

Frequently Asked Questions

Is removing Intellectual Property actually a barrier to increasing the supply of COVID 19 vaccines?

Intellectual Property is a huge problem as it means that just a handful of pharmaceutical corporations have total control over how many vaccines are made, who gets the vaccines and at what price. Removing these monopolies and sharing the vaccine know-how and technology with more qualified vaccine manufacturers around the world as fast as possible is the key to scaling up vaccine supplies and beating this cruel disease. Many months and millions of lives have already been lost, and there is no time to lose.

Removing IP barriers is certainly not the only thing that needs to happen to vaccinate the world, but it is a fundamental and essential first step in a global plan to beat Covid-19 and create a People's Vaccine. First remove Intellectual Property barriers. Second- Enforce the sharing of the successful vaccine technology and know-how via the World Health Organisation. Third - invest billions in manufacturing and distribution of vaccines across the world as fast as possible. We have no time to lose.

We need to take back control of these vaccines from Pharmaceutical Corporations- vaccines that we paid for with public money- and removing Intellectual Property barriers is fundamental to doing this.

Why is the transfer of technology and vaccine know how so important to increasing the supply of COVID 19 vaccines?

We need both- remove intellectual property barriers <u>and</u> enforce the sharing of vaccine know-how and technology by Pharma corporations. Companies are currently failing to share their vaccine technology and know-how on anything like the scale that is required and with Intellectual Property barriers in place, whether they choose to share is completely up to them. We need to take back control of these vaccines from Pharmaceutical Corporationsvaccines that we paid for with public money- and both removing Intellectual Property barriers and ensuring the vaccine recipes and know-how are shared are both fundamental to achieving vaccines for everyone who needs them.

Some companies have taken steps to transfer some technology but on nothing like the scale required and in most cases resulting supplies are under the complete control of the parent company which gets to decide how many doses are made, who gets to buy them and at what price. This industry-controlled monopoly model continues to deny developing countries



sufficient access to vaccines as pharmaceutical corporations prioritise supplies for lucrative contracts with rich countries at the expense of people in developing countries.

Examples include AstraZeneca using supplies produced by the Serum Institute of India, a supply intended for developing countries, to make up shortfalls in contracts for Europe, the UK and Canada (prior to the India export restrictions). And the fact that Aspen in South Africa has been contracted to manufacture the J&J vaccine but has only been able to negotiate retaining a tiny fraction of this supply for use domestically.

We need governments to insist that pharmaceutical corporations share their vaccine science and know-how via the World health Organisation's Covid Technology Access Pool – C-TAP. C-TAP provides a one stop shop for managing the pooling of IP and tech transfer. To avoid delay we want pharmaceutical corporations to step forward and join the pool and for governments to use all policy and legal tools available to them to insist that they do.

Is all spare capacity to make vaccines in the world not already being used?

This is simply not the case. Experienced manufacturers who are willing to make hundreds of millions of doses have come forward from all over the world, including from Bangladesh, Pakistan, Senegal, Denmark and Canada. Biolyse in Canada (who have approached J&J and AstraZeneca) say they could be producing vaccines within 6 months; Incepta in Bangladesh (who estimate they can make between 600m to a billion doses), Teva in Israel (who report capacity ready to go) and Bavarian Nordic in Denmark have all asked to assist in the manufacture of vaccines. As yet, none has a deal.

The Director General of the World Trade Organization, Ngozi Okonjo-Iweala has reported that the governments of Pakistan, Bangladesh, Indonesia, South Africa and Senegal have all said that they have facilities that could possibly be retooled to produce coronavirus vaccines. UNICEF data suggests that when counting **only** those manufacturers already involved in some way in Covid-19 vaccine manufacturing, only half of them are working to produce the approved vaccines. This suggests plenty of capacity that could be re-purposed. In addition, Knowledge Ecology International, a People's Vaccine Alliance member, have identified an additional 125 vaccine manufacturers globally who have potential capacity for producing Covid 19 vaccines.

India already produces 60% of the world's vaccines and just over a fifth of the world's Covid-19 vaccines to date. Yet only a handful of the country's 20+ vaccine manufacturers are currently involved in Covid-19 vaccine production. In addition, there are over 100 biologics manufacturers in the country who could potentially be engaged in vaccine manufacturing.

On mRNA: The argument that there is no existing additional mRNA vaccine production expertise or capacity to utilize, holds no water given that prior to April 2020 there was zero



mRNA vaccine production capacity. BioNTech, Pfizer and Moderna have themselves demonstrated how quickly this capacity can be built at scale. For example, BioNTech bought and re-purposed a Novartis plant in Germany that had never previously been used for mRNA technology and began commercial production of its vaccine at a scale of 750 million doses per year in less than 6 months.

