COVID-19 Vaccine Research, Development, Regulation and Access

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The ability to embrace doubt in the middle of a crisis is a sign of strength…if we can bring ourselves to live consciously then we will be able to embrace both stability and change, which means we may do better at dealing with crises.[2]

Abstract

Will the regulation of a vaccine for COVID-19 be left in the hands of health standards administrators and research conventions or will an alliance of political and economic imperatives, chorused by a loud philanthropic/humanitarian cadre push both the roll-out and access challenges? This brief review identifies current developments in the vaccine race and reflects on the way that political, commercial, hegemonic and humanitarian realities will influence law's regulatory relevance particularly through intellectual property regimes. The conclusion, because of this speculative moment, is *watch this space*.

The paper accepts the argument that substantive IP rights on their own are not to blame for adverse access outcomes, if they arise. But the need for compulsory licences and TRIPS exceptions reveals that a state cannot rely on the good intentions of successful manufacturers to promote social good when profits are potentially significant and market competition is constrained. The political and economic externalities pressuring more socially responsible commercial decision-making in the vaccine case are unique but even so law's normative framework for justice and fairness is a counterbalance to private property exclusion when world health is at stake.

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[2] J R Saul, *Voltaire's Bastards: The dictatorship of reason in the west,* (201Simon & Schuster).

Keywords

COVID-19, vaccine, pandemic, regulation, intellectual property, health and safety, universal access

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Overview

Much speculation surrounds the ultimate control 'technology' in the current COVID-19 pandemic. Conjecture clouds any certain reliance on antibody immunity and the race to find a vaccine intensifies daily, taking on the dimensions of a major international relations battle as much as a scientific breakthrough. There is little doubt that with a health and safety control environment currently largely located in nation state policy and fragmented national self-interest, the global co-operation in genetic sharing and collaborative immunological research, makes the vaccine quest unique in this pandemic eradication struggle. That said, there is mounting concern that without major philanthropic investment, the roll out of a vaccine may see a return to parochiality and hegemonic discrimination.

We are yet to confirm the 'front-runner' in the vaccine race and despite some foreshortening of clinical trials and relaxing of regulatory conventions that are standard for new drug production, no date for public release is mooted despite much talk, so the aspirations of this brief review must be modest. It is necessary to place the vaccine ambitions in the context of other less clinical control policies such as safe distancing, tracking, tracing and mass testing. Besides describing the stage that has been reached in vaccine research and the challenges encountered to this point the paper speculates on the role of regulation, and particularly law in clarifying the access agenda and ensuring just and fair availability of whatever protection a vaccine can provide is not purely predicated on market forces.

The regulatory dimension of the paper moves from reflections on ensuring the science is safe, to assisting in access to resultant inoculation across the globe. Accepting that substantive IP rights on their own are not to blame for adverse access outcomes, the need for compulsory licences and TRIPS exceptions reveals that a state cannot rely on the good intentions of successful manufacturers to promote social good when

profits are potentially significant and market competition is constrained. Sustainable markets for life-saving medications are not only a matter of money. The political, economic, hegemonic and social externalities pressuring for more socially responsible commercial decision-making in this vaccine development context are unique but even so law's normative framework for justice and fairness is a powerful counterbalance to private property exclusion when world health is at stake.

I. Introduction

On 31 December 2019, the Wuhan Municipal Health Commission reported that the city of Wuhan in Hubei Province, China, was facing several cases of pneumonia caused by a virus of unknown origin.[3] On 21 January 2020, the World Health Organization (hereinafter referred to as "the WHO") issued "Novel Coronavirus (2019-nCoV) Situation Report – 1", detailing how cases of a pneumonia of unknown aetiology was detected in Wuhan, the outbreak of the novel coronavirus was possibly associated with exposures from a seafood market in Wuhan and that Thailand, Japan and South Korea had all reported cases of the novel coronavirus.[4] Since that time there has been questions raised about whether a virus of similar nature had also left traces in parts of Europe.[5]

The outbreak of the novel coronavirus was declared as a "Public Health Emergency of International Concern"[6] by the WHO on 30 January 2020. The novel coronavirus has since been renamed as "SARS-CoV-2" (hereinafter referred to as "the Virus") and the disease caused by it was named as "COVID-19" by the International Committee

[3] **黃瑞**黎, "武汉不明原因肺炎确诊 59 例，政府称排除 SARS", *纽约时报中文网* (7 January 2020) <http://cn.nytimes.com/china/20200107/china-sars-pneumonialike/> (accessed 23 June 2020)
[4] "Novel Coronavirus (2019 n-CoV) Situation Report – 1", *World Health Organization* (21 January 2020) <http://www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf> (accessed 23 June 2020)
[5] Chang Ai-Lien, "Coronavirus: What is the European strain?¨, *The Straits Times* (19 June 2020) < https://www.straitstimes.com/asia/east-asia/coronavirus-what-is-the-european-strain> (accessed 29 June 2020); "WHO: Coronavirus from new Beijing cluster closely related to the European strain", CGTN (20 June 2020) < https://news.cgtn.com/news/2020-06-20/WHO-Virus-from-Beijing-cluster-closely-related-to-the-European-strain-Rt018B7dMk/index.html> (accessed 29 June 2020)
[6] "Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)", *World Health Organisation* (30 January 2020) <http://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)> (accessed 23 June 2020)

on Taxonomy of Viruses on 11 February 2020.[7] Persons who have been infected with the Virus may exhibit symptoms such as fever, dry cough, sore throat, shortness of breath, etc.[8] In severe cases, the Virus is known to cause severe damage to a patient's lungs, resulting in a patient having to rely on ventilators to "ensure sufficient oxygen circulation in the body"[9]. In some of these severe cases, death inevitably results due to respiratory failure and/or a cytokine response induced by the Virus which leads to multiple organ failure.[10] Of those that recover from serious bouts of infection, recent studies are suggesting that damage to the lungs, symptoms of dementia and post traumatic stress may exhibit in the longer term.[11]

