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Review Article

Bangladesh to Benefit from TRIPS Waiver: An Academic Perspective

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ABSTRACT: An inventor can protect the property right of his or her technique, material, or product by obtaining a patent to preserve both academic and financial interest. In the last decades, Bangladesh has shown comparable progress in basic and applied bioresearch. The major accomplishments include the jute genome sequencing, novel tolerant rice varieties, rapid diagnostic methods for tuberculosis etc. Despite the progresses in biological research, our academics are not fully aware of their intellectual property rights (IPRs) and the importance of patenting their potential inventions which could ultimately benefit the nation. In parallel to the public research institutes, pharmaceutical industry can significantly contribute to translate research into wellbeing. To be noted, Bangladesh and other Least Developed Countries (LDC) have been exempted from the TRIPS agreement on patenting pharmaceutical inventions until the year 2033. This article will focus on two points, first, awareness on intellectual property rights can advance the scientific status of Bangladesh; second, collaborations between industries, multidisciplinary academics, and policy makers can utilize local inventions to solve the health problems in Bangladesh.

KEYWORDS: Intellectual property protection, patent, TRIPS agreement, Sustainable Development Goals, Least Developed Country, Bangladesh, health sciences, pharmaceuticals, reverse engineering, collaboration.

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INTRODUCTION

According to the definition of the World Intellectual Property Organization (WIPO), "Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce". Inventors of novel and productive ideas, especially if they are of commercial interest, would certainly want to protect the invention by, for example, patents, copyrights and trademarks. Protection of IP enables them to earn recognition, academic-, or financial benefit from what they invent or create. By striking the right balance between the interest of innovators and consumers, IP protection fosters an environment where economy and innovation can flourish together. Patent is a sort of IP protection to award an inventor exclusive right to protect the inventions from making, selling, distributing, importing, or using by others, without license or authorisation, for a fixed period of time. Thus, patent promotes the progress of science by securing the inventor and providing stimulus to build up a competition among the intellectuals to accelerate and harness innovations.

Principle steps to obtain a patent are more or less similar across the world, and have been described in details by Latimer et al[1]. The process begins with an invention (figure 1). If anyone has a potential invention, the first step is to search the

patent databases to verify whether this innovation is novel and or anywhere in the world somebody already have had a patent for this same product or concept. To be noted by the scientists that patent cannot be claimed if the innovation has been published or disclosed publicly. Next, the innovator has to submit a complete application to the respective patent office. The application should adequately define and describe the invention so that the examiner can decide whether it is patentable or not. A poorly described claim is often the reason of rejection. This period of substantive examination of an application varies from country to country, for example, at least 18 months in United States[2] and 6 months in Europe[3]. The examiner can refuse or accept a patent claim. Upon rejection of the claim, innovators in some countries in Europe can ask for oral proceeding, while other countries do not allow any further discussion, such as, United States and Bangladesh. Period of patent protection varies per regions and per nature of the patented property. In USA, protection period lasts for 15 years [2] whereas it is 20 years and 16 years for Europe[3] and Bangladesh[4] respectively. Extension of this period is strict in most cases except pharmaceuticals. Patent of pharmaceutical formulations, particularly biologics, biosimilars, and bioequivalents, is now the centre of attention among the LDC countries (Box 1).The top inventions over the last few decades have emerged in the field of biological sciences. Particularly to achieve the goals of sustainable development (SDG) by 2030[5], special attention is needed to strengthen the base of health research institutes and industries. Hence the awareness among the scientists and the health personals about the patent of biological products and how to exploit the patents to achieve the national benefits is crucial. Unfortunately, least developed and developing countries, including Bangladesh, in general, stands far behind regarding the consciousness of IP development and use although they are one who have to make the maximum progress for achieving SDG. Patents are mostly territorial rights, although it is possible to seek international patents covering a number of countries. An agreement called TRIPS

