
World Trade Organization

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**PATENT-RELATED ACTIONS TAKEN IN WTO MEMBERS
IN RESPONSE TO THE COVID-19 PANDEMIC**

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ABSTRACT

COVID-19, caused by SARS-Cov-2, was declared to be a pandemic by the World Health Organization on 11 March 2020. Since then, the issue of the relationship between patent protection and the development of and access to medical treatments and technologies – a longstanding and enduringly important public policy issue – has become central to the debate on the linkages between IP, innovation, access, and public health between stakeholders with divergent interests. This working paper provides an overview of the patent landscape of medical treatments and technologies related to COVID-19, and of the patent status of two investigational medical treatments: remdesivir and lopinavir/ritonavir. It then presents various patent-related actions taken by legislators, policymakers, industry sectors, and civil society organizations in WTO Members since the outbreak. Furthermore, it elaborates on patent-related policy options provided by the TRIPS Agreement, and WTO Members' national implementation and utilization of these options in their response to the COVID-19 pandemic.

Keywords: COVID-19 pandemic, patent, open innovation, patentable subject matter, repurposed medicines, exceptions and limitations, licences, government use, transition periods, LDCs, WTO, TRIPS

JEL classifications: K11, K15, K30, O30, O31, O34, I18

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1 INTRODUCTION

COVID-19, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared to be a pandemic by the World Health Organization (WHO) on 11 March 2020.¹ Since the outbreak, the issue of the relationship between patent protection and the development of and access to medical treatments and technologies – a longstanding and enduringly important public policy issue – has become central to the debate on the linkages between intellectual property (IP), innovation, access and public health between stakeholders with divergent interests.²

COVID-19 is neither the first coronavirus nor the first pandemic in human history. The first "novel coronavirus" in humans was caused by the SARS coronavirus (SARS-CoV-1). It occurred in late 2002, spread swiftly to 8096 cases and resulted in 774 deaths (a death rate coming to 10%) across 30 countries.³ While no effective medicine was found, the outbreak ended with the last known transmission in 2004.⁴ The most recent pandemic prior to COVID-19 was an influenza pandemic involving H1N1 virus, commonly referred to as the swine flu, which infected in the first year since its outbreak (between the spring of 2009 and the spring of 2010) as many as 1.4 billion people across the globe and resulted in between 151,700 and 575,400 deaths.⁵

While the nature of the COVID-19 pandemic is similar to that of previous global health crises – outbreaks in the absence of effective medical treatments and vaccines – what makes the current debate so dramatically different from previous discussions in the context of H1N1, SARS, MERS and Ebola, is both the scale of the global outbreak and the resulting deaths, coming, from 19 January 2020 to the time of writing this paper, to 35 million cases worldwide and around 1 million deaths.⁶

In response to the COVID-19 pandemic, pharmaceutical research and development (R&D) institutes and industries have engaged in unprecedentedly intensive, costly and risky R&D activities for developing vaccines, effective medical treatments and technologies.⁷ Meanwhile, governments, civil society organizations and other stakeholders have expressed strong concerns over affordable and

¹ WHO, 'Timeline: WHO's COVID-19 Response' <www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline> accessed on 4 September 2020.

² It should be noted that there are many determining factors which have an impact on the access of medical treatments and technologies, such as production capacity, cross-border distribution and procurement, each country's payment mechanism as well as the existence of other IPRs, including trade secret. This paper is focused on one of these factors: patent protection. This should not be taken as the only factor.

³ Wikipedia contributors, 'Severe acute respiratory syndrome coronavirus' (Wikipedia The Free Encyclopedia, 12 September 2020) <https://en.wikipedia.org/w/index.php?title=Severe_acute_respiratory_syndrome_coronavirus&oldid=978074179> accessed 17 September 2020.

⁴ WHO, 'Summary of probable SARS cases with onset of illness from 1 November 2002 to 31 July 2003' <https://www.who.int/csr/sars/country/table2004_04_21/en/> accessed 4 September 2020. The death rate of SARs was reported to be higher than that of COVID-19 by about 10%.

⁵ CDC, '2009 H1N1 Pandemic (H1N1pdm09 virus)' <<https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html>> accessed 4 September 2020.

⁶ WHO, 'Coronavirus disease (COVID-19): Situation Report' <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/>> accessed 6 October 2020.

⁷ IFPMA, 'COVID-19: The Biopharmaceutical Industry is Leading the Way in Developing Vaccines, Treatments & Diagnostics' <<https://www.ifpma.org/covid19/>> accessed 4 September 2020. Live Blog, 'R&D response to COVID-19 pandemic' <<https://sciencebusiness.net/live-blog/live-blog-rd-response-covid-19-pandemic>> accessed 4 September 2020.

equitable access to these treatments and technologies.⁸ The international community has made urgent calls for global collaboration to address these concerns.⁹

A balanced patent system is in the interest of all stakeholders. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides considerable policy options that are instrumental to reaching such a balanced system and pursuing public health objectives.

The COVID-19 pandemic provides a real scenario to test out each country's capacity to deploy these options in order to meet two policy goals: affordable public access to medicines, and adequate incentives for R&D efforts. The COVID-19 pandemic also puts a strain on the operability of the international legal framework established by the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration)¹⁰ and the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Paragraph 6 Decision)¹¹ as a response to calls for global cooperation in this regard.

This working paper provides an overview of the patent landscape of COVID-19 related medical treatments and technologies,¹² as well as the patent status of two investigational medical treatments: remdesivir and lopinavir/ritonavir (LPV/r).¹³ It then presents patent-related actions which have been taken by legislators, policymakers, industry sectors and civil society organizations in WTO Members since the outbreak of the pandemic. Furthermore, it elaborates on patent-related TRIPS policy

⁸ See the statements made by WHO Members at the 73rd World Health Assembly held on 18-19 May 2020. WHO, 'Statements Submitted by Member States and Other Participants at the Seventy-third World Health Assembly' (World Health Organization) <<https://apps.who.int/gb/statements/WHA73/>> accessed 22 September 2020. While almost all countries called for international collaboration in responding to the pandemic, certain countries made more specific statements that relate to IP as follows: Estonia stressed the right to health as a basic human right. The Netherlands welcomed the patent pool initiative put forward by Costa Rica and the WHO. Denmark, Ireland and Belgium stressed the importance of access to essential medicines, with the latter highlighting existing threats to public health such as malaria, tuberculosis and HIV. Congo hoped that countries make effective use of vaccines/medicines in the context of IP systems and allow equitable access to health care. Australia stressed the importance of prioritizing finding a vaccine and allowing timely access. Chile supported the EU and Costa Rica's initiative to identify relevant health technologies. Ghana stressed the importance of ensuring access to public health. Germany urged strengthening the global public health and announced doubling its contribution to WHO emergency fund to € 50 million and committing € 176 million to WHO's various recent plans. Algeria urged for prioritizing making prices [of health care] affordable. Qatar called for any action to be aligned with the Doha Declaration on Intellectual Property and Public Health. Luxembourg and Finland viewed any treatment as a global public good. Slovakia called for not commercializing any vaccines to be developed in this regard. MSF, 'In focus Coronavirus COVID-19 pandemic – Key concerns during COVID-19' <<https://www.msf.org/covid-19>> accessed 22 September 2020; WHO, 'CSO open letter to UNITAID, the World Health Organization (WHO) and its Member States' (15 May 2020) <<https://extranet.who.int/nonstateactorsstatements/meetingoutline/6>> accessed 4 September 2020.

⁹ UN, 'Resolution adopted by the General Assembly on 20 April 2020: International Cooperation to Ensure Global Access to Medicines, Vaccines and Medical Equipment to Face COVID-19' (21 April 2020) A/RES/74/274; WHO, 'Resolution adopted by the World Health Assembly: COVID-19 Response' (19 May 2020) WHA73.1. The WHO Resolution recognizes the dramatic impact of the global outbreak on health systems, which has, in some cases, entirely overwhelmed existing capacity and, in others, placed systems under immense strain and accentuated the utmost importance of global collaboration in tackling the virus.

¹⁰ WTO, 'Declaration on the TRIPS Agreement and Public Health' (20 November 2001) WT/MIN(01)/DEC/2.

¹¹ WTO, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Decisions of 30 August 2003' (2 September 2003) WT/L/540 and Corr.1.

¹² Medical treatments and technologies are used in this paper in its broadest meaning to include medicines, vaccines, medical equipment and technology, medical supplies and personal protective products developed to solve a health problem. This meaning is consistent with the WTO Information Note on Trade in Medical Goods in the Context of Tracking COVID-19 which identifies four main groups of medical products. WTO, 'Information Note on Trade in Medical Goods in the Context of Tracking COVID-19' <https://www.wto.org/english/tratop_e/covid19_e/services_report_16092020_e.pdf> accessed 22 September 2020.

¹³ Since the information on patents or patent applications for COVID-19 vaccines that is available up to the time of writing this paper is very scarce, and few patent-related actions focus solely on vaccines, this paper does not commentate on vaccine-related issues.

options that are most pertinent to the issue of patent protection and public health and to WTO Members' responses to the COVID-19 pandemic.

It is of utmost importance to note that this paper confines itself to actions that had already been taken at the time of its writing and that solely relate to patents. Given this scope, it does not address measures and issues that relate to other IP rights, although there are clearly significant issues in those domains as well with bearing on the innovation and access dimensions of the pandemic response. Equally, as an analytical and empirical paper, it does not seek to venture into the ongoing policy discussions undertaken at government level. In addition, since the overall response to the pandemic is highly dynamic and fluid, the actions covered may not be exhaustive.

2 PATENT LANDSCAPE OF COVID-19 RELATED MEDICAL TREATMENTS AND TECHNOLOGIES

2.1 Overview of COVID-19 related medical treatments and technologies and their patent status

Since the outbreak of COVID-19, several dedicated patent databases and search facilities have been established by national and regional intellectual property offices and the World Intellectual Property Organization (WIPO).¹⁴ Owing to the patent system's disclosure requirement, which obligates patent applicants to sufficiently disclose their patent information to the public, these databases provide a vast amount of easily accessible and searchable legal and technical information.¹⁵ The expeditious access to these information not only advances R&D activities by enabling scientists and researchers to build on the divulged knowledge and coordinate these activities, but also helps legislators, policymakers and procuring entities make well-informed decisions.

A search of the WIPO database conducted at the time of writing this paper (on 16 September 2020) for patent families referring to SARS in their (1) claims, and (2) title or abstract, yields 837 distinct patent families. Based on their publication dates, which typically occur 18 months after filing a patent application, we observed that in the first few years after 2002, the year in which SARS hit, there was a surge in the patent filing activity that dwindled rapidly a few years after the epidemic. For example, in 2004 155 filings were published, generally reflecting applications filed in 2002 and 2003 during the peak of the SARS outbreak. In 2005 there were 216 publications, before dropping to 85 in 2006 and down to 33 in 2008. In 2020 there were 62 filings, the first of which was published in late February, after almost a year with no publication of filings.

These 873 patent families can be divided into three main technology groups: prevention-related technology, detection-related technology and treatment-related technology. In the prevention-related technology group, filings mainly focus on compositions of matter for the prevention of infection by boosting immunity, including various natural products, such as natural extracts and traditional medicines, as well as pharmaceutical compositions, such as vaccines; manufactures and methods for preventing infection by reducing contact, such as breathable barrier fabrics, special masks and filters; as well as compositions for preventing infection through disinfection, including natural or pharmaceutically prepared antiseptics.

In the detection-related technology group, filings are mainly on detection methods useful for both diagnostic and research purposes, such as molecular and serological testing methods; compositions, methods and manufactures that form a part of these testing methods, such as nucleic acids, antibodies, and methods for collecting specimens for testing; as well as kits comprising a combination of the above-mentioned compositions, methods and manufactures.

¹⁴ These databases include: WIPO PATENTSCOPE COVID-19 INDEX, available at <https://patentscope.wipo.int/search/en/covid19.jsf>; China Patent Information Center – Information Sharing Platform for Patents on Epidemic Prevention against COVID-19, available at <http://ncp.patentstar.com.cn/>; Korean Intellectual Property Office, COVID-19 Patents Information Navigation, available at https://www.kipo.go.kr/ncov/index_e.html; European Patent Office "Fighting coronavirus" platform, available at <https://www.epo.org/news-events/in-focus/fighting-coronavirus.html>.

¹⁵ The ability to easily access and search patent information is also a result of the increasing availability of technical documents in digital format and the progressive development of electronic means of distribution and retrieval.

The treatment-related technology group includes compositions for the treatment of SARS, with either general claims, such as antivirals for the treatment of infection in the upper and lower tract, or the treatment of various infections including HIV, Ebola, Hepatitis C, or specific claims, such as those reciting efficacy only as regards to SARS; other compositions, such as those with claims reciting traditional medicine or natural extracts; as well as devices, such as respirators and apparatuses for increasing ventilation in the lung area.

2.2 Two investigational medical treatments and their patent status

None of the medical treatments that are in use at the time of writing this paper were developed specifically for the treatment of COVID-19. Technological situation in response to the pandemic has been evolving on a daily basis, which brings about the difficulty in prescribing specific innovation and access strategies in advance. It also leads to the overall uncertainty of the ultimate necessary choices for recommended treatments and vaccines and the corresponding uncertainty as to the nature and extent of relevant patent holdings.

For instance, since the outbreak, some clinical trials supported the efficacy of a number of medicines initially developed for the treatment of other diseases, including lopinavir/ritonavir (LPV/r), remdesivir, favipiravir and tocilizumab. However, some subsequent clinical trials suggested that these medicines have little or no effect on the overall mortality, initiation of ventilation and duration of hospital stay in hospitalized COVID-19 patients.¹⁶ Clinical trials for the efficacy of these treatments are still ongoing, and their results will help us define the best way to treat COVID-19 and reduce its symptoms and complications.

This section analyses two investigational medical treatments: LPV/r and remdesivir, and their corresponding patent status. It should be noted that this analysis is provided not as endorsement or prediction of the ultimate value of these treatments, but rather setting out a foundation for understanding section 3 on patent-related actions taken in WTO Members, and for assessing these actions' effectiveness in the future. More importantly, the analysis serves as a case study to appreciate the patent context for forthcoming medical treatments and technologies.