The Virus has proven itself to be an extremely elusive disease to combat. Firstly, the Virus is easily transmitted from one human to another. Even though the WHO claims that the transmission of the Virus is generally limited to droplet transmission[12], there is an increasing body of research showing that aerosol transmission of the Virus is possible.[13] Indeed, as of 28 June 2020, there are 10,015,904 confirmed cases of

[7] "Naming the coronavirus disease (COVID-19) and the virus that causes it", *World Health Organisation* <http://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it> (accessed 23 June 2020)

[8] "Coronavirus: All you need to know about symptoms and risks", Al Jazeera (25 June 2020) <https://www.aljazeera.com/news/2020/01/coronavirus-symptoms-vaccines-risks-200122194509687.html> (accessed 26 June 2020)

[9] L Maragakis, "I've Been Diagnosed With the New Coronavirus (COVID-19). What Should I Expect?", *Johns Hopkins Medicine* (17 April 2020) <http://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/diagnosed-with-covid-19-what-to-expect> (accessed 23 June 2020)

[10] A Mckeever, "Here's what coronavirus does to the body", *National Geographic* (18 February 2020) <http://www.nationalgeographic.com/science/2020/02/here-is-what-coronavirus-does-to-the-body/> (accessed 23 June 2020)

[11] Paolo Spagnolo, Elisabetta Balestro, Stefano Aliberti, Elisabetta Cocconcelli, Davide Biondini, Giovanni Della Casa, Nicola Sverzellati, & Toby M Maherf, *Pulmonary fibrosis secondary to COVID-19: a call to arms?,* Elsevier Public Health Emergency CollectionPMC7228737 (2020) < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7228737/>; Alessandro Morlacco, Giovanni Motterle & Filiberto Zattoni *The multifaceted long-term effects of the COVID-19 pandemic on urology,* Nature Reviews Urology (2020) < https://doi.org/10.1038/s41585-020-0331-y>; Vellingiri Balachandara, Iyer Mahalaxmib, Mohandev iSubramaniamc, Jayaramayya Kaavyab, Nachimuthu Senthil Kumard, Gracy Laldinmawiie, Arul Narayanasamyf, Patur Janardhana Kumar Reddyg, Palanisamy Sivaprakashh, Sivaprakash Kanchanai, Govindasamy Vivekanandhanj, Ssang-GooCho, *Follow-up studies in COVID-19 recovered patients -is it mandatory?*, Science of Total Environment Volume 729, 139021 (2020), < https://www.sciencedirect.com/science/article/pii/S0048969720325389>

[12] "Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations", *World Health Organisation* (29 March 2020) <http://www.who.int/news-room/commentaries/detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations> (accessed 23 June 2020)

[13] See, for example, R Zhang *et al*, "Identifying airborne transmission as the dominant route for the spread of COVID-19", *PNAS* (16 May 2020) <https://www.pnas.org/content/early/2020/06/10/2009637117> (accessed 23 June 2020)

COVID-19 globally with 499,486 deaths.[14] Secondly, persons infected with the Virus may exhibit little or no symptoms.[15] This renders traditional disease detection methods, such as thermometers, with "very limited efficacy in detecting possible carriers of the [Virus] in order to limit the transmission of the [Virus]."[16]

Therefore, in order to combat COVID-19 by achieving a flattening of the curve, most countries have elected to adopt lockdown measures of various extents in order to break the chain of transmission of the Virus. Such lockdown measures include, for example, imposing travel restrictions on foreign visitors, ordering businesses (such as movie theatres, restaurants, bars and pubs) to shut down, factories to stop working, banning mass gatherings (such as large-scale conferences and church congregations), etc.[17] Inevitably, in addition to the cost in terms of human lives, COVID-19 has caused much economic damage as well, and a more dominant pecuniary discourse is motivating political strategies away from tested but restrictive safety measures, in favour of risky and pre-emptive commercial 'opening-up'. The Secretary-General of the Organisation for Economic Co-operation and Development (the OECD) warned that COVID-19 "brings with it the third and greatest economic, financial and social shock of the 21st Century, after 9/11 and the Global Financial Crisis of 2008 [via] a halt in production in affected countries, hitting supply chains across the world, and a steep drop in consumption together with a collapse in confidence."[18] Health authorities are equally strident against a dominant economic realism.[19]

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[14] "COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University", *Johns Hopkins University of Medicine* <http://coronavirus.jhu.edu/map.html> (accessed 28 June 2020)

[15] S Aziz, "Asymptomatic COVID-19: Five things to know", Al Jazeera (12 June 2020) http://www.aljazeera.com/news/2020/06/asymptomatic-covid-19-200612101747386.html (accessed 23 June 2020)

[16] B Tham and J Loke, "Sunset clause for contact tracing apps could build trust and aid wider adoption", *The Straits Times* (12 May 2020) <http://www.straitstimes.com/opinion/sunset-clause-for-contact-tracing-apps-could-build-trust-and-aid-wider-adoption> (accessed 23 June 2020)

[17] J Irish *et al*, "Lockdowns and entry bans imposed around the world to fight coronavirus", *Reuters* (15 March 2020) <http://www.reuters.com/article/us-health-coronavirus/lockdowns-and-entry-bans-imposed-around-the-world-to-fight-coronavirus-idUSKBN21208S> (accessed 23 June 2020)

[18] A Gurria, "Coronavirus (COVID-19): Joint actions to win the war", *OECD* <http://www.oecd.org/about/secretary-general/Coronavirus-COVID-19-Joint-actions-to-win-the-war.pdf> (accessed 26 June 2020)

[19] Carlo A Favero. Andrea Ichino & Aldo Rustichini, *Restarting the Economy While Saving Lives Under COVID-19* (2020), <https://ssrn.com/abstract=3580626>; Daron Acemoglu, Victor Chernozhukov, Iván Werning, Michael D. Whinston, Optimal Targeted Lockdowns in a Multi-Group SIR Model, The National Bureau of Economic research Working Paper No. 27102 (2020) < https://www.nber.org/papers/w27102>

The fallout from COVID-19 has therefore culminated in an ongoing global race amongst laboratories to develop an efficacious yet safe vaccine in order to stem the damage caused by COVID-19. An efficacious yet safe vaccine, once administered to sufficient numbers in a country's population, will allow a country to move towards herd immunity.[20] If and when herd immunity is achieved, a country would be able to ease any existing distancing and quarantine measures put in place and allow more engaged economic activities to resume without having to unnecessarily endanger their healthcare system's capacity in doing so via risking successive waves of infection.

