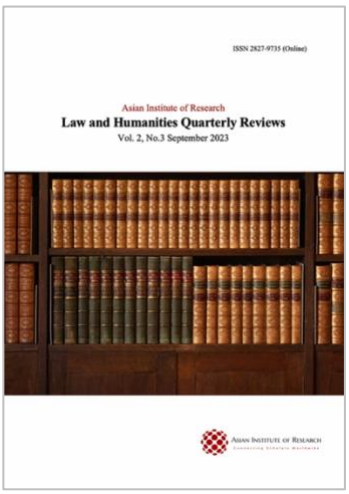

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Access to Medicine in Post-LDC Era: Challenges in Intellectual Property Law Framework of Bangladesh

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Abstract
After witnessing the effects of a global pandemic, the need for affordable medicines is higher than ever. Many developing countries are suffering to provide accessible medicine for their citizens. Although Bangladesh, as one of the most successful least developed countries (LDC), has gained remarkable success in the pharmaceutical industry, the impending LDC graduation might have some adverse effects. This study intended to analyze the implications Bangladesh might face and how to work around the new situation. Although most medicines that treat common diseases are off-patent, LDC graduation can increase prices of patented drugs like vaccines as it will limit the direct policy support given to the exporters. As LDC graduation will force Bangladesh to comply with the TRIPS agreement by 2026 rather than 2033, an extension is badly needed. Bangladesh will also have to amend its intellectual property laws to fully comply with the agreement, which puts an added burden. Finally, this study shows that although measures like parallel importation and compulsory licensing may help in easy access to medicine, the best thing for Bangladesh will be to apply for an extension to graduate from the LDC category.

Keywords: Intellectual Property, Trips Agreement, LDC Graduation, Patent, Medicines

1. Introduction

1.1. Introduction of Study

As a Least-developed country, Bangladesh has a right to manufacture any patented medicine without procuring any license. Although Bangladesh was predicted to graduate in 2024, due to covid 19, it was deferred two years at the government's request. The LDC status has allowed Bangladesh to flourish in its pharmaceutical sector without being confined to the rigorous regulations of the intellectual property law defined by the TRIPS agreement. Article 66 of the TRIPS agreement gives developing countries more time to implement all the agreement provisions. The Doha declaration initiated the special and differential treatment to help the LDC members, which includes extended periods for implementing agreements, helping increase trade opportunities, helping to implement WTO provisions, etc. After the COVID-19 pandemic, life-saving medicines like vaccines are needed more than ever. However, most of these medicines are patented, which makes it harder for some

countries to access them. Many argue that while TRIPS may hike the prices of medicines, there is no proof of a threat to access to them. Compulsory licensing has been considered a viable option for the LDCs. Retrieval and analysis of 51 observations of pre- and post-compulsory licensing prices indicate that a compulsory licensing event will likely reduce the cost of a patented drug, albeit with some caveats. With the question of access to medicine, intellectual property rights are attached like two sides of a coin. This study analyzes intellectual property law regarding the patent of medicine, how it works, the argument surrounding the topic, the stance of developed countries, and finally, how Bangladesh will fare after graduating as a developing country.

1.2. Study Scope

This study seeks to analyze the TRIPS Agreement of the WTO, the legal provisions related to patents, the demands of medicine in the least developed country, the complications of compulsory licensing, parallel importation, and the current situation of Bangladesh regarding medicine. It also analyzes international laws, treaties, conventions, online research journals, articles, and opinions of politicians, researchers, and journalists regarding giving access to medicine in developing countries.

1.3. Studied Materials

Though research on intellectual property has a long tradition in developed countries, the momentum has started only recently in Bangladesh. With many international agreements and laws regarding this topic, books, and research papers, I have tried to shed some light on this matter to understand the problems more and fill some research gaps. To understand the importance of a smooth LDC graduation in Bangladesh, I used Mohammad Abdur Razzaque's book. I have used articles by Rakshita Singh, Abbas, Abbott, Cohen-Kohler JC, and Cullet to gather knowledge about parallel importation, compulsory licensing, and how it can benefit countries like Bangladesh. To understand the current scenario regarding vaccine production, newspaper articles from The Financial Express, The Guardian, The Daily Star, MSNBC, etc. have helped me tremendously.

2. Study Methodology

This study aims to understand the pharmaceutical position of Bangladesh after graduating as one of the least developed countries. This study is mainly based on the doctrinal method. Since this study is concerned with access to medicine, the analysis methods are designed to evaluate the prices of the medicines, manufacturing issues, and their availability to general people. This study is based on existing national and international laws as a primary source as well as data collected from books, online journals, judicial decisions, international legal instruments, publications from journals, research papers, articles, etc., as secondary sources.

