PATENT PROVISIONS IN MEGA-REGIONAL PREFERENTIAL TRADE AGREEMENTS: PUBLIC HEALTH IMPLICATIONS FOR DEVELOPING COUNTRIES

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Abstract

The trade bargaining platforms provide an avenue to particular industry groups for achieving objectives what might not otherwise be achievable while approaching a foreign national legislature through lobbying or otherwise. Since the inception of bilateral and regional negotiations to supplement the rules of the TRIPS Agreement and other multilateral rules, there has been a progressive encroachment into national regulatory space in the field of public health. This continues a trend of viewing national government regulation as a part of reciprocal bargaining subject matter in trade negotiations. Recent trend of IP norm setting by mega regional agreements appear to be more aggressive leaving developing countries at the crossroads of choosing between a mega trade alliance or sticking to multilateral trade negotiation regime under WTO. These trade negations/rules liberate all trade and investments but the commitments undertaken by member countries could potentially impact on the health of the public in these countries. The paper analyses the impact of patent norm-setting on public health policy making in developing countries.

I. Introduction

U.S. pharmaceutical industry was the major force behind TRIPS Agreement demands which required developing countries like India and Brazil to bring along a lot of compromises on public health. The industry, envisaging progressive tightening of IP rules at the new WTO, though accomplished several of its objectives under TRIPS, still it was an incomplete success

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for them as the prospect to secure additional concessions like protection of regulatory data were surrendered.[1] The provisions concerning exceptions and compulsory licence were less stringent than those preferred by United States.

Unable to gain terms they wanted through the multilateral trading system under WTO concerning intellectual property protection(patents specifically) and enforcement standards, U.S. and other developed countries abandoned WTO for bilateral and regional trade agreements.

United States and other developed nations initiated negotiations under these bilateral and regional partnerships mostly with developing countries for expanding the base of protectable subject matter, for a broader and much extensive coverage in terms of subject matter and rights of patent holder, for dilution/ erosion of flexibilities granted to developing and least developed countries under the WTO-TRIPS Agreement and for a more efficient enforcement mechanism and to increase the potential for commercialization of their inventions. All of which lead to multiple overlapping trade commitments of increasing complexity.[2]

However, the era of global multilateralism and regionalism is over in international trade and there is an emergence of second generation preferential trade and investment agreements, the mega-regional agreements[3] which may indirectly but effectively rewrite the rules of the

[1] Frederick M. Abbott, The Evolution of Public Health Provisions in Preferential Trade and Investment Agreements of the United States in Pedro Roffe and Xavier Seuba, *Current Alliances in International Intellectual Property Law-making: The Emergence and Impact of Mega-Regionals*45(ICTSD & Centre for International Intellectual Property Studies,Germany,2017).

[2]Deborah Gleeson, Sharon Friel, Emerging threats to Public Health from Regional Trade Agreements, (2013) 381 *The Lancet 1507* at 1508*available at:* https://www.nzcphm.org.nz/media/61306/emerging_threats_to_public_health_from_regional_trade_agreements_-_gleeson_friel_-_lancet_2013__2_.pdf (last visited on June 4,2019)

[3]Max-Planck Encyclopaedia of Public International Law [MPEPIL]- The term 'mega-regionals' describes a trend in international trade law to negotiate free trade agreements ('FTAs'; Free Trade Areas) among countries encompassing a considerable share of world trade. Unlike regional trade agreements, they span across sub-regions. Examples are the Transatlantic Trade and Investment Partnership ('TTIP') between the United States and the European Union, accounting for almost half of global GDP; the Regional Comprehensive Economic Partnership ('RCEP') between the Association of Southeast Asian Nations (ASEAN) members and the countries with which ASEAN has FTAs in place, i.e. Australia, China, India, Japan, Korea, and New Zealand; and the Trans-Pacific Partnership ('TPP') between twelve Pacific-rim countries, to wit: all North American States (Canada, the United States, Mexico), the Asian countries Brunei Darussalam, Japan, Malaysia, Singapore, Vietnam, and the South American countries Peru and Chile, as well as Australia and New Zealand. The Canada-EU Comprehensive Economic and Trade Agreement ('CETA') can also be counted among those mega-regionals. So far, only CETA and the TPP have been concluded *Available at:* https://opil.ouplaw.com/view/10.1093/law:epil/9780199231690/law-9780199231690-e2177 (last visited on June 6,2019).

global economy and change geopolitical power structures.[4] These mega- regional trade agreements are expected to upset the current international framework balancing minimum standards for exclusive rights on one hand, and the access rights of the public, innovators, on the other.

