



Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines

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The leaked Trans-Pacific Partnership Investment Chapter¹ has been analyzed extensively with respect to its dangerous extra-judicial investor-state dispute resolution provisions.² In contrast, this analysis focuses on the particular risks of the Investment Chapter with respect to access to medicines. These risks are compounded because of other proposed provisions in the proposed US IP chapter that would strengthen, broaden, and lengthen intellectual property rights with respect to pharmaceutical patent, data, and pricing provisions and that would expand IP enforcement mechanisms. In essence, the IP-Chapter gives investors more “investment rights” upon which to base their abusive investor-state dispute resolution claims against sovereign governments’ regulations and decisions.

There are four main dangers in the Investment Chapter that threaten access to medicines:

- First, the ***minimum standard of treatment, including fair and equitable treatment, and indirect expropriation concepts contain significant ambiguities*** that could greatly restrict countries’ ability to enact, use, and defend flexibilities that enhance access to medicines.
- Second, it is ***dangerous to include IP rights at all in the investment chapter***, given the extensive private enforcement rights that rightholders already have, including administrative remedies at borders and judicial remedies for infringing conduct, and given drug companies’ proclivities to bring suits against governments.³
- Third, the bracketed ***limited exception to IP-related investment rights for compulsory licenses does not provide the security against investor claims*** that TPP Parties might need to safeguard TRIPS-compliant measures that promote access affordable medicines for all as promised by the Doha Declaration on the TRIPS Agreement and Public Health.⁴
- Finally, the ***Investment Chapter prevents certain performance requirements*** that in the IP context might give developing countries the leeway to develop domestic pharmaceutical manufacturing capacity in order to ensure a self-sufficient and uninterrupted supply of medicines and to legitimately promote their own industrial development.

1. The “minimum standard of treatment/fair and equitable treatment” standard and indirect expropriation standard contain dangerous interpretive ambiguities that could negatively impact government policies and decisions.

Article 12.6.1 requires that “Each Party shall accord to covered investments treatment in accordance with customary international law, including fair and equitable treatment and full

¹ Available at <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf>.

² See e.g., Public Citizen, *Public Interest Analysis of Leaked Trans-Pacific Partnership (TPP) Investment Text* (June 13, 2012) available at <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/gwtppinvestmentanalysis.pdf>; Jane Kelsey, *New TPP Leaked Text: National Says ‘Yes’ to Investor Rights to Sue* (June 14, 2012) available at <http://www.scoop.co.nz/stories/PO1206/S00186/national-says-yes-to-investor-rights-to-sue.htm>.

³ Bayer unsuccessfully sued India to achieve judicially mandated patent-registration linkage, and is suing again to reverse a properly issued compulsory license on a cancer medicine. Novartis sued India to invalidate Section 3(d) of the Indian Amended (2005) Patents Act.

⁴ Available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

protection and security.” Although paragraph 1 does not require treatment in addition to or beyond that required by customary international law, paragraph 2(a) interprets “fair and equitable treatment” to include “the obligation not to deny justice in criminal, civil, or administrative adjudicatory proceedings in accordance with the principle of due process embodied in the principal legal systems of the world.”

The “minimum standard of treatment” standard set forth in proposed Art. 12.6 has been variously and inconsistently interpreted by arbitral tribunals in the past. The 2004 NAFTA case known as *Waste Management, Inc. v. United Mexican States II*⁵ interpreted a violation of the minimum standard of treatment as entailing state conduct that is “arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or involves a lack of due process leading to an outcome which offends judicial propriety.”⁶ The tribunal noted that this might be the case where there has been a “manifest failure of natural justice in judicial proceedings or a complete lack of transparency or candor in an administrative process.”⁷ More problematically, if a state breaches “representations” that were “reasonably relied upon” by investors at the time of investment, that breach constitutes evidence of unfair or inequitable treatment that violates the minimum standard of treatment.⁸ Some commentators go so far as to argue that the minimum standard of treatment should protect the “reasonable expectations” of an investor even in the absence of direct representations let alone binding commitments allowing potential market participation or profit-making opportunities.⁹

In the pharmaceutical context, companies might claim that they have reasonable expectations about future profits arising from intellectual property filings. Changing IP standards or applying exceptions to granted rights (e.g., compulsory licenses or exceptions to data protections) might be interpreted as violating minimum standard expectations (discussed further below). Where IP rightholders disagree with judicial or administrative decisions or think that those decisions were insufficiently transparent or candid, the rightholder could bring investment chapter claims.

