

## LAW IN-DEPTH

# On revocation of mailbox for pharmaceutical patents

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Nobel laureate Joseph Stiglitz in his book *Making Globalization Work* showed that the international pharmaceutical patents law, the WTO Agreement on the Trade related aspects of Intellectual Property Rights (TRIPS) 1994, was framed against the interest of the developing and least developed countries (LDC). However, a few flexibilities were consciously inserted in the Agreement to ensure that ideological dissenters of the agreement would not otherwise lose out in the negotiations in the deeply divided world. Notably, Bangladesh is seemingly unaware of (or at least less concerned about) these flexibilities in international law in order to protect public health by ensuring access to



required of the LDCs to have a mailbox for storing patent applications with Exclusive Marketing Rights (EMR) for pharmaceutical products starting from 1 January 1996. Later, through several decisions from the TRIPS Council, the obligations of the LDCs were waived in phases at different stages. Prime Minister Sheikh Hasina played a crucial role in propounding the latest grant of waiver. In the 64<sup>th</sup> World Health Assembly she advocated for another waiver period for the LDCs. Her bold stand was subsequently followed by a successful formal request to the TRIPS Council on behalf of the LDC group. As the TRIPS currently stands, the obligation of the LDCs to protect pharmaceutical patents including the 'no roll-back' clause have been waived until 1 January 2033 or the graduation of the LDCs to Developing Country

status, whichever is earlier. It means that even countries with existing patent regimes are not only waived of their obligations to grant patent protection but also that they could provide for lesser to no protection than they previously had provided.

Due to its colonial legacy, Bangladesh had been granting product and process patent since 1911 until when the National Drug Policy 1982 disallowed product patent. In the post TRIPS era, the waiver for the LDCs was followed by a prohibition of process patent in 2002 by a notification in the Official Gazette of Bangladesh. In 2007, the Government of Bangladesh issued a questionable executive Order establishing a mailbox which is still storing applications in the mailbox. Professor Mohammad Towhidul Islam in his book *TRIPS*

*Agreement of the WTO: Implications and Challenges for Bangladesh* shows that the establishment of a mailbox by a mere executive notification was beyond the limits of the then government in 2007. Such an opinion is justified on the ground that the Patents and Designs Act 1911 did not give the government power to establish a mailbox. To establish a mailbox, it would have required a legislative enactment. Thus, the mailbox provision goes beyond the tenets of the law. However, the 2015 waiver in international pharmaceutical patent law permits Bangladesh to entirely revoke its mailbox making the submitted applications null and void.

The rationale of an anti-mailbox campaign in Bangladesh is that under the TRIPS Agreement, in cases of mailbox applications, if patents rights are granted after the transition period, they shall come to effect from the date of filing of the application. Very recently in July 2019, Brazil Federal Court of Appeals ruled that Mailbox Patents shall be granted with the validity date of 20 years from the date of filing, resulting in a retrospective effect given to the operation of patent rights facilitating infringement suits for past production of generic drugs. Bangladesh is one of the largest generic medicine producers of the world fulfilling 98% of its own needs and the only LDC in the world that has pharmaceutical manufacturing capacity. Around a fifth of drugs produced in the country is patented in other countries and rest of the manufactured medicines are those the patent protection of which have been expired. All the received

applications in the mailbox shall be burdensome for Bangladesh in the long run if proper steps are not taken immediately. Because the day Bangladesh graduates from LDC status, all the generic medicine manufacturer companies shall be sued for their past infringement of patent rights and they will be required to immediately suspend such production. Being forcefully stopped to manufacture generic medicines and being sued for past production thereof shall bring a disastrous impact on the public health and economy in general of Bangladesh.

Moreover, the increase of medicine price due to such legal proceedings shall result in losing out export business of these pharmaceuticals. The revocation of the mailbox in its entirety would result into no suits for infringement of patent rights during the pre-graduation days.

For long Bangladesh seems to have been unaware about its approach to international law with regard to the protection of public health and pharmaceutical industry. As a result, the country seems to have taken additional international obligation on itself without being required to do so. In the context of Bangladesh's booming economy till Covid 19 outbreak, the rapid progress of Bangladesh towards attaining a developing country status, Bangladesh now needs to use all the impending flexibilities of international law at hand to safeguard its citizens' public health and to ensure smooth growth of the pharmaceutical industry of the country.