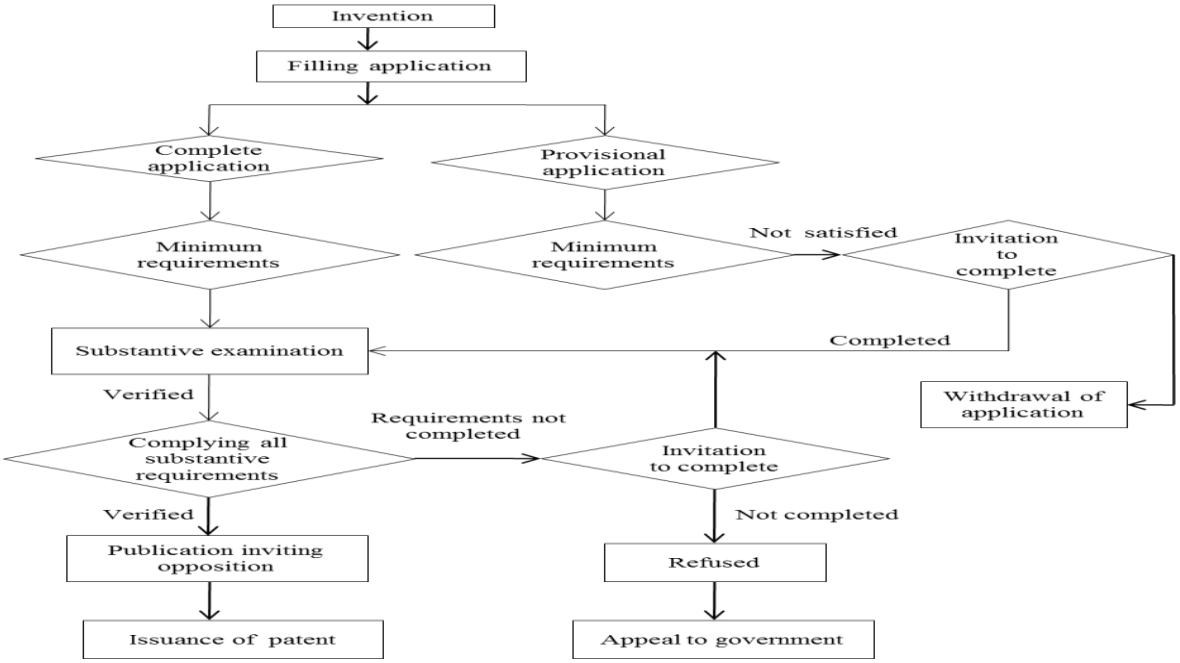

Figure 1: A schematic representation of major procedures during a patent examination and issuance in Bangladesh [4].

After a patent application is filed to the respective patent office, local or foreign, the examiners verify if the application provides necessary information and fulfil the requirements of the patent laws.An application must describe the innovation well enough so that examiners can understand its novelty, inventiveness, and lack of obviousness. Besides, the claim part should be specific about the degree of legal right protection. Examiners are appointed by the patent office, who are trained both in the basic concepts of the patent law, as well as in an specialized research discipline, for example, molecular biology, genetics, immunology etc. It often takes long to verify an application and respond to the applicant due to the backlog of applications and lack of available expert of the respective field.An application, satisfying all the requirements of patentability, is issued a patent. In case of incomplete applications, which fail to satisfy one or more requirement of patent laws, examiners write to the applicants to modification of application.Examiners, if not satisfied with response of the applicant, may reject the application. A rejected applicant may choose to either abandon the application or appeal to government to argue for the patentability of the invention, which has the power to override the decision of examiners.

(Trade-related Aspects of Intellectual Property Rights) by WTO (World Trade Organization) aims to make the patent system uniform across the world. However the minimum patent requirements according to this agreement are relatively strict and sounded unfair to be applied to the low economy countries. After rounds of negotiation, Least-developed Countries (LDC), including Bangladesh, got waiver from TRIPS on pharmaceutical products until 2033. This article aims to raise concern among the scientists to protect our local inventions, and to call for collaboration among people involved in health science and industry to best use the waiver period. In the first part of the article, we will discuss about patents in biosciences and where Bangladesh stands in this race. The second part will focus on the changes necessary to be adopted by policy makers, research institutes, and pharmaceutical industries in Bangladesh before the enactment of TRIPS.

