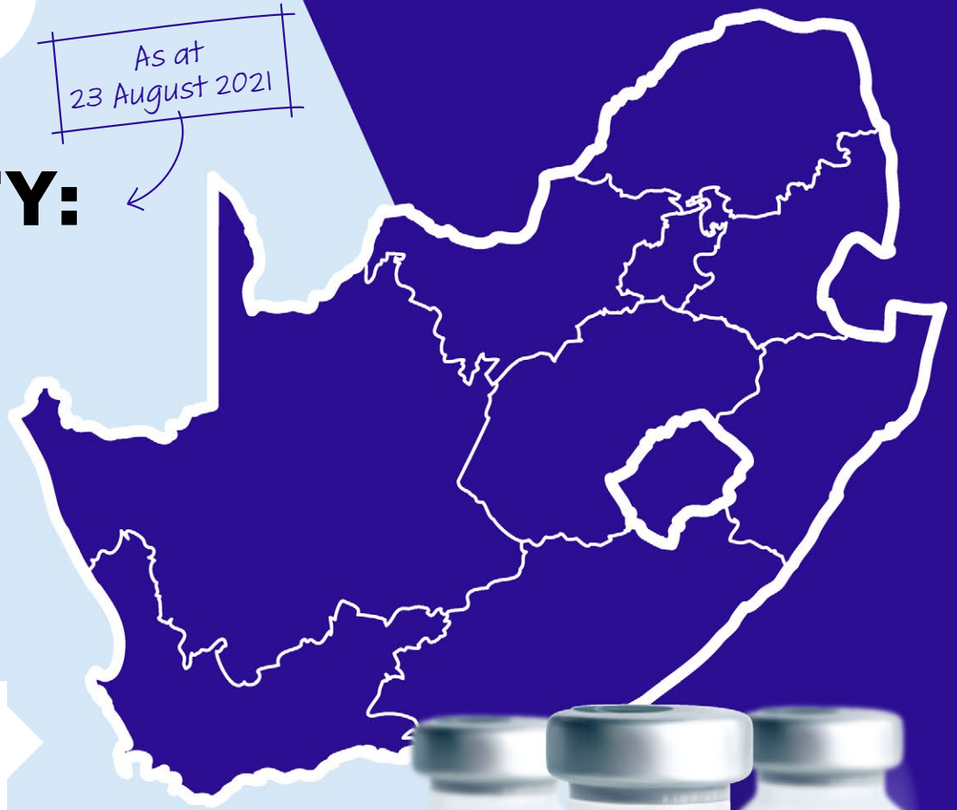
EXPLAINER

VACCINE LICENSES FOR COVID-19

As at
23 August 2021

1: VACCINE CAPACITY: CURRENT STATE OF AFFAIRS



Until 2001, South Africa manufactured some vaccines (TB, polio, smallpox, rabies).

South African pharmaceutical companies manufacture or 'Fill and Finish' medicines/vaccines not only for the South African market, but also for export to other African countries, as well as European and other markets.

Africa imports about 99% of all its vaccines.

There continues to be a dire need for manufacturing of pharmaceutical products and the production of Active Pharmaceutical Ingredients (APIs) as well as vaccine drug substance throughout Africa.

South Africa has several pharmaceutical companies, but only two produce APIs.

Mostly, South Africa imports APIs for those products it manufactures.

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2: THE DIFFERENT TYPES OF LICENSES

A 'Fill & Finish' License

A license granted to a contractor by a manufacturer to utilise the vaccine drug substance at the tail end of the manufacturing process, to fill the product into more useful containers, (elastomer stoppered vials) or devices (pre-filled syringes) - to be used in a clinic and for delivery to patients.

A 'Voluntary License' (VL)

A contractual agreement signed between a patent holder (licensor) and other entities (licensees) that specify the terms and conditions under which a patented medical product or materials can be used, produced or marketed by licensed or generic manufacturers.

A 'Compulsory License' (CL)

An authorisation granted by a government to a third party for production or importation of a medical product from a competitor or alternative manufacturer at a more affordable price, without the consent of the patent holder (who is nevertheless compensated by payment of a royalty). A CL by itself does not facilitate technology transfer if it is needed by the third party.

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3: WHAT A LICENSEE CAN DO WITH A 'FILL & FINISH' LICENSE

A Fill the product into more useful containers, (elastomer stoppered vials) or devices (pre-filled syringes).

'Fill & Finish' does not include any activities included in the definition of 'Labelling and Packaging'.

B Formulate the *Licensed Product* using *Vaccine Drug Substance* and other excipients.

