

## Effects of TRIPS Plus Provisions in International Trade Agreements upon Access to Medicines in Developing Countries

Sandeep Mittal<sup>†</sup>

LNJN National Institute of Criminology and Forensic Science, Delhi-110 085, India

*Received 05 July 2016; revised 06 February 2018*

Though the UN has envisaged that accessibility to essential medicines is a basic human right, a large number of people in developing countries are denied access to essential medicines. MNCs having the branded medicines have a tendency to choke the supply chain of cheaper generic medicines using the weapon of intellectual property rights. The TRIPS Agreement has set the minimum standard of protection of Intellectual Property but it has provisions of flexibilities such as compulsory licenses, parallel imports limitations to patent rights, etc., which can be used by member states to provide access to these essential medicines to their people. However, countries like US are using provisions which are over and above the flexibilities incorporated in TRIPS to deny access to essential medicines to people in developing countries. The accessibility of essential medicines to the population in developing countries as affected by these FTAs, ACTA, TPP and TTIP agreements have been examined in this paper and a case has been made out for the unity of the developing and least developed countries to deter US from choking the supply lines of the essential medicines to poor and needy.

**Keywords:** Doha Declaration, TRIPS, Free Trade Agreements, ACTA, TPP, TTIP, intellectual property rights, TRIPS Plus, TRIPS Flexibilities

Both the Universal Declaration of Human Rights, 1948, (*the Declaration*),<sup>1</sup> and the International Covenant on Economic, Social and Cultural Rights (*the Covenant*) require that “medicines are available, accessible, acceptable and of good quality”.<sup>2</sup> All the states that are a party to the Covenant have the “legal obligation not to interfere with the rights conferred under *the Declaration* and *the Covenant*”.<sup>3</sup> However, horizontal and vertical spatial inequalities in healthcare, including in terms of access to medicines, persist throughout the world.<sup>4</sup> The mortality rate due to tuberculosis in the WHO African Region during the year 2013 was 42 per a population of 100,000, which is more than twice the global mortality rate (of 16 per a population of 100,000) and 42 times the mortality rate of the WHO American Region (of 1 per a population of 100,000).<sup>5</sup> In 2013, in sub-Saharan Africa, out of 25 million people living with HIV, about 64 per cent did not have access to any ART.<sup>6</sup> The lack of access to essential medicines in a country is the result of many factors, but the primary reason is the prevalence of high prices of the medicines, stemming from strong intellectual property protection.<sup>7</sup> A “secondary analysis of medicine prices, availability,

[and] affordability, in 36 developing and middle income countries”<sup>8</sup> indicates that the median price difference for originator medicines is substantially higher, reaching up to a whopping figure of 380 per cent as compared to the generic equivalents of these medicines. This reinforces the demand for “switching from originator brand medicines to generic equivalents in the developing countries”, which could facilitate savings of up to 80 per cent on expenditures incurred on essential medicines, as illustrated in Fig. 1.<sup>9</sup> Although, the TRIPS Agreement<sup>10</sup> lays down minimum standards for the protection of intellectual property, and offers safeguards and flexibilities to prevent patent abuse, the developed countries like the US and the European Union (EU) nations are signing bilateral trade agreements to usurp the flexibilities ingrained in TRIPS. However, the US is consistently and aggressively using such FTAs to deny access to essential medicines to populations in developing countries. Therefore, the scope of this paper is limited to an analysis of the FTAs initiated by US. The flexibilities available in TRIPS are listed out in the paper with the objective of examining how the US is using bilateral FTAs<sup>11</sup> and plurilateral (ACTA<sup>12</sup>, TPP<sup>13</sup>, TTIP<sup>14</sup>) agreements to coerce developing countries into accepting stringent ‘TRIPS

