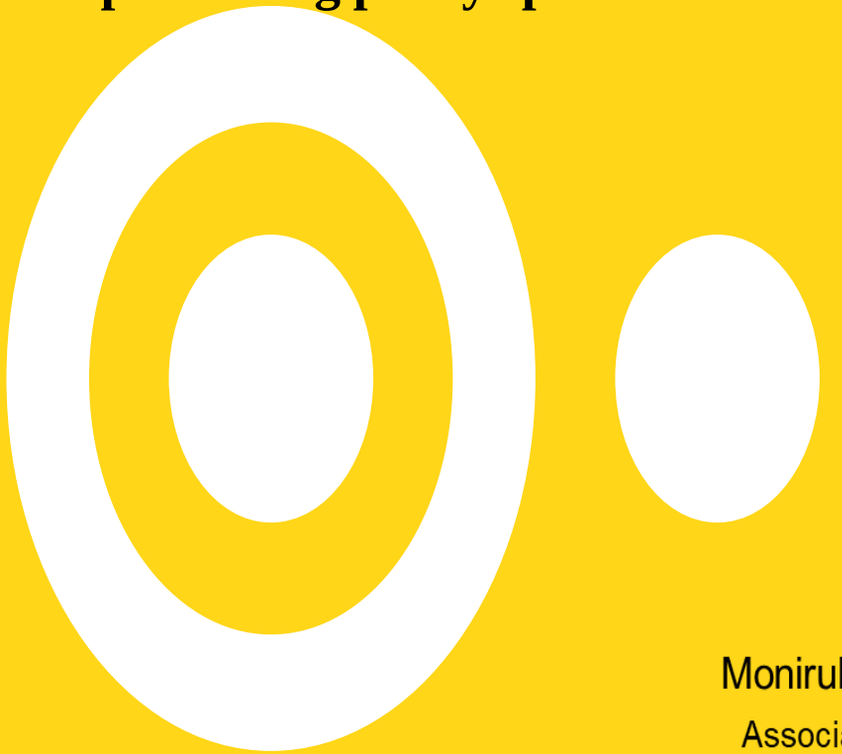
# The implementation of the TRIPS Agreement by Least Developed Countries: preserving policy space for innovation and access to medicines

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# The TRIPS Agreement

- The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) was negotiated in the Uruguay Round between 1986-1994 as part of the Marrakesh Agreement establishing the World Trade Organization (WTO), with the objectives of ensuring global protection of the Intellectual Property (IP) rights of the Multinational Companies mostly based in the developed countries with mandatory enforcement mechanism.
- The motivation was to set global minimum standards for IP protection therefore all WTO Member states are required to comply with the Agreement by introducing necessary changes including institutional and infrastructural set-ups in respective national regulatory frameworks.
- The TRIPS obligations are applicable for all inventions in all fields of technology (as per Article 27.1 of the TRIPS Agreement), which required huge financial, institutional and technical burdens for the Least Developed Countries (LDCs) considering their socio-economic conditions, low levels of infrastructure, weak industry and institutions, fragile economy and extreme poverty.
- Pharmaceutical inventions were particularly received huge attention because of its direct impact on public interests particularly accessibility and affordability of medicines.

# Background:Contention over Intellectual Property and Public Health

- 80% of the global population in the developing countries only represent about 20% of global pharmaceutical sales (Medecins Sans Frontieres [MSF], 2001; The Cambridge Textbook of Bioethics, Eds: Peter A. Singer and A. M. Viens, 2008).
- MSF estimates that 90% of the world's health R&D expenditure is devoted to only diseases that affect just 10% of the world's population in the developed world.
- Of 1393 new drugs approved between 1975 and 1999, only 16 were specifically indicated for tropical diseases and tuberculosis (Trouiller et al., 2002).
- Given its broader public health and developmental implications, access to essential medicines has become a fundamental human rights concern (Commission on Intellectual Property Rights, Innovation and Public Health [CIPIH], 2006).

# COVID 19 Vaccine

- **Countries representing just 13 percent of the world's population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine (See, Oxfam, 2020).**

- "**Even in the extremely unlikely event that all five vaccines succeed, nearly two thirds (61 percent) of the world's population will not have a vaccine until at least 2022**."-see, https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19.

