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TRIPS SAGA: IMPLICATIONS FOR DEVELOPING COUNTRIES

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ABSTRACT

The free trade agreements have bewildered the developing nations because of the snags associated with it. Amidst such chaos is buried the political unrest and gambits of the developed nations to regulate and sequentially dominate the international market. They have accomplished this task by restricting the flexible provisions of the TRIPS agreement in the FTAs with their leverage. On the other hand the developing nations have been active participants in the TRIPS negotiation in order to address and resolve the problem of healthcare at large. This has been stomped over by the developed nations by negotiating free trade agreements, after considering bilateralism as an exit line from multilateral constraints. This paper deals with the subjugating free trade agreements and their bearing on the developing nations.

The case of U.S.-Jordan FTA affirms the negative impact arising from the implementation of comparable FTAs in developing countries, particularly in the area of public health and access to medicines which contains various provisions like patent term extension, restriction on compulsory licensing etc. Thereafter the essay focuses on Anti-Counterfeiting Trade Agreements (ACTA) which contains TRIPS-Plus provisions and its implications for India's generic medicine export.

Lastly, the essay proposes and recommends a "price" solution for better access to medicines in developing countries. Differential pricing can be effectively implemented to trim down the detrimental provisions of TRIPS-Plus on the aggrieved nations.

TRIPS SAGA: IMPLICATIONS FOR DEVELOPING COUNTRIES

I. INTRODUCTION

TRIPS was considered a minimum standard for application of intellectual property rights for the developed nations while was a benchmark for the developing nations. This was rectified by Maxim Medvedkov, Russia's lead negotiator on WTO accession who said that "I think we have to draw a line between WTO and bilateral issues..." thereby considering TRIPS to be a ceiling and not a floor for Russia.[1] TRIPS comprehends provisions for balancing patent protection and public health services which can be an impediment for the developing countries since they are open to interpretations.

Thus the bilateral free trade agreements were the initiatives of the developed nations in order to combat the onslaught of "the active participants" in the decisions and discussions of the WTO. These agreements assisted in divesting the developed world of many problems like compulsory licensing and provisions of the Doha declarations.

II. DOHA DECLARATION AND COMPULSORY LICENSING

The uncertainty of the TRIPS provision was a political gizmo for the U.S which threatened to impose sanctions on Thailand in 1997 and on Brazil in 2000, for their use of compulsory licensing. The upshot of this discourse led to the formation of a transnational coalition inclusive of NGOs, WHO and countries facing health crises.[2] These provided assistance to the developing nations for addressing their concern on public health. This was considered as one of the many reasons for the initiation of the Doha negotiations in 2002.[3] This declaration emphasized on the chief aim of the TRIPS agreement[4], stating that it should be interpreted and implemented in order to promote access to medicines for all. Most importantly the Doha Declaration on Public Health stated that the TRIPS agreement should be implemented considering the public health issue at large. However this declaration failed to make requisite recommendations on compulsory

[1] *See* IP-Watch(2005), Official: In WTO Talks US Pushes Russia to Restrictive TRIPS Standard, available at: http://www.ip-watch.org.

[2] Sell, S. and Prakash, A. (2004) 'Using ideas strategically: the contest between business and NGO networks in intellectual property rights', International Studies Quarterly, Vol. 48, pp.143–175.

[3] *Id.*

[4] Para 4: "it can and should be interpreted and implemented in a manner supportive of the WTO members' right to protect public health and, in particular, to promote access to medicines for all"

licensing which was emanating as a huge defence tool for the developed nations. Thus the WTO went one step further by providing circumstances under which a country inefficient in manufacturing drugs can efficaciously use compulsory licensing.[5] They fancied free trade agreements in order to provide enhanced intellectual property protection. These agreements enforced insensitive restrictions on the developing countries which are as follows:

1. **Patentability of new medicines:** The FTAs were efficacious in introducing ruthless provisions. All FTAs replicate Article 27 (1) of the TRIPS agreement which provides that the "patent shall be available for any invention whether product or processes". As per this statement, there are two kinds of patentable inventions: product innovation and process innovation. However the TRIPS agreement is silent about the patentability of new inventions. Some construe it to be comprehended in process innovation like in U.S. law[6], while some rest it on the members to decide its inclusion. Article 27(3) (b) precisely mentions that the members can exclude therapeutic, diagnostic and surgical methods for the treatment of humans and animals from patentability. However the FTAs signed between the U.S. and Australia in 2005 ended such flexibilities by including patentability for new uses and methods of using a known product in the free trade agreement. Subsequently USTR, which seeks for consistency, went one step further by comprehending patentability of new uses and methods of known products including "for the treatment of humans and animals", in the FTAs with Morocco and Bahrain in 2006.[7]
2. **Protection of data and data exclusivity**: Article 39(3) of the TRIPS agreement provides for minimum international standard for the protection of marketing approval of data by providing for protection of undisclosed data of the new product against unfair commercial use except where necessary to protect the public or where steps are taken to ensure that the data is protected against unfair commercial use. Some WTO members choose to limit the protection of data that involves considerable effort to financial investment. This was trounced by the U.S. by embracing a stricter provision in the FTAs

[5] Hoen, E. (2002) 'Public health and international law: TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha', Chicago Journal of International Law, Vol. 3, No. 1, pp.27–46.
[6] *See* Kantor, M. (2005) US Free Trade Agreements and the Public Health, http://www.who.int/intellectualproperty/submissions/US%20FTAs%20and%20the%20Public%20Health.pdf.
[7] MFTA, Art 15.9.2; BFTA, Art 14.8.2

signed with Singapore, Chile, Australia, Morocco, Bahrain,[8] where undisclosed data that involves considerable effort as well as the information that is linked with the safety or efficacy of the product that contains a new chemical entity was protected. It also applied to the chemical entity that is not new.[9] Additionally, the FTAs provide for a minimum patent protection of five years to the patent owners, which was contradictory to the TRIPS approach of unfair competition law. Thus the data is unavailable to the second party who applies for marketing approval of such data within the term of patent protection. There are two additional rights conferred on the patent owners:

- Patent owners shall be made aware of the third party's marketing approval application
- Patent owners shall give their consent for such issuance.

  This restriction creates a monopoly which is not required by the TRIPS agreement and therefore makes it impossible for the countries facing health crises to use compulsory licensing.[10] Moreover practically a patent term extends beyond the term of patent protection. In some of the cases the patent may not be issued or the development period was so long that the patent term had expired. In such cases the data protection period acts as a substitute, thereby preventing the competitors for a five year period. In addition to this, the relationship between compulsory licensing and data exclusivity presents yet another predicament. Due to immense pressure mounting on the developing countries, undisclosed data was excluded from compulsory licensing.[11] This was a significant achievement precisely for brand name companies and generally for developed countries, particularly U.S.

3. **Protection of an effective patent term**: Article 33 of the TRIPS agreement provides for the term of protection as 20 years. This is counted from the date of filing. Thus the effective term of protection is put at peril by two administrative procedures which can substantially reduce the term of protection. These are patent examination process and marketing approval process. Article 62 (2) of the TRIPS agreement states that the

[8] SFTA, Art16.8; CFTA, Art.17.10; CAFTA, Art.15.10; AFTA, Art. 17.10; MFTA Art. 15.10; BFTA, Art. 14.9
[9] Correa, Carlos, Implications of Bilateral Free Trade Agreements on Access to Medicines, 84 Bulletin of the World Health Organization (2006), p. 399, 401.
[10] 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, Occasional Paper 14, April at http://www.quno.org 1, 7 (2004).
[11] IP Watch (2005) 'Clash continues on US-central America trade deal', IP Watch, Vol. 2, No. 1, pp.1, 2, 6, 7.

procedure shall provide the granting of patent within a reasonable period of time without unwarranted curtailment of the protection period. However such reasonable period was again subject to interpretations. To guarantee an effective patent period of 17 years, the U.S. enacted Patent term Guarantee Act, 1999,[12] which was later adopted in the FTAs signed with the developing countries. It stated that the patent shall be extended at the request of the patent owner to compensate for the unreasonable delays that occurred in granting patents.[13] The second procedure that is the marketing approval procedure was of serious concern for the U.S. since its Food and Drug Administration procedures are particularly rigorous and long. Therefore Congress enacted the Hatch Waxman Act, 1984[14] which stated that each party shall make available an extension of the patent term to compensate the patent owner for the unreasonable curtailment of the patent term as a result of the marketing approval process. This was again replicated by it in the FTAs. This is problematic for the developing countries where the patent offices are understaffed and involves quite large number of departments. Notwithstanding the predicament, there was legal transplantation of U.S. law into foreign countries.