<sup>†</sup>Email: mittals.ips@gmail.com

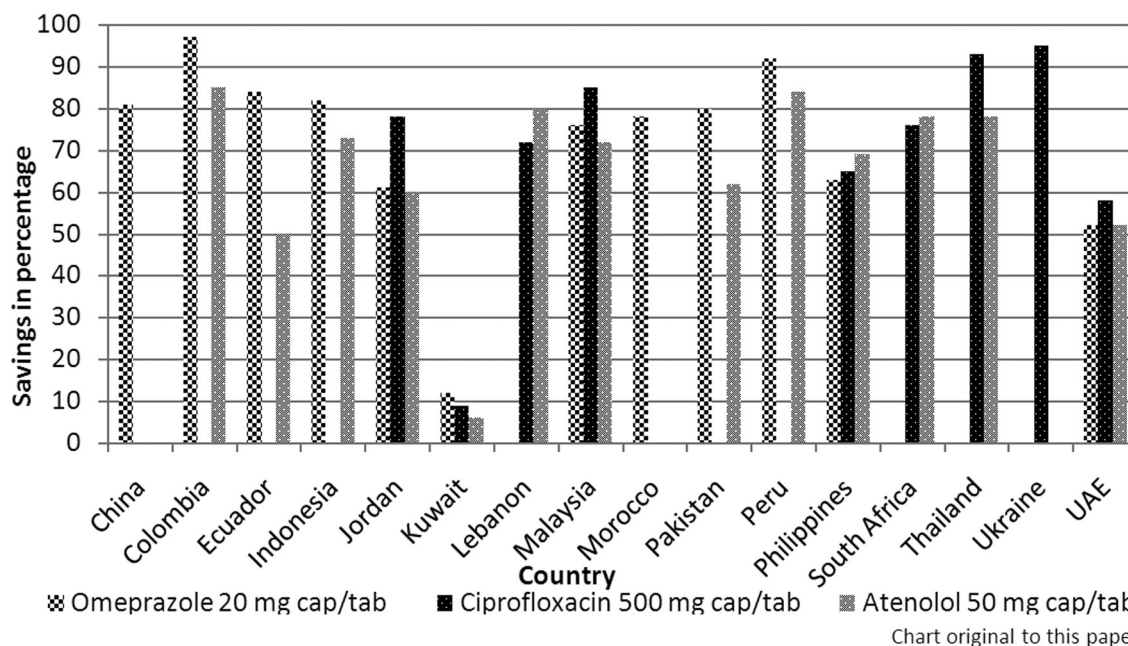


Figure 1 — Average percentage savings obtained by switching from originator brands to lowest priced generic equivalents for three individual medicines in the developing countries<sup>15</sup>

plus' provisions for satiating the ever-growing greed of the pharmaceutical industry and denying the poor and needy access to essential medicines. The paper also assesses other factors that constrain the availability of essential medicines for those in desperate need of the latter.

### TRIPS Flexibilities, the Doha Declaration and Public Health

The TRIPS Agreement delineates the minimum global standards for the protection of intellectual property, and offers sufficient liberty ('flexibilities') to the Member States to adapt the 'IP Regimes' in consonance with their own socio-economic needs. It is legally binding and enforceable through the Dispute Settlement Understanding and is backed by sanctions. A consolidated overview<sup>16</sup> of these 'TRIPS-flexibilities' aiding the availability of essential medicines is presented in Table 1. The 'Doha Declaration'<sup>17</sup> was adapted after a compromise was reached between the developing countries (mainly India and Brazil) and the developed countries (mainly US), which read as follows:

*"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in*

*particular, to promote access to medicines to all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*<sup>18</sup>

The Doha Declaration further recognises various flexibilities, "according to and in the light of Paragraph 4 of Declaration, while maintaining commitments in the TRIPS Agreement".<sup>19</sup> Going a step further, it reiterated, and even more explicitly, that public health rights prevail over individual IP rights. This move was possible as the developing countries were well prepared and operated as one block, while also enjoying the active support of international NGOs.<sup>7</sup>

Recently, UNHRC passed the following resolution,<sup>20</sup> despite objections from UK, Switzerland and European Union, which is a big leap for the poor populations in accessing essential medicines,

*"1. Recognizes that access to medicines is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; [OP1, HRC resolution 12/24 and OP 2, HRC resolution 23/14]*

*2. Stresses the responsibility of States to ensure access for all, without discrimination, to medicines, in particular essential medicines, that are affordable, safe, efficacious and of quality; [based on OP2, HRC resolution 12/24]*

Table 1 — ‘TRIPS flexibilities’ aiding the availability of essential medicines<sup>28</sup>

