Voluntary Licensing and Access to Medicines

Project Summary

Background of the Problem.

Covid-19 has caused millions of deaths and much suffering and economic disruption. Governments have relied heavily on vaccines and other medications in efforts to reduce its adverse impacts. Distributions of those medications have, however, been highly disparate. While the U.S. and other relatively wealthy societies have achieved levels of vaccination ranging from 60% to 90% of their populations, many relatively poor and populous countries have much lower levels of vaccinated people, some under 5%.

The proposal initially tabled in early 2021 by India and South Africa to overcome this disparity through the waiver of intellectual property rights is widely considered ineffective and has been rejected by many countries and opposed by major pharmaceutical companies. Efforts to secure vaccinations through gifts and purchases failed to ramp up as quickly as hoped and is one of the reasons that as of early 2022, the significant disparity in vaccination rates between wealthier and poorer countries remains. Sales at cost and gifts by manufacturers are ramping up, but only recently, after market-driven commercial sales mainly to the wealthier countries were prioritized. Projects that contemplate the shipping of complete manufacturing lines to developing countries have encountered substantial headwinds and thus far have come to naught.

Perhaps most importantly, none of these efforts, even if successful, would contribute to expanding the ability of low and middle-income countries to meet their own immediate health-care needs let alone prepare for needs that arise in future pandemics.

The voluntary licensing (VL) approach taken by Gilead Sciences Inc., which began in 2006, has allowed millions of people across low- and middle-income countries to have access to low-cost, high-quality generic medicines for HIV, viral hepatitis and COVID-19. In the context of COVID, Merck and Pfizer have both announced plans to employ VLs to expand access to their COVID anti-viral treatments. A few other companies have engaged in VLs in the past to expand access to their medicines. However, other than Gilead's large-scale, strategic and systematized use of VLs, the use of VLs has been rare and episodic.

This project will examine the potential role of expanded use of voluntary licensing as a strategic approach that could unite wealthy countries and innovator pharmaceutical companies with their counterparts in low and middle-income countries (governments and generic manufacturers) to meet the needs of low and middle-income populations in the current pandemic and to prepare for and respond to future global health emergencies.

Rationale and Specific Needs to be addressed by the proposed project.

As illustrated by the painfully slow access to COVID vaccines in low- and middle-income countries, current approaches do not ensure adequate supplies or capacities needed for current or long-term response in those countries. As such, we believe it is vital to examine the possible expanded role of voluntary licensing to meet these needs, drawing on the lessons of past successes in the use of VLs, such as in response to the HIV/AIDS pandemic. It is also important to understand why, if VLs could be a helpful tool to addressing deficits in LMIC access to medicines, they are not employed more regularly today, and what factors should be considered and recommended to create an ecosystem to incentivize and expand their use.

To this end, the project leads have identified a number of issues that, if addressed effectively, could contribute to creating such an ecosystem. These needs (and others that may be identified) also illustrate that the increased utilization of VLs will require collaboration among many players, including innovator pharma companies, generic manufacturers, governments in high-income countries, governments in LMICs, and multilateral organizations and NGOs. A brief summary of the initial list of issues to be examined in this project is as follows:

- *Licensing details*: The specific details within the voluntary licenses themselves, including royalty levels, and technology transfer. For example, VLs should provide foreign manufacturers legal authority to make generic versions of vaccines and other medicines and should include transfer of know-how and technical information needed to manufacture, store, and distribute such medications.
- *Regulatory Approval Pathway*: The regulatory approval pathway in the countries where innovators and licensees operate can and should be modified to create a fast-track system that removes impediments to availability of innovator and licensed products, while also ensuring the maintenance of safety and efficacy standards.
- *Pricing*: Low pricing of licensed generic vaccines and medicines is the key to enhanced access. Several factors affecting pricing should be examined, including competition (e.g., number of licensees active in any market), pricing policies of governments (including price controls), taxes and tariffs, and the presence of a branded product in the marketplace.
- *Quality control*: Several factors must be considered. Manufacturers/licensees should be required to obtain Tentative FDA approval or WHO Pre-Qualification for generic substitutes to ensure that high-quality products with demonstrated safety and equivalence are offered for sale in resource-challenged countries. The U.S. imposed this requirement for the PEPFAR (AIDS relief) program. Other steps must be taken downstream, including the ability to track and trace product, thereby ensuring supply-chain security, and local quality control and monitoring, to ensure bona fide product in the destination country.
- *Health Financing and Capacity Building*: Any private sector B2B voluntary licensing program can only go so far in expanding access to vaccines and other medicines since VLs relate only to manufacture and supply. What approaches can be taken by all stakeholders to complement VLs with the demand side of health financing and health systems capacity building in low and middle-income countries (e.g., infrastructure, cold chain/storage, number of trained medical staff, and availability of diagnostic tools)?
- *Advance Purchase Agreements*: During the current effort to vaccinate worldwide, leading innovators are relatively safe in assuming they should source raw materials, acquire space

and machinery, and hire the personnel needed to maximize production. In normal times, however, and currently for many if not most manufacturers, there is significant, unmitigated risk. Advance purchase agreements and volume guarantees can provide helpful data for more accurate planning and added security to mitigate production of sizeable quantities of medicines at risk.

- *Patent Protection*: Voluntary licenses that result in low-cost generics depend on effective patent protection of the underlying IP. This protects both innovators and generic manufacturers of licensed products from unauthorized sales by unlicensed actors (whose products may also threaten patient health due to suboptimal GMP practices).
- *Patent Incentives*: Governments in which innovators (i.e., licensors) are located can supplement patent protection and data exclusivity with other incentives to encourage the development and widespread distribution of new medicines, including business models such as voluntary licensing. One existing tool that could be adapted to this purpose is the U.S. "Patents for Humanity Program", which issues priority certificates for FDA review to patent owners who develop innovative medicines that address humanitarian challenges.

Specific Objectives of the Project.

(1) Ascertain whether and how VLs could become a leading mechanism that the international community systematizes for expanding access to medicines in LMICs, and what are the key issues that need to be addressed in doing so.

(2) Develop findings and recommendations (with a goal of publishing a "tool kit") that would become the basis for governments, multilateral institutions, industry, and NGOs to establish norms and implement policies to expand the use of VLs to accelerate access to medicines in LMICs in response to and preparation for pandemics and health emergencies.

(3) The long-term benefit sought through this project is faster and more universally available access to vaccines and treatments for transmittable diseases in pandemics and other health emergencies in LMICs. This model could also be applied to other technologies, including diagnostics and medical devices.