The IP provisions in these trade agreements are potential obstacles for the developing countries to the accomplishment of important public health initiatives. Going beyond the provisions codified in WTO TRIPS in 1994(which may be imperfect but are more balanced) they present profound new threats to global health and health equity (fair and just opportunity to a human to obtain their highest level of health).

They will deepen global economic integration by constraining domestic public health policy space[5] for the governments to adopt and enforce therapeutic formularies, reimbursement policies and other price moderating mechanisms within public health systems [6]than any other trade agreement, and intend to introduce new and much stronger intellectual property and investor rights than previously experienced.[7]

Further, recent outcomes in *Eli Lily*[8] and *Philips Morris*[9] case highlight how protection and enforcement of intellectual property rights has been contested under international investment law. The extensive investor rights and the ISDS framework might provide a legal framework by which corporations may challenge any government measure, thus engendering a "chilling effect" on government regulation and action. This is a major deviation from an earlier regime shift two decades ago when developing countries utilized forums outside the WTO[10] (World Health Organization and the United Nations) to provide balance to the new minimum IP standards in TRIPS for greater flexibility.

[4]Jeremy de Beer, The Rise of Mega-Regionalism: Revealing Canada's Blind Spots, *Policy Brief No. 140* — October 2018, Centre for International Governance Innovation.
[5]Policy space is the ability of the governments to choose, design and implement public policies to fulfil their aims.
[6]Flynn, Sean; Kaminski, Margot E. et.al., "Public Interest Analysis of the US TPP Proposal for an IP Chapter" (2011). *PIJIP Research Paper Series. Paper 21*. *Available at:* http://digitalcommons.wcl.american.edu/research/21
[7]*Supra* note 3.
[8]e *Eli Lilly* v *Canada*, ICSID UNCT14/2, Final Award (16 March 2017).
[9]*Philip Morris Asia Ltd* v *Australia*, PCA Case No 2012-12, Award on Jurisdiction and Admissibility (17 December 2015).
[10]James Gathii Cynthia Ho, Regime Shifting of IP Law-making and Enforcement from WTO to the International Investment Regime, 18 *Minnesota Journal of Law, Science & Technology*, 427 (2017*). Available at:* http://scholarship.law.umn.edu/mjlst/vol18/iss2/1.

This paper attempts to analyse how trade commitments, under these regional and mega regional agreements could interact with and impact on public health in developing countries. This article focuses upon the impact of mega-regional commitments, by inclusion of TRIPS-like and TRIPS-plus standards, on intellectual property (patents specifically) protection rules and even modification of such rules by partner countries, thus impacting the access of people in developing countries to life-saving drugs and medicines.

II. International Trade Harmonisation and IP: TRIPS and Beyond

International free trade agreements, bilateral or plurilateral, attempt at harmonising rules regulating cross border trade among members and reducing costs faced by businesses through elimination of barriers(tariffs and non-tariff) including obstacles caused by regulatory disparity across countries.[11] The traditional focus on tariff reduction is gone and new tools of trade facilitation-standardisation, harmonisation, co-operation and convergence are pursued in recent agreements. Since the tariff barriers are already low between TPPA parties, and even lower between the US and the EU, the mega-regionals attempt to lower transaction costs for business within respective trade bloc.[12] These agreements cover a growing number of sectors by substantive provisions in the form of sector specific rules or chapters.

