



WTO COVID-19 TRIPS waiver proposal

Myths, realities and an opportunity for governments to protect access to lifesaving medical tools in a pandemic

Introduction

As the COVID-19 pandemic has unfolded, one of the challenges is the negative impact that intellectual property (IP) barriers [have had in the past and are anticipated to have](#) on the scale up of manufacturing and supply of lifesaving COVID-19 medical tools across the world. Because the pandemic is an exceptional global crisis, the World Trade Organization (WTO) can invoke [a waiver](#) of certain IP rights on these technologies under WTO rules. Given this, South Africa and India submitted [a landmark proposal](#) earlier this year to the WTO requesting that WTO members waive four categories of IP rights – copyright, industrial designs, patents and undisclosed information under the Agreement of Trade-Related Intellectual Property Rights (TRIPS) until the majority of the world population receives effective vaccines and develops immunity to COVID-19.

As of 20 November 2020, Eswatini, Kenya, Mozambique and Pakistan are officially co-sponsoring this proposal. After initial discussions at the Council of TRIPS in October and November, 100 countries have welcomed or fully supported the proposal. A small group of WTO members – [Australia, Brazil, Canada, the EU, Japan, Norway, Switzerland, the UK, and the US](#) – are withholding support that would help build much needed consensus on the proposal. Some of these countries have traditionally backed the interests of their pharmaceutical corporations through a proprietary IP system.

In the course of discussion, opponents of the TRIPS waiver proposal have promoted some myths regarding the impact of IP on COVID-19 technologies. This Médecins Sans Frontières (MSF) briefing document dispels those myths and explains why all countries should support the waiver proposal to protect access to lifesaving medical tools in a pandemic.

COVID-19 IP myths vs reality

Myth: There is no indication that IP issues have been a barrier for COVID-19 medicines and technologies.

Reality: Past precedents and emerging evidence demonstrate how IP is a growing barrier to COVID-19 medicines and technologies.

MSF's [briefing document](#), governments and media have highlighted various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines in the pandemic.

Diagnostics: South Africa faced challenges accessing key chemical reagents for COVID-19 diagnostic testing due to [proprietary protection on the machines and the reagents](#). The Swiss pharmaceutical corporation [Roche rejected](#) a request from the Netherlands to release the recipe of key chemical reagents needed for increasing production of diagnostic kits and only released it after facing pressure from the European Commission.

Medical equipment: In Northern Italy, patent holders threatened producers of [3D printing ventilator valves](#) with patent infringement lawsuits. [N95 masks](#) that offer much better protection than surgical masks have hundreds of patents on them by the multinational company 3M, and other entities. To address the short supply of N95 masks, in March 2020 the Governor of Kentucky in the United States even called on 3M to waive their patents so that more manufacturers can start producing masks.

Treatments: Preliminary data have demonstrated that primary and secondary patent applications have been widely filed or granted for some of the antiviral and monoclonal antibody therapeutic candidates, such as [AT-527](#) and [baricitinib](#), including in developing countries. The pharmaceutical company [Regeneron also obtained a US patent](#) on the experimental REGN10933 + REGN10987 monoclonal antibody therapy, which only expires in 2040. Regeneron has chosen to only partner with Roche, and has shown no plan to license the IP or transfer technology to monoclonal antibody producers in developing countries who can scale up supply and reduce the prices of these monoclonal antibody therapies. This is just the tip of the iceberg. Since the pandemic started, patent claims have been filed across the globe but are yet to be published fully because of an 18-month procedural embargo under international and national patent rules.

If these and other therapeutic candidates show efficacy, the current situation would compel countries to depend on patent-holding corporations' determinations of where to supply, at what price, and whether they will allow multiple producers to meet the global demand. Already the pharmaceutical corporation Gilead Sciences has set a negative precedent early on in the pandemic by patenting and licensing a COVID-19 medicine – now being delisted by World Health Organization (WHO) [due to lack of efficacy](#) – in a manner that excluded nearly half of the world's population from accessing alternative suppliers at a lower price.

