**EXAMPLES OF IP ISSUES AND BARRIERS IN COVID19 PANDEMIC**

**Preliminary patent landscape of selected priority COVID-19 candidate therapeutics (2020.11.8)**

*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://worldwide.espacenet.com) *,* [*https://patentscope.wipo.int*](https://patentscope.wipo.int)

1. **INTRODUCTION**

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.

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](https://msfaccess.org/sites/default/files/2020-07/MSF-AC_COVID-19_IP-monopolies_briefing-doc_July2020.pdf).

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.

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 which only expires in 2040. The access strategy of Regeneron on this therapy remains unknown.

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 officers, 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.

**REGN10933+REGN10987**

**Company: Regeneron**

**Category: monoclonal antibody therapy**

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| --- | --- | --- | --- | --- |
| **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) | June 25, 2040 | US | US |

**Molnupiravir (MK-4482)**

**Company: Merck**

**Category: anti-viral medicine**

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| **Description** | **PCT Publication/Application** | **Estimated expiry** | **Filed in** |
| Molnupiravir and analogues (Markush structure) and their use as antivirals | WO/2016/106050  PCT/US2015/066144 | Dec 16, 2035 | Albania, Armenia, Australia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, Canada, China, Eurasian Patent Organization (EAPO),[[1]](#footnote-1) European Patent Office (EPO),[[2]](#footnote-2) India, Israel, Kazakhstan, Korea, Kyrgyzstan, Japan, Moldova, Montenegro, Morocco, North Macedonia, Russia, Serbia, Singapore, South Africa, Tajikistan, Turkey, Turkmenistan |
| Molnupiravir compound and its use as antiviral | WO/2019/113462  PCT/US2018/064503 | Dec 7, 2038 | Albania, Armenia, Australia, Azerbaijan, Belarus, China, EAPO, EPO, Israel, Kazakhstan, Korea, Kyrgyzstan, Japan, Mexico, North Macedonia, Russia, Serbia, Singapore, Tajikistan, Turkey, Turkmenistan |

**AT-527**

**Company: Atea Pharmaceutical**

**Category: ant-viral medicine**

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| **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 | March 07, 2036 | Albania, , Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, Canada, Egypt, EAPO, EPO, Georgia, India, Indonesia, Israel, Japan, Kazakhstan, Korea, Kyrgyzstan, Malaysia, Mexico, Moldova, Montenegro, Morocco, New Zealand, Nigeria, North Macedonia, Philippines, Russia, Serbia, Saudi Arabia, Tajikistan, Thailand, Turkey, Turkmenistan, Ukraine, United Arab Emirates, Viet Nam | Australia, Botswana, China, Colombia, Eswatini, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Singapore, South Africa, Sudan, Tanzania, Zambia, Zimbabwe[[3]](#footnote-3) |
| Use of AT-527 and similar compounds for RNA virus treatment (other than HCV) | WO/2018/048937  PCT/US2017/050323 | Sep 06, 2037 | Albania, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, EAPO, EPO, Indonesia, Japan, Kazakhstan, Korea, Kyrgyzstan, Malaysia, Moldova, Nigeria, North Macedonia, Russia, Serbia, Singapore, South Africa, Tajikistan, Thailand, Turkey, Turkmenistan, Viet Nam |  |
| AT-527 hemisulfate salt | WO/2018/144640  PCT/US2018/016301 | Jan 31, 2038 | Albania, Argentina, Armenia, , Azerbaijan, Belarus, Brazil, Canada, China, Egypt, EAPO, EPO, Colombia, Eswatini, Gambia, India, , Israel, Georgia, Ghana, Japan, Kazakhstan, Kenya, Korea, Kyrgyzstan, Lesotho, Liberia, Malawi, Malaysia, Mexico, Mozambique, Namibia, New Zealand, Nigeria, North Macedonia, Russia, 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**

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| --- | --- | --- | --- | --- |
| **Description** | **PCT Publication/Application** | **Estimate expiry** | **Filed in** | **Granted in** |
| Arthritis, Rheumatoid  COVID-19 (drug candidate) | WO/2009/114512  PCT/US2009/036635 | March 10, 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, Korea, Malaysia, Mexico, Morocco, Nigeria, North Macedonia, Panama, Peru, Philippines, Russia (term extended to 2033), Serbia, South Africa, Tajikistan, Turkey, Ukraine, UAE, Uzbekistan, Viet Nam |