2.2.1 Remdesivir

Background

Remdesivir, or GS-5734, is a nucleoside analogue drug able to inhibit or interfere with RNA polymerase, the mechanism of which allows viruses to replicate inside a human host. Remdesivir is sold by Gilead Sciences Inc. (Gilead) under the brand name Veklury®. Its development began in 2009 as part of trials for antiviral compounds initially designed for hepatitis C (HCV) and respiratory syncytial virus (RSV), which suggested its potential for having a broad-spectrum antiviral activity in 2013 and early 2014. Hence, remdesivir was investigated for its antiviral potential against Ebola,¹⁷ and then against the SARS and MERS infections.¹⁸ However, despite proving safe in phase I and

¹⁶ WHO, 'Latest update on treatment arms' < <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments> > accessed 19 October 2020.

¹⁷ Following the 2014 Ebola outbreak in West Africa, Gilead filed in July 2015 an investigational new drug (IND) application, and in August 2015 initiated its own phase I study evaluating the safety and pharmacokinetics of remdesivir in healthy volunteers. In 2018, based on an interim review of the data, the remdesivir arm of this trial was discontinued, as two other investigational treatments in the trial were associated with greater survival. For more information on the efficacy of remdesivir in the treatment of Ebola see Timothy P Sheahan and others, 'Comparative Therapeutic Efficacy of Remdesivir and Combination Lopinavir, Ritonavir, and Interferon Beta against MERS-CoV' (2020) 11 Nat Commun < <https://www.nature.com/articles/s41467-019-13940-6> > accessed 25 September 2020.

¹⁸ In 2016-2018, Gilead provided study drug and input on the design and conduct for studies of remdesivir in a non-human primate model of MERS infection conducted by the National Institute of Health (NIH). Despite positive preclinical data, remdesivir has not yet advanced into clinical development for MERS, due to the lack of adequate numbers of potential study participants, although various studies are still on going. See for example recent positive results for remdesivir's antiviral activity against MERS in monkeys. NIH 'Prophylactic and therapeutic remdesivir (GS-5734) treatment in the rhesus macaque model of MERS-CoV infection' (February 13, 2020) < <https://www.nih.gov/news-events/news-releases/remdesivir-prevents-mers-coronavirus-disease-monkeys#:~:text=The%20scientists%20indicate%20that%20the%20promising%20study%20results,received%20the%20drug%20under%20a%20compassionate%20use%20protocol> > accessed 25 September 2020.

phase II clinical trials for Ebola, it did not perform well in phase III due to the lack of adequate efficacy,¹⁹ which led to the halting of its clinical trials. It could not be advanced into clinical trials for SARS and MERS either, due to the lack of adequate numbers of potential study participants.²⁰

In January 2020, the first patient to test positive for COVID-19 in the United States was treated with remdesivir under Gilead's compassionate use of an investigational therapy and his clinical conditions improved significantly within the next 24 hours without observation of adverse effects.²¹ Since then, remdesivir has been tested as a potential cure for COVID-19 in China, the European Union and the United States, and has gained more recognition as a promising antiviral drug.²²

Notably, on 24 February 2020, the WHO announced remdesivir's potential for efficacy against COVID-19.²³ On 18 March 2020, the WHO launched global megatrial of the four most promising coronavirus treatments ("Solidarity Trial"), one of which is remdesivir. In early May 2020, remdesivir was approved through exceptional approval pathways for emergency use in the treatment of COVID-19 in the United States and Japan, while India, Singapore and other countries followed shortly thereafter.²⁴

By the end of May 2020, data from the randomized controlled Adaptive COVID-19 Treatment Trial, sponsored by the National Institute of Allergy and Infectious Diseases of the United States, showed that patients who received remdesivir had a 31% faster time to recovery than those who received placebo ($p < 0.001$), with the largest benefit observed among individuals who required oxygen supplementation but were not mechanically ventilated.²⁵ Positive results from an additional phase III study evaluating remdesivir were announced by Gilead in early June, offering additional encouraging data regarding remdesivir and its ability to improve clinical outcomes for patients.²⁶

Despite all the promising information, it must be noted that up to the date of writing this paper, and as acknowledged by Gilead itself, "remdesivir is an experimental medicine that does not have established safety or efficacy for the treatment of any condition."²⁷

¹⁹ Sabue Mulangu and others, 'A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics' (2019) 381 N Engl J Med <<https://www.nejm.org/doi/full/10.1056/NEJMoa1910993>> accessed 28 August 2020.

²⁰ The number of clinical MERS infections was limited, with almost exclusive localization in the Kingdom of Saudi Arabia, and there were no SARS infections. CDC 'About MERS' (CDC, 2 August 2019) <<https://www.cdc.gov/coronavirus/mers/about/index.html>> accessed 25 September 2020.

²¹ Michelle L. Holshue, 'First Case of 2019 Novel Coronavirus in the United States' (2020) 382 N. Engl J Med <<https://www.nejm.org/doi/full/10.1056/NEJMoa2001191>> accessed 27 August 2020.

²² The initial studies found promising results against a broad spectrum of RNA viruses, including MERS-CoV infections, in cultured cells (mice and non-human primate models. See Sheahan (n 17); Emmie de Wit and others, 'Prophylactic and Therapeutic Remdesivir (GS-5734) Treatment in the Rhesus Macaque Model of MERS-CoV Infection' (2020) 117 (12) PNAS <<https://www.pnas.org/content/117/12/6771>> accessed 27 August 2020. More recent results from a preclinical study indicating that, in vitro, the compound remdesivir could be highly effective in controlling the SARS-Cov-2 infection. Manli Wang and others, 'Remdesivir and Chloroquine Effectively Inhibit the Recently Emerged Novel Coronavirus (2019-nCoV) in Vitro' (2020) 30 Cell Research <<https://www.nature.com/articles/s41422-020-0282-0>> accessed 27 August 2020.

²³ Tony Owusu, 'Gilead's Remdesivir May Be Effective Against Coronavirus, WHO Says' (TheStreet, 24 February 2020) <<https://www.thestreet.com/investing/gilead-remdesivir-coronavirus>> accessed 26 August 2020.

²⁴ US Food and Drug Administration, 'Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment' (1 May 2020) <<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>>; Gilead Sciences Inc., 'Gilead Announces Approval of Veklury® (remdesivir) in Japan for Patients With Severe COVID-19' (07 May 2020) <<https://www.gilead.com/news-and-press/press-room/press-releases/2020/5/gilead-announces-approval-of-veklury-remdesivir-in-japan-for-patients-with-severe-covid19>> accessed 26 August 2020.

²⁵ John H. Beigel and others, 'Remdesivir for the Treatment of Covid-19 — Preliminary Report' (2020) 383 N Eng J Med <https://www.nejm.org/doi/full/10.1056/NEJMoa2007764?query=featured_home> accessed 27 August 2020.

²⁶ Gilead Sciences Inc., 'Gilead Announces Results From phase III Trial of Remdesivir in Patients With Moderate COVID-19' (1 June 2020) <<https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/gilead-announces-results-from-phase-3-trial-of-remdesivir-in-patients-with-moderate-covid-19>> accessed 26 August 2020.

²⁷ Gilead Sciences Inc., 'About Remdesivir' <<https://www.gilead.com/purpose/advancing-global-health/covid-19/about-remdesivir>> accessed 2 October 2020.

Patent status

Gilead applied for four main patent families covering nucleoside analogues' use as antivirals in humans leading to remdesivir or GS-5734. While these patent families recite antiviral activity against distinct virus families, and cover different chemical structures, they share the same core (a carba-nucleoside labelled as "Formula I" in Figure 1 below) that is present across all patent applications, from the parent compound to remdesivir. Remdesivir (as shown in Figure 1 below), most-notably, replaces one hydrogen atom by an anionic phosphate moiety that is attached to McGuigan/ProTide prodrug moieties (phenol and l-alaninate ethylbutyl ester), an addition that is known to enhance cell permeability.²⁸

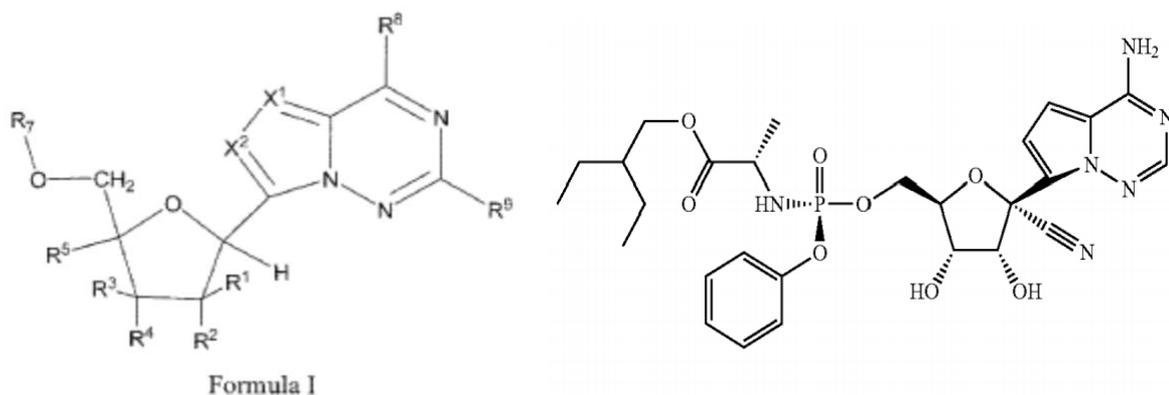


Fig 1: the basic antiviral nucleoside analogue () from Gilead's first PCT application US2009/041432 (left) and remdesivir (right).

Gilead's first patent family covering the basic compound GS-441524, a carba-nucleoside antiviral, recites use against viral infections caused by flaviviridae family and Hepatitis C. Mainly through PCT application US2009/041432 (WO2009132123), this filing led to broad geographic patent coverage in dozens of jurisdictions, including the United States, members of the European Patent Office (EPO), China and India. The filing relies on a US priority claim from 2008, and therefore the patents are set to expire around 2029 if maintained for their full normal terms. It is worth noting that the corresponding patent applications are still pending in Brazil, were rejected in Colombia, were opposed in Ecuador, and were not applied for in Bangladesh.

It should be noted that some researchers claim that Gilead's parent compound GS-441524, covered within the first patent family above, is similar or superior in its anti-viral activity against COVID-19.²⁹ On 20 August 2020, following a letter from a civil society organization raising these claims to the National Institute of Health of the United States (NIH), the latter agreed that GS-441524 merits further exploration, and launched an independent preclinical test on the therapeutic hypothesis for GS-441524 in treating COVID-19.³⁰

²⁸ Youcef Mehellou, Hardeep S. Rattan, and Jan Balzarini, 'The ProTide Prodrug Technology: From the Concept to the Clinic' <https://pubs.acs.org/doi/pdf/10.1021/acs.jmedchem.7b00734?ref=vi-chemistry_coronavirus_research> accessed 27 August 2020.

²⁹ Victoria Yan and Florian L. Muller, 'Advantages of the Parent Nucleoside GS-441524 over Remdesivir for Covid-19 Treatment' (2020) 11 (7) ACS Med <<https://pubs.acs.org/doi/10.1021/acsmchemlett.0c00316>> accessed on 31 August 2020; James Westgate, 'Vet science 'being ignored' in quest for COVID-19 drug' (*Vet Times*, 7 May 2020) <<https://www.vettimes.co.uk/news/vet-science-being-ignored-in-quest-for-covid-19-drug/>> accessed 31 August 2020; Sven Siebenand, 'Remdesivir-Metabolit noch schärfere Waffe gegen Covid-19?' (*Pharmazeutische Zeitung*, 15 May 2020) <<https://www.pharmazeutische-zeitung.de/remdesivir-metabolit-noch-schaerfere-waffe-gegen-covid-19-117613/>> accessed 31 August 2020. A Letter from Michael T. Abrams, Michael A. Carome, Sidney M. Wolfe, Florian L. Muller, and Victoria C. Yan to the U.S. Department of Health and Human Services (Public Citizen, 4 August 2020) <<https://www.citizen.org/wp-content/uploads/2535.pdf?eType=EmailBlastContent&eId=ab7987b8-616e-4966-b5dd-5b9d7fd0c85c&eType=EmailBlastContent&eId=ab7987b8-616e-4966-b5dd-5b9d7fd0c85c>> accessed 31 August 2020.

³⁰ A Letter from US Department of Health and Human Services to Michael T. Abrams, Michael A. Carome, Sidney M. Wolfe, Florian L. Muller, and Victoria C. Yan (Public Citizen, 20 August 2020) <<https://www.citizen.org/wp-content/uploads/WF-393848-NCATS-Reply-FINAL.pdf?eType=EmailBlastContent&eId=a60735a4-147d-4405-a421-51c7acbee176>> accessed 30 August 2020.

The second patent family, which also led to a broad geographic patent coverage, recites the compound's use for treating paramyxoviridae virus infections. Mainly through PCT application US2011/045102 (WO2012012776), this filing led to patent coverage in dozens of jurisdictions, including the United States, members of the EPO, China, India and Colombia. The filing relies on a US priority claim from 2010 and hence the patents will expire around 2031. The filing is still pending in Brazil and was not applied for in Bangladesh.

The third family, which also led to a broad geographic patent coverage, recites the compound's use for treating filoviridae virus infections. Mainly through PCT application US2015/057933 (WO2016069826), this filing also led to patents in dozens of jurisdictions, including the United States, members of the EPO, China and India. It is worth noting that this patent application family covers a chemical structure identical to remdesivir or GS-5734, as shown in the first embodiment in Figure 2 below. Since these rely on US priority claims from 2014 and 2015, they are set to expire in 2035 if the patents run their full normal terms. This patent has not been applied for in Brazil nor Bangladesh.

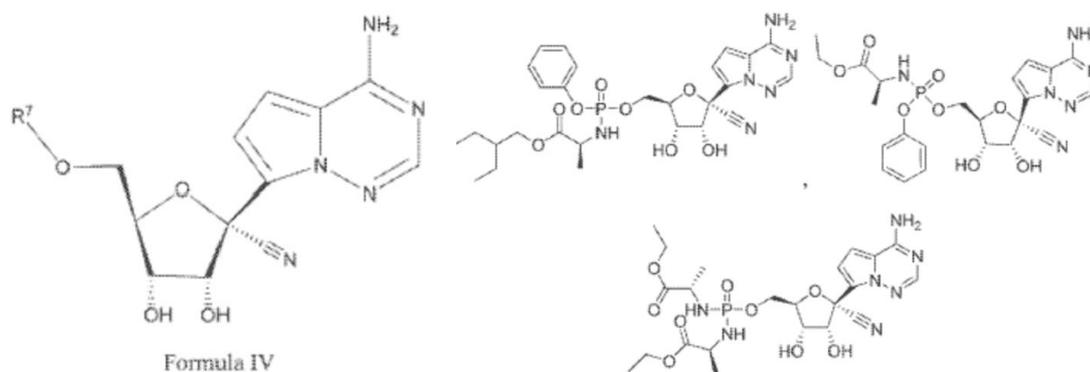


Figure 2: formula and embodiments from claims of PCT application US2015/057933 (Gilead's third main patent family) (left to right).