Intellectual properties in biosciences: where does Bangladesh stand?

Bangladesh stands far behind the crowd in respect to development and patent of intellectual properties (figure 2). Economic growth of the country is

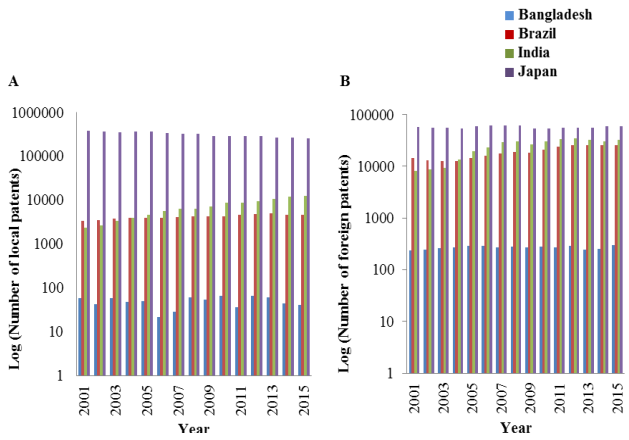

Figure 2. Comparison of A) local and B) foreign patent number over the last 15 years among four countries of different economic growth.

Here, one LDC member Bangladesh (blue); two developing countries, Brazil (red), India (green); and a representative developed country,Japan (purple) have been presented. Japan, has significantly higher number of local and foreign patent compared to the developing countries,Brazil (red) and India (green), and the least developed country, Bangladesh (blue).

upward over the last few years due to relative political tranquility. But in terms of innovation and creation, the outcome is quite unsatisfactory **(**figure 2 and figure 3**)**. Number of patent is still in preliminary stage than we should have had (Table 1). Over the last years, the number of local patents (Patents obtained by the resident Bangladeshi) is very low and almost constant. However the number of foreign patents (Patents obtained by the non-residents, mostly by multinational companies) is quite higher compared to the local ones (figure 3). Disappointingly, over the years in the last decades, number of foreign patents has decreased. This reduction in foreign patent number reflects the fact that other non-developed countries have

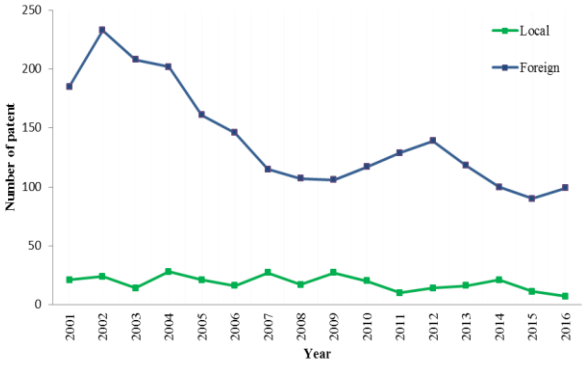

Figure 3. Number of accepted patent in Bangladesh over the last 16 years.

Number of foreign patents,(blue line), granted to and utilized by the multinational companies, is eight to ten times higher than the number of local patent (green line). While number of local patent is almost constant, number of foreign patents has decreased two times.

