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Impact of TPP on International, Regional and other Plurilateral IP Norm Setting

Pankhuri Agarwal[†]
National University of Singapore, Singapore - 119 077

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In the wake of recent signing of the U.S. led Trans-Pacific Partnership Agreement (TPP) between twelve Pacific-Rim countries on 4 February 2016, need has arisen for analysing the impact of plurilateral intellectual property (IP) negotiations like TPP and Anti-Counterfeiting Trade Agreement (ACTA) as opposed to that of the multilateral IP negotiations at forums like World Trade Organization (WTO) and World Intellectual Property Organization (WIPO). The paper describes the meaning of multilateral and plurilateral agreements and the reasons for the shift from former to the latter. It then analyses the negatives and positives ofplurilateral agreements. Further, it provides a critical comparative analysis of some of the patent law provisions of the TPP and Agreement on Trade Related Aspects of Intellectual Property (TRIPS) to illustrate how the plurilateral IP agreements may take away the flexibilities that TRIPS allows to its members considering the different stages of development they are in and thereby adversely impact public interest. Lastly, the paper analyses the impact of the plurilateral negotiations, especially that of TPP, on multilateral, regional as well as other plurilateral IP-norm setting.

Keywords: Patent, Trans-Pacific Partnership Agreement, Anti-Counterfeiting Trade Agreement, The Association of South East Asian Nations, Regional Comprehensive Economic Partnership, WTO, WIPO, TRIPS

Plurilateral v Multilateral IP Norm Setting

Multilateral to Plurilateral Agreements

Multilateral agreements are those, the norm-setting of which, is open to all countries that want to participate, though the agreement once concluded may not be binding on all countries.[1] These agreements are usually negotiated through multilateral organizations like the WTO and WIPO and are binding on the members of these multilateral organisations.[1] On the other hand plurilateral agreements are those that are negotiated by a limited number of countries, whether part of the same region or not, which after conclusion are generally open to accession by other countries.[1] These agreements are also, sometimes, referred to as country club agreements.[1] ACTA, TPP and RCEP are a few examples of plurilateral agreements. Another characteristic of plurilateral agreements that makes it different from multilateral agreements is that their negotiations are conducted in secrecy.[1]

Plurilateral agreements are said to be a result of vertical forum shifting i.e. shifting from a multilateral level to a level below it instead of shifting to another multilateral level institution.[1] Earlier, U.S., Japan and EU had pushed for horizontal forum shifting for setting of IP standards from WIPO to a trade regime of GATT and then WTO due to WIPO's increasing attention towards developing countries and lack of enforcement mechanisms.[2] However, after the victory of the developing countries with the Doha Declaration on TRIPS and Public Health and a TRIPS amendment supporting their public health needs, U.S. and EU made a return to WIPO for negotiations of Substantive Patent Law Treaty to achieve TRIPS-plus standards.[2] However, the efforts of the developed countries led WIPO to adopt the Development Agenda, which in turn led the unhappy powerful countries to make a vertical forum shift to plurilateral negotiations of ACTA and TPP.[2] Thus, plurilateral IP agreements are largely a result of inability of the stronger countries to achieve their goals i.e. TRIPS-plus standards of IP protection at the multilateral forum.[2]

TPP started as a quadrilateral agreement among four countries, namely, Brunei, New Zealand, Chile and Singapore.[2] Later, U.S. joined the TPP to pursue its own interests as explained above. It was gradually followed by other Pacific Rim countries, namely, Australia, Peru, Vietnam, Malaysia, Mexico, Canada and Japan.[2] The TPP negotiations continued among these twelve TPP members for a few years, till it was recently signed by them on 4 February 2016 in Auckland, New Zealand.[1] However, the agreement is yet to come into force.[3] Although TPP, one of the most ambitious trade agreement, covers a range of

[†]Corresponding Author: Email: pankhuri.nujs@gmail.com

issues, its provisions on intellectual property that provide far stronger protection than TRIPS provisions shall be the focus in this research paper.

