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NEWS ANALYSIS

Covid-19: How will a waiver on vaccine patents affect global supply?

The US proposal to waive patents has been hailed as a much needed boost for global equity, but **Gareth Iacobucci** hears that obstacles remain

Gareth Iacobucci

Last week the Biden administration made the surprise announcement that the US would support a proposal to waive patents on covid-19 vaccines in response to the pressing need for more global supply.

Until now the US, like other high income countries such as the UK, Switzerland, Germany, and Japan, had opposed the proposal to suspend intellectual property (IP) rights on covid vaccines that was first put to the World Trade Organization last October by India and South Africa.¹ But in a statement issued on 5 May the US trade representative, Katherine Tai, signalled a U-turn.²

"This is a global health crisis, and the extraordinary circumstances of the covid-19 pandemic call for extraordinary measures," she said. "The administration's aim is to get as many safe and effective vaccines to as many people as fast as possible."

The news was welcomed by people who have been pushing for IP protections to be waived to get more vaccines to low and middle income countries, particularly given the current crises in countries such as India and Brazil, which have seen huge surges in numbers of covid-19 cases and deaths.

The World Health Organization's director general, Tedros Adhanom Ghebreyesus, praised the US's commitment as a "monumental moment in the fight against covid-19," commending the leadership for its "historic decision for vaccine equity."

Michele Heisler, medical director at Physicians for Human Rights and professor of public health and internal medicine at the University of Michigan, described the move as a "major first step." She said, "The current stark vaccine inequalities around the globe are unacceptable, unnecessary, and dangerous, given the rise of new variants."

WHO estimated that as at 5 May 80% of the more than 1.1 billion doses of vaccine that had been administered went to high and upper middle income countries, with just 0.3% administered in low income countries.³

Opposition from pharma

In response to the US's announcement the European Union said it was "ready to discuss" the proposal, but Germany remains against the move, as do other high income countries.⁴ The drug industry also reacted negatively.

In a statement the International Federation of Pharmaceutical Manufacturers and Associations

argued that waiving patents was not the answer to the crisis: "It is likely to lead to disruption, while distracting from addressing the real challenges in scaling up production and distribution of covid-19 vaccines globally: namely elimination of trade barriers, addressing bottlenecks in supply chains and scarcity of raw materials and ingredients in the supply chain, and a willingness by rich countries to start sharing doses with poor countries."

Steve Bates, chief executive of the Bioindustry Association, a trade association for innovative life sciences in the UK, argued that removing IP protections was "not a panacea."

"Just handing countries' governments a recipe book without the ingredients, safeguards, infrastructure, and sizable workforce with the high skills needed to deliver safe and effective vaccines will not speedily deliver help to all those that need it," he warned.

The World Trade Organization has not yet approved the waiver, but if it did experts believe that it would be 2022 at the earliest before the world could expect to see additional capacity.

Logistical hurdles

Critics of the waiver proposal have questioned whether low and middle income countries in particular have the infrastructure, technology, and raw materials to scale up their manufacturing.

Nathalie Moll, director general of the European Federation of Pharmaceutical Industries and Associations, argued that increasing capacity required "skills and technical knowhow of the vaccine developer to bring on board partner manufacturing organisations."

"You simply cannot achieve this kind of capacity expansion by waiving patents and hoping that hitherto unknown factories around the world will turn their hand to the complex process of vaccine manufacture," she said. "A waiver risks diverting raw materials and supplies away from well established, effective supply chains to less efficient manufacturing sites where productivity and quality may be an issue. It opens the door to counterfeit vaccines entering the supply chain around the world."

Javier Guzman, technical director of the Medicines, Technologies, and Pharmaceutical Services programme at Management Sciences for Health, a global non-profit organisation, told *The BMJ* that some middle income countries did have the capabilities to make vaccines and some were already

producing covid vaccines. He cited the voluntary licensing agreements made by AstraZeneca with Indian and Brazilian manufacturers.

But he added, “It is important to distinguish between viral vectors (such as the AstraZeneca vaccine) and mRNA vaccines (Pfizer and Moderna) and between producing the liquid vaccine solution (the active ingredient) and filling and capping sterile vials (known as “fill-and-finish”). More manufacturers in low and middle income countries are in the position to manufacture viral vectors and/or contribute with the fill-and-finish stage of the process.”

Technology pooling

Guzman acknowledged that a waiver was “not a silver bullet” but said he supported it because it “opened the possibility for legal certainty using the current multilateral trading system.”

“This certainty is likely to increase public and private investment in low and middle income countries and therefore manufacturing capacity to produce covid vaccines without the threat of being sued or prosecuted,” he said.

“It [also] signals that the US government is serious about moving beyond the status quo to increase access to covid vaccines, and it offers the world the possibility to learn about using measures that were previously seen as radical or unthinkable and even re-examine IP rights in the context of health emergencies.”

But Guzman cautioned, “The waiver does not replace the additional measures the world and the US government should put in place to increase the global vaccine supply, including incentivising and funding the transfer of technology and knowhow to LMIC [low and middle income country] manufacturers, facilitating the supply of equipment and raw materials, and donating excess covid-19 vaccine doses to Covax.”

Abraar Karan, an internal medicine physician at the Brigham and Women’s Hospital and Harvard Medical School who previously worked on Massachusetts’s covid-19 response, also backed the waiver, while emphasising the need for parallel measures.

He told *The BMJ*, “The technology transfers needed for vaccine manufacturing still need to happen, as do provision of essential materials for this manufacturing. If the only thing we do is liberalise patents, that does not guarantee that high quality vaccines get into the arms of those who need them.”

Should rich countries just make more?

Waiving patents was not the only solution, Karan noted.

“Alternatives to sharing IP would have been to scale up production by building more factories directly under Pfizer, Moderna, AstraZeneca, and Johnson & Johnson, earmarking several billions of vaccines for poorer countries that don’t have access, and distributing these without affecting the patents,” he said. “This would potentially have been another way forward, but this wasn’t done.”

However, Karan said such an approach would not be straightforward. “If production is far away from where the vaccines need to go, you have to consider supply chain issues as well, given some of the storage requirements,” he said.

Regardless of logistical issues, and going beyond the “moral imperative,” Guzman argued that an “all-hands-on-deck approach” that included a waiver was in every country’s interests, because rich countries could not control the pandemic on their own.

“Any existing or potential manufacturing capacity should be used, developed, [or] repurposed to increase global vaccine supply,” he said.

“It is not just a matter of getting manufacturers in high income countries to make more vaccines and share them more widely. They are already producing at maximum capacity, and high income countries still need to vaccinate their populations and prepare for potential future boosters.”

In response to the concern that a waiver would do little to increase vaccine supplies around the world and create an undesirable precedent for future pandemics, Guzman said he thought such fears “might be overstated,” given that a patent waiver was not being considered beyond vaccines.

“The Biden announcement was clear on the potential scope of the waiver and the fact that these were extraordinary circumstances,” he said.

- 1 World Trade Organization. Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of covid-19: communication from India and South africa. Oct 2020. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q/IP/C/W669.pdf>.
- 2 Office of the US Trade Representative. Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver. 5 May 2021. <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.
- 3 WHO. Director-general’s opening remarks at One Shared World event. 5 May 2021. <https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-one-shared-world-event>.
- 4 Covid: Germany rejects US-backed proposal to waive vaccine patents. BBC News. 7 May 2021. <https://www.bbc.co.uk/news/world-europe-57013096>.

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