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.

Industry-led innovation has delivered on COVID-19 therapeutics

As a result of investment in research and development, the pipeline for COVID-19 therapeutics is strong. 75% of this investment has been made at risk by the private sector, including both innovative pharmaceutical companies and generics companies. This investment is made possible by the incentives provided by the intellectual property (IP) framework.

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.

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

COVID-19 therapeutics candidates pipeline

548
in preclinical development (**396** inactive)

623
in active clinical development (**107** discontinued **138** inactive)

42
approved

7
WHO endorsed

Source:
Airfinity, January 2024

Innovation ecosystem is at risk under a potential TRIPS 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

Innovation ecosystem at risk

- 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

Benefits of effective, flexible and voluntary licensing partnerships

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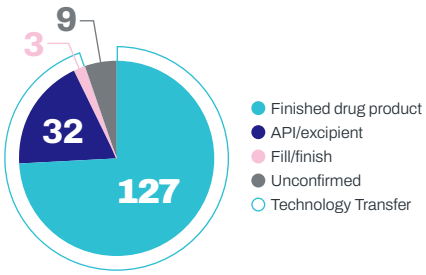
- Builds on a global network
- Encourages technical assistance
- Ensures use of skilled workforce
- Building local industry and investment
- Reduced production time
- Ensures there is assistance for regulatory filings
- Places no burden on the exchequer
- Flexible approach allows for quick response
- 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 237 production channels, of which 137 are intended for production and distribution for LMICs and UMICs.

Collaborations on COVID-19 therapeutics mainly involve technology transfer



171
Collaborations*

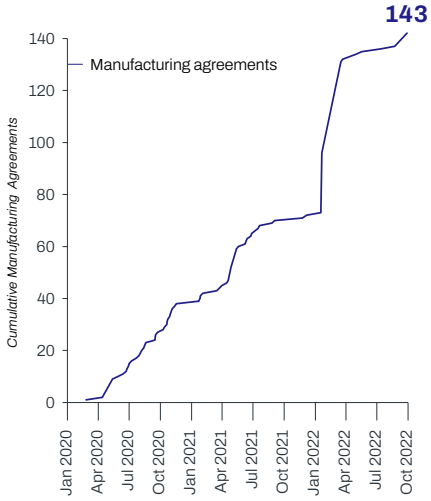
*Collaborations include: Distribution partners, Voluntary licensing agreements, Manufacturing partners, Medicines Patent Pool sublicensees

Source: Airfinity, January 2024

Top 5 locations for generic companies involved in voluntary licensing agreements:

- India **34 licensees**
- China **12 licensees**
- South Korea **2 licensees**
- Bangladesh **2 licensees**
- Pakistan **2 licensees**

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



Source: Airfinity, January 2024

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.