Negatives of Plurilateral Agreements

Plurilateral agreements have attracted severe criticism. Secrecy and lack of transparency has been one of the major criticisms of plurilateral agreements like TPP and ACTA.[4] The entire negotiation process of these agreements is conducted behind closed doors and no provision, text or draft of these agreements is released to the public until the entire agreement has been concluded.[2] Thus, there is no democratic participation or engagement of the civil society.[5] This is despite that IP-norm setting impacts "development issues such as health, food and agriculture" and has, of late, been paid great attention to by the civil society organizations.[6] The stakeholders like the consumers do not get an opportunity to scrutinise and voice their grievances related to the issues being negotiated. Only the private industry actors are said to have heavily influence the negotiations although they are not formally part of it.[2] Thus, plurilateral agreements may often emerge unbalanced, for instance, ACTA and TPP have turned out to be a copy of the wish-list of the entertainment industry and the pharmaceutical industry respectively.[7] It is ironic that TPP, a treaty that calls for transparency, was developed non-transparently.[6] The confidentiality also leads to lack of accountability of the governments to their citizens.[8] The citizens would not be able to exercise influence they do on national legislatures by mass mobilization or exercise of voting power because the legislative power with respect to plurilateral negotiations is exercised at the transnational level by the executive on behalf of the national legislators.[9] The non-transparent negotiations are also said to make countries, whether they offer much political freedom or not, incur significant political costs.[6]

Non-multilateral negotiations can be very time consuming and resource intensive.[10] Additionally, in plurilateral negotiations, resources are spent on maintaining secrecy as well.[11] These resources and time spent may often go waste if the legislature rejects the agreement. Non-engagement of the civil society may lead to mass protests, once the text of the agreements has been made available, calling upon the legislatures to oppose the agreement. As a result, these agreements may be rejected by the legislature the way ACTA was rejected in 2012 by the European Parliament as a result of massive protests held against ACTA by the people throughout Europe.[6] TPP may also meet similar fate in many TPP countries where such protests have been made.[12]

Another criticism of plurilateral agreements is that it may result in "regime complexity" by creating different standard of obligations in different regimes.[13] Also, agreements like ACTA, that create additional governance institutions without elaborating on how they would mesh with multilateral institutions like WIPO and WTO, may cause uncertainty in the global IP regime.[2] These agreements are feared to "kill the WTO" by undermining its role in setting trade and IP standards.[9] Some fear if these agreements continue to progress in the same way, they may lead to formation of a tri-polar world dominated by United States, Europe and China and thereby inconsistent standards that may undermine the multilateral trading systems.[6] These agreements may also raise the global standards of IP protection as they their TRIPS-plus standards are likely to reappear in other bilateral and regional agreements.[9] Given the economic power of most of the ACTA and TPP members, for instance U.S. and Japan which are members of both, other countries may be coerced to comply with the high standards in these agreements even though it may be against their interests.[9] Thus, plurilateral agreements, according to some, may "construct, reinforce, and deepen inequity".[2]

Positives of Plutilateral Agreements

Despite the above criticism of plurilateral agreements, TPP has been praised by some to have broken the North-South divide by getting the developed as well as some developing countries to agree on the same trade standards.[14] WTO Director-General Roberto Azevedo himself, upon conclusion of the TPP, said, "*The success of the TPP negotiations is proof that a diverse group of countries can strike a deal on a broad and complex trade agreement if the political will and determination are there*".[14] The difficulty in obtaining consensus among countries due the North-South has stalled the multilateral IP negotiations for a long time. However, given that only a few developing countries are members of TPP, that they may have agreed to TRIPS-plus standards for larger trade advantages from TPP and that other developing countries like India have opposed the TPP IP standards, it may not be right to be say that the North-South divide on IP issues has been broken and that TPP will act as an inspiration for future IP-norm setting.