The fourth family recites the compound's use for treating arenaviridae and coronaviridae virus infections. This filing filed mainly through PCT application US2016/052092 (WO2017049060) in only a handful of jurisdictions relying on a US priority claim from 2015. Corresponding patents were already issued in the United States, such as US Patent Number 10,251,904 issued on 9 April 2019 for example. However, the applications are still pending at the EPO, Brazil and China. A corresponding application was not filed in India nor Bangladesh and was opposed in Argentina.

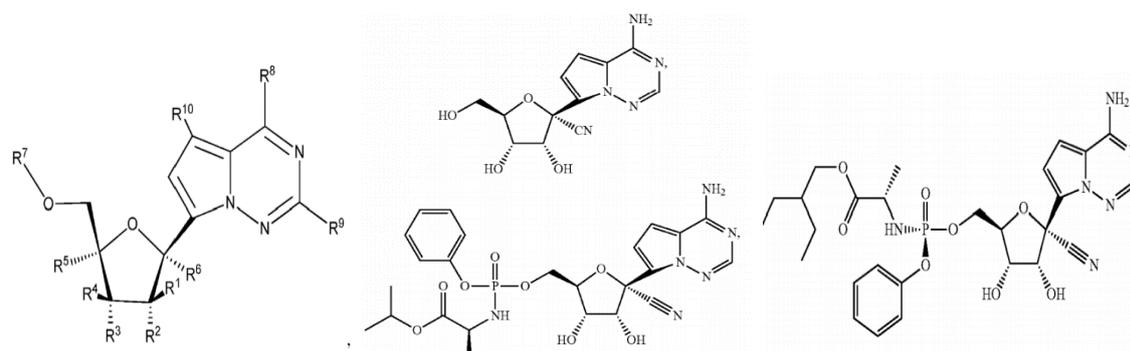


Figure 3: formula and embodiments from claims within US patent 10,251,904 "METHODS FOR TREATING ARENAVIRIDAE AND CORONAVIRIDAE VIRUS INFECTIONS" (Gilead's fourth main patent family) (left to right).

2.2.2 Lopinavir/Ritonavir (LPV/r)

Background

Lopinavir/Ritonavir (LPV/r) is a fixed dose combination medication, sold by AbbVie Inc. (AbbVie) (formerly Abbot Laboratories Inc.) under the brand name Kaletra®. LPV is a retroviral protease inhibitor with high specificity for HIV-1 and HIV-2, while the added ritonavir increases LPV plasma

concentration.³¹ The combination was first approved by the US Food and Drug Administration (FDA) in September 2000 in its soft-gel capsules form, and then in its heat-stable tablets form in October 2005.

The potential efficacy of HIV medications, including LPV/r, in the treatment of COVID-19 was first touched upon by medical publications in February 2020. The compound had been already tested in patients with SARS infection and demonstrated favourable outcomes. Building on this initial positive outcome, the combination was evaluated in patients with MERS-CoV infection.³² In March 2020, a publication of a randomized, controlled and open-label trial that was carried out in 199 hospitalized patients with severe COVID-19 infection,³³ concluded that in hospitalized patients with severe COVID-19, no benefit was observed with LPV/r treatment beyond standard care.³⁴ However, claims were raised regarding the validity of the trial's methodology, namely that the timing for administering the compound as carried out in the trial came after the period in which it would lead to desired results.³⁵

On 4 July 2020, the WHO accepted the recommendation from the Solidarity Trial's International Steering Committee (the Committee) to discontinue the trial's LPV/r arm,³⁶ after assessing the LPV/r vs standard-of-care trial interim results, and from a review of the evidence from all trials presented to the WHO Summit on COVID-19 Research and Innovation on 1 July 2020. The Committee found LPV/r to produce little or no reduction in the mortality of hospitalized COVID-19 patients when compared to standard of care.³⁷

Patent status

AbbVie filed for three main patent families covering LPV and/or LPV/r. The first family is mainly on the basic patent reciting LPV, and patents more specifically reciting LPV/r soft-gel capsules. These patents were applied for mainly through PCT applications US1996/020440 (WO9721685) and US1997/020794 (WO9822106) respectively and led to patents across a broad geographic coverage. These applications relied on US priority claims from 1995 and 1996 and hence had expired in the years of 2016 and 2017.

The second patent family recites LPV/r heat-stable tablet formulation, which was filed mainly through PCT application US2004/027401 (WO2005039551) but led to patents only in a small number of jurisdictions. These patents rely on a US priority claim from 2003, and therefore are set to expire in 2024. In most jurisdictions, including the United States, members of the EPO, India, China and Brazil, the patent applications did not succeed. In the United States, the patent was deemed abandoned in July 2007 after the applicant's failure to timely respond to an office action requiring 'restriction or election' (of claims). At the EPO, the patent and its analogues were opposed by several competitors

³¹ Risto S. Cvetkovic and Karen L. Goa, 'Lopinavir/Ritonavir A Review of its Use in the Management of HIV Infection' (2003) 63 (8) Adis International Limited <https://infekt.ch/content/uploads/2013/11/Cvetkovic_2003_drugs.pdf> accessed 23 August 2020.

³² Tiantian Yao and others, 'A Systematic Review of Lopinavir Therapy for SARS Coronavirus and MERS Coronavirus – a Possible Reference for Coronavirus Disease-19 Treatment Option' 92 (6) (2020) Journal for Medical virology <<https://onlinelibrary.wiley.com/doi/abs/10.1002/jmv.25729>> accessed 26 August 2020.

³³ Patients were randomized to receive the combination lopinavir/ritonavir plus standard care for 14 days or standard care alone. According to study's results, no differences between the combination treatment and the standard treatment, in terms of clinical improvement, mortality at 28 days and the percentages of patients with detectable viral RNA could be demonstrated. Moreover, adverse events, especially gastrointestinal ones, were more common in the group of patients receiving the combination treatment, while serious adverse events were more common in the standard-care group. Bin Cao and others, 'A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19' 382 (19) (2020) N Eng J Med <<https://www.nejm.org/doi/full/10.1056/NEJMoa2001282>> accessed 28 August 2020.

³⁴ *ibid.*

³⁵ Angus Liu, 'AbbVie's HIV Drug Kaletra Stumbles in COVID-19 Trial, but One Analyst Begs to Differ' (Fierce Pharma, 19 March 2020) <<https://www.fiercepharma.com/pharma-asia/does-abbvie-s-hiv-drug-kaletra-also-works-covid-19-maybe-not-nejm-study-finds>> accessed 29 August 2020.

³⁶ Likewise for the hydroxychloroquine arm.

³⁷ WHO, 'WHO discontinues hydroxychloroquine and lopinavir/ritonavir treatment arms for COVID-19' <<https://www.who.int/news-room/detail/04-07-2020-who-discontinues-hydroxychloroquine-and-lopinavir-ritonavir-treatment-arms-for-covid-19>> accessed 4 September 2020.

and generic drug manufacturers on the grounds of the lack of novelty and inventive step. The EPO Opposition Department issued a decision allowing the patent to remain registered. The decision was appealed and while on appeal, the patent was revoked based on a March 2020 request from the AbbVie.

The third patent family recites a solid form of the combination, which was filed mainly through PCT application US2006/005944 (WO2006091529) in a large number of jurisdictions. These applications rely on a US priority claim from 2005 and were set to expire in 2026. However, these applications were either opposed or refused or abandoned or withdrawn in most jurisdictions. It is worth noting that while AbbVie did not file for the basic patent in India – a jurisdiction which did not grant patents on pharmaceuticals before the full implementation of the TRIPS Agreement – it did so for applications corresponding to the second and third patent families above. As mentioned, these applications were also refused for the lack of inventive step or withdrawn or abandoned in India following a series of pre-grant oppositions and post-grant review proceedings that were filed by civil society organizations or generics producers. A similar pattern can be identified as regards this patent's status in Brazil, Belarus, Ukraine and Viet Nam.³⁸

3 PATENT-RELATED ACTIONS TAKEN IN WTO MEMBERS IN RESPONSE TO THE COVID-19 PANDEMIC

Mobilized by health concerns since the outbreak of the pandemic, many countries and stakeholders have taken patent-related actions in order to encourage R&D activities for the development of vaccines and effective medical treatments as well as affordable and equitable access to them. Most of these actions relate to open innovation, technology pooling, voluntary licensing, waiver of rights, compulsory licensing and authorization of government use.

3.1 Open innovation and global public goods

The notion of open innovation, and related innovation models such as open source and commons-based peer production, traditionally entail collaborating on the development of a product through a shared technological platform for innovation.³⁹ While open source, which originates from software development, usually emphasizes open access and permits others to use and adapt the software and redistribute it, open innovation describes a similar but broader concept that emphasizes seeking synergies and collaboration more openly including with external actors to advance the development of new technologies.⁴⁰ In the context of the COVID-19 pandemic, civil society organizations have been primarily calling for open innovation initiatives. What particularly might have triggered these calls is the vast amounts of funds being raised as part of various initiatives for the promotion of collaborative R&D activities – many of these can be seen at least as extensions to traditional open innovation.

These initiatives include but are not limited to:

- The COVID-19 Clinical Research Coalition, which counts 155 institutional members, including governmental agencies, international organisations, non-governmental organizations, public research institutes and academia from 56 countries and 84 individual health experts from 35 countries, aiming to accelerate research by collecting, peer reviewing and sharing COVID-19 related health solutions and information;⁴¹

³⁸ Patent Oppositions, 'Patent Opposition Database for Lopinavir/Ritonavir' <<https://www.patentoppositions.org/en/drugs/4f1081f604a7f937af000010>> accessed 27 August 2020. Lynne Taylor, 'India Rejects Abbott Patent on Kaletra' (PharmaTimes, 5 January 2011) <http://www.pharmatimes.com/news/india_rejects_abbott_patent_on_kaletra_979826> accessed 26 August 2020.

³⁹ See for example the definition of open innovation proposed by Henry Chesbrough in 2003, which is still relevant a definition today: Henry William Chesbrough, *Open Innovation: The New Imperative for Creating and Profiting from Technology* (Harvard Business Press, 2003).

⁴⁰ Antony Taubman, 'A Typology of IP Management For Public Health Innovation And Access' (2010) 4 *The Open Aids journal* 4 <<https://benthamopen.com/contents/pdf/TOAIDJ/TOAIDJ-4-4.pdf>> accessed 22 September 2020.

⁴¹ Covid-19 Clinical Research Coalition, 'Accelerating research on COVID-19 in Resource-limited Settings' <<https://covid19crc.org/>> accessed 1 September 2020.

- The Access to COVID-19 Tools (ACT) Accelerator, which is an international collective pledging bid initiated by the European Union in late April 2020 with an aim to ensure the collaborative development and universal deployment of diagnostics, treatments and vaccines with equitable access to all;⁴²
- The WHO Solidarity Response Fund, which was created by the United Nations Foundation and the Swiss Philanthropy Foundation, together with the WHO to raise fund from a wide range of donors to support the work of the WHO and partners by taking actions outlined in the COVID-19 Strategic Preparedness and Response Plan to help countries respond to the COVID-19 pandemic;⁴³
- The WHO Solidarity Trial, a multinational clinical trial launched in March 2020 by the WHO and joined by more than 100 countries addresses the significant need for a timely and large scale clinical trial to evaluate potential treatments for the disease, namely comparing the effectiveness of the local standard of care against four different drugs – hydroxychloroquine, remdesivir, LPV/r and LPV/r plus interferon among patients hospitalized for COVID-19;⁴⁴ and
- The COVID-19 Therapeutics Accelerator, which was launched in late June 2020 by Bill & Melinda Gates Foundation, Wellcome and Mastercard to use more than \$125 million in both new funding and money already earmarked to tackle the epidemic to identify potential treatments for COVID-19, accelerate their development and prepare for the manufacture of millions of doses for use worldwide.⁴⁵

The common denominator of these open innovation initiatives is that they all use public or philanthropic funds, conduct collective innovation and coordinate R&D efforts, in order to research, develop and bring about effective treatments to the public quickly and accessibly.

On the national level, publicly funded R&D has been credited for an integral part of the overall innovation in the area of medical treatments and technologies throughout contemporary history. However, its applicability on the international level is unprecedented, and hence evokes a number of questions that may require further thought. One such question relates to the concept of "global public good", which has been endorsed by many involved parties and organisations when referring to the yields of such collaborative research.⁴⁶

While the meaning of "public good" in the field of economics is generally well-defined, the term's application to specific IP-related issues, and distinctions regarding public good particularly in the context of COVID-19, remain undrawn. A lingering question is whether the inventions resulting from ongoing innovation efforts will be automatically released into the public domain, or whether inventors will claim patent rights thereon and then license rights on a charitable or humanitarian basis. The latter case raises the questions of who would be the named right holders for inventions funded by the public; how would the distribution of such medication be carried out; and given the tremendous global demand that would be experienced and the consequent assumption that many manufacturers ought to be involved, what would be the licensing terms and conditions for such manufacturers.

⁴² Co-hosted by the Director-General of the World Health Organization, the President of France, the President of the European Commission, and the Bill and Melinda Gates Foundation, the ACT took place between 4 May 2020 to 31 May 2020 and eventually raised a little under US\$ 8 billion. WHO, 'The Access to COVID-19 Tools (ACT) Accelerator' <[https://www.who.int/initiatives/act-accelerator#:~:text=The%20Access%20to%20COVID%2D19%20Tools%20\(ACT\)%20Accelerator%2C,tests%2C%20treatments%2C%20and%20vaccines](https://www.who.int/initiatives/act-accelerator#:~:text=The%20Access%20to%20COVID%2D19%20Tools%20(ACT)%20Accelerator%2C,tests%2C%20treatments%2C%20and%20vaccines)> accessed 1 September 2020.

⁴³ WHO, 'UN Foundation and partners launch first-of-its-kind COVID-19 Solidarity Response Fund' (13 March 2020) <<https://www.who.int/news-room/detail/13-03-2020-who-un-foundation-and-partners-launch-first-of-its-kind-covid-19-solidarity-response-fund>> accessed 1 September 2020.

⁴⁴ WHO, 'Solidarity Clinical Trial for COVID-19 Treatments' <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>> accessed 1 September 2020.