In a pandemic, delivering universal and affordable access to critically important medical treatments should not be left to monopoly market forces. The waiver can provide expedited legal certainty and clarity to enable competent manufacturers to develop and supply these potential treatments without the fear of expensive litigation.

Vaccines: Industry and some institutions claim that IP is not an issue for COVID-19 vaccine access. However, when alternative vaccine producers independently developed 13-valent pneumococcal conjugate vaccines (PCV13), Pfizer's aggressive patenting strategy compelled a South Korean company to stop its development and [delayed the availability](#) of more affordable alternative versions of the pneumonia vaccine for children. [MSF found that](#) patents have also been applied for or granted across the entire vaccine development, production and delivery process. These patents increase uncertainty and costs, delay competition and keep prices high for low- and middle-income countries, hindering people's access to important vaccines. Others have [published similar findings](#). IP issues, including patents, can be a barrier to cheaper vaccines entering the market.

In fact, several IP issues on COVID-19 vaccines need to be addressed:

Patents on background platform technologies: Some of the main platform technologies used to develop COVID-19 vaccines were used for the development of other vaccines before the pandemic and remain under patent control, such as those concerning the Oxford/AstraZeneca vaccine candidate.¹ Patents have been identified on some of the frontrunner vaccine candidates, including the [Pfizer/BioNTech](#) candidate and the [Moderna/NIH](#) candidate. There is also a large portfolio of IP, such as hundreds of patents on mRNA technology – an alternative to traditional vaccine platforms – [owned by different entities](#). One of the corporations [has decided not to enforce their patents](#) on mRNA vaccine technology during the pandemic, but this is not sufficient to provide legal certainty for all competent developers and manufacturers. Recent [patents disputes on COVID-19 vaccine technologies](#) demonstrate the impact of these IP barriers on the access options and

¹ At least two patents cover the recombinant adenoviral vector and the method of composition on Oxford/AstraZeneca vaccine candidate. [WO2012172277](#) (PCT/GB2012/000467) is filed or granted in at least 13 jurisdictions, expiring in May 2031. [WO2018215766](#) (GB201708444 A) is filed in the UK and expires in May 2037, if granted.

prices of future vaccines, as possible injunctions could suspend the development and potential royalty payments could keep the final prices high.

Patents on newly developed technologies related to COVID-19 vaccines: With the ongoing research and development (R&D), different types of new IP might be sought on COVID-19 vaccine product, manufacturing process, method of use and related technologies, such as the [cold-chain management system](#) for vaccine storage. This calls for an all-encompassing solution that not only addresses patent barriers related to vaccines but also to related technologies and equipment. [According to preliminary data](#), some patenting trends in vaccines have also started emerging. However, primary patents might only become visible in the coming months due to the 18-month embargo period.

Non-patent IP and exclusivities: For vaccine development and production, other types of IP and materials – including, for instance, manufacturing know-how, test data and cell lines – are needed to facilitate diversified production and supply worldwide. Countries have very limited experience in dealing with barriers caused by non-patent IP and exclusivities, such as data exclusivity and trade secret/commercial confidential information.

The large portfolio of background patents, emerging new patents and non-patent IP and exclusivities comprise a legal minefield for competent developers to quickly enter into vaccine development, production and supply. The waiver, if granted, can provide the needed legal certainties to competent developers without solely relying on the IP holders' willingness. This is especially relevant because most multinational corporations holding COVID-19 vaccine IP have shown insufficient plans or no plans to openly license or transfer technologies to all competent vaccine developers globally.

Myth: IP enabled the R&D breakthrough in COVID-19 medicines and vaccines.

Reality: Public funding and collective efforts are driving progress of COVID-19 R&D.

Opponents of the India-South Africa proposal argue that IP promotes innovation. This has been a long-standing argument in favour of IP protection, promoting stricter and more stringent laws. But evidence points to a different reality.

