Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

TRIPS PLUS, TPP MINUS

How the U.S. Intellectual Property Provisions in the TPP Threaten the Trans Pacific Partnership and the Doha Declaration on Public Health

By Akshay Bhushan

December 17th 2013

Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

I. Introduction

The Trans-Pacific Partnership (TPP) agreement has recently come under heavy criticism for leaked intellectual property (IP) provisions. Secret negotiation documents published by WikiLeaks have drawn attention to attempts by the United States Trade Representative (USTR) to push aggressive new rules for patent protection, particularly within the pharmaceutical industry. Market access to pharmaceuticals has frequently conflicted with industry goals to protect intellectual property. In regards to the international trade regime, WTO signatories are obligated to comply by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which sets minimum standards for domestic patent regimes, as well as promote global health under the 2001 Doha Declaration. However, over the past decade the U.S. has gone beyond TRIPS requirements in its bilateral agreements to set demanding IP protections for trade partners. This trend has continued in TPP negotiations and has stalled overall progress on the multinational effort. This paper will argue that proposed U.S. "TRIPS-plus" (TRIPS+) provisions not only create significant barriers to market access to pharmaceuticals, but threaten the completion of the Trans-Pacific Partnership. I conclude that the U.S. stance on pharmaceutical patent law violates the spirit of the Doha Declaration on Public Health and isolates the U.S. in negotiations.

Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

II. TRIPS, the Doha Declaration, and the Battle for Market Access

The primary governing document for intellectual property protection within modern free trade agreements is the Agreement on Trade-Related Aspects of Intellectual Property, also known as "TRIPS". Negotiated in 1994 at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), the agreement was the product of developed countries efforts to establish IP preservation as a component of global trade liberalization.[1] In theory, all IP law prevents the free flow of goods and services and thus functions as a trade barrier. However, because intellectual property rights are necessary to incentivize continued innovation and ensure market efficiency, they are consistent with free trade. TRIPS required countries provide patents for "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application."[2] These patents must provide the holder with "exclusive rights to prevent development, use, sale, and importation by others without consent of the patent holder"[3]

Overall, the level of IP protection established in the agreement is quite high, although TRIPS does contain certain "flexibilities." The accord allows for compulsory licensing, in which third parties can "obtain limited use rights for a drug without the

---

[1] Doane, Michael L. "TRIPS and international intellectual property protection in an age of advancing technology." Am. UJ Int'l L. & Pol'y 9 (1994): 465-1015.
[2] "Uruguay Round Agreement: Standards concerning the availability, scope and use of Intellectual Property Rights." World Trade Organization. http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (accessed December 18, 2013).
[3] "Agreement on Trade-Related Aspects of Intellectual Property Rights" art. 27, § 1, Apr. 15, 1994, Annex 1C, 1896 U.N.T.S. 299, 33 I.L.M. 1197 (1994) Marrakesh Agreement Establishing the World Trade Organization.

patent owners consent."[4] Users must attempt to negotiate authorization on reasonable terms, yet if these efforts fail after a "reasonable period of time" they may receive a license. [5] Additional exceptions are allowed for case of "national emergency, extreme urgency, non-commercial use by the government, or to remedy anti-competitive practices."[6] However, TRIPs Article 31(f) adds a stipulation to the distribution of compulsory licenses in that it prohibits the manufacture of the patented drug in a third-party country for export. If a country does not have indigenous pharmaceutical manufacturing capacities, the license is functionally useless. [7]

Because adherence to TRIPS rules was a prerequisite to WTO membership, these countries viewed the agreement as an unfavorable condition on an otherwise valuable deal. However, it quickly became clear that the IP protections lobbied for by the United States, Japan, and European Union came at a significant cost: TRIPs limited developing countries' access to generic drugs. In 2001, amidst a growing HIV/AIDS crisis, South Africa enacted a law permitting its government to import fluconazole, an antiretroviral drug, from countries which manufactured them at a lower cost than the original patent holder. Yet parallel import directly violated TRIPS. American firms quickly filed suit with the WTO, arguing that the agreement violated the 1994 GATT. The lawsuit claimed that the new law allowed "the health minister to act unilaterally without first having to

