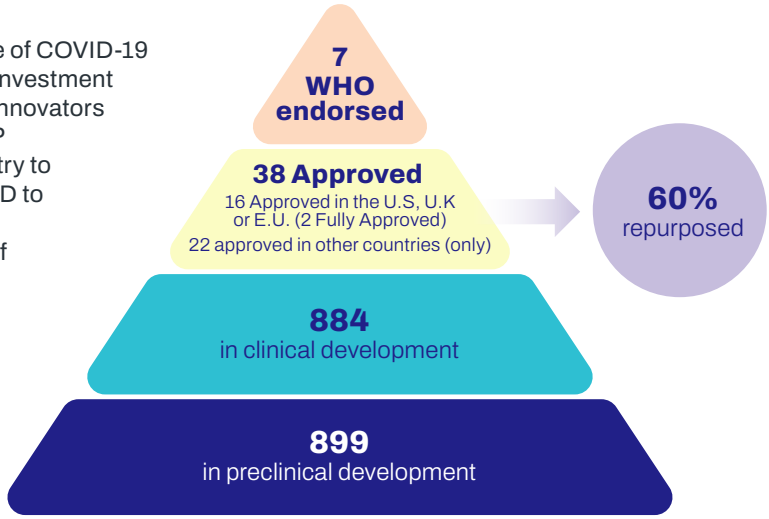
# IMPACT OF A WAIVER OF INTELLECTUAL PROPERTY RIGHTS FOR COVID-19 THERAPEUTICS

Incentives provided by Intellectual Property (IP) protections have underpinned the biopharmaceutical industry's ability to quickly respond to the COVID-19 pandemic. IP incentives remain critical for effective accelerated research, development and manufacturing of COVID-19 vaccines, therapeutics and diagnostics, and aid voluntary partnerships and technology transfer. IP protections are also critical for development of new COVID-19 medicines and for future health emergencies. R&D and manufacturing partnerships have resulted in global equitable access to COVID-19 therapeutics at breakthrough speed. Despite these efforts, real challenges to access exist. **We call on the World Trade Organization (WTO) and its Member States to focus on action to address these challenges.**

## Industry-led innovation has delivered on COVID-19 therapeutics

There is a healthy pipeline of COVID-19 therapeutics. 75% of the investment has been done at risk by innovators and generics. A reliable IP framework enables industry to continue to invest into R&D to fight new variants and to address new symptoms of COVID-19 through new and novel therapeutics.




COVID-19 therapeutics candidates pipeline

**A waiver of rights would remove critical important incentives for companies to continue investing at-risk in this pipeline and undermine future R&D.**

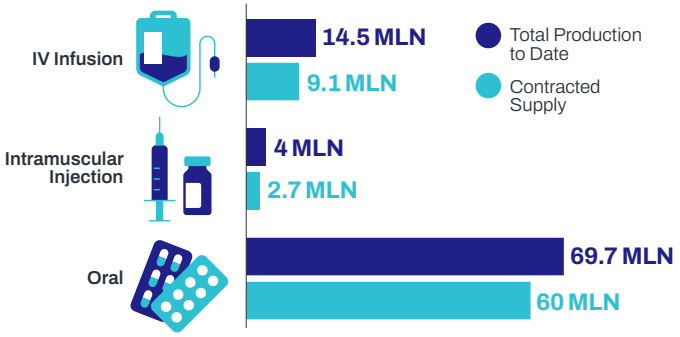
Source:
Airfinity, December 2022

## Innovation ecosystem is at risk under a potential waiver for COVID-19 therapeutics

- Impact on ability to treat patients against COVID-19
- Negative impact on current pipeline of COVID-19 therapeutics
- Will remove incentives to explore dual-use of therapeutics
- Undermine trust and knowledge-sharing between partners
- Hamper access to safe quality and effective medicines
- Weaken pharmacovigilance and increase burden on regulators
- Potential proliferation of falsified and substandard medicines
- Inefficient use of limited resources


- Undermining effective and voluntary technology transfers and flexible licensing
- Impact on R&D and investment into new areas
- Adversely affect geographic diversification of production
- Adversely affect geographic diversification of R&D
- Limit the market and investment for SMEs and biotech companies
- Hamper industry's ability to address future health crises
- Stagnation of scientific research

# As of Dec 2022, supply of COVID-19 therapeutics exceeds demand




- According to Airfinity, global demand in both high and lower-income countries has constantly been revised downwards.
- Of the 10 million oral treatments procured by the Global Fund and UNICEF for lower-income countries in 2022, only 13% have been requested. Evidence suggests supply far exceeds current levels of demand for COVID-19 therapeutics.
- Low levels of testing against COVID-19 and insufficient country readiness are hampering greater use of therapeutics.

Airfinity, December 2022.