The COVID-19 pandemic has caused significant illness, deaths and disruption to people's livelihoods in communities around the world, which has motivated researchers and funders alike to invest in and undertake R&D for COVID-19 health products at an unprecedented scale. In this pandemic, governments and public funding agencies have invested billions of US dollars to support COVID-19 R&D. Many of the pharmaceutical corporations aim to commercialize [scientific breakthroughs originating in public labs and from public funding](#) around the world. In addition, governments, health care workers, patients, COVID-19 survivors and the general public have contributed enormously to clinical trials and other R&D activities on different therapeutics and vaccines.

The claim that IP enabled the breakthrough of COVID-19 medicines and vaccines is misleading. Public sector resources, philanthropic funding and the common cause of ending a deadly pandemic have been the main drivers of the unprecedented research efforts to date. Providing monopoly control over key health tools to a single corporation in a pandemic is both unjustified and counterproductive. Such monopoly control hampers the scale up of production needed to ensure global equitable access to these products to end the pandemic. Defending monopoly protection also contradicts the call for COVID-19 medicine and vaccines to be treated as global public goods. Only a worldwide right to use, produce and supply, as would be enabled by granting the TRIPS IP waiver, appropriately matches these collective efforts.

Myth: Voluntary licensing measures are sufficient.

Reality: Voluntary measures have limited impact.

Since the beginning of the pandemic, non-enforcement and voluntary contribution of IP and technologies by companies to facilitate the open access and right to produce and supply globally [have been encouraged](#). Yet, relying on voluntary willingness and contribution by companies has delivered limited effects.

The [pharmaceutical sector has collectively decided not to engage](#) with the WHO COVID-19 Technology Access Pool (C-TAP) initiative that encourages the voluntary contribution of IP, technology and data to support global sharing and scale-up of manufacturing and supply of COVID-19 medical products. [MSF's recent study](#) on the lessons learned from voluntary licensing also demonstrates that IP-holding corporations could apply restrictive licensing terms such as limited geographic coverage of supply and other conditions that limit the benefits of competition and global supply. This practice has already occurred in the pandemic.

While AstraZeneca has signed licensing agreements facilitating technology transfer on COVISHIELD – one of the first vaccine candidates to reach phase III – with manufacturers in Argentina, Brazil, China, India, and Indonesia, these agreements are shrouded in secrecy. The limited details that have been released reveal worrying terms. For example, while India has multiple manufacturers of vaccines, the license is restricted to the Serum Institute of India (SII). Further, SII is barred from supplying upper-middle-income and high-income countries, the most profitable markets for AstraZeneca. The corporation's deal with Brazilian public research body Fundação Oswaldo Cruz (Fiocruz) gives AstraZeneca the power to declare the pandemic over as soon as July 2021. This implies that, after July 2021, AstraZeneca can charge governments and other purchasers [higher prices for a vaccine](#) that was [funded by public research and investments](#).

As previously mentioned, Gilead left half of the global population without access to remdesivir in its voluntary license strategy when the product was considered a potential treatment. Other major vaccine and therapeutic developers, such as Pfizer/BioNTech and Regeneron, have taken no action to license or transfer technologies to developing country manufacturers.

These actions by pharmaceutical corporations show that relying on their charity and limited voluntary actions are not the solution in a global pandemic. Given these common challenges and the pharmaceutical industry's refusal to routinely offer non-exclusive licenses with worldwide coverage to facilitate global access, governments must address this global crisis as they did nearly 20 years ago under the Doha Declaration on the TRIPS Agreement and Public Health amidst the HIV/AIDS epidemic, by supporting the temporary waiver proposal.

Myth: Existing TRIPS flexibilities are sufficient.

Reality: TRIPS flexibilities are important public health safeguards but may not be sufficient in the pandemic.

There are a number of important safeguards already enshrined in the TRIPS Agreement that countries can use to protect public health and increase access to medicines. These include, for example, countries' rights to issue a compulsory license to override a medicine patent, right to introduce pre-grant patent opposition systems and strict patentability criteria and the discretion to not allow exclusivity over test data. The [EU](#), [Japan](#), [Switzerland](#) and the [US](#) have long undermined the use of TRIPS flexibilities in developing countries to protect the interests of their pharmaceutical industries. Yet these countries are now pointing to the availability of these same flexibilities to discourage the waiver proposal.