II. COVID-19 Vaccine Research and Development

As of 24 June 2020, according to the WHO, there are 141 candidate vaccines currently under development by biotech and pharmaceutical companies globally, some with the support of governments, international coalitions and private organisations.[21] Sixteen candidate vaccines are currently under clinical evaluation, that is they are currently being tested to varying degrees on humans. Before we turn to the two candidate vaccines which have made the most progress and have received significant amount of funding in relation to their respective research and development, namely, ChAdOx1 nCov-19 and mRNA-1273, some context as regards how clinical trials for candidate vaccines are carried out may be apposite.

A. Conducting clinical trials for candidate vaccines

Candidate vaccines generally go through three phases of clinical trials. Phase 1 trials are usually not randomised in nature and are performed on a very small group of healthy volunteers. Dose escalation studies may be conducted during phase 1, where an escalating dosage of the candidate vaccine may be administered on the volunteers

[20] "Herd immunity and COVID-19 (coronavirus): What you need to know", *Mayo Clinic* (6 June 2020) <http://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808> (accessed 23 June 2020)
[21] "DRAFT landscape of COVID-19 candidate vaccines – 24 June 2020", *World Health Organization* (24 June 2020) <http://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> (accessed 26 June 2020)

in order to determine the lowest effective dose required to generate the strongest immune response without serious side effects arising.[22]

In phase 2, the clinical evaluation is expanded, and the candidate vaccine is administered to volunteers divided into certain classes, such as, sex, age, health status, etc.[23] This allows the researchers to assess whether, for example, side effects are observed at a higher frequency in a particular class of persons as opposed to another. For example, side effects for Vaccine XYZ occur in higher frequencies in men than women.

In phase 3, the candidate vaccine is administered to thousands of volunteers under "natural disease conditions"[24]. It is not uncommon for the candidate vaccine to be administered to volunteers across different hospitals and/or various countries during phase 3, which are generally randomised in nature.[25] Therefore, phase 3 generally serves as the litmus test for a candidate vaccine. If a candidate vaccine successfully survives the scrutiny under phase 3, it then "gets submitted to the WHO and various government agencies for approval."[26]

B. ChAdOx1 nCoV-19

The candidate vaccine which has made the most progress as of 24 June 2020 is ChAdOx1 nCoV-19 (also known as AZD 1222), which is developed by the University of Oxford's Jenner Institute, licensed to AstraZeneca and supported by (*inter alia*) the US Government through Operation Warp Speed.[27] Under Operation Warp Speed, an

[22] "Phases of clinical trials", *Cancer Research UK* (13 February 2019) <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/phases-of-clinical-trials> (accessed 23 June 2020)
[23] B Gates, "What you need to know about the COVID-19 vaccine", *GatesNotes* (30 April 2020) <http://www.gatesnotes.com/Health/What-you-need-to-know-about-the-COVID-19-vaccine> (accessed 23 June 2020)
[24] *Ibid*
[25] *Supra* n 22
[26] *Supra* n 23
[27] A Kemp, "AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for Oxford's potential new vaccine", *AstraZeneca* (21 May 2020) < http://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html> (accessed 23 June 2020)
Operation Warp Speed is a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug

agreement was concluded between AstraZeneca and the Biomedical Advanced Research and Development Authority ("BARDA") (which is part of the US Department of Health & Human Services), whereby the BARDA will provide up to US$1.2 billion to support the development of ChAdOx1 nCoV-19 and, in return, secure 300 million doses of the potential vaccine for the US.[28]

Before explaining how ChAdOx1 nCoV-19 works (in theory at least), it may be helpful to briefly chart the transmission pathway of the Virus. The Virus is a type of coronavirus, so named for the spike proteins (which resembles crowns) that protrude from the virus' membrane.[29] When droplets containing the Virus enter the body through the nose, mouth or eyes, the spike proteins of the Virus bind onto cell surface receptors in the respiratory tract known as ACE2. Upon successful binding of the Virus' spike proteins to the ACE2 receptors, the Virus fuses with the host cell and releases its viral RNA into the host cell. The infected host cell then uses its own cell machinery to manufacture proteins necessary to keep the host's immune system at bay and for viral replication. Each infected host cell then manufactures, and release millions of copies of the Virus. These new Viruses would then proceed to infect other healthy cells or other hosts when they are released via droplets.[30]

Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. It will coordinate existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA. aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures). "Fact Sheet: Explaining Operation Warp Speed", *Department of Health and Human Services (HHS)* (16 June 2020) <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html> (accessed 30 June 2020)

[28] A B, G Faulconbridge and K Holton, "U.S. secures 300 million doses of potential AstraZeneca COVID-19 vaccine", *Reuters* (21 May 2020) <http://www.reuters.com/article/us-health-coronavirus-astrazeneca/us-secures-300-million-doses-of-potential-astrazeneca-covid-19-vaccine-idUSKBN22X0J9> (accessed 23 June 2020)

[29] J Corum and C Zimmer, "Bad News Wrapped in Protein: Inside the Coronavirus Genome", *The New York Times* (3 April 2020) <http://www.nytimes.com/interactive/2020/04/03/science/coronavirus-genome-bad-news-wrapped-in-protein.html> (accessed 23 June 2020)

[30] J Corum and C Zimmer, "How Coronavirus Hijacks Your Cells", *The New York Times* (13 March 2020) <http://www.nytimes.com/interactive/2020/03/11/science/how-coronavirus-hijacks-your-cells.html> (accessed 23 June 2020)

How then does the ChAdOx1 nCoV-19 vaccine work? Briefly, ChAdOx1 nCoV-19 operates using the concept of a non-replicating viral vector. ChAdOx1 nCoV-19 is made from a virus known as ChAdOx1, which is an attenuated version of a common cold virus (a form of adenovirus) that causes infections in chimpanzees. ChAdOx1 nCoV-19 is genetically modified so that it does not replicate in humans. Hence, it functions as a non-replicating viral vector. It is also genetically modified to manufacture and express the Virus' spike proteins. Therefore, when ChAdOx1 nCoV-19 is inoculated into a healthy human, it is hoped that the body's immune system would recognise the spike proteins and develop an immune response to them. If a successful immune response can be generated by the body when injected with ChAdOx1 nCoV-19, should the host be infected with the Virus subsequently, the host's immune system would be able to recognise the spike proteins and trigger an immune response to take down the Virus.[31]

