Private Ordering and the TRIPS Waiver: A Critical Blind Spot in the Debate

Siva Thambisetty

(This is work in progress, please do not circulate or cite without checking with me).

In our paper on the legal and political case for a TRIPS waiver we address many arguments against the waiver. [1] In this paper I attempt to work out different trajectories of analysis of good faith opponents to the waiver before building on an element that many such scholars either miss or underplay. Private ordering is the coming together of private actors, and even States,[2] in self-enforcing and voluntary arrangements when they cannot rely on centralised enforcement to solve problems.[3] Producers of private order, be they purely private, combination of private and public or States, need room to manoeuvre in order to work out what kinds of positive obligations to each other can resolve IP-led scarcity of public health goods. The plea for TRIPS waiver is a plea for greater degrees of transnational private ordering to emerge to meet public health goals.

Justificatory discourse on patents tends to focus heavily on exclusivity as reward and proportionality as a social construction to achieve vaguely defined goals such as 'innovation' or 'R&D'. Inadequate characterisations of functions[4] of intellectual property rights different from those that arise from the control legal rules confer on protected subject matter is damaging because it reduces the margin of risk for policy experimentation, even as such alternate functions become subsumed under the 'exclusivity' banner. The entitlements of the patent or IP holder is a simpler narrative for public consumption (particularly when defended by those who have already accrued such entitlements) and diverts attention from arguments that place these rights in a policy context with different end games to play for, as this paper does. The political discourse on Covid-19 vaccine patents during the pandemic has mostly

---

*Associate professor of law, London School of Economics and Political Science. I am grateful to many colleagues, activists and others who have engaged with me on the TRIPs waiver since late 2020.

[1] Thambisetty, McMahon, McDonagh, Kang and Dutfield 'Addressing Vaccine Inequity During the Covid-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond' Forthcoming CLJ 2022

[2] B H Druzin 'Opening the Machinery of Private Order: Public International Law as a Form of Private Ordering' 2014 (58) St Louis Univ L J 423

[3] E Stringham *Private Governance: Creating Order in Economic and Social Life* OUP 2015

[4] C Long 'Patent Signals', Thambisetty 'Credence Goods', Hemel and Oullette 'Plurality of innovation', Robin Feldman (negative innovation) Arti Rai (top up disclosure).

followed this conventional script, contributing to prolonging the Pandemic both in time and human suffering.

In the first part of this paper, I lay out arguments put forward by scholars who disagree with the waiver because it is 'ill-conceived for structural reasons' and arguments that a waiver will not work, even if it were not so ill-conceived. We could call this 'ill-conceived for functional reasons'.

I find that disagreements on the waiver is mostly a disagreement about the state of degradation of centralised enforcement in meeting public health goals. Implicitly or explicitly following theoretical models of patent policy that leave coordination of commercialisation and innovation to exclusive rights owners, backed by the centralising force of international IP agreements frames the crisis of which vaccine inequity is a direct manifestation. I agree that political schisms make the possibilities of a 'global' solution extremely limited[5], but those who characterise the waiver as a global solution are wrong, it is a particularising solution that can potentially be applied globally. The waiver would allow cash and governance poor developing countries to rely on short and long term private ordering to help resolve immediate needs and develop technological resilience for this and the next public health crisis.

In the second part, I characterise the current outlook for the supply of Covid-19 vaccines, including Covax, the voluntary initiative to provide donated vaccine doses, as an integral part of the global market for vaccines created by the pandemic. The 'ask nicely and trust the market' approach is not working well enough to meet the demand of an unsegregated market with vast coordination and governance needs. The current reliance on IP owners to do the right thing and share technology while also ramping up enhancements to the technology follows a forward looking 'prospect' view of patent ownership. This approach is not suitable for global public health needs, even if there was no catastrophic loss of life to contend with.

In order to make sense both of the unreliability of the prospect view and what we might do about it, in the third part I tease it how a revised understanding of competition and innovation can help to make sense of the need for private ordering. In this part, I come back to speculation about what the waiver seeks to achieve. In LMICs private ordering – self-enforcing use of private rights and means of exchange through contracts, can build new relationships between

[5] FM Abbott and JH Reichmann 'Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic' 2020 (23) J of IEL 535-561

state and private actors, and between private actors with a variety of motivations coming together to solve complex problems. Private ordering needs appropriate leverage so that different kinds of organisations, devices and actors can be drawn together. If that leverage can be provided by lifting intellectual property restrictions, we free up providers of private ordering and their problem-solving capacity. Diverse sources of private ordering gives us a better chance of capitalizing on private rights exercised with good intentions.[6] A positive and accurate normative construction of the TRIPS waiver requires us to see it as providing leverage and therefore a chance, at a critical private governance function[7] around public health goals that is currently denied to low and some middle income countries.

Part I: Arguments in favour of the status quo

(A)The waiver is ill-conceived for structural reasons: It's going to take too long

The consensus-based decision-making process on the waiver at the WTO leaves much to be desired given that the TRIPS waiver was proposed in Oct 2020 when we were seeing a great deal of suffering in unvaccinated populations. The consensus process is designed to enable good faith negotiations but countries can easily engage in measures that divert time, attention and diplomatic goodwill. The trade lawyers are acutely aware of this. Scepticism is heightened by the compromises that have to be waded through before negotiations can even begin.

Experience of negotiating the Doha Declaration led to calls for the aborted 12th WTO ministerial conference to delink the TRIPS waiver from other issues. And while Switzerland, a fierce opponent seemed to soften its stance on the waiver in Nov 2021, more recently it has called for the waiver to be discussed in a virtual ministerial that would also tackle four areas in one package – the WTO response to Covod-19, fisheries subsidies, agriculture and WTO reform.[8] This would of course provide numerous wedges to dissociate the positions of the 65 co-sponsors to the waiver proposal as well as the so called 'friends of the proposal'. As Peter Yu reminds us:

> 'Although WTO members adopted the Doha Declaration in November 2001 and a protocol to amend the TRIPS agreement four years later, the proposed amendment

[6] Private ordering is not an unmitigated good, the ills of its self-governing nature can be curbed by diverse actors, and state framing.

[7] See A McMahon 'Biotechnology, Health and Patents as Private Governance Tools: the Good, the Bad and the Potential for Ugly' IPQ 2021. McMahon builds on the control that patent holders have on healthcare provision and argues for state intervention to mediate this control using CLs and VLs. My view of private ordering is related but broader as it draws on decentralised possibilities that might ensue from a TRIPS waiver.