In light of the above listed harms of the plurilateral IP-norm setting and its benefits only being illusory, it can be said that plurilateral agreements should not be

the future. However, it may also be that the harms are more associated with the combination of countries that are members of a plurilateral agreement, for instance, the inclusion of U.S. but exclusion of Indian and China in the TPP, instead of the fact that only a few countries are involved.

TPP, TRIPS Flexibilities and Impact on Public Interest

Plurilateral IP agreements may take away the flexibilities that TRIPS allows to its members considering the different stages of development they are in and thereby adverse impact publicinterest. TPP is a perfect example of this. Itspatent law provisions, *inter alia*, go far beyond the ones in TRIPS and they take away the flexibilities permitted to the TPP members as WTO members by TRIPS.[2] These TPP provisions have been very controversial and have been said to impact the access to affordable medicines in the member countries. The U.S. has got other TPP members to agree to some of the provisions similar to its national patent law provisions in the TPP to provide enhanced patent protection to its innovator companies, especially, the pharmaceutical companies. Some of the main differences between the TPP and TRIPS on this count are critically analysed below.

Scope of Patentability

TRIPS mandate its members to grant patents to any product or process invention that is new, involves an inventive step and are capable of industrial application.[15] It leaves it up to the parties to define what would or would not amount to an 'invention'.[1] This flexibility of the WTO members has been taken away by TPP to some extent. Article 18.37(2) of TPP mandates TPP members to treat new uses of or new methods or processes of using a known product as inventions. This means that a drug based on an existing drug and involving very little innovation, e.g. a new form of a known drug not having any increased therapeutic efficacy, could also receive a patent.[7] This would, in effect, amount to extending the patent term of existing drug by grant of multiple patents, also known as ever-greening.[2] This would delay the entry of generic drugs into the market and also harm pharmaceutical innovation.[2]

Patent Revocation

TRIPS do not stipulate grounds for revocation of patents and thus gives parties the leeway to legislate upon it.[16] However, Article 18.39 of TPP takes away that leeway by restricting the grounds for revocation of patent to grounds for refusal of grant of patent. This means that a TPP member cannot revoke a patent on any other grounds like that of public interest.[1]

Patent Term Extensions

TRIPS provides for patent protection for a term of a minimum of twenty years from the filing date.[17] Article 18.46(3) of TPP takes advantage of the fact that TRIPS does not provide for a maximum term by mandating extending of patent term to compensate for unreasonable delay in issuance of a patent. Unreasonable delay refers to, as per paragraph 4, as delay of more than five years from the date of filing or three years from the date of request for examination, whichever is later. Further, Article 18.48(2) mandates a similar extension in patent term of a pharmaceutical product for compensation of unreasonable delay in grant of marketing approval to it, though 'unreasonable' has not been defined. A similar provision exists in the U.S. Hatch-Waxman Act.[18,19] However, no such patent term extensions have been provide for in TRIPS despite recognition of delays.[1] Such extensions would amount to a grant of monopoly to patent holders for more than twenty years and thereby delay the entry of generics in the market.[20] Also, the time pressure on the overly-loaded patent offices may result in them granting invalid patents or marketing approvals to unsafe or inefficacious drugs.[1]

Data Exclusivity

TRIPS requires the parties to protect undisclosed data or other data submitted for approval of pharmaceutical or agricultural chemical products only against commercial fair use and also disclosure unless if necessary to protect public interest.[21] However, Articles 18.47, 18.48 and 18.51 of TPP provide for data exclusivity i.e. prohibition for a certain period on use of the data submitted by first applicant must not be used for issuance of marketing approval to a subsequent one. With respect to new agricultural chemical products the exclusivity period is ten years, with respect to new pharmaceutical products, five years and with respect to new biologics, five to eight years. Such data exclusivity impacts access to medicines in two ways. First, it delays the entry of generic drugs by requiring the generic manufacturers to either wait for the exclusivity period to expire or conduct their own clinical trials and produce data.[7] Second, it may raise the prices of generic drugs if the generic manufacturers spend their time and resources in duplicating clinical trials and other testing.[22] Such data exclusivity provisions are

again a reflection of U.S. law (Hatch-Waxman Act) provisions creeping into the TPP.[23]