3. Conceptual Framework

In developing and least-developed countries, most people don't have access to the medicine they need. With many life-threatening diseases in the world, many developing countries suffer from it despite the existence of medicine due to accessibility problems. During the pandemic, these countries also experienced a shortage of medicine production. Here, accessibility refers to the affordability of the medicines. Accessibility of medicines and poverty are connected because these problems intensify poverty, poor economics, manufacturing issues, etc. Developing countries also have less money than developed countries, which can increase the cost of medicine. That's why the TRIPS agreement has some exceptions for developing countries to help them transition to afford these basic necessities for their citizens. The TRIPS agreement, in the way of being progressive, seemingly gives the LDCs many flexibilities in their provision. Still, the reality is most countries can't use these provisions in their advances. Many LDCs cannot use things like compulsory licensing due to the absence of adequate pharmaceutical manufacturing capability, while countries with this capability can use them effectively. Geopolitics also plays a considerable part in these flexibilities. In reality, many countries that are about to

graduate from LDC status cannot afford to provide sustainable medicine to their citizens and abide by the provisions of the TRIPS agreement at the same time. Bangladesh may be one of them. This paper intends to analyze the discrepancies between the TRIPS agreement's initiatives for the LDCs and the reality of the situation and find out about the problems that many countries like Bangladesh can face in providing affordable medicine for their citizens. Also, it analyzes the question most developed countries raised about intellectual property rights regarding patented medicines and whether these rights should be protected in the event of a massive humanitarian crisis.

3.1. Provisions of the TRIPS Agreement and its Exceptions

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO). It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 and is administered by the WTO. TRIPS has brought a significant difference in international morality relating to intellectual property rights. Before TRIPS, Intellectual property rights were highly diverse from country to country. Now, all patented products fall under this agreement. With its pragmatic outlook on the developing country on improving their financial status, it is considered one of the most argumentative elements of the WTO system. For the benefit of developing countries, there are provisions in TRIPS that seemingly help LDC countries to use these protected items for their benefit. The LDCs are also given an extended transition period to fence intellectual property under the WTO's Agreement on TRIPS.

The objective of TRIPS is to help transfer and disseminate technological innovation and promote it. Where article 7 established the transfer of technological innovation, article 66.2 mentions that these transfers will help developing countries secure a stable base for technologies. It is to be noted that there is no clear, standard definition of transfer of technology in the TRIPS agreement so that countries can interpret the terms to their liking. Articles 7 and 8 of the TRIPS Agreement give protection to the patent, and Articles 27.2 and Article 30 provide some exceptions to the scope of patentability. Article 27.2 refuses the patent of innovation if it poses a threat to human life or health. Still, the restriction cannot be simply imposed to stop the exploitation of the said innovation. This means pharmaceutical products cannot be put under this restriction. The main difference between Article 27.2 and Article 30 is that Article 30 only regulates drug use. The state cannot reject the drug's patentability.

According to Article 30 of the TRIPS, the least developing countries get many flexibilities like pharmaceutical manufacturing, compulsory licensing, patent extension, parallel importation, etc., for non-commercial purposes. Compulsory licensing is when the government allows the manufacturing of a patented product to a third party without the patent holder's consent. Under Article 31, a compulsory license for manufacturing or importing is available to all members. According to this article, generally, the person or company applying for a license must have attempted unsuccessfully to procure a voluntary license from the right holder on rational commercial terms. If it is issued, the patent holder must still be paid remuneration. But in national emergencies, there is no need for a voluntary license. According to TRIPS Article 73 (b) (iii), there is an allowance for a country to carry off 'any action which it considers necessary for the protection of its essential security interests 'during the time of war or other emergencies in multinational relations.'

The TRIPS agreement also supports parallel importation. Parallel importation is when a country imports a patented product without the patent holders' consent from another country where it is marketed by the patent holder or with their permission.

Many LDCs used their long transition period to use the flexibility the TRIPS Agreement provides them. But up until the amendment of 2005, which took effect in 2017, not all countries could use them. Many LDC countries cannot take advantage of compulsory licensing due to the absence of adequate pharmaceutical manufacturing capability, while countries with this capability can use them effectively. Although some countries are capable of utilizing a compulsory license in the pharmaceutical division to manufacture patented medicine effectively, they

are consistently forced by the developed countries to refrain from issuing this license. According to Article 31 (f), the exportation of generic medicine produced under such a license is barred because, most of the time, it is issued for the domestic market of the license-issuing country. So, countries with limited manufacturing power could not use this flexibility in their regards. But The amendment of the obligations of Articles 31(f) & 31(h) allowed countries to export medicine to these countries.

3.2. The Amendment through the Doha Declaration

Pharmaceutical patents provide opportunities for drug manufacturers to create monopolies over medicine production and marketing, which allows them to maximize profits by setting up high prices. The WTO-TRIPS Agreement has some rigorous obligations that create a sky-high standard for the protection of intellectual property. Provisions like minimum twenty-year patent protection and recognizing products to process patents will ensure the elimination of any kind of competition. This concern was shared by quite a few countries, which was settled in the main Doha Ministerial Declaration of 14 November 2001. This declaration intended to give a public health-friendly interpretation and implementation of the TRIPS agreement, which also promotes easy access to existing medicine and facilitates the development of new ones. After that, a new declaration on TRIPS and Public Health was adopted. In this declaration, it was agreed that the TRIPS agreement should not create a situation that prevents its members from taking protective measures for their public health. Also, countries should have opportunities to explore the flexibilities provided by TRIPS, such as compulsory licensing and parallel importation.