- **As of 10 February 2021 –** "Of the 128 million vaccine doses administered.., more than three quarters of those vaccinations **are in just 10 countries that account for 60 per cent of global GDP.** …130 countries, with 2.5 billion people, are yet to administer a single dose" (see, https://www.unicef.org/press-releases/covid-19-vaccine-race-we-either-win-together-or-lose-together).

- COVAX –to deliver 2 billion doses to people in 190 countries-to ensure 92 poorer countries will receive access to vaccines along with 98 wealthier countries. The scheme is steered by the World Health Organization and involves the Global Vaccine Alliance (Gavi) and the Coalition for Epidemic Preparedness Innovations (Cepi).As per present situation, the scheme could cover the doses needed only for 20% of a country's population.

- So here is a question of utilizing available policy spaces and potential to allow the developing countries and the LDCs having technical capacity to local manufacture of pharmaceuticals to have access to required technologies for the mass production of the Vaccine.

- See, https://www.bbc.com/news/world-55795297.

# Facts and Evidence

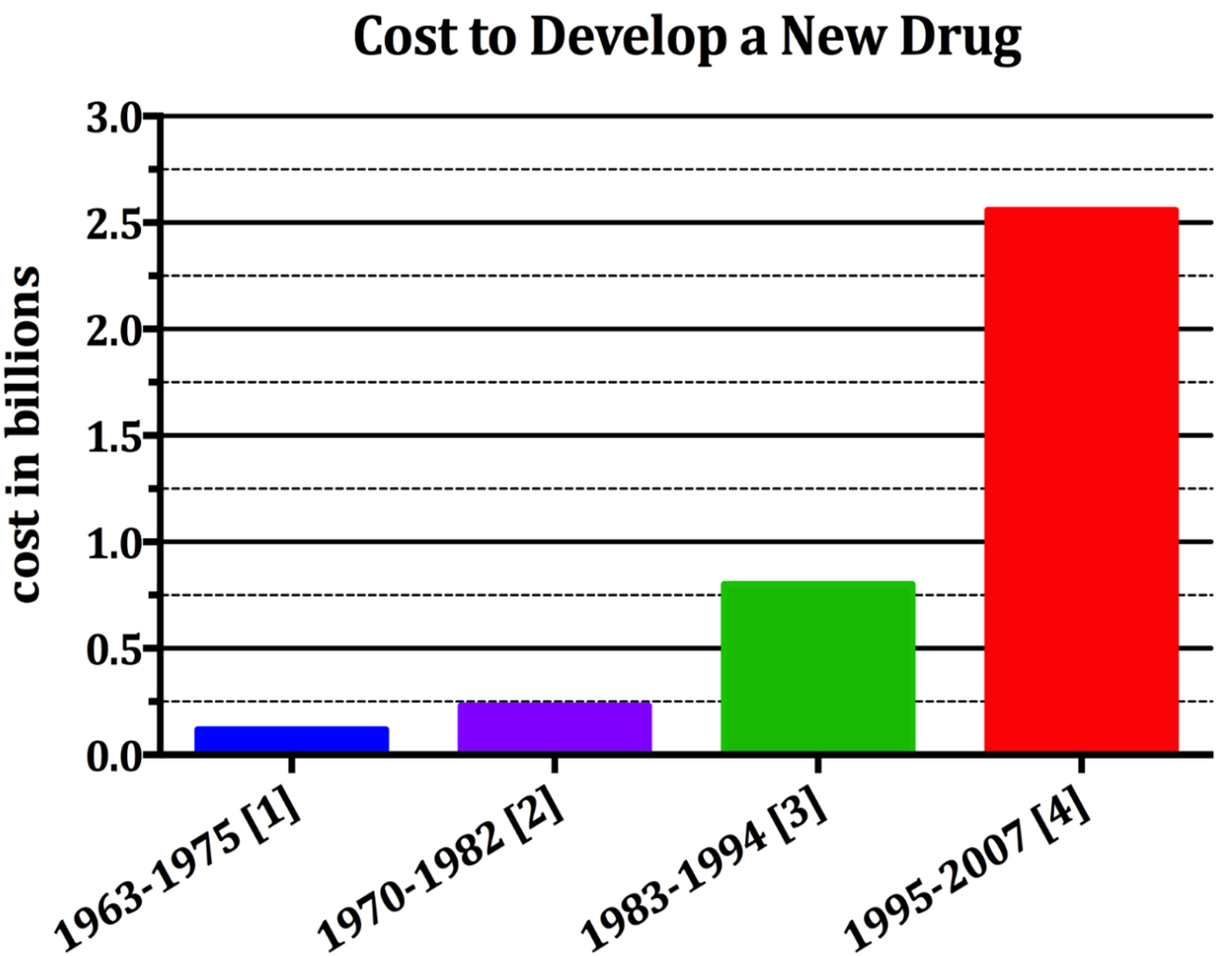


**Figure: Cost to develop a new drug.** Cost in billions is represented according to the contemporary values of the period. Graph data collected from published CSDD Tufts studies [1-4].

106 investigational new drugs from 10 organizations around the world were tested in humans between 1995 and 2007. The grand total life-cycle cost of developing a new drug to nearly $3 billion.

# Facts and Evidence

- It is often argued by the developing countries patent protection drive up drug prices, restrict access to technologies and hence turn into a barrier for access to medicines.
- Prior to the TRIPS Agreement, over 50 countries provided no patent protection for pharmaceuticals, many provided only process and not product patents, and in many others the duration of patents was much less than 20 years (WHO, 2001).
- But many essential drugs are off patent. Of the drugs on the World Health Organization Essential Drugs list, 75% are not currently the subject to patent protection.

