

## **Consistency of Bangladesh Patent Law with TRIPS**

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### **ABSTRACT**

Bangladesh has recently achieved impressive advancement in social and economic performance. At present, it has to be exposed to innovation friendly governance and uplift its impression as a good custodian of IPRs to attract more foreign investment. Like many other areas, it is suffering with policy deficiency, as well as enforcement lacking, in IPRs regime. But as a signatory of the WTO, it has to be compliant with TRIPS. So, a hundred years old British colonial patent law is under questions of fitness with international standard and it is undergoing revision process. Policy options are required to be scrutinized to keep balance between international obligation and national interest i.e., economic implication of the patent law provisions. This paper tries out with some of such important issues of existing patent law of Bangladesh in light of TRIPS obligations and flexibilities.

### **INTRODUCTION**

#### **Background of the study**

Bangladesh has achieved considerable social gains and fairly impressive economic performance in the past decade that indicates its enormous potential but it continues to remain as a development paradox as these achievements were made despite poor governance, an adverse domestic political environment, a lack of infrastructure and repeated natural calamities. As a leading least developed country (LDC) with high potential and remarkable economic progress, Bangladesh, is facing so many crucial challenges to move towards development that push aside the Intellectual Property Rights (IPRs) from becoming a priority for any corner of the society. So, the key issues related to Intellectual Property Rights have either been addressed only partially or left unaddressed. Signing to the international treaties including the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has obliged Bangladesh to rethink about its Intellectual property laws, particularly the patent law. Reformulation process of the patent law is passing through paradoxical situation because of divergence between fulfillment of the international obligations and reluctance or unawareness of inventors' society, business community and policy makers about the

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importance of IPRs as well as inadequacy of specialized and skilled professionals. IPR remains a hard to understand subject to almost every corner of the society. The limited number of patent applications by the residents (WIPO 2013), patent authority with very limited qualified staffs, few countable academic publications on patent law, very few number of specialized IPR attorneys and few number of IP litigation, weak demand side of IP learning and unavailability of IP knowledge providers are the indicators of this unawareness and reluctance about IPR. This may not be an identical fact for Bangladesh only but also similar or even more deter for other LDCs. The patent data and availability of academic literature can be used as proxy indicator for understanding the IPR regime of LDCs. The availability of literature on IPRs of advanced economies is huge and for developing countries it has been increased over last two decades, but, literature on IPRs of LDCs is comparatively still very limited. However, considering the international obligation to be TRIPS compliant the exercise on the policy options of the patent law of Bangladesh and derivation of their economic implications are deemed necessary not for only Bangladesh but for the other LDCs of similar condition.

### **Objective and Importance of the study**

This paper deals with two folds of specific objectives:

- i. Develop a check list which can be useful for least developed countries to diagnosis their national patent law to make it TRIPS compliant.
- ii. Analysis of patent law of Bangladesh to make it TRIPS compliant.

As a LDC, Bangladesh is enjoying the transition period to be TRIPS compliant. The deadline of the transaction was initially granted until December, 2005. After that it has been extended for three times and lastly on June 11, 2013 WTO members agreed to extend the deadline of the transition period for the LDCs until July 1, 2021 to be compliant to protect the IPRs in accordance with TRIPS agreement. It is vital for the LDCs, like Bangladesh, to utilize the transitional periods properly to update their patent law regimes and other supporting governmental policy options so that after the expiration of the transitional period, LDCs can be able to balance pharmaceutical innovation and access to medicines (Azam 2014). For optimum utilization of this transition period requires rigorous academic exercise and cross disciplinary discussions on patent law to open up the options and probable socio-economic implications of the options. This paper attempts to add some of the essential notions to the ongoing exercise and discussion on patent law of Bangladesh.

