

## **TRIPS and Innovative Capacity of Bangladesh's Pharmaceutical Industry: Promotion of Access to Essential Medicine**

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***Abstract:** The WTO agreement on Trade- Related Aspect of Intellectual Property Rights (TRIPS) evolved some significant flexibilities in the Intellectual Property Rights on pharmaceutical product, especially regarding right of access to affordable medicine for the developing and least developed countries people as recognized in its Doha Declaration and in a related post-declaration decision. However, provisions of granting uniform character of pharmaceutical patents in all developing and least developed countries put forward a strong debate over the globe for ensuring access to essential medicine to the poorer section of the member states of the WTO. Though Bangladesh, as a least developed country, has extended time up to 2016 to implement the pharmaceutical patent complying with the provisions of the TRIPS, such flexibilities seem to be a great challenge especially for Bangladesh where local technological capabilities and developed infrastructures to produce generic version of medicine still in nascent stage. In this context, this article demonstrates whether, in term of socio-economical conditions of the developing and least developed countries, this Western-style of IP provisions, is suited for Bangladesh. This paper seeks to explore and argue that in the absence of a strong institutional innovative capacity and the local technical expertise, whether Bangladesh's pharmaceuticals sector can be able to supply marginal-cost substitutes of essential drug to other developing and least developed countries in the frame work of TRIPS flexibilities. To find out an effective and comprehensive solution this paper concentrates on the*

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*innovative capacity and competitiveness of the pharmaceutical sector and status of current pharmaceutical regulation and patent law in Bangladesh.*

## **1. Introduction**

The WTO Agreement on Trade- Related Aspect of Intellectual Property Rights (TRIPS)<sup>1</sup> introduced some significant flexibility in the field of Intellectual Property Rights relating to pharmaceutical products, especially regarding the rights of access to affordable medicine for the developing and least developed countries. These include compulsory licensing, parallel importation, and certain exception to the exclusive rights. However, the global harmonization of pharmaceutical patents protection across all WTO Members have given rise to a strong debate on access to essential medicines by the poorer member states of the WTO. This debate evolves around three issues, namely i) the barriers introduced by harmonization on reverse engineering opportunities for pharmaceutical industries in developing and least developed countries, including Bangladesh; ii) excessive drug prices and availability of affordable medicine; iii) and access to technology.

Developing and least developing countries are feeling tension for reasons that such TRIPS-style patent protection may harm their nascent pharmaceutical sectors and impair the access to affordable medicines by their citizens. Specially, while the WTO certainly benefits countries seeking large foreign markets access for their products, observers have been extremely concerned about TRIPS 'one size fit all' approach which ignores the heterogeneity of the world's population and the problems that confronts developing and least developed nations.<sup>2</sup> However at the Doha Ministerial Meeting<sup>3</sup> in November 2001 the members agreed that TRIPS can and should be interpreted in a manner supportive of Member's right to protect public health and promote access to medicine for all.

As a country with a LDC status in the WTO, Bangladesh has an extension to implement the TRIPS pharmaceutical patent obligations until 1<sup>st</sup> January 2016. This flexibility offers Bangladesh the opportunity to copy patented drugs for domestic consumption at affordable price as well as export them to other markets, especially to LDCs. Unlike many other LDCs, Bangladesh has a thriving domestic processing sector that are actively engaged in producing generic drugs along with Ready Made Garments (RMGs) and processed food

products.<sup>4</sup> While the base of Bangladesh's pharmaceutical manufacturing is strong, absence of an integrated approach to innovation and some structural constraints prevent firms from meeting global standards for price and quality competitiveness.