While no one should downplay the complexity of making any vaccine, experts suggest that mRNA vaccines may be more straightforward and cheaper to produce at scale than other vaccine technologies since they are developed using synthetic processes instead of unpredictable biological processes involving living cells; they require smaller production facilities than other kinds of vaccines and are faster to scale-up.

The former director of chemistry at Moderna has said that with the blueprint and technical advice, a modern factory should be able to get mRNA vaccine production going in at most three to four months. Further, mRNA production could in theory be undertaken by a wider set of pharmaceutical manufacturers besides those working on vaccines already because it does not involve living materials. For example, India alone has over 200 injectable drug manufacturers who could potentially play a role in mRNA production.

In a recent WHO call for companies interested in mRNA technology production 50 companies responded within the first two weeks alone indicating significant untapped opportunity for mRNA vaccine tech transfer.

Is the real problem not a shortage of materials?

If raw materials are in short supply then we need a more collaborative and co-ordinated government-led approach to fix this. And it's crucial to note that the shortage of many of the key inputs for the vaccines are also a result of intellectual property barriers and monopolies in production. The large plastic bio reactor bags for example are protected by over 1800 patents and produced by only one or two companies in the world. Waiving IP would also help diversify and ramp up the production of these key inputs.

If all we do is fix the shortages in raw materials for the handful of big pharmaceutical corporations making Covid 19 vaccines today, we will have done nothing to fix the broken model that continues to block vaccine access in developing countries and is costing lives now. That's why we need to remove the intellectual property barriers that prevent more production AND that keep raw materials in short supply.



Is vaccine hesitancy not a big problem- people don't want to take these vaccines, especially in poor countries?

Vaccine hesitancy is a big problem in rich and poor nations- it is huge in France and Germany for example. We need to do all we can to fight it. But many poor nations have only a tiny number of available vaccines right now so vaccine supply is the primary issue- and to ensure billions of safe and effective vaccines for the world we need to end Big Pharma monopolies and force them to share the vaccine recipe and know-how.

When mass vaccination is achieved and death rates fall, vaccine hesitancy falls too.

Where does COVAX fit in to the solution for the pandemic?

A COVAX is the programme established by the WHO and supported by a number of other organisations to purchase and distribute Covid 19 vaccines equitably on a global basis.

COVAX is a welcome and vital process and it needs massively more support – but it alone is struggling to meet the scale of need. Even if it meets its goals, only 20% of people in developing countries dependent on it will get the dose by the end of this year- and that is now looking very unlikely.

Ultimately donations are neither a sufficient nor sustainable solution, especially as not enough vaccines are being produced and rich countries are reluctant to let go of supplies they may need for booster shots or tackling variants.

Charity is simply not going to fix the huge supply problem nor should people's lives in so many countries around the world be dependent on unpredictable and uncertain charitable giving from rich nations. Donations should never be a substitute for sharing the rights to produce these vaccines and ensuring distributed manufacturing around the world so that countries have their own supplies they can rely on.

Do developing countries have the expertise to make complicated vaccinescould this lead to unsafe vaccines being produced?

Sixty percent of the world's vaccines are already made in India, with many world-class manufacturers and a highly skilled workforce. All the major pharmaceutical companies use Indian producers and producers from other developing nations in normal times. Very highquality vaccine producers and industrial chemists exist all over the developing world – from Senegal to Bangladesh, Brazil to Indonesia. The WHO has a clear process for approving vaccine producers and over half of the 125 already approved on its books are based in developing countries. Pfizer's partner, BioNTech has worked with a Chinese company to set up a new facility in six months that can produce a billion doses.



Of course, only safe, certified and qualified vaccine producers should be producing Covid-19 vaccines. All vaccine producers wherever they are in the world must be approved by national regulatory authorities and get approval from the World Health Organisation if being purchased by international agencies like COVAX or UNICEF. Safe, qualified and professional vaccine manufacturers exist on every continent.

Will removing intellectual property protections stop innovation and jeopardize future vaccine and medicine production- including the development of booster shots for Covid-19?