4. **Restriction on the authorised exceptions**: There are certain exceptions laid down in Article 30 of the TRIPS agreement to the exclusive rights conferred on a patent.[15] However such exceptions are general and not specific. These exceptions as alluded to in the agreement should be such as to not conflict with the normal exploitation of the patent, or prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. This general exception is restricted in the FTAs[16] by a provision which states that if a party permits a third party to use the subject matter of a subsisting patent solely to support an application for the marketing of that pharmaceutical product then the party shall assure that the product produced under such authority shall not be made, used or sold in the territory of that party, to generate information for the approval of marketing of the product once the patent expires. This exception popularly known as

[12] *See* 35 USC 154
[13] *Id*.
[14] *See* 35 US 156
[15] "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties."
[16] JFTA, Art. 4.19; SFTA, Art. 16.7.5; CFTA, Art. 17.9.4; CAFTA, Art. 15.9.5; AFTA, Art. 17.9.6; MFTA, Art. 15.9.5; BFTA, Art. 14.8.5

"bolar exception" was considered regulatory exemption and therefore fell within the general conditions of Article 30. The permitting of competitors to produce and stockpile a product for sale after the expiration of the patent was considered "substantial curtailment" and excluded from Article 30. Not only this, it also restricts exporting of the patented product to marketing approval. This restriction refrain the countries having insufficient industrial capacities from making effective use of compulsory licensing.

5. **Additional restriction on compulsory licenses**: Article 31 of the TRIPS agreement prescribes general conditions under which compulsory licenses can be issued by a WTO member. These conditions remained undetermined by the agreement and the members are free to determine circumstances under which these licenses can be granted. However these grounds have been restricted to three conditions in the recent FTAs signed by the U.S. These are: to remedy an anti competitive practice, provided it has been declared as such after a judicial or administrative process; to use for non commercial purposes or in national emergency, or extreme urgency, where it can only be used by the government or legislative entity under the government and on the ground of failure of meeting working requirement provided importation constitute working. Later these restrictions were further constricted by the U.S. in the FTAs signed with Singapore and Australia.[17]
6. **Prohibition of the international exhaustion doctrine**: The U.S championed national exhaustion and then used their leverage to dissuade the developing countries from complying with the doctrine of international exhaustion. The result was somewhat ambiguous[18] which was later made conspicuous by the Doha Declaration which stated that it is upon the will of each member to establish its own regime for such exhaustion without challenge.[19]Thus bilateral trade agreements were again an opportunity for the U.S. to prevent full application of the international exhaustion doctrine. Since the U.S. relied on national exhaustion doctrine so it compelled many people of U.S to drive to Canada in the past several years in order to buy cheaper version of the brand name drugs.
7. **Restrictions on the ground of revocation**: The TRIPS agreement under Article 32 provides for revocation. However it leaves it on the WTO members to determine the

[17] SFTA, Art. 16.7.6, AFTA, Art. 19.9.7

[18] "For the purposes of dispute settlement under this Agreement, […] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

[19] "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge."

grounds of revocation which could be construed as circumstances involving public interest, abuses that might result from the exercise of exclusive rights and for compliance with the public health law. However such grounds of revocation were restricted in the FTAs.[20] The revocation was permissible in case if it justified a refusal to grant the patent, if it involved fraud, misrepresentation or inequitable conduct. This was another embodiment for the rescue operation conducted by the bilateral agreements when the multilateral agreements failed to meet their ends.

Thus the FTAs were incompatible with the Doha Declaration which was a first step towards providing flexibility to the provisions of the TRIPS agreement.