[4] Bucci, Christina. "Responsible Patent Protections: Preserving Public Health Objectives in the Trans-Pacific Partnership Agreement." Pac. McGeorge Global Bus. & Dev. LJ 26 (2013): 213-315.
[5] "Agreement on Trade-Related Aspects of Intellectual Property Rights", Section 31(b)
[6] *Ibid*, Section 31(b)-31(k)
[7] Kumar, Swarup. "SCRIPTed - A Journal of Law, Technology & Society." Compulsory Licensing Provision under TRIPS. http://www2.law.ed.ac.uk/ahrc/script-ed/vol7-1/kumar.asp (accessed December 18, 2013).

prove a drug manufacturer abused its patent" and contained "no provision for compensating the patent-holder."[8] GlaxoSmithKline executive John Kearney explained the essence of the disagreement succinctly: "intellectual-property rights are the lifeblood of our industry."[9] Pharmaceutical companies continue to argue their massive investments into the research and development of new drugs should be protected. If South Africa simply imported the drugs from foreign companies, firms such as GlaxoSmithKline would be unable to turn a profit. While sympathetic to the needs of countries like South Africa, the industry maintains that strong intellectual property rights are necessary to preserve the economic rationale for pharmaceutical innovation. Nonetheless, the South African case highlights the central conflict concerning public health and the WTO. The global south often does not have access to the innovative solutions from developed countries. Even then, the high costs of purchasing drugs can simply price countries out of the market.

The Doha Declaration on Public Health emerged from this dispute. A non-binding amendment to TRIPS, the 2001 declaration added public-health oriented guidance to the 1994 draft. The amendment explicitly noted that the WTO was supportive of its "members' right to protect public health."[10] It added that TRIPS would recognize "the gravity of the public health problems afflicting many developing and least-developed

[8] Maykuth , Andrew. "Where Aids Is Rampant And Help Scarce For Drugmakers, Many In The Phila. Area, Money Must Be In The Equation.." Philadelphia Inquirer. http://articles.philly.com/2001-03-04/news/25327850_1_aids-drugs-zackie-achmat-generic-manufacturer (accessed December 4, 2013).
[9] *Ibid*
[10] Correa, Carlos María. Implications of the Doha Declaration on the TRIPS Agreement and public health. Geneva: World Health Organization, Essential Drugs and Medicine Policy, 2002.

countries, especially those resulting from HIV/AIDS."[11] Unfortunately, the declaration initially failed to address the issue of parallel imports and simply called on countries to find an "expeditious solution"[12] The WTO would eventually address the issue on August 30th, 2003 when it negotiated the creation of a new waiver system in which countries could legally import generics.[13] In 2007, Rwanda became the first country to test the waiver process. Its experience demonstrated that little had changed from the initial TRIPs agreement.[14] The administrative process for filing compulsory license waivers is saddled by administrative and bureaucratic hurdles.[15] The question of waiver approval ultimately remains a political one. WTO member states whose interests disagreed with the distribution of a powerful new compulsory license to a new country could simply halt the process. As a result, members negotiating on behalf of the original pharmaceutical industry became veto-players. The balance between market access and intellectual property rights has changed little since 1994. As one observer reflected after negotiations concluded, "None of the parties involved in the negotiations believed that this was not the result achieved, nor did the negotiators overlook the possibility of attaining a more user-

[11] "Declaration on the TRIPS agreement and public health." World Trade Organization. http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed December 18, 2013).
[12] *Ibid*
[13] Vandoren, Paul, and Jean Charles Eeckhaute. "The WTO decision on Paragraph 6 of the Doha Declaration on the TRIPS agreement and public health." The Journal of World Intellectual Property 6, no. 6 (2003): 779-793.
[14] Greenbaum, Jessica L. "Trips and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication n the Wake of Paragraph 6 Waiver." J. Contemp. Health L. & Pol'y 25 (2008): 142.
[15] Abbott, Frederick M., and Jerome H. Reichman. "The Doha Round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions." Journal of international economic law 10, no. 4 (2007): 921-987.

friendly or expeditious process."[16] While the Doha Declaration established a right to public health in principle, but TRIPS maintained the upper hand.