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The TRIPS Agreement requires the member states to provide patent protection for both pharmaceutical products and processes while the Least Developed Countries are waived of such obligation. It was initially

## LAW OPINION

## Digitising the NGO Affairs Bureau

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In the context of Covid-19 pandemic, it is evident that governments worldwide have to adapt to unconventional methods and ensure the incorporation of technology in the workplace. Digitisation has become not just a call of the time, but a need for a sustainable development of the economy. The world at large, even after the lockdown measures adopted by countries come to an end, will have to adapt to a 'new normal'. This vision of a 'new normal' for businesses across the countries predictably includes the need to be able to produce deliverables with the help of technology.

While the policy and regulatory framework of most developing economies have not yet adapted to an ideal model of e-governance, the government of Bangladesh has been proactive in the last decade in digitalising the government and non-government sectors, with major investments in high tech parks, establishment of data centres, etc. In light of the Hon'ble Prime Minister Sheikh Hasina's 'Vision 2021' of establishing Bangladesh as a middle-income country at the 50 years of independence, the dream of 'Digital Bangladesh' began to take shape. Several regulatory and legal reforms in the last decade have paved the way for crafting adjustment towards the new normal, by further digitising government and non-government institutions.

With this end in view, it is necessary for the government to immediately take measures to digitise the registration process of the Non-Government Affairs Bureau (NGOAB). Owing to the complex procedure and an influx of Non-Government Organisations (NGOs) in Bangladesh to rehabilitate the Rohingya refugees, there has been a severe backlog of registration, with an average registration taking much longer than the stipulated time (which is supposed to be approximately a period of 5 weeks), and this backlog is expected to get worse with the Covid-19 pandemic.

The contribution of the NGOs in Bangladesh since its inception in 1971 has been significant, with national and global assistance working in harmony to ensure poverty alleviation, healthcare and education, and expediting the process of relief and rehabilitation as a response to all the natural disasters that have hit Bangladesh over the years.

While it remains the State's responsibility to work for the welfare of the citizens during the pandemic, the NGOs can play a significant role in rendering support to the State for reaching

out to the vulnerable and affected people. In this regard, the State needs to facilitate the infrastructure necessary for the NGOs to operate effectively.

While it is evident that the poorer countries have been unable to adopt to the stringent, smart and systematic use of technology like the developed ones, the crisis has in itself presented an opportunity for these countries to adopt bold measures in incorporating the same in their forms of governance. The fruits of this modification, while accrued to address the need of the current time, could eventually outlast the crisis period, and serve the countries in the future.

This pandemic has revealed several layers of fault lines in the system, highlighting particularly the need for a collaborative approach between public and private sectors to ensure basic human rights. While the inertia created by bureaucratic regulations was initially prevalent, the government was expeditious in realising the need to act quickly during the pandemic. As such, approvals were being given online during the early stages of Covid-19. However, with government offices re-opening, there is a likelihood for the system in general of going back to the old practice of inviting hard copy applications followed by lengthy approval procedure. It is important that we carry forward the good practices established during the pandemic and make use of our existing technological framework to ease the functioning of NGO ecosystems.

Sections 19 and 20 of the Foreign Donations (Voluntary Activities) Regulation Act, 2016 provide power to make rules and pass executive orders when necessary. Therefore, the NGOAB can issue an internal notification/circular setting out the steps for digitisation as the 2016 Act itself provides the platform for digitisation of the registration system. Furthermore, in a crisis situation like Covid-19, special notifications easing the requirement to complete the registration process could be waived temporarily, allowing all international NGOs to function without impediments.

It is imperative for the government to realise that technology, perhaps, is the strongest weapon readily available at our disposal to fight the pandemic. This is also in symmetry with the government's vision of a Digital Bangladesh. Every crisis is an opportunity. We must utilise this opportunity to bring about drastic regulatory changes which will outlast the present crisis.

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## REVIEWING THE VIEWS

## Evaluation of factoring rule of Bangladesh Bank

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Bangladesh Bank (BB) issued a circular on June 25, 2020 allowing factoring in Bangladesh. The Government of Bangladesh has not yet ratified the UNIDROIT Convention on International Factoring (Ottawa, 28 May 1988). Factoring is a trade finance product. The rule of factoring issued by BB mostly focuses on recovery of export proceeds but not full factoring services such as export trade finance. It does not have details of other issue of probable disputes and dispute resolution methods. Furthermore, the circular is silent about single factor or two factors methods.

