Building a Bridge to Nowhere:
Promoting Local Production without Addressing Intellectual Property

A rising tide of rhetorical support for diversified local/regional biopharmaceutical manufacturing capacity coincides with low- and middle-income countries' justified outrage over the devastating consequences of rich-country vaccine nationalism and Big Pharma indifference, overreach, and profiteering during the COVID-19 pandemic. Plans and seed resources for building a bridge to local manufacturing abound, but they all have one feature in common, they systematically refuse to address the intellectual property barriers, including patents, data protection, and trade secrets, that will prevent nascent manufacturers from being able to produce, register, distribute and sell medical tools needed to meet global health challenges. Without systematically addressing these IP-related barriers, LMIC producers will not have freedom to operate to research, develop, or commercialize the medical products they need to reduce dependence on high-income countries' drug companies and donor governments..

Building a bridge to a well distributed, capacitated and sustainable manufacturing capacity in LMIC regions will be essential to their ability to respond quickly with adequate supplies of vaccines, medicines, and diagnostics needed to address future pandemics and other unmet needs ranging from neglected diseases to the increased burden of chronic non-infectious diseases.

Many challenges must be met to achieve the goal of quality-assured local biopharmaceutical manufacturing. These challenges may include training up a skilled workforce (where necessary), financing and equipping public and private manufacturing facilities, funding research and product development (R&D), designing and conducting clinical trials, meeting stringent regulatory standards, securing components and strengthening supply systems, developing transportation and energy infrastructure, amassing domestic and regional markets, and many more. Enhanced R&D capacity (including access to pathogens) will be needed to optimize products and manufacturing processes, to adapt existing products for use in resource limited settings, as needed, and to develop vaccines, medicines, and diagnostics / health technologies for previously unmet and emerging health needs. LMIC manufacturers will need to be able to produce vaccines, biologics (including monoclonal antibodies), other complex medicines, and other scientific advances as they emerge.

All of these hopes for local/regional production hinge on whether LMIC researchers and manufacturers have access to IP-protected research tools, technology platforms, product and process inventions, trade secrets, regulatory data, biologic resources (such as cell lines), and other knowledge essential to product development, freedom to operate and to sell medical products in aggregated export-import markets.

Unfortunately, this essential knowledge currently resides in private hands, even when the public has invested heavily in basic science, R&D, clinical trials, and expanded manufacturing capacity. We learned the painful costs of privatization of knowledge during the COVID-19 pandemic when major vaccine producers, including leading participants in the Global Local production forum, refused to license their IP and share their break-through technologies and manufacturing know-how with capable producers in LMIC regions, including the mRNA Technology Transfer Programme.

LMICs can and should build even more plants capable of producing safe and effective health products of assured quality and do so in regions with insufficient capacity at present. Voluntary measures might go part way for some products for some countries, as with Medicine Patent Pool licenses for HIV

antiretrovirals, hepatitis C antivirals, and Covid antivirals. Many middle-income countries, excluded from these and other voluntary licenses, are stuck with often unaffordable tiered prices.

The recently released INB draft of the Pandemic Accord, current state of negotiations on International Health Regulation, public documents on Medical Countermeasures Platform, and UN General Assembly Resolution on Pandemic Prevention, Preparedness, and Response all stop short of recognizing the need to support LMICs in overcoming IP barriers to essential technologies and knowledge. Instead, there is magical thinking that private companies' "voluntary measures on mutually agreed terms" will suffice when past evidence is to the contrary.

Instead of building bridges to nowhere, international and multilateral institutions, HIC and LMIC governments, and health-oriented foundations must finally commit to supporting countries in their collaborative efforts to overcome IP barriers that will otherwise stifle local manufacturing. Just as a bridge needs structural support, viable regional manufacturing can't have insurmountable barriers and roadblocks such as patents, data exclusivity, copyright, and trade secrets. Compulsory licenses, mandatory access to trade secrets, and even IP waivers are needed for sustainable biopharmaceutical self-reliance.

LMICs and local-production proponents, including those attending the 2nd World Local Production Forum, must insist that initiatives to support local/regional production address the legal right and means to overcome IP barriers when needed. We cannot be complacent – or resigned – to the siren song of purely voluntary measures and continued private hegemony over tools and knowledge by which the right to health is realized.