

Intellectual Property and COVID-19 Vaccines: Unpacking a Fraught Debate

Rachel Silverman

GEEOlogue May 6, 2021



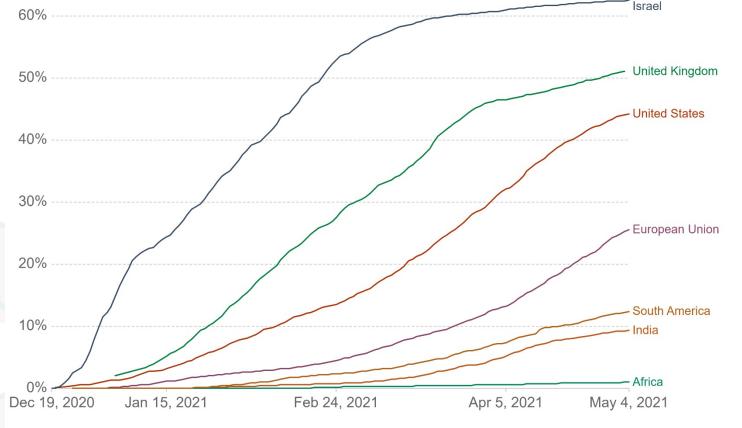
The Problem: Striking Inequities in Vaccine Access



Share of people who received at least one dose of COVID-19 vaccine



Share of the total population that received at least one vaccine dose. This may not equal the share that are fully vaccinated if the vaccine requires two doses.



Source: Official data collated by Our World in Data

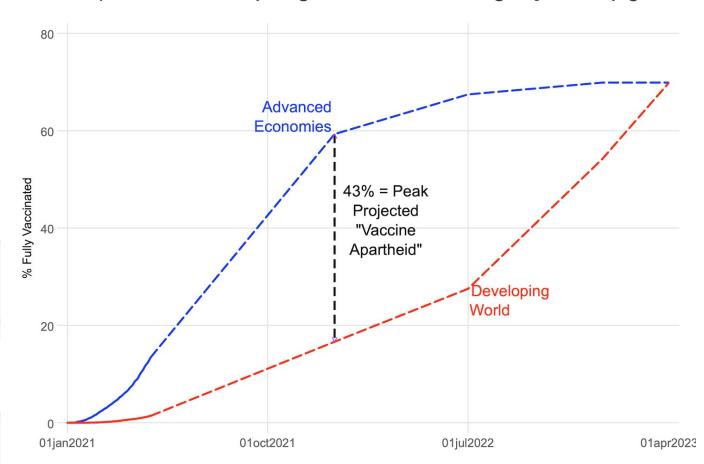
CC BY





Figure 1. An index of global vaccine apartheid

Disparities are likely to get much worse, long before they get better



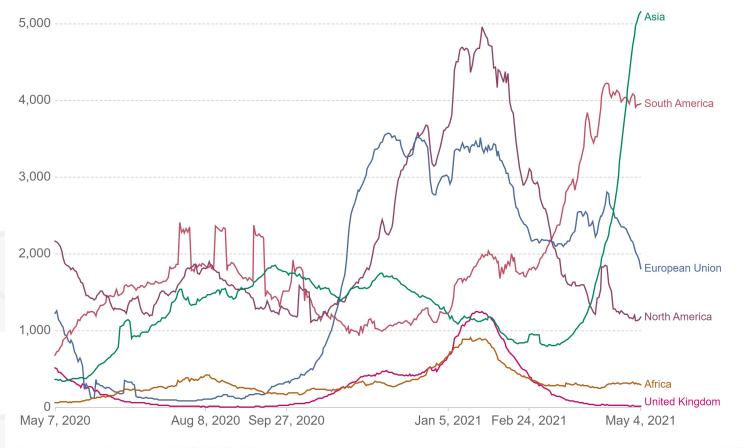
A Changing Pandemic: Toward the Global South



Daily new confirmed COVID-19 deaths



Shown is the rolling 7-day average. Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.



Source: Johns Hopkins University CSSE COVID-19 Data

CC BY

The Case for Vaccine Equity



 Above all, moral imperative: Saving human life, ending ongoing mass casualty event

- Self interest: Ongoing circulation lends itself to new variants, immune escape, reimportation, global instability
- Diplomatic imperative: Allowing inequity will lead to justified global resentment of the West, allow inroads for Chinese/Russian overtures and donations

What's the Problem? Several at Once!



Problem 1: Western countries have bought their way to front of line via APAs, and are using doses on low-priority populations (e.g. teenagers) before high-priority populations in LMICs

Problem 2: Global production is relatively tilted toward Chinese/Russian/AZ/JJ vaccines vs. more desirable mRNA; "two-tier" vaccination, exacerbated by HIC over-caution

Problem 3: Efforts to scale vaccination are running into various material constraints, including existence of qualified personnel, specialized equipment, manufacturing sites, and basic raw materials (e.g. single use bags)

What's the Problem? Several at Once! (Cont.) Velopment

Problem 4: Demand side problems create commercial uncertainty about whether vaccine scale-up will be financially viable

- Not nearly enough \$ to purchase through COVAX
- Some big countries (e.g. India) not procuring on behalf of entire population.
- Feet dragging on regulatory approval (e.g. Pfizer in India)

Problem 5: Limited sharing/dissemination of the know-how and license to produce the vaccine

- Legal right to produce the vaccine (patents/licenses)
- Actual knowhow/recipe that would allow you to actually produce it

What's the Problem? Several at Once! (Cont.) Velopment

Problem 4: Demand side problems create commercial uncertainty about whether vaccine scale-up will be financially viable

- Not nearly enough \$ to purchase through COVAX
- Some big countries (e.g. India) not procuring on behalf of entire population.
- Feet dragging on regulatory approval (e.g. Pfizer in India)

Problem 5: Limited sharing/dissemination of the know-how and license to produce the vaccine

- Legal right to produce the vaccine (patents/licenses)
- Actual knowhow/recipe that would allow you to actually produce it

Are Patents the Problem?