Compulsory licensing is connected with the Doha declaration for its interpretation and amendment. There were some issues in Article 31 of TRIPS regarding the production, exportation, and importation of drugs, which the Doha declaration corrected by cutting them. It acknowledges the challenges that serious diseases like HIV, AIDS, tuberculosis, malaria, and other epidemics present in developing countries, the anguish of people because of them, and the necessity of the compliance of TRIPS agreement nationally and internationally in curbing these diseases. Although the article acknowledged that to progress in making new drugs, IP protection is necessary. It also voiced concerns regarding problems like inflation of prices, the medicine corporations' greedy attitude that puts making money over saving lives, and how it affects poor countries to procure affordable drugs or even manufacture them. The Doha declaration also recognizes that every member has the right to take critical measures to ensure their public health. Granting compulsory licensing, choosing the license's grounds, and determining what will be considered national urgency or extreme national urgency in granting compulsory license are a member's rights. Diseases like HIV, AIDS, tuberculosis, malaria, and other epidemics are generally considered civil emergencies or circumstances of extreme urgency. In these kinds of emergencies, compulsory licensing allows the patent rights to cover public health.

Doha Declaration also supports parallel importation. It has continuously stated that all members are free to demonstrate their administration for these kinds of situations without any problem. According to the principle of exhaustion, a patent holder or any party certified by him cannot outlaw an ensuing product resale if they have put out the patented product cause the selling of the product allowed their claims regarding the market to be absorbed. According to Article 6 of the TRIPS agreement, the WTO dispute settlement system cannot resolve any issues or challenges regarding parallel importation practice. This means that even if a state permits parallel imports in a manner that some other state believes breaches the TRIPS Agreement, it cannot be presented as a dispute in the WTO unless basic nondiscrimination principles are considered. According to the Doha Declaration, this implies that members may decide how to cope with tiredness in a manner that best suits their internal policy goals.

Although the amendment of the obligations of Articles 31(f) & 31(h) allowed countries to export medicine to these countries, it still did not solve the problem of medicine scarcity. And the process remains stiff as always. The exporting country has to guarantee the exportation of the manufactured medicine in that particular country only, and the medicines have to be easily distinguished through their complexion or figure. Only the necessary

amount to fulfill the needs of the qualified importing country will be manufactured, and the TRIPS council has to be notified by the importing country.

4. The Approach of the LDCs and Developed Countries about Patenting the COVID-19 Vaccine

Vaccines have long played a pivotal part in the prevention, mitigation, and eradication of contagious diseases. With the ongoing pandemic, COVID-19 vaccination has become a necessity to live a normal life again. With over 3.8 million deaths in the coronavirus, Vaccine access has become very important. But it is a patented product. As a patent is a prerogative of a patent holder to decide how a patented product can be made, used, distributed, imported, or dealt with commercially, the production of vaccines is in a tangled situation. This makes it very hard to facilitate access to vaccines in low-income and middle-income countries. Studies have estimated that roughly one-third of the world's deaths have been caused by serious diseases, which in most cases stemmed from the lack of proper treatment and medicines. As vaccines are protected by intellectual property rights, The weight of vaccine capitalism is experienced most in these countries and Africa in particular.

4.1. The Issues regarding Patenting the Covid-19 Vaccine and its Access

The fact that access to medicine is a big issue in the developing country is an issue that has been raised over the years. All of the concerns have been proved right throughout the COVID-19 pandemic. In any kind of serious disease, developing countries do get hit harder than developed countries because of lack of research and development, high cost of medicine, and inadequate health infrastructure. Because of these serious diseases like HIV/AIDS, tuberculosis, and malaria, COVID-19 spreads much faster in these countries. Studies showed that by the end of 2008, only 4 million people were receiving antiretroviral treatments for AIDS out of the 12 million people in developing countries who were going to die without immediate access to affordable treatments. In 2018, about 822 people died of AIDS-related complications in the European Union against their 512 million population, while in Mozambique, 54000 people died against their 29 million population.

The COVID-19 pandemic has created a massive need for pharmaceutical patent waiver more than ever. And with the Marrakesh agreement, it is possible to waive the patent rights in emergencies, which the current pandemic certainly is. In Article IX.3 of the Marrakesh Agreement, "exceptional circumstances" are described as an obligation that the WTO or any other multilateral trade agreement imposed on a WTO member country that can be waived if it is supported by three-quarters of the members. According to Article IX.3 (b), when the waiver request concerns the multilateral trade agreements given in Annexes 1A, 1B, or 1C, it will be first submitted to the Council for Trade in Goods, Council for Trade in Services, and then Council for TRIPS. However, the term exceptional circumstances are not defined in the WTO agreement. Nonetheless, through common knowledge, the words imply that in a situation of urgency, certain liabilities that have the intention to be legalized and embraced by nations enable nations to waive those liabilities that would otherwise violate the WTO measures. In simpler terms, the power of waiver defined in Articles IX.3 and IX.4 enables flexibility in difficult situations where a member country might not have the luxury to comply with WTO morals.

