

The role of IP in addressing the COVID-19 pandemic

On October 2, India and South Africa circulated a waiver [proposal](#) to the World Trade Organization (WTO) Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding COVID-19 and intellectual property (IP). Despite a lack of any evidence, IP rights are identified as hindering the response to the pandemic and the two countries proposed that the TRIPS Council waives on a temporary basis the application and enforcement of critical provisions of the WTO TRIPS Agreement.

If implemented, this proposal would eliminate Member States' obligations to grant IP rights, including but not limited to patents, on a broad range of technologies related to COVID-19 until "widespread vaccination is in place globally and the majority of the world's population has developed immunity." This proposal represents an extreme measure for an unidentified problem and leads towards a significant escalation in anti-IP positioning in multilateral fora, with potential consequences around the globe.

The TRIPS agreement represents carefully-negotiated social balance of rights and obligations. The waiver would call into question 25 years of multilateral negotiations by setting a precedent to suspend substantial parts of a core WTO Agreements and result in the dilution of intellectual property standards globally. It would also set a negative precedent to other sectors. Erosion of IP rights, particularly if done through a blunt tool like a TRIPS waiver, will have long term negative impact for medical innovation, including preparedness for future pandemics.

IP underpins industry's capacity to address this pandemic

Intellectual property has never been more important than it is now. This has been true for any previous responses to global health crisis such as in HIV. The key to success in these responses has been partnership, not weakening of IP.

Relying on strong IP protections and incentives, biopharmaceutical innovators are collaborating with governments, foundations and universities to quickly research, develop and test potential COVID-19 treatments and vaccines. According to BioCentury, there are nearly 1100 potential treatments and vaccines in development.

IP protections have enabled the biopharmaceutical industry's rapid response to COVID-19 and are facilitating the collaborations and partnerships needed to defeat the virus and end the pandemic, as illustrated in the annexes to this document. Much of the work underway builds on products, knowledge and research capacity developed over many years with the support of IP protections and incentives.

Practically, this has put biopharmaceutical innovators in a unique position to rapidly deploy potential therapeutics during a period where time is of the essence. As such, any proposals concerning IP in COVID-19 related technologies should respect and preserve the current IP system so that it can continue to spur innovation after this crisis is over and ensure we have the R&D capacity to fight future pandemics and diseases.

IP has not been a barrier to collaboration or access, much to the contrary

There is no evidence that IP has been or will be an impediment to the research, development and testing of potential COVID-19 treatments and vaccines or to the many research partnerships

underway between companies and institutions around the world. On the contract, IP is an enabling force that guides research and development and ensures that the next generation of inventors and investors will remain engaged.

Biopharmaceutical companies have committed publicly and are already working closely with governments and other stakeholders to ensure that when new treatments and vaccines are approved, they will be available and affordable to all who need them.

This extraordinary proposal will further polarize important conversations on countries' engagement to combat the pandemic and divert attention away from key issues of country preparedness which are needed to ensuring availability and access of the vaccines and therapeutics currently being developed. A more constructive and impactful conversation should focus on timely regulatory approval, supply chain scrutiny and effective distribution of the treatments and vaccines under development. There is also a risk that the momentum generated by this proposal creates a spillover of an anti-IP narrative to other multilateral fora, and divert attention away from real access challenges worldwide.

Local production is not a panacea to enhancing access to COVID-19 vaccines and therapeutics, as few countries have the local capacity to develop and manufacture copies of high quality and safe vaccines and complex therapeutics being developed. In the cases where manufacturing capacity can and needs to be expanded, developers of the approved vaccines may engaged in manufacturing agreements, which may include technology transfer, process with carefully selected licensees or contract manufactures.

If adopted, this waiver would still require complex national implementation, as countries would subsequently need to change their laws, consuming considerable time and political capital, which would be better spent addressing the issues identified above.

The Annexes below provide ample evidence of the many collaborations the research-based pharmaceutical industry has engaged to drastically expedite R&D, manufacturing and access to COVID-19 therapeutics and vaccines. They would not have taken place without a robust IP system underpinning it.

ANNEX I – Selected examples of collaborations with IFPMA companies for development and manufacturing of promising COVID-19 vaccines

IFPMA member companies are at the forefront of the global effort to develop a safe and effective COVID-19 vaccine and scale up manufacturing to ensure equitable access to people around the world. In less than an year, several vaccines candidates have concluded or are in advanced [Phase III](#) clinical trials with encouraging results. An impressive and unprecedented manufacturing scale-up is also taking place. Most collaboration involved some sort of licensing and transfer of technology, which would not be possible in the absence of a robust global IP system.