The domestic pharmaceutical market in Bangladesh is highly variable, protected from imports and has a weak regulatory mechanisms. In addition, several countries like India and China which played an important role as producers and exporters of generic copies of patented pharmaceutical products cannot produce such drugs anymore after 2005 except under the compulsory licensing system as per Art. 31bis of TRIPS and they are still considered extremely competitive in low-cost pharmaceutical manufacturing. Therefore, a strong debate concentrates on the issue whether Bangladesh's pharmaceuticals sector can gradually enable the supply of low-cost substitutes of essential drug to other developing and least developed countries. In this context Bangladesh's Department for Patents, Design and Trademarks and the Directorate of Drug Administration have an immense responsibility in order to explore this competitive advantage in a way that it is also preserved in the post-TRIPS era.<sup>5</sup>

## **2. International Legal Framework**

### **A) The TRIPS Agreement: Patent Regime and Access to Medicine**

The TRIPS Agreement establishes the minimum standards for intellectual property protection that WTO members must implement in their regimes and also provide their government with a number of tools to design domestic industrial property laws which are conducive to the promotion of access to medicines through importation and local production of drugs.<sup>6</sup> Article 7 of the Agreement explicitly mentions that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive social and economical welfare and to a balance of rights and obligations." Moreover, Article 8 further contemplates that "WTO members may, when implementing TRIPS rules adapt measures necessary to protect public health provided that such measures are consistent with the TRIPS Agreement." Reasserting their commitment to the TRIPS Agreement, members recognized that the agreement can and should be interpreted and implemented in a manner supportive of WTO member's right to public health, in particular, to promote access

to medicines for all.<sup>7</sup> Although Doha Declaration seems to have resolved the issue with access to medicines, there still remain major challenges for developing and least developing countries to interpret and implement the TRIPS Agreement and other related rules in manner supportive of their efforts to protect public health and promotion of access to medicines for all.

The authorization of LDC members not to enforce rights provided for under the TRIPS provisions implies that an LDC may choose not to grant product patents on Pharmaceutical until 2016.<sup>8</sup> The question arises as to what extent members taking advantages of the above mentioned transition periods have to comply with the ‘mailbox’ obligation under Art. 70.8 of the TRIPS Agreement.<sup>9</sup> This obligation refers a procedure through which a patent application can be filed and kept during the transition period by the WTO Members that do not provide patent protection on pharmaceutical products. For generic producers this may have important implications, as products they have used during transition period may become subject to a patent once the transition period expires in 2016. LDC members concerned may face some legal uncertainty, the degree of which depends on the design of their current domestic patents legislation and regulatory measures applied in order to alleviate the effects of patents that emerge from the mailbox.<sup>10</sup> This type of obligation is essentially adverse to the pivotal policy objective of the transition period that is extended to waive the TRIPS patent rules from acting as a restriction for LDC’s effort to protect public health.

The requirement under ‘mailbox obligation’<sup>11</sup> to initiate and follow an administrative procedure for examination of pending pharmaceutical patent applications after 2016 may entail considerable and administrative efforts and thus would burdens poor LDC’s health budget. Some stakeholders apprehend that it strain capacity of least developed countries to address those non-IP related infrastructural and healthcare bottlenecks that is an impediment to access to affordable medicines.

Moreover, Article 66.2 provides that “developed countries shall provide incentive to enterprises and institution in their territories for the purpose of promoting and encouraging technology transfer to least developed countries in order to enable them to create a sound and a viable technological base”. In reality, many developed countries are reluctant to fulfil this obligation. In the Doha Decision on Implementation-Related Issues<sup>12</sup> the mandatory nature of this requirement is re-affirmed,

directing the TRIPS Council to set a mechanism ensuring the monitoring and implementation of the obligation. Accordingly, all developed countries were bound to submit detailed reports on the performance in practice of the incentive they provide as to the direction and these reports are to be reviewed by the TRIPS Council annually.<sup>13</sup>

### **B) Tension between Patent Regime and the Right to Health**

Fundamental rights are playing a key role to protect the public interest in different segments of society. In addition to fundamental rights other rights must be highly respected including exploitation and enforcement of intellectual property rights. The TRIPS provisions on patenting and marketing process of pharmaceutical drugs introduce a conflict between pharmaceutical industry and the objective of ensuring sound public health issues relating to HIV/AIDS and other epidemic diseases.<sup>14</sup> Developed countries argue that strong intellectual property rights (IPR) protection is needed to promote innovation and to stimulate the development of new technology providing incentives through pharmaceutical patent protection. This kind of incentive for innovation would consequently encourage greater domestic and foreign investment in research on new pharmaceuticals and tropical diseases.<sup>15</sup> This argument lies on the rationale that developing and least developing countries in turn would benefit by those foreign investment and technology transfer.

