TRIPS Agreement and Public Health: The Post Doha Crises

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Though the Doha Declaration on TRIPS Agreement and Public Health has clarified that public health has predominance over private commercial interests, the victory of public health over trade interests appears to be momentary. The big pharmaceutical industries and the developed countries, using trade sanctions, effectively prevented developing countries from making full use of the flexibilities in the TRIPS Agreement procured by the Doha Declaration. Ultimately free trade agreements are made use of by developed countries to impose TRIPS plus obligations on developing countries. These developments once again ascertain that trade forum has its limits in protecting public health interests against trade interests.

Keywords: Doha Declaration, TRIPS Agreement, TRIPS flexibilities, public health, post Doha challenges, compulsory licence

The Saga of Doha Declaration

Doha Declaration of Public Health was the outcome of the realization by the developing countries of the actual implications of an overarching trade agreement on their policy-making power, especially with respect to one of the primary responsibility of a nation, viz., of protecting public health over trade interests. It was also a reaction to the aggressive tactics used by the pharmaceutical companies, and the industrially and technologically developed countries, to ensure that TRIPS flexibilities have only restricted application among the developing countries. When South Africa was dragged to court and Brazil to WTO Disputes for making use of the so-called TRIPS flexibilities to provide access to medicines for the thousands of HIV/AIDS patients who were dying due to lack of means to access already available medicines, it shocked the public conscience. A clarification on the exact scope of the flexibilities available under the TRIPS Agreement was strongly needed to know if TRIPS flexibilities were mere illusions or they really existed for the developing countries. With the unflinching support from different national and international NGOs and media, the coalition of likeminded developing countries succeeded in building a global public opinion against further abuses of the trade agreement, at least in the context of issues like public health. The US double standard, which was glaringly visible, when it threatened Bayer with compulsory licence (CL) for Ciprofloxacin during the anthrax scare in the US added to the global support to developing countries. The contest, thus, changed from one between private property rights and its violators, as presented by the multinationals while negotiating the TRIPS Agreement, to one between the right of states to protect public health and the power of patent monopoly, as presented by NGOs, and the outcome was Doha Declaration, which elevated right to public health over extension of patent monopoly.

The Promises of Doha Declaration and its Legal Status

The major achievement of the Doha Declaration is that it stressed the need for the TRIPS Agreement to be part of the wider national and international action to address the public health problems afflicting the developing and least developed countries. In pursuing that objective, it came to the agreement that the TRIPS Agreement ‘does not and should not prevent members from taking measures to protect public health’ and it ‘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 for all’. It also reaffirmed the right of WTO Members to use the TRIPS flexibilities to the fullest extent possible for the purpose of protecting public health and promoting access to medicines. The TRIPS flexibilities were recognized to include: (i) the mandate to read each provision of the TRIPS Agreement in the light of the objects and purpose of the Agreement, as expressed in

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its objectives and principles, (ii) the right to grant compulsory licences, with freedom to determine the grounds upon which such licences are granted, \(^6\) (iii) the right to determine what constitutes a national emergency or other circumstances of extreme urgency, which has to be understood to represent public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, and (iv) freedom to adopt its own exhaustion regime. Apart from these flexibilities specifically listed out in the Declaration, the flexibility in identifying the standards of patentability, freedom to refuse data exclusivity and to determine scope and extent of limitations and exceptions, other than compulsory licence, to be followed by each country etc., also form part of TRIPS flexibilities mentioned under paragraph 5 of the Doha Declaration, as paragraph 5 provides an inclusive definition. However, it is left for the TRIPS Council to find an expeditious solution to the problem of WTO Members with no or insufficient manufacturing capabilities in pharmaceutical sector, in making an effective use of compulsory licensing for ensuring access to medicines. The WTO General Council, later on, came up with the paragraph 6 solution in 2003, which finally culminated in the Protocol to Amend TRIPS Agreement in 2005.

Since the operative language of paragraph 4 is in the form of an agreement, and it was adopted by consensus of Ministers of the Member Countries, this may be interpreted as a ‘decision’ of the Members under Article IX: I of the WTO Agreement.\(^7\)Abbott\(^8\) and Gathii\(^7\), using Article 31 (3) (a) of the Vienna Convention on the Law of the Treaties (VCLT), argue that the legal status of Doha Declaration is substantively equivalent to that of the TRIPS Agreement.