Despite the UN High-Level Panel on Access to Medicines' call for governments to "[refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities](#)," the

systematic undermining of their use by the EU, Japan, Switzerland and the US through free trade agreements and bilateral pressure is well documented. Over the years such pressure has undermined the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively.

Since India issued its first compulsory license on pharmaceutical patents, [the US has applied continuous pressure on India](#) to discourage any further compulsory licensing on patented medicines. The US Trade Representative (USTR)'s annual Special 301 report systematically criticises developing countries who either reform their IP law to include TRIPS flexibilities or make use of compulsory licenses. The [EU's annual IP enforcement report](#) also criticises a number of developing countries for compulsory licensing laws and other uses of TRIPS flexibilities. This kind of [pressure continued at the peak of the COVID-19 pandemic in April 2020](#).

The “case-by-case” or “product-by-product” approach required when using flexibilities to address IP barriers at the national level could be [limiting during the pandemic](#). Early in the pandemic, a number of countries amended their national laws to make government use of compulsory license easier and quicker – including Australia, Canada, Germany and Hungary. This shows that laws both nationally and at the international level need to be prepared for crisis situations that require expedited and extraordinary measures. Countries should support the waiver as the proposal allows members of the WTO to quickly overcome IP barriers to safeguard public health. The use of TRIPS flexibilities and waiver are not mutually exclusive, they are complementary.

Myth: The global initiatives such as ACT-A and its vaccine pillar – COVAX – can deliver effective vaccines across the globe and the waiver will undermine these initiatives.

Reality: Wealthier countries' bilateral actions undermine the global initiatives.

The Access to COVID-19 Tools Accelerator (ACT-A) coordinated by WHO is an important global initiative. MSF has been actively participating in all product pillars of ACT-A. MSF recognises the importance of the various multilateral approaches such as ACT-A, its vaccine access arm (COVAX), C-TAP and now the TRIPS waiver. Each global initiative serves different, complementary policy objectives. It is divisive to polarise the discussion on the waiver proposal by imposing a binary logic of policy choices.

Opponents of the waiver point to their financial contributions to COVAX as a display of global solidarity. These contributions are important and will certainly help ensure better access. There is however a fundamental difference between using financial contributions to advance market commitments to increase the supply provided by a limited number of manufacturers and increasing the number of suppliers.

COVAX has so far secured a few deals with limited numbers of doses of vaccines and faces [a significant funding gap](#) to reach its target. Specifically, it has reserved some 700 million doses while countries included in the COVAX advance market commitment (AMC) represent over 3 billion people. In contrast, the EU aims to reserve 1.5 billion COVID-19 vaccine doses for a population of [fewer than 450 million people](#). The European Commission has in fact urged EU member states not sign agreements through COVAX as it was able to secure more doses under better conditions in direct agreements with the manufacturers. Such practices applied by all high-income countries opposing the waiver have eroded COVAX negotiation and purchasing power and undermined the application of the WHO fair allocation framework.

ACT-A and COVAX are also limited by the remaining production capacity of IP-holding manufacturers to supply doses and tools. Since its inception, MSF has called on COVAX to ensure a global scale up of production, including in the Global South, to increase and diversify supply. As long as COVAX primarily competes with high-income countries to secure supply from the same limited number of manufacturers, rather than increase the number of suppliers, the problem of global scarcity of COVID-19 vaccine doses will not be resolved. Global efforts should prioritize increasing the number of suppliers.

In addition, the waiver has a wider application than vaccines and can also be used for medicines, diagnostics and other medical tools needed to combat COVID-19. The recent [global trade report issued](#) by the UN Conference on Trade and Development (UNCTAD) shows that since the recovery of the global production capacity of medical supplies (personal protective equipment, disinfectants, diagnostic kits, oxygen respirators and other related hospital equipment) for COVID-19 control, only a fraction of supply has reached low-income countries while most of the recovered capacities have benefited wealthier countries. For these medical supplies, lifting any IP and technology barriers would facilitate increased collaboration in development, production and supply.