See for details, Amir Attaran, How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?, Health Affairs , Vol. 23, No.3, *p.155*

# Extending the TRIPS Transition Period: Is it a Measure for Making a Viable Technological Base or Simply a Further Waste of Time?

- **Art. 66.2 and 67-disputed adequate technical and financial cooperation from the developed countries to the LDCs.**
- **Technology need assessment and initiation of legislative, institutional and infrastructural adjustments to utilize the policy spaces in the LDCs.**

# TRIPS Waiver and Transitional Periods

- While the initial deadline for transition to full compliance for LDCs was 1 January 2006, the TRIPS Agreement provides that the TRIPS Council "shall, upon duly motivated request by a LDC Member, accord extensions of this period".
- Accordingly, there have been three subsequent extensions in favour of the LDCs. The first was particularly related to pharmaceutical patents and lasted until 1 January 2016.
- The second was approved by the TRIPS Council on 29 November 2005 and meant that LDCs would not have to apply TRIPS provisions (in general, not just as they apply to pharmaceuticals) other than Articles 3, 4 and 5 until 1 July 2013; this was again extended to 1 July 2021 by a TRIPS Council decision on 11 June 2013.
- The Doha waiver that specifically addressed pharmaceutical patents was further extended until January 2033 based on a request from the LDC group.
- On 1 October 2020, Chad, on behalf of the LDC members of the WTO, has presented a proposal to the Council for TRIPS for the extension of the transition period for LDCs under Article 66.1 of the TRIPS Agreement.
- The 2005 TRIPS Council decision to extend the transitional period for the LDCs acknowledged the continuing needs of LDCs for technical and financial cooperation, "to enable them to realize the cultural, social, technological and other developmental objectives of intellectual property protection" as laid down in Articles 7 and 8 of the TRIPS Agreement.
- Council for TRIPS, 'Extension of the Transition Period under Article 66.1 for Least-Developed Country Members', 30 November 2005, WTO document IP/C/40.