At the time of writing, ChAdOx1 nCoV-19 is undergoing a phase 3 clinical trial to determine the "safety, efficacy, and immunogenicity of the non-replicating ChAdOx1 nCoV-19 vaccine" and volunteers from Brazil are recruited for this purpose.[32]

For the avoidance of doubt, being ahead in the race by no means guarantees that a particular candidate vaccine will cross the finish line. The University of Oxford have publicly stated that the failure of ChAdOx1 nCoV-19 nevertheless remains a possibility.[33]

C. mRNA-1273

The other candidate vaccine which had shown significant promise thus far is mRNA-1273 developed by Moderna in collaboration with the National Institute of Allergy and Infectious Diseases ("NIAID"). Moderna is an American pharmaceutical company

[31] "Oxford COVID-19 vaccine to begin phase II/III human trials", University of Oxford (22 May 2020) <http://www.ox.ac.uk/news/2020-05-22-oxford-covid-19-vaccine-begin-phase-iiiii-human-trials> (accessed 23 June 2020)
[32] "A phase III study to investigate a vaccine against COVID-19", *ISRCTN Registry* (12 June 2020) <http://www.isrctn.com/ISRCTN89951424> (accessed 23 June 2020)
[33] *Supra* n 29

which is similarly receiving financial and other forms of support from the US government under Operation Warp Speed.[34]

Moderna/NIAID's candidate vaccine, however, operates quite differently from ChAdOx1 nCoV-19. mRNA-1273 functions as a novel lipid nanoparticle ("LNP") encapsulated mRNA vaccine. The encapsulated mRNA encodes for a prefusion stabilised form of the spike protein of the Virus.[35] When the LNP-encapsulated mRNA vaccine is injected into a healthy human, cellular uptake of the liquid nanoparticle (containing the mRNA) takes place. The mRNA is then released in the host cell's cytoplasm, which is then expected to direct the host cell's cell machinery to express the Virus' spike protein in its prefusion conformation. The spike protein is then released from the host cell, and it is hoped that an immune response will be elicited, i.e. the body's immune system would recognise the spike proteins and develop an immune response to them.[36] Should the host be infected with the Virus subsequently, the host's immune system would be able to recognise the spike proteins and trigger an immune response to take down the Virus (in theory at least).

At the time of writing, the development of mRNA-1273 is at the phase 2 stage.[37]

Similarly, there is no certainty that clinical trials for mRNA-1273 will be successful. There are numerous technical difficulties regarding the use of mRNA vaccines. These include, for example, the susceptibility of the encapsulated mRNA from nucleases produced by the host cells (which would break down the mRNA), ensuring successful delivery and release of the mRNA into the host cell's cytoplasm, limitations in nucleic acid length with viral vectors, etc.[38]

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[34] N Weiland and D Sanger, "Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists", *The New York Times* (15 June 2020) <http://www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html> (accessed 23 June 2020)

[35] "Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19)", *ClinicalTrials.gov* (29 May 2020) <http://clinicaltrials.gov/ct2/show/NCT04283461> (accessed 23 June 2020)

[36] "Messenger RNA Payloads", *Precision Nanosystems* <http://www.precisionnanosystems.com/areas-of-interest/payloads/mrna> (accessed 23 June 2020)

[37] "Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 COVID-19 Vaccine in Adults Aged 18 Years and Older", *ClinicalTrials.gov* (18 June 2020) <http://clinicaltrials.gov/ct2/show/NCT04405076?term=moderna&cond=covid-19&draw=2&rank=1> (accessed 23 June 2020)

[38] *Supra* n 37

III. Regulatory Motivations for COVID-19 Vaccine Research and Development

Bearing in mind the health and economic destruction caused by COVID-19, there may be concerns that governmental regulations may pose impediments in the timely approval of a vaccine for COVID-19 upon the successful conclusion of clinical trials. This would then potentially lead to either delays in vaccine availability and/or drive the costs of the successful vaccine higher if the production process was burdened with additional compliance costs, and competitive edge sacrificed through non-uniform national regulatory regimes.

Firstly, it is axiomatic that health regulators have a duty to ensure the safety of the use of any successful vaccine developed. There simply is no point in urgent energies, if the vaccine turns out to be more harmful than the disease it is supposed to help guard against. Any potential obstacles posed by regulatory approval in this regard would obviously have to be contextualised as well. For example, assuming that mRNA-1273 turns out to be the successful vaccine upon the conclusion of clinical trials, it might be expected that the regulatory approval process may take longer than that for ChAdOx1 nCoV-19 (assuming it is also successful) because this would be the first ever RNA vaccine ever made for human use. In addition, it is currently unclear whether LNP-encapsulated mRNA vaccines would be a viable platform for vaccines in other forms.[39]

Secondly, under certain circumstances, health regulators may in fact be willing to cut down on previously required regulatory hurdles on grounds of public health during an emergency. In fact, some authorities for drug certification already have exceptional provisions to call on. Take, for example, s564 of the US Federal Food, Drug, and Cosmetic Act, which provides that "the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be applied in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions cause by CBRN threat agents where there are no adequate, approved, and

[39] *Supra* n 18

available alternatives."[40] Another case in point is in the prioritised use of Remdesivir for the clinical treatment of COVID-19[41] despite there being insufficient clinical evidence that it is clinically effective as a cure[42], especially when balanced against the side effects in terms of liver inflammation/damage that attend on its administration for some patients[43].

