Intellectual Property Rights and Advance Purchase Agreements in a Crisis

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Abstract

The role that intellectual property law has played in the development and delivery of Covid-19 vaccines has attracted a great deal of public attention, policy focus and academic commentary since early 2020. IP rights are simultaneously presented as a key driver of health inequities, as well as central in facilitating unprecedented cooperation in vaccine development. This paper contributes to two interrelated areas of this debate, both of which are central to understanding how IP rights should function in a pandemic context. The first is the role that IP rights play, contractually, in permitting or restricting access to protected technologies and associated knowledge. The second is the reward IP rights ought to hold for their owner when the technological development in question is funded by the state. It addresses these two questions through analysis of the terms and conditions included in the publicly accessible Advanced Purchase Agreements (APAs) concluded by the UK government and EU Commission for the supply of Covid-19 vaccines. We argue that these voluntary contractual arrangements are suitable mechanisms for controlling the exploitation of IP in exceptional circumstances to safeguard the wider public interest. In so doing, we first investigate the nature and scope of the IP and IP related contractual clauses included in the APAs concluded by the UK government and EU Commission. Access to commercially sensitive data is rare and the relative transparency of the Covid-19 purchasing arrangements permits an almost unprecedented opportunity to examine the legal arrangements in depth. We find that the nature and scope of the IP and IP-related contractual clauses included in the APAs concluded by the UK government and EU Commission maintain strong rights in favour of the suppliers, with limited safeguards in favour of states. Secondly, our study breaks new ground by examining the role that IP controls play in these procurement contracts, arguing that IP safeguards are vital, and should be a core part of APAs. Third, we situate our analysis in the context of incentive-based theories of IP rights. APAs are established mechanisms for incentivising research and development in areas where the market-based incentives of IP rights fail to achieve state policy objectives. In this role they act as alternatives to these rights. They also operate to reallocate risk away from the IP owner and on to the state. For both these reasons we conclude that the existing approach to advance purchase agreements is inadequate to address these concerns. We therefore argue that their use justifies restricting IP rights in those agreements beyond the limitations currently provided for in statutory IP regimes. Our work evidences a clear need for change - greater attention to controls over the exercise of IP rights is warranted.

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Introduction

The development and delivery of COVID-19 vaccines[1] has attracted a great deal of public attention, policy focus and academic commentary since early 2020. While COVID-19 vaccines were developed with almost unprecedented speed and became publicly available outside of the research context in December 2020,[2] their widespread availability globally has been and remains poor.[3] Although there are multiple reasons for the availability problems, as in other fields of global health, attention has turned to the role that intellectual property law has played in the global supply of these vaccines.[4]

In this context, IP rights are simultaneously presented as a key driver of health inequities, as well as central in facilitating unprecedented cooperation in vaccine development.[5] This paper seeks to contribute to two interrelated areas of this debate, both of which are central to understanding how IP rights should function in a pandemic context. The first is the role that IP rights play, contractually, in permitting or restricting access to protected technologies and associated knowledge. The second is the reward IP rights ought to hold for their owner when the technological development in question is funded by the state. It addresses these two questions through analysis of the terms and conditions included in the publicly accessible Advanced Purchase Agreements (APAs) concluded by the UK government and EU Commission for the supply of COVID-19 vaccines.[6]

APAs are contractual arrangements which bind one party, e.g. a government, to purchase products, such as vaccines, that have yet to be developed, licensed and manufactured.[7] As Thornton *et al* explain, "In essence, they are binding commitments to individual suppliers to purchase not-yet-available products, if certain conditions are met."[8] They are regularly used as a strategic funding mechanism to incentivise technological development where the traditional market-based incentives of IP rights fail to drive innovation forward.[9] For example, APAs have been proposed, and used, for the