**TRIPS Flexibilities in the Post Doha Context: Experiences of the Developing Countries**

Paradoxically, but rather unsurprisingly, a murky future awaited the Doha achievements. Developing countries continued to experience setbacks with reference to all types of TRIPS flexibilities. Every attempt by the developing countries to pursue the Doha principles met with severe resistance in the form of trade sanction from the developed countries and the Big Pharma. It could also be seen that the developed countries simultaneously resorted to forum shifting once again, this time from the TRIPS Agreement to bilateral or regional Trade Agreements, to serve their trade interests. These bilateral or regional trade agreements quite often reveal a tendency to go TRIPS plus.

A brief overview of how the developed countries, prompted by the Big Pharma, continued to resist the developing countries when they attempted to make use of different TRIPS flexibilities is given below:

**Compulsory Licence**

Despite the fact that the most prominent clarification made under the Doha Declaration is with reference to compulsory licence, the number of compulsory licences issued in the seventeen years between 1995 till date is very low. Till 2003, there were no traceable incidents of compulsory licensing. A study based on database of all episodes of compulsory licences on pharmaceutical products from commencement of the TRIPS Agreement in 1995 to 6 June 2011\(^8\) reveals that the period from 2003 to 2005 saw the greatest volume of compulsory licensing activity. The period from 2006 to June 2011 saw a substantial decline in activity.\(^8\) This information is interesting as well as disturbing from the public health point of view since it is contrary to the normal expectation that after the shift into product patent regime in 2005, compulsory licence will be used more frequently to promote access to medicine, or as part of industrial interests to tap the most promising opportunity to manufacture generic medicine.

Another interesting information revealed by the database, is the higher level of compulsory licensing activity in Upper Middle Income Countries (UMICs) than in Low Income Countries (LICs) and the Least Developed Countries (LDCs). The reason for LDCs and LICs not resorting to compulsory licensing could be traced to many factors: alternative sources for generic drugs available to those countries from countries like India which enjoyed the benefits of transition period up to 2005; lack of manufacturing ability of those countries even after the lapse of more than ten years of the commencement of TRIPS Agreement as result of non-fulfilment of the TRIPS obligation under Article 66.2; and fear of political and trade sanctions from developed countries. Since the chances for getting generic drugs from India have reduced after 2005, the real reasons must be the poor manufacturing ability due to lack of transfer of technology or fear of trade sanctions. The study confirms this view when it attributes the high UMIC activity to the comparatively high production and distribution capacity of UMICs over LICs and LDCs and their ability to withstand political pressure and threats of retaliatory action.\(^8\)
The study finds it highly probable that ‘the efforts put forth during the Doha conference in regard to pharmaceutical CLs will have a negligible long-term impact on the regular use of CLs or on global access to pharmaceuticals. This may be unsurprising given that TRIPS is neither a health nor a pharmaceutical access framework, but a trade framework. Nevertheless, health advocates who pushed for the Doha Declaration reforms have had far less success in engaging trade as a positive, proactive force for addressing health gaps.18

A major impediment for the developing countries in utilizing TRIPS flexibilities is the concern that it could provoke retaliatory actions including market withdrawal by the patent owning pharmaceutical companies and trade sanctions from the governments of developed countries representing those companies.9 A policy brief prepared by the South Centre to commemorate the 10th anniversary of the WTO Ministerial Doha Declarations on TRIPS and Public Health has expressed concern over the fact that ten years since the Doha Declaration, multinational pharmaceutical companies and developed countries continue to exert commercial and political pressure on developing countries not to make use of TRIPS flexibilities for public health.10

These concerns are further substantiated by instances like the European Union Commissioner for External Trade intimidating the Thai Minister for Commerce warning that the Thailand’s action of issuing compulsory licences for Abbott Laboratories’ antiretroviral drug, Kaletra in 2007 could lead to the isolation of Thailand from the global biotechnology investment community.11 The US also responded similarly by placing Thailand on its ‘Special 301’ Priority Watch List on the reason of the lack of transparency and due process exhibited by Thailand in issuing compulsory licence.12 The pharmaceutical company, Abbott Laboratories, also responded sharply, by announcing withdrawal of applications to sell seven new drugs in Thailand.13 Despite the fact that public health crises situations are not limited to cases involving epidemics alone, Thailand was concerned about issuing compulsory licences to heart disease, cancer and other ‘life-style’ diseases 14 fearing that such compulsory licences may be criticized as impermissible under TRIPS on the ground, inter alia, of absence of national emergency.15

The responses of the Thai16 and the Taiwan17 governments disclose the political pressure endured by them from the European Union and the US. Both the governments were concerned about the potential damage to their images in a trade regime and both were justifying their acts giving a restrictive interpretation to the TRIPS flexibilities.17