## **LITERATURE REVIEW**

By using standard search options a few books, articles and reports are found about patent law of Bangladesh. The literature on IPRs of Bangladesh is not even so large. All most all the available relevant literatures on patent law and TRIPS based on the national context of Bangladesh were reviewed. The academic and official exercises on rethinking about the IP regime, inherited from colonial era, are observed after signing of TRIPS agreement. The process of knowledge accumulation may be initiated earlier but the literatures on patent law of Bangladesh are available only since beginning of this century. In 2003, a report of law commission (Afzal & Sadeque 2003) proposed to substitute the prevailing Patent and Design Act, 1911 by enactment of a new law instead of suggesting amendments to that Act. This report also contains a draft of the proposed new law which is seemed to be influenced by both EU and US legislations. For example, it mentioned 'inventive step' as a patentability requirement but it include manufacturing process as a subject matter of patent. In the same year, a leading think-tank published an occasional paper that discusses linkage between international IP regime and importance of patent protection for local pharmaceutical industry of Bangladesh, policy options for Bangladesh IP laws for optimizing gain from the mentioned industry to be TRIPS responsive and suggests pre-2016 and post-2016 strategies as the transition period was scheduled to be ended by 2015 (VanDuzer T 2003). This paper also recommended higher patent protection, such as, limiting breadth of patent claims, high thresholds of novelty and inventive step, high level of patent disclosure, strong compulsory licensing.

Afterward, the issue relating, TRIPS obligations and the pharmaceutical industry of Bangladesh, had dragged the attention of the researchers and number of literatures are published on it which covers various aspects ranging from firm level commercial potentials under IP protection to the overall innovation capacity of the industry (Sampath 2007), (Azam and Richardson 2010), (Chowdhury 2011), (Royhan 2013). A book, 'TRIPS Agreement of the WTO: Implications and Challenges for Bangladesh' covers various aspects of implication of the TRIPS in Bangladesh including agriculture, public health, economic development and the way forward (Islam 2013) Earlier, an article named 'an overview of Protecting Intellectual Property rights in Bangladesh' cover a brief description on the related issues (Naznin 2011). Bangladesh has been included in a regional comparative analysis, of patent intensity, with India, Pakistan and Sri Lanka (Jana T *at el* 2014).

Two recent reports namely 'Draft Report on Developing National Intellectual Property Policy for Bangladesh: An assessment of National Intellectual Property System' and 'Draft Report on Innovation and Intellectual Property Policy and strategy for Bangladesh' have accommodated almost all the background information related to IP law and IP system of Bangladesh.

But, relatively a few academic exercises are available, particularly, on the specific provision of patent law of Bangladesh. 'Globalization Standard of Patent Protection in WTO Law and Policy Options for the LDCs: the Context of Bangladesh' is an exception which is a publication of the recent time and can be considered as a foundation block of the legal academic literature that provides specific suggestion on various provisions for the restructuring of the patent law of Bangladesh (Azam 2014).

In addition to these, various reports of World Intellectual Property Organization also provide useful guidance in understanding the issues related to Bangladesh patent law.

### **Existing IP legal framework of Bangladesh**

The existing IP legal framework of Bangladesh is evolved from its early 20<sup>th</sup> century foundation of British colonial era. However, some new laws have been enacted and old ones under gone through few amendment processes. Bangladesh patent regime is governed by Patent and Design Act, 1911 (date of effect: 26 March, 1971, the date of Independence) and Patent and Design Rule, 1933 (Uddin 2014).

### **Development of Patent law in Bangladesh**

The Patents and Designs Act, 1911, is the law in force in Bangladesh on patents and designs which was enacted in 1911, during the British colonial age, along with other provinces of Indian sub-continent, mainly on the basis of the principles laid down in the British Statute of Monopolies, Patents, Design and Trade Marks Act, 1883 and Patents and Designs Act, 1907.

The laws relating to patents and designs have, therefore, been consolidated in a single enactment in Bangladesh, namely, the Patents and Designs Act, 1911. The Act is divided into three parts. In part I laws relating to patents, in part II laws relating to designs and in part III general provisions have been included. In some countries, two separate acts prevail for patents and designs respectively. In India, a separate Patents Act was enacted in 1970 and the provisions relating to designs continue to be governed by the provisions of the Patents and Designs Act, 1911, and for the purpose suitable

amendments by way of omission, addition, substitution etc. were made in the Patents and Designs Act, 1911, by the Patents Act, 1970 (Act 39 of 1970).

The law commission report in 2003 opined that it would be convenient to keep the provisions relating to both patents and designs in one enactment as in the present Act. If the provisions relating to patents and the provisions relating to designs were made in a single enactment, the administering authority who would enforce the provisions relating to both patents and designs, would feel convenient if the authority found the provisions relating to both the matters in a single Act rather than in separate Acts (Afzal and Sadeque 2003).