C Freeze dry the *Vaccine Drug Substance* for incorporation into the Licensed Product.

D Test, including ongoing stability testing, and release the product.

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‘FILL & FINISH’ LICENSE DETAILS :

J&J AND ASPEN

SOUTH AFRICA

The Fill & Finish License was announced in late 2020.

The Fill & Finish licensing agreement may be for:

J&J is headquartered in the USA.

Janssen is headquartered in Belgium

Aspen is in the Eastern Cape, South Africa.

The supply of at least 32 million vaccines for South Africa (2021)
About 220 million vaccines for the AU (other African states for 2021 and 2022 and includes an option for 180 million more for the AU).
An undisclosed exact number of vaccines for North American and European and/or other markets.

The terms and conditions and other details of the licensing agreement are not public, what we know so far is:

The NYT has revealed that since March 2021, at least **32 million vaccines** were EXPORTED from South Africa for Europe from Aspen. The exports are continuing. It also revealed that a separate contract that the South African government signed with J&J precludes the state from imposing ANY export restrictions on any of J&J’s supplies filled in South Africa!

The vaccine drug substance is sourced from US and Europe.
J&J mixes the injectibles and then bottles the vaccines.
Technology transfer is restricted to the requirements of ‘Fill & Finish’ only.
There is no transfer of technology on the vaccine drug substance.
The vaccines are filled & finished in the Eastern Cape for South Africa, Africa and other places including Europe, as J&J extracted a ‘no export ban’ waiver: it therefore decides when and where supplies are released.

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‘FILL & FINISH’ LICENSE DETAILS :

PFIZER/ BioNTech & BIOVAC

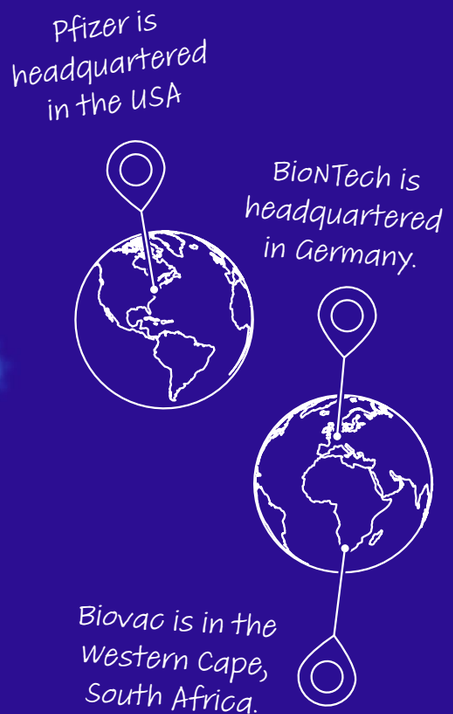
SOUTH AFRICA

The terms and conditions and other details of the licensing agreement are not public – what we know so far is:

The vaccine drug substance will be sourced from BioNTech in Germany.
Biovac will buy specialised equipment for the process, but no other rights and technology will be transferred.

CONTINUED...

The Fill & Finish License was announced in mid-2021



The agreement fails to share Pfizer-BioNTech's technology and know-how to independently manufacture vaccines, and instead requires Biovac to remain dependent on vaccine drug substance from Pfizer-BioNTech's European facilities.
The vaccines will be filled & finished from 2022 onwards, and for Africa only.
It is estimated that this will be in the region of at least 100 million doses for Africa, per annum (Note: 2 dose regimen).