S.No.	Flexibility	TRIPS Article(s)	Implications
1.	Transition periods	65,66 Doha Declaration	Extended time-lines for implementation of TRIPS for developing countries and LDCs. Doha Declaration extended the timelines which could promote generic medicines. <sup>29</sup>
2.	Criteria of Patentability	27	Developing countries and LDCs can use the flexibility in fixing higher criteria for patentability and exclude some inventions from patentability to address the ever greening in the pharmaceutical sector. <sup>30</sup>
3.	Compulsory licensing	31 TRIPS Para 5(b) of Doha Declaration	Freedom to determine circumstances under which a compulsory licence can be issued to encourage the production of generic medicines, thus making these medicines available at cheap prices. <sup>31, 32</sup>
4.	International exhaustion to facilitate parallel importation	6	Freedom given to member countries to decide principle of exhaustion can be used to make essential medicines available by adopting international exhaustion regime thus facilitating parallel importation of essential medicines. <sup>32, 33</sup>
5.	Limited exceptions to patent rights	30	Exceptions for research and experimental use can be used by the pharmaceutical industry to innovate and produce new medicines. <sup>32</sup>
6.	Procedures for opposition and revocation	Silent	With TRIPS being silent on these issues, the Member-States can use higher scrutiny of patent applications, before and after the grant of patents, as a useful tool to encourage the production of generic medicines. <sup>34</sup>
7.	Pro-competitive measures	40 31	The Member-States can use the anti-competition law and pro-competitive measures as a tool to access essential medicines. Developing countries can learn lessons from the European Union in detailing anti-competitive practices in the pharmaceutical sector. <sup>35</sup>

3. *Calls upon States to promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights which provide flexibility for that purpose, recognizing that the protection of intellectual property is important for the development of new medicines, as well as the concerns about its effects on prices; [OP7, “g”, HRC resolution 17/14 and OP 5, “h”, HRC resolution 23/14]”*

However, in order to benefit from such flexibilities, a country needs to not only frame or amend its national IP laws but also ensure the availability of and access to technology, financial resources, and trained interdisciplinary humanresources. The experiences of developing countries like South Africa,<sup>21</sup> Thailand,<sup>22, 23</sup> and India<sup>24,25</sup> are indicative of the difficulties being faced by the other developing and the Least Developed Countries (LDCs) in implementing ‘TRIPS flexibilities’ for making essential medicines available to their populations at affordable rates. Significantly, the failure to push through its own public health draft at Doha did not deter the US from using its domestic laws to ‘arm-twist’ countries like Argentina, South Africa and Guatemala by putting them on the ‘USTR 301 Watch List’. This action compelled them to toe the US line in bypassing the “TRIPS flexibilities

and accepting ‘TRIPS Plus’ laws to institute more stringent pharmaceutical intellectual property protection”, thereby preventing access to essential medicines in these countries.<sup>26</sup> There is no clear definition of ‘TRIPS plus’ but in principle, it refers to commitments that go beyond the TRIPS Agreement.<sup>27</sup>

#### **The US-FTAs: ‘TRIPS Plus’...or ‘US Plus’...or ‘TRIPS Multiple’...**

The consistent differential perspective on the standard of protection in TRIPS as the ‘floor’ (minimum standard) of the US and as the ‘ceiling’ (maximum standard) of the developing countries continues to be a driving force behind the aggressive efforts being made by the US to raise the ‘ceiling’, eliminate TRIPS flexibilities and plug loopholes in TRIPS.<sup>36</sup> While playing the multi-level, multi-forum global governance card, countries like the US are able to extract TRIPS plus commitments from the economically vulnerable parties through Bilateral Investment Treaties, Bilateral Free Trade Agreements and Regional Free Trade Agreements<sup>37</sup> by exerting pressure through the use of the Special 301 clause under the Trade Act, 1974, and the imposition of unilateral sanctions and negotiation of investment treaties.<sup>38</sup> The US has signed a slew of such agreements and is currently negotiating a few more as listed in Table 2. Most of these stringent provisions,

crafted in close nexus with the branded originator drugs pharmaceutical industry,<sup>36</sup> aim at promoting originator drugs and eliminating or delaying the entry of generic medicines, thus preventing access to essential medicines at an affordable cost.<sup>39</sup> The US–Morocco FTA is considered as the most stringent of all the US FTAs. A summary of the general ‘TRIPS plus’ provisions affecting the availability of essential medicines in the US FTAs is presented in Table 3.