Since enactment of the Patents and Designs Act, 1911, the concepts of patents and designs have undergone enormous development through decisions of courts around the world. In addition, a large number of international conventions have been adopted recommending enactment of uniform laws on intellectual property including patents and designs. The attempt for up gradation of law has started on 2003 but it is yet to be finalized. Bangladesh continues with (essentially) the inherited British law. A few minor amendments have been enacted such as the establishment of Department of Patent Design and Trademarks (Azam and Richardson 2010).

### **Features of current patent law in Bangladesh**

According to the current patent law, a patent application is required to be accompanied with either a complete or provisional specification. If an applicant applies with a provisional specification, a complete specification is required to be submitted within nine months. If not, after a period of ten months the application is deemed to have been abandoned. A complete specification is required to include following particulars, such as: The name and address of the inventor, the title of the invention, an abstract or summary of the invention, a description of the invention, the process of invention with drawings and a claim or claims defining the scope of the invention for which protection is sought.

The application is then sent to an examiner for examination. The examination will trigger one of three outcomes: (1) the specification is correct and the invention is patent-worthy, or (2) the specification is not reflected any new invention and is rejected, or (3) the specification is accepted with modification or amendment. If the examiner raises no objections, the specification is published in the Gazette. Interested parties may raise objections within four months.

Importantly, in 2008 the Department of Patents, Designs and Trademarks suspended the patenting of pharmaceuticals in Bangladesh until 1 January 2016 in accordance with the Doha Declaration. The Department's notification provides that applications relating to patents for medicines and agricultural chemicals will be preserved in a 'mail box' and will be considered after January 2016 (Azam and Richardson 2010). But this notification is yet to be incorporated in the text of law.

### **Bangladesh under TRIPS obligation: consistency of Bangladesh Patent law with TRIPS**

As a signatory to the TRIPS, Bangladesh is now in transition period for meeting the compliance deadline. However, it is pre-loaded with certain IPRs laws. Almost all of them are taken to serve the trade liberalising agenda and for protecting IPRs owners' interests, since they provide for similar treatment to IPRs owners irrespective of their country of origin. The IPRs laws in Bangladesh also contain broad terms for the extension of IPRs protection to any improvement or modification (Islam 2013). Bangladesh is under going through a process of amending of old IPRs laws as well as enactment of new IPRs laws. However, in this process of changing and enactment of such laws, the classical argument of principle of public interest, the application of the principle of balance of rights and obligations was adopted with the lock of the consistency test. As worded in TRIPS Article 8.2, any measure taken under the umbrella of this article must be "consistent with" the provisions of the TRIPS Agreement (Azam 2014). Some of the important legislative options for patent law of Bangladesh, such as, subject matters eligibility, disclosure requirement, duration of patent protection, provision for parallel import, provision for compulsory licensing, pre-grant and post-grant oppositions, are examined in the following discussion:

#### **Patentability: subject matter eligibility**

Article 27(1) of the TRIPS requires that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The agreement however allows a certain freedom of interpretation to members in respect of what constitutes an "invention", and how the requirements of novelty, inventive step and industrial applicability are determined (Thorpe, 2002). According to the existing Patent law of Bangladesh, any invention is patentable and the invention is defined as 'any manner of new manufacture that includes an improvement and an alleged invention. About subject matter eligibility, the TRIPS provision is not entirely clear and provision of existing patent law of Bangladesh has no direct conflict with TRIPS but it is very

ambiguous and difficult to understand its meaning. BD P&D Act, 2011, allows patent of both product and process, in legal text it is written 'patented article or process' but does not lay down any specific criteria of patentability of an invention nor even define the 'process'. Though it is not a compliance issue with TRIPS but still it is very important to define the process and its concept with business method. Specially, as the patentability of business methods is a debatable issue among the dominant jurisdictions of the present time (eBay Inc. v. MercExchange L.L.C. 2006 Ct. 1837, 2006) and (Kennedy, J., and Alice Corp. v. CLS Bank International 2014) The debate of patentability of business methods also include the question of patentability of software but there is no mention of patentability of the software in the existing patent law of Bangladesh whereas it is very important issue for the sharply growing Information and communication sector of the country.

