WTO IP waiver too simplistic

Global vaccine tech-transfer needs other strategies

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Since October 2020, India and South Africa, joined by two-thirds of the WTO Members (African Group, LDCs and most of the developing world) have been actively pursuing other developed country Members to agree to their request to waive global intellectual property (IP) rules. The waiver asserts that by suspending IP protection for COVID-19 technologies, countries will be able to quickly augment production and foster equitable access for COVID-19 related products.

The push for the IP waiver proposal rests on an often simplistic textbook assumption that IP controls exercised through legal rights allow IP owning firms exclusive control on production by reducing output (by restricting competitive copycat entry) and thus increasing prices. Of course, this is something no country wants during a pandemic where equitable access is paramount.

However, truth be told, the IP waiver proposal, even if passed by approval of three-fourths of current WTO Members (a minimum requirement under WTO Rules) or with a consensus, will not enable India or any other country (even with decent production capabilities) to quickly access complex technologies and augment production, particularly in the context of COVID-19 vaccines.

The critical issue surrounding access to COVID-19 vaccine technologies involves an active technology licensing component, which the waiver/suspension of IP laws cannot achieve (e.g. by suspending patents or trade secret protection).

Most complex technologies such as vaccines and other biological products contain two major knowledge components. One component is the knowledge that can be copied by competitors and hence patented to legally prevent copying for at least 20 years in India. Another component involves any undisclosed information such as a trade secret or know-how, including hard tacit knowledge of manufacturing/quality control measures for production and clinical data required for regulatory clearances.

IP waiver simply can't achieve access to tacit knowledge components which are in the exclusive possession of a firm in the form of trade secrets or any other undisclosed information. Any IP lawyer with an understanding of IP intensive industries would confirm that trade secrets do not require any 'exclusivity' type of legal protection (e.g. like patents). Trade secret laws provide defensive protection to a firm that already has exclusive possession of some undisclosed information against industrial espionage, breach of confidence/contracts by its employees or by connected parties who benefit from such misappropriation. Of course, unconnected parties (i.e. competitors) are always free to come out with their own products/processes through capital intensive and time-consuming (months/years) reverse-engineering or independent innovation, which the law on trade secrets does not prohibit.

So even if the WTO IP waiver will allow countries like India to suspend legal protection for trade secrets/undisclosed information, it means nothing in the real world unless the law (and often a draconian criminal measure) is used against a firm and its employees physically located in its territory to engage in forced technology transfer (FTT). Such FTT requirements have never worked in practice without

other social and economic costs. India has already had a taste of it in its unsuccessful bid to get Coca-Cola to reveal its know-how under foreign exchange laws in the late 1970s. It led to Coke's exit from India and return in the post-liberalisation era in the early 1990s.

Realising such complexities and the potential futility of blunt legal instruments early on, the Serum Institute of India (SII) actively collaborated with AstraZeneca/Oxford for obtaining a technology licence involving a reported fee of Rs. 75/- per jab. This allowed SII access to AstraZeneca's tacit knowledge (trade secrets/other undisclosed information) and clinical trial data to engage in quality-controlled production. Scaling-up is a different challenge altogether as it requires both time and investment in heavily quality-controlled production facilities.

Similarly, India's Council of Scientific & Industrial Research (CSIR) – Centre for Cellular and Molecular Biology (CCMB), which already has certain expertise in mRNA technologies, is pursuing Moderna to engage in vaccine technology licensing. Although Moderna has allowed free access to its mRNA patents for COVID-19 vaccine production, the crux lies in active technology licensing.

In fact, even in the case of an indigenously developed vaccine technology by Bharat Biotech with early-stage lab support from the publicly-funded Indian Council of Medical Research (ICMR) – National Institute of Virology (NIV), the Department of Biotechnology had to recently nudge Bharat Biotech to engage in talks with Panacea Biotech(the only other company in India which is currently equipped to produce Covaxin) to scale-up production.

So, a WTO IP Waiver to suspend IP obligations domestically will not help unless India engages in FTT – a recipe for complete disaster, particularly when we have finally decided to open up to more foreign players. The Government of India must not waste its valuable energy in pursuing the waiver proposal in trying to look for solutions that are far removed from the real-world complexities and constraints posed by the economics of vaccine technologies and production, and an equally complex IP ecosystem in the context of global tech-transfers. Where blunt legal instruments don't work, using track-1 and track-2 diplomacy to place moral coercion on western governments to nudge firms to actively engage in technology licensing may still work wonders.

Allowing manufacturers to strike early deals with tech players to facilitate risk-sharing and exploration of synergies driven by a predictable and transparent entry-enabled regulatory environment is a prerequisite for sustainable vaccine production. Securing cheap upfront volume discounts for state-sponsored distribution and allowing private players to cross-subsidise through differential pricing in private sales will help in meeting the demand. This will facilitate the scaling-up of production and pave the way towards healthy competition by driving down vaccine prices in order to attain vaccine equity.

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