\*V = Vietnam, J = Jordan, S = Singapore, C = Chile,

Table 2 — List of US-FTAs and Mega-FTAs<sup>40</sup>

Agreements Already Signed	Agreements under Negotiation
1. NAFTA (1994)	1. Thailand
2. Vietnam (2001) (not a FTA)	2. Panama
3. Jordan (2001)	3. TTIP (US–EU)
4. Singapore (2003)	
5. Chile (2003)	
6. Morocco (2004)	
7. Australia (2004)	
8. DR–CAFTA (Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua) (2005)	
9. Bahrain FTA (2006)	
10. Colombia (2012)	
11. ACTA (signed by 10 parties including EU (+22) in 2011-12. Rejected by European Parliament. (not in force)	
12. TPP signed 2016 (not in force)	

M = Morocco, A = Australia, D = DR-CAFTA, B = Bahrain

Consider the views of the pharmaceutical industry on TRIPS plus provisions, as put forward by Micky Kantor,<sup>44</sup> a former USTR turned lobbyist for the pharmaceutical industry, while trying to explain that the provisions of free trade agreements are not violative of the TRIPS Agreement, which reads as follows:

*“Characterizing these provisions as TRIPS-plus is misleading,.... While it is true that these provisions often are more specific and provide greater intellectual property protection than that provided by the TRIPS Agreement, that does not mean they violate the TRIPS Agreement.”*<sup>45</sup>

However, subsequently in the same document, he made his dubious intention clear, which read:

*“Article 31, the Doha Declaration and the Paragraph 6 Compromise are fundamentally ‘exceptions’ to the intellectual property protections embodied in the TRIPS Agreement....But these exceptions can not swallow the rule: strong intellectual property protections remain essential to foster innovation and creativity.”*<sup>46</sup>

An analysis of the TRIPS plus provisions listed above leaves no doubt that these FTAs undermine the TRIPS flexibilities with their intention to block the supplychain of generic medicines and are thus fatal in terms of ensuring accessibility to essential drugs.<sup>31,47</sup>

Table 3 — General ‘TRIPS plus’ provisions<sup>@</sup> affecting the availabilityof essential medicines in US FTAs<sup>40, 41, 42, 43, 36</sup>

S.No.	Issue	Provisions	Bilateral countries*
1.	Patent term	Extension in patent terms in the case of a delay in the regulatory approval process or grant of the patent.	V, J, S, C, M, A, D and B
2.	Second-use patents	Grant of patent for new uses of known products.	M, A and B
3.	Patenting of life forms	Compulsory accession to UPOV convention, 1991.	V, J, S, C, M, A and B, and D <sup>#</sup>
4.	Compulsory licences	Invocation in ‘national emergencies’, as an ‘anti-trust remedy’, and for ‘public non-commercial’ use.	V, J, S & A
5.	Approval for marketing of drug linked to patent status	Approval for marketing of a generic drug is prohibited during the patent term, except on the patent owner’s authorization, who is to be informed about the company requesting such approval.	S, C, M, A, D and B
6.	Protection of test data for pharmaceuticals	Test Data Protection for 5 years which may be further extended up to 3 years in case of new use.	S, C, M, A, D and B
7.	Parallel imports of patented products	Patent holders may use licensing contracts to limit parallel imports.	S, M and A
8.	Institutional flexibility in IPRs enforcement	Resource constraints should not be used as an excuse for non-compliance with specific enforcement obligations.	S, C, M, D and B
9.	Border Enforcement Measures	Apply even to transiting goods in addition to imported/exported products	S, C, M, D and B
10.	Civil and administrative procedures	Penalty for infringers even if no injury to rights holders.	V, J, S, C, M, A, D and B
11.	Criminal procedures and remedies	Criminal liability for even knowledge of counterfeited labels.	M, A, D, B and S

Notes: <sup>@</sup> Some less stringent provisions are not included. <sup>#</sup> Reasonable efforts to provide this.

**The Free Trade Agreements, from Bilateral to Plurilateral Mechanisms**

The success in coercing many countries to sign FTAs encouraged the US to take bilateral negotiations to the next higher level of plurilateral negotiations. The US had been unsuccessful in imposing its own intellectual property standards on the developing countries since the advent of the TRIPS and Doha negotiations. Consequently, it began negotiating bilateral trade agreements, with each successive agreement building more ‘pluses’ on the predecessors, to achieve a cumulative effect,<sup>48</sup> and creating more regional trade blocks likes ACTA, TPP and TTIP. The negotiations for these regional agreements were shrouded in secrecy, away from the gaze of the public and NGOs, to avoid pre-emption of their next moves by these democratic stakeholders. When some of these draft agreements were leaked into the public domain, there was a hue and cry because of their ominous implications for civil liberties and access to essential medicines. The European Parliament rejected it, despite the fact that the EU and its 22 members had signed the agreement. The TPP has been signed in 2016, but is still not in force while the TTIP is still under negotiation. The TPP and TTIP together would be the largest critical mass of support for ‘US-forced’ TRIPS plus laws (Fig. 2).