*The examples below highlight a few selected collaborations with IFPMA companies. According to Airfinity data, as of November 2020 at least **216 manufacturing and production deals** for COVID-19 vaccines around the globe were made public.*

Pfizer and BioNTech are [jointly developing](#) a promising mRNA vaccine. [Primary efficacy analysis](#) demonstrates the vaccine to be 95% effective against COVID-19 beginning 28 days after the first dose. Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world. The companies have developed specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of -70°C±10°C. They can be used as temporary storage units for 15 days by refilling with dry ice. Based on current projections the companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. BioNTech is also collaborating with [Fosun Pharma](#) to supply the Chinese market.

AstraZeneca and the **University of Oxford** joined forces for the development, worldwide manufacturing and distribution of a vaccine, developed by the Jenner Institute and Oxford Vaccine Group. [Positive high-level results](#) showed the vaccine had efficacy of up to 90% on a certain dosing regimen. To expand manufacturing capacity of the vaccine candidate, the company also entered into collaborations with [Catalent Biologics](#) (Italy), [Symbiosis Pharmaceutical Services](#) (UK), [Oxford Biomedica](#) (UK), [Emergent BioSolutions](#), [BioKangtai](#) (China), and [R-Pharm](#) (Russia). AstraZeneca also reached a [\\$750m agreement with CEPI and Gavi](#) to support the manufacturing, procurement and distribution of 300 million doses of the vaccine. In addition, AstraZeneca reached a [licensing](#) and technology transfer agreement with Serum Institute of India to supply one billion doses for low and middle-income countries

Johnson & Johnson began efforts to [develop a vaccine](#) in January 2020, as soon as the COVID-19 sequence became available. Research teams at Janssen, in collaboration with the Harvard Medical School, constructed and tested multiple vaccine candidates using the Janssen [AdVac® technology](#). The vaccine entered Phase III clinical trials on September 2020. The Company is committed to bringing an affordable vaccine to the public on a [not-for-profit basis](#) for emergency pandemic use and anticipates the first batches of a COVID-19 vaccine to be available for emergency use authorization in early 2021, if proven to be safe and effective. It also aims to manufacture more than one billion doses to be distributed globally through 2021. In July, [Emergent BioSolutions](#) and J&J announced a five-year manufacturing services agreement for large-scale drug substance manufacturing for its vaccines. J&J also signed a [deal with Catalent](#) to accelerate rapid scale-up of manufacturing capacity over the coming months to support the production of the vaccine candidate. [Aspen](#) announced that it entered into a preliminary agreement with Janssen Pharmaceuticals, for the technical transfer and proposed commercial manufacture of their COVID-19 vaccine candidate.

GSK and Sanofi committed to join forces and jointly develop a vaccine using innovative adjuvanted recombinant protein-based technology. Together, they bring significant manufacturing capacity, and, if successful, will be able to make hundreds of millions of doses annually by the end of next year. They have [publicly committed](#) to making any vaccine that is developed through the collaboration affordable to the public and through mechanisms that offer fair access for people in all countries. In this sense, they [signed](#) a Statement of Intent with Gavi to make available 200 million doses of their COVID-19 vaccine, if approved by regulatory authorities, to the COVAX Facility

MSD and IAVI [partnered](#) to advance the development and global clinical evaluation of a COVID-19 vaccine candidate. This vaccine candidate would use the recombinant vesicular stomatitis virus (rVSV) technology that is the basis for MSD's Ebola Zaire virus vaccine, ERVEBO®. MSD also acquired Vienna-based biotech company Themis to [accelerate the development](#) of its COVID-19 vaccine candidate.

Takeda, Novavax and the Japanese Ministry of Health, Labour and Welfare are [partnering to increase manufacturing capacity](#) of Novavax's COVID-19 vaccine candidate NVX CoV2373 in Japan. Takeda anticipates to manufacture over 250 million doses of the COVID-19 vaccine per year.

ANNEX II – Briefing on COVAX¹

IFPMA is a founding member of the ACT Accelerator and is heavily engaged in the COVAX pillar. Through the COVAX facility, 92 middle- and lower-income countries that cannot fully afford to pay for COVID-19 vaccines themselves are expected to get equal access to COVID-19 vaccines as higher-income self-financing countries and at the same time.

COVAX is the vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator. It brings together governments, global health organisations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments and vaccines. IFPMA is a founding member of the ACT Accelerator and is heavily engaged in COVAX.

The initial aim of COVAX is to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as frontline healthcare workers. For lower-income funded nations, who would otherwise be unable to afford these vaccines, as well as a number of higher-income self-financing countries that have no bilateral deals with manufacturers, COVAX is a lifeline and the only viable way in which their citizens will get access to COVID-19 vaccines.

What is the COVAX Facility?