[8] Informal General Council meeting Jan 10 (reported by @ThiruGeneva)

> did not enter into effect until Jan 2017, after two thirds of the WTO membership had ratified the amendment. If this past track record provides any guide, any waiver deliberation that is being undertaken to combat Covid-19 will likely impact the next pandemic, no the current one.'[9]

The EU while opposing the waiver has thrown in a self-styled 'counter proposal' to urge use of existing measures - compulsory licensing. We give six reasons in our paper why the CL route does not work or at least has not worked so far for developing countries and is unlikely to work in a context where multiple patents filed may not be published and trade secrets and exclusive data are unavailable. Take the example of India. There is no way for companies in India to know what patents are involved in a product because there is no orange or purple book like process (showing patent linkage or communication between national regulatory authorities and the patent office).[10] Even if a list of applicable patents were to be made it would take months in government process, and crucially any grant would be challenged and could last years.[11] That is even before a firm can work out what kinds of information might be protected as trade secrets or have other forms of confidential or exclusive protection.

I have characterised the EU's proposal elsewhere[12] as performative (it restates existing rules), reductive (because it equates the logic of the waiver to CLs on patents) and selective (as it ignores well documented problems in using CLs). Clearly, the existence of the EU proposal is an attempt to defang the TRIPS waiver proposal and it's working. It has also driven a wedge between the EU Parliament which is supportive of the waiver[13] and the commission. This means the EU is not really expending any time in thinking about how the waiver might work.

Even a rudimentary understanding of the unfulfilled Bolivia and Biolyse agreement shows problems in using the Art 31bis route.[14] Canada is silent on the request to add Covid-19 to Schedule 1 of the Canadian Patents Act to allow Art 31bis of the TRIPS agreement to be used via the Canadian Access to Medicines Regulation. Despite contradicting their own statement at the WTO, and international calls to respond there is no estimated time frame for when a

---

[9] Peter Yu 'A Critical Appraisal off the Covid-19 TRIPS Waiver (2021)

[10] M Neelankantan and S Thambisetty 'What's the Point of a TRIPS waiver?' https://ipkitten.blogspot.com/2021/07/whats-point-of-trips-waiver-reply.html

[11] Example of litigation over Bayer's Nexavar in India.

[12] TWN/MSF panel.

[13] MEP Resolution calls on the EU to support the granting of a TRIPS Waiver 'to enhance timely global access to affordable COVID-19 vaccines, therapeutics and diagnostics by addressing global production constraints and supply shortages.'

[14] Bolivia's notification to the WTO that it seeks to import vaccines announced in May 11 2021 sets out the difficulties.

Covid-19 vaccine may be added to the schedule.[15] Bolivia's agreement will potentially enable Biolyse to supply the first 15 million doses of J&J vaccine *if* a CL is granted. The inaction is possibly linked to Canada's desire to attract vaccine manufacturers.[16]

Related to the question of time taken for negotiations is the need to move on to 'text-based negotiations' so that we can begin disagreeing about specifics rather than the generic. Peter Yu, while deeply sceptical about the functional value of a broad IP waiver agrees that it would be a positive step to move on to the text of an eventual waiver. As a starting point, the draft put forward in May 2021 has been criticised as overbroad. It refers to different types of IP – copyright, industrial designs, patents, trade secrets and their enforcement. New Zealand and the US have only supported waivers for vaccines.[17] Although the text proposes 3 years, usually consensus is required to agree an end date, so even if one country objects any potential waiver will continue.

The text also proposes that there will be no legal challenge by members against measures taken in conformity with agreed waivers or via the WTO dispute settlement mechanism. As Peter Ungphakorn points out[18] how would 'conformity' be established if no legal challenge is allowed. This would include in 'non violation' cases where an expected right is lost because of a country's actions. These non-violation cases could be measures in low income or high income countries where regulatory changes will be needed in order to operationalise any waiver.

We can expect haggling over other key areas of the text, and what is not mentioned in it – what happens when products produced in a country that has taken measures to implement the waivers is imported in a country that has not done so or does not intend to?[19] Domestic changes to law in order to implement the waiver have to be notified.[20] Such requirements for exporters and importers to notify the WTO is seen as onerous and time consuming. There is

[15] An account of Biolyse previous experience producing Tamiflu under a CL in 2006 is here < https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2021-2-CAMR-Canadian-Compulsory-Licensing.pdf> Biolyse claims it can produce about 20million doses of J&J vaccine a year if allowed to.
[16] Canada has in Aug 2021 struck a deal with Moderna which will offer its 'mRNA development engine' to support Canada's pandemic response. < https://www.pharmaceutical-technology.com/news/moderna-mrna-vaccine-plant-canada/>

[17] The text refers to 'health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for thee prevention, treatment or containment of Covid-19.'
[18] May 22, 2021
[19] Doha was an explicit recognition of aa 'right to export' for patent holders despite that not being recognised in any of the major country's legislation or Art 28 (T Cottier)
[20] GATT Art10, GATS Art3, TRIPS Art63.2)

no doubt that further disagreements can further scupper the need for a swift resolution if/when they lead to further disagreements. The most disappointing element and diversionary tactic so far in my view, is that none of the countries that have opposed the waiver have come up with a middle ground text that they can live with. Expecting relatively inexperienced countries, that are not part of the club of vaccine producers in the middle of a pandemic with changing priorities to embark on diplomatic drafting exercise is a steep ask.

(B) The waiver is ill-conceived for functional reasons: (it will never work!)

Most of the arguments that the waiver will simply have no impact on the most acute need – that is the need to increase the production of vaccines are based on a static view of current manufacturing capacity and exceptionalism. Learning capacity has a dynamic quality – people and entities learn, can increase absorptive capacity and apply their learning to emerging contexts. The exceptionalism is the view that entities outside of a small group of self-validated entities in HICs and their allies in LMICs cannot learn to produce these vaccines.