# Benefits of effective flexible and voluntary licensing

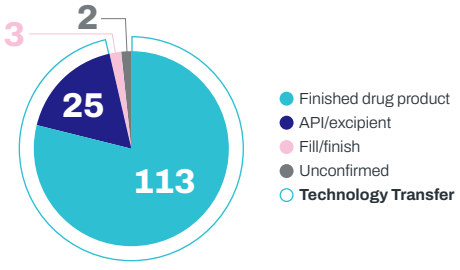
- Builds on a global network
- Encourages technical assistance
- Ensures use of skilled workforce
- Building local industry and investment
- Reduced production time
- Ensures there is assistance for regulatory filings
- Places no burden on the exchequer
- Flexible approach allows for quick response
- Ensures that there are no major shortages
- Requires no government or courts
- Supports with quality assurance
- Key to scaling-up manufacturing
- Based on mutually agreed terms
- Flexible and robust supply chain
- Encourages long-term collaborations
- Promotes access
- Encourages effective and quick tech transfer and know-how sharing
- Ensures optimum use of raw materials
- Adverse event mitigation to meet surges and precursor supply difficulties

# IP underpins voluntary licensing agreements that are key to scaling up manufacturing and access

The IP framework has enabled production and research sites across the world. There are 201 production sites across the world, and 677 R&D sites. Over 67% of licensees are located in LMICs. Every single licensee can supply to the countries covered under the license and determine a price.

## Collaborations on COVID-19 therapeutics mainly involve technology transfer

**96.5%** of collaborations involve technology transfer

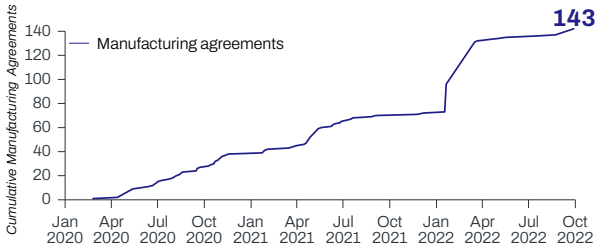



**143 Collaborations***

***Collaborations include:** Distribution partners, Voluntary licensing agreements, Manufacturing partners, Medicines Patent Pool sublicensees

Source: Airfinity, December 2022

## 43 licensing agreements were signed in the first year of the pandemic, number tripled by June 2022




**Licensing Type:**


Source: Airfinity, December 2022

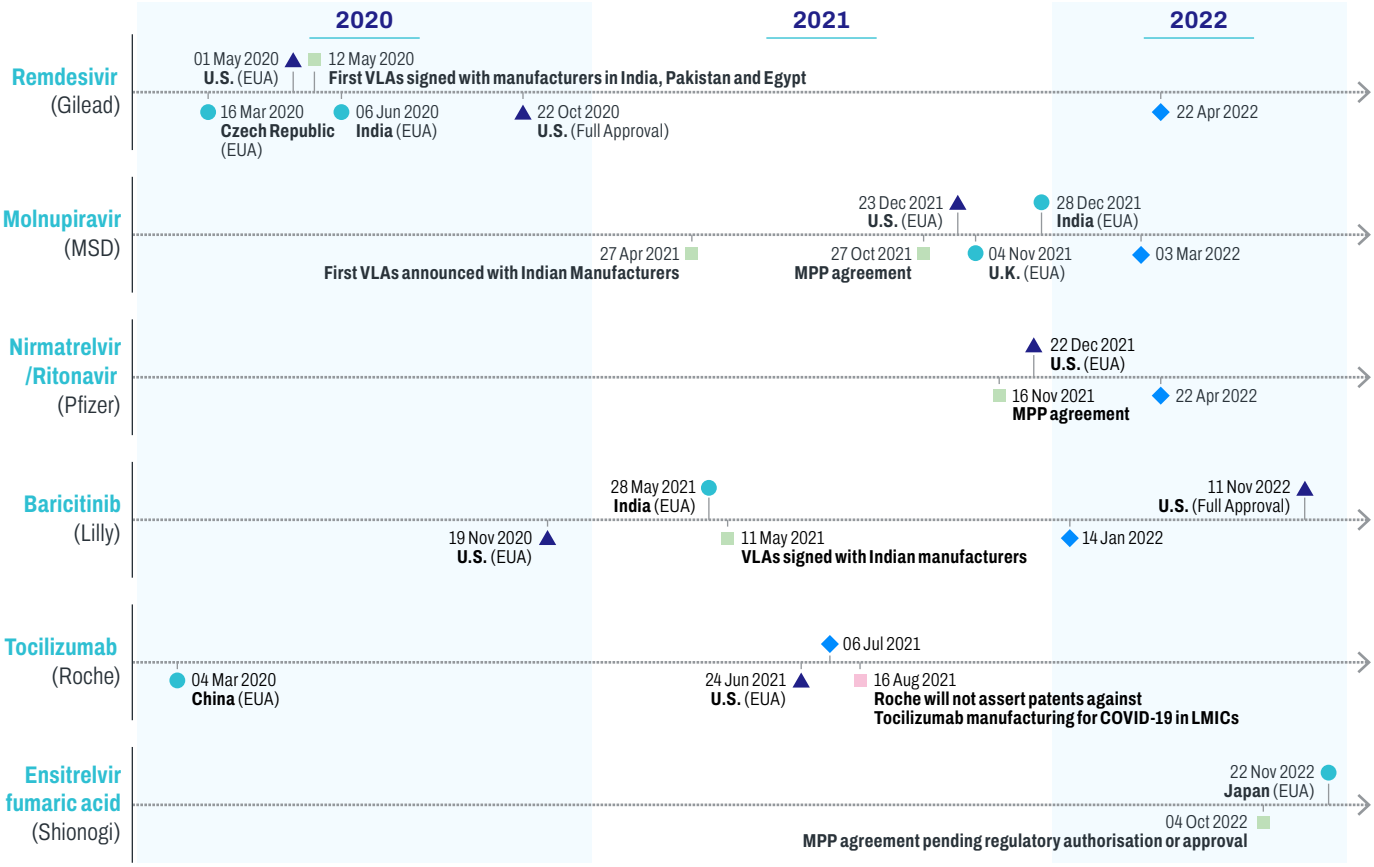
**A waiver would undermine the trust and potentially the resources that make these collaborations work, and would also undermine regulatory systems and patient safety and manufacturing scale up. In the long term, it would affect geographical diversification of R&D and production.**

