Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

South Africa and India push for COVID-19 patents ban

They want the WTO to temporarily suspend intellectual property rights so that COVID-19 vaccines and other new technologies are accessible for poor countries. Ann Danaiya Usher reports.

South Africa and India have called for the World Trade Organization (WTO) to suspend intellectual property (IP) rights related to COVID-19 to ensure that not only the wealthiest countries will be able to access and afford the vaccines, medicines, and other new technologies needed to control the pandemic. The pharmaceutical industry and many high-income countries (HICs) staunchly oppose the move, which they say will stifle innovation when it is needed most.

Without special measures, proponents argue, rich countries will benefit from new technologies as they come onto the market, while poor nations continue to be devastated by the pandemic. The proposal states that IP rights such as patents are obstructing affordable COVID-19 medical products. A temporary ban would allow multiple actors to start production sooner, instead of having manufacturing concentrated in the hands of a small number of patent holders.

"What this waiver proposal does is it opens space for further collaboration, for the transfer of technology and for more producers to come in to ensure that we have scalability in a much shorter period of time", says Mustaqeem De Gama, counsellor at the South African Permanent Mission to the WTO, who helped write the proposal.

WTO decisions are normally reached through consensus. Dozens of low-income and middle-income countries (LMICs) support the proposal. However, HICs including the UK, the USA, Canada, Norway, and the EU have rejected it outright, saying that the IP system is required to incentivise new inventions of vaccines, diagnostics, and treatments, which might dry up in its absence. They dismiss the claim that IP is a barrier to access, and argue that equitable access can be achieved through voluntary licensing, technology transfer arrangements, and the donor-funded COVAX Advance Market Commitment for vaccines.

An EU spokesperson said: "There is no evidence that IP rights in any way hamper access to COVID-19-related medicines and technologies." The UK Government declared that the world urgently needs access to these new products to fight the pandemic, "which is why a strong and robust multilateral IP system that can meet this challenge is vital". The UK, by far the largest funder of the COVAX Facility, urges other countries to contribute more.

> **"...the South African Government responded to objections, pointing to examples of how IP has created barriers to access."**

The patent waiver proposal was presented to the WTO's Trade-Related Aspects of Intellectual Property (TRIPS) Council on Oct 16, 2020, and discussed again at a council meeting on Nov 20. There, the South African Government responded to objections, pointing to examples of how IP has created barriers to access. Manufacturers of monoclonal antibody therapeutics that are under patent protection, such as Regeneron and Eli Lily, have locked up most of their capacity in bilateral deals. "Disparity in access is certain unless concrete steps are taken to address intellectual property barriers", South Africa's statement reads. For vaccines, South Africa cites the legal battle in India between Médecins Sans Frontières (MSF) and Pfizer over its pneumococcal vaccine, where a patent has blocked development of alternative versions of the vaccine. In South Korea, Pfizer sued SK Bioscience, which had developed a pneumococcal conjugate vaccine (PCV), forcing the Korean developer to close production of PCV-13. South Africa argues that a similar situation will arise with COVID-19 vaccines unless steps are taken to address the IP barriers.

John-Arne Røttingen, who chairs the WHO Solidarity Trial of COVID-19 treatments, agrees that technology transfer is crucial, but says that voluntary mechanisms are a better way to achieve this. The patent waiver, he says, is the "wrong approach" to the problem because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. "IP is the least of the barriers", he says.

Røttingen, recently appointed as Norway's Global Health Ambassador, says waiving IP might help in producing small molecular weight substances. "But if you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria" to be able to document to regulatory agencies that you have an identical product. Instead, he says, individual companies should be pressured to allow non-exclusive licences and technology transfer of their products, along the lines of the agreements that AstraZeneca and Novavax have established with the Serum Institute of India for vaccines. This partnership model would be much faster, he says. "Instead of going for an unreachable, 'ideal' solution that will not fly, they should identify where the barriers are and work on those."

MSF has been advocating for a waiver on COVID-19 patents for several months, arguing that it is justified on emergency health grounds

and necessary for LMICs that cannot afford to pay HIC prices for vaccines and treatments.

Yuanqiong Hu, Senior Legal and Policy Adviser at the MSF Access Campaign, says the India–South Africa proposal would also make it easier for non-patent holders to produce necessary medical equipment like ventilators, masks, and protective gear. Regarding the need for technology transfers, she says, it is not an "either/or" question. Governments need the full package of toolkits, including technology transfer deals and legal measures such as the patent ban.

