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The role of licensing and patent pools in manufacturing of pandemic countermeasures

In order to make and supply a product – be it medicine, a vaccine or another pandemic countermeasure – it will often be necessary to have access to the intellectual property such as patents and manufacturing know-how, data and regulatory filings. The issue of technology transfer- in which a package of knowledge needed to produce and supply a particular product is shared - is especially important in the case of vaccines. Vaccines are more complex products than small molecules. For example, antiretroviral medicines needed to treat HIV are easy to replicate and generic companies do so when there are no patent barriers (that is when a patent was never filed, expired or there exists a voluntary or compulsory licence).

In order to replicate a vaccine, a simple patent licence or absence of a patent is not sufficient. In addition to a patent licence or non-enforcement declaration, the transfer of the knowledge by the originator company is required to make sure that the vaccine that is produced is indeed the same as the original product. And you do that by sharing the process. Collaboration in technology transfer also

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means that clinical trials do not have to be replicated, which shortens the time to production.

When the originator company collaborates in technology transfer, new production capacity can be quickly established. For example, a study of mRNA vaccine contract manufacturing (outsourcing agreements) shows that the time from signing the agreement to first production is around 6 months.[2, 3] According to the WHO, mRNA Covid-19 vaccine production in South Africa can be created within a year if the originator company collaborates. However, until today neither Moderna nor Pfizer/BioNTech are engaged in technology transfer for that purpose. You have asked me for positive examples. While the infrastructure exists to enable technology transfer, for the mRNA Covid-19 vaccines, these initiatives lack collaboration from the pharmaceutical industry.

Of the vaccines approved there is the exception of AstraZeneca, which brought the Oxford University Covid-19 vaccine to market.[4] AstraZeneca has committed to not-for-profit pricing, transparency and from the beginning has licensed the intellectual property and technology to vaccine producers in the developing world notably India and Brazil.

Examples of Patent Pooling for therapeutics

In 2009, UNITAID established the Medicines Patent Pool (MPP). The MPP initially aimed at licensing patents related to antiretroviral medicines for the treatment of HIV. Today the MPP is a success story and holds all the intellectual property necessary to produce low-priced generic medicines needed to treat people with HIV. This has helped to keep the price of the combination treatment low (HIV is generally treated with three antiretrovirals at once). Generic treatments can be delivered to around 95% of the people living with HIV in low and middle-income countries, and the MPP saved almost 1 billion US$ and delivered 50 million patient-years of treatment since 2012.

Today, the MPP works to license all patented essential medicines and in early 2020 expanded its mandate to include Covid-19 products. Licensing of intellectual property for HIV treatments to the MPP has become the norm. The same should be the case for Covid-19 vaccines and treatments.

In October ‘21 MSD licensed its patents covering the covid therapeutic molnupiravir to the MPP and in November Pfizer followed with a licence for

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[2] https://docs.google.com/spreadsheets/d/1ozD5-ebf7txIGQa0wpbVVXkrM3Nil04Quws5OUhOSVA/edit#gid=0

[3] https://www.keionline.org/35364

[4] https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf

Paxlovid. Generic companies using the licence may be based anywhere in the world and supply in about 105 low- and middle-income countries. They may supply outside the territory of the licence agreement in case of compulsory licence or government use licence of the patent (s). Both licences offer the option of technology transfer should a generic company need this. MPP licences are in general royalty bearing, which means that the generic company that makes use of the licence pays a per cent of their sales to the originator company. The MPP licences contain public health-oriented terms and conditions which means that they protect policy space countries have under their patent laws and the WTO TRIPS Agreement and the Doha Declaration on TRIPS and Public Health.[5] For molnupiravir, the MPP has signed agreements with 27 generic producers.

In the early days of the Covid-19 pandemic, to be precise in May 2020, the WHO established the Covid-19 Technology Access Pool (C-TAP) to be ready with a technology and IP sharing platform for pandemic countermeasures. The idea was that this would be particularly important for vaccines. So far, vaccine producers have refused collaboration with C-TAP. C-TAP is financially supported by UNITAID, Spain and Belgium. The MPP works closely with the WHO C-TAP.

Another initiative by the WHO is the vaccine technology transfer hub. This is modelled after the successful flu vaccine transfer hubs WHO launched in 2007.[6,7] Today for Covid-19, one such hub is operational. WHO works with a vaccine manufacturer in South Africa to reverse engineer Moderna's mRNA vaccine. Their intention is to then transfer the technology to other vaccine producers in low- and middle-income countries. And on 3 February of this year the MPP signed an agreement with the South African company Afrigen to establish a technology transfer hub for Covid-19 mRNA vaccines with financial support of the French government.[8] The Hub and WHO's work for it is also supported by Germany, Belgium, Norway, Canada and the European Commission.