Perhaps most importantly, with every passing day that a successful vaccine is not distributed, billions of dollars in terms of economic damage is caused due to the restrictions on commerce and business which distancing measures and impediments of open borders/free movement produce. The spread of the pandemic is evidence enough that we live in an inevitably interconnected world. No national economy is immunised against the shocks caused to global trade and cross-border supply chains. Under such circumstances, perhaps, any concern should lie in the possibility that there may be insufficient regulation as regards the safety of the use of the "successful vaccine" with the general population when roll out is driven by economic imperatives rather than regulatory prudence. Unlike any other health crisis in living memory, because of its infectious spread and the unusual reality that morbidity is not largely over-represented in small and medium income economies, the desire for vaccine protection is now also a powerful political agenda. In this atmosphere of desperation, it is difficult to represent regulatory caution as anything more than another impediment to returning to some *new normal*. As has been witnessed in the rush to rely on digital tracing apps, with their operational limitations and attendant public opposition, as a means of getting people back to work, the regulatory parameters are no longer objectively or scientifically dispassionate. One needs no better evidence than the funding conditions exacted by Operation Warp Speed – millions of first preference doses going to the donor state before the market has a measure. The counter

[40] "Emergency Use Authorization", *U.S. Food & Drug Administration* (24 April 2020) <http://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> (accessed on 24 June 2020)
[41] See, for example, C Chong, "Remedsivir approved for Covid-19 treatment in Singapore", *The Straits Times* (10 June 2020) <http://www.straitstimes.com/singapore/remdesivir-approved-for-covid-19-treatment-in-singapore> (accessed on 24 June 2020)
[42] Y Wang et al, "Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial" The Lancet; 395(10236): 1569-1578
[43] "Fact Sheet for Patients And Parents/Caregivers: Emergency Use Authorization (EUA) Of Remdesivir For Coronavirus Disease 2019 (COVID-19)", *U.S. Food & Drug Administration* (June 2020) <http://www.fda.gov/media/137565/download> (accessed on 24 June 2020)

argument is that without preferential access sponsorship may not be forthcoming and this would have a more wide-spread disadvantage. Even so, this preferential approach reveals the fallacy in raising patent registration as the primary impediment to universal access at the earliest opportunity, if this is defined as a just and fair outcome.

IV. Promoting or Retarding Access to a successful COVID-19 vaccine? Law's role

Assuming that a candidate vaccine has successfully survived the emergency scrutiny posed by clinical trials and the necessary regulatory approval for public use has been obtained, there may be some concerns that intellectual property rights, in particular, patents, may pose an impediment to access to the successful vaccine.

A. A successful manufacturer may elect not to file for a patent

In terms of intellectual property rights protection, a successful manufacturer may elect to file for a patent or may not. Depending on the precise science and technology behind the successful vaccine and the manufacturing process thereof, a successful manufacturer may be able to file two types of patents for the successful vaccine. These are, namely, a product patent (for the successful vaccine) and a process patent (for the manufacturing process thereof). A successful manufacturer can file for either or both of such patents in order to exploit them for commercial profits.

Bearing in mind that the usual approval of a patent application is generally a lengthy process, both a patent and an application for a patent are similarly regarded as personal property and can commodified as such. For example, s41(1) of the Singapore Patents Act[44] ("SGPA") provides that "[a]ny patent or application for a patent is personal property (without being a thing in action), and any patent or any such application and rights in or under it may be transferred, created or granted in accordance with this section." s41(3) SGPA further provides that "[a]ny patent or any

[44] (Cap 221, 2005 Rev Ed). Singapore law is cited here for convenience. The authors accept that major vaccine developments are happening in the UK and the USA, and as such any variants in their patent law conventions would apply.

such application or right shall vest by operation in law in the same way as any other personal property and may be vested by an assent of personal representatives."

However, that there is generally no legal obligation on a patent owner to exploit his patent (unlike the case for trademarks where a mark may be revoked on the grounds of non-use), be it for manufacturing, use or sale. The rights conferred onto a patent owner under a patent nevertheless entitles him to injunctive relief and damages against infringers.[45]

It is possible that, even if a patent(s) was filed in relation to the successful vaccine, a patent owner may not only choose not to exploit his patent but also additionally elect not to enforce it. Indeed, there have been instances where patents were filed but the patent owner nevertheless declared that they will not be enforced.[46] In the present circumstances where the access issue is highly politicised at least in the pandemic transit stage, a patent holder could choose to protect the property interests in the product and process, but not use exclusionist royalty claims to impede other counter-pressures for more universal access. Once the pandemic has been reduced through mass inoculation, no-doubt the vaccine will require regular administration down the track and at a less politically charged moment, the patent-holder could activate commercial rights.

Alternatively, a successful manufacturer may elect not to file for a patent for various reasons. For example, a successful manufacturer may elect not to file for a patent out of altruism (tempered by political pragmatism). Penicillin was an example where a patent was not filed out of altruism. Even though Alexander Fleming is often credited with the discovery of penicillin, there was considerable technical difficulty in the manufacturing of mass quantities of penicillin. Howard Florey and Ernst Chain managed to overcome this technical difficulty subsequently. However, neither Fleming nor Florey tried to patent penicillin and/or the manufacturing process thereof. Fleming refused to patent penicillin because he recognised the potential of penicillin in drug

[45] *Compulsory Licensing: Practical Experiences and Ways Forward* (K C Liu and R Hilty gen eds) (Springer, 2015) at p 151

[46] See, for example, E Wesoff, "Tesla's Elon Musk Declares 'All Our Patent Are Belong to You'", *gtm* (13 June 2014) <http://www.greentechmedia.com/articles/read/teslas-elon-musk-declares-all-our-patent-are-belong-to-you > (accessed 24 June 2020)

discovery research. Florey viewed patents as unethical for such a life-saving drug.[47] There is an enormous 'head of steam' coming from economically and politically potent philanthropic foundations for open access and it would be a brave 'pharma' that would come out early and deny more universal inoculation for commercial gain.[48]

At the opening of the 73rd session of the World Health Assembly, President Xi stated that: "COVID-19 vaccine development and deployment in China, when available, will be made a global public good, which will be China's contribution to ensuring vaccine accessibility and affordability in developing countries."[49] Political pragmatists might view this not so much as a noble sentiment but evidence of China adding medical imperialism to its economic hegemony, particularly with the reference to developing economies. In any case, there is some distinction in China's assurance when put against the financing conditions imposed by the USA in terms of preferential access for its citizens.