On the other hand, developing countries claim that in the present situation of economic and industrial development the Western-style IP regulations do not fit the least developed and developing countries. One of the potential consequences of pharmaceutical patents is that the prices of essential drug will be increased and their availability for poor decreased.<sup>16</sup> Such negative impact of the pharmaceutical patent protection not only places the WTO least development countries in a disadvantage condition but also may cause injury to the non-WTO LDCs which depend on the imported cheap generic drugs.

In this situation the ability of least developed countries to access affordable and essential medicines varied in terms of their procurement method, local production capabilities, public health policies and available financial resources. The prime factors behind the limitations of supply are not of formal legal character rather depend on the reverse engineering capacities of generic suppliers and their pricing policies; on the availability of key Active Pharmaceutical Ingredients (API) on

the world market; on the pricing policies of the big pharmaceuticals companies and investment in R & D directed at diseases that primarily afflicted the poorer countries.<sup>17</sup> Despite these challenges the pharmaceutical industries continue investing in this sector and the main reason behind such big investments is probably for the provisions of patent protection.

The World Health Organization WHO, UNAIDS and different NGO have constantly raised their voice from the very beginning of the establishment of WTO about the negative effects of TRIPS on the availability of affordable drugs for epidemic diseases. In this relation, the High Commissioner of the UN Commission on Human Rights issued an elaborate document on 27 June, 2001 titled “The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights”. The document urges the WTO members to take full consideration of the human rights of the AIDS victims in their efforts to implement the TRIPS.<sup>18</sup> Similarly, it is also noted that the TRIPS Agreement impliedly tries to strike a balance between IPRs and Human Rights in non-conflicting manner as illustrated in Articles 7 and 8 of the Agreement.

However, there is a rare and unprecedented opportunity for less developed countries to reshape the intellectual property debate. The international intellectual property regime has expanded to cover issues that are covered by other international regime or fora creating some complexities. As a result of these complexities present international intellectual property regime is likely to harm least developed countries more than the developed countries.<sup>19</sup>

### **C) Doha Declaration and Public Health:**

Virtually since the TRIPS Agreement entered into force as part of the WTO in 1995, member states and interested observers have observed that some important uncertainties exist in the agreement regarding patent protection and access to life saving medicines in developing and least-developed countries. At the WTO Doha ministerial Conference in 2001 Members adopted a Declaration on TRIPs and Public Health restating and affirming the rights of the Member States to take measures to protect public health inserting Paragraph 6 to grant compulsory license.<sup>20</sup> Interestingly it did not completely resolve the debate over the patent protection in developing world and many of the member states could not effectively use the policy tool for public

health purpose due to insufficient or lack of manufacturing capacity in pharmaceutical sector as the TRIPS Article 31(f) conditions the issuance of compulsory license.<sup>21</sup> In response to these concerns the Doha Declaration on the TRIPS Agreement and Public Health acknowledged in para.5(b) the existence of flexibilities in the TRIPS Agreement with respect to the right to grant compulsory licenses and that each WTO Members has the freedom to determine the grounds on which such licenses are granted.<sup>22</sup> In this environment, Para.6 of the Declaration went on to recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.<sup>23</sup>

### **3. The Patenting Regime in Bangladesh**

In Bangladesh the patent protection is governed by the age old Patents and Designs Acts of 1911, as amended repeatedly, and the Patents and Designs Rules of 1933.<sup>24</sup> Patents protection can be obtained for both the process and product patent rights for pharmaceutical products. As a least developed country, Bangladesh is exempted from bring its patents regime into compliance with TRIPS by granting patent protection of pharmaceutical products until 2016. However, Bangladesh is obliged to have already in place a system of 'mailbox' applications for pharmaceutical product patents.<sup>25</sup> Moreover, Bangladesh is now working towards a gradual compliance with the TRIPS Agreement pursuant to a bilateral treaty with the EU that requires the country to amend it's to make them compatible with the TRIPS Agreement.<sup>26</sup>