TRIPS Art. 27(3)(b) provides that Members may exclude from patentability: plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Alike software, there is no mention of patentability of genetic resources, plant or plant variety in the existing patent law of Bangladesh. But these policy issues have to be noticed for intensive exercise and implication analysis as Bangladesh economy has a traditional high dependency on agricultural sector. TRIPS does not contain any specific provisions concerning the patentability of inventions consisting of genetic material such as DNA sequences. Bangladesh may exclude such inventions by, most likely, rely on the morality exception of Article 27(2).

### **Patentability: need for rephrasing the definitions (of novelty, inventive step and industrial applicability)**

To set the required level of the patentability, the meanings of 'Novelty and Inventive step' have to be clearly defined. In the existing patent law of Bangladesh, the term 'novelty' is not used but it is expressed with the term 'new' but there is no clear indication of 'globally' or 'territorially' new. Neither the term 'inventive step' nor 'non-obviousness' is used as a patentability criteria in the law under scrutiny but only once the term 'inventive step' is used in the section of petition for revocation of patent. In this context, TRIPS requires merely that inventions for which patents are sought should be new. The Agreement does not however define how the novelty of an invention should be assessed and in particular what constitutes the prior art against which this criteria is determined (Thorpe 2002). Though it is not a direct question of compliance with TRIPS but, no doubt, it is a fundamental issue that has to be decided under legal

provision of the patent law of Bangladesh. Most of the scholars opine for global novelty and higher inventive step. There is no counter argument about the novelty but for deciding about the inventive step suggestion can be made in favor of lower inventive step, as both the local innovation capacity and the number of filing of the patent is low in Bangladesh. Lower inventive step seems to be more supportive to the growth of local SME sector as well their attachment in the IP regime. More of those, absence of provision of utility model within the patent law also create argument in favor of lower inventive step.

### **Disclosure requirement**

TRIPS Article 29 specifies the requirements that may be imposed on patent applicants. These include the requirement to 'disclose the best mode' for carrying out the invention as well as providing information concerning corresponding applications and grants. The patent law of Bangladesh, does not uses the term 'disclosure requirement' but strong procedural steps are described to provide the 'specification of the invention'.

To be TRIPS compliant the disclosure requirement has to be on best mode, but a relaxation is observed in American Invent Act, 2011 which is a recent adaptation of major initiator of TRIPS agreement. So, requirement of level of disclosure can be rethought up to a certain completeness of understanding of the specification as ensuring best mode is not always practically applicable.

### **Duration of patent protection**

The existing patent law of Bangladesh, allows patent protection for 16 (sixteen) years from date of filing, whereas, TRIPS Article 33 specifies the requirement of the term of protection as not less than twenty year counted from the date of filing. So, to be TRIPS compliant, Bangladesh should extend its legal provision of minimum term of protection to 20 years from 16 years. It is mentionable that, in Bangladesh, though the term of protection is limited to 16 years, but still there is a provision for application of the extension of the term of protection least six months before the time limited for the expiration of the patent. The petition for extension of term of protection can be disposed of by the patent authority or even can be sent to High Court Division decision.

### **Provision for parallel import**

The existing patent law of Bangladesh does not say anything on parallel importation, whereas, this issue is a subject to Article 6 of TRIPS which states that nothing in [TRIPS]



shall be used to address the issue of exhaustion of intellectual property rights. A WTO Member therefore has a degree of freedom in choosing the exhaustion of rights regime to apply in the patent field. So, this is a neutral provision. It does not impose any exhaustion regime (national, international or regional) leaving countries free to adopt the system that best suit their needs. The same open scope is reiterated in para.5(d) of Doha Declaration on the TRIPS Agreement and Public Health. But this self deciding scope is seen as a result of a compromise between countries supporting a national exhaustion system (namely industrial countries) and supporter of international exhaustion and parallel import, e.g. many developing countries and least developed countries and net importers of IPR-protected goods (Bonadio E 2011). Bangladesh has to utilize the TRIPS flexibility and, as a least developed country with cheap labour services, can be more benefited from international exhaustion than the national exhaustion regime. The other possibility of regional integration with the neighbouring countries is yet too far to foresee even after repeated attempt.

