



EXAMPLES OF IP ISSUES AND BARRIERS IN COVID-19 PANDEMIC

COMMUNICATION FROM SOUTH AFRICA

Preliminary patent landscape of selected priority COVID-19 candidate therapeutics¹

1 INTRODUCTION

1. The current global pandemic of COVID-19, caused by infection with the novel coronavirus SARS-CoV-2, poses an unprecedented global health challenge. There are no proven effective cures or vaccines to date. A few hundreds of therapeutic candidates are in different stages of clinical trials, including the World Health Organization (WHO) international Solidarity Trial. Although many candidates are off-patent medicines, other repurposed and new therapies are either under patent protection or could be subject to new patent applications. Once safety and efficacy of any of the candidate therapeutics are demonstrated, ensuring access to the effective therapeutics for all people will be an immediate challenge facing all countries.

2. Multiple barriers may hinder rapid and ample production and sufficient supply of effective and affordable therapeutics. At the centre is the use of intellectual property (IP) and other exclusivities to restrict manufacturing and supply options that would lower drug prices and increase patient access. These exclusivities may also enable companies to charge high prices and profiteer from the pandemic or prioritise wealthier countries over ones with less financial capacity. [Governments need to prepare and take actions to address the anticipated IP barriers on therapeutics.](#)

3. The preliminary patent landscape offers a non-exhaustive snapshot of the patent filing and granting status on five selected therapeutics candidates that are under review by the WHO Access to COVID-19 Tools Accelerator (ACT-A) therapeutics pillar. Out of the five candidates, four are repurposed medicines that were developed for treating other diseases. Due to the interval between the time of patent filing and publication, which can take up to 18 months, new patent applications that might have been filed this year may emerge in the coming months.

4. The table below demonstrates that new patent has emerged on new monoclonal antibody with the Regeneron REGN10993+REGN10987 was granted a patent in the US in June 2020 which only expires in 2040. The access strategy of Regeneron on this therapy remains unknown.

5. There are high levels of patent filing and granting on anti-viral therapies. Merck's Molnupiravir (MK-4482) has primary patent applications filed in at least 28 jurisdictions, including two regional patent offices, expiring between 2035-2038. Atea pharmaceutical's AT-527 has primary and secondary patents and applications filed or granted in nearly 60 jurisdictions, expiring between 2036-2038. Incety Corp's baricitinib has primary patent and application filed or granted in nearly 50 jurisdictions, expiring in 2029. Roche's monoclonal antibody therapy tocilizumab has primary and secondary patent and applications filed or granted in nearly 30 jurisdictions, expiring between 2022-2028.

¹ Sources: [https://www.medspal.org/?disease_areas%5B%5D=COVID-19+\(drug+candidate\)&page=1](https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&page=1); <https://worldwide.espacenet.com> , <https://patentscope.wipo.int>

REGN10933+REGN10987

Company: Regeneron

Category: monoclonal antibody therapy

Description	PCT Publication/Application	Estimated expiry	Filed in	Granted in
A patent application covering REGN10933 and REGN10987 antibodies	N/A US patent granted as US10787501(B1)	25 June 2040	US	US

Molnupiravir (MK-4482)

Company: Merck

Category: anti-viral medicine

Description	PCT Publication/Application	Estimated expiry	Filed in
Molnupiravir and analogues (Markush structure) and their use as antivirals	WO/2016/106050 PCT/US2015/066144	16 December 2035	Albania, Armenia, Australia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, Canada, China, Eurasian Patent Organization (EAPO), ² European Patent Office (EPO), ³ India, Israel, Kazakhstan, Republic of Korea, Kyrgyz Republic, Japan, Republic of Moldova, Montenegro, Morocco, North Macedonia, Russian Federation, Serbia, Singapore, South Africa, Tajikistan, Turkey, Turkmenistan
Molnupiravir compound and its use as antiviral	WO/2019/113462 PCT/US2018/064503	7 December 2038	Albania, Armenia, Australia, Azerbaijan, Belarus, China, EAPO, EPO, Israel, Kazakhstan, Republic of Korea, Kyrgyz Republic, Japan, Mexico, North Macedonia, Russian Federation, Serbia, Singapore, Tajikistan, Turkey, Turkmenistan

AT-527

Company: Atea Pharmaceutical

Category: ant-viral medicine

Description	PCT Publication/Application	Estimated expiry	Filed in	Granted in
AT-527 compound and analogues (Markush structure) & their use in HCV	WO/2016/144918 PCT/US2016/021276	7 March 2036	Albania, , Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, Canada, Egypt, EAPO, EPO, Georgia, India, Indonesia, Israel, Japan, Kazakhstan, Republic of Korea, Kyrgyz Republic, Malaysia, Mexico, Republic of Moldova, Montenegro, Morocco, New Zealand, Nigeria, North Macedonia, Philippines, Russian	Australia, Botswana, China, Colombia, Eswatini, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi,

² Eurasian Patent Office covers 8 member states of the Eurasian Patent Organization: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan and Turkmenistan: <https://www.eapo.org/en/members.html>