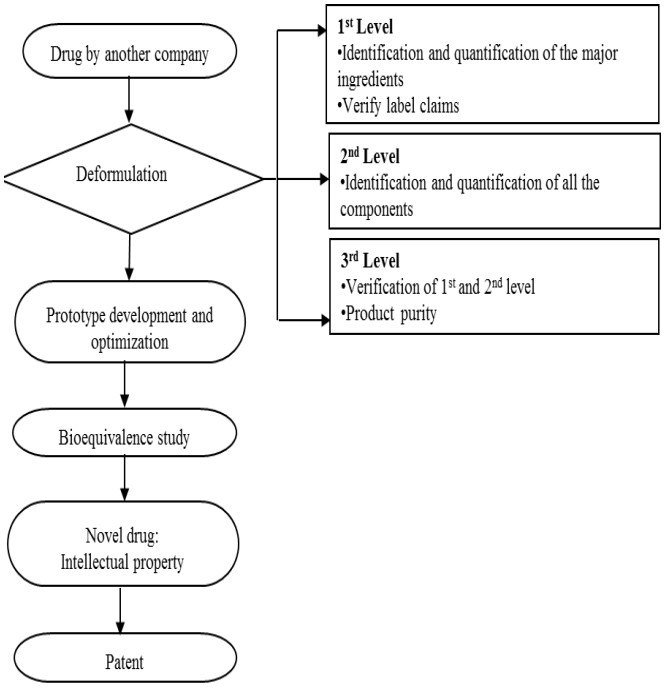

Figure 4. Schematic representation of reverse engineering of drug formulation. Only Principle steps are shown.

Reverse engineering includes deformulation of a branded drug, formulation of a new drug based on this information, and bioequivalene study of the novel drug. Deformulation of a branded drug includes identification, characterization, and quantification of the major ingredients, that is the active pharmaceutical units, and the excipients. Knowledge extracted from deformulation is used to reformulate the drug. If the bioequivalence study of the novel drug is satisfactory, it can be considered as an intellectual property. The inventor or the employer of the inventor can claim for right protection of the novel drug.

come in competition with Bangladesh to serve the purpose of the foreign investors. That is a clear indication of imbalance in demand of intellectual properties and the local infrastructures to meet that demand. This scenario is in contrast to the developed countries where number of local patents outnumbers the foreign one[6]. Such advancement in the developed countries is made by linking the industrial companies with the researchers, providing adequate funding, infrastructures, and a market oriented goal. M Volume 3, Issue 2, July 2017 Countries like Bangladesh are yet to form this bridge between the researchers and industries. A universal call, Sustainable Development Goals

Table 1: Statistics of patent applications in Bangladesh

	Number of patent application			Number of patent granted		
Year	Local	Foreign	Total	Local	Foreign	Total
2001	59	236	295	21	185	206
2002	43	246	289	24	233	257
2003	58	260	318	14	208	222
2004	48	268	316	28	202	230
2005	50	294	344	21	161	182
2006	22	288	310	16	146	162
2007	29	270	299	27	115	142
2008	60	278	338	17	107	124
2009	55	275	330	27	106	133
2010	55	287	342	20	117	137
2011	32	274	306	10	129	139
2012	65	289	354	14	139	153
2013	60	243	303	16	118	134
2014	44	249	293	21	100	121
2015	40	300	340	11	90	101
2016	72	272	344	7	99	106
Total	**792**	**4329**	**5121**	**294**	**2255**	**2549**

(SDGs) has focused to ensure peace and prosperity to all people of the planet. These goals will remain only in papers without uniformity in development in each sector. Good health and wellbeing is the goal number 3 among 17 Goals [5]. Targets of that goal include reduction of some epidemic diseases like AIDS, Tuberculosis, and Malaria. It also aims to support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries[5].

21st century is called the century of Biological sciences. Inventions arising from biological researches such as, machine, software, method, and biological molecule can be patented. According to the compilation of Latimer et al, typical patentable biological invention includes nucleic acids, genes, tolerant plant lines, proteins, buffers, reagent and diagnostic kits, pharmaceuticals, microarrays, bioinformatics software pieces and pipelines, industrial-scale processes for food and medicine production, disease model, cDNA, recombinant DNA, monoclonal antibodies, antisense DNA and RNA, recombinant vectors, and expression vectors etc. Biological inventions generally take time, huge funding, and expertise. The picture of innovation in health science in Bangladesh can be summarized by the fact that only one patent (method for early and precise detection of tuberculosis by icddr,b in 2011) has been reported in the last few decades[8]. The most flourishing health sector in Bangladesh is the pharmaceutical industry. Unfortunately, pharmaceutical companies are focused heavily towards the generic drug rather than their own invention. Most of the local drugs are off-patented. But patent may be a crucial issue in case of multidrug resistance and chronic diseases such as cardiovascular diseases, AIDS, cancer; since price, availability and affordability of a drug or vaccine are related to patent[9].