In October 2020, the WTO was asked by India and South Africa to waive certain TRIPS conditions, which would have helped the LDC countries give people affordable access to COVID-19 medical products as early as possible. The TRIPS council was asked by the countries for a recommendation of waiver on the implementation, application, and enforcement of 4 sections within the second part of the agreement. In that proposal, it was said that "*developing countries “especially” may face institutional and legal difficulties when using flexibilities available within the TRIPS Agreement." "This waiver would cover obligations from four sections of the TRIPS Agreement — Section 1 on copyright and related rights, Section 4 on industrial designs, Section 5 on patents, and Section 7 on the protection of undisclosed information. It would last for a specific number of years, to be agreed by the General Council, and until widespread vaccination is in place globally and the majority of the world's population is immune. Members would review the waiver annually until termination.”*

Although many developed countries and vaccine manufacturing companies like Moderna and Pfizer also refused this vaccine patent waiver, in 2022, the WTO provided a partial waiver for five years. WTO waived patent rights on vaccines and allowed the use of confidential clinical trial data for vaccine approvals. However, the vaccination rate in the developing countries is still low. Currently, India and South Africa are attempting to extend this waiver time.

4.2. A Possibility of Increasing Access to Medicine through Parallel Importation and Compulsory Licensing

Patent protection of pharmaceutical products gives inventors exclusive rights and a chance to monopolize the market. It allows them to sell products at a price that wouldn't be possible in a competitive market. As a consequence, these medicines become unaffordable for people with limited income. With the expectation of price hiking of patented medicines that came along with the implementation of the TRIPS agreement, provisions like compulsory licensing and parallel importation were expected to handle the negative impacts. Though these provisions have legality, international politics curtail most of the opportunities for generic manufacturing.

Parallel importation is an exception given to the LDC's use. Under Article 6 of the TRIPS agreement, parallel importation cannot be brought to the dispute settlement, leaving the members to adopt this measure in their trying times. The COVID-19 epidemic has put a strain on the majority of the world's healthcare systems. Governments, particularly in resource-constrained low- and middle-income nations, are struggling to satisfy their citizens' health demands. Patent exclusivity raises the cost of healthcare by enabling protected technology to be sold at prices that are above the market. Parallel importation of patented health technology is a legal policy alternative for obtaining patented health innovations at a lower cost. Parallel imports enable IP owners to reap the advantages of international price discrimination by setting different prices in various jurisdictions while maintaining the purchasing power of a particular market in mind. Parallel importation appears to be a safer choice since the Member States are not required to verify the presence of certain medical crises to exploit this flexibility. The TRIPS Agreement's Art. 28(1)(a) clearly states that the patent holder's power to regulate import is subject to Art. 6 of the TRIPS. Article 6 of the TRIPS Agreement states that *"For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."* So, Art. 6 states 'exhaustion' but does not control it. The International Exhaustion of Rights Convention says that the rights of IP Rights holders expire after the first sale in any market. The national exhaustion of IP Rights, however, only exhausts the rights of the IP holder when the first sale is made in any sort of national market, preventing parallel imports from accessing local marketplaces. Furthermore, under regional exhaustion of IP rights, the IP rights holder's rights cease to exist immediately after the first sale in any regional market. The Doha Declaration, in combination with the TRIPS agreement, serves as a key pillar in the idea of parallel importation. The primary goal of this proclamation is to protect and defend public health.

Though the TRIPS Agreement provides adequate policy room for WTO Member States to address exhaustion rights, parallel importation of patented medications has historically been a contentious problem because it may dramatically reduce manufacturers' earnings by substituting sales in low-price areas for sales in high-price regions. Brand-name pharmaceutical corporations have a tendency to respond violently when other parties, especially when using legal methods, attempt to interfere with their revenues.

Compulsory licensing is mentioned in articles 31 and 31*bis* of the TRIPS agreement. With compulsory licensing, a government can use a patented product without the holder's permission. Even generic medicines can be produced by this. TRIPS agreement allowed scenarios where compulsory licensing could be used instead of strict regulations. Though many people argue that compulsory licensing can be used for affordable drugs, this theory only exists in assumption. There is no substantial study to prove this theory. However, there is evidence that proves that compulsory licensing can lower the price of patented medicine. It might be argued that compulsory licensing only works in richer nations since residents in these countries can afford to buy more costly pharmaceutical items due to strong patent rights. But in battling a crisis like COVID-19, compulsory licensing can be a very useful tool. By facilitating compulsory licensing, many developed countries have

managed to get COVID-19 vaccines and other related drugs. Canada enacted the COVID-19 Emergency Response Act as a law to allow the states to produce, sell, and use patented medicines. Germany passed the Prevention and Control of Infectious Diseases in Humans Act, which allows compulsory licensing. So, compulsory licensing can be used for quick access.