### **Provision for compulsory licensing**

In the existing patent law of Bangladesh, one provision (section 22.1) provides for the grant of compulsory licensing, but the option is never been used, as it is extremely cumbersome (Chowdhury 2011). Article 31 TRIPS addresses compulsory licences and sets forth the conditions for their issuance. Its wording does not include the term 'compulsory licence', but it generally refers to "Other Use without Authorization of the Right Holder". This is probably due to political reasons and in particular to the fact that the Uruguay Round negotiators wanted to avoid using a strong word: indeed the term "compulsory licence" might have been perceived, especially in industrialised and R&D intensive countries, as synonym of expropriation of property rights (Bonadio 2012). However, Article 31 of TRIPS provides a series of detailed measures that must be followed when issuing a compulsory license. So, Bangladesh should go for strong and explicitly defined compulsory licensing provision which has to be compliant with the series of detailed measures described in the TRIPS provision.

### **Pre-grant and post-grant oppositions**

In Bangladesh patent law, the pre-grant objection is limited by two conditions. The first is that the objection must be made within four months of the advertisement of the acceptance of application and the second is that the objection can only be based on the statutory grounds provided by section 9(1) of the Act. The TRIPS Agreement does not prescribe any specific type of opposition system, The existing Bangladeshi pre-grant

opposition regime is not sufficient and should be amended to include more extensive pre-grant heads of objection and include a process for post-grant opposition as well.

### **Leveraging the transition period and using TRIPS flexibility**

Both the Government and the business leaders of Bangladesh are occasionally intended for lobbying for extension of the transition period and retain the position as a leader of least developed countries (LDCs) in the international bargaining processes. But the interest of the least developed countries are divergent, specially no least developed country has so intensive interest on ready-made garments and pharmaceutical sectors like Bangladesh. On the other hand, Bangladesh has already graduated to low middle income country and very much potential to be graduated to a middle income country by 2021, subject to its political stability. So, it becomes paradoxical to have a strong pledge to come out of LDC bracket by 2021, and simultaneously, to take initiatives to enjoy extension of transition period as a LDC beyond 2021. So, Bangladesh a limited time of 6 years to form out the patent regime as well as whole IPR regime to get the confidence of the foreign investors as well as to expand overseas market of own products. A comprehensive analysis of the economic implication of changes and alternative provisions of IPR law has to be done. For example, how many of the essential drugs are yet under patent protection and how much licensing fees may be required after expiry of the transition period has to be assessed. A comparative dynamics model has to be developed to assess the cost-benefit of reviewing the list of essential drug, benefit under transition, cost of compliance with international IPRs regime i.e., cost for licensing fees, effect of increased income of the poor people and their affordability of essential medicine, required rate of public subsidy in relation to the phase out of the patent protection of those medicine. More of that discussion about IPRs regime of Bangladesh is over concentrated on pharmaceutical sector. Bangladesh has that potential to have commendable improvement in other sectors like Information Technology. It may take initiatives to be benefited from technology transfer and to use of technologies which are already in public domain. By widening the thought line of actions, Bangladesh can take leverage of the transition period that may improve its poverty situation as well as affordability of essential medicine where IPR, more specifically patent law, will remain as a key issue. But definitely, to realize the optimum benefit of the transition period the improvement of the overall governance and enforcement of the law is a pre-condition.

## **CONCLUSION**

As a leading least developed country Bangladesh has been playing a vital role for lobbying for extension of the transition period. The LDCs nominated Bangladesh as their coordinator at WTO again for the year 2015. But adequate internal initiative for utilization of the transition period, and be prepared to be competitive in the global market, is not evident enough, specially, in the areas of encouraging research and development sector, awareness building for innovation management by the local business houses, the capacity building and up gradation of the national patent office and enforcement of present IPR laws. In the comparison with the above mentioned factors the progress in law making is comparatively better in which a major setback is the delay in up gradation of the patent law. But the law is under process of drafting. So, this is very critical period of examine and re-examine of the provisions in the draft patent law before enactment of it. The provision of the law has to be complaint with TRIPS provision as well as in alignment of the national interest and non-conflicting with other national policies. Some of the vital issues are discussed in this paper but lot of other issues, such as, general exceptions, research exceptions, 2nd medical use, multiple independent claims, grace period, protection of undisclosed information, utility models, and improvement patents remained uncovered. More scholastic discussions are required in this regard as it is very essential for a country at the take off period like Bangladesh as well as it can be an eye opener for other least developed countries to be aware of taking timely measures about their own patent regimes.

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