⁴⁵ Mark Suzman, 'Announcing the COVID-19 Therapeutics Accelerator'(The Optimist) <<https://www.gatesfoundation.org/TheOptimist/Articles/coronavirus-mark-suzman-therapeutics>> accessed 1 September 2020.

⁴⁶ WHO, 'Several Heads of State Spoke during the Opening of the Assembly', <<https://www.who.int/about/governance/world-health-assembly/seventy-third-world-health-assembly/speeches-and-news-releases>> accessed on 4 September 2020.

In the same breath as these questions, a distinction should be drawn between privately held rights and private interests – the private sector does not always opt for exercising exclusivity, and similarly, public interest oriented IP management does not always eschew all leverage over IP rights.⁴⁷ The fact that a significant proportion of patenting activity in the public health domain is carried out by government agencies, public institutions or other public interest bodies, illustrates that the exercise of private rights need not be solely directed towards private interest, and public interest oriented IP management can also include judicious deployment of legal exclusions. No view is advanced in this paper on the legitimacy of or relative efficiency and equity in any existing or potential models, or between the fundamental choice between private or public good structures. These questions lead to the following sections, which address additional actions involving less than full exploitation of patent rights by patent right holders, such as voluntary licensing, patent pooling and waiver of patent rights.

3.2 Production, voluntary licences and waiver of rights by patent right holders

Another aspect of the global response to the concerns over shortages in medical treatments comes from within the R&D industry and other involved institutes. Many industry stakeholders have made substantial efforts to increase their own production capacity as well as the global production capacity in order to meet the rapidly growing demand. A typical example of such efforts is Gilead's scaling up of its own manufacturing capacity for remdesivir. Through establishing new supply chains and streamlining its manufacturing processes, Gilead managed to reduce the timeline for large-scale production of remdesivir from 9-12 months to 6-8 months. Gilead is aiming at producing more than 190,000 treatment courses by the end of June 2020, more than 2 million by December 2020, and several millions in the course of 2021.⁴⁸

In addition to improving its own production capacity, and to further expand the supply of remdesivir, since May 2020, Gilead has signed non-exclusive voluntary licensing agreements with a number of generic pharmaceutical manufacturers ("the licensee") based in Egypt, India and Pakistan.⁴⁹ The agreements provide that a technology transfer from Gilead consisting of remdesivir's manufacturing process shall be made to the licensees, and allows the licensees, which include Cipla Ltd., Ferozsons Laboratories Ltd., Hetero Labs Ltd., Jubilant Lifesciences Ltd. and Mylan N.V., to manufacture both the active pharmaceutical ingredients (APIs) and formulation and distribute them in 127 countries. The countries consist of nearly all low-income and lower-middle income countries, as well as several upper-middle- and high-income countries that face significant obstacles to healthcare access.⁵⁰ The licences are royalty-free until the WHO declares the end of the Public Health Emergency of International Concern regarding COVID-19, or until a pharmaceutical product other than remdesivir or a vaccine is approved to treat or prevent COVID-19, whichever is earlier. The licensees are also eligible to set their own price for the generic remdesivir. It is worth noting that the licence

⁴⁷ Antony (n 40).

⁴⁸ Gilead Sciences Inc., 'Working to Supply Remdesivir for COVID-19' (24 June 2020) <<https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19>> accessed 31 August 2020.

⁴⁹ Gilead Sciences Inc., 'Voluntary Licensing Agreements for Remdesivir' <<https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir>> accessed 31 August 2020.

⁵⁰ The agreements permit distribution in the following countries: Afghanistan; Algeria; Angola; Anguilla; Antigua and Barbuda; Armenia; Aruba; Azerbaijan; The Bahamas; Bangladesh; Barbados; Belarus; Belize; Benin; Bermuda; Bhutan; Botswana; British Virgin Islands; Burkina Faso; Burundi; Cabo Verde; Cambodia; Cameroon; Cayman Island; Central African Republic; Chad; Comoros; Congo; Cook Islands; Costa Rica; Côte d'Ivoire; Cuba; Curacao; Democratic Republic of the Congo; Djibouti; Dominica; Dominican Republic; Egypt; El Salvador; Equatorial Guinea; Eritrea; Eswatini; Ethiopia; Fiji; Gabon; The Gambia; Georgia; Ghana; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; India; Indonesia; Jamaica; Kazakhstan; Kenya; Kiribati; Korea, Dem. People's Rep. (North Korea); Kyrgyz Republic; Lao People's Democratic Republic; Lesotho; Liberia; Libya; Madagascar; Malawi; Maldives; Mali; Marshall Islands; Mauritania; Mauritius; Federated States of Micronesia; Moldova, Republic of; Mongolia; Montserrat; Morocco; Mozambique; Myanmar; Namibia; Nauru; Nepal; Nicaragua; Niger; Nigeria; Pakistan; Palau; Panama; Papua New Guinea; Philippines; Rwanda; Saint Kitts and Nevis; Saint Lucia; Saint Vincent and the Grenadines; Samoa; Sao Tome and Principe; Senegal; Seychelles; Sierra Leone; Sint Maarten (Dutch part); Solomon Islands; Somalia; South Africa; South Sudan; Sri Lanka; Sudan; Suriname; Tajikistan; Tanzania; Thailand; Timor-Leste; Togo; Tonga; Trinidad and Tobago; Tunisia; Turkmenistan; Turks & Caicos; Tuvalu; Uganda; Ukraine; Uzbekistan; Vanuatu; Viet Nam; Zambia; and Zimbabwe. *ibid.*

agreements do not prohibit the licensees from selling to countries that are not included in the agreements when such countries issue a compulsory licence.⁵¹

The terms of Gilead's voluntary licences for remdesivir are very similar to those licences granted through patent pool mechanisms, akin to that of the Medicines Patent Pool (MPP).⁵² The MPP is a pooling platform that was established by UNITAID in July 2010 to facilitate voluntary licensing between patent right holders and generic companies in low- and middle-income countries with a focus on medical products related to HIV-AIDS, tuberculosis and hepatitis C.⁵³ MPP's *modus operandi* entails negotiating with patent holders for voluntary licences, and then sublicensing to generic pharmaceutical companies to manufacture and distribute generic versions of patented medicines in selected countries.

While the MPP's portfolio encompasses thirteen medicines (twelve for HIV antiretrovirals and one for hepatitis C direct-acting antiviral), up until May 2020, the MPP included only two COVID-19-related products: LPV/r, and LPV/r paediatrics. However, on 3 April 2020, in response to the COVID-19 pandemic, the MPP temporarily expanded its above-mentioned focus to "any health technology that could contribute to the global response to COVID-19."⁵⁴

The licensing agreement for LPV/r (non-paediatrics formulation) was reached between the MPP and AbbVie in December 2015.⁵⁵ Pursuant to the agreement, the MPP commenced offering sublicenses which are available to any technically qualified entity globally ("sublicensees"),⁵⁶ allowing them to manufacture both the API and the finished formulation of LPV/r and distribute in 54 African countries. The sublicense is royalty free, although the MPP retains the right to terminate sublicenses in certain circumstances, such as when a sublicensee fails to promote access to the medicine.⁵⁷ Neither the licensing nor the sublicensing agreement prohibits sales to countries that are not included in the agreement, as long as no granted patent is being infringed, such as in India where the company has withdrawn its patent applications for LPV/r or other countries in which a compulsory licence is issued.⁵⁸

⁵¹ Ellen 't Hoen, 'Remdesivir developed country price announced' (Medicines Law & Policy, 30 June 2020) <<https://medicineslawandpolicy.org/2020/06/remdesivir-developed-country-price-announced/>> accessed 1 September 2020.

⁵² It is worth noting that Gilead had signed a licensing agreement with the MPP for generic production of a different drug (tenofovir alafenamide, an investigational agent for the treatment of HIV and chronic hepatitis B) back in 2014. Gilead Sciences Inc., 'Gilead Announces New Agreement with Medicines Patent Pool for Access to Medicines in Developing World Countries' (24 July 2014) <<https://www.gilead.com/news-and-press/press-room/press-releases/2014/7/gilead-announces-new-agreement-with-medicines-patent-pool-for-access-to-medicines-in-developing-world-countries>> accessed 6 October 2020.

⁵³ Since 2018, the MPP has expanded its mandate to other patented essential medicines on the WHO's Model List of Essential Medicines (EML) as well as medicines with strong potential for future inclusion on the EML. MPP, 'The Medicines Patent Pool Presents New Five-Year Strategy for Improving Access to Priority Treatments in Developing Countries' (Medicines Patent Pool, 24 May 2018) <<https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-presents-new-five-year-strategy-for-improving-access-to-priority-treatments-in-developing-countries/>> accessed 1 September 2020.

⁵⁴ MPP, 'About Us' <<https://medicinespatentpool.org/who-we-are/about-us/>> accessed 1 September 2020.

⁵⁵ MPP, 'The Medicines Patent Pool and AbbVie Sign Licensing Agreement to Increase Access to Crucial HIV Treatments Throughout Africa' (Medicines Patent Pool, 18 December 2015) <<https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-abbvie-sign-licensing-agreement-to-increase-access-to-crucial-hiv-treatments-throughout-africa/>> accessed 1 September 2020. MPP, 'The Medicines Patent Pool (MPP) Signs Licensing Agreement with AbbVie for HIV Paediatric Formulations of Lopinavir and Ritonavir' (Medicines Patent Pool, 1 December 2014) <<https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-mpp-signs-licensing-agreement-with-abbvie-for-hiv-paediatric-formulations-of-lopinavir-and-ritonavir/>> accessed 1 September 2020.

⁵⁶ To qualify, sublicensees must obtain approval from WHO Pre-qualification or a Stringent Regulatory Authority. Where such approval is not yet available, temporary approval from a WHO Expert Review Panel may be obtained. *ibid.*

⁵⁷ The MPP Sublicensing Agreement Form, § 10.3 and 10.4 <<https://medicinespatentpool.org/uploads/2020/04/MPP-AbbVie-Sublicense-Agreement-form-Africa-Sept-2018.pdf>> accessed 1 September 2020.

⁵⁸ *ibid.* s 2.3.

On 24 March 2020, AbbVie decided that, in light of the COVID-19 pandemic, it would waive any restriction on MPP licensees that would prevent them from supplying LPV/r anywhere in the world for any purpose.⁵⁹ It also indicated that it would be doing the same with regards to enforcing patents relating to adult or paediatric LPV/r. The MPP-AbbVie agreements cover 102 countries of which more than 65 are classified as middle-income nations.

In addition to the MPP, several new platforms have been established to facilitate patent holders to grant voluntary licences as part of efforts in alleviating the COVID-19 pandemic. The features of these platforms vary and in certain cases not all pertinent details are laid out unequivocally or fully agreed upon.

One such example is Costa Rica's March 2020 initiative for the pooling of COVID-19 related technologies for the disposal of all, which led to the Solidarity Call for Action platform launched by the WHO and Costa Rica on 29 May 2020.⁶⁰ The platform does not specify the exact terms governing the distribution and disposition of the pooled technologies and instead raised the possibility of "working out the details at a later date, including the ultimate decisions on which technologies to share, and the terms of the authorizations, including possible remuneration."⁶¹ At the time of writing this paper, the call was supported by Argentina, Bangladesh, Barbados, Belgium, Belize, Bhutan, Brazil, Chile, Dominican Republic, Ecuador, Egypt, El Salvador, Honduras, Indonesia, Lebanon, Luxembourg, Malaysia, Maldives, Mexico, Mongolia, Mozambique, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Portugal, Saint Vincent and Grenadines, South Africa, Sri Lanka, Sudan, The Netherlands, Timor-Leste, Uruguay and Zimbabwe.⁶²

As opposed to the Solidarity Call for Action, the Open COVID Pledge ("the Pledge") is an example where the disposition and distribution of technologies is more clearly defined.⁶³ The Pledge was originally developed by an international group of researchers, scientists, academics and lawyers seeking to accelerate the rapid development and deployment of solutions amid the public health crisis.⁶⁴ It requires its "pledgers" to make a public offer for free licences to their IP rights for the purpose of ending and mitigating the COVID-19 pandemic. Regarding patents, the Pledge provides a standard licence, referred to as Open COVID License – Patent (OCL-P 1.1).⁶⁵ The offer of licence is available from 1 December 2019 until 1 January 2023 or a year after the WHO declares that COVID-19 is no longer a pandemic.

According to the standard licence, the pledgor (patent holders) offers to grant a non-exclusive, non-assignable and royalty free licence for his patent rights, which allows licensees to make, use, sell, and import patented inventions for the above-mentioned purpose. The individual licensing agreements can be further customised upon agreement between patent holders and patent users, to provide more permissions and less limitations as to the use by the licensee in comparison to the standard licence, which merely serves as a floor for other agreements. The patent holders also pledge not to claim any regulatory exclusivity in any jurisdiction, or to seek judicial or regulatory relief for the use of patent rights by licensees.

⁵⁹ Donato Paolo Mancini and Hannah Kuchler, 'AbbVie drops patent rights for Kaletra antiviral treatment' (Financial Time, 23 March 2020) <<https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b>> accessed 22 September 2020.

⁶⁰ The Solidarity Call for Action platform called for governments, research and development funders, institutions and companies to express their support for pooling Covid-19 related technologies. WHO Director-General and President of Costa Rica, 'Solidarity Call to Action' (29 May 2020) <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-nCoV/covid-19-technology-access-pool/solidarity-call-to-action>> accessed 1 September 2020.

⁶¹ *ibid.* See KEI, 'Knowledge Ecology International (KEI) comments on the resolution WHA73: "Covid-19 Response" proposed by the European Union' <https://www.keionline.org/wp-content/uploads/KEI-comments-on-the-EU-resolution_WHA73_-%E2%80%9CCovid-19-Response%E2%80%9D.pdf> accessed 1 September 2020.

⁶² MPP (n 53).

⁶³ InfoJustice Eds, 'WHO Recognizes the Open COVID Pledge as a Means to Advance Research and Science in the Fight Against COVID-19' (9 June 2020) <<http://infojustice.org/archives/42391>> accessed 1 September 2020.

⁶⁴ It is now administered by Creative Commons, whose mission is to overcome legal obstacles to the sharing of knowledge and creativity to address the world's pressing challenges. Open COVID Pledge, 'About Us' <<https://opencovidpledge.org/about/>> accessed on 6 October 2020.

⁶⁵ Open COVID Pledge, 'OCL/OCL-P v1.1' <<https://opencovidpledge.org/v1-1-ocl-p/>> accessed 1 September 2020.