A 'limited time offer' to develop and benefit from pharmaceutical intellectual properties

Since the foundation of World Trade Organization (WTO) in 1995[10], the member states were obliged to follow common patent laws to comply with the agreement of Trade-related Aspects of Intellectual Property Rights (TRIPS)[11]. In essence, TRIPS stresses for adoption of a minimum but strict standard for patent laws by all the WTO members. The member countries of WTO belong to the economic growth of an wide range: developed, developing, and Least-developed Countries (LDC)[10]. Bangladesh is one of the 34 WTO members belonging to the LDC category[12]. In support of TRIPS enactment, the representative developed countries of WTO claimed a minimum and strict patent protection for pharmaceuticals and other inventions, with the rational that implementation of a worldwide standard law would give incentive to the non-developed countries to develop their own products and bring competition to the market. Competition leads to an ultimate drop in the product price and thus an

increase in accessibility of the product by the locals. However, it appeared too challenging for the LDC members to comply with TRIPS due to the factors, such as, lack of infrastructure, logistics, funding, and expertise in those countries. They argued that TRIPS enactment would rather monopolize the market, raise the product price, ultimately making the products unaffordable by a huge percent of the world population. As a consequence of this debate, WTO offered a waiver to the LDC members until December 2005[13] to allow them the time for capacity building, restructuring, and so on, so that they could comply with TRIPS once the waiver would expire. This waiver was extended few times, first, until July 2013[14], and then again until June 2021 [15]. The final extension for the LDC members to get exemption from TRIPS was made on only pharmaceuticals through a request placed by Bangladesh. This waiver is now effective for any LDC member until 1 January 2033, or the date when a LDC member cease to qualify as LDC, whichever date comes earlier [16]. It has been reported in the United Nation Conference on Trade and Development in December 2016 that Bangladesh will graduate from LDC category by 2024 if the country focuses on human resource development[17]. Thus the waiver will possibly expire for Bangladesh in 6 to 7 years, and we have a limited time in hand to set up facilities to be able to compete in the market with the developed countries. These dates also closely overlap with the '2030 agenda for sustainable development'[18]. Among the 17 SDG goals, the third one specifies to 'ensure health and well-being for all, at every stage of life'[18]. Thus there is pressure from both sides to ensure minimum health facilities in the country, graduate out of LDC, and to compete in the global market. Having this pressing few years in hand, leading experts in different fields of Bangladesh should move fast and forward and take the responsibilities to set the scene.

Box 1. Definitions

Biosimilar: Medical products highly similar to an existing approved biological product or reference biologics rendered by the inherent complexity and the proprietary details of that product.

Biologics: Biological products derived from living cells to diagnose, cure, prevent or treat a variety of diseases. Generic drug: Pharmaceutical drugs that have exact copies of active ingredients of a brand named product. They are same as those branded drugs in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

Bioequivalent: Therapeutic agents that have the same pharmacologic potency and bioavailability as another drug at the same dose in vivo.

LDC:According to the United Nations, "LDCs are countries that exhibit the lowest indicators of socioeconomic development, with the lowest human development index (HDI) ratings of all the countries in the world. A country is classified as an LDC if it meets three criteria: low income (three-year average GNI per capita of less than $992, which must exceed $1,190 to leave the list), human resources weakness (based on indicators of nutrition, health, education and adult literacy) and economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic smallness and the percentage of population displaced by natural disasters)" 12.

R&D: Research and development, a facility which aims innovation or improvement of the existing ideas and inventions.

Reverse engineering: Process of extracting knowledge by disassembling something, analysing thecomponents,and reproducing it based on the extracted information.