When the Senate passed the Trade Promotion Authority, the US President termed it as “.....an

important step toward ensuring [that] the United States can negotiate and enforce strong, high-standards trade agreements.....”<sup>49</sup>

A summary of the TRIPS plus provisions in the ACTA and TPP and their effects on the availability of affordable medicines is presented in Table 4, clearly pointing to a systematic attempt to create more stringent standards, thus increasing the “barriers to access generic medicines either by intensifying such IP protections as existence and duration of exclusivity or by reducing the use of flexibilities such as compulsory licenses or parallel import”.<sup>50</sup> The introduction of third-party liabilities, exemplary deterrent penalties and criminal offences illustrates how the US is determined to choke the global supply lines of essential medicines.

The US Government explicitly leveraged bilateral FTAs to influence regional and multilateral negotiations on ‘TRIPS plus’, thus triggering the onset of plurilateralism through six distinct mechanisms, viz., “chain reaction, pressure for inclusion, coalition building, emulation, legal interpretation and adherence”. This has fostered instability and fragmentation among the WTO members.<sup>55</sup> The ‘TRIPS plus’ bilateral, regional and plurilateral agreements have also made it difficult for the affected populations to access essential medicines not only due to the lack of capacity and resources but more so because of strikes by the developed countries.

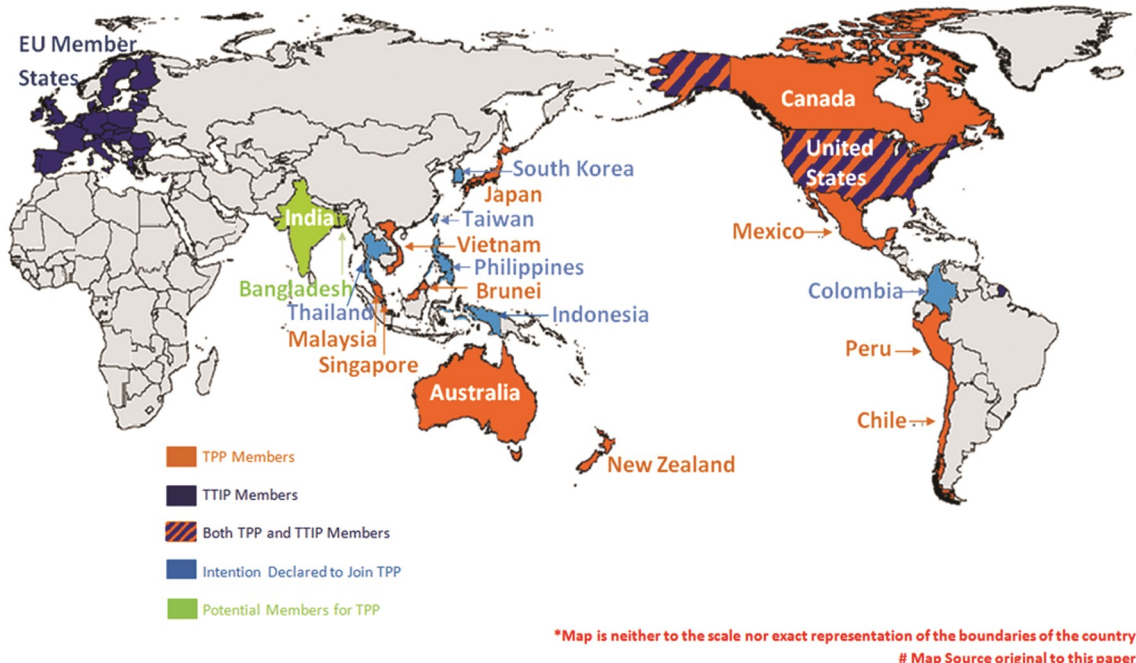


Figure 2 — Schematic map showing the emergence of a Mega Free Trade Area

Table 4 — ‘TRIPS-plus’ Provisions of “ACTA” and “TPP” and their effects on the availability of essential medicines<sup>51,52,53,54</sup>