In June 2006, the Committee on International Trade Law passed a resolution expressing concern over some WTO members' concrete steps taken for their self preservation through bilateral and regional free trade agreements and urged the governments to refrain from incorporating any such provision which serves as an impediment in the promotion of public health and access to medicines for all.[21]

Bilateral FTAs between powerful, industrialized countries, particularly the United States and European Union, and poorer developing countries proliferated over the past decade. The signing of an FTA represents the beginning of a long and winding road, but there is little analysis of what happens following the conclusion of bilateral free trade agreement. One reason for the lack of analysis of the implantation of FTAs is that these agreements are negotiated and implemented secretly, behind closed doors with little public debate [22]. The case of U.S.-Jordan FTA affirmes the negative impact arising from the implementation of comparable FTAs in developing countries, particularly in the area of public health and access to medicines[23].

[20] SFTA, Art. 16.7.4; CFTA, Art. 17.9.5; CAFTA, Art. 15.9.4; AFTA, Art. 17.9.5; MFTA, Art. 15.9.5; BFTA, Art. 14.8.4

[21] ''composed of experts from around the world (including individuals who have served in important positions at the WTO and the European Commission, who are members of national Supreme Courts, who have served as senior trade negotiators and so forth)'' Frederick Abbott, Resolution of the International Law Association on Trade Agreements and Public Health, IP-Health Digest, vol. 1, #2088, message, available at: http://www.cptech.org

[22] *See* Brian J. Schoenborn, 'Public participation in trade negotiations: open agreements, openly arrived at?', 4 MINN. J. GLOBAL TRADE 103 (1995).

[23] *See* OXFAM INT'L, ALL COSTS, NO BENEFITS: HOW TRIPS-PLUS INTELLECTUAL PROPERTY RULES IN THE US–JORDAN FTA AFFECT ACCESS TO MEDICINES (2007).

III. U.S- JORDAN BILATERAL FREE TRADE AGREEMENT[24]

The close relationship between Jordan and the U.S. is evidenced by the exceptional military and financial support Jordan has received from the U.S. over the years.[25] U.S. backing ensured Jordan's speedy accession to the WTO in 2000 and subsequently paved the way for the signing of the first bilateral free trade agreement (FTA) between the U.S. and an Arab country in 2001 (the U.S.-Jordan FTA).[26] High levels of collaboration between the two countries in the area of intellectual property have existed for some time. However, it was often U.S. pressure, triggered by industry groups, which dictated the terms of the relationship between the two countries. For instance, until 1998 Jordan was still placed on the United States ―Section 301 Watch List. In the same year, the Pharmaceutical Research and Manufacturers of America (PhRMA) went even further, by formally asking the USTR to name Jordan in the next year as a ―Priority Watch country, for ―failing to provide adequate intellectual property protection[27]. The relationship became less turbulent following the country's accession to the WTO and its signing of an FTA with the U.S. in 2000 and 2001, respectively.

The case of Jordan not only conforms to these observations, but also sheds new light on the inconsistencies and loopholes present in intellectual property regulation, given the explicit influence of the U.S. The key players representing the United States' private sector interests include a number of historically well-established and organized business groups and associations. For instance, both the Business Software Alliance (BSA)[28] and the International Intellectual Property Alliance (IIPA)[29] have been vocal in their push for strengthened copyright

[24] Agreement on the Establishment of a Free Trade Area, U.S.-Jordan, Oct. 24, 2000, 41 I.L.M. 63 [hereinafter U.S.-Jordan FTA]

[25] *See generally* on relations AVI SHLAIM, LION OF JORDAN: THE LIFE OF KING HUSSEIN IN WAR AND PEACE (2007).

[26] The U.S. State Department website explains, ‖ Relations between the United States and Jordan have been close for 6 decades, with 2009 marking the 60th anniversary of U.S.- Jordanian ties.‖ Bureau of Near Eastern Affairs, *Background Note: Jordan*, U.S. DEPARTMENT OF STATE (Dec. 30, 2011), http://www.state.gov/r/pa/ei/bgn/3464.htm.