III. The United States, Bilateralism, and the TRIPS-Plus Era

The lack of success in multilateral trade rounds following the early 2000s created a global shift towards bilateral trade agreements (BTAs). Economists have argued that such agreements generally provide stronger patent standards than multilateral agreements.[17] Economically powerful states may have an asymmetric advantage and can push for added conditions related to intellectual property rights during negotiations.[18] More importantly, the fewer number of stakeholders at the negotiating table make it easier for countries to agree on certain norms.[19] Given these structural advantages and the fact that BTAs increase the revenue of patent holders, the United States has made an emphasis on bilateral FTAs a component of its trade negotiating strategy. The Bush and Obama administrations have completed full-fledge trade agreements that include IP chapters with Singapore, Chile, and Central American countries, Dominican Republic, Australia, Morocco, Bahrain, Oman, Peru, Colombia, Panama and Korea.[20]

---

[16] *Ibid*, 925
[17] Caporaso, J. A. (1992) 'International Relations Theory and Multilateralism: The Search for Foundations', International Organization, 46 (3), 599–632.
[18] Greenaway, D. and Milner, C. (2001) 'Multilateral Trade Reform, Regionalism and Developing Countries', in S.Lahiri (ed.), Regionalism and Globalization: Theory and Practice. Routledge, New York, pp. 144–69.
[19] Yarbrough, B. V. and Yarbrough, R. M. (1987) 'Cooperation in the Liberalization of International Trade: After Hegemony, What?', International Organization, 41 (1), 1–26.
[20] Crawford, Jamie. "Fact Check: Has Obama 'not signed one new free-trade agreement'?." CNN. http://www.cnn.com/2012/10/08/politics/fact-check-romney-trade/ (accessed December 14, 2013).

The USTR's strategy is to use bilateral agreements in order to shape the outcome of larger, multinational agreements. Former U.S. Trade Representative Robert Zoellick and current chief of the World Bank has labeled the approach "competitive liberalization." The goal was to use a slew of bilateral agreements to "ratchet up" base IP standards at the multilateral level. "By moving forward simultaneously on multiple fronts," Zoellick argued, "the United States can … create a fresh political dynamic by putting free trade on the offensive"[21] By starting with leading reformers the U.S. hoped to create a domino effect. [22]New trade partners would hopefully negotiate similar provisions with other countries, creating a floor for IP protection. The fact that this base standard is more favorable to developed countries has meant these BTAs are known as "TRIPS-Plus" agreements. However, many economists have vehemently opposed the turn to bilateralism, arguing that it "presents powerful states with an alternative path in creating desired norms that they would not be able to negotiate successfully at the multilateral level."[23]

Indeed, the U.S. has often attached stringent IP requirements to its FTAs, all of which have significant implications for market access of pharmaceuticals if they are applied to the multinational or regional level. These can generally relate to three topics:

---

[21] US Government Accountability Office (2004) International Trade: Intensifying Free Trade Negotiating Agenda Calls for Better Allocation of Staff and Resources, US Government Document GAO-04-223.
[22] Yu, P. (2004) 'Currents and Crosscurrents in the International Intellectual Property Regime', Loyola of Los Angeles Law Review, 38, 323–444.
[23] Morin, Jean-Frédéric. "Multilateralizing TRIPs-Plus Agreements: Is the US Strategy a Failure?." The Journal of World Intellectual Property 12, no. 3 (2009): 175-197.

data exclusivity, parallel importation, and patent-registration linkage. This section will briefly discuss each topic's relation to IP law and its implication on market access.