Patent Linkage

TRIPS doesn't require parties to make any linkage between issuance of marketing approval to a generic version of a pharmaceutical product and the patent claimed on it, also known as, patent linkage.[24] However, Article 18.53 of TPP mandates this linkage to be adopted in either of two ways. The first option is to provide for notification of application for marketing approval to the patent holder and adequate time and opportunity to seek judicial or administrative remedies against patent infringement prior to marketing.[25] The second option is to adopt a system whereby issuance of marketing approval is precluded based upon patent information provided by the patent holder for marketing approval or direct co-ordination between the patent office and the marketing approval authority.[26] This linkage system, in effect, allows the patent holder to prevent issuance of marketing approval until the generic manufacturer challenges the validity of the patent and it is declared to be invalid.[1] This may be harmful to access to medicines in several ways. One, the generic drug may not be able to enter the market for some period even after the expiry of the patent because the marketing approval application, in effect, may be made only after expiry.[20] Second, in cases of a clearly invalid patent also, the market entry of the generic drug may be delayed until the patent is declared invalid.[1] Third, apart from the delay, the huge cost of litigation involved may deter the generic manufacturers from entering in the market during the term of the patent.[1] Fourth, it may affect effective use of compulsory licenses as even if the license is granted, the marketing may be prevented as a result of the linkage.[1]

Therefore, a comparison of the TPP and TRIPS patent law provisions shows that the former has taken away the flexibilities provided by the latter. This is not to suggest that it must not have contained any TRIPS-plus IP provisions, it is irresponsible to include those that may impact the access to essential drugs, especially in the developing countries members of the TPP.[7]

Impact of Plurilateral Negotiations on IP-norm Setting

Multilateral International IP-Norm Setting

Plurilateral negotiations, as briefly mentioned before, may have an impact on the multilateral IP-norm setting by WIPO and WTO.[27] It would not be right to say they have abandoned it because WIPO treaties, namely the Beijing Treaty on Audio Visual Performances and Marakkesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled have been adopted in 2012 and 2013 respectively alongside plurilateral negotiations.[28] The WIPO Director General Francis Gurry on adoption of the Marakkesh Treaty said, "*This treaty is a victory for the blind, visually impaired and print disabled, but also for the multilateral system.*" However, it is yet to be seen if the TPP, now having been concluded, would benefit the multilateral IP-norm setting by leading to consolidation or harm it by having fragmented the IP regime.[28] Some have feared that the TRIPS-plus IP standards may be "pulled into WTO itself" as the U.S. is expected to push hard for it.[29] The recent Nairobi Ministerial Declaration has stated that "some" members wish to explore new issues at the WTO, therefore its being speculated that the U.S. may push for the TPP to be the "negotiating template" for those issues.[30] The developing countries may be forced to accept the TPP standards in light of their increasing acceptability by other countries and larger economic benefits that other trade standards may offer, even though it will be detrimental to the interests of their citizens. Also, as the post- TRIPS WTO negotiations have not been successful, concluded plurilateral agreements may give rise to other plurilateral IP agreements,[31] which may make the international IP regime so complex that there may be an increasing difficulty in achieving consensus among countries at multilateral forums. Therefore, it is yet to be seen how the plurilateral agreements like TPP will affect the multilateral IP-norm setting.

Regional IP-Norm Setting

Those plurilateral IP agreements to which only a few countries in a particular region are parties may adversely affect that region's IP rights co-operation and thereby its economic integration. This can be illustrated by the potential impact of TPP on ASEAN IP-norm setting and economic integration.