Firstly, if the aim is to geographically diversify manufacturing because vaccine inequity is a result of the concentration of production in the US and Europe, there are now credible accounts of manufacturing capacity in LMICs. mRNA vaccines are made through biochemical rather than biological processes, which makes for simpler production, fewer steps and is more 'predictable and easier to transfer to other manufacturers than previous vaccine technologies'.[21] The NYT reported on at least ten manufacturing units in developing countries with capacity – it includes three in South America, two in Asia outside of India, public institutions already testing their own mRNA vaccines for Covid-19 and entities tapped by the WHO as potential regional centres for mRNA development.[22]

[21] https://accessibsa.org/mrna/ and S Nolan 'https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html'

[22] Those who point to the success of the HIV/AIDS ARV experience are often batted down because of the difference between mRNA based vaccines, and small molecules. Reporting on a study by MSF and Imperial, Achal Prabhala and Alain Alsahani write 'Recent research into requirements for mRNA vaccine manufacturing from MSF and Imperial College13 reveals that any pharmaceutical company currently manufacturing sterile injectables (a process that requires similar competencies and facilities to those required for making an mRNA vaccine) satisfies the minimum criterion to manufacture an mRNA vaccine. Applying this criterion, and adding in a stringent quality filter, returns at least 8 sites in Africa and 6 sites in Latin America that can make mRNA vaccines, as opposed to 1 and 3 sites respectively for older vaccine technologies. In short, choosing mRNA technology for vaccines resulted in a more than threefold increase of the potential vaccine supply base.' In 'Pharmaceutical manufacturers across Asia, Africa and Latin America with the technical requirements and quality standards to manufacture mRNA vaccines' (10th Dec 2021) https://accessibsa.org/mrna/

The transparent methodology used to produce a list of over 100 entities by journalists and academics[23], suggest that the small circle of manufacturers that form the 'vaccine club' of producers are kept small for reasons other than competence and capacity to handle licenses to increase production. Endogenous rules of inclusion in the vaccine club appear to include reputation and reciprocity that carefully curate self-interest of leading vaccine producers.[24] Despite the dire need when SII suspended supply to Covax in April 2021 due to rising deaths in India, AZ did not engage in technology transfer with another entity to begin production. Only late in 2021 it was reported that AZ agreed a technology transfer agreement with Fiocruz in Brazil to commercialise their vaccine[25] having previously claimed that it did not have enough engineers to share its technology with other global manufacturers.[26] It's possible that the additional deal was influenced by the development of the patent free Corbevax, also a vector based vaccine which will be made available to manufacturing units in a no frills technology transfer agreement.[27]

Second, many of the accounts of lack of manufacturing ability seems to attribute a different rate of absorption of technology in LMICs than HICs. Technological proficiency is a dynamic quality that can be enhanced and built on. Indeed govt intervention, acute need, protected markets and pledges of future sales in developed countries ramped up the development of these vaccines considerably. Where previously no vaccine had been produced in less than four years, within minutes of scientists in China uploading information on the structure of the virus, work had begin on the design of an mRNA vaccine on the back of 30 years of painstaking research. Moderna was not manufacturing vaccines at the start of 2020.

---

[23] ibid.

[24] Two examples with very different outcomes are provided by the deal negotiated by Gates with AZ and the SII. By all accounts (including his own) Gates identified SII as a great, capable vaccine manufacturer. 'We told Oxford that they needed to seek someone with expertise' and AstraZeneca impressed Bill Gates by putting 'their best people on it'. In Aug 2020, the Gates foundation provided £150 million to the SII for the production of vaccines. This anointing of worthy transferees of technology suggests underlying credence factors at play – either through personal connections or a history of reputable work. A contrary case is provide by Canadian company Biolyse that has been trying for almost a year now to obtain a CL to the J&J vaccine in order toe supply Bolivia.

[25] https://ghiaa.org/mapguide-home/search-results/?qs=Fiocruz+-+AstraZeneca,+COVID-19+Vaccine+Technology+Transfer+Agreement (the Gates story

[26] https://www.independent.co.uk/news/health/covid-vaccine-astrazeneca-doses-latest-b1841840.html

[27] https://www.theguardian.com/us-news/2022/jan/15/corbevax-covid-vaccine-texas-scientists. In pre-Covid promotional literature, Moderna Therapeutics declares that 'All of Moderna's mRNA vaccines can be produced with a single 'plug-and-play' platform technology and manufactured at a single facility, which enables unprecedented versatility; accelerated research and early-development efforts; efficient, large-scale, standardized production; and a faster response to unanticipated threats. < https://www.nature.com/articles/d43747-020-00281-3>

There are reports that Africa's mRNA technology hub is trying to reverse engineer the Moderna-NIH vaccine.[28] Bangladesh may be in very good position to take advantage of its LDC status and extension of the WTO transition period to enter the mRNA vaccine market.[29] And by all accounts Cuba has been phenomenally successful in producing home grown vaccines. No one is denying that advance orders, public sector money, protected markets can work miracles as incentives. If an entity in a developing country had been handed 10 billion USD like Moderna was, who is to say that an mRNA vaccine producer might not have emerged in an LMIC? People and institutions can be taught, learn and be supported in doing both. What is unpalatable and inaccurate is the exceptionalism argument – that only firms in HICs can take advantage of such measures.[30]

Third, the waiver is not a solution that will work for different countries in the same way – the technological starting points will be very different, and so is their experience of the pandemic. I agree with Peter Yu when he observes that wide disparities in both vaccine availability and vaccination rates vary significantly now and will in the future. But I disagree with his characterisation that functionally, the waiver fails because it adopted that very 'one size fits all' solution that is so derided by critiques of the TRIPS Agreement and TRIPS-plus bilateral, regional or plurilateral agreements. The waiver will result in a permitted suspension of rules under the WTO and in each case will require legislative changes and other measures that will be governed by domestic political will and trade strategies.

Many countries may opt to do nothing even if a broad waiver does pass through the structural challenges, and we will end up with the opposite of 'one size fits all'. Not only can low or middle income countries decide not to take action, without the cooperation of wealthy countries the waiver may have no impact at all. So the greatest value of a waiver is in disaggregating the interests of countries where IP holders usually reside by allowing them to

---

[28]

[29] BANCOVID, an mRNA vaccine candidate recently showed good results and Bangavax entered human trials last June. https://www.biorxiv.org/content/10.1101/2020.09.29.319061v1 In a country that is not an LDC, such an advance may give additional pause because even an independently produced mRNA vaccine could be a potential infringement if it turns out that relevant patents have been filed in the non-LDC country.

[30] Bryan Mercurio's claim that unlike the pharmaceutical industry the vaccine market is not a free and open market because they contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 'Moreover, the manufacturing process for vaccines is much more complex as it requires facilities and equipment with aa high degree of specialization'. And yet, pre-pandemic India almost exclusively supplies vaccines to low and middle income countries, and it forms the mainstay of many UN approved and led population based vaccine drives. Bryan Mercurio 'WTO Waiver from Intellectual Property Protection for Covid-19 Vaccines and Treatments: A Critical Review' (On SSRN). For data on pre-pandemic vaccine production see 'A World Divided: Global Vaccine Production and Distribution< https://www.bruegel.org/2021/07/a-world-divided-global-vaccine-trade-and-production/>

respond on a needs-based or political-appeal based platform. Indeed Prof Reichman is very dispirited about the possible implications of 'deviant', national interests-led responses in domestic legislations following the TRIPS waiver.[31] In fact, it is this possibility of 'deviance' that is currently lacking in the particular responses to the pandemic – to meet localised conditions of need. Deviance is a positive attribute when centralised arrangements fail irredeemably.