While reports from the hub in South Africa are encouraging[9], one has to recognize that had Moderna licensed its IP and engaged in technology transfer, the vaccine could have been in production in various sites in the world today. (We also learned last week from the British Medical Journal that a German Covid-

[5] https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

[6] https://pubmed.ncbi.nlm.nih.gov/21684422/

[7] See also: https://www.who.int/phi/publications/Increasing_Access_to_Vaccines_Through_Technology_Transfer.pdf

[8] https://medicinespatentpool.org/news-publications-post/afrigen-signs-grant-agreement-with-mpp-to-establish-a-technology-transfer-hub-for-covid-19-mrna-vaccines

[9] https://www.nature.com/articles/d41586-022-00293-2

19 vaccine company has enlisted a Foundation to undermine efforts to increase production of vaccines in Africa.[10] This has to stop.)

Questions on patent barriers to producing the vaccine however remain and in the absence of a licence a TRIPS waiver would of course offer the certainty that producers nevertheless can operate and supply the vaccines. A TRIPS waiver may provide extra protection to those who develop vaccines and medicines through reverse engineering because it would protect them against infringement suits.

Options for local pharmaceutical production and support needed

It is important to define what is meant by local production. To be prepared to respond to a pandemic the world needs vaccine manufacturing capacity in all continents of the world. It would not be sensible to pursue a strategy of each country producing for its own needs. But regional production capacity is essential and the creation of this capacity, in particular in Africa, should be a priority.

We should also acknowledge the current existence of vaccine manufacturing capacity that is *not being used today* because western companies refuse to share their patents and know-how. A recent study by MSF and the AcccessIBSA project published in Nature found 120 manufacturers that meet the technical requirements and quality standards to produce mRNA vaccines across Asia, Africa and Latin America.[11,12,13] This capacity could have been used as soon as the vaccines were developed.

This manufacturing capacity can be quickest operationalised through licensing and technology transfer as I have explained earlier. These companies need the legal certainty to be able to produce and supply without fear of patent infringement suits. I would urge you to consider supporting the WHO C-TAP and the MPP both politically and financially to make this happen. Not all health products require technology transfer. Therefore, the TRIPS waiver can be useful in cases where an entity has the know-how to produce a certain product but hesitates to do so for fear of patent infringement suits. Also, for the South African technology transfer hub a waiver could be useful when companies continue to refuse to offer licences. Germany should therefore support the TRIPS waiver in addition to supporting the 'voluntary' initiatives and providing financial support

[10] https://www.bmj.com/content/376/bmj.o304

[11] https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines

[12] https://www.nature.com/articles/s41562-022-01304-y

[13] See also: https://www.nature.com/articles/d41586-021-02383-z

for technology transfer and expanding production capacity. Germany should also engage with BioNTech to ensure meaningful technology transfer.

Another problem is the lack of conditions attached to R&D funding. The Covid-19 vaccines have been produced with billions of public financing in order to de-risk the companies in bringing vaccines to market rapidly. But governments and the European Commission should have conditioned this funding with the requirements to share the knowhow developed with the funding more broadly and in particular in developing countries. It will be important to ensure that the new EU European Health Emergency Preparedness and Response Authority (HERA) which is planning to spend 300 million Euro for R&D of pandemic countermeasures will ensure that the knowledge developed with this money becomes global goods.[14]

We also need to prepare for the future. There will likely be other pandemics and Covid-19 has shown us that sorting out the sharing of vaccine knowledge during a health crisis was not a viable strategy. The pandemic treaty currently under negotiation at the WHO offers an opportunity to regulate the access to patents, data, know-how needed to scale up regional production of pandemic countermeasures.

To conclude:

Patent pooling can be very effective provided they come with public health-oriented terms and conditions. Patent Pools such as the MPP, C-TAP and initiatives such as the WHO mRNA tech transfer hub can also provide necessary technology transfer. However, such initiatives are dependent on the voluntary collaboration of those that hold the IP and know-how and in the case of Covid-19 vaccines, corporations have mostly been unwilling to share this know-how with others outside their trusted circle of contract manufacturers. They became the holders of the IP, despite the fact that the R&D was largely financed with public resources. This practice calls for a policy change in which public financing comes with the condition that know-how created with public money becomes available for others to use. This should be a key feature of the new EU new European Health Emergency Preparedness and Response Authority (HERA). Pandemic countermeasures and the knowledge how to make them should be public goods. This is essential to tackle an international health crisis of the kind we are experiencing today.

[14] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_928