Impediments in Implementation of TRIPS Flexibilities

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The Dilemma of Patent rights and Patient rights

Right to health as a human right has been recognized under:

- Art.25(1) of the United Nation's Universal Declaration on Human Rights (UDHR) 1948; adequate standard for the health
- Art. 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR) 1966; highest attainable standard of physical and mental health
- Art. 24(1) of the Convention on the Rights of Child (CRC) 1989; right of access to health care services
- Art. 12(1) of the Convention on Elimination of all forms of Discrimination Against Women (CEDAW) 1979; access to health care services
- Art. 5(e)(iv) of the International Convention on the Elimination of all forms of Racial Discrimination (ICERD) 1965; right to public health
- Constitutions of around 135 countries.

The Dilemma of Patent rights and Patient rights

- Patents provide monopoly rights to patent holders. Patent protection on drugs renders prices of drugs unaffordable for most of the patients in the developing world.
- Before 1995 (Prior to TRIPS Agreement), more than 50 countries had excluded drugs from patent protection.
- Under Article 27(1) of the TRIPS Agreement, signatory states are obliged to protect innovations in **all fields of technology** including pharmaceuticals.
- Signing TRIPS Agreement is a condition for WTO membership. Transition periods were afforded to developing (2000, 2005) and least developed countries (2006, 2013, 2016).
- TRIPS came with its enforcement mechanism and therefore had **teeth**.

TRIPS Flexibilities

The conflict between patent rights and patient rights came to the limelight in the wake of outbreak of HIV/AIDS in Africa.

- Art. 30 of the TRIPS Agreement provided limited exceptions to the exclusive right of patent holders.
- Art. 31 allows members to authorize '**other use**' of the subject matter of a patent without patent owner's consent subject to payment of adequate remuneration to the right holder. (**Compulsory licensing**)
- **Doha Declaration 2001** recognized the gravity of public health problems faced by the poor countries and reaffirmed that the TRIPS Agreement does not and should not prevent member states from taking measures to protect public health. It further recognized that 'each member has the right to grant compulsory licenses and the freedom to **determine the grounds** upon which such licenses are granted'.

TRIPS Flexibilities

- Art. 31(f) stipulates that the use be authorized predominantly for the supply of the domestic market of the member authorizing such use.
- Because of the condition of the "**domestic market**", the developing and least developed countries lacking drug manufacturing capacity could not take advantage of the flexibilities provided under Article 31.
- Under Paragraph 6 of the Doha Declaration, the Council for TRIPS was instructed to find an expeditious solution to this problem.
- **WTO General Council 's Waiver Decision 2003** waived the "domestic market" condition provided under Art. 31(f) but it imposed cumbersome notification and transparency requirements.

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1. Complexity of the Procedural Requirements

- The system introduced by the WTO General Council's Waiver Decision to deal with the cases of national emergency or other circumstances of extreme urgency came with the following conditions:

i) The eligible importing member must notify the Council for TRIPS of the names and expected quantities of the required pharmaceutical products; that it has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question; and (if the product is patented in its territory) that it will grant a compulsory license in accordance with article 31 for its import;

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ii) The compulsory license issued by the exporting member must specify that: only the amount required by the importing member may be manufactured; the entirety of the production under the license must be exported to that member; and products manufactured under the license must be clearly identified as being made under the system by specific labelling and distinctive coloring;

iii) The exporting member must notify the Council for TRIPS of the grant of the license and the attached conditions, including the quantity to be manufactured and the country of export; and

iv) Eligible importing members must 'take reasonable measures within their means to prevent re-exportation of the products imported under the system.

-The **complexity of the procedural requirements** for implementing the waiver makes the process very difficult to use.

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2. Foreign Direct Investment (FDI)

- A country may lose a potential source of economic growth by issuance of compulsory licenses because there is a straightforward relationship between foreign direct investment and intellectual property protection.
- Developing states may have to pay a heavy price for providing affordable access to medicines to their citizens. The patent holding pharmaceutical companies may withdraw from the states not fulfilling their commitments of patent protection; at least, they may withhold their new drugs.
- For instance, in the wake of Thailand's decision to issue compulsory license for Abbott's HIV/AIDS drug Kaletra, Abbott withdrew all of its new products from Thailand and threatened to stop registering drugs in Thailand.

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3. Unilateral Trade Sanctions

- The advanced countries have the tendency to exert pressure on the developing world by their own unique mechanisms. For instance, the 'Special 301' mechanism of the United States is used as an economic leverage to pressure the poorer countries.
- Special 301 mechanism of the United States empowers United States Trade Representative (USTR) to prepare an annual 'Special 301 Report' and place countries in the 'watch list' or 'priority watch list' on the basis of which unilateral trade sanctions can be imposed.
- In 2007, when Thailand granted compulsory license for Abbott's HIV/AIDS drug Kaletra to improve access to the needed drug, it was included in the 'Priority Watch List' as a trading partner. European Union Trade Commission also objected to Thailand's decision.

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4. The Risk of Retaliatory Action

- Well funded and organized giant pharmaceutical companies are supported by powerful governments like the United States and the European Union who exert economic and political pressure on poorer countries to bar them from availing TRIPS flexibilities.
- For instance, in 2002, when South Korea decided to grant compulsory license for Novartis Pharmaceutical Corporation's drug Gleevec, the US government pressured her not to do so.
- Similarly, in 2006, Pfizer pressured Philippine when she decided to parallel import a generic version of Norvasc.
- In the same year, when Thailand granted compulsory license for Merck's drug efavirenz, the United States, with the threat of high tariffs for Thai exports, exerted pressure on Thailand to revoke the compulsory license.

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5. High Litigation Costs

- The cost of patent litigation is exorbitantly high. Owing to high litigation costs, third world countries are extremely reluctant to become party to patent litigation. Drug patents are the most litigated patents and developing and least developed countries can hardly be expected to have significant capacity and economic incentive to litigate claims against authorization of parallel importation and grant of compulsory licenses.
- In 1997, after the outbreak of the HIV/AIDS epidemic, when South African government attempted to authorize parallel importation of affordable medicines through a controversial legislative proposal, it triggered reaction of pharmaceutical companies. **39 multinationals** moved the High Court of South Africa whereby they challenged the constitutionality of the proposed amendment.

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6. Lack of Technical Expertise

- TRIPS Agreement's provisions especially those regarding compulsory licenses and parallel importation, are coupled with conditions which make them difficult to invoke effectively and speedily.
- In order to use flexibilities provided under TRIPS Agreement and Doha Declaration, member states need to review and amend their national laws. Lack of technical expertise in the field of intellectual property in the underprivileged countries has been an impediment in fully availing the flexibilities provided under the TRIPS by interpreting and incorporating them in the national laws.

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7. Reducing Incentives to Innovate

- The drugs can be divided into two broad categories: First, 'global drugs' like cancer drugs and HIV/AIDS vaccines that are primarily created for rich markets but are also needed by the developing world. Second, the drugs that are needed only by poorer countries like drugs to treat tuberculosis or malaria. The drugs specific to third world are not priority of multinational pharmaceutical companies because of less financial gain.
- It is claimed that 10% of global health research is devoted to conditions that account for 90% of the global disease burden.
- Threat of compulsory licensing in the developing world further adds to the concerns of the multinationals.

CONCLUSION

- To sum up, there are implementation gaps between theory and practice of TRIPS flexibilities; WTO member states have been provided flexibilities under TRIPS Agreement but third world countries are not able to avail the flexibilities due to numerous practical implications which restrict them from availing the legitimate flexibilities.

Thank you for your time and patience.