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Covid-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health

Dr Enrico Bonadio & Professor Andrea Baldini

Enrico Bonadio, Andrea Baldini
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**COVID-19, Patents and the Never-Ending Tension between
Proprietary Rights and the Protection of Public Health**

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Enrico Bonadio & Andrea Baldini

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Introduction

In January 2020 Chinese researchers at the Wuhan Institute of Virology filed for a patent covering the use of remdesivir, an experimental antiviral drug, to treat COVID-19. Normally, this might be cause for celebration: COVID-19, a deadly pneumonia-like disease caused by the novel coronavirus, has killed so far thousands of people world-wide and sickened many more, sending researchers scrambling to develop an effective treatment.¹ Only, the Wuhan Institute of Virology didn't develop remdesivir. The drug was researched and produced by Gilead Sciences, a California-based pharmaceutical company, which had filed patent applications at several patent offices, including in China, covering a "method for treating Arenaviridae and coronaviridae virus infection".²

The remdesivir was originally developed to treat Ebola virus disease (EVD). From November 2018 to August 2019, the drug underwent a Phase 3 experimentation trial.³ A relatively large sample of patients with EVD were treated with remdesivir, which appeared less effective than other drugs. However, in early 2020, scientists became suddenly interested in some studies indicating that Gilead's product could have activity against coronaviruses like MERS and, hopefully, the rapidly spreading COVID-19.⁴

The institute's decision, made in the midst of a rapidly escalating health crisis, to claim rights over an unproven use of the drug was heavily criticized.⁵ It is worth noting that the Institute's patent application was filed before scientists started experiments investigating the effectiveness of remdesivir against the COVID-19. In effect, the Wuhan Institute of Virology's first in vitro studies suggesting that both remdesivir and an anti-malarial drug called chloroquine could effectively inhibit COVID-19 was published in early February 2020.⁶ However, this study's evidence depended on testing the efficacy of these drugs against

¹ Ye Roulin, "Wuhan's Much-Maligned Virology Institute Seeks Patent on US Drug," *Sixth Tone*, February 11, 2020, <http://www.sixthtone.com/news/1005169/wuhans-much-maligned-virology-institute-seeks-patent-on-us-drug>.

² See Chinese patent application No CN108348526A, available at <https://patents.google.com/patent/CN108348526A/en?q=US2017071964>.

³ Sabue Mulangu et al., "A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics," *New England Journal of Medicine* 381, no. 24 (2019): 2293–2303, <https://doi.org/10.1056/NEJMoa1910993>.

⁴ Timothy P. Sheahan et al., "Comparative Therapeutic Efficacy of Remdesivir and Combination Lopinavir, Ritonavir, and Interferon Beta against MERS-CoV," *Nature Communications* 11, no. 1 (2020): 1–14, <https://doi.org/10.1038/s41467-019-13940-6>.

⁵ Wu Haiyun, "China To Begin Testing Ebola Drug on Coronavirus Patients," *Sixth Tone*, February 3, 2020, <http://www.sixthtone.com/news/1005155/china-to-begin-testing-ebola-drug-on-coronavirus-patients>.

⁶ Manli Wang et al., "Remdesivir and Chloroquine Effectively Inhibit the Recently Emerged Novel Coronavirus (2019-NCoV) in Vitro," *Cell Research*, 2020, 1–3, <https://doi.org/10.1038/s41422-020-0282-0>.

another version of coronavirus, SARS-CoV-2. Earliest Phase 3 studies of remdesivir in COVID-19 infected patients started after the publication of that study.⁷

Given the scale of the COVID-19 pandemic, one would expect a virology institute located at its original epicentre to devote its resources and energy to containing the spread of the underlying virus, or perhaps to researching new therapies and vaccines — not to patenting (supposedly new) uses for drugs it neither developed nor tested. Though legally admissible, the institute's decision to seek a patent in this case is ethically questionable and may have a negative impact on China's public health and medical research cooperation efforts.