The principal role of the COVAX Facility is to maximize the chances of people in participating countries getting access to COVID-19 vaccines as quickly, fairly and safely as possible. By joining the Facility, participating countries and economies will not only get access to the world's largest and most diverse portfolio of COVID-19 vaccines, but also an actively managed portfolio.

Self-financing countries and economies participating in the Facility can request vaccine doses sufficient to vaccinate between 10-50% of their populations. The amount they pay into the Facility will reflect the number of doses they have requested.

What is the GAVI COVAX AMC?

The primary focus of the Gavi COVAX AMC is to ensure that the 92 middle- and lower-income countries that cannot fully afford to pay for COVID-19 vaccines themselves get equal access to COVID-19 vaccines as higher-income self-financing countries and at the same time. Funding for the Gavi COVAX AMC is entirely separate from that of the COVAX Facility, which means that the AMC is not cross-subsidised by the funds of self-financing participants. Instead the AMC will be funded mainly through Official Development Assistance (ODA), as well as contributions from the private sector and philanthropy.

How will vaccine doses be allocated?

Once any of the COVAX portfolio vaccines have successfully undergone clinical trials and proved themselves to be both safe and effective, and have received regulatory approval, available doses will be allocated to all participating countries at the same rate, proportional to their total population size. A small buffer of about 5% of the total number of available doses will be kept aside to build a

¹ Adapted from <https://www.gavi.org/vaccineswork/covax-explained>

stockpile to help with acute outbreaks and to support humanitarian organisations, for example to vaccinate refugees who may not otherwise have access.

Even though self-financing participants can request for enough doses to vaccinate between 10-50% of their population, no country will receive enough doses to vaccinate more than 20% of its population until all countries in the financing group have been offered this amount. The only exception is those countries who have opted to receive fewer than 20%.

ANNEX III – Selected examples of collaboration to increase manufacturing and enhance access to promising COVID-19 Therapeutics

*IFPMA member companies are committed to work with governments, insurers and international organizations to ensure equitable access to COVID-19 medicines. The examples below illustrate different initiatives IFPMA companies are taking to enhance access. In all of them licensing, enabled by a well well-functioning intellectual property system, is a key enabler. Sector-wide, according to Airfinity data, **at least 44 manufacturing and production deals** for COVID-19 therapeutics around the globe were made public (as of November 2020).*

Eli Lilly and Company and the Bill & Melinda Gates Foundation, as part of the COVID-19 Therapeutics Accelerator, [have entered into an agreement to facilitate access](#) to future Lilly therapeutic antibodies under development for the prevention and treatment of COVID-19, to benefit low- and middle-income countries. Therapeutic antibodies have the potential to prevent and treat COVID-19, reducing the burden on healthcare systems worldwide. Commercial manufacturing will commence in April 2021 at the FUJIFILM Diosynth Biotechnologies facility in Denmark, where the Therapeutics Accelerator reserved manufacturing capacity in an agreement announced in April. Lilly has already started the manufacturing technology transfer at risk, in anticipation of regulatory authorization for its antibody therapy. In the interest of making supply of COVID-19 therapeutic innovations available globally as quickly as possible, Lilly will make certain volumes of its antibody therapeutic manufactured in other facilities available to lower-income countries prior to April 2021. Lilly's collaborators, AbCellera Biologics Inc., Shanghai Junshi Biosciences Co., Ltd. and Columbia University have agreed to waive their royalties on the Lilly therapeutic antibodies distributed in low- and middle-income countries as part of this initiative.

Gilead has entered into [voluntary licensing agreements](#) with nine generics manufacturers to further expand supply of remdesivir to 127 countries that represent nearly all low-income and lower-middle income countries. Gilead has completed technology transfers with these companies, and they are beginning the manufacturing process. Moreover, Gilead has expanded its global network of both internal manufacturing sites and external organizations, including partnering with industry peers, to add manufacturing capacity around the world. Veklury manufacturing network now includes more than 40 companies in North America, Europe and Asia. [Pfizer](#) announced a multi-year agreement with Gilead to manufacture and supply Gilead's remdesivir.

Merck, IAVI, and Serum Institute of India are [collaborating to develop a neutralizing monoclonal antibodies](#) (mAbs) co-invented by IAVI and Scripps Research as innovative interventions to address the COVID-19 pandemic. The global development plan is being led by the three organizations in partnership. If the highly potent and broadly cross-reactive SARS-CoV-2 neutralizing antibody candidates being advanced through this partnership are shown to be efficacious in clinical trials, either as a single antibody or a potential combination of both candidates, Merck will lead commercialization in developed countries and the Serum Institute will lead global manufacturing as well as commercialization in low- and middle-low-income countries, including India.