Article 12.12 of the Investment Chapter separately prohibits indirect expropriation of a covered investment, which includes failure to pay full market value upon expropriation. Although there is an exception in subsection 5 with respect to “compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement,” this exception would not appear to cover exceptions to data exclusivity or patent-registration linkage rights (discussed further below). Even the broader bracketed portion of subsection 5, which includes “the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter __ (Intellectual Property Rights),” does not give rights to create TPP-minus exceptions to intellectual property rights in the absence of full remuneration. Partial liability payments or royalties would not suffice.

The possible meanings of indirect expropriation are addressed further in proposed Annexes 12-B, C, and D and also include the likelihood of protecting investor expectations. Annex 12-C is the most far reaching and requires a case-by-case, fact-based inquiring that considers, among other factors: “4(a) (i) the economic impact of the government action, although the fact that an action or series of actions by a Party has an adverse effect on the economic value of an investment, standing alone,

⁵ Available at <http://www.state.gov/documents/organization/34643.pdf>.

⁶ *Id.* ¶ 89.

⁷ *Id.*

⁸ *Id.*

⁹ See, Fiona Campbell, *Fair and Equitable Treatment in International Investment Agreements*, Institute for Sustainable Development (2007) available at http://www.iisd.org/pdf/2007/inv_fair_treatment.pdf.

does not establish that an indirect expropriation has occurred; (ii) the extent to which government action interferes with *distinct, reasonable investment-backed expectations* (emphasis added); and (iii) the character of the government action.” Subparagraph (b) clarifies that “Except in rare circumstances, non-discriminatory regulatory actions by a Party that are designed and applied to protect the legitimate public welfare objectives [23 For greater certainty, the list of legitimate public welfare objective in this subparagraph is not exhaustive] such as public health, safety, and the environment, do not constitute indirect expropriations.” Although this public welfare exception helpful, it is not an absolute privilege, and investors can claim that their cases are rare, that the regulatory actions are discriminatory, e.g., targeted solely at pharmaceutical investors, or that the interests being protected are not legitimate.

2. The implicit and explicit inclusion of IP rights as protected investments is deeply problematic

The Article 12.2 definition of “investment” is broad enough to cover medicines-related intellectual property rights (patents, data and other trade secrets) as an investment only requires “commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk.” Accordingly, unless IP rights are expressly excluded from the investment chapter and from the term “investment,” there is a risk that IPRs, which routinely require both commitments of capital and an expectation of profit, would be implicitly covered. However, the proposed definition of investment goes further to directly reference: (g) “intellectual property rights [which are conferred pursuant to domestic laws of each Party].” The unbracketed text protecting any and all intellectual property rights is problematic in at least five ways, given uncertainty about the intended breadth of its coverage:

- First, “intellectual property rights” could be interpreted over broadly to include all of the IPRs codified in the loose language of the TRIPS Agreement. For example, TRIPS Agreement Art. 39.3 currently provides data protection against “unfair commercial use” for undisclosed data compiled at consideration expense and submitted to regulatory authorities. Big Pharma and EU and US trade negotiators have consistently interpreted this language as requiring data exclusivity – monopoly control over the data so as to prevent regulatory reliance on or reference to the data when considering a generic company’s attempt to register an equivalent product. Many other countries and leading expert commentators believe that Art. 39.3 does not require data exclusivity, a protection explicitly rejected during the negotiation of the TRIPS Agreement.¹⁰ At present, the only way that this interpretive battle can be decided multilaterally is for an aggrieved WTO Member to bring a WTO complaint against another Member, such as India, which refuses to provide data exclusivity. However, despite intense industry lobbying on this issue, the Office of the United States Trade Representative (USTR) has initiated only one such complaint and subsequently abandoned it¹¹ because of concerns that it would lose and because of other complex political calculations that structure a Member’s decision to fully prosecute a WTO complaint or not. However, if the Investment Chapter is adopted, even if the

¹⁰ See, e.g., Carlos Correa, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT (2002).