The WTO-TRIPS framework of 1994 expanded international trade to include trade in services, intellectual property and agriculture in addition to goods along with providing enforceable minimum standards on intellectual property protection for the member countries in lieu of market accessibility and trade facilitation. TRIPS was both sweeping in scope and legally binding. It was considered to be the most controversial treaty of its time, mostly because of the implications that the agreement is said to have on the pharmaceuticals and agro chemical sectors which are crucial to the developing world. It provided stringent standards for patent protection which affected accessibility and affordability of medicines in developing and least developed countries in the name of market penetration and participation in world trade.

[11]Paolo R Vergano, TobiasDolle, Free Trade Agreements and Regulatory Change: Examples from the Generic and Biosimilar Sectors' (2017) *51 Journal of World Trade*, Issue 2, pp. 205–232

[12]Christian Riffel, Mega-regionals,Max Planck Encyclopaedia of Public International Law [MPEPIL],2016 *available at:* https://opil.ouplaw.com/view/10.1093/law:epil/9780199231690/law-9780199231690-e2177(last accessed on June 3,2019).

However, TRIPS was just another step in the pursuit of stronger IPRs in international trade, it was never the end point rather the beginning of it.[13] After the adoption of the Doha Declaration on the TRIPS Agreement and Public Health[14] and the General Council Decision for the implementation of paragraph 6 of that Declaration, it became more visible.[15] Since they could not achieve what they desired for under the TRIPS framework, United States and other developed nations initiated negotiations for expanding the base of protectable subject matter, for a broader and much extensive coverage in terms of subject matter and rights of patent holder, a more efficient enforcement mechanism and dilution/ removal of flexibilities granted to developing and least developed countries under the TRIPS Agreement and Doha Declaration to increase the potential for commercialization of their inventions through international trade.

There was, therefore, a noticeable shift from the WTO multilateral level to the regional and bilateral one where a number of post-TRIPS Free Trade Agreements (FTAs) were signed and that too with developing countries. These agreements mandated stronger and broader standards of intellectual property protection -TRIPS-plus standards[16], particularly relating to patents, eliminating the legally permitted flexibilities under TRIPS. The negotiations on rules related to pharmaceuticals affecting generic and follow on biologics (biosimilars) are more

[13]"..we got 95% of what we wanted," that 5% has always mattered, and 95% was never enough", Susan K Sell, TRIPS was Never Enough-Vertical Forum Shifting, FTAs, ACTA and TPP,18 (2011) *Journal of Intellectual Property Law* 447-478 *available at:* http://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1186&context=jipl, last visited on March 26,2018;
Roma Patel, A Public Health Imperative The Need for Meaningful Change in the Trans-Pacific Partnership's Intellectual Property Charter, 16 *Minn. J.L. Sci. & Tech*. 477 (2015) *available at:*https://conservancy.umn.edu/bitstream/handle/11299/172106/Patel.pdf?isAllowed=y&sequence=1, last visited on March 21,2018.

[14]Christoph Spennemann, The impact of FTAs on Public Health Policies and TRIPS Flexibilities, *Int. J. Intellectual Property Management*, ,(78) Vol. 1, Nos.1 /2/(2006) *available at*: http://www.ictsd.org/downloads/2008/08/roffe-spennemann.pdf . (last visited on March 21,2018); DOHA WTO MINISTERIAL 2001: TRIPS, WT/MIN(01)/DEC/2, 20 November 2001.

[15]*Ibid*.; WTO document WT/L/540 of 2 September 2003; WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health .

[16]TRIPS -plus is an informal term signifying intellectual property rights which go beyond the requirements of the TRIPS Agreement. TRIPS-plus standards are encountered in different bilateral and regional agreements including bilateral trade and investment agreements, Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines, Report of a workshop organized by the International Health Policy Programme, Ministry of Public Health, Thailand and the World Health Organization, Regional Office for South-East Asia, Bangkok, 22-24 November 2006 *available at:*http://apps.searo.who.int/PDS_DOCS/B2072.pdf (last accessed on June 3,2019).

controversial in comparison to earlier multilateral trade agreements like WTO. These agreements mandate stronger and broader standards of intellectual property protection, eliminating the legally permitted flexibilities under TRIPS.