At the time of writing the paper, Amazon Corporation, Hewlett Packard Enterprise, IBM Corporation, Microsoft Corporation and Sandia National Laboratories have signed the Open COVID Pledge, granting free access to all of their patented technologies for the purpose of diagnosing, preventing, containing and treating COVID-19.⁶⁶

3.3 Governments' authority to grant non-voluntary licences: government use and compulsory licences

Another noteworthy aspect of the response to concerns over shortages in medical treatments for COVID-19 involves amendments to national legislation carried out in several countries around the world. Countries such as Canada, Germany, Hungary and France have either amended their national laws or issued additional regulations to clear or smooth the way for government authorities to issue government use, compulsory licences or other measures. In other countries, such as Chile and Ecuador, legislative bodies issued resolutions expressing their respective views on the need to take initiatives to facilitate access to COVID-19 related technologies, including the issuance of compulsory licences.⁶⁷ It should be noted that, before the outbreak of COVID-19, a large number of WTO Members already had frameworks governing the issuance of government use and/or compulsory licences as part of their national patent legislation.⁶⁸ Provisions in these existing legal frameworks usually stipulate the issuance of government use and/or compulsory licences on the fulfilment of certain conditions.

Canada

On 25 March 2020, Canada notified the WTO TRIPS Council of the Act Respecting Certain Measures in Response to COVID-19 (referred to as Bill C-13; "the Bill"), as part of the Canadian Government's response to the COVID-19 crisis.⁶⁹ The Bill amends section 19 of the Patent Act on government use.

Under section 19 of the Patent Act, the Commissioner of Patents, upon application by the Government of Canada or of a province, can exercise discretion in deciding whether government use should be authorized. The Bill adds a new section 19.4, which made three substantive changes to the current provision on government use.

First, it specifies that upon the application of the Minister of Health, the Commissioner of Patents shall authorize a licence to the Government or a third party to manufacture, construct, use and sell a patented invention to the extent necessary in response to a public health emergency.

Second, in addition to the several conditions for authorizing government use under the current Patent Act, which include adequate remuneration to patent right holders, limited scope and duration of the authorized licence, and prohibition on its assignability, the Bill provides an additional condition to safeguard the interests of patent holders: the Chief Public Health Officer must confirm that there is a public health emergency as a matter of national concern.

Third, the Bill waives the requirement to show unsuccessful efforts to obtain authorization to use the invention from the patentee on reasonable commercial terms within a reasonable period before the government use is granted – a requirement that previously applied to the authorization of government use, except for cases of national emergency or extreme urgency or where the use is a public non-commercial use. Waiving the said requirement under Article 31(b) of the TRIPS Agreement is discussed under section 4.3 of this paper.

It is important to note that the Bill is not a permanent amendment of the Canadian Patent Act, but rather a temporary arrangement with a built-in time limit. The Commissioner of Patents cannot make

⁶⁶ Open COVID Pledge, 'Pledgors, Founding Adopters' <<https://opencovidpledge.org/partners/>> accessed 1 September 2020.

⁶⁷ WTO, 'Report of the Trade Policy Review Body from the Director-General on Trade-Related Developments from mid-October 2019 to mid-May 2020' (10 July 2020) WT/TPR/OV/W/14, para 5.8.

⁶⁸ WIPO, 'Draft Reference Document on the Exception Regarding Compulsory Licensing' (21 May 2019) SCP/30/3. WIPO, 'COVID-19 IP Policy Tracker: national patent law provisions on compulsory licences' <<https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>> accessed 44 September 2020.

⁶⁹ WTO, 'Notification of Laws and Regulations under Article 63.2 of the TRIPS Agreement Document – Canada: Bill C-13 an Act Respecting Certain Measures in Response to COVID-19' (23 April 2020) IP/N/1/CAN/30.

any authorization under section 19.4 after 30 September 2020. Any licences issued under section 19.4 before 30 September 2020 will expire either one year after the authorization is granted or when the Minister of Health advises the Commissioner that the authorization is no longer necessary to respond to the public health emergency, whichever occurs first.

Germany

On 27 March 2020, Germany adopted an amendment to the German Act on the Prevention and Control of Infectious Diseases in Humans (IfSG), effective on 28 March 2020.⁷⁰ Under the IfSG, if the German Federal Diet (known as the Bundestag, the legislative body in Germany) finds that there is an epidemic situation of national significance, the Federal Ministry of Health can take measures to ensure the supply of medicinal products.

Under section 13(1) of the German Patent Act, a patent shall have no effect in a case where the federal government orders that the invention is to be used in the interest of public welfare. The amendment authorizes the Federal Ministry of Health to issue such order, upon an appropriate finding by the Federal Diet. The effect is that the patent holder cannot prevent others from using the patented invention although the patent holder retains the right for equitable remuneration. Like the Canadian Bill, the IfSG also provides for a built-in time limit deeming the amendment to expire on 31 March 2021, or upon the revocation of the finding of an epidemic situation of national significance.

On 25 March 2020, the Federal Diet found that the spread of the COVID-19 in Germany constitutes an epidemic situation of national significance as required by section 5.1 of IfSG. However, the Federal Ministry of Health has not yet identified any medical product which shall be used in the interest of public welfare.

Hungary

On 29 March 2020, the Hungarian National Assembly adopted Act XII of 2020 on the Containment of Coronavirus (the Act), which declares a state of emergency and authorizes the government to take extraordinary measures necessary for the prevention and mitigation of the COVID-19 pandemic as a natural or industrial disaster.⁷¹ Since the Act entered into force on 31 March 2020, the government adopted a number of decrees which suspend the application of certain existing laws, deviate from certain provisions and impose some other extraordinary measures.⁷²

Among these decrees, Decree 212/2020 on Public Health Related Compulsory Licensing ("the Decree") was issued on 16 May 2020 and entered into force on 17 May 2020.⁷³ The Decree modified article 33/A of the Hungarian Patent Act (Act No. XXXIII of 1995 on the Protection of Inventions by Patents), under which public health related compulsory licences are only available for a third party who wishes to make a specific patented pharmaceutical product solely for the purpose of exporting it to a developing country with a particular public health problem.⁷⁴ This article was enacted to

⁷⁰ WIPO, 'COVID-19 IP Policy Tracker: national patent law provisions on compulsory licences: Germany' <<https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/accesshttps://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>> accessed 30 August 2020.

⁷¹ Library of Congress, 'Hungary: National Assembly Adopts Act Giving Government Special Powers during Coronavirus Pandemic' <<https://www.loc.gov/law/foreign-news/article/hungary-national-assembly-adopts-act-giving-government-special-powers-during-coronavirus-pandemic/>> accessed 4 September 2020.

⁷² *ibid.*

⁷³ WTO, 'Notification of Laws and Regulations under Article 63.2 of the TRIPS Agreement – Hungary: Government Decree 212/2020 on Public Health Compulsory Licenses for Exploitation within Hungary' (4 June 2020) IP/N/1/HUN/3.

⁷⁴ Act No. XXXIII of 1995 on the Protection of Inventions by Patents of Hungary, arts 31, 32 and 33/A. Under the Act, there are three grounds for the granting of compulsory licenses: lack of exploitation, dependent patents, and public health. Article 31 provides that if within four years from the date of filing a patent application or within three years from the date of granting a patent, whichever expires last, the patentee has not exploited the invention in Hungary to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a licence for such purpose, a compulsory licence shall be granted unless the patentee can justify the lack of exploitation.

incorporate EC Regulation No 816/2006, which implements the paragraph 6 system⁷⁵ and is directly applicable in all EC Member states.⁷⁶

The Decree introduces a new article – article 33/B, which allows the Hungarian Intellectual Property Office (HIPO) to issue compulsory licences for the exploitation of patent protected healthcare products, including medical products, investigational medical products, active substances, processes, equipment or supplies to satisfy domestic needs in mitigating the COVID-19 pandemic. Compulsory licences issued under the Decree shall be non-exclusive and non-assignable, and the period and fee of the licences are determined by HIPO.

It should be noted that the Act declaring a state of emergency was terminated on 18 June 2020, and thus the Decree ceased to have effect on the same day.⁷⁷

France

On 23 March 2020, France issued Emergency Law No 2020-290 to combat the COVID-19 pandemic,⁷⁸ which introduces a new article (article L3131-15) into the Public Health Code.⁷⁹

Under the new article when a state of health emergency is declared, and for the sole purpose of guaranteeing public health, the French Prime Minister has the authority to order the requisition of all goods and services necessary to fight the health disaster as well as any person necessary for the operation of these services or the use of these goods,⁸⁰ and to take all measures to make available to patients appropriate medicines for the eradication of the health disaster,⁸¹ provided that such measures are "strictly proportionate to the health risks at stake and appropriate to the circumstances of the time and place" and are "terminated without delay when they are no longer necessary".⁸²

It was argued that the requisition procedure would be more expeditious to make patented products available to the public compared to granting compulsory licences, as it can circumvent the conditions provided in the Intellectual Property Code.⁸³

Chile

On 17 March 2020, the Chilean Chamber of Deputies, the lower house of Chile's Congress, adopted a resolution which requires the Government of Chile to declare that the COVID-19 epidemic constitutes sufficient justification for the granting of compulsory licences on vaccines, drugs, diagnostics, devices, supplies and other technologies for the surveillance, prevention, detention, diagnosis and treatment of COVID-19.⁸⁴ It also requires the Minister of Health to declare the existence of public health reasons for the granting of compulsory licences for all patent applications and granted patents related to the above-mentioned products and technologies according to the

⁷⁵ See section 4.4 below for more on the Paragraph 6 System.

⁷⁶ EUR-Lex, 'Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems'.

⁷⁷ WTO, 'Notification of Laws and Regulations under Article 63.2 of the TRIPS Agreement – Hungary: Act LVIII of 2020 on Transitional Rules Related to the Termination of State of Danger and on Epidemiological Preparedness' (10 July 2020) IP/N/1/HUN/4.

⁷⁸ Emergency Law n° 2020-290 of 23 March 2020 to deal with the covid-19 epidemic, <<https://www.legifrance.gouv.fr/loda/id/JORFTEXT000041746313/2020-09-16/>> accessed 4 September 2020.

⁷⁹ Emergency Law n° 2020-290, Title I: State of Health Emergency, Article 2 creates the Public Health Code – art. L3131-15, <<https://www.legifrance.gouv.fr/loda/id/JORFTEXT000041746313/2020-09-16/>> accessed 16 September 2020.

⁸⁰ Public Health Code, art L3131-15 7°.

⁸¹ Public Health Code, art L3131-15 9°.

⁸² *ibid.*

⁸³ Francois Pochart, Mathilde Rauline, Océane de La Verteville, 'Compulsory Licenses Granted by Public Authorities: an Application in the Covid-19 Crisis in France?' (23 April 2020) <<http://patentblog.kluweriplaw.com/2020/04/24/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-2/>> accessed 30 August 2020.

⁸⁴ Chilean Chamber of Deputies, 'Resolution for the granting of non-voluntary licences referred to in Article 51° N° 2 of Industrial Property Law N° 19.030 to facilitate access and availability of medicines and technologies for the prevention, treatment and cure of the coronavirus' <https://www.camara.cl/legislacion/resoluciones/resolucion_documentos.aspx?prmId=6028#info-ficha> accessed 14 September 2020.

Industrial Property Law.⁸⁵ Meanwhile, the Minister of Health was called upon to instruct the corresponding ministerial authorities, the health services and the supply centre to inform on any products and technologies which are considered essential, so that the National Institute of Industrial Property can determine whether the existence of patents or other industrial rights restrict their importation or national production.

Ecuador

On 20 March 2020, the Ecuadorean Education, Culture, Science and Technology Commission, as a permanent body of the National Assembly, approved a resolution, which, among others, urges the President and the Minister of Public Health to include in the declaration of state of health emergency administrative and technical mechanisms for the issuance of compulsory licences for pharmaceutical products and technologies, including vaccines, medicines, diagnostic kits, medical equipment, medical supplies and other technologies for the surveillance, prevention, detection, diagnosis and treatment of COVID-19.⁸⁶ The purpose of these mechanisms is to ensure the availability of and access to the above-mentioned products and technologies either free of charge or on affordable terms so as to avoid price and shortages issues.⁸⁷

3.4 Authorization of government use

On 18 March 2020, the Israeli Ministry of Health (MoH) authorized, in coordination with the Attorney General of Israel, a government use of LPV/r, which is patented in Israel. This is the first time that sections 104 and 105 of article 3 of the Israeli Patent Law 5727-1967⁸⁸ titled "Use of Inventions in the Interest of the State" have been invoked since its enactment.

The use of LPV/r was ordered by the MoH, within its Permit to the State to Exploit an Invention Pursuant to Chapter 6, Article 3 of the Patent Law 5727-1967 ("the Permit").⁸⁹ The power to issue the Permit was delegated to the MoH a few days earlier in Government Decision No 4888 (13 March 2020) – a decision deputizing the MoH as the competent authority to issue licences under article 3 "as regards the New Corona Virus 2019."

The Patent Law distinguishes between the issuance of compulsory licences (chapter 7) and government use authorizations (chapter 6). The framework for compulsory licensing, which has been invoked in the past, authorizes the Commissioner of Patents to issue a licence upon a motion submitted by any interested party in cases of abuses of monopoly by a patentee. The framework for government use, which has never been invoked since the enactment of the patent law, is in the competence of any minister chosen by the government, on grounds of national security or for the maintenance of essential supplies and services. Chapter 6 of article 3 affirms that the chosen minister may permit the exploitation of an invention by a government department or by an enterprise or agency of the state, despite any granted patent or filed patent applications thereon. The framework for government use is much less detailed and provides less 'protection' to the patentee. For example, unlike compulsory licences which can be issued only after three years from the granting of patents, government use can be authorized anytime. The patentee does not enjoy certain 'rights to respond' prior to the government use authorisation, including a right to petition for re-examination of the permit and its conditions thereafter.⁹⁰

While not required under the law, it has been reported that the determination to invoke sections 104 and 105 came after futile attempts to obtain LPV/r directly from AbbVie and its authorized

⁸⁵ *ibid.* According to arts. 51° N° 2, 51° bis C and 30° of the Law, one of the grounds for the granting of compulsory licenses is the existence of public health emergence declared by the competent authority, and non-commercial use.

⁸⁶ The Resolution by the National Assembly of Ecuador
<<https://www.asambleanacional.gob.ec/es/noticia/65715-comision-de-educacion-aprueba-proyecto-de-resolucion>> accessed 16 September 2020.

⁸⁷ *ibid.*

⁸⁸ Israel, Patents Law 5727-1967.

⁸⁹ *ibid.* § 104-115.

⁹⁰ *ibid.* cf § 117 and 127.

importer. AbbVie, along with its importer, reportedly notified the relevant Israeli authorities that they were unable to supply the ordered quantities of LPV/r within the requested time frame.⁹¹

Whether AbbVie's consent was sought or not, section 107 provides that the issue of compensation for the use (which in this case will likely turn on the metrics chosen for the computation thereof: compensation according to the brand name price, generic price, or a compromise therebetween) shall be decided by consent.⁹² In this regard, AbbVie's consent seems likely given the scale of the global urgency, as well as its response thereto as outlined in sections 2.2.2, 3.1 and 3.2.

It should be noted that the authorized government use is narrowly tailored for the sole purpose of medicinal treatment of COVID-19 patients and therefore has limited impact on AbbVie's exclusive rights with regard to other uses of the invention. In other words, since the government use does not affect AbbVie's right to exploit the invention beyond treating COVID-19, it is likely that the importation of the medication as a treatment for COVID-19 is carried out in parallel with the continued use of the original medication as a treatment for HIV, which remains protected in Israel. Furthermore, the government use authorization is narrowly drafted to authorize import of LPV/r from only one manufacturer, Hetero Ltd., which is based in India where, as mentioned in section 2, LPV/r is free from patent protection.

Finally, Israel's MoH had also fast-tracked LPV/r's approval, along with seven other medicines for the treatment of COVID-19, including chloroquine, remdesivir, rezolsta (darunavir/cobicistat), xofluza, favipiravir, hyperimmune globulin and interferon alfa-2b.⁹³

3.5 Patent applications for repurposed medical treatments

Since the outbreak of COVID-19, some R&D projects have focused on developing new medicines while others have concentrated on testing and repurposing existing medicines, including remdesivir, LPV/r, chloroquine and dexamethasone, for their possible efficacy against COVID-19.⁹⁴

Compared to developing new medicines, repurposing existing medicines can be a more efficient and cost-effective way for identifying effective medical treatments, as existing medicines have already gone through pre-clinical trials and phase I or II clinical trials and have established their relative safety.

Reported domestic practices vary considerably as to the extent to which patents should be available for repurposing existing medicines, and as to the applicability of patentability standards concerning novelty, inventive step and utility.⁹⁵ There is, accordingly, significant policy interest in determining the settings in patent law and policy, alongside other measures, that would best enable pharmaceutical institutes and industries to invest necessary resources in determining the efficacy of existing medicines for new indications, including taking such repurposed medicines through necessary testing in phases II or/and III clinical trials, while not at the same time patenting routine uses that may not be considered truly inventive in patent terms.

⁹¹ Thiru Balasurbramaniam, 'Israel issues compulsory license to allow the government to import generic versions of Kaletra' (Knowledge Ecology International, 23 March 2020) <<https://www.keionline.org/32503>> accessed 5 September 2020.

⁹² The section's framework provides merely that the rates for compensation to the patentees for government use licenses are determined upon agreement with the patentee, failing which, it is determined by the Compensation and Royalties Committee.

⁹³ Tzvir Joffre, 'Health Ministry approves experimental treatments for coronavirus' (J Post, 16 March 2020) <<https://www.jpost.com/israel-news/health-ministry-approves-experimental-treatments-for-coronavirus-621209>> accessed 5 September 2020.

⁹⁴ James Gallagher, 'Coronavirus cure: What progress are we making on treatments?' (BBC News 22 July 2020) <<https://www.bbc.com/news/health-52354520>> accessed 4 September 2020.

⁹⁵ Clara Ducimetière, 'Second Medical Use Patents - Legal Treatment and Public Health Issues' (South Centre Research Paper 101, December 2019) <https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf> accessed 20 October 2020. AIPPI, 'Working Guidelines - Second Medical Use and Other Second Indication Claims' <https://www.aippi.fr/upload/Totonto2014/wgl_q238_final_e_200114.pdf> assessed 20 October 2020.

A recent example has arisen in China, with the report that, on 21 January 2020, four Chinese research institutes filed for a Chinese patent application and a PCT application on the new use of remdesivir as a treatment for COVID-19, entitled "The Usage of Anti-2019 Novel Coronavirus".⁹⁶

Patent protection for the new use of existing medicines is available in China. The Chinese Patent Law, the Implementing Regulations of the Patent Law, and the Guidelines for Patent Examination ("the Guidelines") set out detailed legal and technical requirements for such applications. In particular, these applications are subject to a heightened standard of examination in terms of enablement, novelty and inventive step.

The enablement requirement is typically reviewed as part of the disclosure requirement. Under the Guidelines, a patent application for the new use of a known product must provide experimental evidence in its description to prove the new use and its effects.⁹⁷ Without experimental evidence, the application can be deemed as failing to meet the enablement requirement. Clinic trials for determining the safety and efficacy of remdesivir's new use (as a treatment COVID-19) had reportedly been launched in China in February 2020.⁹⁸ However, two clinic trials were halted due to low enrolment of qualified patients.⁹⁹ In light of the reported status of the clinical trials, it is unclear whether the said patent applications have furnished sufficient experimental evidence as required.

As to inventive step, the Guidelines require taking into account the proximity of the technical field of the new use of known products to that of the prior use, as well as its technical effect.¹⁰⁰ The new use cannot be derived or contemplated from the structure, composition, molecular weight, known physical/chemical property and the existing use of the known product, and the new use should utilize a newly discovered property of the known product and produce an unexpected technical effect.¹⁰¹

With respect to novelty, the Guidelines list specific factors which should be considered when determining the novelty of an application for a new medical use of a known chemical product. The factors include (1) the new use should be different in substance, and not different merely in the form of expression, from the known use; (2) the new use is not disclosed directly by the mechanism of action or pharmacological action of the known use, nor is it directly equivalent to the mechanism of action or the pharmacological action of the known use; (3) the new use does not belong to the generic form of the known use; and (4) features relating to the new use, such as the object, mode, route, usage, amount and interval of administration, that can impact the manufacturing process.¹⁰²

Foreshadowed by these guidelines, the patentability of remdesivir's new use will largely depend on remdesivir's existing patents and patent applications in China, as well as the scope of the claims therein. As indicated in section 2, Gilead's four main patent families cover remdesivir's basic compound, modified versions thereof and the compounds' use in the treatment of various viral infections. All these granted patents and patent applications will be considered in the substantive examination of the patent application for the new use of remdesivir as a treatment for COVID-19.

Since the present patent application has not yet been published, it is too early to evaluate whether or not it meets the multi-faceted and highly legal and technical requirements described above. However, given the sensitivity surrounding this issue and high profile of remdesivir, as well as the heightened standard of patentability for new use inventions within China's patent law, there is little doubt that the patent examination process will place every aspect of the purported patent application for the repurposed remdesivir under close scrutiny.

⁹⁶ 我国学者在抗 2019 新型冠状病毒药物筛选方面取得重要进展 (ScienceNet 4 February 2020) <<http://news.sciencenet.cn/htmlnews/2020/2/435384.shtml>> accessed 4 September 2020.

⁹⁷ The Guidelines for Patent Examination, p II: Substantive Examination, c 2: Description and Claims, art 2.1.3 Enablement.

⁹⁸ 国家知识产权局, '抗击新型冠状病毒肺炎专利信息研报' (国家知识产权局 2020 年 2 月 14 日) <<http://www.cnipa.gov.cn/docs/2020-02/20200214204433302086.pdf>> accessed 4 September 2020.

⁹⁹ Gilead Sciences, Inc., 'Remdesivir Clinical Trials' <<https://www.gilead.com/purpose/advancing-global-health/covid-19/remdesivir-clinical-trials>> accessed 4 September 2020.

¹⁰⁰ The Guidelines for Patent Examination, p II Substantive Examination, c 4 Inventive Step, art 4.5 Invention of New Use of Known Products; c 10 Provisions on Examination of Invention Applications in the Field of Chemistry, art 6.2 Inventive Step of Use Invention of Chemical Products.

¹⁰¹ *ibid.*

¹⁰² The Guidelines for Patent Examination, p II Substantive Examination, c 10 Provisions on Examination of Invention Applications in the Field of Chemistry, art 5.4 Novelty of Use invention of Chemical Products.

3.6 Request for invalidation of patents for medical treatments

As indicated in section 2, among the four main patent families related remdesivir, Gilead has patents covering the basic compound (filed through PCT/US2009/041432), the compound and related compound's use for treating paramyxoviridae virus infections (filed through PCT/US2011/045102), as well as the compound and related compound's use for treating filoviridae virus infections (filed through PCT/2015/057933) in India. A patent application (Indian application no. 201727012821 for the compounds' use for treating filoviridae virus infections was submitted in India on 11 April 2017 through PTC application PCT/US2015/057933 and was granted an Indian patent (patent no. 332280) on 18 February 2020.

On 9 April 2020, the Cancer Patients Aid Association (CPAA)¹⁰³ addressed to the Central Government of India requesting revocation of the granted patent on the compound's use for treating filoviridae virus infection (patent no. 332280) on three grounds under the India's Patents Act, 1970: (1) the invention lacks novelty and inventive step under sections 64(1)(e) and 64(1)(f); (2) the invention's claims are directed to a non-patentable subject matter under section 64(1)(d) and section 3(d); and (3) the grant of a patent for the invention is against public interest under section 66.¹⁰⁴

Regarding novelty and inventive step,¹⁰⁵ the CPAA presented three prior art documents: two PCT applications: PCT/US2011/045102 and PCT/US2015/057933 filed by Gilead in July 2011 and in October 2015 respectively, and one article published by Gilead's employees in 2012.¹⁰⁶ Both PCT applications have been filed in India. It was argued that patent no. 332280 lacks novelty and inventive step as the modifications of the compound it recites were already disclosed in and anticipated by each of the three prior art documents (lack of novelty), and that alternatively, these modifications would have been obvious to a person skilled in the art in light of the disclosure made in the prior art documents taken together (lack of inventive step).

Regarding subject matter, it was contended that the invention is not patentable based on the well-known section 3(d) of the Patents Act.¹⁰⁷ Section 3(d), which deals with incremental modifications, defines "what are not inventions" and reads: "the mere discovery of a new form of a known substance is not a patentable subject if it does not result in the enhancement of the known efficacy of that substance." Section 3(d) further explains that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be *the same substance*, unless they differ significantly in properties concerning efficacy."

In April 2013, the Indian Supreme Court issued a decision interpreting section 3(d) for the first time.¹⁰⁸ The decision upheld a decision by the Intellectual Property Appellate Board (IPAB) which rejected, under section 3(d), a patent application filed by Novartis International AG (Novartis) that recites an incremental modification: the beta crystalline form of Imatinib mesalate – a therapeutically substance which was in the public domain in India before the TRIPS transition period expired in 2005. In its decision, the Court took a relatively strict approach in interpreting the efficacy

¹⁰³ The CPAA had played a central role in the country's first pharma patent litigation under the amended Patents Act (2005) involving Novartis' blood cancer drug Gleevec.

¹⁰⁴ Cancer Patients Aid Association (CPAA), 'Letter dated 9 April 2020, Re: Revocation of patent no. 332280 in Patent Application No. 201727012821 under § 66 and 64(1) of the Patents Act, 1970' <<https://cancer.org.in/images/CPAA-Rev-of-Patent-2020.pdf>> accessed 4 September 2020. Namratha Murugesan, 'Govt Urged to Revoke Patent for Gilead's Potential Anti-COVID19 Drug Remdesivir' (SpicyIP 24 April 2020) <<https://spicyip.com/author/namratha-murugesan/page/2>> accessed 4 September 2020.

¹⁰⁵ The Patents Act, 1970 § 64(1)(e) and 64(1)(f).

¹⁰⁶ Aesop Cho and others, 'Synthesis and antiviral activity of a series of 10 -substituted 4-aza-7,9-dideazaadenosine C-nucleosides' (2012) *Bioorganic & Medicinal Chemistry Letters* 22 2705-2707 <https://www.researchgate.net/publication/221974857_ChemInform_Abstract_Synthesis_and_Antiviral_Activity_of_a_Series_of_1'-Substituted_4-Aza-7,9-dideazaadenosine_C-Nucleosides> accessed 9 September 2020.

¹⁰⁷ The Patents Act, 1970, § 3(d). § 3(d) is one of significant amendments in the India patent law after the TRIPS transitional period for developing countries for their obligation of patent protection for pharmaceutical products had expired in 2005.

¹⁰⁸ Novartis AG v. Union of India (UOI) and Ors.; Natco Pharma Ltd. v. UoI & Ors.; M/S Cancer Patients Aid Association v. UoI & Ors. Civil Appeal No. 2706-2716 of 2013.

requirement, opining that 'efficacy' in pharmaceutical products is interpreted as 'therapeutic efficacy', therefore not all advantageous or beneficial properties are relevant.¹⁰⁹

Concerning the public interest ground, it was argued that patent no. 332280 may be reciting an effective treatment for COVID-19 and hence it is imperative to the public interest that the patent should be revoked under section 66. Under section 66, the Government of India has the power to revoke a granted patent if it is of the opinion that the patent is "mischievous" to the State or generally prejudicial to the public interest.¹¹⁰ Historically, India had revoked two granted patents on this ground: one was a process patent for genetically transformed cotton revoked in order to preserve the farmer's rights in 1994; and the other was a traditional knowledge-related patent revoked in 2012.¹¹¹ Interestingly enough, the CPAA relies on section 66 instead of section 3(b) to invalidate the granted patent. According to section 3(b), if an invention's primary or intended use or commercial exploitation is contrary to public order or morality or causes serious prejudice to human, animal or plant life or health, or to the environment, the invention is deemed as reciting non-patentable subject matter.¹¹²

It should be noted that the CPAA has not yet launched the post-grant revocation procedure, which can be activated under section 25(2) any time before 21 February 2021, i.e., one year from the date of publication of the granted patent.¹¹³ The revocation procedure would involve a large amount of technical information and bring up many legal issues, such as the scope of prior art, the scope of claims, and the IPAB's examination criteria for patentability and the efficacy requirement. The many complex variables involved make it almost impossible to predict at this stage what would be the determination as to the validity of the granted patent.

3.7 Manufacture of patented medical treatments in least developed countries (LDCs)

As mentioned above, one of the challenges posed by the COVID-19 pandemic is meeting the rapidly growing demand for effective medical treatments which significantly outstrip the current existing supply. One of the potential solutions to address this challenge is to decentralize manufacturing activities and establish and strengthen manufacturing capacities in developing countries and LDCs where people are the most vulnerable.