S.No.	Concern	TRIPS provisions	TRIPS+ provisions in ACTA	Effects of TRIPS+ provisions in ACTA	TRIPS+ provisions in TPP	Effects of TRIPS+ provisions in TPP
1.	Border measures	58	12:1(a), 13,16:1(a), 16:2, 17.1	Authorises seizure if the medicine label is “suspected” to be “confusingly similar”	QQ.H.6	Covers only “counterfeit and piracy goods” destined for “imports”. Goods in “transit” not covered.
2.	Injunctions and provisional measures	44.1 50.1(a)	8:1, 12:1(a), 12:3	Enabling a country to issue injunctions to prevent the entry of medicines in a third country, irrespective of whether its own laws are infringed.	QQ.H.4(8), QQ.H.4(17) QQ.H.5, QQ.H.4(6)	Entry of infringing goods can be prevented through injunctions.
3.	Third party liability	NIL	8:1, 12:1(a)	Liability for third party suppliers of goods and services to medicine suppliers accused of infringing IP Rights	NIL	NIL
4.	Calculation of damages	45	9:1, 9:3, 9:3(b)n.3	Over-deterrence by allowing the calculation of damages at “market price” or “suggested retail price”.	QQ.H.4	Similar to ACTA but more generous damages including punitive elements to deter similar infringements in future.
5.	Information disclosure	47	11	Giving a tool in the hands of IP Right holders for accessing private data of generic companies	QQ.H.4(14)	Imposition of sanctions for violating confidentiality of information against parties, experts, counsels or others.
6.	Criminal offences	61	34	Criminalisation of intentional importation and use of counterfeited trademark goods.	QQ.H.7(1) and (2)	Similar to ACTA. Also covering the importation or exportation of trademark/copyright infringing goods.
7.	Seizure and destruction of goods	61	25:1	Allowing for seizures and destruction of ‘suspect violations’.	NIL	NIL

This prompted the developing countries to strike back at the WTO, WIPO, and international regimes, giving rise to fears of a potential TRIPS-war.<sup>56,57</sup> If a sufficient number of countries sign these agreements, leading to the adoption of TRIPS plus standards, the US would be able to use Article 4 of TRIPS to legitimately exert pressure upon multilateral forums like the WTO and WIPO,<sup>50</sup> for laying down new international standards in line with the TRIPS plus provisions.<sup>48</sup> The intellectual property protection regime is hence seen to be monopolistically shifting from the ‘TRIPS plus’ to a ‘TRIPS multiple’ regime in congruence with the US Government’s ‘military-political’ goals.<sup>58</sup>

However, access to essential medicines is also dependent on the political will and policies of individual countries. Public interest groups and NGOs play a crucial role in improving accessibility to medicines. Ensuring stringent checks on corrupt practices by pharmaceutical companies and procurement officials would also help improve the situation. The capacity building of countries in terms of technology

and human resources for generic manufacturing would be an important factor in making countries self-reliant in the manufacture of generic medicines. However, the apprehension persists that geo-political considerations may influence governments to succumb to pressures from their military allies, compelling them to fall in line with the efforts of the US to block access to generic medicines throughout the world.

### Conclusion

The right to public health, including access to essential medicines, is a basic human right and has precedence over the individual right of intellectual property. Ample flexibilities in this regard have been incorporated in the TRIPS Agreement and have been reiterated in the Doha Declaration. However, countries like the US are using the mechanism of bilateral and plurilateral FTAs having ‘TRIPS plus’ provisions to usurp these ‘TRIPS flexibilities’ for denying access to essential medicines to populations in developing and least developed

countries. The emerging mega-regionals like ACTA, TPP and TTIP would worsen the situation by putting the affected populations to more hardships. The developing and least developed countries need to unite to prevent the US from altering the international law in world trade in the near future. In addition, international NGOs, all citizens, legislators and the judiciary in these countries need to become decisively proactive to ensure the uninterrupted supply of essential medicines for the public. This can be achieved only by curtailing the hegemony of the West and allowing the less developed nations to exercise their prudence and freedom to make essential medicines easily available for their populations while keeping the complicated issue of patents at bay.

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