Fourth, to make the case that a waiver will make a difference functionally – we can only base our analysis on past experience, and present or emerging trends.[32] Many opponents to the waiver ask for evidence that the waiver will work.[33] On the one hand what kind of evidence can you produce for something that has not transpired yet. And yet on the other hand, the fact that Pfizer and Moderna have not entered into voluntary agreements to increase production capacity, or the tight control that AZ keeps over technology transfer, is often taken to be evidence of lack of manufacturing capacity in LMICs. It is simply that these companies have not seen it fit to invest in making that technology transfer possible, rely instead on 'fill and finish' contracts. It is possible that Pfizer and Moderna are more concerned about keeping monopoly control of a multi-use technology platform rather than meeting current demand for Covid-19 vaccines.[34]

Fifth and finally, the current picture is one of carefully curated market segmentation, of which unfortunately Covax is a part. Gavin Yamey at Duke who was part of the working group convened by GAVI in early 2020 to discuss Covax describes it as 'a beautiful idea, born out of solidarity. Unfortunately it didn't happen. Rich countries behaved worse than anyone's worst nightmares.'[35]The donated doses have enabled a free flowing supply to higher income countries by assuaging, but not resolving equity considerations. No country has responsibility to supply Covax in full so a version of plausible deniability allows entities like the EU or

[31] Georgetown – HKU conference, panel 3.
[32] See M Neelankantan and Thambisetty 'What's the Point of a TRIPS Waiver' for a discussion of such trends and past experience in an Indian content < https://ipkitten.blogspot.com/2021/07/whats-point-of-trips-waiver-reply.html>
[33] Iancu, Kappos, Rai event < https://www.ipwatchdog.com/2022/01/12/iancu-kappos-trips-ip-waiver-proposal-will-kill-people-saves/id=142795/>
[34] Short term resolutions that favour public health can lead to long term self-interest and vice versa. Consider the Medicines Patent Pool managed technology transfer process that will see Molnupirivir produced by generic companies in 27 countries. Even if Molnupirivir is not the best antiviral, the diffuse production of the drug will in itself make it the lead competing product making it harder to dislodge it even if a better product came along.
[35] As reported in https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01367-2/fulltext

individual governments to claim to have paid for hundreds of millions of doses.[36] The real picture of course ought to be represented by how much has been donated to Covax in comparison with how much is being supplied to higher income countries, or even how much is needed to make a dent in achieving herd immunity globally, defined as 70% coverage[37] (currently 22 billion by end of 2024).

As a matter of design, GAVI was unable to get agreement that frontline medical staff everywhere would be first in line to receive vaccines. There was aa startling admission by Moderna on Nov 21st 2021 that it was allowing the EU to donate doses of its vaccine purchased under the EU vaccines strategy to Covax, suggesting inadvertently that the EU had been unable to do so prior to the agreement. In June 2021 a Lancet Editorial reported that in Bangladesh not a single vaccine had been administered in Cox Bazaar, the world's largest refugee camp. [38] Even as late as Dec 2021 GAVI is struggling to donate Covax vaccines to refugees and migrants displaced by the crises in Myanmar, Afghanistan and Ethiopia who are beyond the reach of national governments' vaccination schemes because of concern from manufacturers about liability. Those applying for doses, mainly NGOs, cannot bear the costs of legal risks and manufacturers won't accept liability.

Early in Jan 2022 Danish media reported that Rwanda rejected 250,000 Covid-19 vaccines from Denmark over claims the donation was attached to Kigali hosting asylum centres for Denmark, a proposal since rejected. As activists have long pointed out, the unpredictability of supply from Covax is a challenge because it makes it more difficult to plan when there is no continuity. This is particularly true given the need for multiple doses.[39] Donation of vaccine doses close to expiry has also been reported. Fatima Hassan calls the unpredictability of supply through Covax the 'drip, drip, boom' model. Supply in fits and starts presents a logistical challenge and reportedly also fuels vaccine hesitancy.[40]

---

[36] Many countries have in fact gone out of Covax arrangements to make donations not directly validated. IAVG validated only 10% of doses distributed globally, the rest was donated directly by governments (730 milllion of 8 billion distributed so far). See Van der Loyen announcements.

[37] Diab et al 'Low and Middle Income Countries: A Model of Projected Resource Needs' (Lancet Preprint Apr 2021)

[38] Protecting Refugees During the Covid-19 Pandemic June 19th 2001 < https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01366-0/fulltext>

[39] Nepal.

[40] Thambisetty 'Opposition to the TRIPs Waiver: Dispatches from the frontline' < https://blogs.lse.ac.uk/politicsandpolicy/trips-waiver-one-year-on/?

As such Covax is a function of wealth and asymmetric power relationships and an example of philanthropo-capitalism that is about making a market work or work better.[41] As a phenomena it also reduces transparency, participation and deliberation in the public domain.[42] Without even this deeply unsettling model it would be harder for HICs to simply consume first, second and booster doses and maintain the current functionality of the market. The presence of Covax has dampened down the political will to find more effective resolutions to the problem of supply of vaccines. This is not dissimilar to early pandemic claims that vaccines will be made available at a 'not for profit' price. As Abbott and Reichman note: '…the recipients of federal subsidies are already under scrutiny by legislators and the public, and they lack a 'reservoir of goodwill'. A not-for-profit approach to the pandemic may thus be a way to improve the image of the industry and forestall future price regulation.'[43]

Part II: Coordination by IP holders - A blind spot in theoretical approaches to servicing a pandemic market.

Given what we know of the Covid-19 mRNA vaccine market, and grave demand, where can we expect higher levels of innovation – under monopoly or perfect competition? Competition can create a strong incentive to innovate because improvements can provide a bigger share of the market. But firms working under perfect competition need all their resources to keep ahead of the game, and consequently have less to spend on R&D. While a monopolist will have the wealth to engage in R&D, he lacks incentive to do so as he has already achieved dominance in the market. Monopolies in markets that are difficult to enter can create conditions that work against further engagement in productive innovation – such as narrow focus on similar, not better products and a lack of innovation for types of products that may return fewer profits such as antibiotics and ironically, in pre-pandemic times, vaccines.