ASEAN or The Association of South East Asian Nations was established in 1967, under the ASEAN Declaration, and is now a group of ten south-east Asian countries, namely, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Cambodia, Vietnam, Laos and Myanmar.[32] On 31December 2015, the ASEAN Economic Community (AEC) was established to achieve economic integration in ASEAN.[33] One of the

characteristics and elements of AEC, as mentioned in the AEC Blueprint 2015, is a competitive, innovative and dynamic ASEAN,[34] and strengthening of IP rights co-operation has been considered to be critical for it.[34] Efforts have been made on this front since the adoption of the ASEAN Framework Agreement on IP Cooperation in 1995.[35] The ASEAN Working Group for IP Cooperation (AWGIPC) was established in 1996 "to develop, coordinate and implement all IP-related activities in the region".[36] This was followed by various IP harmonization initiatives like the Hanoi Plan of Action (1999-2004) in 1997, ASEAN IPR Action Plan 2004-2010 in 2004, Work Plan for ASEAN Cooperation on Copyrights,[36] AEC Blueprint in 2007 and ASEAN IPR Action Plan 2011-2015 in 2011.[35] The successor ASEAN IPR Action Plan 2016-2020 adopted will be out soon.[37] Thus, ASEAN has shown perseverance in pursuing its goal of building a "harmonized and integrated regional IP system".[36] However, a major challenge it is facing in achievement of this goal is the disparity in the level of development and the scope and significance of IP rights among its member states.[38] Therefore, for attaining IP harmonization in ASEAN to ensure well-functioning of AEC, arguably "a high degree of alignment of IP laws",[39] and narrowing of the developmental gaps among the ASEAN countries is essential.

TPP poses a threat to ASEAN IP co-operation and economic integration. Only four out of the ten ASEAN countries, namely Malaysia, Brunei, Singapore and Vietnam are members of the TPP. While some have noted that TPP would be a driving force for ASEAN co-operation,[40] many have voiced fears about the harm it may cause to it.[40] It may drive away investment and trade from the non-TPP ASEAN countries, especially the lesser developed ones like Cambodia, to the TPP ASEAN countries due to the TPP benefits of lower tariffs and better regulatory treatment,[41] thereby furthering the already existing[3] economic differences among the ASEAN countries.[43] This diversion will also attack another characteristic of AEC: an integrated and cohesive economy, one of the objectives of which is to establish a more unified market.[44] The TPP-ASEAN countries may pursue their own economic interests at the detriment of the collective interests of the region, the avoidance of which was one of the aims of the AEC.[43] Further, as TPP requires its members to adopt TRIPS-plus standards of IP protection, it will lead to widening the disparity in IP laws between the TPP ASEAN countries and non-TPP ASEAN countries.[45] This, in turn, will negatively impact ASEAN's efforts for achieving IP harmonization in ASEAN or the ASEAN IP-norm setting. Also, the TPP ASEAN countries may push for adoption of TPP standards at the ASEAN level.[29]

Other Plurilateral IP-Norm Setting

Plurilateral negotiations may not only affect multilateral and regional IP-norm setting but also other plurilateral IP-norm negotiations involving some countries in common. TPP's potential to impact the on-going Regional Comprehensive Economic Partnership (RCEP) negotiations between some TPP and non-TPP members is a good illustration of the same.