The 21st century mega regional agreements like TPP, TPPA, CETA are comparatively very detailed, embedding various trade facilitation mechanisms and sector specific sections. The most recent Trans Pacific Partnership Agreement (TPPA) is a large regional trade agreement consisting of 11 countries around the Pacific Rim—Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, USA, and Vietnam (more willing to join). Combined together these countries account for almost 10% of the world's population. They include some of the biggest economies in the world, accounting for more than 30% of the world's gross domestic product (with a combined value of US$20 734 billion in 2011), represents 40% of global trade.

Even though TPPA seems to have collapsed recently after U.S. pullout, along with TTIP (Transatlantic Trade and Investment Partnership)[17] but these were not the only manifestations of this evolving infrastructure in international trade.[18]

A growing number of sectors are covered by the substantive provisions by these agreements, catering to the requirements of countries/industries. Unlike the customary focus on tariff reduction under WTO and FTAs, these agreements emphasise upon standardisation, harmonisation or regulatory cooperation and convergence across different sectors including intellectual property as discussed later in this essay. They extend international minimum standards for domestic regulation beyond intellectual property and into health policy itself and undermine countries' policy space to adopt and enforce therapeutic formularies, reimbursement policies and other price moderating mechanisms within public health systems.

[17]Jayant Raghu Ram ,Crouching Tiger, Hidden Dragon: The TPP'S IPR Chapter – Issues and Concerns for India, *WP/CWS/200/16/Rev. 4available at* http://wtocentre.iift.ac.in/workingpaper/TPP%20IPR%20WP.pdf. (last visited on March 20,2018).

[18]Arjun Jayadev,TPP is Dead, but its Legacy Lives On, *The Hindu*, February 10,2017 *available at:*http://www.thehindu.com/todays-paper/tp-opinion/TPP-is-dead-but-its-legacy-lives-on/article17280477.ece (Last visited on March 26,2018).

III. RATCHETING UP: TRIPS-Plus Provisions and their Public Health Implications

A new IP regime was established with the coming of WTO TRIPS Agreement in 1995 which provided for enforceable common minimum standards for all member states with the aim of implementing standardisation, eventually framing IP as a commodity. TRIPS, was considered highly controversial predominantly in relation to patents for its impact on public health and access to medicines, specifically in developing countries. Prior to the coming of this Agreement, more than forty countries withheld any patent protection for pharmaceuticals, while many others allowed patents only for processes and not for products. Even India was not providing product patents on pharmaceutical products under the Patents Act, 1970. TRIPS mandated patent protection on all products in all fields of technology.

Though the TRIPS Agreement was the first attempt at providing some minimum standards, it did not impose uniform IP standards, leaving scope for member countries to tailor their intellectual property rights in accordance with their policy preferences and national development objectives.[19]

The agreement leaves room for national variation in how countries treat intellectual property.[20] Article 8 recognizes the right of WTO members to "adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the Agreement".[21] Some of the flexibilities available for member countries are:

- Transition period for compliance for developing and least developed countries;
- Define patentable subject matter as the agreement allowed some exclusion from patentability under Article 27.2 and 27.3;

[19]Gathii and Ho, Regime Shift of IP Law-making and Enforcement from WTO to the International Investment Regime, 2017 p.429.

[20]Ken Shadlen, Policy Space for Development in the WTO and Beyond: The Case of Intellectual Property Rights, *Global Development and Environment Institute Working Paper* no. 05-06,2005 *available at:*http://www.ase.tufts.edu/gdae/Pubs/wp/05-06PolicySpace.pdf (last visited on 6 June,2018)

[21]Badri G. Narayanan, Sangeeta Khorana, Mega- regional trade Agreements: Costly distractions for developing countries?, Economic Structures (2017) 6:29

- Determine the grounds for issuing compulsory licences and government use of the patented invention;
- determine their own system of IPR exhaustion (national, regional, or international) to allow/disallow parallel imports;
- use of invention for research and development (bolar and gillete exemptions); etc.