Functionally, market monopolies coterminous with exclusive property rights can foster negative consequences when improvements in technology weaken their dominance of the follow-on market. Feldman discusses the example of a lower dose of Imbruvica which if approved might have fallen out of the scope of the patent and allowed generic competitors to enter the market sooner once the primary compound had lost exclusivity. It was therefore not pursued by the patent holder as even though there were indications that a lower dose was safer and better for patients. This and other cases like Gilead Sciences reputed delaying of a less-toxic version of its HIV medicine until just a few year before the original version's patent

[41] Behrooz Morvaridi 'Capitalist Philanthropy and Hegemonic Partnerships'
[42] Carol Thompson 'Philanthropocapitalims: rendering thee public domain obsolete'
[43] Abbott and Reichmann JIEL 2020 above n

expired suggest the broader possibility of negative innovation. It is difficult to prove the absence of good R&D control, and subject matter spread over different kinds of IP rights add to the difficulty of establishing when 'innovation' becomes negative.

There are three leading Covid-19 vaccines – AZ, Pfizer and Moderna. Based on sales of doses, mRNA vaccines Pfizer and Moderna lead the market, followed by AstraZeneca. The AstraZeneca vaccine, based on a viral vector, has less burdensome cold storage requirements and is the mainstay of Covax. Given the extraordinary and sudden demand for vaccines, the share of Pfizer and Moderna is truly astonishing. While AZ has supplied more doses, Pfizer and Moderna have made more money.[44] While its possible to characterise the small number of vaccine suppliers as an oligopoly, it might be more accurate to separate the markets into small segments – the single dose vaccine, the two dose vaccine and thee multiple dose vaccine in which case we approximate monopoly conditions for particular market needs (pricing, ease of distribution, mRNA boosters for viral vector vaccines, etc). Here it is worth revisiting – Kitch, Schumpeter and Arrow to characterise the current market for Covid-19 vaccines in terms of the role we expect exclusive rights to play.

First an assumption and a qualification. I am assuming post-grant commercialisation is the same as follow-on innovation as the market needs are acute, well-defined and compressed in time. Contingencies such as emergence of new variants, need for boosters or variation in timing between doses are all directed towards a remarkably homogenous need that defines the post-grant market. Secondly – the monopoly position of the three market leaders – Pfizer, Moderna and AstraZeneca flow not just from patents but a wide variety of different IP and non-IP related measures - trade secrets, non-disclosure agreements, expedited regulatory approval, large scale public sector investment, robust demand in the foreseeable future, future orders all play a part. Restrictive export orders protecting ingredients, in addition to extraordinary pandemic led demand which cannot be attributed to the IP holder's efforts, have all contributed to the monopolists' position. So rather than discuss the prospect view of patents, its more accurate to discuss the prospect function of intellectual property rights.

Kitch's prospect theory asserts that post-grant markets should involve little or no competition, and infers from this that patents should be broad. In the very early stages of a technological development broad patents issued should have a scope that goes well beyond what the reward function might necessitate.[45] This move provides 'an incentive to make investments to

[44]

[45] Duffy 'Rethinking the Prospect Theory of Patents' p

maximise the value of the patent without fear that the investment may produce unpatentable information appropriable by competitors'. [46] It is also an attempt to anticipate and prevent duplication of effort and wastage of resources post-grant. As Duffy puts it Kitch's justification for the patent system is 'forward-looking': The function of the patent system is to encourage investment in a technological prospect after the property right has been granted. 'Prospect patents thus put their owner 'in a position to coordinate the search for technological and market enhancement of the patent's value' and that coordination 'increases the efficiency with which investment in innovation can be managed.'[47] Let's call this the 'forward looking incentive'. Crucially Kitch's paper does not really dwell on the detail of how such organisational benefits of control and coordination may come about.[48]

The reward function has a moral weight that is intuitive and appeals to most peoples notion of fairness and justice. The other, incentive function is more unstable and predicated on the desire, ability and disposition of the IP holder to engage in R&D which may not always be forthcoming. Indeed Kitch's paper is based on seeing 'the right to innovate' that all firms have as a problem to be managed and minimised.[49] The prospect theory benefits both from the moral weight of the reward argument and its strong association with tangible rights (Gold rush). The appeal is unfortunately beyond its explanatory or predictive value as a theory on which to base a property rights view of innovation.

It is remarkable how closely the current picture matches onto a theoretical account of prospect patents. Current vaccine inequity that is functionally tied to IP-led scarcity is based on the assumption that allocation of strong property rights leads to efficiency gains because coordination is centralised in the market monopolist/ IP owner. In this view, efficiency will lead to greater investment in the technology itself. But the theoretical assumption of broad transaction rights leading to efficiency of post grant commercialisation is oblivious to real world complex demand scenarios, ability to pay,[50] nature of the product (life saving vaccines) and

[46] (It is also noteworthy that the reliance on patents is to be expected for easy to copy technology (or elements of such technology) rather than those that are genuinely difficult to replicate, which might explain the ring fencing around mRNA vaccines?

[47] Duffy 'Rethinking the Prospect Theory of Patents' at 443 and 458

[48] Of course a prospect patent does not also eliminate the risk of other claims being developed independently and undermines a theory largely predicated on the organisational benefits of centralising control in a single patent holder.

[49] Originally positioned as a response to Barzel's solution (auction), patents as a publicly recorded system (patents) centralise the 'right to innovate' in one firm.

[50] Diab et al 'Low and Middle Income Countries: A Model of Projected Resource Needs' (Lancet Preprint Apr 2021). Assuming 70% coverage to develop herd immunity – they estimate the cost of achieving herd immunity in LMICs at USD 74 billion (2/3 for procurement, 1/3 for deliver). For 20% of LMICs, this cost is at least ten times their baseline annual immunization spend.

above all, differences in quality of governance[51] and conflicts with self-interest. In any time the prospect view of patents would seem like a bad idea, but in a pandemic it's a flawed assumption with catastrophic results.

Here's an illuminating exchange with Bill Gates which shows the failures of coordination when global, variegated public interest is at play. (Jan 11, with Devi Sridhar)

> Gates: *'During 2021 the supply of vaccines was limited and they mostly went to wealthy countries. Now we have a lot of supply overall and the problems are logistics and demand. The health systems in developing countries are a limiting factor'.*
>
> *'mRNA vaccines still cant meet all the demand so figuring out who gets what is complicated.'*
>
> Qn/ Sridhar: There's been a lot of discussion on responsibility of pharma companies like Pfizer/Moderna for access. What is the role of these companies in ensuring pricing and availability esp in low and middle income contexts?'
>
> Gates: *When we have adequate supply then tiered pricing is used where the rich countries pay a lot more than middle income and low income pay the least which is funded by Gavi. When supply is limited rich countries have to not outbid the others so governments are key to this.*

In public and policy discourse – the two different roles of reward and 'forward looking incentive' are often mixed up.[52] The idea that Pfizer and Moderna must be rewarded for coming up with a solution – the reward function - does not refer to the enormous amounts of public money that was invested in order to energise the race pre-grant to find a solution and glosses over the dictatorial[53] ways in which the exclusive rights that followed have been exploited. Gavira and Kilic's network analysis of the mRNA patent landscape shows considerable development of the technology prior to the pandemic hitting. Pfizer and Moderna winning the patent race (with all the duplication that entails), is more akin to plucking the ripe fruit of the tree, than

[51] India 'smart immunisation' 1/3 INC report. Even wealthy countries made mistakes..

