FACTSHEET ON COVID-19 THERAPEUTICS SEPTEMBER 2022

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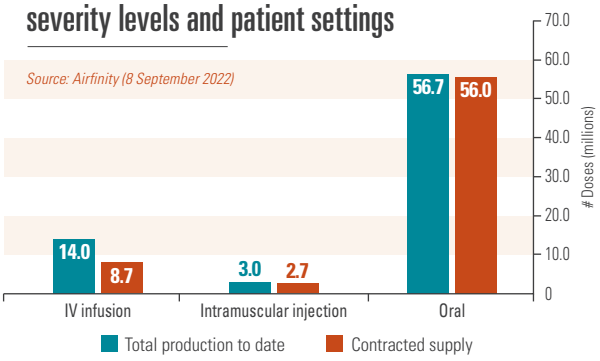
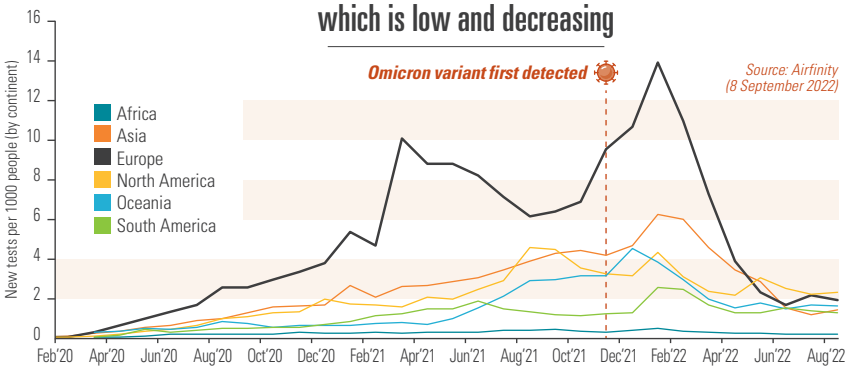
THERE IS NO SHORTAGE PROBLEM FOR A COVID-19 TRIPS WAIVER EXTENSION TO ADDRESS

Production exceeds demand for all variants, disease severity levels and patient settings



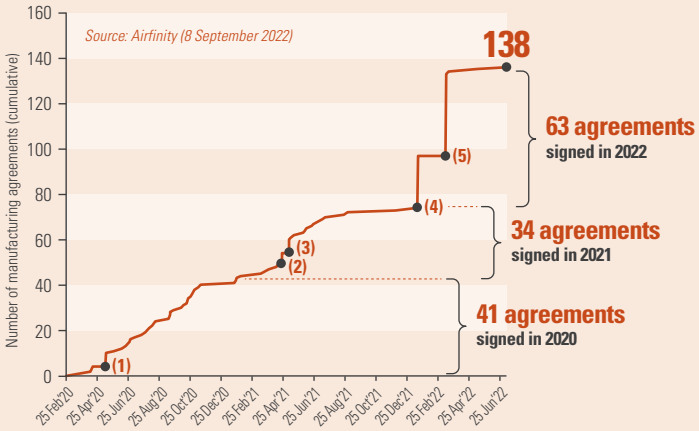
Demand for COVID-19 treatments is linked to global testing, which is low and decreasing



There is no supply shortage for any type of COVID-19 treatment, looked at across all variants, disease severity levels and patient settings. Testing for COVID-19 is declining since the January 2022 peak of the Omicron wave, leading to lower and less predictable demand for treatments.

A COVID-19 TRIPS WAIVER EXTENSION NOT ONLY IGNORES ACCESS INITIATIVES, BUT COULD HARM THEIR EFFECTIVENESS

138 voluntary licensing agreements have been signed



COVID-19 therapeutic access initiatives are already in place

Sources: Business Today (2021); Airfinity (2022); Politico (2022)