The Doha Declaration of 2001 reaffirmed the rights of WTO members to use TRIPS flexibilities to protect public health.[22]

Despite the conclusion of a global agreement on IP standards, developed countries viewed TRIPS and Doha as falling short of their objectives. This intensified the need for negotiations to bring in stronger protection under multilateral or bilateral FTAs. As a result, hundreds of bilateral and regional free trade agreements were signed and negotiated.[23]

This led to TRIPS-plus standards of protection in patents specifically by way of expanding the scope of patentability, extending the term of patent and constraining the exercise of TRIPS flexibilities. The invidious TRIPS-Plus provisions in these FTAs provisions in FTAs undermine public health safeguards and objectives—notably access to medicines, as well as delay generic market entry and competition.[24]

Heightened IP protection and exceeding the requirements of the TRIPS Agreements also a core feature of mega-regionals.[25] The dwindling up of IP protection through bilateralism is not new however, but not all previous-generation FTAs included provisions on IP rights or, if they did, some merely incorporated the existing standards of other agreements by reference. In contrast, all new and emerging mega-regionals contain rules that go beyond multilaterally established minimum standards.[26]

[22]Christoph Spennemann, *Supra* note 2, Paragraph 4 of the Declaration on the TRIPS Agreement and Public Health . (DOHA WTO MINISTERIAL 2001: TRIPS WT/MIN(01)/DEC/2
20 November 2001).
[23]GRAIN, "TRIPS-PLUS" through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO 8 (2001), *available at* http:/ / grain.org/briefingsjfiles/ trips-plus-en.pdf . (last visited on March 20,2018).
[24]*Supra* note 22 Badri Narayanan Sangeeta Khorana
[25]Jeremy de Beer , The Rise of Mega-Regionalism: Revealing Canada's Blind Spots
[26]*Ibid.*

These agreements are becoming more complex, more encompassing and more significant economically and politically. But they also pose new and great challenges to public health because of the unequal distribution of powers under it and difference in economic and health objectives of developed and developing countries.

There are two major ways in which such economic partnerships are likely to affect public health:

- Reducing access to medicines through imposition of very high levels of intellectual property protection and diluting the flexibilities available under WTO-TRIPS framework.
- Limiting the ability of the states to regulate on public health grounds. They could restrict the flexibility—or policy space—for governments to be able to set and implement these important public health policies.[27]

The TRIPS-plus standards frustrate and delay entry of generics and biosimilars medicine which are crucial for providing access to affordable medicines especially in developing countries like India. Some of the TRIPS-plus provisions that can limit the flexibilities available to countries to facilitate access to medicines include:

a. ***Extending Scope of Patentability:*** Article 8.1 of TPPA for example, proposes to allow patenting of new forms and uses of known substances even if such invention does not result in the enhancement of the known efficacy of that product. It could require countries to open flood gates to patent applications on minor modifications or variations of existing chemical entities creating threat of ever greening in pharma patents. This is also inconsistent with the laws of some of the negotiating countries like Malaysia, Australia etc. but it is basically drafted to counter policy initiatives embedded in section 3(d) like provisions emerging from India even though India is not a party.[28] Patent protection for plants and animals and diagnostic, therapeutic and surgical methods (which could be excluded under TRIPS) under article 8.2., is indirect

[27] *Supra* note 3.

[28] Flynn, Sean; Kaminski, Margot E.; Baker et al., "Public Interest Analysis of the US TPP Proposal for an IP Chapter" (2011). *PIJIP Research Paper Series*. Paper 21. *Available at:* http://digitalcommons.wcl.american.edu/research/21(last accessed on June 3,2019).

contradiction to TRIPS article 27.3 and laws of negotiating countries and will lead to license fees and royalty payments for the use of such diagnostic and treatment methods.

b. Extending Term of Patent Protection: Patent term extension (restoration) provisions i.e., granting of an additional patent life to compensate for administrative delays either in the granting of patents or marketing approval process, leading to delays in generic market entry maintaining monopoly protections and higher prices during the extension.[29]

c. ***Limitations on Patent Revocation, opposition and exhaustion mechanisms***
Pre- grant oppositions and revocation allow opportunities to contest a patent as it is filed, providing a potentially important source of information to patent examiners and generally improving patent quality. TPPA art. 8.7 contain TRIPS- plus restrictions on the grounds for patent revocation and on processes for permitting pre- grant opposition of patent applications.