In response to the public outcry, the Wuhan Institute of Virology defended its patent application by claiming it was made in the national interest. It added that it would be willing to forgo enforcing its patent rights if foreign pharmaceutical companies — in this case, Gilead — collaborate with Chinese authorities to stop the pandemic.⁸ But this argument is weak. If the institute was really only concerned about public health and access to vital drugs in an emergency, there is already a mechanism that gives countries IP flexibility in just such an event: compulsory licenses. While controversial, compulsory licenses allow eligible drugmakers to legally manufacture and sell copycat versions of patented drugs during national emergencies, public health crises, or in other instances of extreme need. As a form of compensation for the original patent holder, the competent authority — in China's case, it'd be the National Intellectual Property Administration — would require manufacturers to pay a "fair market price" for the drug.⁹

Compulsory licences are explicitly allowed under Articles 48-50 of Chinese patent law, although the country has yet to issue one, and in line with the World Trade Organization's TRIPS Agreement, which outlines global standards for protecting intellectual property (IP) rights. The 2001 Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference, confirmed that compulsory licences can be used subject to certain conditions. And where they've been granted, they have led to significant reductions in drug prices. In 2012, for example, Indian generic drugmaker Natco was granted a compulsory licence for Sorafenib, an anticancer drug, after that country's patent office ruled that Bayer AG, Sorafenib's patent holder, had not done enough to make the drug available to Indian citizens. Natco was required to pay 6% royalties to the German company — a figure based

⁷ <https://clinicaltrials.gov/ct2/show/NCT04252664?term=remdesivir&draw=2&rank=2>;
<https://clinicaltrials.gov/ct2/show/NCT04257656?term=remdesivir&draw=2&rank=1>.

⁸ Aaron Wininger, "Wuhan Institute of Virology Applies for a Patent on Gilead's Remdesivir," *The National Law Review*, February 6, 2020, <https://www.natlawreview.com/article/wuhan-institute-virology-applies-patent-gilead-s-remdesivir>.

⁹ See the webpage <http://english.cnipa.gov.cn/>

on UN guidelines — and proposed selling its version for 97% off Bayer's price.¹⁰

Given the scale of the ongoing health crisis, a Chinese company filing for a compulsory licence would not necessarily be perceived as an attempt to unjustifiably circumvent Gilead's patent rights. After all, in the wake of the coronavirus crisis, in March 2020 Israel has issued a compulsory licence in relation to Kaletra, an HIV medicine which is currently being tested for effectiveness in the treatment of Covid-19. The patent is owned by US pharmaceutical company Abbvie and the licence will allow Israel to import the generic version of Kaletra produced by the Indian company Hetero.¹¹ Also, the Chilean parliament¹² and Ecuador's National Assembly¹³ have adopted resolutions that would pave the way for the issuance of compulsory licences to tackle the coronavirus outbreak; and the German government has started plans to limit patent rights in view of this pandemic.¹⁴ In North America, Canada is also following this lead.¹⁵

The unusual strategy that the Wuhan Institute of Virology settled on — seeking to patent an untested use of a drug in such a way that it might interfere with patent rights owned by a foreign corporation — has raised hackles. Some critics have accused the institute of trying to get out of paying Gilead a licencing fee should a compulsory license be granted.¹⁶ Others have read its move as an attempt to secure bargaining chips in possible upcoming pricing negotiations with the company.¹⁷

Another Chinese entity has come under fire from patent advocates. It's Suzhou-based BrightGene Bio-Medical Technology, which may also be in for a fight after confirming that it had synthesized remdesivir's active ingredient without first obtaining permission from the patent holder. Though the company says it's interested in setting up a voluntary licensing

¹⁰ Enrico Bonadio, Compulsory Licensing of Patents: The Bayer/Natco Case (2012) European Intellectual Property Review (Issue 10), pp. 719-728.

¹¹ Dani Kass, Israel Defies AbbVie IP To Import Generic Drugs For COVID-19, 19 March 2020, available at <https://www.law360.com/articles/1255079/israel-defies-abbvie-ip-to-import-generic-drugs-for-covid-19>.

¹² See Resolution 896 adopted by the Chile Chamber of Deputies on 17 March 2020, available at <https://www.keionline.org/chilean-covid-resolution>.

¹³ See the webpage <https://www.keionline.org/32429>.

