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Investor-State Attacks on Public Interest Policies: Access to Medicines

ISDS: Enforcer for Big Pharma Wish List; Health at Stake

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Fewer than six months after threats to access to affordable medicines were unveiled through WikiLeaks' publishing of the Trans-Pacific Partnership (TPP) Intellectual Property (IP) Chapter, a new leak of the draft [TPP Investment Chapter](#) reveals new risks for health.

Most worrying is the chapter's inclusion of the [investor-state dispute settlement](#) (ISDS) system. ISDS fundamentally shifts the balance of power between investors, states and the general public, creating an enforceable regime that formally prioritizes corporate rights over the right of governments to regulate. ISDS provisions elevate individual foreign corporations and investors to the same status as sovereign governments, empowering them to privately enforce a public treaty by skirting domestic courts and directly "suing" signatory governments over public interest policies before extrajudicial tribunals. Under the TPP, tens of thousands of foreign firms would be newly empowered to seek cash compensation from taxpayers by challenging non-discriminatory government actions, laws and court rulings before such unaccountable foreign tribunals.

The leak reveals that the TPP would replicate the ISDS language found in past U.S. agreements under which tribunals have ordered more than \$3.6 billion in compensation to foreign investors attacking health, safety and environmental protections; financial stability policies and more. The leaked text would dramatically expand the number of firms that could use ISDS to attack such public interest policies. The text does not include new safeguards to protect those policies.

The threats to public health policies from the leaked investment chapter compound those from the leaked IP chapter, which would require countries to change their domestic laws governing patents and medical test data. These TPP rules would compromise access to medicines by expanding pharmaceutical monopolies, limiting generic competition and keeping prices high. Many lives are at stake.

The leaked investment text would apply the flawed ISDS enforcement mechanism to the TPP's harmful patent rules – and, in a dangerous new twist, possibly to standards imported from World Trade Organization (WTO) patent rules as well. Eli Lilly and Company is already using the North American Free Trade Agreement's (NAFTA) investment chapter to attack Canada's patent standards. The leaked TPP chapter would offer pharmaceutical companies new opportunities to attack more countries. This in turn could limit access to affordable medicines.

Example: Eli Lilly and Company v. Government of Canada

In September 2013, U.S. pharmaceutical giant Eli Lilly launched a \$481 million claim against Canada under NAFTA's investment chapter. Eli Lilly is challenging Canada's invalidation of secondary patents related to the previously-known active ingredients atomoxetine (Strattera) and olanzapine (Zyprexa), drugs used to treat attention deficit hyperactivity disorder, schizophrenia and bipolar disorder. Eli Lilly argues that this "improper" and "discreditable" invalidation of its patents constitutes a NAFTA-prohibited "indirect expropriation" and a breach of NAFTA's guarantee of a "minimum standard of treatment" for foreign investors. Eli Lilly claims that NAFTA country patentability practices should coincide, should remain static from NAFTA's 1994 implementation and that the Canadian judicial decisions violated Canada's obligation to provide "fair and equitable treatment" by frustrating the company's claimed "expectations."

But patents are subject to potential court review. It is not very unusual for courts to overturn initial patent grants. Countries provide patents for new and useful inventions, according to national legal rules that evolve with purpose over time. According to Canada's rules, Lilly should have demonstrated or soundly predicted their inventions' usefulness at the times of patent filing. [Canada has the right](#) to implement its own rules for patent utility and disclosure, as allowed by NAFTA's IP chapter and the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Lilly's ISDS claims should fail, but this outcome is not guaranteed at an ISDS tribunal, which exist to protect investor rights and do not specialize in intellectual property. ISDS tribunals, composed of three private attorneys, are not accountable to legal precedent. There is no outside appeal to ISDS rulings. Meanwhile, Lilly is using the case to bring U.S. political pressure to bear against Canada to seek changes to Canada's patent rules.

The TPP Investment Chapter: Much More of a Very Bad Thing

Several TPP negotiating countries have prior agreements with the United States that include ISDS. The leaked TPP investment chapter would newly expose others, including Australia, Brunei, Japan, Malaysia, New Zealand and Vietnam, to investor-state attacks from any of the more than 18,000 U.S.-owned firms operating in those countries. Similarly, the TPP would

newly empower about 9,000 firms from Japan and other TPP nations operating in the United States to launch ISDS cases against the United States. Canada and Mexico are currently exposed to ISDS claims from U.S. firms through NAFTA, but unlike NAFTA, the TPP explicitly names “Intellectual Property” as an “investment” over which ISDS claims can be launched.

A Partial Protection for Access to Medicines – or a New Threat?