³ European Patent Office covers 38 member states of the European Patent Organization: <https://www.epo.org/about-us/foundation/member-states.html>

Description	PCT Publication/Application	Estimated expiry	Filed in	Granted in
			Federation, Serbia, Kingdom of Saudi Arabia, Tajikistan, Thailand, Turkey, Turkmenistan, Ukraine, United Arab Emirates, Viet Nam	Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Singapore, South Africa, Sudan, Tanzania, Zambia, Zimbabwe ⁴
Use of AT-527 and similar compounds for RNA virus treatment (other than HCV)	WO/2018/048937 PCT/US2017/050323	6 September, 2037	Albania, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, EAPO, EPO, Indonesia, Japan, Kazakhstan, Republic of Korea, Kyrgyz Republic, Malaysia, Republic of Moldova, Nigeria, North Macedonia, Russian Federation, Serbia, Singapore, South Africa, Tajikistan, Thailand, Turkey, Turkmenistan, Viet Nam	
AT-527 hemisulfate salt	WO/2018/144640 PCT/US2018/016301	31 January 2038	Albania, Argentina, Armenia, Azerbaijan, Belarus, Brazil, Canada, China, Egypt, EAPO, EPO, Colombia, Eswatini, The Gambia, India, Israel, Georgia, Ghana, Japan, Kazakhstan, Kenya, Republic of Korea, Kyrgyz Republic, Lesotho, Liberia, Malawi, Malaysia, Mexico, Mozambique, Namibia, New Zealand, Nigeria, North Macedonia, Russian Federation, Rwanda, Sao Tome and Principe, Serbia, Sierra Leone, , South Africa, Sudan, Tajikistan, Tanzania, Thailand, Turkey, Turkmenistan, Uganda, Ukraine, Uzbekistan, Viet Nam, Zambia, Zimbabwe	Australia, Colombia, Indonesia, Singapore

Baricitinib

Company: Incyte Corp

Category: anti-viral medicine

Description	PCT Publication/Application	Estimate expiry	Filed in	Granted in
Arthritis, Rheumatoid COVID-19 (drug candidate)	WO/2009/114512 PCT/US2009/036635	10 March 2029	Ecuador, Egypt, El Salvador, Guatemala, Honduras, Pakistan, Paraguay, Thailand, Trinidad and Tobago, Tunisia, Uruguay, Venezuela	Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Bosnia and Herzegovina, Brazil, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, EAPO, EPO, India, Indonesia, Kazakhstan, Republic of Korea, Malaysia, Mexico, Morocco, Nigeria, North Macedonia, Panama, Peru, Philippines, Russian Federation (term

⁴ Many African countries included in the table are member states of the African Regional Intellectual Property Organization (ARIPO). ARIPO's member states include Botswana, Eswatini, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, Sudan, Tanzania, Uganda, Zambia, Zimbabwe. <https://www.aripo.org/member-states/>

Description	PCT Publication/Application	Estimate expiry	Filed in	Granted in
				extended to 2033), Serbia, South Africa, Tajikistan, Turkey, Ukraine, UAE, Uzbekistan, Viet Nam

Tocilizumab

Company: Roche

Category: monoclonal antibody therapy

Description	PCT Publication/Application	Estimate expiry	Filed in	Granted in	Rejected/Revoked/Refused in
Tocilizumab or any IL-6 receptor antagonist use to treat infant chronic arthritis-relating diseases	WO/2002/080969 PCT/JP2002/003312	2 April 2022	Albania, Israel, EPO, Republic of Korea, North Macedonia, Norway, Turkey, Ukraine, United States	Australia, Canada, China, Japan, Mexico, Poland, Russian Federation, New Zealand	Brazil
Anti-IL-6R antibody compositions comprising methotrexate for treating IL-6 related diseases	WO/2004/096273 PCT/JP2004/006211	30 September 2024	Albania, Brazil, EPO, India, Israel, North Macedonia, Norway	Australia, Canada, China, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, Russian Federation, South Africa, Ukraine, New Zealand	Chile, Colombia
Anti IL-6 receptor antibody-containing solution (with sucrose and Polysorbate)	WO/2003/068260 PCT/JP2003/001563	14 February 2023	Croatia, Israel, Russian Federation, Norway, United States	Australia, Albania, Canada, China, Brazil, EPO, India, Japan, Republic of Korea, Philippines, Poland, South Africa, Mexico, New Zealand	Colombia
An antibody containing liquid formulation (not been subject to lyophilisation)	WO/2009/084659 PCT/JP2008/073798	26 December 2028	Argentina, Brazil, Ecuador, Egypt, India, South Africa, Venezuela	Australia, Canada, Chile, China, Costa Rica, EPO, Indonesia, Japan, Republic of Korea, Morocco, Malaysia, Mexico, Peru, Philippines, Russian Federation, Thailand, Ukraine, UAE, United States, Viet Nam	Colombia