5. The Implications of LDC Graduation for the Pharmaceutical Sector of Bangladesh

currently, LDCs benefit from two kinds of transition periods provided by the TRIPS Agreement: a general transition period and a particular transition period for the pharmaceutical sector. The general transition time has been prolonged until July 1, 2034, while the particular transition term for the pharmaceutical sector has been renewed until January 1, 2033. LDCs, on the other hand, will forfeit the advantages offered during the transition periods once their LDC membership expires. Bangladesh was scheduled to depart the LDC category in 2024, as per a previous CDP plan. But, because of the COVID-19 epidemic and a request from the Bangladesh government, the graduation year was postponed by two years to 2026. Bangladesh's excellent healthcare accomplishments in recent decades have been aided by the presence of a thriving and low-cost pharmaceutical sector. Access to medications, infant survival, vaccination, sanitation, and other health outcomes have all significantly improved. Bangladesh would lose access to this transition period if it graduated from LDC classification in 2026 without an extension and would be forced to comply completely with TRIPS in medicines by 2026 rather than 2033. Recent advances, as well as the country's capacity to deal with continuing and emerging health concerns, may be compromised. Covid-19 is one of the clearest examples of such a danger. Combating the pandemic's economic destruction and long-term consequences would need complete international cooperation, for which the transition period for drugs needs to be more than 2026.

5.1. An Overview of the Pharmaceutical Sector of Bangladesh and Its Current Status

In Bangladesh, Development in the pharmaceuticals sector has been fueled by an active, domestic industrial strategy, which has been aided in recent years by the World Trade Organization (WTO) transition phase for LDCs, which enables Bangladesh to avoid patent enforcement. Until the 1980s, multinational corporations controlled the pharmaceutical sector. This supremacy was characterized by significant imports of pharmaceuticals and raw ingredients for pharmaceuticals. Eight MNCs produced about 75% of all pharmaceuticals (in value terms), with the remaining drug manufacturing being done by 160 small and medium-sized enterprises. Bangladesh implemented its first drug policy regime in 1982, resulting in a substantial revamp of the pharmaceutical sector. The National Drugs Policy (NDP) attempted to discipline the pharmaceutical business by instituting medication pricing limits, lowering MNC market dominance, and restricting pharmaceutical patents to achieve different public health objectives. To make the NDP aims a reality, the government also enacted the Drugs (Control) Ordinance (DCO) 1982, which regulated several elements of the fundamental distribution networks, such as manufacture, distribution, importation, and sales. Bangladesh additionally implemented two more drug policy regimes throughout time, the first in 2005 and the second in 2016.

The pharmaceutical sector, as the largest white-collar employment, provides 97 percent of the local market and 131 other nations. Since 1982, nominal production has increased exponentially, reaching US$2.8 billion in 2018, or 1.2 percent of GDP, and from 2014 to 2018, with 8.3 percent average annual growth, it was growing faster than GDP growth. It also has a positive impact on people's lives. According to a World Bank report, life expectancy grew to 72.3 in 2018 compared to 46.6 in 1971, and infant mortality reduced from 148.4 to 25.1, both statistics beating the overall number in South Asia.

With an annual average growth rate of 16%, Bangladesh's pharmaceutical sector has reached an all-time high since 2006. In 2019, with 25.5%, this sector earned $130 million in exports alone. Many speculate that exports would reach $1.3 billion by 2030 if the average annual export growth rate of the past five years was 23%. Exports will exceed $400 million by 2030 if the ten-year average of 10% is maintained. A conservative 5% annual growth rate will bring revenues to $222 million by 2030. While Bangladesh has developed a substantial

formulation manufacturing capacity, API production has been fairly restricted. Currently, eight firms in the nation manufacture more than 40 API compounds. Even though few local enterprises manufacture APIs, the pharmaceutical sector mainly depends on imported APIs from diverse overseas sources such as China and India. So, pharmaceuticals are not only a rising source of production, foreign cash, and jobs but also an increasingly important source of inexpensive medications for other LDCs and developing nations.

5.2. The Necessity of Extending the Pharmaceutical Transition Period After the Pandemic

TRIPS transition period has allowed the pharmaceutical business to cut costs both domestically and internationally and boosted health outcomes. Bangladesh will lose access to this transition period if it graduates from LDC criteria in 2026 without an extension and will be forced to comply completely with TRIPS in medicines by 2026 rather than 2033. If so, all of the progress might be jeopardized.

Because of the flexibility, manufacturers in LDCs can export patented medicines to other countries where the patent on the medicines has expired or is missing. On patented drugs, generic producers are not required to pay royalties or compete on an equal playing field with inventors. In Bangladesh, laws like The Drugs Control Ordinance of 1982 empowered the government to set prices and limit imports of any drug if it or a replacement was manufactured in the nation. The 1940 Drugs Act lets the government control how to label any imported drugs and requires the full formulaic information to be accessible. There is no patent protection for plant and animal types; organizations other than the government may impose compulsory licensing, and international patents can be invalidated after four years if the product is not also produced locally. As an LDC, Bangladesh can export generic versions to countries without patent protection or with compulsory licensing. Currently, Vietnam, Myanmar, and Kenya are important markets. Bangladesh has achieved self-sufficiency in the pharmaceutical industry by using the patent waiver, supplying about 97 percent of drugs for the domestic market, and exporting to over a hundred nations, like the United States.