Another reason why a successful manufacturer may elect not to file for a patent could be over possible doubts in the patentability of the inventions in relation to the successful vaccine. There are three thresholds for an invention to overcome in order for it to be patentable. These are, namely, novelty, inventive step and industrial application.[50] Assuming that the requirements for novelty and industrial application do not pose an impediment to patentability in this context, it is, however, not guaranteed that the requirement for inventive step would be satisfied.

In relation to inventive step, s15 SGPA provides that "[a]n invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art". The inquiry for obviousness begins with a construction of the relevant state of the art. Following which, the

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[47] Burcu Kilic, *Boosting Pharmaceutical Innovation in the Post-TRIPS Era: Real-Life Lessons for the Developing World* (Edward Elgar, 2014) at p 64

[48] "Covid 19 Action for Access Campaign", *Medecins Sans Frontieres* (20 May 2020) <https://msfaccess.org/covid-19-action> (accessed 29 June 2020); Tung Thanh Le, Zacharias Andreadakis, Arun Kumar, Raúl Gómez Román, Stig Tollefsen, Melanie Saville & Stephen Mayhew, *The COVID-19 vaccine development landscape*, Nature Reviews Drug Discovery 19, 305-306 (2020) <https://www.nature.com/articles/d41573-020-00073-5>

[49] "China's COVID-19 vaccine to become global public good when available: Xi", *Xinhuanet* (18 May 2020) <http://www.xinhuanet.com/english/2020-05/18/c_139066851.htm> (accessed 24 June 2020)

[50] See, for example, s13 SGPA

assessment of obviousness is then conducted. In this regard, the Singapore courts adopt the approach taken in the English case of *Windsurfing International v Tabur Marine* [1985] RPC 59, which comprises of the following steps (at 73):

(a) Identifying the inventive concept embodied in the patent in suit;
(b) Assuming the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art in question;
(c) Identifying what, if any, differences exist between the prior art and the alleged invention; and
(d) Asking whether, viewed without knowledge of the alleged invention (i.e. without hindsight), those differences constitute steps that would have been obvious to the skilled man or whether they require any degree of invention

Assuming that ChAdOx1 nCoV-19 turns out to be a successful vaccine and the successful manufacturer has intentions to file a product patent in relation to the successful vaccine, it should be noted in this regard that the use of ChAdOx1 as a non-replicating viral vector is not something new and the technology to do so had existed for at least a decade.[51] ChAdOx1 had also previously been used as a non-replicating viral vector to manufacture vaccines for the human papilloma virus.[52] It is therefore submitted that there remains a possibility that the differences between the ChAdOx1 nCoV-19 vaccine and prior art may not be sufficient to overcome the threshold required for inventiveness to exist for patentability. A successful manufacturer may therefore be discouraged to file a product patent for the successful vaccine in this regard.

Another possible reason why a successful manufacturer may refrain from filing a patent for the successful vaccine and/or manufacturing process thereof is to avoid having to disclose, in precise terms, how the respective invention works. An application for a patent may be refused (s25(4)(c) SGPA) or a patent may be revoked

[51] See, for example, US Patent US201500447766A1 titled “Simian adenovirus and hybrid adenoviral vectors”, which was filed on 25 May 2011
[52] G Hancock *et al*, “A multi-genotype therapeutic human papillomavirus vaccine elicits potent T cell responses to conserved regions of early proteins” *Nature* (10 December 2019) <http://www.nature.com/articles/s41598-019-55014-z> (accessed on 24 June 2020)

(s80(1)(c) SGPA) if it does not adequately disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art. The UK Patents Act 1977 contains similar provisions (see s14(3) and s72(1)(c) thereof).

This is otherwise known as "enabling disclosure", which is part of the quid pro quo for the patent monopoly granted to the patent owner by the State. This requirement essentially "compels the inventor to tell the world how his invention works so that, after the expiry of the patent and his invention falls into the public domain, others would have sufficient information to make the invention and to improve upon it."[53]

Therefore, if a successful manufacturer decides to patent a proven vaccine, it is required to make all necessary disclosures. There is nothing to stop a successful manufacturer rejecting the patent pathway and retaining the intellectual asset as a trade secret instead. If a successful manufacturer is confident that the vaccine cannot be easily reverse engineered, the invention can similarly be exploited without filing for a patent.

In the context of this vaccine development, the discussion of the law's protectionist potential through exclusionist property rights can no longer be divorced from wider concerns of social good.[54] From this brief coverage of patent law options it is clear that much depends on what influences the mind of a successful manufacturer regarding choices of legal protections and options. And the discretionary considerations are not restricted to commercial decision-making. The race for a vaccine has demonstrated pre-considerations of state reputational value and parochial national interests. Thus, whether a nation state is minded to resist the patent application, through narrowly interpreting the application requirements and implicitly preferring more open market access, in the current political and economic pressure-cooker, a COVID-19 vaccine will certainly not escape social good evaluation or considerations of national economic and social priority. While patentability is a legal determination, the agents of the law do not operate in a vacuum and as with

[53] W L Ng-Loy, *Law of Intellectual Property of Singapore* (Sweet & Maxwell, 2nd Ed, 2014) at p 488.
[54] M. Findlay, *Law's Regulatory Relevance? Power, property and market economies* (Edward Elgar, 2017).

compulsory licensing, the consideration of how requirements will be fulfilled (in common law at least) does not escape appreciations of normative principle.

B. Compulsory licences – social good alternatives

In the event that a patent owner is determined to exploit and/or enforce his rights under the patent(s) conferred in relation to the successful vaccine, this would nevertheless not pose an impossible impediment to access to the successful vaccine.