[27] See Ghalia Alul, *Pharma Requests Jordan be Placed on "Priority Watch" List*, JORDAN TIMES, April 15, 1998

[28] On its website, the BSA presents itself as the ―voice of the world's commercial software industry and its hardware partners before governments and in the international marketplace. BSA programs foster technology innovation through education and policy initiatives that promote copyright protection, cyber security, trade, and e-commerce. *See* BUSINESS SOFTWARE ALLIANCE, http://www.bsa.org/GlobalHome.aspx (last visited Dec 9, 2012).

[29] The International Intellectual Property Alliance is a private sector coalition, formed in 1984, consisting of trade associations representing U.S. copyright-based industries in bilateral and multilateral efforts working to improve

protection in Jordan. Meanwhile, the Pharmaceutical Research and Manufacturers of America (PhRMA)[30] continues their pursuance of higher levels of intellectual property protection in the area of pharmaceutical patents in the country. These business groups and associations are also supported by their local representatives, agents, and networks of contacts. What is of concern here is the evident lack of public input and the absence of public participation and civil society representation in these discussions, particularly from the Jordanian side.

Moreover, the U.S. - Jordan FTA was one of the first bilateral agreements to include extensive TRIPS-Plus provisions. These provisions had noticeable impacts on many development-related areas.[31] In particular, the agreement contains several TRIPS-Plus provisions, which directly impact public health and access to medicines in the country. These may be summarized as follows:

1. **"New use" legal protection for chemical entities.**

Although the TRIPS Agreement does not oblige member states to provide legal protection for new use, the U.S.-Jordan FTA includes reference to this type of protection. In this regard, Footnote 10 of Article 4.22 the U.S.-Jordan FTA states that:

"It is understood that protection for ―new chemical entities‖ shall also include protection for new uses for old chemical entities for a period of three years."

2. **Patent term extension:**

international protection and enforcement of copyrighted materials and open up foreign markets closed by piracy and other market access barriers.‖ For more see *About IIPA*, INTERNATIONAL INTELLECTUAL PROPERTY ALLIANCE, (Dec. 9, 2012) http://www.iipa.com/aboutiipa.html.

[30] The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the US's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $49.4 billion in 2010 in discovering and developing new medicines. Industry-wide research and investment reached an estimated $67.4 billion in 2010. For more see *About PhRMA*, PHRMA (Feb. 9, 2012), http://www.phrma.org/about/about-phrma.

[31] For more on FTAs' impact on the Arab World, see MOHAMMED EL SAID, WORLD HEALTH ORGANIZATION & INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, PUBLIC HEALTH RELATED TRIPS-PLUS PROVISIONS IN BILATERAL TRADE AGREEMENTS: A POLICY GUIDE FOR NEGOTIATORS AND IMPLEMENTERS IN THE WHO EASTERN MEDITERRANEAN REGION (2010), *available at* http://www.emro.who.int/publications/Book_Details.asp?ID=1081.

Article 33 of the TRIPS Agreement provides that legal protection shall be granted to patents for a period of twenty years from the date of filing. The U.S.-Jordan FTA further extends this period in order to compensate the applicant for the time spent during the examination of the application and/or marketing authorization. Article 4.23 of the U.S.-Jordan FTA states that:

"With respect to pharmaceutical products that are subject to a patent:

a. Each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of marketing approval process."

3. Restrictions on compulsory licensing.

The TRIPS Agreement grants member states the right to grant compulsory licenses. However, the agreement does not list nor specify the grounds whereby such licenses may be granted, but instead awards member states the discretion to define such grounds. On the other hand, the U.S. - Jordan FTA lists the grounds where such licenses may be granted, hence eroding the policy space available to Jordan, by broadly defining these grounds. Accordingly, Article 4.20 of the *FTA states:*

"Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:-

a. to remedy a practice determined after judicial or administrative process to be anti-competitive;

b. in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government"

The impact of these TRIPS-Plus conditions in the area of public health and access to medicines is grave. In brief, such measures would result in prolonging the monopoly terms granted to pharmaceutical patents and would delay the entrance of generics into the market at an earlier stage.[32] Lastly, U.S. interest groups and local agents collaborate to achieve higher levels of intellectual property protection without taking into consideration the public interest and

[32] To this effect, a recent study stated that ―Reportedly overlaying U.S.-style rules over Jordan's pharmaceutical sector negatively affects the ability of generic industries to operate, which is why many from Jordan's generic pharmaceutical industry view the FTA as TRIPS-Minus

consumer rights of local communities. This "act of state-sponsored violence," as some have proclaimed it[33], jeopardizes the lives of millions of citizens across the globe.