Description	PCT Publication/Application	Estimate expiry	Filed in	Granted in	Rejected/Revoked/Refused in
Anti-IL-6R antibody use in preventing or treating vasculitis	WO/2005/061000 PCT/JP2004/019463	17 December 2024	India, South Africa, Venezuela	Australia, Brazil, Canada, China, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Philippines, Russian Federation, United States	Bosnia and Herzegovina, North Macedonia, Serbia, UAE, Colombia

Patent landscapes and databases of COVID-19 medical products

- a. MedsPal database captured patent data on some selected COVID-19 candidates for therapeutics under the review of the ACT-A (antiviral medicines and monoclonal antibody therapies):

Product	Jurisdictions Granted	Expiry
AT-527	primary patents and applications filed or granted in nearly 60 jurisdictions	expiring between 2036-2038
Baricitinib	primary patents and applications filed or granted in nearly 50 jurisdictions	expiring in 2029
Molnupiravir (MK-4482)	primary patent filed in at least 28 jurisdictions	expiring between 2035-2038
Tocilizumab	primary and secondary patents filed or granted in at least 30 jurisdictions	expiring between 2022-2028

- b. Preliminary patent landscapes of mRNA vaccine technology:

- Pfizer/BioNTech: https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/#_ftn6
- NIH-Moderna: <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/>

- c. Nature: Preliminary patent landscape of mRNA technologies identified 113 patent families:

- <https://www.nature.com/articles/d41573-020-00119-8>

Examples of IP barriers hindering development, production and supply

- a. *Therapeutics:*

Gilead:

- Gilead signed restrictive voluntary license on Remdesivir, excluding half of the world population: <https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/>
- Shortage of remdesivir in UK and EU countries: <https://www.biospace.com/article/eu-faces-remdesivir-shortages-amidst-sharp-spikes-in-new-covid-19-cases/>

b. Vaccines:

i. Trade secrets and know-how:

- BioNTech claims to rely on know-how and trade secrets in COVID-19 vaccine production: <https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm>

ii. Disputes over COVID-19 vaccine patents:

- Pfizer-BioNTech, Regeneron sued for patent infringement with COVID-19 products <https://www.fiercepharma.com/pharma/pfizer-biontech-regeneron-sued-for-infringement-allele-s-patent-their-covid-19-products>;
- Lawsuit reveals intellectual property is holding back production of CEPI- and Gates Foundation-funded COVID-19 vaccine candidate: https://twm.my/title2/briefing_papers/twn/Hammond.pdf;
- Inovio sued by subcontract over COVID19 vaccine technology: <https://www.bizjournals.com/philadelphia/news/2020/07/09/inovio-plymouth-meeting-covid-19-vgxi-vaccine.html>
- Moderna lost key patent challenge on its mRNA vaccine candidate for COVID-19: <https://www.nature.com/articles/s41587-020-0674-1#:~:text=A%20dispute%20over%20a%20key,claim%20by%20the%20vaccine%20maker>
- Moderna failed to disclose US federal government grant in patents on its COVID-19 vaccine candidate <https://www.statnews.com/pharmalot/2020/08/28/moderna-covid19-vaccine-coronavirus-patents-darpa/>

iii. Past experience with vaccines:

- Pfizer patents on PCV13 hindering independent vaccine developer in South Republic of Korea: http://www.Republic_of_Koreabiomed.com/news/articleView.html?idxno=1979
- Report disclose excessive patenting on vaccine technologies and method of use: https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf

c. Other technologies:

- Governor of Kentucky asks 3M to release patents on N95 respirators: <https://eu.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/>
- Northern Italy producers threatened by originator for using 3D printed ventilator valve: <https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm>
- Bloomberg reported that Bloomberg has found that “[t]here are hundreds of patents on things related to N95 respirators, the gold standard used to protect health-care workers from transmission”: <https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots>

Voluntary license and technology transfer issues

- Gilead signed restrictive voluntary license on remdesivir, excluding half of the world population: <https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/>
- Vaccine developers: Pfizer/BioNTech: [no steps taken on licensing and technology transfer](#)
- C-TAP rejected by IFPMA: <https://www.ifpma.org/resource-centre/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/>
- Overall issues of voluntary licenses: https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf

Examples of political pressures on developing countries on the use of compulsory license and other flexibilities.

- Timeline of US pressure on India IP law (2015): https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf
- Novartis letter to Colombia on compulsory license: <https://www.publiceye.ch/en/news/detail/glivec-in-colombia-new-leaked-letter-from-novartis-attests-to-pressure-at-highest-level>
- Switzerland pressured Colombia over compulsory license: <https://www.keionline.org/22864#:~:text=However%2C%20in%20a%20letter%20of,a%20compulsory%20license%5Bii%5D.&text=By%20sending%20this%20letter%2C%20the,needs%20of%20the%20Colombian%20population>
- USTR pressure on Colombia over the use of compulsory license and other regulatory measures <https://www.keionline.org/27256>
- <https://www.keionline.org/wp-content/uploads/2018/03/Lighthizer-letter-to-Colombia-Feb-14-2018-re-OECD.pdf>
- Pressure on Malaysia over the use of compulsory license <https://www.ip-watch.org/2019/02/13/malaysia-still-pressure-make-hepatitis-c-medicine-expensive/>