A. Data Exclusivity

Pharmaceutical companies must provide testing and other data to their national drug regulatory authority to register new medicine they wish to market within the country. It is in the interest of the original developer of the drug to conceal this data from other companies. After all, if generic manufacturers had access to essential information concerning the drug, they could simply mass produce it and sell it. To protect the IP of the company which invested research and development into the drug, generic manufacturers must apply after a pre-determined date to produce the medicine. During this period of "data exclusivity", the drug regulatory authority is not authorized to release information on the drug or register generic version of the medicine. [24]

TRIPS contains articles concerning data exclusivity and requires WTO member countries to take measures which protect testing data against "unfair commercial usage."[25] The United States provides for data exclusivity within its domestic patent regime. New chemical entities will not have their testing information released by the Food and Drug Administration (FDA) for five years. In the fifth year, generic

[24] Abbott, Frederick. "The Doha Declaration on the TRIPS Agreement and public health and the contradictory trend in bilateral and regional free trade agreements." Quaker United Nations Office (Geneva)(QUNO), Occasional Paper 14 (2004).
[25] "Agreement on Trade-Related Aspects of Intellectual Property Rights", art. 39.3.

manufacturers may apply for rights to produce the drug and begin an 18 month process to receive FDA approval.[26]

The U.S. has pushed for data exclusivity provisions in its bilateral agreements. The USTR language in BTAs notes that "the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time ..." Any other definition of this term would be inconsistent with logic and the negotiating history of the [TRIPS] provision"[27] Many have argued that the USTR is incorrect and data exclusivity is well above minimum requirements. Nor is exclusivity the only method to preserve IP rights at the international level-a liability style system would work equally well and require countries to compensate companies for the right to manufacture drugs in the short-term while keeping such data secret.[28] Yet because the five-year ban on authorization provides the pharmaceutical industry with ironclad protection, such alternatives are considered unfavorable for U.S. interests.

B. Parallel Importation

Developing can also increase their market access to generics by procuring the drug from a third country. Because these generics are manufactured at a lower cost, otherwise vulnerable populations are then able to afford these drugs. Parallel importation

[26] Baker, Brook K. "Ending drug registration apartheid: taming data exclusivity and patent/registration linkage." Am. JL & Med. 34 (2008): 303.
[27] Correa, Carlos María. Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS agreement. Geneva: South Centre, 2002.
[28] Fellmeth, Aaron Xavier. "Secrecy, monopoly, and access to pharmaceuticals in international trade law: protection of marketing approval data under the TRIPs Agreement." (2009).

is a pro-competitive policy which contradicts even the initial 1994 TRIPS accord.[29] The worry is not only that it would create a list-price differential which would erode companies' profits, but that it would create significant trade diversion. Pharmaceutical companies worry that allowing other countries to manufacture their drugs would allow for them to become black markets.[30] Certain individuals could buy generics at a low-cost and sell them for profit in a developing country, with the original innovator receiving no compensation. While in many cases, certain developed countries have granted exemptions to parallel importation restrictions, the U.S. has not agreed to award these privileges on many drugs.[31] This is seen as morally objectionable to many public health officials. Because developed countries have greater resources control the flow of drugs into their national market, the burden should fall on them to regulate this possibility. Regardless, strict restrictions on parallel importation are another way the U.S. has ratcheted up IP standards in TRIPS+ BTAs.

C. Patent-Registration Linkage

The basic concept behind patent-registration linkage is to make the drug regulatory authority a patent enforcer.[32] The 1984 Hatch Waxman act codified this protection, forcing the Food and Drug Administration to certify, when considering a drug

[29] Bond, Patrick. "Globalization, pharmaceutical pricing and South African Health Policy: managing confrontation with US firms and politicians." International Journal of Health Services 29, no. 4 (1999): 765-792.
[30] Duhan, Dale F., and Mary Jane Sheffet. "Gray markets and the legal status of parallel importation." The Journal of Marketing (1988): 75-83.
[31] Fink, Carsten, and Patrick Reichenmiller. "Tightening TRIPS: Intellectual property provisions of US free trade agreements." 00 Trade, Doha, and Development (2006): 289.
[32] Li, Y. A. N. G., and L. I. Ye. "Study on the Drug Patent Linkage System in the USA." China Pharmacy 4 (2007): 005.

application, that "there were no competing patents, that all patents had expired, that the registration would not become final until patent expiration, or that the alleged patent was invalid or would not be infringed"[33] This creates significant bureaucratic hurdles for generics manufacturers. Patent owners, if they believe the new application infringes upon their existing drug, can bring the question to court. Even if the outcome results in the invalidation of the original patent, the result is a process mired in litigation that favors large pharmaceutical companies.[34] Because the vast majority of patents are not entirely new chemical entities, patent-registration linkage allows businesses in developed countries to layer patents to prevent possible competitors from developing new drugs. Not only do linkage regimes deter innovation, they also delay market-entry for generics in developing countries due to the barrage of litigation each license or patent claim must pass through.[35] This type of TRIPS+ provision is particularly widespread in U.S. FTAs because it is a new loophole through TRIPS flexibilities. The Central American Free Trade Deal, for example, mandated such patent-linkage articles within the laws of all foreign countries.