¹⁴ Thomas Musmann, German Government Plans Possibilities to Limit Patents In View of Corona Pandemic, 24 March (2020) Kluwer Patent Blog.

¹⁵ Rory O'Neill, Canada Authorises Compulsory Licences for COVID-19, 27 March 2020, available at <https://www.lifesciencesipreview.com/news/canada-authorises-compulsory-licences-for-covid-19-shortfalls-3972>.

¹⁶ Joe McDonald – Linda A. Johnson, Chinese scientists ask for patent on US drug to fight virus, 6 February 2020, ApNews, available at <https://apnews.com/1fe943717b56b56cce5e733790f016dd>.

¹⁷ Susan Decker – Dong Lyu – Haze Fan, Gilead Declines on HIV Patent Fight Loss, China IP Interest, 5 February 2020, available at <https://www.bloomberg.com/news/articles/2020-02-05/gilead-declines-after-hiv-patent-fight-loss-china-ip-interest>.

agreement with Gilead at some point in the future, it also claims that its work hasn't infringed that company's patent rights because the final product is not being sold on the market.¹⁸ But this is highly debatable. Indeed, under both international and national patent laws, manufacturing a patented medicine, even if it's not yet on sale, still amounts to patent infringement.¹⁹

There are real risks to the strategies adopted by the Wuhan Institute of Virology and BrightGene. In particular, they may raise international companies' suspicions regarding their Chinese peers. This in turn may hamper vital research cooperation between China and the world. Gilead, for example, has offered samples of remdesivir for use in clinical trials during the current outbreak. Other leading international pharmaceutical firms currently working on vaccines for COVID-19, like Johnson & Johnson and GlaxoSmithKline, may have less incentive to do so in the future if they believe China will not support their IP claims. A collaborative attitude has also been shown by AbbVie, which in March 2020 informed that due to current health emergency it would stop enforcing its patent anywhere in the world, also in relation to the treatment for HIV.²⁰

The Wuhan Institute of Virology and BrightGene are not the only entities which have been criticized. Gilead itself came under fire after its version of remdesivir obtained in March 2020 the orphan drug designation from the US Food and Drug Administration. Under the US Orphan Drugs Act, such designation gives a seven-year market exclusivity period, as well as tax and other incentives for pharmaceutical companies which produce medicines for rare diseases that hit fewer than 200,000 people. Gilead was reprimanded for applying for such status and thus seeking exclusive rights "despite call for solidarity" to face the pandemic.²¹ After criticism, Gilead informed the public that it had requested to rescind the orphan drug designation.²²

As mentioned, one may argue that these behaviors are ethically questionable – and in particular that the patent system should not be used to make access to drugs more difficult,

¹⁸ Angus Liu, Chinese firm copies Gilead's remdesivir, the most promising drug against the new coronavirus, 12 February, available at <https://www.fiercepharma.com/pharma-asia/chinese-firm-copies-gilead-s-remdesivir-most-promising-drug-against-new-coronavirus>.

¹⁹ See for example Article 28 of the WTO TRIPS Agreement.

²⁰ Ellen 't Hoen, Covid-19 and the comeback of compulsory licensing, *Medicines Law and Policy*, 23 March 2020, available at <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/>. Donato Paolo Mancini, AbbVie drops patent rights for Kaletra antiviral treatment, 23 March 2020

²¹ Donato Paolo Mancini, Gilead criticised over 'orphan status' for potential virus treatment, *Financial Times*, 24 March 2020, available at <https://www.ft.com/content/9fea4f1c-6dba-11ea-89df-41bea055720b>.

²² See Gilead's press release at <https://www.gilead.com/-/media/gilead-corporate/files/pdfs/company-statements/remdesivir-orphan-drug-designation.pdf?la=en&hash=ED14BC7B26E2FEAA2E31E7741A8C9692>.

especially during a pandemic. Can we really justify IP laws that are used in a way which limits the availability of medicines and aims at increasing profits in times of health emergency? This moment of crisis is teaching us a clear lesson in matter of philosophical justifications of IP: Egoistic theories are incapable of offering convincing arguments grounding IP protection.²³ In effect, theories that consider personal gain (both in terms of existential self-realization²⁴ or economic gain²⁵) as the only legitimate source of an ethical defense of IP and as an overarching reason in cases of conflicts between individual and societal well-being appear untenable. The COVID-19 pandemic shows the essential interconnectedness of human beings as a community of unity, where individual happiness becomes possible only in cases where a certain level of welfare is collectively shared.