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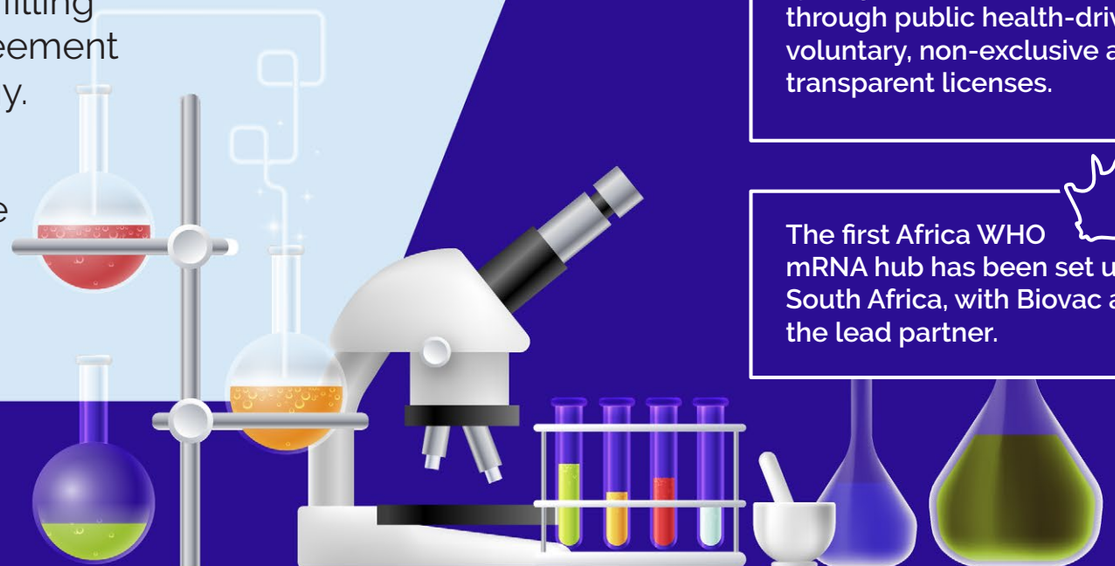
4: WHAT RIGHTS AND/OR TECHNOLOGY ARE ACTUALLY SHARED WITH A ‘FILL & FINISH’ LICENSE?

- Not a lot
- While personnel are trained on the use of the equipment needed for filling and finishing, the license agreement does not share the technology.
- A ‘Fill & Finish’ license still creates dependency because vaccine drug substance still have to be imported.



C-TAP and WHO mRNA Hubs

‘C-TAP’ and the ‘WHO mRNA Hub’ are both World Health Organisation (WHO) led initiatives:

The registered mRNA vaccine companies Pfizer/BioNTech and Moderna, have failed to share their technology with C-TAP or the WHO mRNA Hub that has now been set up in South Africa.

C-TAP is meant to provide a platform for ‘developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to voluntarily share their intellectual property (IP), knowledge, and data, with quality-assured manufacturers through public health-driven voluntary, non-exclusive and transparent licenses.

The first Africa WHO mRNA hub has been set up in South Africa, with Biovac as the lead partner.

The WHO mRNA Hubs are being set up to encourage the sharing of mRNA technology held by universities, labs and pharmaceutical companies to increase the capacity of low- and middle-income countries (LMICs) to produce mRNA vaccines and scale up manufacturing – and thus, increase global access to these critical tools to bring the pandemic under control – it will provide appropriate training to interested manufacturers in LMICs.

5: WHY THE TRIPS WAIVER IS IMPORTANT TO UNLOCK MANUFACTURING CAPACITY IN AFRICA AND ELSEWHERE

Progressive IP experts and health justice and medicine access activists indicate that:

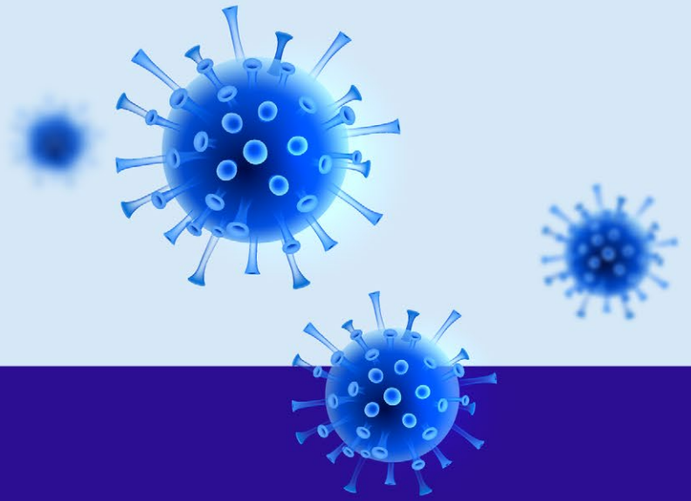
1: The TRIPS Waiver will allow companies to produce COVID-19 vaccines/medicines without fear of being sued by the entity that currently holds the IP on the technology.

2: The Waiver will provide the opportunity to overcome not just patent barriers but other IP barriers such as allowing for access to undisclosed data - available via pharmaceutical regulators.

3: The "compulsory license" flexibility provided for in the TRIPS Agreement is important, but MSF's analysis has found that compulsory licenses alone would not be enough to achieve urgent access to lifesaving COVID-19 medical tools.

4: Contributions to the COVAX facility and vaccine donations by rich countries fall far short of the current need.

5: Neither donations nor CLs are a substitute for supporting the TRIPS Waiver.



"HJI is grateful to Professor Yousuf Vawda (UKZN) and Leena Menghaney (MSF Access Campaign IP Advisor) for their valuable input in preparing this FAQ."