¹¹ The United States brought a complaint before the dispute resolution body of the WTO against Argentina, on the grounds that Argentinian law had no exclusivity for test data. (30) After almost 2 years, the dispute was settled at the consultation stage and without a hearing. On May 2002, the Governments of the U.S and Argentina agreed "should Argentinean law be inconsistent with Article 39.3 ... Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3." See Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, 20 June 2002, (IP/D/18/Add. 1, IP/D/22/Add. 1), available at www.wto.org.tw/SmartKMS/fileviewer?id=18205. As expected, Argentina did not accept the U.S. claim that exclusive rights should be granted for test data and left its law unchanged.

US proposal for data exclusivity in its IP Chapter were to be rejected, a pharmaceutical company could bring an extra-judicial arbitral claim against a TPP Party based on a dispute over its interpretation that TRIPS requires data exclusivity. The company would hope that the revolving-door trade lawyers selected to lead the investor-state dispute resolution tribunal would adopt the company's position despite convincing expert opinion and widespread state practice to the contrary. In essence, the investor will have gained an alternative forum for seeking to enforce novel interpretations of TRIPS and thereby gain new data monopolies.

- Second, not only might the loose and sometimes ambiguous language of TRIPS be interpreted expansively by Big Pharma so as to justify an investor-state arbitral proceeding, but that same IP investor might over-strenuously interpret the expanded IP rights conferred by the TPP itself.¹² For example, a Party might decide that it had a public health flexibility – and a human rights need – to enact an exception to TPP-based data exclusivity rights in the event of the issuance of a TRIPS- or TPP-compliant compulsory license. The adversely affected “investor” might conclude that the express language of the TPP IP chapter does not authorize such an exception and that the failure to pay total compensation (not a mere royalty) is an indirect expropriation or alternatively that its reasonable expectations of data-based market exclusivity has been violated. This later, minimum-standards-of-treatment claim would be strengthened since there is little international state practice at present of enacting exceptions to data exclusivity. Once again a U.S.-based foreign investor would not need to convince the USTR to file a WTO dispute, it could do so unilaterally; moreover, it could bypass the Party's judicial procedures and jump straight into pro-industry arbitral proceedings. The company would bet that the revolving door justice of non-democratically selected arbitrators, who move seamlessly from representing IP rightholders, advising and representing governments, and putting on the false cloak of arbitral neutrality, would prevail. Worse yet, the mere threat of such a lawsuit could deter Parties from adopting lawful flexibilities that they might otherwise believe exist in the TPP because of the prohibitive costs of arbitral hearings and the risk of excessive judgments should they lose.
- Third, a pharmaceutical investor might simply rely on the TPP-compliant law of the TPP Party and claim that its investor rights had been infringed by an adverse decision on a pending IP claim, especially if the bracketed text of Art. 12.12.5 is not adopted. For example, if the TPP IP chapter requires countries to allow patents on new forms of existing medicines, a patent office might still conclude that a particular new form lacks an inventive step. The pharmaceutical company could argue that the TPP-compliant national law actually creates a presumption in favor of patentability of new forms and thus that it has an expectation of profit from exclusive rights on an evergreened patent. Instead of challenging the denial of its secondary patent application in court, the company could jump over that step and immediately charge dilution of its putative – but not yet granted – IP rights and expectations of profit in an investor-state proceeding.
- Fourth, there is a risk that IP an rightholder might bring claims because of what it considers to be inadequate enforcement efforts, e.g., the failure to criminally prosecute a trademark counterfeiter because of scarce prosecutorial and judicial resources or a failure to impose the level of damages that the IP rightholder proposes. Although the TRIPS Agreement mainly relies upon private enforcement, e.g., the creation of a procedurally fair judicial system for the private prosecution of IP infringement claims, the proposed IP Chapter creates multiple new enforcement rights with respect to criminal sanctions, civil remedies, and border measures.

¹² This possibility has strong support in another section of the Investment Chapter, Art. 12.12.5, which, in bracketed text, creates an exception with respect to remedies for direct or indirect expropriation pertaining to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with the IP chapter.