She says voluntary transfer via company-led initiatives has delivered limited results. AstraZeneca's vaccine manufacturing agreements with Indian and Brazilian companies lack transparency about costs, and Pfizer and BioNTech, whose vaccine candidate has shown promising results, have shown no sign of licensing or technology transfer of their patented products, she says. Pfizer told *The Lancet* that it will consider all viable options to ensure vaccines get to those who need them, but "a one-size-fits-all model disregards the specific circumstances of each situation, each product and each country".

Regeneron, which has received emergency use authorisation for its monoclonal antibody treatment, is collaborating with Roche to more than triple the supply of its antibody cocktail. Hu says that if Regeneron adapted a global non-exclusive strategy of licensing, transferring know-how and technologies, "many more companies than Roche would be able to start getting ready to produce and supply".

A Regeneron spokesperson points out that when both companies are at full capacity, they expect to produce at least 2 million treatment doses per year and would look to increase that even further should the need exist. "Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic", the spokesperson says. Hu says putting the recipe online and committing not to sue "would be a welcome first step".

The co-sponsors of the patent waiver proposal say COVAX, funded through donations from HICs, is insufficient for ensuring timely and equitable access to COVID-19 products. COVAX aims to procure 2 billion doses of vaccine and to share them equally between HICs and LMICs. However, according to data collected by Duke University, the COVAX Facility has reserved only 700 000 vaccine doses so far. By comparison, HICs have reserved 6 billion doses for themselves through bilateral deals with pharmaceutical companies. Low-income countries, meanwhile, with a combined population of 1·7 billion people, have not yet signed a single bilateral vaccine deal.

COVAX is part of a larger effort, the Access to COVID-19 Tools Accelerator (ACT-A), to supply not only vaccines, but also new medicines such as monoclonal antibodies, diagnostic tests, personal protective equipment, and oxygen to LMICs. An ambitious collaboration—led by WHO; The Global Fund to Fight AIDS, Tuberculosis and Malaria; Gavi, The Vaccine Alliance; and the Bill & Melinda Gates Foundation—ACT-A has set specific, time-bound procurement targets. For example, of the 2 billion vaccine doses that the COVAX Facility aims to deliver, fewer than 1 billion would go to LMICs. If the vaccine requires two doses, as Gavi assumes, this amount will be enough for fewer than 500 million people. Similarly, ACT-A's diagnostics pillar aims to procure 500 million tests which, says Peter Sands, executive director of The Global Fund, is "only a fraction" of what is required.

As such, ACT-A is, even if fully financed, at best a partial solution to the access problem. Moreover, because of a massive funding gap, even these targets are far from being reached. To date, donors have provided US$5 billion of ACT-A's $43 billion required budget for LMICs over the next year.

India's statement to the Nov 20 TRIPS Council meeting reads: "On one hand, these countries are buying up as much of the limited supply as they can, leaving no vaccines in the pie for developing and least-developed countries. On the other hand, and very strangely, these are the same countries who are arguing against the need for the waiver that can help increase the global manufacturing and supply to achieve not just equitable, but also timely and affordable access to such vaccines for all countries."

de Gama says ACT-A fails to address the supply constraints and gives no guarantee of the universal access that is required. He compares it to a small plaster on a gaping, bleeding wound. "In a perfect world, we would only need instruments like [ACT-A]. Unfortunately, it is insufficient to address the consequences of COVID-19", he says.

Given the entrenched positions on the proposal, reaching a consensus in the TRIPS Council is unlikely. Putting the matter to a vote is theoretically possible, but members have never let it happen in the past, and they are unlikely to do so now, says Peter Ungphakorn, former senior information officer at the WTO Secretariat.

"It would be difficult to go in the direction of a vote", de Gama admits. "But that is not the only mechanism we have". South Africa hopes to elevate the issue to the WTO General Council and to spur a broader debate on public health issues in general. "We realise this waiver is not a silver bullet. But COVID has proven that the IP system doesn't work. It is not designed to deal with pandemics. Hopefully, this puts us on a path to talk about how to reform the IP system to react to the needs that members have. Because this is not the only pandemic we will face."

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