No wonder there were very few compulsory licences after the Thai incident. Recently, when Indian Patent Office issued first compulsory licence in the TRIPS regime for Bayer’s anti-cancer drug, Nexavar (sorafenib tosylate) on the grounds that the reasonable requirements of the public in respect of the patented invention had not been satisfied, because of lack of availability at affordable price and of non-working of patents within the territory of India18, there were similar reactions both from the pharmaceutical industry and the US Government.19

All these incidents show that in spite of the Doha Declaration, the developing countries are reticent in making use of compulsory licensing.17 Only countries which have the ability to resist the pressures from the Big Pharma and the developed countries, who vigorously uphold the interests of the Big Pharma, can be expected to come up with further experiments of this nature. This has to be read in contrast with the use of compulsory or other forms of non-voluntary licensing by the developed countries especially the US.20 This shows weakness of the trade forum to safeguard public health interests of developing countries, in spite of the high public opinion in their favour.

Paragraph 6 Decision and the Protocol Amending the TRIPS Agreement

In the negotiations over the implementation of the mandate in paragraph 6 of the Doha Declaration, the United States and other developed nations tried to limit compulsory licensing strictly to the most severe public health problems and to the neediest nations.21 Developing countries remained firm in rejecting the idea of restricting the solution to a limited scope of diseases, and their position ultimately prevailed.22 The paragraph 6 decision, with lengthy rules that specify conditions under which an importing country would be able to bring in a consignment of drugs from an exporting country, reveals that developing country negotiators have agreed to a solution without considering the realities of commercial life.23 The major drawback of the paragraph 6 decision is the rule complexity. Generic drug manufacturers need transparency and certainty, for having a clear understanding of their market potential and a minimum assurance of the safety of their investment,
when they apply for compulsory licence. The high degree of rule complexity disincentivizes pharmaceutical companies from using this provision to export generic medicines to countries having limited/no manufacturing capabilities. It is no wonder, since the adoption of the paragraph 6 decision it was invoked only once and the amendment to TRIPS is not yet ratified by the required majority.

NGOs like CPTech, MSF, Oxfam and Health Action International preferred Article 30 to Article 31 (f) of the TRIPS, for exporting health care inventions to countries having no or insufficient manufacturing capabilities. They thought that Article 30 has much potential to create new exceptions and limitations on patent rights. The NGOs, therefore, suggested that an Article 30 solution could be so drafted that the WTO members could simply agree that in cases where a country lacked manufacturing capacity and needed medicines, Article 30 would permit the creation of an exception to the restriction imposed by Article 31(f). However, pharmaceutical industries were worried about an Article 30 solution since Article 30 route would result in a broad and automatic exception that allowed the exporting country to manufacture and export without compulsory licence at all.

Use of Exhaustion Principle

The EU and the US wanted to limit international exhaustion to marketing with the consent of the patent holder. However, both the TRIPS Agreement and paragraph 5 (b) of the Doha declaration, left it for the Member Countries to adopt their own regimes of exhaustion and gave them ample freedom to identify the scope of exhaustion by leaving the term undefined.

One crucial issue in relation to the principle of exhaustion is its scope. Can it be interpreted to cover importation of products manufactured under compulsory licensing? Does importation of products manufactured in a country which does not allow patent protection to such products come within the purview of exhaustion? Since exhaustion is not defined under the TRIPS, the Member Countries enjoy the freedom to define it. If the flexibility is interpreted to its fullest extent, as expected under the Doha Declaration, it will permit countries having no manufacturing capabilities to use Article 31(b), which is procedurally much simpler than the waiver decision under Article 31(f), to import pharmaceutical products from generic manufacturers of countries having better manufacturing capabilities.

If products manufactured under compulsory licence are incapable of being exported, Article 31 (f) would have used a totally different language. The implication of Article 31(f) which states that compulsory licence should be predominantly for supply of domestic market to permit importing products made under compulsory licence, if it is mainly meant for the supply of domestic market. The word ‘predominantly’ is not defined, and it could encompass both quantitative and qualitative factors. For example, it might require that more than 50 per cent of the pharmaceuticals manufactured under the licence be sold on the domestic market (calculated by sale value or volume), or that the purpose of a compulsory licence cannot be to export it to a foreign country in need. In any case, this requirement means only that a relatively lesser portion of pharmaceuticals manufactured pursuant to compulsory licences may be legitimately exported to countries in need and lacking in manufacturing capacity. Exhaustion principle also covers situations where consent from the patent holder has been forcefully obtained.

Similarly pharmaceutical products manufactured in countries which do not extend protection to such products can be lawfully imported since such situations do not violate the exhaustion principle. In such situations, the products were never attached to any form of patents and therefore they could be imported just like any other goods.