As a result, the Department of Patents, Designs and Trademarks within the Ministry of Industry has drafted a new draft bill called Patents and Design Act, with the assistance of the World Intellectual Property Organisation (WIPO) that excludes pharmaceutical patents from patent protection and introduces the 'Bolar Provisions' and 'parallel importation'.<sup>27</sup> Until this new law will come into force, the patent protection regime of Bangladesh will be governed by the old legislation mentioned above which grants patent protection for a total of sixteen years calculated from the date of filling allowing a further extension of ten years.<sup>28</sup>

The current patents law of Bangladesh contains no specific provisions that enable firms to export to other least developed countries as per the

TRIPS flexibilities. One provision provides for the grant of compulsory license but the option has never been used as it is extremely cumbersome.<sup>29</sup> It is matter of hope that the new draft patent law will incorporate all the flexibilities relating to medical products in compliance with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. This new legislation is expected to be enacted next year.

#### **4. Present Pharmaceutical sector in Bangladesh**

As noted above, Bangladesh is exempted from the pharmaceutical patent protection prescribed by the TRIPS. On the other hand, it has limited exporting advantages to be used until 1 January 2016 as per the provisions of the TRIPS Agreement under the Doha Declaration of the TRIPS and Public Health. Bangladesh imports approximately 80% of its Active Pharmaceuticals Ingredients (APIs) for domestic production, 20-25% of which are patented.<sup>30</sup> Though Bangladesh can benefit from the advantages offered by the TRIPS flexibilities in the exporting of generic drugs, these advantages are not unfettered given the pace and competitiveness of the Indian and Chinese generic markets. Yet the objective of Bangladesh is to rely on the standard business practices to produce the highest quality products at the lowest price to compete on the international market of generics.<sup>31</sup>

However, Bangladesh enjoys some specific facilities in exporting medical products. Firstly, it can export to any country if the medicine is not under patent; secondly now Bangladesh can export to another LDC or non-WTO country that has not implemented product patent protection; thirdly, it can export to a country where patent holder has not filed for patent protection on the apprehension that sales and profit prospects are not up to the expectation; lastly export to a country that issued compulsory license and awarded the production contact to Bangladesh.<sup>32</sup> Interestingly, among the 49 LDC countries Bangladesh is the only country which has adequate manufacturing capability and a quasi self-sufficient pharmaceutical sector where firms are legally producing newly patented generic drugs. India and China on the other hand are no longer able to engage in this practice except under compulsory licensing as provided by Art. 31bis of the TRIPS.<sup>33</sup> Assessing the thriving local pharmaceutical industry and the export volumes over the years, it can be concluded that Bangladesh has the capacities to produce cheap generic version of patented medicines and supply them to other poor countries with no or low manufacturing



capacity. It therefore plays an important role in the promotion of access to essential drugs for public health.<sup>34</sup>

Bangladesh has a highly protected pharmaceutical industry coupled with a weak regulatory commission. The proper utilization of TRIPS flexibilities regarding the waiver of pharmaceutical patent protection until 2016 that Bangladesh could enjoy is almost depending on the nature, scope and potential of the domestic pharmaceutical industry of the country. Bangladesh currently exports a big portion of therapeutic and dosage forms of pharmaceutical products to about 72 countries<sup>35</sup> in Asia, Africa and Europe while Bangladesh's pharmaceutical industry caters to 96 percent of the country's pharmaceutical needs. Local total exports were estimated to amount to US\$ 28.12 million in the 2006-2007 fiscal years with a growth rate of 47 percent.<sup>36</sup>

Bangladesh Pharmaceutical firms generally engaged in branded generic final formulation of APIs in which 80% of the drugs are generics and 20% are patented drugs. In this context the country manufactures about 450 generic drugs for 5300 registered brands which have 8,300 different forms of dosages and strength.<sup>37</sup> Some reputed firms of Bangladesh are now investing to produce life saving drugs like anti-cancer, anti-retroviral drugs for the HIV/AIDS treatment and anti-bird-flue drugs.