d. ***Unlimited Amendments to Patent Applications***: Art. 8.9 TPPA forces countries to allow patent applicants to make multiple amendments to their patent claims prior to approval on the merits. This goes beyond KORUS[30] which in Art. 18.8.8 allow applicants only one opportunity to make amendments, corrections and observations in connection with their applications. Aapplicants under TPPA will have more opportunities to game the system in their favor and can demand the elongation of processes and gain priority dates over other potential inventors.

e. ***Data Exclusivity:*** Data exclusivity is a TRIPS- plus provision which restricts access to essential clinical trial data and prevent generic manufacturers from using existing clinical research to gain regulatory approval of their medicines, forcing them to perform duplicate clinical trials or wait for the 'data monopoly' period to end.[31]

[29] TPPA- 2 Art. 8.6.
[30]Free Trade Agreement between the United States of America and the Republic of Korea, U.S.-S. Korea, June 30, 2007 [hereinafter KORUS], *available at*http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_ FTA/Final Text/Section_Index.html(last accessed on June 3,2019).
[31]TPPA- 2 Art. 9.2 [31] Flynn, Sean; Kaminski, Margot E.; Baker, *supra* note 28.

f. ***Unlimited Amendments to Patent Applications***: Art. 8.9 of TPPA forces countries to allow patent applicants to make multiple amendments to their patent claims prior to approval on the merits. This goes beyond KORUS[32] which in Art. 18.8.8 includes a TRIPS- plus requirement to allow applicants at least one. Applicants will have more opportunities to game the system in their favor and can demand the elongation of processes and gain priority dates over other potential inventors.

g. ***Patent Linkage provisions***: TPPA is KORUS-Plus in patent linkage provisions which require regulatory authorities to provide notifications to patent holders and delay marketing approvals till dispute is settled between applicant and patent holder. This linkage of non-IP authority and procedure with patent right is neither mandated by TRIPS nor they are possible without making legislative provisions in respective IP legislations in negotiating countries.

Such protectionist standards of protection under these trade arrangements would require substantial amendments in patent laws in many of the negotiating developing countries thus, eroding the flexibilities available under TRIPS framework[33], the Doha Declaration and its implementing decision. It would also allow for broader claims for protection for pharmaceuticals and biologics and obstruct access to medicines in such countries which are already struggling to make drugs affordable for much of their population. Theydo not often contain the type of flexibilities contained in the TRIPS Agreement, or the subsequent Doha Public Health Declaration that were designed to promote interpretations that foster public health..

These 21st century trade partnerships are likely to extend further into domestic policy space through complex set of rules and obligations focussed on harmonising regulatory frameworks

[32]Free Trade Agreement between the United States of America and the Republic of Korea, U.S.-S. Korea, June 30, 2007 [hereinafter KORUS], *available at*: http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_ FTA/Final_Text/Section_Index.html(last visited on June 15,2019)

[33]TRIPS includes specific provisions on compulsory licensing, parallel importation and non-patentable inventions for safeguarding the socio-economic interests such as public health

as well as procedures across many sectors like investment, services, state procurements and enterprises, encroaching deeper than any FTA to date.[34]

These may eventually become de facto global standards because of the increasing number of countries joining or willing to join these mega regionals adopting these together with the MFN(Most Favoured Nation) provision[35] of WTO-TRIPS Agreement,limiting/restricting domestic health policy space. Though the TRIPS Agreement was the first attempt at providing some minimum standards, it did not impose uniform IP standards, leaving scope for member countries to tailor their intellectual property rights in accordance with their policy preferences.[36]

The law/policy making discretion is now threatened by the preferential trade and investment agreements, negotiations over obligations to provide enhanced IPR protection and protection of foreign investors.[37] These treaties contain provisions which expand the minimum standards of protection granted under TRIPS Agreement which may have vertical[38] as well as horizontal[39] dimensions. This progressive trade agenda is bound to influence laws and policies in other countries in following ways:

(i) Pushing for enactment of laws for creating TRIPS-plus standards by negotiating partners in their countries;

(ii) Exporting policy settings of developed countries (mostly U.S.) to eliminate/circumscribe domestic measures for promoting pharmaceutical access and coverage.