**Tocilizumab**

**Company: Roche**

**Category: monoclonal antibody therapy**

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| **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 | April 02, 2022 | Albania, Israel, EPO, Korea, North Macedonia, Norway, Turkey, Ukraine, US | Australia, Canada, China, Japan, Mexico, Poland, Russia, New Zealand | Brazil |
| Anti-IL-6R antibody compositions comprising methotrexate for treating IL-6 related diseases | WO/2004/096273  PCT/JP2004/006211 | Sep 30, 2024 | Albania, Brazil, EPO, India, Israel, North Macedonia, Norway | Australia, Canada, China, Indonesia, Japan, Korea, Malaysia, Mexico, Russia, South Africa, Ukraine, New Zealand | Chile, Colombia |
| Anti IL-6 receptor antibody-containing solution (with sucrose and Polysorbate) | WO/2003/068260  PCT/JP2003/001563 | Feb 14, 2023 | Croatia, Israel, Russia, Norway, US | Australia, Albania, Canada, China, Brazil, EPO, India, Japan, 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 | Dec 26, 2028 | Argentina, Brazil, Ecuador, Egypt, India, South Africa, Venezuela | Australia, Canada, Chile, China, Costa Rica, EPO, Indonesia, Japan, Korea, Morocco, Malaysia, Mexico, Peru, Philippines, Russia, Thailand, Ukraine, UAE, US, Viet Nam | Colombia |
| Anti-IL-6R antibody use in preventing or treating vasculitis | WO/2005/061000  PCT/JP2004/019463 | Dec 17, 2024 | India, South Africa, Venezuela | Australia, Brazil, Canada, China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Philippines, Russia, US | Bosnia and Herzegovina, North Macedonia, Serbia, UAE, Colombia |

1. **Patent landscapes and databases of COVID-19 medical products**

1. MedsPal database captured patent data on some selected COVID19 candidates for therapeutics under the review of the ACT-A (antiviral medicines and monoclonal antibody therapies):

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| **Product** | **Jurisdictions Granted** | **Expiry** |
| [AT-527](https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&product_standardized_name%5B%5D=AT-527&page=1) | primary patents and applications filed or granted in nearly 60 jurisdictions | expiring between 2036-2038 |
| [Baricitinib](https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&product_standardized_name%5B%5D=Baricitinib+2+mg&product_standardized_name%5B%5D=Baricitinib+4+mg&page=1) | primary patents and applications filed or granted in nearly 50 jurisdictions | expiring in 2029 |
| [Molnupiravir (MK-4482)](https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&product_standardized_name%5B%5D=Molnupiravir+(formerly+MK-4482)&page=1) | primary patent filed in at least 28 jurisdictions | expiring between 2035-2038 |
| [Tocilizumab](https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&product_standardized_name%5B%5D=Tocilizumab++162+mg%2F0.9ml&product_standardized_name%5B%5D=Tocilizumab++20+mg%2Fml&page=1) | primary and secondary patents filed or granted in at least 30 jurisdictions | expiring between 2022-2028 |

1. 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/>

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

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

1. **Examples of IP barriers hindering development, production and supply**
2. *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 remdevisir in UK and EU countries: <https://www.biospace.com/article/eu-faces-remdesivir-shortages-amidst-sharp-spikes-in-new-covid-19-cases/>

1. *Vaccines:*
2. Trade secrets and know-how:

* BioNTech claims to rely on know-how and trade secrets in COVID19 vaccine production: <https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm>

1. 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](file:///Users/yuanqiong/Documents/MSF/IP%20Regulatory/WTO/TRIPS%20Council/https)[://twn.my/title2/briefing\_papers/twn/Hammond.pdf](https://wp.twnnews.net/sendpress/eyJpZCI6IjU3MzQwIiwicmVwb3J0IjoiMjM5NiIsInZpZXciOiJ0cmFja2VyIiwidXJsIjoiaHR0cHM6XC9cL3R3bi5teVwvdGl0bGUyXC9icmllZmluZ19wYXBlcnNcL3R3blwvSGFtbW9uZC5wZGYifQ/);
* 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 COVID19: <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 COVID19 vaccine candidate <https://www.statnews.com/pharmalot/2020/08/28/moderna-covid19-vaccine-coronavirus-patents-darpa/>

1. Past experience with vaccines:

* Pfizer patents on PCV13 hindering independent vaccine developer in South Korea: <http://www.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>

1. 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>

1. **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](https://assets.oxfamamerica.org/media/documents/A_Shot_at_Recovery.pdf)
* 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>

1. **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/>

1. Eurasian Patent Office covers 8 member states of the Eurasian Patent Organization: Armenia, Azerbaijan, Belarus, Kazakstan, Kyrgystan, Russia, Tajikistan and Turkmenistan: <https://www.eapo.org/en/members.html> [↑](#footnote-ref-1)
2. European Patent Office covers 38 member states of the European Patent Organization: <https://www.epo.org/about-us/foundation/member-states.html> [↑](#footnote-ref-2)
3. 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/> [↑](#footnote-ref-3)