Biotechnology.Technology that uses living system to create or modify products.

Recombinant DNA technology. Production of novel generic combinations in a living organism by inserting joined DNA pieces.

How waiver period can be best utilized

Like charity begins at home, the first line of modifications got to come from the policy makers to provide with platforms that would deliver the right atmosphere to foster research. Lack of collaboration among the ministries, or the regulatory bodies under the ministries is often the reason why good initiatives do not reach the end. To make a strong platform, collaborations are crucial among Ministry of education, ministry of agriculture, ministry of information, ministry of industries, ministry of finance, ministry of health and family welfare, ministry of planning, ministry of commerce, and ministry of science and technology. An interactive higher authority can make the best initiative and execution to provide the platform where the actors can perform their best. These platforms would hypothetically be an estuary of scientists and industries. Bangladesh needs to shift toward a country that develops technologies rather than a country that imports

technologies. Research in Bangladesh is limited mostly in the public universities and institutes and conducted by the faculties and young investigators. Funding is the rate limiting factor for execution of good quality research. Major logistics problems that scientists face include,1) minimal funding and often lack of grant extension impede the high impact projects while many projects remain unfinished, 2) lack of funding in hiring experts for the maintenance of instruments, 3) lack of science personalities in policy making, and 4) most importantly, system loss in public service offices, namely bureaucracy. A proper distribution of the budget in instrument, reagents, maintenance, and expertise, is as important as significant increase in the budget. Priority funding can be assigned for projects focusing on local burning health issues. Apart from the administrative problem in funding and distribution, our backdated and poorly designed education system is another reason why we did not succeed to develop sufficient skilled personals. For a strong foundation of research, we must consider the following options. First, university authority can modify their policies where faculties are assigned enough time to conduct research. Allotment of seed money for the foreign-trained returning faculty and thesis students would encourage them to initiate and continue research. Second, courses in the universities of the LDC members are often theory oriented and fail to produce skilled manpower. Thus, introducing internships and trainings at different semesters would turn them into assets. Third, the priority to produce skills to solve local issues could partly be solved by attracting potential students to pursue their doctoral and/or further studies in Bangladesh with incentives, such as attractive scholarships. Fourth, a coordination of research in different public institutes is vital and for that foundation of a national core platform is crucial. The core platform will make sure that funding and cutting-edge technologies are available to the scientist and will also make sure that no local health issues remain unattended by researcher. Besides building up national core facilities, it is essential that universities have their own common facilities/platform to accelerate research work and to make facilities accessible to as many researchers as possible. National Core facilities with state of the art technologies including the cutting edge computational facilities will also attract the drained brain to return and contribute to their homeland. Although more and more universities and departments of biological science are being founded every year, an increase in quantity will not translate into quality unless these policies are implemented. Fifth, a technology transfer office is core to every research institution to identify potential inventions, in order to protect them, and to extract commercial benefit out of them. This would also give incentive to the alumni and the faculties to initiate entrepreneurship/startup companies or to collaborate with industries. Finally private universities, who are often having surplus budget but lack infrastructure to involve their faculties in research, could invest in funding research and utilize the laboratory facilities and expertise in public universities. This would solve the scarcity of funding in public universities and increase research outcome.

How collaboration would benefit

In addition to the ones of research institutes, industries in Bangladesh also need to transform their logistics to increase their research facilities, such as they should develop their own intellectual property. Currently Bangladesh produces final formulations of branded generics while the raw materials and even the Active Pharmaceutical Ingredients are imported with higher duty from our competitors leaving the country behind in this competition. Our only advantage over our competitors is cheap labor. This problem is expected to be solved by the API Park in Munshiganj, soon to be started by producing 70% of the raw materials inside the country [19]. The market is going to be very competitive after the year 2033 as the other LDC members are trying to develop and strengthen their health sectors. If we

Box 2. Suggestions on utilizing TRIPS waived years.