The developed countries, in violation of the TRIPS Agreement and the Doha Declaration, often attempt to defeat the flexibility available with respect to exhaustion by seizing goods in transit between two countries which follow the principle of international exhaustion. This action also violates the ‘freedom of transit’ recognized under Article V of GATT. The impact of such seizure will be shocking if one considers the situations under which the importing country might have legally manufactured the generic drug. Such situations include lack of patent protection in a WTO Member for a number of reasons, such as, no patent were ever sought; patent has expired; a patent application was rejected because the claimed invention was deemed not to meet the criteria of patentability; the claimed invention did not constitute patentable subject matter under the law of the particular Member. If a generic drug company manufactures drugs under these situations and if it is seized while in transit from that country to another developing country which is in need of the drug, in a
situation when the exporting and importing countries follow the principle of international exhaustion it may have drastic consequences. Seizure in transit also affects other TRIPS flexibilities since if as the result of a high patentability standard fixed by a country, it rejects patents and the generic manufacturers’ goods are seized, it may have the impact of taking away the territorial nature of patent protection.

Between 2008 and 2009, Dutch, and on one occasion German, customs officials detained nearly 20 shipments of generic medicines, mostly from India, to destinations in Latin America, Oceania, and Africa. Abbot says that ‘Seizure of generic drugs moving legitimately in transit is a frontal assault by the EU on the object and purpose of the Doha Declaration’. He puts up scathing criticism against the European Union for disregarding the sovereign rights of foreign WTO Members by refusing to give effect to their decisions as to patent status.

Subsequent to the high rate of seizure in transit, Brazil and India have initiated dispute resolution procedures against EU at the WTO in 2010. However; EU appears to have resorted to bilateral arrangements with India to tackle this issue. On 28 July 2011, the Ministry of Commerce and Industry of the Government of India announced an ‘Understanding’ in principle with the EU concerning a pending WTO complaint challenging EU customs measures that had been used to justify seizures of Indian generic medicines in transit through Europe to destinations in Latin America, Oceania, and Africa. In exchange for these undertakings and as long as they are adhered to, India has assured the EU that it will not request the establishment of a dispute settlement panel at the WTO. However, India retains the option to revive the dispute if the EU does not abide by the core principles agreed to in the Understanding. Shifting of forum to reach at solution in these types of issues and the highly confidential nature of these FTAs make one suspicious and agree with Brook K Baker when he says that in the context of the present border regulation measures adopted by the EU, and the proposed amendments to it, India and Brazil should not suspend their WTO disputes against EU.

**Data Exclusivity and Patent Linkage**

The freedom enjoyed by developing countries to make use of other flexibilities in TRIPS also met with similar challenges. Other areas were the developing countries were pressed to follow a restrictive interpretation of TRIPS flexibilities related to data exclusivity, standard of patentability and the scope of subject-matter of patent protection.

Article 39.3 of TRIPS does not require Member States to provide exclusive rights to the originator of data but only demands protection of ‘undisclosed data’ against ‘unfair’ and ‘non-commercial use’. Therefore, it does not create a property right or a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair commercial practices are involved. Data exclusivity is an independent monopoly which provides for an additional period of protection, even where no patent exists, and the TRIPS Agreement does not envisage such protection. Providing protection to data exclusivity beyond what is required under the TRIPS Agreement may lead to ‘patent evergreening’ and can prevent entry of generic medicines even on compulsory licence. It may also confer monopolistic property rights for drugs which are not protected by patents, which will have drastic consequences on access to medicine.

According to Médicins sans Frontières, in Guatemala, generic manufacturers for most ARVs need to wait five years from the date of approval of the original medicine in the country before obtaining registration of generic medicine. In Jordan, an analysis of 103 medicines registered and launched since the signing of the US-Jordan FTA in 2001, found at least 79% have no generic competition as a consequence of data exclusivity introduced under the agreement. US and EU have shown a trend to include provisions relating to data exclusivity in bilateral or regional trade agreements.

Another tendency of the developed countries is to link patent protection to regulatory data and deny regulatory approval for generic medicines in cases where the originator medicines are still under patent protection. This also affects the access to medicine as the market approval is blocked till the end of the term of patent.