[33] Baker, "Ending drug registration apartheid: taming data exclusivity and patent/registration linkage." 303.
[34] Bucci, Christina. "Responsible Patent Protections: Preserving Public Health Objectives in the Trans-Pacific Partnership Agreement." 213-315.
[35] Kapczynski, Amy. "Harmonization and its discontents: a case study of TRIPS implementation in India's pharmaceutical sector." California law review 97 (2009): 1571.

Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

IV. The Trans Pacific Partnership and TRIPS+ Provisions

The TPP is a developing agreement with the United States and its Asia-Pacific partners. Current negotiations include Australia, Brunei, Chile, Canada, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam.[36] The IP components of the agreement will be a significant test for U.S.'s strategy of competitive liberalization. This is the first time the USTR has sought such a comprehensive agreement which attempts to harmonize the "overlapping and inconsistent [free trade agreements] proliferating the globe."[37]

However, the U.S. push for TRIPS+ provisions already has many economists concerned. In the words of one congressional report the TPP "looks like a series of bilateral U.S. FTAs with exclusions for products the United States considers sensitive."[38] While the U.S. will inevitably pursue its goals, a self-interested approach makes it "less likely the TPP will attract other countries to accede."[39] These concerns are amplified by the fact that negotiations are secret. Critics worry private interests, such as the pharmaceutical industry, could have undue influence on the process.

---

[36] Fergusson, Ian F., William H. Cooper, Remy Jurenas, and Brock R. WIlliams. "The Trans-Pacific Partnership Negotiations and Issues for Congress." (2013).
[37] "Trans-Pacific Partnership Leaders Statement." Office of the United States Trade Representative. http://www.ustr.gov/about-us/press-office/press-releases/2011/november/trans-pacific-partnership-leaders-statement (accessed December 16th, 2013).
[38] Fergusson, Ian F., William H. Cooper, Remy Jurenas, and Brock R. WIlliams. "The Trans-Pacific Partnership Negotiations and Issues for Congress."
[39] *Ibid*

Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

The anxiety over the TPP's treatment of intellectual property was magnified in both September 2011 and November 2013, when leaked drafts of the agreement were released to the public. The September 2011 leaks revealed that in order to compensate countries for agreeing to data exclusivity and patent-linkage rules, the USTR would create a new strategic initiative: the "Trade Enhancing Access to Medicines" (TEAM). Its goal is to find a middle ground between U.S. IP interests and the Doha Declaration. The primary TEAM measure to reassure less-developed countries of market access is to create a market access window.[40] This tool allows countries to receive marketing approval for drugs using procedures from another country. That is, to begin the patent process the manufacturer does not necessarily have to rely on the lengthy procedures of the Food and Drug Administration. It can file a patent under the procedures of a "reliance" country in which its patent regime may be more lenient. [41]

However, critics of the access window note that the policy does little to help developing countries. Most designated "reliance" countries have the exact same data exclusivity and patent-linkage protections as the U.S., oftentimes due to the very BTAs the U.S. negotiated earlier in the decade. The window also does little to distribute new, innovative drugs to the global south. If GlaxoSmithKline develops a new antiretroviral in the U.S., it can still use patent law to ensure that no country is capable of reproducing its drug for over five years, if not more. The policy is the equivalent of pointing developing

[40] Gordon, Bernard K. "Trading Up in Asia: Why the United States Needs the Trans-Pacific Partnership." Foreign Aff. 91 (2012): 17.
[41] Flynn, Sean, Brook K. Baker, Margot Kaminski, and Jimmy Koo. "The US Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement." American University International Law Review 28, no. 1 (2012).