## Case Study on Bangladesh

- Among the 47 countries classified as LDCs (of which 36 are WTO members), Bangladesh is one of the few with an adequate pharmaceutical manufacturing capability, and it is nearly self-sufficient in pharmaceuticals.
- Bangladesh's pharmaceutical industry now accounts for 97% of the country's pharmaceutical needs (the remaining 3% includes insulin, vaccines and high-end, anti-cancer drugs, the production of which are very capital intensive and hence not economically feasible for Bangladesh.
- Bangladesh devoted too much of its developmental efforts and economic diplomacy to exploiting the benefits of its LDC status and TRIPS waiver, including for pharmaceutical patents.
- Bangladesh has reached eligibility for LDC graduation in 2018 and following two triennial reviews by the Committee for Development Policy (CDP), the country will graduate out of the LDC group in 2024.
- Once Bangladesh graduates out of the LDC status, it will no longer be able to enjoy the TRIPS transitional periods and extended waiver periods for the pharmaceutical patents.

# Balancing Innovation and Societal Goals

1. Utilise TRIPS Flexibilities
2. Support Measures
3. Institutional and Infrastructural Development

# TRIPS Flexibilities

•While TRIPS ensures strong and universal patent protections, the Agreement also provides flexibilities for greater public good and societal goals.

•However, there is always the risk of retaliatory political and economic measures for using these flexibilities.

•Again, to take the benefits of these flexibilities, countries need to have adequate regulatory, institutional and technical expertise.

# TRIPS Flexibilities

- high threshold for patentability and exclusion clause from patentability provisions,
- a best mode of patent disclosure and disclosure of origin,
- narrowing the scope of patent claims to prevent ever-greening
- providing exceptions to product patent rights such as early working,
- parallel imports, and research and experimental-use exceptions,
- a strong compulsory licensing mechanism,
- prior-use exceptions,
- pre-grant and post-grant oppositions
- making the duration of patent protection subject to exceptions, and
- not adopting overprotective enforcement provisions.

- See, M. Monirul Azam, Globalizing Standard of Patent Protection in WTO Law and Policy Options for the LDCs, Vol. 13.2, Chicago-Kent Journal of Intellectual Property, 2013, USA, pp.402-488.

# Support Measures

1. **Drug Price Control-Essential Medicines List**
2. **National Competition law**
3. **Innovation in bargaining and drafting of contracts**
4. **Governmental bulk procurement and/or advance buyouts**
5. **Patent Pool on country specific diseases**
6. **Introduction of Patent Prize system**
7. **Traditional Knowledge**

**See, M. Monirul Azam, The Experiences of Patent Law Reforms in Brazil, India and South Africa and Lessons for Bangladesh, Vol. 7.2, Akron Intellectual Property Journal, 2014, USA, pp.61-100.**

# Changes need to be in place for TRIPS compliant Pharmaceutical Regulation

| Issues | Existing Pharmaceutical Regulation in Bangladesh | Changes need to be in place for TRIPS compliant |
|---|---|---|
| • Product patent for pharmaceuticals. | • As of February 2021, pharmaceutical patents are prohibited in Bangladesh. | • Both process and product patents for pharmaceuticals need to be introduced. |
| • Duration of Patent protection | • Exiting patent law of Bangladesh provides protection for only sixteen years. (Patents and Design Act, 1911). | • This needs to be extended until 20 years. |
| • Local production facilities and local working. | • Certain pharmaceutical products are excluded from licensing unless having local production facilities by the MNCs. | • It is not mandatory to have local production facility. However, there is a debate regarding local working provision as a ground for issuing compulsory license. |
| • Import Restrictions. | • Import restrictions on the pharmaceuticals and pharmaceutical raw materials that are locally produced. Again, if it is not within the essential drug lists of DGDA but produced by at least three local companies may not be imported. | • No import restrictions whether locally produced or not as it will be discrimination and hence violation of WTO and TRIPS principles. |
| • Marketing Approval restrictions. | • Marketing approval is not granted to MNCs if a particular pharmaceutical product is locally produced. | • No restrictions on the marketing based on produced locally or imported. |
| • Production restrictions. | • MNCs are not allowed to produce some drugs such as vitamins, antacids. | • There must not be any restriction as it will be discrimination. |
| • Single ingredient. | • Only single ingredient products are allowed for production and distribution in the local market. | • Combination drugs need to be allowed. |
| • Advertising restrictions. | • No advertising is allowed on the pharmaceutical products. | • Although unethical advertising may be restricted, advertising need to be allowed. |
| • Test data protection. | • There is no test data protection for pharmaceuticals in Bangladesh. | • There may be pressure from the MNCs and developed countries like USA and the EU for the introduction of test data protection. |



See, M. Monirul Azam, The Impacts of TRIPS on the Pharmaceutical Regulation and Pricing of Drugs in Bangladesh: In Search of Policy Direction, International Journal of Law and Management, Vol.59.3, 2017, Emerald Publishing, UK, pp. 376-393.