Roche and Regeneron joined forces to [significantly increase global supply](#) of REGN-COV2, Regeneron's investigational antiviral antibody combination, to at least three and a half times the current capacity, with the potential for even further expansion.

ANNEX IV – Selected examples of collaboration for therapeutics R&D

Licensing is a core part of industry's successful business model and has been a cornerstone in its robust response to the COVID-19 crisis. As the selected examples listed below illustrate, a well-functioning IP system allows industry to partner with confidence with academia, research institutes, foundations and other private companies, significantly expediting the research and development of medicines to address the worlds' many unmet medical needs

[AbbVie](#) partnered with global authorities to determine the effectiveness of HIV drugs lopinavir/ritonavir in treating COVID-19. [AbbVie](#) also entered into a collaboration with Harbour BioM, Utrecht University, and Erasmus Medical Center to develop a novel antibody therapeutic. [AbbVie](#), and partners of the COVID R&D Alliance, Amgen, and Takeda, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icanatibant in hospitalized COVID-19 patients. [Amgen](#) and Adaptive Biotechnologies are partnering to combine expertise to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2.

[Astellas](#) is providing compounds in response to a request from the government to cooperate in the “Basic Screening Plan for Drugs for Coronavirus Disease”.

[Chugai](#) entered into a license agreement for worldwide non-exclusive rights of several Chugai's antibody engineering technologies with Eli Lilly.

[CSL Group](#) is collaborating with Takeda, Biotest AG, Bio Products Laboratory, LFB and Octapharma to accelerate development of a potential COVID-19 Hyperimmune therapy.

[Eli Lilly](#) and AbCellera collaborate on AbCellera's rapid pandemic response platform for the rapid development, manufacturing and distribution of therapeutic antibodies. [Eli Lilly](#) and Amgen announced a global antibody manufacturing collaboration to significantly increase the supply capacity available for Lilly's potential COVID-19 therapies.

[Eisai](#), in collaboration with the Global Coalition for Adaptive Research and the University of Pittsburgh Medical Center, joined REMAP-COVID, a study that tests multiple interventions for the treatment of patients hospitalized with COVID-19. [Eisai](#) announced that it has entered into a joint research agreement with four research organizations in Japan concerning the “Development of Therapeutics to Prevent the Aggravation of the Novel Coronavirus Infectious Disease (COVID-19)”.

[GSK](#) and Vir Biotechnology Inc entered into a collaboration using Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies.

[Johnson & Johnson](#), in partnership with the Rega Institute for Medical Research, and the University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19.

[Roche](#) and Atea Pharmaceuticals announced that they are joining forces in the fight against COVID-19 to develop, manufacture and distribute AT-527, Atea's investigational oral direct-acting antiviral, to people around the globe.

[Takeda](#) and CSL Group formed the CoVig-19 Plasma Alliance with other leading global plasma companies to develop a potential plasma-derived therapy for treating COVID-19.

[UCB](#) is working with the Seattle Structural Genomics Center for Infectious Disease to identify crystal structures of SARS-CoV-2 proteins. In the UK, the company partnered with Diamond Light Source and the University of Oxford to design inhibitors of SARS-CoV-2's main protease for treatment of COVID-19 patients.

ANNEX V – IFPMA position and resources

IFPMA public statements:

[IFPMA/IGBA “Considerations on equitable access to COVID-19 medicines and vaccines”](#)

[IFPMA statement on “Intellectual Property and COVID-19”](#)

[Innovative health industries united in welcoming UNGA Resolution on “Comprehensive and Coordinated Response to the COVID-19 Pandemic”](#)

[Innovative vaccine industry strongly committed to rigorous regulatory standards for approval of COVID-19 vaccines](#)

[IFPMA Statement on the “Solidarity Call to Action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data”](#)

Resource hub:

The [IFPMA COVID-19 Hub](#) brings a wealth of information about industry’s commitments and actions to tackle the pandemic

IFPMA Global media briefs:

On 28 May 2020, IFPMA organised a global [media briefing](#) on the status of collaboration and risk-sharing to speed up the research, development and manufacturing of vaccines against COVID-19. The briefing included an overview of R&D for the COVID-19 vaccines pipeline and how IFPMA member

On 3 September 2020, IFPMA organised a global [media briefing](#) on COVID-19 therapeutics: innovation, trials and access. The briefing included an overview of R&D for the COVID-19 therapeutics pipeline and how IFPMA member companies are collaborating to develop and deploy safe and effective treatments at scale.

Other:

[Life Science Companies and the Bill & Melinda Gates Foundation: Commitments to Expanded Global Access for COVID-19 Diagnostics, Therapeutics, and Vaccines](#)