[1] COVID-19 is the disease caused by the coronavirus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) and vaccines provide immunisation against the virus to protect against the COVID-19 disease.
[2] NHS England, "Landmark moment as first NHS patient receives COVID-19 vaccination" https://www.england.nhs.uk/2020/12/landmark-moment-as-first-nhs-patient-receives-covid-19-vaccination/
[3] Although there is currently sufficient global supply of the vaccine, inequities between the global south and global north mean that these vaccines are not equitably distributed globally: WHO, "COVAX calls for Urgent Action to Close Vaccine Equity Gap" (20 May 2022): https://www.who.int/news/item/20-05-2022-covax-calls-for-urgent-action-to-close-vaccine-equity-gap.
[4] Aisling McMahon, "Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance" (2021) 47 Journal of Medical Ethics 142.
[5] For a more detailed view of these contrasting perspectives see Reto M Hilty *et al,* "Covid-19 and the Role of IP: Position Statement of the Max Planck Institute for Innovation and Competition" (7 May 2021) https://www.ip.mpg.de/en/publications/details/covid-19-and-the-role-of-intellectual-property-position-statement-of-the-max-planck-institute-for-innovation-and-competition-of-7-may-2021.html ; Siva Thambisetty *et al,* "Addressing the Vaccine Inequity During the COVID-19 Pandemic: The TRIPS IP Waiver & Beyond" (2022) Cambridge Law Journal 1; Javier Lezaun & Catherine M.Montgomery, "The Pharmaceutical Commons: Sharing and Exclusion in Global Health Drug Development" (2015) 40 Science, Technology & Human Values 3.
[6] As a result of the enhanced public scrutiny around COVID-19, in comparison to other areas of health care, many of the agreements for research and development, manufacturing and supply of the vaccines are publicly available.
[7] Alexandra L Phelan, *et al,* "Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access" (2020) 396 Lancet 800-802.
[8] Ian Thornton, Paul Wilson and Gian Gandhi, "'No Regrets' Purchasing in a Pandemic: Making the Most of Advance Purchase Agreements" (2022) 18 Globalization and Health 1.
[9] David Webber and Michael Kremer, "Perspectives on Stimulating Industrial Research and Development for Neglected Infectious Diseases" (2001) 79 Bulletin of the World Health Organization 735; Mark Turner, "Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1" (2015) 11 Glob Public Health 322; The Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership between public, private, philanthropic, and civil society organisations established in

development of treatments for neglected infectious diseases, such as malaria,[10] and vaccines, such as those developed to protect against pneumococcal infections in low income countries.[11] Yet, despite these successes, their use has proved controversial. Accusations of vaccine nationalism, the act of amassing millions of doses of new vaccines for domestic use at the expense of low- and middle-income countries, have been directed at western governments following the use of APAs during the outbreaks of the Zika, swine-flu (H1N1), and, more recently, the viruses responsible for COVID-19.[12] However, this paper focusses on another controversial feature of Advance Purchase Agreements– their intersection with IP rights.

COVID-19 vaccines are protected by various IP rights. For example, new technologies involved in the development of the vaccines are the subject matter of patent applications filed at patent offices around the world.[13] In addition, the underlying technology together with the developments in manufacturing, transportation and storage of pharmaceutical products are protected by patent rights or as 'know-how' under trade secret laws.[14] These proprietary rights are recognised as important tools in encouraging the development of new technology. However, they also present as a mixed blessing, especially in a health crisis. These strong and extensive levels of IP protection require those who wish to access the technology, either as an end product user or for the purposes of manufacture, to contract with the owners of the IP rights.[15] Therefore, IP rights have a limiting impact on access.

Significant attention has focused on responses at the international level to temporarily waive patents and certain other IP rights associated with COVID-19 vaccines and therapeutics.[16] These efforts are important, but they do not represent the only option in the armoury for improving access to vaccines. In terms of IP governance, little attention has been given to the APAs that supported the initial development and roll out of the vaccine programmes.[17] For reasons that we link back to incentive-

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2017, seeks to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. APAs are one such means of incentive: 'CEPI' https://cepi.net.

[10] Ernst R Berndt, *et al*, "Advance Market Commitments for Vaccines Against Neglected Diseases: Estimating Costs and Effectiveness" (2006) 16 Health Economics 491.

[11] Michael Kremer, Jonathan D Levin and Christopher M Snyder, "Advance Market Commitments: Insights from Theory and Experience" (2020) American Economic Association Papers and Proceedings 110.

[12] Turner, "Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1"; Phelan, *et al,* "Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access"; Ana Santos Rutschman, *Vaccines as Technology: Innovation, Barriers and the Public Health* (OUP 2022) Chapter 4.

[13] WIPO, "Patent Landscape Report: COVID-19-related vaccines and therapeutics: Preliminary Insights on Related Patenting Activity During the Pandemic" (2022) https://www.wipo.int/publications/en/details.jsp?id=4589

[14] Mario Gaviria and Burcu Kilic, "A network analysis of COVID-19 mRNA vaccine patents" (2021) 39 Nature Biotechnology 546; WIPO, "Patent Landscape Report: COVID-19-related vaccines and therapeutics: Preliminary Insights on Related Patenting Activity During the Pandemic".

[15] Richard A. Epstein, "IP and the Law of Contract: The Case Against 'Efficient Breach'" (2013) 9 European Review of Contract Law 345, 348.