Following graduation, pharmaceutical industries would lose access to patent waivers seven years before the transition period's end, potentially limiting their capacity to create and import generic copies of patented drugs. Graduated LDCs will be required to include patent protections for pharmaceutical items and techniques. When the TRIPS Agreement goes into effect, local pharmaceutical producers will struggle to compete against cheaper products. If an importer can provide a cheaper price for a similar item of the same caliber, local manufacturers are likely to lose market share. Large-scale generic producers in India and China may prove to be important rivals and dangers because of their pricing advantage. These countries' pharmaceutical businesses have well-established backward-linking sectors that produce raw ingredients and, more critically, active pharmaceutical ingredient (API).

Bangladesh will be required to comply with the TRIPS agreement as well as other international treaties about IPR, except for preserving patents and concealed knowledge for pharmaceutical goods, which will be exempted within a particular transition period. The government would be expected to amend current IP laws or establish new legislation per the TRIPS Agreement, which will be open to yearly review by the TRIPS Council.

Bangladesh will also have to revise its patent legislation, expanding patent protection to pharmaceutical items and methods and granting patent protection on animal and plant species. The 1911 Patent Law will have to grant a minimum of 20 years of patent protection rather than the current 16 years. Patents could no longer be revoked merely because they were registered in another country, and compulsory licenses could only be given by the government. If a patent was violated, Bangladesh would have to allow foreign corporations to seek an injunction so that the authorities could confiscate the items. For fear of disclosing trade secrets and interfering with manufacturers' marketing plans, the government could no longer insist on the components of imported pharmaceuticals being disclosed on packages. Bangladesh will very certainly have to discontinue the import restriction policy followed under the 1982 narcotics control legislation after graduation since it would violate WTO norms.

Also, the law doesn't demand significant novelty or creativity. Without a revised strict condition, Patents might be issued on existing or unoriginal things. After the transition, it is also expected to implement the mailbox requirements and exclusive marketing rights. Through the mailbox rule, LDCs were required to set up a "mailbox" system for receiving and submitting patent applications at the start of the transition phase. So, Bangladesh will have to process all patent applications that were submitted over the years.

Higher medicine costs also have some social impacts. For starters, rising drug costs may lead some families to discontinue using or consume less than the suggested amount. Second, families may cut other types of spending, like groceries or spending on children's education, to compensate for the increased costs of medications owing to rising prices. Thus, rising pharmaceutical costs not only influence the use of treatments but may also lower the intake of meals, education, and other basic necessities required to live a healthy life. Studies suggested that the poorest 20% of families spend 13.5 percent of their income on health-related expenses. Furthermore, Bangladesh's graduation from LDC status may result in a rise in medication spending and, as a consequence, more families suffering poverty as a result of increased health-related costs.

6. Finding and Recommendations

6.1. Study Findings

6.1.1. The TRIPS flexibilities are not fully used by the developing nations. Strict intellectual property rights often lead to monopolies, which create high prices for medicines. Patent holders are also allowed new follow-on innovations along with their patent rights. This is a great barrier to access to medicine.

6.1.2. Implementing the TRIPS agreement to further access to medicine in developing countries is quite difficult due to the reluctance of the developed countries. As a patent is a prerogative of a patent holder to decide how a patented product can be made, used, distributed, imported, or dealt with commercially, the production of life-saving medicines like vaccines is in a tangled situation. This makes it very hard to facilitate access to patented drugs in low-income and middle-income countries.

6.1.3. The LDC graduation of Bangladesh risks derailing the technical learning process that has fueled progress up to this point. The industry association anticipates that the present annual compound growth rate of 15% will continue in the next term. Without mitigating actions, this expansion may decline, with wide-ranging economic, employment, and public health consequences. After LDC, all of the TRIPS exemption benefits will go away, which is not beneficial for Bangladesh right now.

6.1.4. The intellectual property laws of Bangladesh do not fully comply with the TRIPS agreement. For example, the Patents and Design Acts, the Patents and Design Rules, the Drugs Act, and the Drug Control Ordinance, amongst others, will require reviewing after LDC graduation. The primary IPR protection laws in Bangladesh are the Patents and Designs Acts 1911 and the Patents and Designs Rule 1933. These laws have many parts that are inconsistent with the TRIPS agreement, and reforming them is quite challenging in the current scenario.

6.1.5. Although parallel importation can provide low-priced medicine, pharmaceutical companies have reacted harshly towards it. Parallel importation can dramatically reduce manufacturers' earnings by substituting sales in low-price areas for sales in high-priced regions. For this reason, companies and developed countries have sided against them. So, despite being a legal method, many countries are afraid to use it as they will have to face the wrath of a developed country.