countries to apply to other regimes while what they seek is obviously in the hands of U.S. companies.[42] Furthermore, the U.S. definition of "access" in this case is very different from that of other WTO member states. Market access is not solely about being able to file for a patent, but also about the price and availability of medicine on the ground. If we conceive of the Doha Declaration in these terms, it is clear the TPP threatens the right to public health. Certain articles of the provision even extend exclusivity periods, guaranteeing generic medicines will be kept out of the hands of the poor.[43] The sole beneficiary of the access window is innovator companies. To market throughout the range of TPP countries, a company only needs approval from a singular patent regime. This harmonizes regulation across borders, which benefits pharmaceutical companies attempting to sell their specific drug in new markets. It does not, however, introduce competition or reduce constrains in the actual patent process. Pharmaceutical companies are still able to use developed countries' patent regimes to protect their product from competition. [44]

The newer leaked portions of the TPP merely add to the impression that the U.S. is violating the principles set forth in the Doha declaration. Article QQ.A.5 specifically is an attempt to revise and narrow the scope of public health:

> Article QQ.A.4: {Declaration on the TRIPS Agreement and Public Health}
>
> The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).

[42] *Ibid*
[43] *Ibid*
[44] *Ibid*

> Article QQ.A.5: {Understandings Regarding Certain Public Health Measures}
>
> The Parties have reached the following understandings regarding this Chapter:
>
> (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, [US oppose: chagas] and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.[45]

The brackets included in the draft confirm suspicions that the U.S. was downplaying the relevance of the Doha Declaration to diseases outside of "HIV/AIDS, tuberculosis, [and] malaria". While many might view this wording as an issue of lesser importance, language can have an immense impact on how future conflicts over portions of trade law are settled. As one commentator noted,

> …there are subtle tweaks of language, the phrases included or not included from previous treaties; the subtle re wordings that might give a treaty provision an entirely different meaning. Working out the scope of a country's obligations if even half of this text becomes treaty is going to be extremely difficult.[46]

---

[45] Downs, Paul. "The Trans-Pacific Partnership and Conflicting Customary International Norms." Geo. J. Legal Ethics 26 (2013): 661-1107.
[46] Weatherall, Kimberlee . "TPP – Australian Section - by - Section Analysis of the Enforcement Provisions ." Sydney University.

Rather than directly apply the Declaration's right to public health in general, the U.S. has isolated several diseases worthy of special treatment. When the TRIPS+ provisions in the TPP inevitably contradict the accords' commitment to public health, it may very well be this degree of wording which decides the outcome.[47]

The concern for the wording in health-related sections of the TPP extends far beyond Article QQ.A.5. The IP provisions are written like legislation rather than a righteous agreement between two parties. While the majority of high-level trade treaties set basic principles, the chapters of the TPP specify exact punishments for non-compliance with TRIPS+ provisions. Nor does the language of these punishments reassure critics that the discipline will be proportional to the crime. Instead, the emphasis has been placed on retribution and assuring innovator companies the ability to contest possible patent infringement. Some examples of this trend include raising the awarded damages in IP cases or allowing for the seizure of any item used to infringe copyright.[48]

The attempt to push TRIPS+ provisions is a direct challenge to the 2001 Doha Declaration and threatens the very conclusion of the TPP. Not only is the USTR deliberately attempting to narrow the scope of the Declaration, but it is also forcing "ratcheted-up" IP laws upon multilateral negotiations. If stringent patent laws are copied by other TPP signatories, lesser-developed Asian countries will have few options to

---

http://works.bepress.com/cgi/viewcontent.cgi?article=1032&context=kimweatherall (accessed December 10, 2013).

[47] McGrady, Benn. "Narrowing of the Doha Declaration in the Draft TPP IP Chapter." ONeill Institute Blog. http://www.oneillinstitutetradeblog.org/narrowing-doha-declaration-draft-tpp-ip-chapter/ (accessed December 15, 2013).