These life-saving Covid-19 vaccines are the product of public money and public investment so it is wrong to say that intellectual property protections are responsible for their development. Over \$100bn in taxpayers' money went into the vaccine science; 97% of the funding for AstraZeneca and nearly all the funding for Moderna came from government. Pfizer did not take direct public subsidy but benefited from billions in pre-orders from the US government, which had the same impact, and their vaccine was developed by BionNTech, a German company that received hundreds of millions in government support. In contrast, over the last 2 decades, big pharmaceutical corporations have invested almost nothing in coronavirus research and pandemic preparedness. So the real danger lies in continuing to protect the unjustifiable patents that are blocking an increase in vaccine production.

The world is already on track to make 10-12 billion vaccines in 2021 should we not let these companies get on with it?

The evidence suggests these are wildly exaggerated projections on the part of pharmaceutical corporations and we trust these unverified self-reported figures at our peril. The reality is that in 2020 corporations produced just 4% of their projected doses. On current trends production rates would have to increase 8-14 fold to meet the projections claimed by big pharma by the end of the year. And it's still the case that the vast bulk of these doses have already been promised to rich countries.

Are Pharma companies not already getting into voluntary licensing agreements with producers in developing countries?

With a few exceptions the small number of voluntary licenses we have seen to date are limited in scope, achieve only partial sharing of the technology to make these vaccines and the supplies produced and their prices remain under the tight control of the parent pharma company so they can sell where they will make the highest profit. Until we move away from this industry-controlled model we will never achieve fair or sufficient vaccine access in developing countries. That's why we welcome any pharmaceutical corporation urgently



volunteering to share their IP and their vaccine know-how but insist that this must be done via the WHO Covid Technology Access Pool (CTAP). This way governments can take back control from big pharma and allow more manufacturers to make the vaccine, bring prices down and ensure access is scaled up for people in countries currently unprotected.

Have Astra Zeneca and Johnson and Johnson not already said they will sell their vaccines at a not-for-profit price?

It is great that Astra Zeneca and J&J have agreed to do this. Critically though Pfizer and Moderna have refused to- they are making huge profits- the CEO of Moderna recently became a billionaire as did the CEO of Pfizer's partner BioNtech. Their vaccine has become their biggest selling product- bringing in tens of billions for their rich shareholders despite the fact it was paid for with public money. They have focused on selling their expensive vaccines to rich countries with minimal interest in developing countries.

Despite their commitments to not-for profit prices, AZ and Johnson and Johnson get to decide how long they will charge a not for profit price, and who they will sell their vaccine to first and with zero transparency who knows if they are making a profit or not.

This shows we cannot be beholden to the largesse and charitable instincts of Big Pharma. Prices of covid-19 vaccines need to be driven down permanently and the only way to do this is to break up the monopolies and allow competition from other vaccine manufacturers.

Can't countries already issue compulsory licenses and over-ride patents?

It is true that there are provisions within existing trade agreements that countries can override patents for public health use but history has shown this route is rarely used in part because it's complex and time consuming and in part because pharma companies and rich countries use every threat in the book to stop poorer countries from using them. That's why for a global pandemic we need a universal waiver to save time, reduce complexity and ensure no country can be taken to court for trying to save lives.

Has Moderna already offered to not enforce its patents during the pandemic?

Yes. The offer from Moderna is welcome but fairly meaningless given that Moderna doesn't even own the patents for much of the technology used in its vaccine, and is itself licensing it off other companies. Moderna therefore doesn't have all the rights to share which is why a universal waiver of intellectual property is so urgently needed to cover all the technologies in one go for all the Covid 19 vaccines and treatments alongside insisting that the vaccine know-how and technology is shared so that production can be ramped up as quickly as possible.



Should rich countries be vaccinating perfectly healthy young people and children before frontline health workers, and vulnerable people in developing countries?

We shouldn't have to be making choices between vaccinated people in rich countries and people in poorer nations and we wouldn't have to if we did everything we could to increase production. In the long run sharing vaccine blueprints will be much more effective than just sharing vaccines. Having said this, we do need countries to urgently share excess doses because those at highest risk in other countries are not protected and it should be noted that the WHO has come out very strongly against rich countries vaccinating children before health workers and older people and other at risk.

Are you saying rich countries shouldn't be vaccinating everyone, but sharing their doses?

Not at all, rich countries should be doing all they can to protect their citizens. It is great news that countries like the Ireland are rolling out vaccinations. What we are saying is it shouldn't be a choice. Rich countries must use their huge financial and legal power to force pharmaceutical companies to share their technology and intellectual property through the World Health Organization COVID-19 Technology Access Pool. This will enable billions more doses to be manufactured and safe and effective vaccines would then be available to all who need them, in rich countries and in poor nations too.