13 May 2020	Gilead signs 9 voluntary licence agreements (VLA) to expand access to 127 countries. Over 65% of all treatments made available (11 million doses so far), has gone to low- and middle-income countries **(1)**.
27 Apr 2021	MSD signs bilateral VLAs with 8 generic manufacturers in India for providing Molnupiravir to India and low-income countries **(2)**.
11 May 2021	Lilly signs bilateral VLAs with 8 Indian manufacturers for baricitinib **(3)**
18 Jan 2022	MSD signs an agreement with UNICEF to allocate 3 million doses to low- and middle-income countries in 2022.
20 Jan 2022	MSD, through the Medicines Patent Pool (MPP), enables 23 generic manufacturers to supply Molnupiravir to 105 low- and middle-income countries **(4)**.
17 Mar 2022	Pfizer enters into a VLA, through the MPP, enabling 38 generic manufactures to supply 95 low- and middle income countries **(5)**.
22 Mar 2022	Pfizer signs an agreement with UNICEF for 4 million doses of Paxlovid at a not-for-profit price.
22 Sep 2022	Pfizer and the Global Fund sign a deal for 6 million Paxlovid doses for 132 low- and middle-income countries at a not-for-profit price.
	Tiered pricing strategies were announced by companies including Lilly, MSD and Pfizer at or prior to their authorisation.

Through 138 voluntary licencing agreements (supported by IP) and tiered pricing that allows low- and lower-middle income countries to pay a not-for-profit price, and partnerships with multilateral organisations, holistic access strategies for treatments is ensured for 99.9% of Africa and 100.0% of South Asia.

A COVID-19 TRIPS WAIVER EXTENSION WILL LEAD TO OVERSIGHT PROBLEMS AND QUALITY RISKS THAT WILL HURT PATIENTS

Voluntary licence **(VL)** therapeutics have both **patient safety reporting obligations** and guaranteed **high quality standards**. This is not always the case for compulsory licenced **(CL)** products.

VL producers **must report adverse events** to the originator company to support **patient safety data obligations** ("pharmacovigilance").

→ A **CL inherently precludes this critical regulatory reporting framework.**

Medicines Patent Pool (MPP) medicines must follow **WHO pre-qualifications** or a Stringent Regulatory Authority **quality standards** (e.g. EU, US, or Japan).

→ Bad actors could use less regulated environments to **produce adulterated, sub-standard or even counterfeit versions of treatments.**

Source: EFPIA, PhRMA (2022)

Expanding the TRIPS waiver will lead to oversight problems and quality risks that can hurt patients, mainly in low- and middle- income countries where these medicines are most likely consumed.

MEANINGFUL MULTILATERAL EFFORTS TO SUPPORT R&D AND ACCESS TO COVID-19 TREATMENTS

- BASED ON THE FACTS, FIRMLY REJECT A TRIPS WAIVER EXTENSION
- REMOVE TRADE AND REGULATORY BARRIERS
- STRENGTHEN THE HEALTH WORKFORCE
- INCREASE PUBLIC AWARENESS ON TREATMENTS
- IMPROVE LOGISTICS PROCESSES FOR TREATMENTS
- SCALE UP INNOVATION THROUGH VOLUNTARY LICENSING

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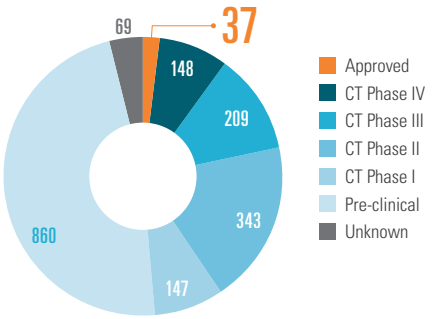
A COVID-19 TRIPS WAIVER EXTENSION WILL JEOPARDISE ONGOING R&D FOR A LARGE NUMBER OF INNOVATIONS AND PATENTS ACROSS INDUSTRIES

COVID-19 treatments pipeline *(n = 1,813)*



Source: Airfinity (8 September 2022)

COVID-19 treatments pipeline and investments

- Only **2.0%** of researched **treatments have been approved**.
- New treatments **enhance protection** against new COVID-19 variants.
- The number of **impacted patents increases from 4,303 to 135,627** affecting industries like pharmaceuticals, chemicals, machinery, etc.
- **75% of all investments** in clinical trials are borne by the private sector.
- **The majority of investments are ongoing or still have to be made.**

Source: Airfinity (8 September 2022), EPO (2021)

A TRIPS waiver extension would expand the scope of patents impacted

135,627
therapeutic and diagnostic patents impacted directly

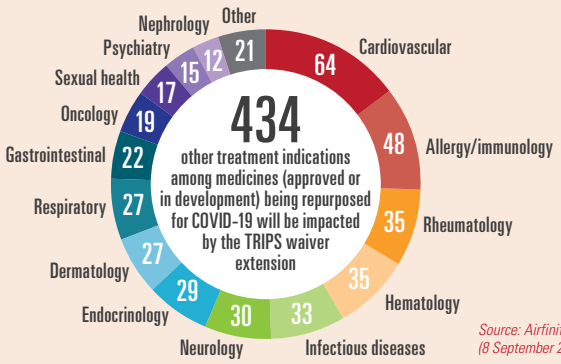
4,303
vaccine patents impacted

Source: EPO (2021)

Most R&D is still ongoing. 135,627 patents could be negatively impacted, undermining R&D efforts into COVID-19 and other treatments in the future, with reverberations for multiple sectors across the healthcare system and beyond.

