines, which are many times cheaper than originator brands, allowing more patients to be treated at a lower cost. In 2005, no generics were available to Vietnam under PEPFAR. By 2008, generics comprised 97% of Vietnam's PEPFAR medicines. The move to use of generics by sixteen countries under PEPFAR was calculated to have saved \$323 million between 2005 and 2008⁴, and another \$380 million in 2010⁵.

The U.S. TPPA Proposal

The U.S. TPPA proposal on intellectual property, however, would work against PEPFAR's health and humanitarian aid objectives, by strengthening intellectual property protections and enforcement, and by placing new restrictions on generic competition.

¹ Human Development Report, 2009, United Nations Development Program, New York, available at http://hdr.undp.org/en/media/HDR_2009_EN_Complete.pdf.

² UNAIDS, Vietnam Overview Country Situation Analysis, available at <http://www.unaids.org/en/regionscountries/countries/vietnam/>.

³ Country Profile: Vietnam, The U.S. President's Emergency Plan for AIDS Relief, PEPFAR, 2006-2009 Archive, available at <http://2006-2009.pepfar.gov/press/75900.htm>.

⁴ Charles B. Holmes, William Coggin, David Jamieson, Heidi Mihm, Reuben Granich, Phillip Savio, Michael Hope, Caroline Ryan, Michele Moloney-Kitts, Eric P. Goosby, Mark Dybul. *The Journal of the American Medical Association*, Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs, 2010;304(3):313-320, available at <http://jama.ama-assn.org/search?author1=Charles+B.+Holmes&sortspec=date&submit=Submit>

⁵ Opening Statement by Ambassador Eric Goosby at PEPFAR Smart Investments Meeting (Feb. 10, 2011), available at <http://www.pepfar.gov/press/remarks/2011/156698.htm>.

In 2000, Vietnam signed a bilateral free trade agreement with the U.S. This agreement already required TRIPS-plus, anti-access-to-medicines changes to Vietnam's laws, including data exclusivity. Now, the U.S. proposal to the TPPA would impose several further limitations.

The U.S. proposal would:

- Expand pharmaceutical patenting and create new drug monopolies.
 - Patent Protection for New Forms, Uses or Methods: In Vietnam, patent protection is not currently available for first, second or subsequent medical use claims. The U.S. proposes to extend patent protection to new medical uses (applying an older known drug to a new health use), as well as new methods and new forms (minor variations) in existing medicines, thereby perpetuating patent monopolies even in the absence of any significant therapeutic advance. This progressive broadening of patentability would result in more 'ever-greening' patents being granted to originator pharmaceutical companies. These patents are instrumental in delaying or blocking the entry of generic drugs to market.
 - Patent Protection for Diagnostic, Therapeutic and Surgical Methods: Vietnam and many other countries exclude diagnostic, therapeutic and surgical methods from patentability to ensure that accepted standards of care are available to patients. The U.S. proposal would eliminate this exception to patentability. This could impose additional costs on Vietnam's healthcare system. Hospitals would be required to obtain licenses for patented treatments that they offer, and pay royalties for the patented diagnostic, therapeutic and surgical methods they use.
 - Scope of Industrial Application: The U.S. patentability standard of specific, substantial and credible utility is more lenient than the industrial applicability standard used by Vietnam and many other countries. The U.S. TPPA proposal would require Vietnam to adopt the broader U.S. standard, leading to patenting of inventions that might be considered more like ideas than actual products or production processes.
- Eliminate safeguards against undeserved patents.
 - Pre-grant Opposition by Third Parties: In Vietnam and many other countries, third parties can oppose patent applications to prevent abuse of the patent system and improve patent quality. The U.S. proposal would eliminate pre-grant opposition, increasing the

likelihood of unwarranted drug monopolies. This would also likely increase the number of post-grant cases before the courts, raising the costs of administering Vietnam's patent system.

- Favor big pharmaceutical companies in court.
 - Presumption of patent validity: There is no presumption of patent validity in Vietnam. The U.S. proposal provides for a rebuttable presumption that a patent and each of its claims are valid. The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge even weak patents.
 - Damages as value submitted by right holder: The Vietnamese law sets clear standards for calculation of compensatory damages. In practice, Vietnamese courts often calculate damages based on the plaintiff's lost sales or the defendant's profits from the infringing activity. But the U.S. proposal would require courts to consider suggested retail price or other measures of value submitted by the right holder. This provision strongly favors the interests of the right holders. A suggested retail price is a hypothetical price. Calculations submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than existing retail prices.

The February 10, 2011 leaked U.S. proposal also leaves placeholders for several controversial provisions that may require changes to Vietnamese law and risk access to medicines. These include:

- Patent Term Extensions: Currently, Vietnamese law does not provide patent term extension/restoration for processing periods over a certain length in the patent examination or regulatory approval processes. Consistent with previous FTAs, it is very likely that the U.S. will propose patent term alterations/extensions for perceived delays at domestic patent offices and other regulatory authorities. Patent term extensions significantly delay the entry of generic drugs into the market, and thus access to affordable medicines.
- Data Exclusivity: The U.S. has previously forced Vietnam to adopt data exclusivity. Now in the TPPA, the U.S. may demand additional three-year periods of exclusivity where right holders file new drug regulatory approval applications containing new clinical studies.
- Patent-Registration Linkage: The Vietnamese law contains no provision that links the patent system to the drug marketing approval process. Many U.S. FTAs have required patent linkage. Patent linkage shifts burdens of early patent enforcement to drug regulatory authorities. As with data exclusivity,

June 16, 2011

linkage could interfere with the marketing of generics produced pursuant to a compulsory license or to meet a public health need.

For further analysis of the effect of the U.S. proposal on Vietnamese law and access to medicines, see: <http://www.citizen.org/tppa-access-chart>.