6.1.6. Though some may argue that compulsory licensing only works in richer nations since residents in these countries can afford to buy more costly pharmaceutical items due to strong patent rights, it can be used to access patented medicines quickly.

6.2. Recommendations

6.2.1. The international health community, led by WHO, should reaffirm nations' ability to employ TRIPS flexibilities to defend public health. Governments may move quickly to implement regulatory and legislative measures to guarantee that patents and other intellectual property rights do not obstruct access to medicines, diagnostics, vaccines, medical supplies, and equipment. There is a need to

analyze national and regional rules to determine the degree to which they allow for TRIPS flexibilities. Particularly whether they allow for efficient forced licensing or government usage of patent-protected items. If not, the relevant changes should be implemented as soon as possible to simplify processes and make such measures easier to execute.

6.2.2. Bangladesh's key task as a prospective middle-income nation is to continue advancing up the technology ladder, creating value, and moving away from the low-cost industry. Limited intellectual property protection has also enabled Bangladeshi enterprises to create their technical foundations by copying or reverse engineering foreign innovations. For further advancement, Bangladesh should apply to extend the TRIPS pharmaceutical transition period.

6.2.3. Bangladesh will have to amend its current intellectual property law to fully comply with the TRIPS agreement. Bangladesh will be required to update its legislation to comply with WTO accords other than TRIPS, such as the WTO Agreement on Subsidies and Countervailing Measures. This may call into question the services and facilities provided to local drug makers under the 2005 National Drug Policy. To fully comply with WTO regulations, new pharmaceutical businesses would have to succeed in the global market with limited financial backing from the government. These amendments should be done after 2033.

6.2.4. By allowing a patent pool, access to medicine can be increased as well. A patent pool is an arrangement between at least two IPR holders to aggregate their rights on a certain innovation and lease the rights to use them to each other and other parties, subject to specified terms such as royalty payment. Patent pools are communal administration systems for intellectual property rights, especially patents. The Medical Patent Pool encourages licenses for HIV/AIDS drugs by acquiring voluntary licenses from patent owners and then non-exclusively licensing to third parties who may manufacture copies to distribute in underdeveloped nations. This approach encourages generic competition, lowering costs and making vital medications more inexpensive, and hence more available, for patients in LDC nations. This model also aids in the reduction of transaction costs. Instead of negotiating several licenses from different patent holders, a generic producer might establish a sublicensing arrangement with the Medical Patent Pool.

6.2.5. Open approaches to Research and development (R&D), akin to an open-source model, might enhance access to medicinal goods in underdeveloped nations. Because of its nature, the open-source model has also been proposed for poor nations, which might aid in the development of pharmaceutical goods, other medicines, and remedies for the most critical diseases that these countries suffer. It is critical to share knowledge because inventing new (and continuing to produce older) medicines is critical for fighting diseases in developing countries. And it's also in everyone's best interests to spread the word. This is one of the motivations behind the Open-Source model, which does not provide exclusive rights like a typical patent system. Furthermore, one of the key reasons why this model has gained popularity is because it is accessible to anyone. This 'Open-Source Pharma' paradigm has also attracted recognition for being a new and competitive model for medical innovation

7. Conclusion

Because of high pricing and poor purchasing power in developing nations, patented pharmaceutical items are well beyond the reach of developing countries. The TRIPS Agreement was believed to be the answer to access difficulties, but it brought in even more complicated challenges, such as confusing phrasing in its articles and different interpretations among member nations. As a result of these factors, the worldwide intellectual property system has become fragmented and uneven. There is a need to figure out how to balance research and development with access to pharmaceutical goods such that neither is harmed. Bangladesh's significant pharmaceutical successes may be attributed to its distinct national history, huge, low-cost labor force, and rising global and national health expenditure. The sector is becoming more important not just for the local economy and health results but also for supplying other LDCs and developing nations at a cheap cost. Covid-19 has struck a tremendous blow, one that will take many years to recover from. Although Bangladesh has dealt with the situation rather well, it will be a wise decision to apply for an extension of the transition period.

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References

Abbas, M. Z. (2021). Parallel Importation as a Policy Option to Reduce Price of Patented Health Technologies. *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector*, 17(4). http://journals.sagepub.com/doi/10.1177/1741134321999418

Abbott, F.M., & Reichman, J.H. (2007). The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions. *Journal of International Economic Law*, 10, 921. https://academic.oup.com/jiel/article-lookup/doi/10.1093/jiel/jgm040

Bhattacharya, D. (2021, March 21). Bangladesh Qualifies for LDC Graduation: What Next?. *The Financial Express.* https://thefinancialexpress.com.bd/views/bangladesh-qualifies-for-ldc-graduation-what-next-1615473209

Cohen-Kohler, J.C., Forman, L. & Lipkus, N. (2008). Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for Remedying the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Imposition of TRIPS-plus Standards. *Health Economics, Policy and Law, 3,* 229. https://www.cambridge.org/core/product/identifier/S1744133108004477/type/journal_article

Cullet, P. (2003). Patents and Medicines: The Relationship between TRIPS and the Human Right to Health. International Affairs (Royal Institute of International Affairs 1944-), 79(1), 139–160. http://www.jstor.org/stable/3095545