On 7 May 2020, Bangladesh's third largest generic pharmaceutical company, Beximco Pharmaceuticals Ltd., produced the first generic version of remdesivir under the brand name Bemsivir, and submitted it to the Directorate General of Drug Administration (DGDA) for regulatory review.¹¹⁴ On 21 May 2020, Beximco received an Emergency Use Authorization for Bemsivir, and instantly donated large amounts of Bemsivir for free of charge treatment of COVID-19 patients in public hospitals in Bangladesh.¹¹⁵ It was reported that to produce Bemsivir, Beximco made formulations mainly from APIs imported from China.¹¹⁶

¹⁰⁹ *ibid.* Novartis claimed that Beta crystalline form has more beneficial flow properties; better thermodynamic stability, and lower hygroscopicity. Those properties would, *inter alia*, improve the processability and storability of Imatinib. However, in view of the Court, these improved properties cannot justify "enhanced efficacy" required by § 3(d). Furthermore, it decided that increased bioavailability as such is not a demonstration of enhanced efficacy either.

¹¹⁰ The Patents Act, 1970, § 66.

¹¹¹ Gopikrishnan M and Akash Patel, 'Central Government's power of Revocation of Patent in Public Interest' (2 January 2014) <<https://www.khuranaandkhurana.com/2014/01/02/central-governments-power-of-revocation-of-patent-in-public-interest/>> accessed on 4 September 2020.

¹¹² The Patents Act, 1970, § 3(b).

¹¹³ The Patents Act, 1970, § 25(2).

¹¹⁴ Beximco, 'Beximco Pharma introduces world's first generic remdesivir for COVID-19 treatment' (21 May 2020) <<https://beximcopharma.com/media-gallery/beximco-news/latest-news/item/654-beximco-pharma-introduces-worlds-first-generic-remdesivir-for-covid-19-treatment.html>> accessed 4 September 2020.

¹¹⁵ *ibid.*

¹¹⁶ Zeba Siddiqui, 'Exclusive: Bangladesh's Beximco to begin producing COVID-19 drug remdesivir – COO' (5 May 2020) <<https://www.reuters.com/article/us-health-coronavirus-bangladesh-remdesi/exclusive-bangladeshs-beximco-to-begin-producing-covid-19-drug-remdesivir-coo-idUSKBN22H1DD>> accessed 4 September 2020.

Bangladesh is one of very few LDCs that have pharmaceutical manufacturing capacities.¹¹⁷ There are 257 licensed pharmaceutical companies, which supply approximately 98 percent of the domestic demand for medicines.¹¹⁸ These companies also supply medical products to 147 countries, the top seven of which are Myanmar, Sri Lanka, the Philippines, Viet Nam, Afghanistan, Kenya and Slovenia.¹¹⁹

As an LDC, Bangladesh benefits from two special transition periods provided under the TRIPS Agreement exempting it from fully implementing the TRIPS Agreement until 1 July 2021, and from providing patent protection for pharmaceutical and agricultural chemical inventions until 1 January 2033 or until it ceases to be an LDC, whichever occurs first. Due to these transition periods, only 20% of the domestically produced medicines are subject to patents, while 80% are generic.¹²⁰ Regarding remdesivir, as indicated in section 2, neither the basic compound nor its use for treating three virus infections is subject to patent protection in Bangladesh.

While it has no obligation to provide patent protection, Bangladesh established in 2008 a 'mail-box' for pharmaceutical and agricultural chemical inventions as required under article 70.8 of the TRIPS Agreement to track filings until the expiry of the transition period.¹²¹ Since then, the Bangladesh Department of Patents, Designs and Trademarks (DPDT) has received 1200 applications, all of which were submitted by foreign applicants.¹²²

It should be noted that Bangladesh met the LDC graduation criteria in 2018 and is envisaged to graduate (i.e., cease to be an LDC) in 2024.¹²³ The DPDT started to amend the patent law in 2012. The current draft of the Patents Act is being reviewed by the Ministry of Industries and is expected to pass into law in 2021.¹²⁴ According to the current draft, patent protection will be granted to any inventions, including those that are chemical compounds and pharmaceutical compositions or new processes for their manufacture.¹²⁵ The term of the patent protection will be 20 years. An international exhaustion regime will be adopted regarding the parallel imports of patented products.¹²⁶ These provisions, in particular the provision on parallel imports, will have important implications on the sustainable development of Bangladesh's domestic generic pharmaceutical industry after the expiration of the LDC transition periods.

4 PATENT-RELATED POLICY OPTIONS IN THE TRIPS AGREEMENT AND WTO MEMBERS' EXPLOITATION OF THESE OPTIONS

The TRIPS Agreement, resulting from the Uruguay Round of multinational trade negotiations, sets out a series of rules for trade-related aspects of intellectual property. In its preamble, the TRIPS Agreement indicates the importance of promoting effective and adequate protection of IP rights, reducing distortions and impediments to international trade and ensuring that IP rights do not themselves become barriers to legitimate trade.¹²⁷ While providing substantive standards concerning the availability, scope and use of IP rights, the TRIPS Agreement stipulates that IP protection should contribute not only to the promotion of technological innovation but also to the transfer and

¹¹⁷ WTO, 'Trade Policy Review – Report by the Secretariat – Bangladesh' (26 November 2012) WT/TPR/S/270/Rev.1.

¹¹⁸ EBL Securities Limited, 'Pharmaceutical Industry of Bangladesh: The Multi-billion Dollar Industry' (3rd Edition) (July 2019) <<https://www.arx.cfa/~media/2A85F9B2CEAB43CFAF325AB54F3EF404>> accessed 4 September 2020; Ibrahim Hossain Ovi and Niaz Mahmud, 'Bangladesh Pharmaceutical Industry Blooms Bigger' (DhakaTribune 22 August 2019) <<https://www.dhakatribune.com/business/2019/08/22/bangladesh-pharmaceutical-industry-blooms-bigger#:~:text=In%202018%2C%20the%20country%27s%20domestic,for%20the%20last%20five%20years>> accessed on 9 September 2020.

¹¹⁹ *ibid.*

¹²⁰ *ibid.*

¹²¹ Under Article 70.8 of the TRIPS Agreement, the mail-box system allows patent applications for inventions to be filed, but these applications do not need to be examined for their patentability until the country starts applying product patent protection for pharmaceutical and agricultural chemical inventions. Once the examination begins, it's carried out by reference to the prior art that had been disclosed when the pertinent application was first filed. The TRIPS Agreement, art 70.8.

¹²² Interview with Ishita Rony, Deputy Secretary, Ministry of Commerce, Bangladesh (Geneva, Switzerland, 15 August 2020).

¹²³ WTO and EIF, Trade Impacts of LDC Graduation (WTO 2020).

¹²⁴ Interview with Ishita Rony (n 122).

¹²⁵ Draft Patents Act, 2019, s 3.

¹²⁶ Draft Patents Act, 2019, s 36.

¹²⁷ The TRIPS Agreement, Preamble.

dissemination of technology in a way that benefits both producers and users of technological knowledge; and that IP protection should make a balance of rights and obligations with the overall goal of promoting social and economic welfare.¹²⁸

In line with these objectives and principles, the TRIPS Agreement establishes minimum substantive standards for IP protection ("the TRIPS minimum standards") which WTO Members are obliged to implement in their national laws. At the same time, the TRIPS Agreement provides for policy options which allow Members to adopt appropriate measures in their national legislation and practices to promote the public interest in the sectors which are of vital importance to their social and economic development.

Concerning the issue of patent protection and public health, the TRIPS Agreement and the subsequent Doha Ministerial Declaration¹²⁹ and the Doha Declaration¹³⁰ highlight the importance of balance between incentivizing R&D in new medicines and providing access to existing medicines. The Doha Declaration makes it clear that the TRIPS Agreement does not and should not prevent WTO Members from taking measures to protect public health and reaffirms the right of WTO Members to fully use the flexibilities available in the TRIPS Agreement for this purpose. It also makes clear that the TRIPS Agreement should be interpreted and implemented in a manner supportive of Members' right to protect public health and to promote access to medicines for all, bearing in mind the objectives and principles of the TRIPS Agreement.¹³¹

Since the TRIPS Agreement entered into force in 1995, WTO Members have gradually brought their patent laws into compliance with the TRIPS minimum standards. Meanwhile, WTO Members have also adopted various policy options provided under the TRIPS Agreement into their national legislations and practices. This section elaborates on the patent-related TRIPS policy options that are most pertinent to the issue of patent protection and public health. Some of those policy options have been deployed as part of WTO Members' response to the COVID-19 pandemic.

4.1 Patentable subject matter

Article 27 is the main provision on the minimum standard of what constitutes patentable subject matter.¹³² Article 27.1 sets out a general rule that patents should be available for inventions in all fields of technology provided that the inventions satisfy three substantive conditions: novelty, inventive step (non-obviousness) and industry application (usefulness). These three conditions are considered as three classic patentability criteria and have been reflected in most countries' patent laws. Among these three conditions, novelty and inventive step need to be assessed to ensure that an invention has new characteristics and makes a non-obvious advance, compared to existing knowledge, referred to as prior art, in its technical field. Therefore, the scope of the existing knowledge or prior art before the date of filing the patent application, plays a key role in evaluating novelty and inventive step of the invention.

Articles 27.2, 27.3(a) and 27.3(b) set out three optional exceptions to the general rule provided for in article 27.1, which allow Members to exclude certain inventions from the patentable subject matter. First, article 27.2 provides Members with an option to exclude an "invention" from the patentable subject matter, if prevention of the commercial exploitation of the invention is necessary to protect *ordre public* or morality, such as for protecting human, animal or plant life or health or for avoiding serious prejudice to the environment. Second, article 27.3(a) allows Members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Third, article 27.3(b) allows Members to exclude from patentability plants and animals, and essentially biological processes for their production, while they must provide patent protection for micro-organisms and non-biological and microbiological processes.

While setting the general rule and the permissible exceptions regarding patentable subject matter, the TRIPS Agreement does not provide definitions or interpretations of several key concepts, including "invention", "novelty", "inventive step", "prior art" and "*ordre public*". The absence of these definitions and interpretations leaves a deliberate policy space for WTO Members to design their own

¹²⁸ The TRIPS Agreement, art 7.

¹²⁹ WTO, 'Doha WTO Ministerial 2001: Ministerial Declaration' (20 November 2001) WT/MIN(01)/DEC/1, para 17.

¹³⁰ WT/MIN(01)/DEC/2 (n 10).

¹³¹ *ibid.*

¹³² The TRIPS Agreement, art 27.

patent systems – according to their national economic and social development – as long as they meet the TRIPS minimum standards.

WTO Members' definitions and interpretations of these key concepts are conveyed through their national patent laws, regulations, patent examination guidelines, and administrative and judicial decisions. Each Member's definitions and interpretations are not necessarily identical to those adopted by other Members, which at times explains, at least in part, the difference in patent protection an invention may enjoy in different countries. This is demonstrated in section 2 outlining the varying patent protection enjoyed by remdesivir and LPV/r across various countries. Meanwhile the patent application for the repurposed remdesivir in China and the request for invalidation of remdesivir in India, as described in sections 3.5 and 3.6, will largely depend on the respective patent offices' interpretations of novelty and inventive step, as well as their adopted standards for patentable subject matter in line with their patent legislation and practices.

4.2 Exceptions and limitations to patent rights

Under the TRIPS Agreement, patent owners are to be conferred exclusive rights to prevent others from making, using, offering for sale, selling, or importing patented products, which however is subject to two permissible exceptions provided for in article 30 and in article 31 respectively.

Article 30 allows Members to provide exceptions to the exclusive patent rights, provided that such exceptions satisfy three cumulative conditions, referred to as a three-step test: that the exceptions are limited; are not unreasonably in conflict with the normal exploitation of the patent; and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.¹³³ Certain uses, including the private use of patented inventions for non-commercial purposes, the use of patented inventions for research or experimental purposes and use before a patent is granted, are considered "exceptions" to patent rights.¹³⁴ These have been discussed in a WTO dispute ruling (*Canada — Pharmaceutical Patents (DS114)*), where the Panel found that the exception, also known as the 'Bolar' exception, permits generic companies to legitimately use patented inventions without patent owners' authorization to produce samples of the patented product for the purpose of obtaining marketing regulatory approval from health regulatory authorities.¹³⁵ Since then, the Bolar exception has been widely adopted in many countries' patent legislation.¹³⁶

4.3 Government use and compulsory licences

Another permissible exception to patent rights is provided for in article 31 of the TRIPS Agreement. Article 31 uses the term "other use without authorization of the right holder", which is understood to cover compulsory licences granted by government authorities to third parties; and government use either carried out by or on behalf of governments without the authorization of the patent holder.¹³⁷

Article 31 recognizes that WTO Members have the right to authorize non-voluntary licences and to determine the grounds upon which non-voluntary licences can be granted. This is expressly affirmed in the Doha Declaration.¹³⁸

While it does not provide a list of grounds for the granting of compulsory licences, article 31 provides nine conditions, as strict safeguards, to protect the legitimate interests of patent holders, including (1) authorization of non-voluntary uses should be considered on their individual merits; (2) as a general rule, the applicant for a non-voluntary use must have made an unsuccessful attempt to obtain a voluntary licence on reasonable commercial terms and conditions within a reasonable period of time before applying a compulsory licence; (3) scope and duration of the nonvoluntary licence

¹³³ The TRIPS Agreement, art 30.

¹³⁴ WIPO, 'Certain aspects of National/Regional Patent Laws: Exceptions and Limitations of the Rights Status as of April 2020' <https://www.wipo.int/export/sites/www/scp/en/national_laws/exceptions.pdf> accessed 16 September 2020.

¹³⁵ WTO, 'Canada — Patent Protection of Pharmaceutical Products: Report of the Panel' (17 March 2000) WT/DS114/R.

¹³⁶ WIPO, 'Draft Reference Document on Exception Regarding Acts for Obtaining Regulatory Approval from Authorities' (20 November 2017) SCP/27/3.

¹³⁷ The TRIPS Agreement, art 31.

¹³⁸ WT/MIN(01)/DEC/2 (n 10).

are to be limited to the purposes for which the licence is granted; (4) and (5) the nature of the non-voluntary licences should be non-exclusive and non-assignable; (6) the products produced under the non-voluntary licence should be predominantly for the supply of the domestic market; (7) the authorization shall be liable to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur; (8) the patent holder still has the right to be paid adequate remuneration; and (9) any decisions relating to the legal validity of grant of the non-voluntary licence and the remuneration should be subject to judicial or other independent review.