**Free Trade Agreements**

The small gains of developing countries in the Doha rounds of negotiations in the backdrop of mounting global public opinion may be one reason for the strong states like the US to opt for a safer forum to push monopolistic interests, at least, in the field of public health. Once again developed countries resorted to shifting of fora, this time from the TRIPS Agreement to bilateral or regional trade agreements. The new trend of FTAs are often meant to defeat the possible upper hand
of developing countries in a multilateral forum, especially related to highly sensitive issues like public health. FTAs are, therefore, resorted to since they are often not affected by the NGO pressure tactics. WTO negotiations were globally visible and transparent in ways that FTA negotiations are simply not. The free trade agreements that the US has negotiated since the Doha Declaration are rapidly eroding the gains of the Declaration for developing countries.

Though the Doha Declaration succeeded in safeguarding the freedom of the Member Countries to interpret TRIPS in such a way as not to conflict with their public health interests, it had a weak spot. It did not consider the possibility of agreements outside the TRIPS forum to defeat the objectives of the Declaration. Therefore, no steps were taken in the Doha Declaration to stop WTO members from entering into agreements, which may run contrary to the objectives of Doha outside the TRIPS forum. The FTAs make use of that flaw in the Doha Declaration and more often go TRIPS plus with respect to all freedoms guaranteed under both the TRIPS Agreement and the Doha Declaration. For example, in the Thai-US FTA, there are provisions which allow patent term extension, five years data exclusivity, patent-registration linkage, etc. The leaked EU-Ukraine FTA reveals much sweeping responsibilities are imposed upon Ukraine. Though Article 219 requires consistency with Doha Declaration on Public Health, the subsequent provisions reveal contrary intentions. Thus, the IP owning countries and pharmaceutical industries successfully make use of the fora of bilateral and regional trade agreements, where the other countries or the public have no space to voice their concerns, to promote their trade interests above the Doha objectives.

Conclusion
Pressure tactics practised by the developed countries at the instance of pharmaceutical industries, both inside and outside the TRIPS forum, promote trade interests rather than public health interests. Even the hard-earned small gains of the developing countries are continuously being thwarted by these methods. This reaffirms the inability of trade fora to handle public health, a basic human right which is to be protected by all members of the United Nations Organizations.

References
1 WT/DS/199, on 5 July 2001, in the consultation stage, the parties to the dispute notified to the DSB a mutually satisfactory solution on the matter.


4 The Doha Declaration on TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November 2001, paragraph 1 and 2. While recognizing the importance of IP for the development of new medicines, paragraph 3 also recognized the concerns about its effect on prices.

5 Paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health.

6 The report of WTO, WIPO and WHO on Promoting Access to Medical Technologies and Innovation (2013) at p. 171 notes that WTO members are free to determine the grounds for granting compulsory licences. Such grounds can include public interest in general and are not limited to public health emergencies.


17 Kerry Vanessa Bradford and Lee Kelley, Debate, TRIPS, the Doha declaration and paragraph 6 decisions: What are the

18 The imported drug, which was to be consumed by the patient for his entire life-time costs Rs 2, 80,428/- for a month therapy whereas the applicant for compulsory licence proposed to sell it at the rate of Rs 8800/- for a month therapy. The imported life-saving drug was available only in limited quantities that too, in pharmacies attached some hospitals in the metro cities like Chennai, Kolkata, Mumbai and Delhi.

19 USPTO criticizes India over issuance of compulsory licence, Do not trade our lives away, 16 July 2012, http://dontradeourlivesaway.wordpress.com/2012/07/16/uspto-criticizes-india-over-issuance-of-compulsory-licence/. The Deputy under Secretary of Commerce for Intellectual Property, United State, in a hearing before the US House of Representatives on 27 June 2012 condemned the Indian Government for issuing compulsory licensing for a patented cancer drug. She mentioned that US embassy is lobbying heavily with Indian officials to prevent any more Compulsory Licences in India.


23 George Tsai, Canada’s access to medicines regime: Compulsory licensing schemes under the WTO Doha Declaration, Virginia Journal of International Law, 49 (4) (2009) 1064.


26 Paragraphs 4 and 5(d) of the Doha Declaration, support such an interpretation, both because they aim at promoting the interests of developing Members in obtaining low-cost access to pharmaceutical supplies and because the countries are free to interpret the term ‘exhaustion’, Abbott Frederick M, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a dark corner at the WTO, Journal of International Economic Law, 5 (2) (2002), 469–505.


36 Article 221.3 tries to enhance the scope of patentability by including ‘Biological material which is isolated from its natural environment’, ‘an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene’, etc. Article 221.11 restricts the scope of compulsory licensing by listing down the situations in which it is possible to issue compulsory licences. Article 222.2 requires Ukraine to provide data protection to medicinal products for 5 yrs prohibiting generic manufacturers from relying on the data for obtaining marketing approval for their products. Article 250 allows parties to seize goods in transit if they are suspected to be infringing goods.