European Centre for Disease Prevention and Control. (2019). *HIV/AIDS Surveillance in Europe 2019. 2018 Data.* WHO Regional Office for Europe. https://www.ecdc.europa.eu/sites/default/files/documents/hiv-surveillance-report-2019.pdf

Gay, D. & Gallagher, K. (2020). *The need to extend the WTO TRIPS pharmaceuticals transition period for LDCs in the COVID-19 era: Evidence from Bangladesh.* United Nations CDP policy Review. https://www.gradjet.org/cdp-review-2020-1/

Gay, D. (2017). *What LDC Graduation Will Mean for Bangladesh's Drugs Industry.* United Nations, LDC Portal- International Support Measures for Least Developed Countries. https://www.un.org/ldcportal/what-ldc-graduation-will-mean-for-bangladeshs-drugs-industry/

Gervais, D. (2012). *The TRIPS Agreement: Negotiating History*. London: Sweet & Maxwell

Gregory, A. (2021, 21 October*).* Only 14% of Promised Covid Vaccine Doses Reach Poorest Nations. *The Guardian.* https://www.theguardian.com/society/2021/oct/21/only-14-of-promised-covid-vaccine-doses-reach-poorest-nations

Islam, M. (2021, 14 September). LDC Graduation: Evaluating the Implications of Implementing the TRIPS Agreement. *The Daily Star*. https://www.thedailystar.net/law-our-rights/news/ldc-graduation-evaluating-the-implications-implementing-the-trips-agreement-2175541

Islam, M. R. & Dr. Zaman, K. (2021, 11 May). TRIPS Patent Waiver for COVID-19 Vaccines: Is It Legally Necessary. *The Daily Star*. https://www.thedailystar.net/world/news/trips-patent-waiver-covid-19-vaccines-it-legally-necessary-2091849

Islam, Md. D., Kaplan, W. A., Wirtz, V. J., & Gallagher, K. P. (2022). The Social Costs of Success: The Impact of World Trade Organization Rules on Insulin Prices in Bangladesh upon Graduation from Least Developed Country Status. Asian Development Review, 39(01), 239–279. https://doi.org/10.1142/s0116110522500093

Magazine, A. & Raghavan, P. (2021, 18 May). Explained: Intellectual property waiver for Covid-19 vaccines. *The Indian Express.* https://indianexpress.com/article/explained/explained-ip-waiver-for-covid-vaccines-7304992/

Ranjan, P. (2021, April 12). The case for waiving intellectual property protection for covid-19 vaccines. Policy Commons. https://policycommons.net/artifacts/1468976/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/2119870/

Rahman, M. (2023, February 10). Lessons for Bangladesh as a graduating LDC. *The Daily Star*. https://www.thedailystar.net/supplements/32nd-anniversary/towards-smart-bangladesh/news/lessons-bangladesh-graduating-ldc-3243446

Razzaque, M.A., Akib, H., Rahman, J., Abbasi, P., Kabir, M., Eusuf, A., Uddin, M., Hasan, E., Zaman, A., Islam, R. & Iftekhar, N. (2020). *Navigating New Waters: Unleashing Bangladesh's Export Potential for Smooth LDC Graduation.* Bangladesh Enterprise Institute

Singh, R & Singh, N. (2021). Importance of Parallel importation of patented medicines due to ongoing Covid-19 crisis. *Nyaayshastra Law Review*, 2(1). https://hcommons.org/deposits/download/hc:38772/CONTENT/importance-of-parallel-importation-of-patented-medicines-due-to-ongoing-covid-19-crisis.pdf/

Surowiecki, J. (2021, October 27). Pfizer's Tactics Have Left Poor Countries without Vaccines. *MSNBC* https://www.msnbc.com/opinion/pfizer-moderna-protecting-their-patents-leaves-much-world-risk-n1282454

Sundaram, J.K. (2021, 3 October). Biden Disappoints: Must Do More, Not Less. *The Daily Star*. https://www.thedailystar.net/views/opinion/news/biden-disappoints-must-do-more-not-less-2189161

Urias, E. & Ramani, S.V. (2020). Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. Journal of International Business Policy 3, 367. https://doi.org/10.1057/s42214-020-00068-4

UNAIDS. (2022). *Mozambique – Overview*. https://www.unaids.org/en/regionscountries/countries/mozambique

Warn, C. (2021, 30 October). *G20's Bitter Divide on Global Vaccine Inequality Could Condemn World to an "Endless Pandemic".* Amnesty International. https://www.amnesty.org/en/latest/news/2021/10/g20s-bitter-divide-on-global-vaccine-inequality-could-condemn-world-to-an-endless-pandemic-charities-warn/

World Trade Organization. WTO. (n.d.). https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

World Trade Organizations. (2021, 11 March) Members discuss TRIPS waiver, LDC transition period and green tech role for small business. *World Trade Organizations*. https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm

WTO | intellectual property (TRIPS) - TRIPS and public health. (n.d.). https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm