



Reflections on the LDC Experience with Article 66.2 of the WTO TRIPS Agreement: Prospects for the Future

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Workshop on the Implementation of Article
66.2 of the TRIPS Agreement: Incentives
for Technology Transfer to LDCs

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Article 66.2 Indeterminacy

- Record of negotiating history limited
 - Developed country inducement to LDCs to create Uruguay Round consensus
 - Formulated as developed country obligation (“shall provide”)
 - “Enterprises and institutions” covers private sector, governmental, and includes foundations
 - “Incentives” not further defined, can find WTO analogies, e.g., Subsidies Agreement
 - Target objective to enable creation of “sound and viable technological base” allows inference of meaningful contribution, but kind and quantum difficult to benchmark
 - See, e.g., “commercial scale” and “sufficient to provide a deterrent” in *WTO China Enforcement* case
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Implementation

- Introduction of reporting requirements added transparency
 - Reports tend to incorporate foreign policy programs with some direct, but mainly indirect, components regarding transfer of technology as that would be understood in terms of industrial development, such as providing access to patents, trade secrets, and know how useful to business development
 - Programs often generally directed to developing countries, and not specifically to LDCs
 - WTO has produced two comprehensive reports on the subject matter of transfer of technology programs from developed to development countries that illustrate difficulties of disaggregating data
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Implementation

- A major point from several developed countries is that LDCs should endeavor to make more specific demands
 - A basic question is whether LDCs consider they have received what they bargained for when they were persuaded to join the TRIPS Agreement consensus
 - A counterbalancing element is that LDCs have largely been relieved of responsibility for implementing IP norms prescribed by the TRIPS Agreement, so arguably they have not traded away much in the bargain
 - General extensions for compliance and specific extensions for pharmaceutical products
 - Turn now to focus on future ...
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Moving forward with focus on public health

- Serving as Chair of the WHO Technical Advisory Group on Local Production and Technology Transfer that operates in conjunction with the Local Production Unit (LPA) at WHO
 - Recently work also with the WIPO Global Challenges Division and the IP and Innovation Ecosystem Sector
 - Substantial attention is being paid to assisting with technology transfer, including to LDCs, and these activities may be helpful in pointing to the types of incentives that LDCs could demanded from the developed countries
 - Interest in local production of pharmaceutical products substantially intensified as consequence of COVID-19 pandemic
 - Recognition that reliance on foreign sources of supply creates vulnerability
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LDCs in the pharmaceutical value chain

- Bangladesh has illustrated that an LDC can successfully develop a relatively advanced pharmaceutical manufacturing sector, though its historical path may be difficult for others to follow
 - 1982 ban on imports of medicines that could be produced locally, with industry base existing based on formulation for multinationals
 - Elimination of pharmaceutical product patent protection in 2008
 - Bangladesh exports widely, though restricted from high income markets when patents in force (Sudip Chaudhuri, 2021)
 - Bangladesh will soon graduate from LDC status and no longer be able to take advantage of newly patented technologies, at least in principle
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Building sustainable pharmaceutical manufacturing capacity

- Market demand
 - African LDCs can integrate pharmaceutical markets and aggregate demand
 - Requires coordination of procurement policies and regulatory framework
 - Value chain
 - Typically, pharmaceutical sector begins at lower end of value chain with packaging and labeling, moving up to formulation, then to API production
 - API production remains very limited in Africa, but South Africa and others making progress. In principle, African value chain could rely on regional API production with LDCs involved in next steps
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Developed country incentives

- Development of a robust pharmaceutical sector in LDCs in Africa and elsewhere provides space for developed country incentives to enterprises and institutions to participate with transfer of technology
 - Assistance with improving regulatory structures through developed country support for national and regional regulators
 - Assistance with improving LDC regional infrastructure in terms of energy and water supply, transport, etc.
 - Developed country enterprise assistance through licensing of patent technologies and know how, and additional support in the implementation of manufacturing process, technologies, quality controls, etc.
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Creating incentives

- Providing direct subsidies to industry to assist with transfer of technology to LDC pharmaceutical manufacturers
 - Use tools such as acceleration of regulatory approvals as incentive for participation, with analogy to tradable preferences for orphan drugs
 - Grant tax benefits (e.g., credits or enhanced deductions) usable against global income
 - Establish conditions on government funding of R&D requiring “making available” for designated developmental uses (e.g., in LDCs)
 - Financial guarantees, such as guarantees of loans made to LDC enterprises
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Analyzing and defining interests

- Most challenging step is persuading developed country enterprises and institutions that there is a self interest in supporting local production in LDCs
 - A logical premise is that creating joint venture enterprises that generate profits for the LDC and developed country participants would not harm the interests of the developed countries, and may make enterprises and institutions “better off” in terms of long-term market positioning and R&D activities
 - Foundations play a substantial role and are incentivized by tax benefits
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Analyzing and defining interests

- The WHO local production unit has developed a strategic assessment tool (SAT), a Biopharmaceutical Training Hub (initially in Korea, and expanding to Africa), and model sector development plans
- The LPA can assist LDCs with identifying specific demands to be made on the developed countries in terms of implementing Article 66.2 of TRIPS

Thank you

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