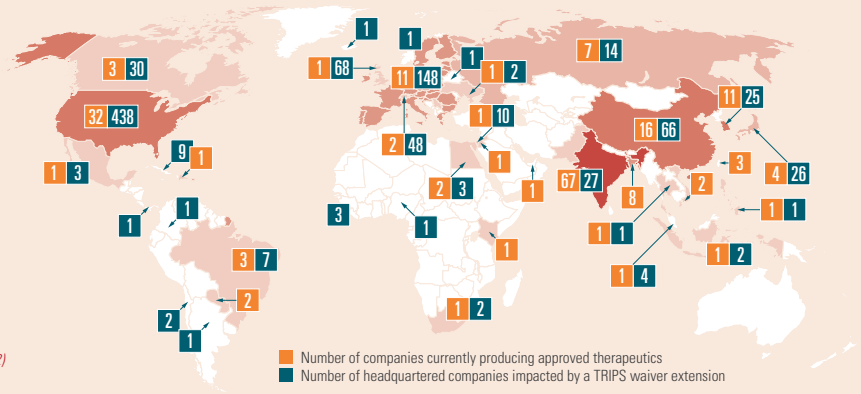
A COVID-19 TRIPS WAIVER EXTENSION WILL INEVITABLY SPILL OVER TO R&D IN OTHER THERAPY AREAS, HURTING GLOBAL PRODUCTION AND THE COUNTRIES WHERE MOST INNOVATIVE COMPANIES ARE ACTIVE

Number of other indications (by therapy area) impacted by a waiver on COVID-19 therapeutics



Source: Airfinity (8 September 2022)

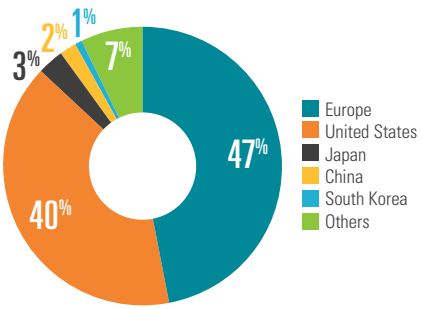
Current global production and companies active in other therapy areas will be affected by a waiver on COVID-19 treatments



A TRIPS waiver extension cannot be limited to COVID-19 and will inevitably spill over into R&D for and marketing of medicines across a host of other disease areas, because of repurposing, parallel development for several indications and multi-purpose manufacturing technologies. This will negatively impact many companies globally, particularly in the US and Europe, but also China.

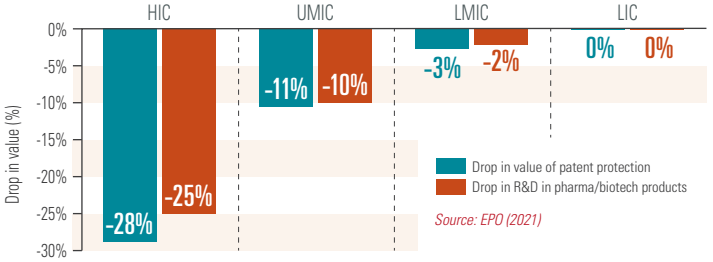
A COVID-19 TRIPS WAIVER EXTENSION WILL HURT INNOVATION AND IS DRIVEN BY DOMESTIC INDUSTRIAL POLICY INTERESTS THAT WILL COME AT THE EXPENSE OF FUTURE GLOBAL PANDEMIC PREPAREDNESS

Geographical split of EPO* patent applications (2015-2020) that were subsequently applied for COVID-19 vaccines



Source: EPO (2021)
** EPO = European Patent Office*

Impact of 3-year COVID-19 waiver on pharma R&D



Source: EPO (2021)

A waiver extension will have a significant negative impact on pharmaceutical R&D in EU, US, Japan, Switzerland, the UK, and others. This does not include negative R&D effects for diagnostics and other related industries following from a long-term decrease in patent value.