- The Directorate General of Drug Administraion (DGDA) under the Ministry of Health & Family Welfare should act immediately to involve researchers from multiple disciplines (for example, chemists, biochemists, molecular biologists, biotechnologists, pharmacists, and informaticians) in developing innovation in R&Ds.
- Pharmaceuticals can invest a certain fraction of their profit in developing R&D facilities, particularly biotechnological facilities given the current trend of recombinant engineered drugs. Establishment of laboratory facilities for bioequivalence study is crucial.
- R&Ds should focus on innovation.
- Regulatory bodies must coordinate to set course of actions to upgrade biological research quality in the upcoming years, take initiatives, and set policy for a research friendly environment in Bangladesh.

cannot develop the drugs for the top prevalent diseases, we will eventually fade away from the competition. Bangladesh can make the best use of the waived transitional period as it is in a unique position compared to the other LDC members[20]. The nation is already quite self-sufficient in pharmaceutical manufacturing capability, accounting for 97% of national need and an export capacity to 133 countries. Despite their multifaceted problems, pharmaceutical industry in Bangladesh is possibly the most advanced industry of the country with plenty of scope to improve. They are well aware of their problems and prospects, and are actively working with the regulatory bodies towards a better future. However, one untouched but most crucial sector to be improved is the R&D sector, which hardly put any attention to innovation (Box 1). Currently R&Ds are focused solely on drug delivery systems and dosage formulations. The cutting edge technologies in the R&D facilities can be exploited to take a transformation of the pharmaceutical industries from generic producers to innovative industries. This is why industries need to either recruit scientists to foster innovation in their R&Ds or collaborate with research institutes. Through sharing of research outcomes, collaborations exempt industries from paying royalties, and benefit scientists both financially and academically. At this moment, collaboration is most essential to reverse engineer drugs of locally prevalent diseases and patent them as novel intellectual property (figure 4). R&Ds should involve multidisciplinary experts to deformulate and produce biosimilars, or bioequivalents of the patented drug. R&Ds that lack sufficient technologies to reverse engineer a drug can outsource to other companies designed for this job (such as, EAG laboratories). Reverse engineering of drugs is an easy bypass for the LDC members. The cost is significantly reduced as it is free from the initial time consuming an expensive process of experimental data generation. Reverse engineering saves the labor of many years of drug development that starts from a selection of targets and ends with clinical trials. Currently the drugs we import include insulin, vaccines, and anti-cancer drugs. According to the Center for Disease Control and rotection, the top ten diseases responsible for deaths in Bangladesh are cancer (13%), lower respiratory infections (7%), chronic obstructive pulmonary disease (7%), ischemic heart disease (6%), Stroke (5%), preterm birth complications (4%), tuberculosis (3%), neonatal Encephalopathy (3%), diabetes(3%), and cirrhosis (3%). Out of the 650 protein drugs available in the world market, 400 of them are currently produced by recombinant technologies [21]. More and more drugs are being produced by recombinant engineering as it is cost effective and at the same time allow required modifications of the protein pharmaceuticals [22]. Lately three of the pharmaceuticals in Bangladesh have set up biotechnological facilities with foreign collaborators to produce recombinant insulin. Apart from insulin, protein drugs include hormones, receptors, inhibitors, erythropoietin, antibodies, cytokines, and many fusion proteins; most of which are used in treating diabetes, hematological disorders, and tumors. If initiative is taken, other protein drugs beside insulin can be produced in Bangladesh. Development of drugs targeting the prevalent health complications before the TRIPS waiver expires will allow Bangladesh to save lives, as well as to take a lead in the world market.

CONCLUSION

While we had to narrow down this article to very briefly discuss the burning points and could not reach enough depth of the subject matter, it is still clear that our experts from different disciplines of biology and computational science, our medical personals, pharmaceutical and diagnostic companies, and above all, the policy makers and regulatory bodies need to extend their hand to each other, collaborate immediately to solve the national health issues, develop our very own intellectual properties, exploit our so far advancements in earning foreign currency, and above all, take a place in the global market within a decade two.

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