- Time-limited legal monopoly on an innovation/invention
 - Prevents entry of competitors
 - Allows inventor to charge above marginal cost and recoup investment
 - Intended to incentivize innovation
- Internationally, patent monopolies are protected under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement
 - Requires all countries to respect minimum IP standards, including vis-a-vis drug patents and trade secrets
- TRIPS includes some "flexibilities" specifically for public health use
 - Specifically, ability to issue a "compulsory license"
- Other legal IP obligations via bilateral or multilateral trade agreements (e.g. USMCA)

A Fraught History



- Longstanding battle between industry and the global South/health advocates about patents and access to medicines
- Patents, by design, restrict generic competition and keep prices higher than they would be in a competitive market.
- Patents thus often lead to restricted access to innovative medicines most notably for HIV pandemic
 - Even industry has apologized for their role in this!
- Advocacy groups broadly challenge role of patent exclusivity, prefer "delinkage" and other non-patent forms of financing innovation

Patents in a Pandemic?!





TRIPS Waiver is a live issue



- Discussions ongoing at the WTO as we speak!
- US yesterday announced its support for the TRIPS waiver



Advocates Say: No Patents in a Pandemic!



- Unacceptable to allow profiteering when people's lives are at stake
- We need a "People's Vaccine" non-profit, unpatented, with know-how widely shared to enable the quickest possible vaccine uptake
 - Public money supported vaccine development so why should private companies get to profit?
- Yes, some originators have licensed to generics companies but this is still
 done on a for-profit, proprietary, non-transparent one-off manner, taking lots
 of time/effort to negotiate and leaving some potential capacity on the table
- Industry should share their know-how and patents openly through C-TAP, a WHO mechanism, to enable wide scale-up
 - (None have done so to date)
- We should temporarily waive international patent protections through a TRIPS waiver on COVID-related IP, allowing others to produce vaccines

Industry Says: We're Already Doing All We Can



- Patents and the modern IP system were what allowed development of these innovations in the first place!
 - Trashing patents would make it hard for us to cooperate in the next pandemic
- Besides, we're already licensing widely there's no unused manufacturing capacity out their in the world
- We need to be directly involved in any licensing to ensure quality control and oversight, preventing sub-standard products from entering the market
- And it's not like we're making insane profits some of us are selling at cost, but even the for-profit producers are only getting about 25% margins
- And you wouldn't want China and Russia getting our trade secrets...would you?

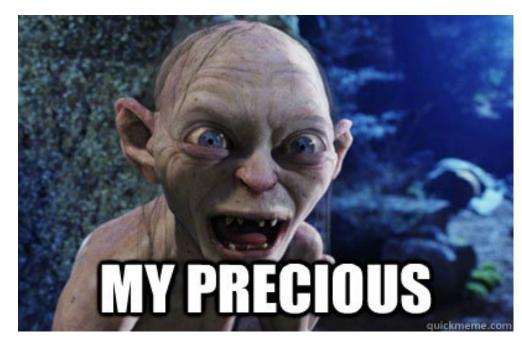
A Dug-In, Polarized Debate





Naïve, Impractical Idealists

Vs.



Greedy, Patent- Hoarding Big Pharma

Both Sides Are Simultaneously Right + Wrong



Advocates Are Right

- Pharma companies are greedy; their entire raison d'etre is to make money
- It is a moral imperative to vaccinate the world—and that's a higher priority than private profit
- With time, resources, IP, and know-how, poor countries can absolutely build capacity to manufacture these vaccines
- Patents are often barriers to access to medicines, and we need to find a structural fix; de-linkage approaches may be helpful, at least for some products
- Pharma companies took public money; the public has a stake in wide access and negotiating leverage

Advocates Are Wrong

- Pharma companies oppose open sharing/waivers because of precedent and loss of control over trade secrets – not because they want to protect COVID-19 market share
- Incentives matter and greed can be good if it's channeled toward social good! Pharma has delivered effective vaccines and should be rewarded, not penalized, for having done so
- IP waivers by themselves are not helpful, because the vaccines cannot be reverse engineered—and a waiver will make it less likely that pharma will proactively share its knowhow

Both Sides Are Simultaneously Right + Wrong



Industry is Right

- Vaccines are hard to make, and patents specifically are not the primary barrier to entry (at least for now)
- There is an important role for the originator in overseeing quality control/safety of production process

Industry is Wrong

- Arguing that giving up trade secrets would save too many lives in China and Russia is laughable
- Not morally tenable to hold on to knowledge that could be used to save lives
- Industry has not shown sufficient urgency to vaccinate the world (and does not, by itself, have the right incentives to do so), inviting government/public intervention

The Way Forward: My View



- With or without an IP waiver...
- Ending the pandemic as #1 global priority
 - Not penny-pinching or profiteering
 - Not fighting battles "on principle" when the stakes are this high—need to be ruthlessly practical
- Rapid donation/reallocation of rich country surpluses
- Massive public subsidy needed to scale manufacturing, particularly for flexible mRNA platform
 - Relatively "cheap" insurance policy against new variants + the next pandemic
- "Easy way or the hard way" negotiations with Pfizer/Moderna to license and transfer needed tech to enable global scale up, incentivized with \$\$\$ and backed up by threat of compulsory license/coercion and non-retaliation
 - May also consider a patent/know-how buy-out