# Examples of different voluntary licensing partnerships entered into by innovators for COVID-19 therapeutics

- **Gilead** has signed 9 bilateral, royalty free voluntary license agreements to expand access of remdesivir to 127 countries, made available to over 4 billion people. This is the largest bilateral license agreement signed by any company;
- **Lilly** signed voluntary royalty free license agreements with 8 generic manufacturers for baricitinib. The licensees set the price;
- **Lilly** announced a donations program making available courses of baricitinib free of charge to L/LMICs and made donations to multiple countries, including India;
- **MSD** signed bilateral voluntary license agreements with 8 generic manufacturers to produce molnupiravir covering 106 countries and to be made available to over 4 billion people;
- **Pfizer** signed an agreement with UNICEF, in December 2021, to allocate 3 million doses of molnupiravir to low- and middle-income countries in 2022, however it took 9 months for UNICEF to deliver its first shipment of 20,000 doses;
- In addition, **MSD**, through the Medicines Patent Pool, signed a royalty free license agreement with 23 generic manufacturers to supply molnupiravir to 106 low- and middle-income countries;
- **Pfizer** entered into a license with the Medicines Patent Pool that enabled 38 generic manufacturers to supply 95 low- and middle-income countries with nirmatrelvir/ritonavir, covering 53% of the world population. The license is provided royalty free for LMICs;
- **Pfizer** signed an agreement with UNICEF for up to 4 million doses of nirmatrelvir/ritonavir at a not-for-profit price;
- **Pfizer** and the Global Fund signed a deal for up to 6 million nirmatrelvir/ritonavir doses for 137 low- and middle-income countries at a not-for-profit price;
- **Shionogi** has signed a voluntary licence agreement with Medicines Patent Pool to enable qualified generic manufacturers to manufacture and supply ensitrelvir to 117 countries.

# Quick response: voluntary partnerships entered into either before or within days of COVID-19 therapeutics approval

**First COVID-19 Approval (EUA or full approval) | First partnerships:**
▲US ●Non-US ◆WHO recommendations ■First Manufacturing Agreements (VLAs or MPP) ■Other




Source: Airfinity, December 2022

**A waiver would undermine investment, undermine any surge predictions that can impact the fragile global supply chain.**

# Real challenges to equitable access to COVID-19 therapeutics

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## Financing & procurement

- Low public health expenditure
- Unspecific, underfinanced procurement mechanisms

## Trade and supply chain

- Burdensome customs procedures
- Trade restrictions
- Inefficient distribution infrastructure
- Logistics constraints

## Workforce

- Limited number of doctors and nurses
- Limited number of hospital facilities
- Lack of skilled workforce

## Regulatory

- Lack of guidelines or delayed guidelines for use to support health care practice
- Impact on regulatory approval timeline
- Resource constraints on regulators
- Burdensome oversight over falsified therapeutics

## Quality & Safety

- Monitoring for counterfeits
- Rise in internet sales of substandard and falsified products;
- Inefficiencies in stock management, potentially leading to loss of product or substandard products making it to the supply chain;
- Insufficient deterrent legislation at national level to tackle substandard and falsified products

**IP has not been a barrier to access.**

# Call on the WTO and its Member States to focus on the real challenges to access

**The IP framework** has been a critical enabler for an unprecedented pace of R&D and manufacturing scale-up, through unprecedented voluntary and flexible partnerships.

**The WTO** and its Member States should focus on action they can undertake to tackle the real barriers to access as highlighted, such as removing trade restrictions on upstream products needed to manufacture quality COVID-19 therapeutics, for timely and equitable access.

**Member States** should consider the facts and evidence as to whether a waiver on IP protections is needed and whether it would achieve its intended purpose.

**For further information:**
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