One provision in the leaked investment chapter, found in past U.S. pacts, aims to insulate a particular health safeguard – compulsory licensing – from investor-state claims of expropriation. A compulsory license is a government authorization to introduce generic competition with a patented product, in exchange for royalty payments to the patent holder. It is an important mechanism for ensuring access to affordable medicines. Similarly, the provision can be used to provide defenses against ISDS expropriation claims for policies that relate to the revocation, limitation or creation of IP rights, so long as those policies are consistent with the agreement’s IP chapter.

However, a new addition to this provision in the leaked TPP investment text introduces a new potential risk for access to medicines. This might not be the interpretation or consequence intended by its drafters. Yet pharmaceutical corporations could use the provision to argue for a right to “sue” governments directly before ISDS tribunals for alleged non-compliance with WTO TRIPS rules. This would be a very dangerous expansion of unaccountable ISDS power.

Article II.7 of the draft TPP Investment Chapter, on “Expropriation and Compensation,” states at point 5:

*The Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter QQ. (Intellectual Property Rights) and the TRIPS Agreement.** [emphasis added]

Prior U.S. trade agreements have included similar provisions, which (ideally) would narrow the scope of IP-related policies that foreign firms could attack as a prohibited “expropriation,” provided the government could convince the ISDS tribunal that the challenged policies complied with the requirements of the agreement’s IP chapter.¹

* For greater certainty, the Parties recognize that, for the purposes of this Article, the term “revocation” of intellectual property rights includes the cancellation or nullification of such rights, and the term “limitation” of intellectual property rights includes exceptions to such rights.

¹ This provision would only be available for claims related to expropriation, however, not for claims, for example, that a given policy violated the government’s obligation to afford foreign investors a “minimum standard of treatment.” This vague obligation – included in most U.S. pacts – has been interpreted so expansively by ISDS

The draft TPP provision includes an additional final four words, relative to past pacts: “and the TRIPS Agreement.” In order to convince an ISDS tribunal that an expropriation claim relating to the revocation, limitation, or creation of IP rights is not valid, governments must satisfy the intellectual property standards of *both the TPP and TRIPS*.

Generally speaking, the intellectual property requirements of the TPP will favor pharmaceutical companies and right holders even more than the WTO’s TRIPS Agreement. The TPP’s draft IP rules are generally worse; more onerous for states. TRIPS could serve as a useful interpretive aide in ISDS cases where the TPP is silent on an intellectual property issue, but TRIPS offers an explicit flexibility. For example, the TPP no longer addresses patents on medical procedures. TRIPS expressly allows countries to exclude medical procedures from patentability. Were a pharmaceutical firm to launch an ISDS case against a government, claiming that the government’s decision not to grant medical procedure patents (for example, for a surgical method or secondary pharmaceutical uses) constituted an expropriation, the government might find it useful if ISDS tribunalists look at TRIPS.

But there are serious parallel dangers in the four new words. Pharmaceutical firms could argue that this language empowers them to privately enforce TRIPS provisions in direct challenges to sovereign governments before ISDS tribunals. ISDS claims of expropriation could be brought against government measures relating to the creation, revocation or limitation of IP rights if those measures might not conform to TRIPS. This could create new avenues of attack for any issues where the TPP IP Chapter is silent, but the TRIPS Agreement provides IP rights.

ISDS tribunals effectively would then be adjudicating WTO standards. Until now, WTO rules have only been enforceable through the WTO’s state-to-state dispute settlement mechanism. TRIPS includes deliberately ambiguous language to allow signatory governments flexibility. ISDS tribunals have a track record of interpreting vague terms broadly to favor foreign investors. Allowing individual corporations to directly challenge countries for supposed violation of WTO rules, and empowering ISDS tribunals to impose their interpretations of those rules, would expose countries to a new level of liability, and potentially have a chilling effect on countries’ willingness to pass public interest laws and regulations.²

Recommendations: Access to Medicines Over Investors’ Rights

Trade agreements should include neither ISDS nor intellectual property chapters. Many of the TPP’s draft provisions would need to be changed or eliminated in order to safeguard access to medicines. Any ISDS system nevertheless adopted and claiming authority to reach patent

tribunals that it has become the basis for three of every four ISDS cases “won” by the foreign investor under U.S. pacts.

² Certainly an improved provision would give countries the option to satisfy either TRIPS or the TPP IP rules (substituting “or” for the draft provision’s last “and”). U.S. negotiators almost certainly would not agree to such an improvement.

disputes should certainly respect the full body of rights available to countries to advance access to affordable medicines and the full range of flexibilities in patent, data and other intellectual property rules. The text of TRIPS and the WTO's accompanying Doha Declaration on the TRIPS Agreement and Public Health may provide useful clarity in some such areas, where countries' rights have not been fully articulated in a trade agreement or investment treaty. But TRIPS or other WTO obligations should not be imported as enforceable standards under ISDS.

More information on the dangers of ISDS is available at: <http://www.citizen.org/investorcases>.

*Further analysis of the leaked investment chapter is available at:
<http://citizen.org/documents/tpp-investment-leak-2015.pdf>*