Regarding "national emergencies" and "other circumstances of extreme urgency" mentioned in article 31, the Doha Declaration clarifies that while these are not the only grounds for Members to issue compulsory licences, they are the only grounds where condition (2) above, i.e., previous efforts to seek voluntary licences before requesting compulsory licences, can be waived.¹³⁹ WTO Members have the right to determine what constitutes "national emergency" or "other circumstances of extreme urgency", while it is understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.¹⁴⁰

As described in sections 3.3 and 3.4, in response to the COVID-19 pandemic, Canada, Germany and Hungary amended their national laws, further empowering the governments to authorize government use and compulsory licences. In Ecuador and Chile, the governments have been urged by legislative bodies to declare the COVID-19 pandemic to be national public health crisis and then to issue compulsory licences. Israel issued the only government use authorization for LPV/r.

4.4 The special compulsory licensing system

In the work leading to the adoption of the Doha Declaration, concerns were expressed regarding WTO Members that have insufficient or no manufacturing capacities in the pharmaceutical sector and could not make effective use of compulsory licensing, mainly because of the condition provided in article 31(f). Under article 31(f), the production under a compulsory licence should be 'predominantly for the supply of the domestic market'. This condition would limit the ability of countries which have manufacturing capacity but are obliged to provide patent protection of medicines to export to countries which have non or insufficient manufacturing capacities, leading to limited supply of these medicines therein.

The Paragraph 6 Decision established a special compulsory licensing system, which waives, under certain circumstances, two conditions provided in articles 31(f) and (h), which are the condition obligating exporting Members to ensure that compulsory licences are only used for the purpose of predominantly supplying the domestic market; and the condition obligating importing Members to pay adequate remuneration to the patent right holder if a compulsory licence is granted, respectively.¹⁴¹ The Paragraph 6 Decision has been converted into a permanent part (article 31*bis*) of the TRIPS Agreement on 23 January 2017 following its acceptance by two thirds of the WTO membership.

Since the adoption of the Paragraph 6 Decision, many WTO Members have implemented this optional special compulsory licensing system in their national patent laws.¹⁴² However, since its adoption, this system has been used only once, in July 2007, by Rwanda for the purpose of importation of a pharmaceutical product from Canada.¹⁴³ A question has been raised in the TRIPS Council's annual review of the operation of the paragraph 6 system on why there has only been a single use of the system so far, much less than expected during the negotiations thereof.

It should be noted that according to the paragraph 6 system, all LDC Members, as well as any other Member that notifies the TRIPS Council of its intention to use the system, are deemed *eligible*

¹³⁹ *ibid.*

¹⁴⁰ *ibid.*

¹⁴¹ WT/L/540 and Corr.1 (n 11).

¹⁴² WTO, 'Members' laws implementing the 'Paragraph 6' system'

<https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm> accessed 4 September 2020.

¹⁴³ WTO, 'Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Rwanda' (19 July 2007) IP/N/9/RWA/1. WTO, 'Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Canada' (8 October 2007) IP/N/10/CAN/1.

importing countries.¹⁴⁴ A number of WTO Members, including Australia, Canada, the European Communities with its member States, Iceland, Japan, New Zealand, Norway, Switzerland and the United States, have agreed to opt out of using the system as importing countries.¹⁴⁵ Some others Members, including Hong Kong, China; Israel; Korea, Republic of; Kuwait; Macao, China; Mexico; Qatar; Singapore; Chinese Taipei; Turkey; and the United Arab Emirates have agreed to only use the system as importing countries in situations of national emergency or other circumstances of extreme urgency.¹⁴⁶

On 7 April 2020, in an open letter to the governments of Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland, the United Kingdom, the United States and the European Union, civil society organizations urged these WTO Members to notify the WTO that they revoke their opting out as importing countries and enable themselves as eligible importing countries, as these countries may also need imports of medical products because of the lockdown or suspension of the global supply chain during the COVID-19 pandemic.¹⁴⁷

The Paragraph 6 Decision provides a legal system for WTO Members to strengthen their cooperation on facilitating affordable access to medical products within the most vulnerable countries and particularly in countries having no or insufficient pharmaceutical manufacturing capacity and are most dependent on international trade for accessing medicines.

The paragraph 6 system is meant to be an expeditious solution to a specific problem identified in the Doha Declaration: a member (importing member) lacks a specific patented pharmaceutical product, which cannot be produced locally, and hence has to be imported from a generic producer in another member (exporting member); the product is subject to patent protection in the exporting member; and thus there is a need to issue a compulsory licence in the exporting member enabling generic producers to manufacture the product exclusively for export to the importing member.

Because of the plurality of development pipelines and the wide range of national needs and circumstances, it is very difficult to speculate in advance whether or when this specific problem would arise in relation to COVID-19 medical treatments and vaccines which are still under development at the time of writing this paper.

Nevertheless, it should be noted that, as indicated in the Doha Declaration itself, the very purpose of the paragraph 6 system is to enable vulnerable countries to make 'effective use' of compulsory licensing. It's important to note that the mere identification of the potential for the system's use may be helpful in leveraging access, whether a compulsory licence is ultimately issued or exercised in any particular procurement scenario. As with any compulsory licensing tool, the paragraph 6 system serves as a reminder that patent rights are not absolute and that public interest considerations could prevail – thus, even the prospect of using it can play a role, including in negotiations on access conditions. The current pandemic may be the first instance to test whether the paragraph 6 system can operate in this regard and provide an effective and expeditious solution to address the current global public health crisis.

4.5 Exhaustion of IP rights

Exhaustion of IP rights, also referred as parallel importation, is one of most important trade-related IP issues. The essence of the debate on the exhaustion of IP rights is whether IP right holders can exercise their exclusive rights in other territories than where the first legitimate sale takes place.

The TRIPS Agreement does not answer this question. Instead, article 6 of the TRIPS Agreement provides WTO Members discretion in regulating their own regimes for the exhaustion issue.¹⁴⁸ This discretion has been further clarified in the Doha Declaration.¹⁴⁹ Accordingly, WTO Members have two policy options: national or international exhaustion. Under national exhaustion, an IP right holder

¹⁴⁴ Annex to the TRIPS Agreement, note 3.

¹⁴⁵ WT/L/540 and Corr.1 (n 11).

¹⁴⁶ WTO, 'General Council – Minutes of Meeting' (13 November 2003) WT/GC/M/82, para 30. WTO, 'General Council – Minutes of Meeting' (27 March 2006) WT/GC/M/100, para 30.

¹⁴⁷ KEI, 'Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country under 31bis of the TRIPS Agreement' (7 April 2020) <<https://www.keionline.org/32707>> accessed 4 September 2020.

¹⁴⁸ The TRIPS Agreement, art 6.

¹⁴⁹ WT/MIN(01)/DEC/2 (n 10).

can prevent importation of IP-protected products into a country's territory from other countries even if they have been put on the market in those other countries by the right holder or with the right holder's consent. Under international exhaustion, the right holder would not be able to do this since all IP rights have been exhausted by his first sale of the product.

As described in section 3.7, Bangladesh has adopted international exhaustion in its Patents Act, which will enable the generic pharmaceutical companies to use patented APIs even after the expiration of the transition period, as long as these APIs are produced and sold by the patent holder or his licensees.

4.6 Transfer of technology

The TRIPS Agreement attaches great importance to technology transfer as part of a balanced IP system. Article 66.2 of the TRIPS Agreement specifically obligates developed country Members to provide "incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer" to LDC Members, to enable those countries "to create a sound and viable technological base",¹⁵⁰ which has been reaffirmed by the Doha Declaration.¹⁵¹

As a follow-up, in 2001, WTO Members agreed to establish a reporting and review mechanism to ensure the monitoring and full implementation of the obligations under article 66.2.¹⁵² In 2003, the TRIPS Council adopted a decision on the 'Implementation of Article 66.2 of the TRIPS Agreement', which provides detailed requirements for the information that developed country Members should provide on actions taken or planned in fulfilling their article 66.2 obligations in annual reports for the Council's review.¹⁵³ The reporting and review mechanism provide Members an opportunity to, *inter alia*, discuss the effectiveness of the incentives provided by developed country Members in promoting and encouraging technology transfer to LDC Members in order to enable them to create a sound and viable technological base.

According to annual reports received from 2003 to 2019, most actions reported fall into sixteen sectors, while the public health is the second largest sector in 2016.¹⁵⁴ The incentives provided in this sector are related to research, capacity building or awareness programmes relating to medicines, vaccines, or diagnostic kits.¹⁵⁵

Since 2008, the WTO Secretariat has organized regular workshops to promote Members' understanding of the operation of article 66.2 and facilitate dialogues between LDC beneficiaries and reporting countries. In the most recent workshops, public health and related areas have been identified by the LDCs as one of the areas with highly prioritized needs for technology transfer. Particular needs in these areas are for enhancing productivity and employment in the public health sector and the formulation of new molecules.

4.7 Transition periods for LDCs

When it entered into force in 1995, the TRIPS Agreement provided various transition periods for the original Members to fully comply with the minimum standards of IP protection according to their development status.¹⁵⁶ All these original transition periods have expired, but for two LDC transition periods, which have been extended in recognition of LDCs' "special needs ... in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base".¹⁵⁷

Article 66.1 originally provided a transition period until 1 January 2006 for LDCs, with an option for extension upon a duly motivated request.¹⁵⁸ In 2002, pursuant to the Doha Declaration, the TRIPS

¹⁵⁰ The TRIPS Agreement, art 66.1.

¹⁵¹ WT/MIN(01)/DEC/2 (n 10).

¹⁵² WTO, 'Implementation-Related Issues and Concerns' (20 November 2001) WT/MIN(01)/17, para 11.2.

¹⁵³ WTO, 'Implementation of Article 66.2 of the TRIPS Agreement' (20 February 2003) IP/C/28.

¹⁵⁴ Jayashree Watal and Leticia Caminero, 'Least-developed countries, transfer of technology and the TRIPS Agreement' (22 February 2018) Staff Working Paper ERSD-2018-01.

¹⁵⁵ *ibid.*

¹⁵⁶ The TRIPS Agreement, art 65.

¹⁵⁷ The TRIPS Agreement, art 66.1.

¹⁵⁸ *ibid.*

Council extended the transition period for LDCs for certain obligations with respect to pharmaceutical products until 1 January 2016, or until they cease to be LDCs, whichever comes first.¹⁵⁹ In 2015, it further extended this period until 1 January 2033.¹⁶⁰ In 2005 and 2013, upon the requests of LDCs, the TRIPS Council also extended the transition period for LDCs regarding their implementation of all other provisions of the TRIPS Agreement, until 1 July 2021 or until they cease to be LDCs, whichever comes first.¹⁶¹

In sum, under currently available transition periods, LDCs have no obligation to implement the provisions of the TRIPS Agreement until 1 July 2021 and have no obligation to provide for protection of patents and clinical trial data in the pharmaceutical sector until 1 January 2033. Up to the time of writing this paper, it is still not clear whether the TRIPS Council will further extend the transition period for LDCs regarding its implementation of all other provisions of the TRIPS Agreement. Given that the transition period for LDCs for patent protection for pharmaceutical products will not expire until 1 January 2033, the expiration of the general transition period will not have direct impact on LDCs' obligations in the pharmaceutical sector.

5 CONCLUSION

WTO Members' ability to promote innovation in effective medicines and technologies while simultaneously ensuring affordable and equitable access to them has never been more challenging. Through a brief overview of the global battle against the COVID-19 pandemic, we observed ongoing intensive R&D activities for the repurposing of existing medicines and the advent of new medicines and vaccines, coupled with dynamic patenting activities for protecting the fruits of R&D. Despite these efforts, up to the time of writing this paper, the availability of effective medical treatments remains limited. We also noted that, due to inadequate manufacturing capacities, and notwithstanding patent right holders' active efforts to utilize the results of R&D and employ licensing practices, a significant shortage in the supply of the currently available medicines persists. Such situation highlights the importance of a transparent, stable and reliable legal framework that can provide a foundation for stakeholders to collaborate with one another on the expeditious development, production, and distribution of forthcoming effective medical treatments and technologies.

The TRIPS Agreement provides an international legal framework for the protection of IP rights, under which WTO Members commit to complying with the TRIPS minimum standards. Members' compliance significantly contributes to an enhanced level of IP protection and, to a certain extent, its harmonization, which leads in turn to a transparent, certain and predictable legal framework for international trade. With a view to accommodating national differences, the said framework also provides considerable policy options for WTO Members. Unique choices as to implementing these options ought to reflect Members' individual stages of industrialization, socio-economic priorities and regard paid to public interest considerations.

Over the past 25 years, WTO Members have gradually developed their patent systems to comply with the TRIPS minimum standards regarding the availability, scope and use of patent rights. Meanwhile they have also adopted and implemented the said policy options through national legislative and judicial mechanisms, in line with their national development priorities and socio-economic context. Nevertheless, neither international treaties nor national legislation is an end in itself, but only a means for relevant stakeholders to achieve desired policy objectives. Specifically, the mere recognition of these policy options in an international treaty or national legislation does not necessarily mean that they are deployed effectively in practice.

The current COVID-19 pandemic provides a real-life scenario to test out countries' capacity to deploy these policy options and take action in simultaneous pursuance of two goals: encouraging innovation and promoting access to it. It is still premature to assess the effectiveness of the patent-related

¹⁵⁹ WTO, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members For Certain Obligations With Respect to Pharmaceutical Products' (1 July 2002) IP/C/25.

¹⁶⁰ WTO, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members For Certain Obligations With Respect to Pharmaceutical Products' (6 November 2015) IP/C/73.

¹⁶¹ WTO, 'Extension of the Transition Period under Article 66.1 for Least-Developed Country Members' (30 November 2002) IP/C/40; WTO, 'Extension of the Transition Period under Article 66.1 for Least-Developed Country Members' (12 June 2013) IP/C/64.

actions described in this paper. However, these actions provide a first-hand and practical experience for WTO Members, the international community, and other stakeholders to learn from one another. Meanwhile, it is equally important to understand which policy options have not been deployed during the COVID-19 pandemic and to appreciate what difficulties or constraints stakeholders face in seeking to utilize the said options, as well as what, if anything, should be done in turn to improve the existing international legal framework. All these national experiences and practices will eventually facilitate the fact and evidence-based debate on the scope and effect of the TRIPS policy options, a task more important today than ever.

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