[52] From the EU statement to WTO 'The rapid development of several safe and effective COVID-19 vaccines has shown the value of intellectual property, in terms of the necessary incentives and rewards to research and innovation. With the support of public financing, pharmaceutical and biotechnology companies throughout the globe have built on their expertise and invested resources to find solutions against COVID-19. With several successful vaccines available, research into alternative vaccines and new treatments against COVID-19 continues. In that context, the role of intellectual property will continue to be essential.'

[53] Dictatorial because of the ways in which supply is controlled, refusal to license voluntarily, refusal to share technology, control over donations to Covax, and harsh liability measures including ones that prevent refugees from receiving these vaccines.

having planted the seed to grow a tree.[54] This is relevant because we must consider whether in situations where societal need and economic conditions are ripe for fruition in this way, a broad prospect function is still the right way to go.

There are two further interconnected assumptions in the prospect theory – first that the scaling up process and the R&D process are different (former preceding the latter) and second that scaling up production through voluntary licensing to external parties does not lead to negative implications for the IP holder.[55] In new platform technologies, sharing even through licenses that restrict use, is a form of loss of control over technology with uncertain implications on the ability to leverage future or emerging markets, or is at least experienced as such by the IP holder. This may explain the reluctance of mRNA vaccine IP holders to engage in voluntary licensing, relying on 'fill and finish' – the final step of the vaccine manufacture when vaccine doses are bottled - type contracts where there is no transfer of technology. Increasing supply through VLs will not affect price and can in fact increase profit because IP holder producers have little additional cost and can be paid royalties. 'It's free money.'[56] That this has not happened at scale is hard to see as anything other than the desire not to relinquish control.[57]

One of the more commonly voiced criticisms of the prospect patent view is that it leads to moving the patent race pre-invention rather than post-grant. But a less well articulated problem with Kitch's view is the assumption that competitive duplication of effort post-grant is necessarily wasteful. Much can be learned and unlearned in the process of trying to achieve the technology resource or product and not all of this is wasteful. In fact one can expect positive externalities from such a learning process, particularly in situations where the barriers to entry are already high ?[58]

This view of productive failures is also in keeping with the long game of innovation. The Schumpeterian view of innovation as part of the economic process is that it is a relentless race

---

[54] 'The tangled history of mRNA vaccines' https://www.nature.com/articles/d41586-021-02483-w and 'The Long History of mRNA vaccines' https://publichealth.jhu.edu/2021/the-long-history-of-mrna-vaccines

[55] Its worthwhile noting that the application of investor expectation models are skewed here because of the substantial public sector contribution to risk in development of the vaccines. 'Stability of investor expectations are secondary at best' as Abbott and Reichmann put it (in their paper such reduced or modest expectations challenge conventional resistance to use of compulsory licenses.

[56] M Neelakantan.

[57] See 'The Fight to Manufacture Covid-19 vaccines in Low income Countries' https://www.nature.com/articles/d41586-021-02383-z

[58] Novavax? https://www.pharmaceutical-technology.com/comment/novavax-rsv-vaccine-failure/ <https://www.ft.com/content/22d3805e-c304-4d95-ae32-f559ff34886a>

in which 'firms are doomed to innovate in order to avoid disappearing.'[59] The lack of fierce competition and the accruing of market power is a necessary condition for innovation driven by 'mutation' from within – a process of creative destruction that 'incessantly revolutionizes the economic structure from within'. Schumpeter had a surprisingly minimalists' view of patents seeing them as factors that slowed down the diffusion of technology but also a necessary evil to 'induce people to embark on such ventures.' Above all he was convinced that firms need market power to innovate.[60]

Arrow's assertion, by contrast, that the competitive firm has more incentive to innovate is based on the opportunity costs of not innovating. Meager profits under fierce competition can be improved by innovating and in efficient capital markets there are ways in which funding for R&D can be raised and pledged based on the credibility of signals given out by the ability to accrue existing and future property rights.[61] However even in Arrow's version the competitive firm faces several challenges of coordination because of asymmetries in information that is hidden, is emerging or needs to be unearthed; and because the coordination function is driven primarily by self-interest. Contrary to the Schumpeterian view (and by extension, Kitch's view), Arrow's expectation was that the firm that dominates the market, and is already earning monopoly profits is not looking to rock the boat. So coordination gains flowing from prospect owners of IP directly compete with their dominance of the market, shifting attention once again to government intervention to provide that coordination.

If we agree that we should be diversifying solutions, [62] then we should focus more on growing manufacturing ability of widely distributed entities, something that the market leaders are predictably not keen on. While there is growing competition in vaccines based on conventional technologies[63] by no stretch of imagination can we say that the two mRNA based vaccine producers face fierce competition. For mRNA vaccines we seem to be stuck with a pattern of variants providing new extractive opportunities, instead of the broad spectrum vaccine that could change the innovative landscape dramatically even as demand is expected to change.

---

[59] Rémy Guichardaz, Julien Pénin. Why was Schumpeter not more concerned with patents?. Journal of Evolutionary Economics, Springer Verlag (Germany), 2019, 29 (4), pp.1361-1369. ff10.1007/s00191- 019-00643-wf

[60] But productive innovation can also be evolutionary, where distributed market power can lead to diversifying innovation. Whether productive innovation can only happen through market power or may be expected to result from competitive innovation there are coordination questions – which model leads to the greatest efficiency in coordination, rather than in innovation?

[61] Thambisetty 'Patents as Credence Goods.'

[62] As Kapczynski also points out 'to vaccinate 70% of the world in the next 9 months we need not just donations but an urgent investment in new manufacturing capacity. Pfizer and Moderna have been unwilling to invest in that capacity or share knowledge.' https://hewlett.org/the-role-of-the-law-in-vaccine-production-and-the-movement-toward-post-neoliberal-legal-scholarship/

[63] For instance India now has Covishield, Covovax, Covaxin, Zydus, Corbevax, Sputnik..