As Francis Gurry, the director-general of WIPO, argued recently in relation to COVID-19: "The IP system recognizes at both the national and the international levels that emergencies and catastrophes may call for measures that may disrupt the normal functioning of the incentive framework upon which the IP system is based during the period of the emergency or catastrophe. The policy measures that are available in international and national IP law to manage and to mitigate emergencies and catastrophes include compulsory licenses and licenses of right of patented technology embodied in vital medical supplies and medicines… These measures, when deployed in a targeted and time-bound manner, may be useful or even vital when there is evidence of a need to which they may be addressed."[55]

Indeed, this is echoed in Art 8(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as "the TRIPS Agreement"), which provides that: "Members may… adopt measures necessary to protect public health… and to promote the public interest in sectors of vital importance to their socio-economic and technological development." Art 8(1) TRIPS has been further affirmed by the World Trade Organisation's Doha Declaration on the TRIPS Agreement and Public Health, which states as such at paragraph 4: "The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner

[55] F Gurry, "Some Considerations on Intellectual Property, Innovation, Access and COVID-19", *World Intellectual Property Organisation* (24 April 2020) <http://www.wipo.int/about-wipo/en/dgo/news/2020/news_0025.html> (accessed on 24 June 2020)

supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[56]

Therefore, countries can enact legislation or take necessary steps to effectively overcome any IP barriers (such as market price deflation) in ensuring access to crucial medicines/vaccines especially during a pandemic. One such way is through compulsory licensing. Compulsory licensing refers to a:

> "mechanism for superseding the exclusivity associated with patents in case of failure on the part of the patent owner to perform his obligations. It is a system whereby the government or government agency allows third parties (other than the patent holder, typically the competitor) to produce and market a patented product or process without the consent of the patent owner. This mechanism enables timely intervention by the government to achieve equilibrium between two objectives of rewarding inventions and in case of need, making them available to the public during the term of the patent. Through such an intervention mechanism, the government balances the rights of the patent holder with his obligations to ensure working of patents, availability of the products at a reasonable price, promotion and dissemination of technological invention, and protection of public health and nutrition."[57]

Most national legislations therefore allow for compulsory licences to be granted, which generally "compels the pharmaceutical company to grant a licence to another company (usually a generic drug company) upon terms (including royalty) to be agreed by the pharmaceutical company and the other company; or, failing agreement, determined by the court."[58]

Taking India as an example, the grounds for granting a compulsory licence are provided for under s84(1) of the Indian Patents Act 1970. These are, namely: (a) that the reasonable requirements of the public with respect to the patented invention have

[56] E S K Ng, "Balancing Patents and Access to Medicine" (2009) 21 SAcLJ 457 at pp 462-463
[57] *Supra* n 54 a p 13
[58] T J Tan, "Will global IP system block access to vaccine?", *The Straits Times* (28 May 2020) <http://www.straitstimes.com/opinion/will-global-ip-system-block-access-to-vaccine> (accessed on 24 June 2020)

not been satisfied (s84(1)(a) Indian Patents Act 1970), or (b) that the patented invention is not available to the public at a reasonably affordable price (s84(1)(b) Indian Patents Act 1970), or (c) that the patented invention is not worked in the territory of India (s84(1)(c) Indian Patents Act 1970). To succeed, the applicant for a compulsory licence must establish at least one of these grounds.

The Indian Controller of Patents and Designs issued a compulsory licence in the decision of *Natco Pharma v Bayer Corp*[59]. The patent in dispute concerned Nexavar, a drug used to treat renal cell carcinoma and hepatocellular carcinoma and the patent thereof was owned by Bayer Corp. The Controller granted a compulsory licence under all three grounds in s84(1) of the Indian Patents Act 1970, holding that "(a) Bayer had made its drug available to only a small percentage of eligible patients, which did not meet the reasonable requirements of the public; (b) the price of close to rupees 280,000/- per month was not reasonably affordable to the purchasing public; and (c) Bayer's patent was not being worked in India as Nexavar was not being manufactured in India."[60]

Therefore, with a robust compulsory licensing framework under national legislations, as permitted under the TRIPS Agreement during a health crisis, "it would be inaccurate to blame any problems in accessing a vaccine on the global IP system."[61] Any successful manufacturer who files a patent and intend to reap massive profits would quite likely anticipate compulsory licenses to be taken out against them.

Despite the paper's confidence in IP not being the exclusionist regime which will retard vaccine access, compulsory licences have been developed to prevent just that outcome. It is a truism to say the law in substance cannot be blamed for the exploitative intentions of those to whom it grants rights. However, compulsory licences and deflated market pricing regimes, as well as the TRIPS exceptions referred to above, are evidence that IP rights protections can prefer individual rather than social interests, particularly where the health of the globe is at stake, and without these alternative measures, social good may not be achieved. IP law offers choices to

[59] MANU/IC/0016/2013
[60] *Supra* n 47 at pp 21-22
[61] *Supra* n 58

successful manufacturers that might bring about high market pricing to the disadvantage of many consumers. Compulsory licences are a device available to the state (and the market) to modify the exclusionist impact of royalty pricing. Again, we return to the consideration of manufacturer's choice enabled through law but moderated either by market intervention or (as is the case with the current pandemic) influential political, hegemonic, economic and social externalities. In such considerations law's strong normative framework which is equal to claims for private property endorsement at the high a cost of equality before the law, should be recalled in debating law's regulatory function, as much as is the substantive property rights options the law offers.[62]

C. Private sector initiatives and global collaboration efforts

History has shown that private sector initiatives and global collaboration efforts had similarly ensured access to vital vaccines and medicines. One such example can be seen in Unitaid, which is an international organisation working in collaboration with the WHO and "invests in innovations to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively" and also "work to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C and human papillomavirus".[63]

One of the initiatives under Unitaid is known as the "Medicines Patent Pool". As explained above, a patent owner has no legal obligation to exploit his patent, but the rights conferred to him under a patent nevertheless allows him to seek injunctive relief and damages against an infringer. The Medicines Patent Pool negotiates voluntary licences with pharmaceutical companies on behalf of middle-and low-income countries. Under such voluntary licences, the patent owner may permit certain generics to manufacture and sell the patented drug or vaccine under negotiated terms and conditions. Such terms and conditions may, for example, limit the generics in

[62] Randall Peerenboom , *Human Rights and Rule of Law: What's the Relationship?,* Georgetown Journal of International Law, Vol. 36 (2005) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=816024>; Oona A. Hathaway, Do Human Rights Treaties Make a Difference?, 111 Yale Law Journal 1935 (2002) <https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1852&context=fss_papers>