IV.TRIPS PLUS THROUGH Anti-Counterfeiting Trade Agreements (ACTA): Implications for India

Unfettered by opposition, a select group of developed countries have resorted to tactics of forum-shopping and have succeeded in initiating the TRIP-plus enforcement agenda through proposed Anti-Counterfeiting Trade Agreement (ACTA). The ACTA would create new standards for enforcement of IPR by establishing a strong legal framework for IPR enforcement, increasing international cooperation, and enhancing enforcement measures. Moreover, recently the failure of ACTA was the major reason for the dropping of criminal sanctions from the Canada-European Free Trade agreement.[34]

IV.1. TRIPS PLUS AGENDA: Elimination of TRIPS Flexibilities

Higher standards for IPR protection under the concept of TRIPS-plus have the effect of reducing the ability of developing countries to protect the public interest. It includes a number of initiatives including: the Anti-Counterfeiting Trade Agreement (ACTA); Interpol's SECURE; the WHO‟ s IMPACT; WIPO‟ s ACE discussions; and many bilateral and regional Free Trade Agreements, Investment Treaties, and Economic Partnership Agreements. ACTA is a glaring example of attempts by the developed countries to eliminate TRIPS flexibilities in IPR enforcement in the developing countries.

IV.2. IMPLICATIONS FOR INDIA

India produces an enormous number of generic products and is an important provider of generic medicines to other developing countries. Due to price differentials, Indian generic products have become particularly popular in developing countries as a cheaper alternative to branded products; for example, Médecins Sans Frontières (MSF) estimates that more than 80% of the AIDS medicines used to treat more than 5 million people across the developing world come from

[33] James Love, In Defense Of WikiLeaks: Looking At Cables On Pharmaceutical Drugs And Trade Pressures, HUFFINGTON POST, Sept. 4, 2011, http://www.huffingtonpost.com/james-love/wikileaks-cables-pharmaceuticaldrugs_ b_947806.html?view=print&comm_ref=false.

[34] IP Watch, Criminal IP Sanctions To Be Dropped From Canada-EU FTA, Documents Show, *available at:* http://www.ip-watch.org/2012/11/28/criminal-ip-sanctions-to-be-dropped-from-canada-eu-fta-documents-show/

Indian companies[35]. Multinational pharmaceuticals companies lobbied against the increasing availability of generic drugs, which are marketed at much lower prices than their products. It seems that attempts are being made to impede India's export of generic products to other markets, particularly in the poor developing countries[36].

During 2008 and 2009, several consignments of generic drugs *in-transit* of Indian companies were seized by the Dutch customs authorities on grounds of alleged IPR violations. This caused a major concern in India because it relates to the supply of generic drugs from India to developing countries and ties into issue of access to medicines in these regions. Seizure of the consignment of losartan potassium in December, 2008 was one such case of what is emerging as a clear pattern[37]. Such instances have caused India great concern due to their systemic and far reaching implications. Indian government raised this issue before the WTO General Council. It pointed out that such acts represent a distorted use of the international IP system and circumscribe TRIPS flexibilities. In addition, this is against the spirit of a rule based trading system and impeding free trade. Repeat of such actions may have an impact on Indian exporters‟ choice of transit routes, which may affect the economics of trade of pharmaceutical products and consequently, adversely affects the Indian economy. Additionally, it has a deleterious effect on access to essential drugs and public health budgets of recipient poor countries. This is further exacerbated by the EU and Japan move to push ACTA to apply to patents according to the law of the transit country, meaning that right holders will be able to stop generic medicines in transition that are alleged to violation the "manufacturing fiction" in the transit country. In effect, proposed ACTA will allow the border detention of in-transit medicines destined for developing countries.