Failure to provide “fair and equitable treatment” in criminal, civil, or administrative adjudicatory proceedings according to principles of due process can constitute an actionable investment violation. Paradoxically, a government could face investor claims for failure to unilaterally enforce what are fundamentally private rights – no longer could Parties use the TRIPS-compliant right not to give priority to publicly funded and initiated IP enforcement.¹³

- Fifth, there is a risk that an IP rightholder might bring a claim because of a failure to intercept alleged infringing goods via stringent border measures. This too might violate the right to “fair and equitable treatment” in administrative border measures. In the pharmaceutical context, drug companies have initiated seizures of medicines-in-transit on multiple occasions in Europe, not because they violated IP rights in the countries of origin or destination, but because they interfered with fictional patent rights in the transit country.¹⁴ This is another context in which IP rights might be enforced through investor-state proceedings not because of IP rights granted in the TPP member country but because of fictional rights or even rights granted in another territory.

3. The compulsory licensing exceptions in the TPP Investment Chapter are insufficient to protect Parties’ legitimate interests

Bracketed subparagraph 1(f) of Art. 12.7 prohibits a TPP Party from imposing or enforcing any investment-related requirement or enforcing any investment-related commitment or undertaking “to transfer a particular technology, a production process or other proprietary knowledge to a person in its territory.” If left in this form, such a provision could eliminate the right to issue compulsory or government use licenses. To partially remedy this problem, subparagraph 12.7.3(b)(i) eliminates this requirement where a TRIPS Art. 31 unauthorized-use license (or alternatively a TPP-compliant unauthorized-use license¹⁵) has been issued.¹⁶ Similarly, with respect to Art. 12.12, which prohibits the expropriation or nationalization of a covered investment either directly or indirectly, subparagraph 5 creates an exception for the issuance of compulsory licenses granted pursuant to the TRIPS Agreement. In addition, there is a bracketed addition to subparagraph 5 that extends the exception against prohibited expropriation or nationalization to other IP-related acts: “or to the revocation, limitation, or creation of IP rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter __ (IP rights).”¹⁷

¹³ Article 41.5: “It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.” (Emphasis added.)

¹⁴ See Request for Consultations by India, European Union – Seizure of Generic Drugs in Transit, WT/DS408 (May 11, 2011), available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm; Request for Consultations by Brazil, European Union – Seizure of Generic Drugs in Transit, WT/DS409, available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm.

¹⁵ The proponent of this bracketed alternative, presumably, the US, would seem to hope that TPP-compliant unauthorized uses might be narrower than TRIPS Art. 31-compliant unauthorized uses. By using the “unauthorized use” language, the bracketed text would exclude limited exceptions under Article 30 of TRIPS and would further exclude judicially granted licenses under Article 44.2.

¹⁶ Subparagraph 3(b)(ii) creates an exception to permit remedies for anti-competitive practices. There are additional limited exceptions for environmental measures, subparagraph 3(c), government procurement, subparagraph 3(e), and other matters.

¹⁷ Note, there are additional exceptions for non-conforming performance requirement measures detailed in Article 12.9. Pursuant to Article 12.9.2, performance requirements for specific sectors, subsectors, or activities are permissible via a negotiated negative list.

These provisions collectively create a partial but incomplete safe haven for only some of the government action that is entirely lawful under TRIPS.¹⁸ For example, TRIPS Article 31, referenced in the bracketed language of TPP Art. 12.7.3(b)(i) and Art. 12.12.5, covers only a portion of legally issued licenses under TRIPS. Specifically, the referenced TRIPS-CL language does not directly reference proposed TRIPS Article 31bis or the current waiver of Article 31(f) found in the WTO Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.¹⁹ Likewise, the bracketed TPP compulsory licensing language in subparagraph 3(b)(i) and the unbracketed TRIPS-CL language in Art. 12.12.5 do not allow the possibility of judicially authorized compulsory licenses such as those granted in the U.S. in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 126 S. Ct. 1837 (2006) and its progeny and in India in *Roche v. Cipla*, CS (OS) No.89/2008. Such judicial licenses are directly authorized by Article 44.2 of the TRIPS Agreement.²⁰

4. The limitations on performance requirements will interfere with ensuring redundant sources of medicines and legitimate technology transfer and industrial development