Finally, the waiver is a matter of global justice. [Access in developing countries should not be defined by the size of financial pledges](#) or spare production capacity of manufacturers in high-income countries, while manufacturing capacity in the Global South remains unutilized. It is an unacceptable injustice that a small group of WTO members are denying other countries' own capacity to supply COVID-19 medical tools when this small group has procured the bulk of the global COVID-19 medicines supply and [pre-booked more than enough vaccines doses for domestic use](#), bypassing global mechanisms.

Myth: Even if IP barriers are waived, developing country manufacturers will not be able to produce COVID-19 health technologies without technology transfer.²

Reality: Past presumptions of limited scientific/technological abilities of countries in the Global South have been proven wrong.

Manufacturers in developing countries have repeatedly proven their advanced scientific and technological abilities. Existing R&D and manufacturing capacity in developing countries is therefore critical to the sufficiency and sustainability of supply of COVID-19 medical tools. However, the limited action and the overall unwillingness to share COVID-19 health technologies by multinational corporations, combined with the inaction, and blockage from high-income countries in the waiver proposal discussions, demonstrate how maintaining structural barriers is prioritised over the achievement of global equitable access to all needed medical tools to combat COVID-19.

The blanket dismissal of R&D and manufacturing capacities in developing countries is not a new phenomenon and has been proven wrong in the past. When most countries could not afford to include the hepatitis B vaccine in their immunization programmes in the 1980s, [Shantha Biotechnics in India](#) sought and was denied a technology transfer to accelerate the development process. It independently developed the recombinant hepatitis B vaccine and supplied the vaccine at less than 1 US dollar (USD) per dose and supplied UNICEF and national immunization programmes.

While pharmaceutical corporations claimed that recombinant conjugate vaccine technology was too complex for developing country manufacturers to master, independent developers in India, South Korea and [China](#) have developed pneumococcal conjugate vaccines for children.

At present, [an Indian manufacturer](#) is a frontrunner in developing a potential COVID-19 mRNA vaccine without the heavy cold-chain requirements usually needed for such COVID-19 vaccines. [A group of Chinese researchers](#) is also working on a thermostable mRNA vaccine for COVID-19.

Other mechanisms and interventions, including transparent and full transfer of technology on certain medical tools are important and can be encouraged alongside the waiver. To date, due to the overall lack of willingness

² A recent Wall Street Journal editorial even said: "It's not clear developing countries even have the ability to manufacture large-scale, complex technologies like Moderna's mRNA vaccine or Eli Lilly's monoclonal antibody cocktail—let alone distribute them." See: <https://www.wsj.com/articles/a-global-covid-vaccine-heist-11605829343>

and sufficient policy intervention, transfer of technology on COVID-19 medical tools to developing country manufacturers remains limited.

In fact, if technology transfer was offered unconditionally and non-exclusively, development would be faster. However, even in the absence of technology transfer, manufacturers in developing countries are producing complex products such as recombinant and conjugate vaccines, monoclonal antibodies for diseases such as cancer and reverse transcription polymerase chain reaction (RT-PCR) testing platforms when patent barriers are absent or expired. The waiver, if granted and used, could facilitate the lifting of legal barriers and further leverage the existing capacity in developing countries.

Conclusion

Governments need to be in the driver's seat and fulfil their core obligations of protecting public health and ensuring access to medicines for all, including in the COVID-19 pandemic.

The COVID-19 TRIPS waiver as proposed appropriately addresses the legal barriers to maximizing production and supply of medical products needed for COVID-19 treatment and prevention. It is limited in time and the scope of application to cover COVID-19-related technologies during the pandemic. Countries that consider the waiver unnecessary for their national context can choose not to use it once granted without blocking the consensus process at WTO.