Moderna's own projections expect Covid-19 to become endemic in high income countries by mid-2022 due to plentiful vaccines and improved treatment; while remaining pandemic through 2023 and beyond LMICs, while Pfizer sees itself as a market leader in both pandemic and endemic markets.[64]

Scherer was the first to suggest in 1967 that competition and innovation may not be monotonically related – in other words the relationship between the two does not mean one decreases (innovation) when the other rises (competition). Instead they retain an inverted-U relationship. Initially competition provides a stronger incentive to innovate but as competition increases further, innovation falls. The ideal of optimal innovation that is achieved at a point where competition is high is supported by recent economic research, summarised by Hovenkamp.[65]

> 'The result is that aggregate innovation – as a function of market competitiveness – takes an inverted-U shape, as illustrated in Figure 2 below. The peak of the inverted-U specifies the exact market structure needed to maximize aggregate innovation in the market. This is the point at which the two marginal effects of competition on innovation are in equipoise.'

Assuming that it would be a weak claim to declare that competition and innovation in the Covid-19 vaccine market are in equipoise, to move the curve along towards the top of the inverted U we need to increase competition. It is fairly obvious that we cannot rely on IP holders to provide the coordination needed to increase competition. This unforthcoming coordination requires trust in the TRIPS agreement as a centralising enforcement measure. The TRIPS waiver is a sign that for a number of LMICs, that trust is broken and that they are no longer willing to resign themselves to a centralised approach to competitive innovation.

Part III – The TRIPS waiver as a plea for private ordering

While superficially the Kitch/Schumpeter – Arrow debate is about competition and innovation, it is essentially about coordination and private ordering and governance, and whether that private governance should come purely from the IP owner rather than diverse sources supported by government intervention. To argue either that optimal innovation can happen only under a monopolist or only under perfect competition is a commitment to different models of private governance. The Kitch/Schumpeterian version relies heavily on the centrality of law

---

64

65 E Hovenkamp 'Patent Prospect Theory and Competitive Innovation' (2016) < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2765478>

and the design of legal arrangements (enforcement of property and contracts) to enable coordination by the monopolist, presumably in society's best interests.

The underlying assumption of such centralism - that the overlap of societal interests with singular exercises of market power, of self-interest with the disposition to invest in R&D - has possibly never failed as robustly as it has in the current context. 'Where legal centralists assume that the government is the source of order and look to additional rules and regulations to deal with potential problems, the necessity and effectiveness of their solutions are usually unconsidered'. [66] In the process private sources of order are crowded out. [67]

Arrow's version in so far as it relies on a larger, more heterogenous and messy group dynamic is more in keeping with private sources of governance. Perfect competition assumes a level of coordinated ordering where there are fewer assumptions about law or the government solving problems because there are diverse actors picking up information to inform actions in diverse ways, and diverse motivations with different lead times.

Reichman and Abbot's paper diagnosing the lack of transnational infrastructure to enable states to implement existing TRIPs flexibilities is I believe very pertinent to my point about centralism and coordination. Reliance on existing flexibilities in TRIPS- primarily CLs - is in their view preferable to voluntary licensing schemes such as the Medicines Patent Pool. Their account of why this is so echoes my views on leverage in the market. Despite their rejection of the waiver, each of their reasons below to prefer the 'compulsory' model over the voluntary one, in principle is an argument *for* the TRIPSs waiver.

Firstly, there is no assurance that most successful and/or most needed treatments would be made available under voluntary pooling arrangements. Second, voluntary measures allow private sector companies to discriminate and exclude countries depending on the short or long game innovation.[68] Third, voluntary schemes rely on 'individual companies to grant licenses for specific products on a case-by-case basis.' 'With respect to COVID-19, patents on relevant

[66] Shobita Parthasarathy identifies four such conflicting priorities in the US system or harms as she calls them - defining accessibility and affordability as issues of health care rather than innovation problems, limiting the range of innovators, distortion of innovation incentives and tolerating harmful, even biased innovation. To these harms one might add the harm caused by a failure to reconcile the extra-territorial implications of legal centralism in innovation given international arrangements related to IP (Health Innovation Policy for the People: The Democracy Collaborative)

[67] Even the IFPMA (through Thomas Cueni) admit that 'everybody is ashamed and embarrassed' at the vast global inequities in vaccine rollout, oblivious it would appear to their own multi-pronged efforts to push back against measures designed to ameliorate.

[68] For instance Chile was excluded from Merck's agreement with the MPP for Molnupirivir leading them to issue a CL.

technologies will likely be held by a wide variety of entities, including foundations, teaching hospitals, and government laboratories, and case-by-case licensing could both be difficult and problematic.' And lastly, they suggest that if governments refrain from pursuing existing flexibilities then it means they have surrendered sovereign authority.[69]

While all of these arguments are sound, they do not lead inevitably to the use of CLs, but to the denigration of voluntary licensing models and prospect based coordination models on the supply side by IP owners. In order to build up leverage to tackle this asymmetry Abbot and Reichmann propose pooling leverage on the demand side through setting up of 'Regional Pharmaceutical Supply Centres' for the collective procurement of products, and the need to coordinate CLs for the production and importation of products and technologies. Such transnational arrangements will overcome administrative and technical issues and to create improved bargaining leverage with potential suppliers.[70]

The proposal is appealing, but it assumes that pooling of transnational infrastructure by the same governments that cannot coordinate individual responses will result in better quality of infrastructure through these 'RPSCs'. Poor governance or capricious regulatory behaviour does not improve simply because it is pooled, the political differences that fragment motivation and pathways to shared goals do not mitigate merely by moving from the national, individual government plane to transnational. Indeed Abbot and Reichmann seem painfully aware of this:

> This problem begins with the internal domestic difficulties of aligning all the government agencies and departments whose inputs and approvals of such action are prerequisites. Once these hurdles are overcome, moreover, there remain the difficulties of negotiating and coordinating affirmative action by two or more governments involved in any pooled procurement strategy, as well as the further need to negotiate licenses for actual production and distribution of the pharmaceuticals in the manner prescribed by Articles 31 and 31bis of the TRIPS Agreement. These problems would be present in almost any situation in which a number of countries were pursuing the procurement of medicines under some form of international arrangement.

Indeed, Covax itself maybe considered a 'transnational infrastructure' to 'improve leverage with potential suppliers'. But consider the problems that have beset this 'solution'. Apart from

[69] A moot point – and one with which a lot of scholars and activists alike will agree.
[70] Its also suggestive of pooling power or sovereignty – and I am not sure the interests protected by 'sovereignty' respond to such pooling.