Article 12.7.1(b), subject to certain exceptions, prohibits a Party, with respect to investor rights, from imposing requirements in order to achieve a given level or percentage of domestic content. Many countries have used such provisions in the past as a development strategy to grow their economies via local content rules and related technology transfer/local working rules. To similar effect, Article 12.7.1(h) prohibits Parties from purchasing, using, or according preferences to their own domestic technologies. Most developed countries, including the US, achieved industrial development in part by fostering rules requiring local content, by favoring local industries, and by procuring and purchasing domestically. Now the US is intent on kicking away the technology ladder and preventing countries from also developing industrial policy to grow their technological base and industrial capacity.²¹

The TRIPS Agreement has vague and largely unenforced obligations to ensure technology transfer to least developed countries,²² but some countries have taken matters into their own hands to try to preserve sovereign rights to promote technological advancement, particularly in important areas like pharmaceuticals. So, for example, both India and Brazil have local production/local working rules in their compulsory licensing schemes that authorize the grant of compulsory licenses when local working, other than by importation, is not achieved. The U.S. filed a WTO complaint against Brazil on this issue in 2001, but the complaint was voluntarily dismissed in accordance with a consultation compromise.²³ Although Brazil has never used the challenged local-working provision, India has just granted its first statutory compulsory license based in part on Bayer's failure to produce any content locally.²⁴

¹⁸ TRIPS currently allows many other flexibilities including limitations and exceptions, exemptions, opposition procedures, exhaustion rules, definitions of patentability, etc.

¹⁹ Available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

²⁰ "Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available." (Emphasis added.)

²¹ Ha Joon Chang, *KICKING AWAY THE LADDER: DEVELOPMENT STRATEGY IN HISTORICAL PERSPECTIVE* (London, Anthem Press 2002).

²² See Articles 7 and 66.2.

²³ See http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

²⁴ *Natco Pharma Ltd v Bayer Corporation*—Compulsory Licence Application No 1 of 2011 (Controller of Patents, Mumbai), 9 March 2012, available at http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf.

Preserving sovereign rights to try to maintain or to develop local pharmaceutical capacity is critical to access to medicines not only for industrialization. When a rightholder has exclusive rights to a single source of supply, not only are there monopoly-based affordability problems, there are also high risks of interrupted supply if manufacturing or insufficient capacity problems occur. Many countries choose to develop local pharmaceutical capacity precisely in order to ensure that they have locally managed sources of supply of essential life-saving medicines to supplement potentially fragile supplies available from only one or a small number of producers on the global market.

5. Conclusion: Strike the Investment Chapter and Otherwise Limit its Application to IPRs

There are many reasons to strike the Investment Chapter from the TPP, a chapter that dramatically increases corporate power at the same time that it restricts government sovereignty to regulate foreign and domestic business activities and to afford the enforcement of claims on an even-handed basis in domestic courts. However, little attention has been given to the grave risks that the Investment Chapter poses to access to medicines. Big Pharma has had a big hand in the US IP Chapter and now in the Investment Chapter as well. Negotiating Parties should reject both TRIPS-plus IP standards and investor-state dispute clauses that will needlessly tie their hands in helping to safeguard the health of their people.

The best solution to IP-specific claims, and to the broader risks of investor-state claims altogether, is to delete the Investment Chapter entirely.

The second-best solution to the risk of dangerous investor-state arbitral proceedings is to explicitly exclude IPRs from the Investment Chapter and to clarify that IPRs are not even indirectly protected by the broader language of the TPP definition of “investment.” This solution could best be accomplished by an addition to Art. 12.3: “4. This Chapter does not apply with respect to the enforcement of any rights conferred pursuant to Chapter __ (Intellectual Property).” Either of these solutions would force IP rightholders to assert their IP-related claims in domestic courts, just as domestic IP companies must do; there would as well be supplemental protection pursuant to state-to-state dispute resolution. By excluding investor-state IPR claims, Parties could obtain sovereign control over the adjudication of IP rights, retain freedom to develop their own IP jurisprudence, and relegate rightholders to previously established private rights and remedies.

The third-best solution is to adopt the bracketed language that allows investor claims only with respect to IP rights actually granted by the Party under its existing IP laws. Limiting IP “investors” to their established rights rather than their wish-list of rights will avoid abusive claims by investors seeking to enforce ephemeral claims and yet unrealized rights under TRIPS, the TPPA, or the national law of other Parties.