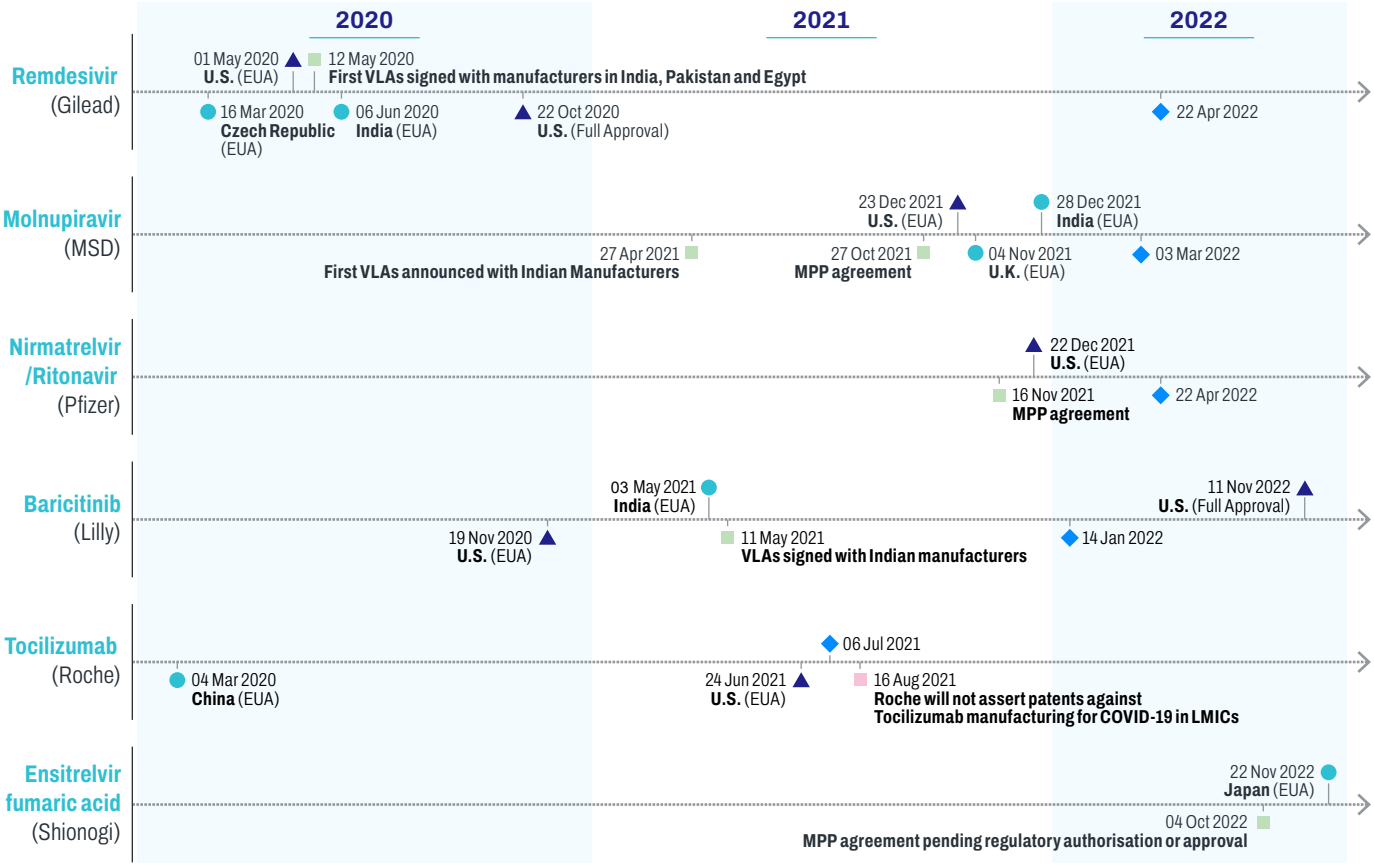
Examples of different access pathways and voluntary partnerships entered into by innovators for COVID-19 therapeutics

- **Gilead** 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;
- **MSD** 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 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 LICs;
- **Pfizer** signed an agreement with UNICEF for up to 4 million treatment courses of nirmatrelvir/ritonavir to 137 eligible low- and middle-income countries;
- **Pfizer** signed an agreement with the Global Fund to supply up to 6 million treatment courses of nirmatrelvir/ritonavir to 132 eligible low- and middle-income countries;
- **Shionogi** has signed a voluntary licence agreement with Medicines Patent Pool to enable qualified generic manufacturers to manufacture and supply ensitrelvir to 117 countries.

For the voluntary licensing partnerships, the price is determined by the licensees.

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.

Supporting global health through international trade

IFPMA

Strengthen innovation incentives

- Maintain a robust intellectual property framework to support continued investment in pharmaceutical R&D and voluntary collaborations.

Remove trade restrictions

- Review and eliminate trade restrictions on health products, including raw materials critical to manufacture health products.
- Reduce tariffs and expand the number of signatories of the WTO Pharmaceutical Agreement.

Promote trade facilitation

- Enhance customs clearance procedures and sharing of best practices, including those of private sector
- Work with stakeholders to put in place policies that support building a skilled workforce.

Strengthen supply chains

- Foster open, secure, sustainable and resilient supply chains
- Enhance supply chain connectivity by addressing the healthcare infrastructure
- Enhance quality and safety of supply chains through monitoring for counterfeit, substandard and falsified products.

Engage with other bodies

- Engage with international bodies and private sector to enhance regulatory strengthening, finance, and procurement mechanisms.

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 Members 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.

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

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