It would affect prioritising profits of pharmaceutical companies over public health goal of affordable access to medicines by facilitating monopolies and inhibiting competition[40].Also the provisions proposed in TPPA restrict the flexibility available to the government in public health policy measures to regulate marketing, pricing, sale

[34]Ruth Lopert and Deborah Gleeson, The High Price of 'Free' Trade: U.S Trade Agreements and Access to Medicines,*The Journal of Law, Medicine & Ethics, 41*(1), 199–223. https://doi.org/10.1111/jlme.12014(last accessed on June 19,2019)

[35]MFN Provision of WTO TRIPS Agreement requires WTO members to extend any enhanced benefits (including IPRs) agreed in preferential trade agreements to all other WTO members.

[36]Gathii and Ho, Regime Shift of IP Law-making and Enforcement from WTO to the International Investment Regime, 2017 p.429.*available at:* https://www.iisd.org/itn/2017/06/12/highly-anticipated-nafta-award-rejects-patent-law-related-claim-against-canada-matthew-levine/?cv=1

[37]*Ibid.*

[38]Like adhering to specific international treaties or enacting new legislation

[39]Providing rules of treatment-fair and equitable and non-discrimination, compensation for expropriation

[40]Ruth Lopert and Deborah Gleeson, *supra*note34.

distribution, advertisement and labelling of unhealthy goods like tobacco, alcohol and highly processed food.

IV. Beyond IPRs: Forum Shifting

These mega regional and free trade/investment treaties recognize intellectual property as a form of investment. Investment provisions under these treaties often provide the option of settling IP-related claims before an arbitral tribunal as per the investment law, giving convenience to choose the venue where to litigate the case which is not just another example of regime shifting but has following reverberations in other venues also[41]-

- rewriting/reinterpreting international and domestic provisions that struck a balance between IPR protection and public interest,
- destabilising those flexibilities contemplated by the TRIPS Agreement and may create uncertainties,
- create friction between recommendations issued by WHO and other UN agencies as regards the promotion of public health and role of investment regime protecting investor's rights.
- Creation of conflicting norms[42]

The investment provisions combine strong investors' rights and high protection standards with a dispute settlement mechanism (the ISDS), which would provide the "teeth" for enforcement of those obligations.

One of the most controversial and concerning issues is the ISDS clause[43] in the investment chapter of the proposed mega regionals which at times is used for challenging many types of domestic public interest regulations, such as public health and safety. For instance, Philip Morris has challenged the plain packaging regulations (meant to discourage smoking) of Uruguay and Australia based on their investment agreements with Switzerland and Hong Kong.[44] Including an ISDS clause would make the TPP countries vulnerable to legal

[41]Laurence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Law-making, 29 *Yale Journal of International Law* (2004).
Available at: https://digitalcommons.law.yale.edu/yjil/vol29/iss1/2 (last visited on June 27,2019)
[42]*Ibid.*
[43]Investor-State Dispute Settlement through arbitration under International Investment Agreements
[44]Philip Morris Asia Ltd v Australia, PCA Case No 2012-12, Award on Jurisdiction and Admissibility (17 December 2015); Australia was the only country opposing ISDS clause in TPPA due to this and there was a specific carve-out that excludes it being used for tobacco control measures.

challenges which could prove to be very detrimental to low to middle income countries. This would mean that a government measure affecting the intellectual property holdings of investors may be considered an "expropriation" or the withholding of "fair and equitable treatment". This raises concern about the ability of governments to implement and use the range of TRIPS flexibilities, many of which could be seen as limitations or restrictions of the exclusive rights granted under a patent like compulsory licensing. Though some treaty proposals (e.g. TPPA) consider compulsory licensing does not constitute an expropriation where such a licence is granted "in accordance with the TRIPS. However, it still leaves room for investor corporations to challenge the compulsory licence using the ISDS on the grounds that it does not comply with TRIPS.