Before the enactment of The Drug Control Ordinance 1982 local pharmaceuticals could provide only 20 percent of the total need. Because this ordinance incorporate a ceiling on selling imported drugs in the local market aiming at promoting self-reliance in its local pharmaceutical sector. As opposed to relying on the foreign companies for 75 percent of their drug supply prior to the Ordinance 1982, local firm now provide 82 percent of the Bangladesh market, whereas local subsidiaries of MNCs supply 13 percent and 5 percent of the drugs are imported.<sup>38</sup> It is thus noted that local firms are now in a dominant position in Bangladesh pharmaceutical sector. The top 30 to 40 companies dominate almost the entire market in which the top 10 hold 70% of domestic market share and the top two - Beximco and Square Pharma - capture over 25% of the market.<sup>39</sup>

## **5. Innovative Capacity and Competitiveness of Bangladesh's Pharmaceutical Industry**

The Local pharmaceutical firms of Bangladesh are however not well equipped and expert to perform the process of manufacturing APIs from scratch, except for very few firms which are able to perform certain steps in the process by using imported technologies. A survey shows that there is a huge deficiency in use of reverse engineering by pharmaceutical companies in Bangladesh which is observed from the investment scale in R&D over the year 2000- 2007 by the local firms. Indeed this lack of capacity reduces the local firms' competitiveness since a big portion of the production cost of drugs has to be allocated to securing APIs from external sources.<sup>40</sup> Bangladeshi pharmaceutical firms are engaged in manufacturing generic formulations by using process development for which the country has to import between 70 to 100 percent of machinery and other production inputs from external sources such as India, China, Italy, Spain, Germany and USA.<sup>41</sup> This seriously hampers the promotion of innovative and competitive capacities of Bangladesh's pharmaceutical sector.

Apart from this, absence of strong infrastructure support to conduct bioequivalence tests along with lack of biotechnological capabilities creates a great hurdle to such firms seeking to produce bio-generics or focus on exporting to regulated markets.<sup>42</sup> It is also presumed that disarticulation and weak level collaboration between university and public sector research and the enterprise sectors involved in R&D are considered as an impediment in playing an active role in the acquisition, use and application of knowledge to newer products. Though different public and private universities of Bangladesh are continuously supplying fresh graduate-trained pharmacists for quality assurance and quality control, they are not trained with the skills necessary for APIs.

In addition, other aspects such as availability of funds, laboratory facilities in pharmaceutical science and biotechnological research which create human resources and skills that can be used by the industry, are not sufficient for generating innovative and competitive capacity of the pharmaceutical sector in Bangladesh.<sup>43</sup>

National Drug Policy (NDP) 2005 enumerated that "another main objective of the NDP is to ensure self-sufficiency in all types of drugs. Therefore all necessary measures should be undertaken to ensure that the current trend of increased rate of local production of drugs is

sustained and further improved". Both foreign and domestic companies having manufacturing capacity are also permitted to conduct manufacture with domestic firms under the new National Drug Policy. Moreover, firms that achieved importing country's standard can also manufacture drugs for export purpose. Thus one of the main objectives of the New Drug Policy of 2005 was to enact a law supporting good manufacturing standard to promote safety and efficiency of drugs for the local market. Unfortunately, we still have no specific law prescribing good manufacturing practices (GMP) and bioequivalence facilities for the pharmaceutical products. As such, diversification of production and export to the global pharmaceutical market has not been enlarged as to the expectation.

Lack of coherent policy regime for the pharmaceutical sector to promote innovation as well as other industrial policy measures for technology transfer and investment are also liable for the difficulties faced by the local firms. Though the present Drug Control Ordinance of 1982 plays a positive role to the growth of the sector, the absence of a consistent strategic policy framework that could gear up a profitable and competitive trajectory traced out its deficiencies more effectively.

The ability of Bangladesh pharmaceutical industry to compete on the global market is not as strong as other country like China and India which are always one step ahead of Bangladesh in terms of technology, management skill, and backward and forward linkages.<sup>44</sup> Generally speaking, some factors such as manufacturing cost, production cost, rate of innovation, skills personnel, business environment and market are considered most basic pre-requisites for a pharmaceutical industry to compete in the international market. Unfortunately Bangladeshi pharmaceuticals are still far away to achieve those pre requisites to become globally competitive.