As explained above, proposed ACTA is a subtle and concert way of circumscribing the flexibilities of the TRIPS Agreement. This also runs counter to the spirit of the TRIPS Agreement which is a minimum standards agreement. In this regard, India's primary concerns

[35] Abbot, Frederick (1998), 'The Enduring Enigma Of TRIPS: A Challenge for the World Economic System' Journal of International Economic Law, vol.1(4).

[36] Swapan K. Bhattacharya (2007), ' Harmonising patent laws with the TRIPS Agreement of WTO: India's stride towards globalisation of intellectual properties. International Journal of Intellectual Property Management' vol 1(3), pp. 253 – 276.

[37] Indian Statement on the Generics Seizure Issue to the WTO General Council, http://indiainthewto.wordpress.com/2009/02/04/indian-statement-on-the-generics-seizure-issue-to-the-wto-general-council/ (last accessed on 23.12.2012).

are based on ACTA's provisions for border measures. If the ACTA is allowed to supersede the TRIPS standards, it would allow for the seizure of medicines in-transit by custom authorities simply on grounds of suspicion. Stringent nature of enforcement measures under the proposed ACTA raise the apprehension for creating a wider scope for injunctions and damages on all IPRs, not only on copyright and trademark violations. More importantly, the proposed ACTA directly oppose India's position on scope of enforcement measures in the customs dispute with the EU, a dispute which could soon land in the WTO if resolution to instances of drug seizures by the Dutch in 2008 and 2009 are not resolved[38].

V.RECOMMENDATIONS

V.1. The "Price" solution for better access to medicine

The price solution for better access to medicine, especially in developing and Least Developed Countries, is based upon the idea of a differential pricing, depending on the income of the country in which the patented pharmaceutical is commercialized.

V.2. Differential Pricing between Developed and Developing Countries

In developed countries with high income, consumers are indifferent to a price change for any given pharmaceutical as long as they can afford it. However, this is not true for all consumers since even in developed countries, incomes differ among consumers. The demand of pharmaceuticals in developed countries is therefore price inelastic. As to the developing countries a change on the price of a pharmaceutical has an impact on the consumer decision to purchase a given drug. In developing countries the demand of pharmaceuticals are price elastic. Demand of pharmaceuticals in developing countries is price elastic since a change in a price has an impact an effect on the demand. For expensive drugs which are needed to be taken over a long period of time, such as AIDS cocktail drugs, consumers in developing countries with low income are particularly sensitive to the price factor.[39] With the differential pricing solution for access to medicine, the drug would be available at lower cost in developing countries and the pharmaceutical would still have enough in capital return in developed countries to sustain

[38] Médecins Sans Frontières (2010). At EU-India Summit, European Negotiators Urged Not to Block Access to Affordable Medicines. Available at http://www.msf-me.org

[39] See, Ringel et al., *The Elasticity of Demand for Health Care, A Review of the Literature and its Application to the Military Health System* (Rand 2002), available at *http://rand.org/pubs/monograph_reports/MR1355/MR1355.pdf.*

competition and R&D. Thus a patent-holder may rationally set prices near marginal cost in low-income markets where demand is highly priced elastic.[40] Therefore charging differential pricing in developed and developing countries would ensure better access to medicines.

VI. CONCLUSION

Consequently politicisation of the IPR through criminal sanctions, inadvertently through PAIPO(an initiative of African Union)[41], which lacks transparency; lack of political obligation evidently through "no response" policy adopted by the nine countries questioned on Trans Pacific Partnership, will only lead to distress. A collective, unbiased and ingenuous step should be taken to combat the emanating dilemma from these FTAs.

[40] Marlynn Wei, 'Should Prizes Replace Patents? A critique of the Medical Innovation Prize Act of 2005', Boston University Journal of Science and Technology Law, Winter 2007, p. 3.

[41] Mohammed El Said, Surpassing Checks, Overriding Balances and Diminishing Flexibilities: FTA-IPRs Plus Bilateral Trade Agreements – From Jordan To Oman, 8 J. WORLD INV. & TRADE 243 (2007).