# FACTSHEET ON COVID-19 THERAPEUTICS SEPTEMBER 2022

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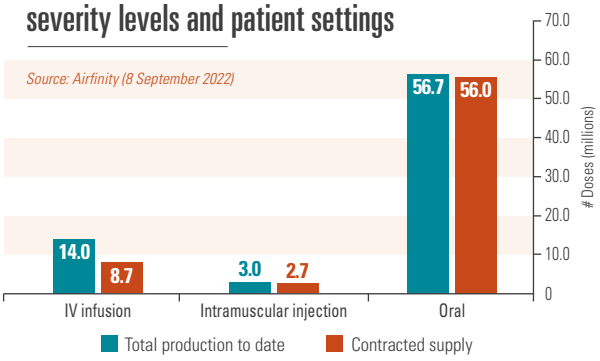
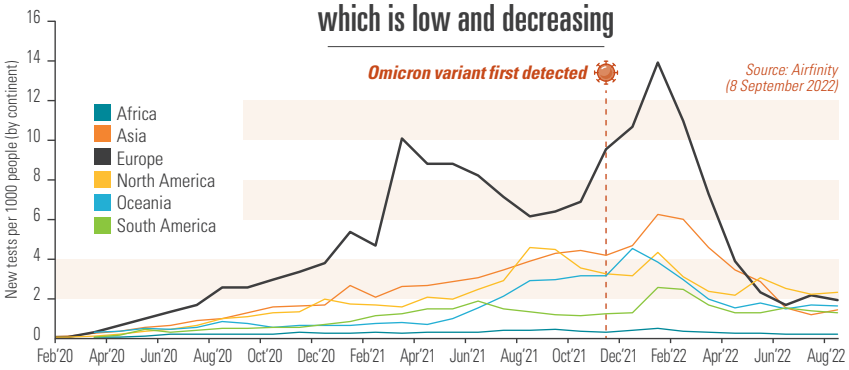
## THERE IS NO SHORTAGE PROBLEM FOR A COVID-19 TRIPS WAIVER EXTENSION TO ADDRESS

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



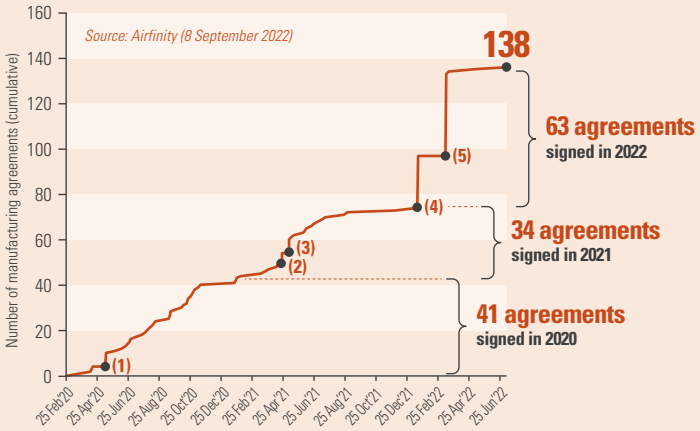

### Demand for COVID-19 treatments is linked to global testing, which is low and decreasing




**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 7 generic manufacturers for its monoclonal antibody treatment **(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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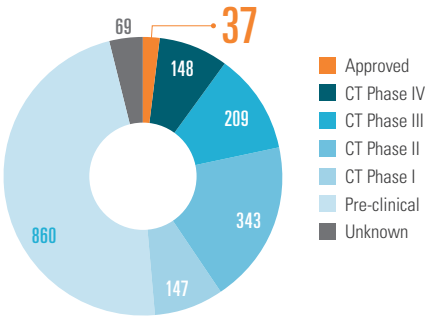
## A COVID-19 TRIPS WAIVER EXTENSION WILL JEOPARDISE ONGOING R&D FOR A LARGE NUMBER OF INNOVATIONS AND PATENTS ACROSS INDUSTRIES

### 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

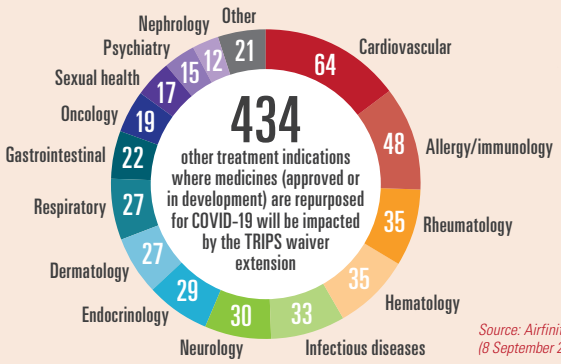
**4,303**
vaccine patents impacted

*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.**

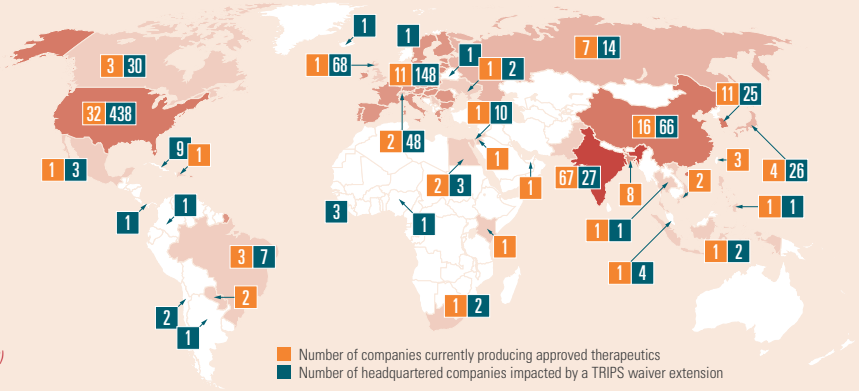
## A COVID-19 TRIPS WAIVER EXTENSION WILL INEVITABLY SPILL OVER TO R&D IN OTHER THERAPY AREAS, HURTING GLOBAL PRODUCTION AND THE COUNTRIES WHERE MOST INNOVATIVE COMPANIES ARE ACTIVE

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




*Source: Airfinity (8 September 2022)*

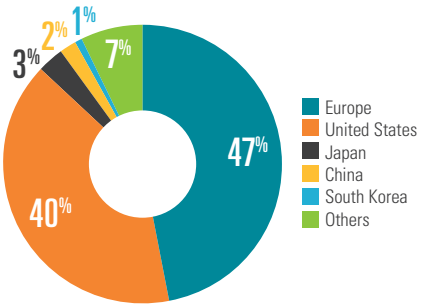
### Current global production and companies active in other therapy areas will be affected by a waiver on COVID-19 treatments




**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.**

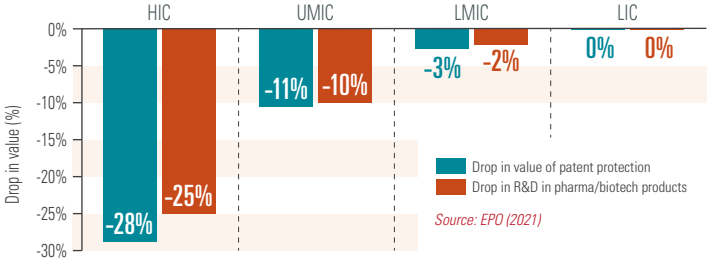
## A COVID-19 TRIPS WAIVER EXTENSION WILL HURT INNOVATION AND IS DRIVEN BY DOMESTIC INDUSTRIAL POLICY INTERESTS THAT WILL COME AT THE EXPENSE OF FUTURE GLOBAL PANDEMIC PREPAREDNESS

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




*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.**