It is true that technology transfer and collaboration helps to develop formulation capacity in the local pharmaceutical industry. Although the new drug policy of Bangladesh prescribed for joint research and technology licensing between local and foreign firms, technology licensing to local firms is found in very rare cases and is not a contributor to innovative efforts in the existing local pharmaceuticals in Bangladesh.<sup>45</sup>

## **6. Potential Mechanism to Address the Challenges in Bangladesh Pharmaceutical Industry**

The TRIPS Agreement has received special attention in the context of pharmaceutical sector of Bangladesh and pharmaceutical patents since Bangladesh is not obliged to make pharmaceutical patent protection in pursuance of extended transition period until 2016. If the local firms are evolved as a producer and exporter of generic version of brand patented medicines at globally competitive rates Bangladesh pharmaceutical industry could potentially provide low-cost generics of patented drugs to other developing countries. In principle, these underserved markets in developing and least developing countries represent export opportunities for Bangladesh producers and create an incentive for domestic and foreign investment in Bangladesh to promote access to affordable medicines for global public health.<sup>46</sup> In the case of Bangladesh it is more obvious that relevant and effective institutional framework and incentives within the pharmaceutical sector in the country might work as a tonic to improve the innovative capacity and competitiveness. Hence, under the current regime, concerted policy efforts are immensely needed to build up science, technology and innovation institutions for economic development leading to export-oriented market incentives for pharmaceutical industry.

However, in order to export essential drugs to regulated market policy should be framed urgently for the formulation of GMP compliant standard for the pharmaceutical sector and establishment of bioequivalence laboratory within the country. Besides, technical assistance to ensure and enhance the capacity and performance within the regulatory agencies of the Department of Patents, Designs and Trademarks and the DDA for regulatory compliance and for other services so that Bangladesh might cope with the challenges of the post-TRIPS regime. Furthermore, strong government supports but not subsidies, like India and China, is needed for the domestic pharmaceutical industry which are generally export-oriented. For instances setting up pharmaceutical park, supporting research and innovation, encouraging foreign firms to invest in Bangladesh, encouraging exports, tax incentives and so on.

At the same time, to be successful, strategy should also include assistance to boost the capacity building of the local intellectual property office in order to be able to develop a database for recording patent applications and granted patents as well as ensuring

transparency and accountability. Policy assistance to set up common industry infrastructure should focus initially on the setting up of the API Park on priority based and starting construction is vital as the TRIPS' 2016 deadline nears.

Lastly, to strength the performance of the pharmaceutical sector of the country an integrated approach to innovation and coordination between different components is needed that pave the way for the development of the workforce, skills and technical resources of relevant sectors.

### **Concluding Remarks**

The TRIPS exemptions offer potential opportunities for boosting exports that would ensure access to affordable medicines for global public health, but these are limited, time-bound, must be undertaken in a very competitive environment, and need significant investments by both government and industry over a short period of time. As well in every prospective export market, it would be necessary o determine issues like what are the patent rights for particular drugs that Bangladesh producers interested in exporting to the market and what competitors are able to sell into or produce in that market. Bangladesh has deserved some important macroeconomic factors along with pharmaceutical manufacturing success but not all. Even though there are other factors affecting the price of pharmaceutical products it is inevitable for Bangladesh to articulate a proper patent regime by 2016 that best reflects flexibilities afforded Bangladesh under TRIPS. Prior to the end of 1<sup>st</sup> January 2016 permi, there is very little to be achieved for Bangladesh by moving to full patent protection for pharmaceutical products. In this environment Bangladesh therefore, needs to strategically consider how to approach the potential advantages of TRIPS and should utilize this short-time opportunity to build long-term successful business with post-2016 in mind, when Bangladesh will have to compete on the global marketplace. At the same time, a focus on creating local expertise, strengthening innovative capacity in a way that is consistent with affordable access to medicines has important benefit of its own in term of investment, employment and technology transfer.

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