[48] Weatherall, Kimberlee . "TPP – Australian Section - by - Section Analysis of the Enforcement Provisions ."

obtain access to generics. Their domestic patent laws will force compliance with the very data exclusivity and patent-linkage systems that are against their own interests. The U.S. access window is far from a concession.[49] It neither reduces the price of drugs nor provides exemptions for poorer nations. Yet perhaps even worse is that these provisions have isolated the U.S. within TPP negotiations. An analysis of the leaked drafts by political scientist Henry Farrell suggests the U.S. negotiating position has impeded its progress. As Farrell notes,

> there is far less overlap between the United States and countries we might normally consider to be "partners" than one might expect. Indeed, the United States does not even appear on the list until two-thirds of the way down. Out of 66 possible dyads, 42 appear more frequently than the United States appears with anyone.[50]

This isolation directly has to do with the U.S. stance on IP, particularly on pharmaceuticals.[51] The idea that the U.S. can enforce data exclusivity and patent-linkage regimes upon the rest of its Asia-Pacific partners has left little maneuvering room for the USTR in negotiations. Few concessions, if any, would justify making TRIPS+ provisions the base IP standard for the majority of the Asia-Pacific.

---

[49] Aldis, W., C. Oh, K. Bhardwaj, and K. Timmermans. "The Trans-Pacific Partnership Agreement: A Test for Health Diplomacy." Journal of Health Diplomacy. Published online June 12 (2013).

[50] Farrell, Henry. "The United States is isolated in the Trans-Pacific Partnership negotiations." Washington Post. http://www.washingtonpost.com/blogs/monkey-cage/wp/2013/11/18/the-united-states-is-isolated-in-the-trans-pacific-partnership-negotiations/ (accessed December 9, 2013).

[51] Gleeson, Deborah, Ruth Lopert, and Papaarangi Reid. "How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand." Health Policy 112, no. 3 (2013): 227-233.

Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

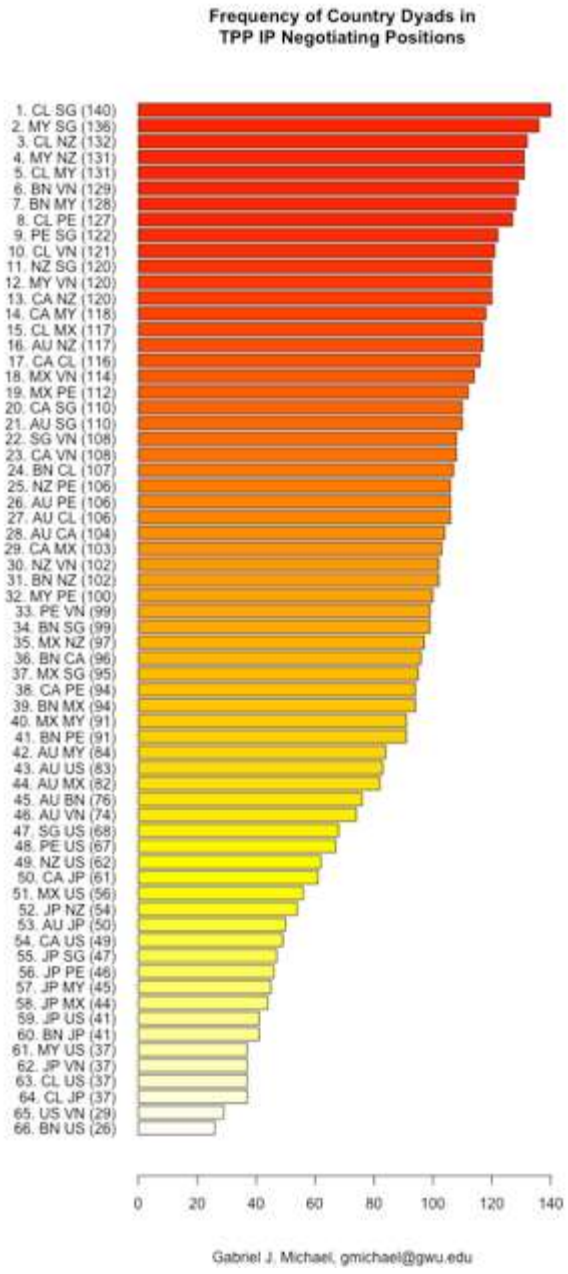
Conclusion

While many are confident in the ability of the USTR and other nations to conclude TPP negotiations soon, U.S. insistence on certain forms of IP protection has become a significant obstacle. Moreover, the attempt to use bilateral agreements to push countries to bargain on its terms is proving difficult. Competitive liberalization will still require concessions from the USTR if a comprehensive partnership is to be completed. These compromises, far from endangering Asia-Pacific integration, will support it. Rather than over-protecting U.S. pharmaceutical interests, improving market access to generics within the Asia Pacific would increase the overall volume of trade.[52] Rather than undermine the spirit of the 2001 Doha Declaration, the USTR should craft an agreement which genuinely balances the interests of lesser-developed countries and U.S. pharmaceutical interests.

[52] Lewis, Meredith Kolsky. "THE TPP AND THE RCEP (ASEAN+ 6) AS POTENTIAL PATHS TOWARD DEEPER ASIAN ECONOMIC INTEGRATION." Asian Journal of WTO & International Health Law & Policy 8, no. 2 (2013).

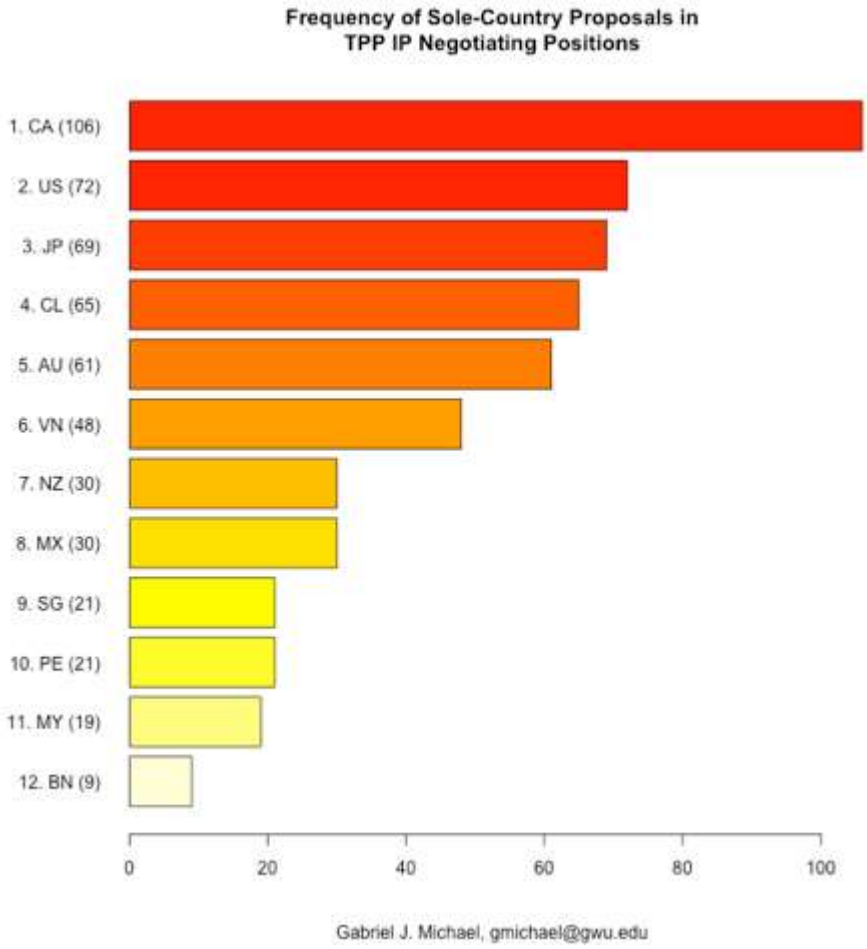
Akshay Bhushan
INAF-367
Trade in the Asia-Pacific
December 17th, 2013

Figure 1: U.S. Isolation in the TPP[53]



[53] Farrell, Henry. "The United States is isolated in the Trans-Pacific Partnership negotiations."

Figure 2: Sole Country Proposals in IP Negotiations[54]



[54] Farrell, Henry. "The United States is isolated in the Trans-Pacific Partnership negotiations."