The traditional bank finance relies on security of mortgage, but the factoring does not require such mortgage of fixed assets and others. A trend has recently started of accepting receivables as collateral, but mostly as supplementary securities. This trend has left many of the SMEs struggling to get funding in the absence of hard collateral and has created a strong basis for development of factoring in the market.

Factoring as per circular has some probable challenges. As per Gazette Notification issued under Section 12 of Foreign Exchange Regulation Act (FERA), 1947, export proceeds must be repatriated within four months of shipment. Factoring is a kind of short-term loan up to 180 days. The Foreign Exchange Regulation should be amended in order to get optimum benefit of this financial product.

The scope of factoring reflects in the definition of the UNIDROIT Convention. It states that the factoring is traditionally associated with functions beyond pure financing to include collection of receivables, debtor management, and protection against default by debtors.

The guideline of international factoring prepared by technical committee and adapted by BB in the rule referred that, -- in factoring, 'invoice' is the only document that gives right to the debt. Section 6 of the circular mentioned that Authorized Dealers (Ads) might allow 'transport documents' to be issued in accordance with underlying arrangements among the parties. It is conflicting with the guideline of technical committee of BB. The circular is silent about single factor or double factors methods although the guideline of BB stated that the assignment of the invoice gives the right to the import factor to recover the money from the importer, which in turn enables import factor to provide the guarantee to the export factor on behalf of the importer. This guarantee is what enables export factor to advance funds to the exporter at



the post shipment stage. It may be presumed that BB will allow single and double factors to provide the services. The rule recognises the designated institutions which are international factoring companies/foreign banks/foreign financial institutions/trade financiers/insurance entities, but historically the insurance companies are not in this finance trade anywhere in the global market and their law does not permit such trade.

Factoring service has many risks in its operation. Commercial risk represents the risk of disputes between the assignor and debtor. The others are performance risk of the exporter and credit and payment risk of the import factor. The other generic risks include defective/false/fake invoices, direct payment by the importer to exporter in spite of assignment of receivables and not to routing all invoices of exporter through the factor. Fraud risk represents the risk of factoring "fresh air" invoices or pro-forma invoices, which are not based on an actual delivery.

There may be documentary risk represents the risk that the receivables or the assignment may not be properly prepared and hence in the event of enforcement procedure the factor may have collecting difficulty. There are many operational risks which represent the risk of human operational error and can be mitigated through minimisation of manual work with the implementation of high end software for managing the factoring transactions, and by applying the four-eye principle. Most importantly, the relevant market risks of volatile foreign exchange and the interest rate risk.

To face those risks and smooth functioning of factoring, several global institutions have been established which support, promote and facilitate factoring activities: Factor Chain International (FCI) and International Factors Group (IFG) and others.

The scope of their activities includes receivables financing, such as promoting best practices on developing markets, training staff in specific skills, as well as participating in the synchronisation of the global legal practices and improvement in the business environment. EU Federation for the Factoring and Commercial Finance Industry (EUF), is the representative body in the EU, acting as a platform between the factoring and commercial finance industry and key legislative decision makers across Europe.

In order to mitigate the risk of the service, the FCI issued (a) the General Rules for International Factoring (GRIF), (b) the edifactoring.com Rules, and (c) the Rules of Arbitration. These rules constitute the basic framework governing co-operation between members and these rules define the rights and obligations of the parties to transactions under the two-factor system. However, the United Nations Convention on the Assignment of Receivables (UNIDROIT) and the UNCITRAL Legislative Guide on Secured Transactions are two important instruments for better factoring services. All those apply to international factoring, and govern the legal principles related to the effectiveness of assignments, the rights and obligations of the factor, the assignee and the assignor, and the subsequent assignments.

Bangladesh should consider ratifying UNIDROIT Convention to facilitate the factoring services. Bangladesh may consider having a law on factoring services. BB should clarify the issues related to general rule of factoring, effective communication with edifactoring and arbitration in order to resolve the disputed and smooth transaction of factoring in domestic and international trade.

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