'design faults' discussed above, it suffers from a lack of ongoing leverage that has resulted in failures in supply and non-enforcement of contracts. Pfizer delivered only 31.3M of a contracted 40 million doses, and Moderna only 21.4million of a contracted 34 million.[71]

Instead of improving the 'transnational infrastructure' to solve a coordination and governance problem on the demand side, I propose that what we need is transnational coordination on the supply side that draw on the problem-solving abilities of private actors providing private ordering. The TRIPS waiver is an argument for greater entropy so that diverse ways of managing risk through private ordering can emerge. It is a plea to allow poorer countries to in fact engage in 'deviant' national interests, find coalitions, and create leverage by allowing private parties with different motivations to enter the field. So I share Abbot and Reichmann's pivot away from voluntary to compulsory mechanisms – but a waiver argument is a plea for gradations and degrees of explicit and implicit compulsion, and intrinsic and extrinsic motivations.

The coordination problem on the supply side is also I believe partially responsible for the seeming paradox that countries are not currently using all existing flexibilities[72] to increase production and supply of vaccines. In order for such flexibilities to be used, participation of private actors is essential. Current TRIPS rules provide no incentive for manufacturers outside the current 'vaccine club' to take a risk and invest in manufacturing when there are any number of ways in which unsupportive rules on IP can jeopardise their positions. The paradox within a paradox is why countries like India have not used greater VLs domestically to increase supply of home grown vaccine, Covaxin. There will always be capricious regulatory behaviour, but we can mitigate the risk of centralising all enforcement by allowing different providers of self-regulating behaviour to organise.[73]

An important feature of the waiver argument that cannot be replicated purely by using existing flexibilities is that a waiver would allow for aligned HICs to respond with tailored measures that can meet global public health needs thus releasing private actors within them to respond to global and particular needs. At the moment global response is based on the highest common denominator of risk averse approaches to IP ownership. Private ordering in HICs can enable coalitions and new relationships between state and private actors, and between private actors with a variety of motivations coming together to solve complex problems even as problems

[71] https://www.who.int/news/item/23-12-2021-achieving-70-covid-19-immunization-coverage-by-mid-2022#_ftn11
[72] South Centre paper
[73] As happened with the HIV/AID access to ARVs.

evolve and mutate. But private ordering and market based interventions need appropriate leverage, a fact that Abbbot and Reichmann recognise fully.

Leverage may come from a combination of licenses to patents, and other IP led contracts and private ordering, credible threats of state intervention through compulsory licenses, facilitation of generic competition, a legal regime that reduces uncertainty in the freedom to operate (linking through orange book-like sources of information for instance) and through investments such as advance purchase orders, or direct public sector hand outs to repurpose, scale and ramp-up production.

Efforts in HICs included a combination of many of these measures, overturning the narrative that private initiative alone led to Covid-19 vaccine discovery and development. Successful outcomes in countries like the UK, Germany and the US are demonstrably the result of an emerging and new private governance model of socialised innovation. As Stringham argues mechanisms of private governance are far more ubiquitous and far more powerful than commonly assumed. Private governance can work on small and large heterogenous groups, friends and strangers, in ancient and modern societies and for simple and complex transactions. The novelty of the model lies in understanding the scale and speed with which public sector measures were harnessed to aid private initiative. Providers of private governance recognise government or international failures and take the initiative to devise private ones. Contrary to the assumption that such private governance happens spontaneously when unfettered IP rights are granted, it has become clear that such a model benefits and indeed relies, on market leverage, and state intervention.

The possibility of enabling such regulated market forces is deeply corroded in the status quo under the TRIPs agreement.[74] Many LMICs face the double jeopardy of being denied licenses to technology and thus are unable to grow technological resilience. IP monopolies that are held outside of low and middle income countries enable extraction of value from LMICs not just because they consume current technology products but also because they are prevented from dynamic learning which has implications for future technology products. It translates into gains for IP holders as they get to define and shape markets that benefit from lack of competitive pressures. Even more damaging in the long run, is being held back from the both the benefits of competitive innovation in the market, and the possibility of adaptive and responsive regulation of private ordering in escalating whole population based health care priorities.

[74] Gruse Kahn; and x study.

Proponents of the waiver do not claim have a full spectrum solution and need others to come in on other issues. One such problem is the disclosure of trade secrets. Most of the solutions proposed so far can be separated into two categories – pricing trade secrets and exclusive information[75] (so they can be bought or sold), and forcing or mandating disclosure[76] All of these proposals in order to be truly effective, require legislative or regulatory changes at least by HICs. A waiver will allow us to trial out and experiment with different levels of risk-taking to find solutions. We should think of it as a dry run for cascading problems of food security and climate resilience.

What can waiver-led private governance do for vaccine equity? First it can break the exclusive club that vaccine production has become. Second it can pull back from the over-provision of rules related to IP ownership that crowd out private ordering and thereby lead to favourable degradation of centralism in IP arrangements. Third, we might also see governments enter into their own version of self-regulated behaviour with like-minded states providing much needed 'transnational infrastructure' on the demand side.[77] Fourth, private governance in combination with responsive regulations provided by states can benefit from periods of learning. There are some signs of this emerging - pressure from asset managers on CEO pay and vaccine equity, identifying investors in vaccine production in order to compel social and governance due diligence are two examples.[78] Export restrictions on vaccine ingredients and Canada not approving covid-19 in CAMA are also examples of responsive regulation that has exacerbated vaccine inequity. China not approving biotech in order to favour homegrown mRNA, or non-exclusive licensing of Corbevax with entities asked to individually negotiate regulatory approval in each country are also non traditional ways in which state intervention can be used to instil greater private ordering.

The 'waiver' is not a blanket rejection of private property rights, on the contrary it is plea to marry private rights with good intentions and diversify motivations. It allows for providers of private ordering to work on solutions, driven by short and long term goals allowing intellectual property rights to be framed by end goals that are more than just control over the subject

[75] Jamie Love, Olga Gurgula.
[76] Rai 'top up disclosure'.
[77] CEPI's agreement with AZ[77] which required reciprocity for funds provided for vaccine development, scale-up of manufacturing and supply of vaccine is an example. The agreements build upon CEPI's initial seed funding for this vaccine candidate, which supported the University of Oxford both for manufacturing development and to manufacture clinical trial materials. CEPI agreed to fund AZ's technology transfer of vaccine production to additional manufacturing sites, the purchase of manufacturing materials, and the reservation of manufacturing slots. The total funding amount is up to $383m of which up to $338 is shared risk and recoverable on product sales.
[78]

matter of an IP right. In sum, the TRIPS waiver is a plea for transnational private ordering and atypical governance measures.