RCEP is an economic partnership agreement under negotiation among ASEAN and six countries that ASEAN has free-trade agreements (FTAs) with, namely Japan, Korea, India, China, Australia and New-Zealand.[46] These countries account for almost half of the world's population and thirty per cent of the world's GDP.[46] RCEP negotiations, which commenced in 2013, are aimed to create a regional free trade area by "harmonizing and integrating existing FTAs between ASEAN and its individual partners",[47] and "addressing the concerns of 'noodle bowl' of overlapping bilateral agreements"[48] between these countries. The negotiations are guided by the Guiding Principles and Objectives for Negotiating the RCEP.[49] TPP and RCEP have seven countries in common, namely, Australia, New Zealand, Japan and four ASEAN countries: Singapore, Brunei, Malaysia and Vietnam. This may shape the content of RCEP final text in the direction of TPP or cause "the standards of RCEP" to "converge to that of TPP".[50]

RCEP, as per the Guiding Principles aims to include, among other issues, issues on intellectual property.[49] It says that RCEP will be consistent with the WTO,[51] and take into consideration the "different levels of development of the participating countries" and accordingly provide certain flexibilities to the developing and least developed countries.[52] The IP chapter in RCEP will aim to "reduce IP-related barriers to trade and investment by promoting economic integration and cooperation in the utilization, protection and enforcement of intellectual property rights".[53]

Thus, from the Guiding Principles it appears that RCEP, unlike the TPP, was not intended to contain TRIPS-plus IP standards and be inflexible for developing and least developed countries.[54] RCEP was seen by some as anti-TPP by pushing back TPP

standards and proposing "home grown standards on IP issues".[55] However, this doesn't seem to be the case now. Two developed RCEP members, Japan and Korea, have proposed TRIPS-plus standards, similar to those in the TPP, in the IP Chapter drafts that were leaked.[56] Some of the controversial ones are the patent term extensions, data exclusivity and low patentability criteria.[57] It is to be noted that Japan is a TPP member and Korea has shown interest in joining the TPP.[58] Thus, the proposed TRIPS+ standards may be a reflection of the TPP standards being pushed by these countries. As opposed to the Japan and Korea drafts, the ASEAN and India drafts are not so ambitious by proposing TRIPS standards.[59] India has raised concerns over stringent protection of IP rights mandated by the TPP, especially patent protection for drugs that will adversely impact the access to affordable medicines in developing countries.[60] It has maintained that it would not be making any commitments in RCEP that go beyond the TRIPS mandate.[61] While Japan is pushing for incremental innovations, Section 3(d) of India's Patents Act, 1970 prohibits patenting of new forms of known substances that do not have increased efficacy over the existing one. By interpreting 'efficacy' to refer to 'therapeutic efficacy' in this provision, the Supreme Court of India, in 2013, rejected grant of patent to Novartis' cancer drug *Glivec* because it did not enhance the 'therapeutic' efficacy of the known substance.[62] Although it was recently speculated that India might be open to a TRIPS-plus IP regime based upon the reports that India has given a private assurance to U.S. that it will not grant compulsory licenses for commercial purposes,[63] the Indian Government clarified this to be factually incorrect.[64] Thus, disparity between positions taken by different RCEP members on IP rights provisions in RCEP leading to a tussle among them, may slow down the RCEP negotiations. The common members may push for or be pressurized by the U.S. to push for TPP WTO-plus provisions including TRIPs-plus IP protection standards to ensure compatibility between the two agreements.[65] Therefore, the TPP IP rights provisions may creep into RCEP negotiations,[66] thereby causing the TPP to change the direction of the RCEP IPR-norm setting from what it was originally intended to be.The conclusion of TPP may accelerate the RCEP negotiations as the non-TPP RCEP members fear the competitive disadvantage they may face as a result of TPP and feel that RCEP may help in mitigating it.[67]

Conclusion

In light of the above discussion it is concluded that the vertical shift adopted by a few countries from the multilateral IP forums like WIPO and WTO to plurilateral negotiations like ACTA and TPP may affect the future IP-norm setting at the international, regional as well as the plurilateral level. In particular, the TPP is likely to affect the IP-norm setting by ASEAN as well as RCEP. Its TRIPS-plus patent law provisions would be harmful to access to affordable medicines to the people of most of the TPP members. However, it must be kept in mind that many of the problems caused by the plurilateral negotiations are based on the combination of countries it includes and excludes.

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