In 2012, Eli Lilly's patents were invalidated for failing to meet the utility requirement in Canadian patent law. After its appeals to the Canadian Supreme Court were dismissed, Eli Lilly initiated an investor-state arbitral claim[45] against the Canadian government, based on the investment chapter of the North American Free Trade Agreement (NAFTA).[46] This claim by Eli Lilly against Canada is an illustration of an innovative attempt to employ an international investment agreement to protect IPRs, with a private actor seeking to claim compensation for the invalidation of its patents.[47]

Though IP(patents more specifically) may qualify to be a cross-border investment but this fact can also not be ignored that its value and existence is contingent upon its validity.

One more concern about which the participating countries are worried about is the loss of sovereignty under a mega-regional involving harmonization across the border and giving of private rights to foreigners. How much of the sovereignty the participating countries are willing to surrender for the sake of economic integration and global governance is an issue that too for a developing country.

[45]*Eli Lilly* v. *Canada*, ICSID Case No.: UNCT/14/2Though the tribunal rejected the claim that judicial invalidation of patents constituted a breach of either Article 1110 (Expropriation) or Article 1105 (Minimum Standard of Treatment) of NAFTA, and awarded Canada legal costs of approximately CAD4.5 million. The claimant was also required to bear the arbitration costs of approximately USD750,000.
[46]Laurence R. Helfer, *supra* note 41.
[47]*Ibid.*

V. Concluding Remarks

The world trading system is making strong efforts to introduce TRIPS plus norms in international trade outside WTO. The obvious and traditional route for pushing these stringent norms is by way of trade agreements signed at bilateral/plurilateral levels between certain developed and developing countries in the name of trade integration and market access. This tiresome process of negotiating FTAs on one to one basis lead to the emergence of TPP,TPIP and RCEP, the mega regional preferential trade and investment agreements. Regional and mega-regional free trade and investment treaties are geopolitical maneuvers which will tilt the axis of economic power and rest global trade rules. These agreements will go beyond the traditional concerns and include unprecedented obligations related to IP and investor protection and are likely to have major implications for public health and access to medicines in developing and least developed countries. These potential health effects, some of which are highlighted in this paper, require attention of negotiating countries including India as the magnitude of overall economic effect may be enormous.

The TRIPS-plus norms will affect changes in the international legislative framework on patent applications, oppositions, revocation etc. to make patents easier to obtain, harder to challenge or revoke, and less beneficial to technology transfer. The provisions on patent linkage and data exclusivity will shift the cost and burden of enforcing private intellectual property rights enforcement to the government/administrative authorities.

The ISDS clause and regime shifting from IP law to investment law allow a company to challenge a nation's laws as violating its investments and seek compensation and pose a major threat to intellectual property norms. Though such instances are few so far, and have not been successful, they have important implications as such disputes may influence law making in other countries (or change their laws)to avoid such disputes when they are not in a position to afford such expensive litigations. This may be considered as an overall win as it could encourage/ induce frivolous litigation or merely threatening do so to get settlement in their favor.

Such disputes challenge previously recognized domestic safeguards available under TRIPS or already established interpretations of exceptions and limitations to IP rights and may create uncertainties. This may also create friction between recommendations issued by WHO and other UN agencies as regards the promotion of public health and role of investment regime protecting investor's rights.

In this context therefore it is imperative for the countries to identify and implement policies in a manner that can achieve goals of trade and economic growth, ensuring access to medicines and implement public health objectives alongside in their countries.

However, the requirement to commit to protectionist IP standards could present varied implications for intellectual property most importantly for patents. It would allow for ever-greening of pharmaceutical patents and will also erode the flexibilities guaranteed to the developing countries under TRIPS Agreement to safeguard their public interests. The apprehensions are more serious for pharmaceutical sector. The data exclusivity requirement could also lead to negative effects on generic drug industry in India by slowing and in some cases halting the production of generic medicines. The presence of public health safeguards ensuring access to medicines under TRIPS Agreement will be diluted to a great extent in such case.