In this sense, plausible justifications of IP protection must address the relationship between individual and collective needs and concerns. Utilitarianism does just that: It offers an argument in favor of IP that recognizes egoistic motives though within a larger altruistic framework, where societal utility functions as ultimate goal of our practices. Traditional versions of this argument suggest that incentives to authors and inventors are instrumental in maximizing social utility, which is the key principle of utilitarian ethical theories.²⁶ In this sense, IP protection rewards innovators, who are then stimulated in investing more time in inventive and creative activities. This in turn is instrumental in obtaining conditions that are favorable for the occurrence of optimal social utility. Rewards are only justified in terms of the good that, indirectly, they bring to the whole of society. In this view, therefore, personal gain is simply a means to a higher purpose. Clearly, such utilitarian approach fits perfectly into the pharmaceutical industry's incentive-focused narrative: "if patents for drugs aren't available, research-and-development efforts will be discouraged".

Traditional forms of utilitarianism show limitations insofar they tend to identify innovators with individual subject (either persons, institutions, or companies). However, as efforts from the scientific community during this time of crisis clearly show, the process of discovery is often distributed and may very well profit from collaborations between different entities. In this

²³ For an instructive survey of philosophical justifications of intellectual property, see Adam Moore and Ken Himma, "Intellectual Property," in *The Stanford Encyclopedia of Philosophy*, ed. Edward N. Zalta, Winter 2018 (Metaphysics Research Lab, Stanford University, 2018), <https://plato.stanford.edu/archives/win2018/entries/intellectual-property/>.

²⁴ Georg Wilhelm Friedrich Hegel, *Elements of the Philosophy of Right*, ed. Allen Wood (Cambridge: Cambridge University Press, 1991).

²⁵ John Locke, *The Second Treatise of Government*, ed. Peter Leslett (Cambridge: Cambridge University Press, 1988).

²⁶ Tom G. Palmer, "Are Patents and Copyrights Morally Justified - the Philosophy of Property Rights and Ideal Objects Symposium on Law and Philosophy," *Harvard Journal of Law & Public Policy* 13, no. 3 (1990): 817–66.

sense, some innovators may very well be collective rather than individual subjects, and their activity should be protected. Therefore, among the less obvious implications of altruistic justifications of IP we have what follows: IP should establish favorable conditions for collaboration and exchange, and speeding up the process of scientific discovery.

It is often difficult to balance these two opposing forces. The AIDS and HIV crisis of the 80s and 90s already showed us how patent laws may be used to oppose policies adopted by democratically elected governments to balance patent rights and make drugs more affordable. Indeed, in 1998 a group of pharmaceutical companies took the South African government to court to try to stop it introducing legislation aimed at reducing the price of medicines, the main objection being that the 1998 South African Medicines Act had arbitrarily reduced patent protection (the legal action was abandoned in 2001).²⁷

What these (old and recent) disputable behaviours teach us is that IP protection and in particular patent regimes must be managed with great care, as well as a willingness to occasionally set aside financial considerations in favour of ethical or moral concerns, especially when it comes to facing unprecedented global health emergencies like the COVID-19 pandemic. While IP laws are certainly crucial as they incentivise the development of (often) vital drugs, they are far from perfect, and may very well require further adjustment or reform to meet overarching public interests. The solution is not to erode the mutual trust required to make international public health cooperation work.

²⁷ William W. Fisher III - Cyril P. Rigamonti, The South Africa AIDS Controversy A Case Study in Patent Law and Policy (2005) Cyber Harvard, available at <https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf>.

The City Law School
City, University of London
Northampton Square
London EC1V 0HB

T: +44(0)20 7040 3309
E: law@city.ac.uk



Email enquiries:
law@city.ac.uk



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