[63] Unitaid website <http://unitaid.org/about-us/#en> (accessed on 25 June 2020)

terms of the quantities of the patented drug or vaccine which it may be permitted to produce, stipulate whether royalties are payable and to whom the generics can supply the patented drug or vaccine, etc.[64] Such a voluntary patent licensing pool scheme had been shown to succeed in "lowering prices and ensuring fair and equitable distribution of the medicines relating to those diseases to poor countries."[65]

Specifically, in the context of COVID-19, pharmaceutical companies such as Johnson & Johnson (which is receiving support from the US Government under Operation Warp Speed) has pledged its commitment "to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use."[66] Alex Gorsky, CEO of Johnson & Johnson, said in this regard: "The world is facing an urgent public health crisis and we are committed to doing our part to make a COVID-19 vaccine available and affordable globally as quickly as possible. As the world's largest healthcare company, we feel a deep responsibility to improve the health of people around the world every day."[67] Other private sector initiatives, such as the collaboration between Gavi and the Bill & Melinda Gates Foundation, have pledged "to purchase COVID-19 vaccines for lower-income countries as soon as they are available."[68]

Again, this is a situation where the conciliatory intervention of 'honest brokers' has ameliorated the royalty impact of patent rights enforcement, particularly when some countries cannot meet the protected market price. In his seminal work on the pharmaceutical industry John Braithwaite not only indicates how the protection of patent rights can reduce market competition and increase consumer pricing, but exposes how assurances from these rights holders that they will 'do the right thing'

[64] "Unitaid's approach to intellectual property", *Unitaid* (December 2016) <http://unitaid.org/assets/Unitaids-approach-to-intellectual-property.pdf> (accessed on 24 June 2020)
[65] *Supra* n 51
[66] "Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use", *Johnson & Johnson* (30 March 2020) < http://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use> (accessed on 24 June 2020)
[67] *Ibid*
[68] B Gates, "When a COVID-19 vaccine is ready, this group will make sure the whole world can access it", *Bill & Melinda Gates Foundation* <http://www.gatesfoundation.org/TheOptimist/Articles/coronavirus-gavi> (accessed on 24 June 2020)

need at least the counterbalance of community debate, civil society scrutiny and a strong humanitarian counter-movement.[69]

V. Conclusion

Much of the discussion above could, admittedly, be rendered moot, even perhaps wishful. No one knows at this stage in the race, whether or not a human body is even able to gain immunity to COVID-19 via a vaccine. It remains unclear whether individuals are vulnerable to contract COVID-19 more than once.[70] Indeed, the WHO has issued a statement declaring that there is "currently no evidence that people who have recovered from COVID-19 and have antibodies, are protected from a second infection."[71] This inevitably casts doubt on gaining permanent immunity to COVID-19 via vaccination, so that the silver bullet may remain in the chamber.

Much of this uncertainty stems from our relatively brief relationship with this contagious virus, against which a vaccine seems the final control aspiration. Similarly it is not entirely clear "which parts of the immune system are triggered by the virus for some people, nor why individuals react to it so differently."[72] Indeed, as Francis Gurry reminds us, what we should be concerned with presently is "not access to vaccines, treatments or cures for COVID-19, but the absence of any approved vaccines, treatments or cures to have access to. The policy focus of governments at this stage should therefore be on supporting science and innovation that will produce a vaccine, treatments or cures."[73]

Successful vaccine or not, it would be negligent either to relax regulation on its promise, so the limitations of any panacea are not to the fore, and the negative side-effects (if

[69] J. Braithwaite, *Corporate Crime in the Pharmaceutical Industry* (Routledge, 2013).
[70] N Davis, "Can you catch coronavirus twice? What we know about Covid-19 so far", *The Guardian* (27 May 2020) <http://www.theguardian.com/world/2020/may/27/can-you-catch-coronavirus-twice-what-we-know-about-covid-19-so-far> (accessed on 24 June 2020)
[71] ""Immunity passports" in the context of COVID-19", *World Health Organization* (24 April 2020) <http://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19> (accessed on 24 June 2020)
[72] A Ahuja, "Commentary: The road to a COVID-19 vaccine is long and narrowing", *Channel News Asia* (19 June 2020) <http://www.channelnewsasia.com/news/commentary/vaccine-coronavirus-covid-19-when-ready-soonest-why-so-long-12847568> (accessed on 24 June 2020)
[73] *Supra* n 56

any) are known for informed patient choice. In this paper we have recognised that to date, and perhaps well into the future, scientific fact is illusory when it comes to taming the virus. It is common when faced by a crisis like the present that regulators lag behind innovation unless and until the nature and consequences of new developments are reducible to empirical risk evaluation. Faced with the prospect of reluctant or compromised regulatory objectives, the outcomes can revert to self-interest over social good. Such cannot be achieved at present. As Saul states in his timely reflection on *impotence till certainty* and our over-reliance on all things rational;

> 'As western humanist ideas of responsible individualism and engaged citizenry have declined, leaving us with the individual consumer, selfish, cut off from shared responsibilities with *the other*, so people elsewhere have turned against the West, partly in embarrassment. They don't wish to be associated with our naivety.'[74]

In the current pandemic the neoliberal voices of property rights and individualist wealth creation above all, have been muted by a wider discourse of social good, even if the motivations for it are as much economic as they are humanist. Law's regulatory relevance will be revealed not so much through the substance of intellectual property rights protection but by assisting a chartered course which draws on the other options we have discussed above reflecting emergency conditions in an atmosphere of shared risk and fate.[75]

Regulation, whether it be for health and safety assurance, for property rights protection, for market resilience, ensuring universal access and social good, involves a humanist commitment to see the best results for the largest population in this age of uncertainty. Political, hegemonic, economic and philanthropic forces shaping our regulatory responses to the pandemic more than scientific certainty, determine that law will not be applied to the letter of the property rights it ensures if these defy law's own more pervasive normative commitments for justice and fairness. As we argued, the law cannot be blamed if its application produces the opposite results.

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[74] *Supra* n 2. p.xiv.
[75] M. Findlay, *Contemporary Challenges in Regulating Global Crises* (Palgrave Macmillan, 2013)