# Institutional and Infrasturctural Issues

1. Institutional Innovation: National IP Office and Drug Regulatory Authority.
2. National Innovation System, National Health Policy and IP Policy
3. Triple Helix-Government-Industry-University Collaboration from public interest perspectives
4. National health insurance system

## Capacity Building in the Department of Patents, Designs and Trademarks (DPDT)

- *Patent Information System*. A database is required of patents, non-working patents and expired patents. In Bangladesh there is currently no patent information system at the DPDT, and public access to the patent database is mostly restricted and subject to slow bureaucratic processes.
- *Traditional Knowledge Database*
- Considering the low level of IP awareness in Bangladesh, it is necessary to establish information centres around the country with support policies for SMEs.
- The DPDT could take initiatives to promote innovation and patenting practices among local SMEs and research institutions: more than 70% patent applications by the foreign companies and non-resident.
- Using the experience of Brazil, Bangladesh could examine potential policy spaces to examine pharmaceutical patent applications from public health dimension in a post-TRIPS situation.
- Training of patent examiners and other relevant stakeholders to consider the TRIPS flexibilities from a balancing perspectives of promoting innovation and accessibility of technologies particularly pharmaceuticals.

## Capacity Building in the Directorate General of Drug Administration (DGDA)

- *To promote Investment in R&D and requirements for domestic supply*
- *Developing Standards for Pharmaceutical Companies*-Good Manufacturing Practices (GMP).
- Setting up Excipient based pharmaceutical companies
- *International Certificates for Export, and Modern Test Facilities*
- the establishment of the Active Pharmaceutical Ingredients (API) Park and adequate facilities for bio-equivalency lab
- the DGDA needs to have continuous supervision to maintain the quality of medicines both produced locally and imported for local market.
- the DGDA should enhance expertise to determine counterfeiting medicines.
- Infrastructural facilities like cost effective and adequate supply of energy, efficient local transport, one stop services for permits and other administrative requirements to avoid bureaucratic delay, port facilities for export and import and international transportation.
- As infrastructural facilities could reduce cost of production and facilitate the import of raw materials and export of medicines efficiently, these need to be taken into consideration for determining competitiveness of the local industry.

# Necessity of National Development-centred Intellectual Property Policy and a National Health Strategy

- **Integrating Long-term Innovation and Access Objectives**

- **Having a public-interest based national health strategy and national IP policy could help national institutions such as DPDT, DGDA and Courts to utilise the policies while making interpretations of the IP laws in the context of public health and other societal objectives.**

- **National health insurance system-to avoid burden of excessive out of pocket expenditure for the patients.**

# University–Industry–Government Collaboration and Public–Private Partnerships

- Not simply for promoting patenting in the Universities!!!!
- Government should set objectives making short term and long-term action plan for promoting R&D in the local institutions on the country specific and urgently needed areas.
- Universities should have access to adequate funding and establish collaboration with the Industry to innovate and commercialise inventions.
- Local pharmaceutical industry and MNCs active in Bangladesh mostly concentrate on generic medicines and generating more profits out of exporting to other countries and hence lack of interest to invest or re-invest in basic R&D and collaborate with the local universities.
- Cooperation between industry-government and universities can help to develop an environment of self dependence and confidence, entrepreneurship, and experimentation that brings together researchers, practitioners, and policy makers, across disciplines to solve some of the pressing health problems facing by Bangladesh.
- There is no problem that Bangladesh and its pharmaceutical companies should take advantage of its LDC status and TRIPS waiver as much as possible, but it should also learn to think and act for when and how it could make graduation from LDC status, how it could utilize available policy spaces and progression towards innovation and TRIPS compliance.

# Thank you all for attention.