[16] The TRIPs Waiver was adopted on 17 June 2022: Ministerial Decision on the TRIPs Agreement, Ministerial Conference, Twelfth Session, Geneva, 12-15 June 2022, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf; See also Thambisetty *et al,* "Addressing the Vaccine Inequity During the COVID-19 Pandemic: The TRIPS IP Waiver & Beyond"; "A Patent Waiver on COVID Vaccines Is Right and Fair" (2021) 593 Nature 478; Hilty *et al,* "Covid-19 and the Role of IP: Position Statement of the Max Planck Institute for Innovation and Competition"; and Bryan Mercurio, "The IP Waiver for COVID-19: Bad Policy, Bad Precedent" (2021) 24 IIC 1.

[17] Issues of cost and transparency have been the focus of criticism directed at the APAs. Few commentators look beyond these issues when analysing the agreements. Notable exceptions include a paper produced by the Medicine Law and Policy team on behalf of The Left MEPs in the European Parliament Environment, Public Health and Food Safety Committee (ENVI), Pascale Boulet *et al,* "Advanced Purchase Agreements for

based theories of IP law, we view these voluntary contractual arrangements as suitable mechanisms for controlling the exploitation of IP in exceptional circumstances to safeguard the wider public interest.

IP is an exclusive property right, and as such is a strong right, to which safeguards can and do attach. Patent regimes in the UK and elsewhere include provisions that prevent patentees unreasonably exercising their proprietary interests to limit access by, for example, not meeting demand on reasonable terms. Compulsory licensing and Crown/government use provisions allow for the lawful exploitation of the patented technology without the right holder's permission in limited circumstances. However, as has been well documented elsewhere, the deployment of these measures is hampered by significant restrictions placed on their use.[18] Furthermore, limiting patent rights alone is unlikely to be sufficient. Many non-patent barriers, including those restricting access to manufacturing know-how and test data, may equally create legal and practical obstacles for access. As an alternative, we see no reason why appropriate IPR safeguards, including but extending beyond the patent context, cannot be considered alongside other measures, such as price, during procurement negotiations by governments. Therefore, we advance the argument that APAs provide a focussed environment where subject matter, including IP licensing, access to technology know-how and test data, among other matters, can be addressed.

We acknowledge that this discussion sits squarely at the controversial interface of the public interest and private law. Access to vaccines is clearly a matter of global public interest. Epidemiologists, global public health scholars as well as bioethicists and lawyers have made clear the imperatives of vaccinating the world against COVID-19 to reduce disease severity and mortality – no one is safe until all are safe.[19] IP also exists to serve the public interest – exclusionary rights provided by IP laws are justified on the basis that they improve society overall through incentivising innovation, the so-called 'patent bargain'.[20] However, the use of IP by third parties normally depends on a series of voluntary contractual relationships, with legal regulation mostly limited to giving effect to the intentions of those who are party to the agreement.[21] In the case of vaccine development and delivery, there are a mixture of private and public parties involved in the chain of agreements,[22] which does, to

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COVID-19 Vaccines: Analysis and Comments" (July 2021) https://medicineslawandpolicy.org/2021/07/new-analysis-advanced-purchase-agreements-for-covid-19-vaccines/. See also data and commentary provided by Knowledge Ecology International https://www.keionline.org/coronavirus.

[18] For a detailed analysis of the compulsory licensing and Crown/government use provisions in the COVID-19 context see, for example, Johnathon Liddicoat and James Parish, "Ironing out the Wrinkles: Reforms to Crown Use and compulsory licensing to help prepare the Patents Act 1977 for the next health crises" [2021] IPQ 245; Christopher Strothers and Alexandra Morgan, "IP and the Supply of COVID-19-related drugs" (2020) 15 JIPLP 590; and Michael S Sinha, Sven Bostyn and Timo Minssen, "Addressing Exclusivity Issues During the COVID-19 Pandemic and Beyond" in *COVID-19 and the Law: Disruption, Impact and Legacy* (CUP 2023, forthcoming).

[19] Seth Berkley, "No One Is Safe until Everyone Is Safe" Gavi, the Vaccine Alliance https://www.gavi.org/vaccineswork/no-one-safe-until-everyone-safe.

[20] The importance of the patent bargain, as one of the key justifications underpinning patent law, has been noted in recent case law: *Regeneron Pharmaceuticals Inc v. Kymab* [2020] UKSC 27, [2020] R.P.C. 22, [23]; *Warner-Lambert v. Generics (UK) Ltd t/a Mylan* [2018] UKSC 56, [2018] R.P.C. 21, [17]. We acknowledge that the extent to which patents serve to increase innovation as an empirical question is contested. However, it is uncontroversial that the justification for the monopoly granted is the benefit to the public interest, although some would question whether the actual practical benefit to the public justifies this monopoly. For an exploration of the intersection between the public interest and patentability, see Naomi Hawkins (ed), *Patenting Biotechnical Innovation: Eligibility, Ethics and Public Interest* (Edward Elgar 2022)

[21] The contractual exploitation of IP is subject to some legal oversight from both within the IP system and beyond. The most obvious legal mechanism outside of IP law itself is competition law.

[22] John P Moore and Ian A Wilson, "Decades of Basic Research Paved the Way for Today's 'Warp Speed' Covid-19 Vaccines" (5 January 2021) https://www.statnews.com/2021/01/05/basic-research-paved-way-for-warp-speed-covid-19-vaccines/.

some extent, draw in public interest considerations.[23] The role that public parties can, and should take, in negotiating the IP related content of these agreements to protect the public interest is, therefore, key.

COVID-19 will not be the final pandemic.[24] It is therefore essential that lessons are learnt about the procurement of COVID-19 vaccines to ensure that every advantage is taken by the state to enhance the public interest in the future.[25] Moreover, our arguments on how states should leverage their bargaining power to contractually secure IP rights-related safeguards, has potential significance beyond vaccine contracts, to state procurement of any innovative product where there is a public interest at stake.

This paper, therefore, contributes to this process of accountability and future preparedness in three key respects. First, we investigate the nature and scope of the IP and IP-related contractual clauses included in the APAs concluded by the UK government and EU Commission.[26] Access to commercially sensitive data is rare and the relative transparency of the COVID-19 purchasing arrangements permits an almost unprecedented opportunity to examine the legal arrangements in depth. Secondly, our study breaks new ground by examining the role that IP controls play in procurement contracts. In doing so, we look beyond issues of price, distribution, and transparency, which have, to date, dominated the critical commentary of COVID-19 APAs.[27] While we acknowledge that these other safeguards are important, and they can and should exist, in our view, IP safeguards are also vital, and should be a core part of APAs. Third, we situate our analysis in the context of incentive-based theories of IP rights. APAs are established mechanisms for incentivising research and development in areas where the market-based incentives of IP rights fail to achieve state policy objectives. In this role they act as *alternatives* to these rights. They also operate to reallocate risk away from the IP owner and on to the state. For both these reasons we conclude that the existing approach to advance purchase agreements is inadequate to address these concerns. Our work evidences a clear need for change, and greater attention to controls over the exercise of IP rights is warranted.

APAs and IPRs – Understanding the relationship

Access to vaccines – the ultimate product of innovative activity incentivised through various means, including the grant of intellectual property rights – is typically secured through procurement agreements. Generally, vaccines for pandemic diseases are procured by governments and

[23] In this sense, this paper does not seek to engage with debates about the appropriateness of restrictions to freedom of contract. Any suggestions for reform proposed here are entirely consistent with a robust approach to freedom of contract, by arguing that the parties to the contract should leverage their bargaining power to implement suggested reforms.
[24] "Sleepwalking into the next pandemic" (2022) 28 Nat Med 1325.
[25] As noted by Nigel Boardman in his review into pandemic procurement, "National resilience to future pandemics needs to be strengthened in every area, including stockpiles, supply chains…and *purchasing frameworks*." "Boardman Review of Government Procurement in the COVID-19 Pandemic" (8 December 2020) [emphasis added] https://www.gov.uk/government/publications/findings-of-the-boardman-review.
[26] Although most of these agreements are redacted, the analysis nonetheless allows important conclusions to be drawn.
[27] See, for example, Emma McEvoy, "Procuring in a Pandemic: Assessing the use of the EU Public Procurement Directives, the Joint Procurement Agreement and the Advance Purchase Agreements" (2022) 73 NILQ 3; Transparency International & WHO Collaborating Centre for Governance, Accountability, and Transparency in the Pharmaceutical Sector, "For Whose Benefit? Transparency in the Development and Procurement of COVID-19 Vaccines" (May 2021) 17 https://www.transparency.org.uk/publications/whose-benefit-transparency-development-and-procurement-covid-19-vaccines; For a recent critical review of the Commission's vaccine supply strategy see European Court of Auditors, "Special Report – EU COVID-19 Vaccine Procurement" (12 September 2022) https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=61899.

administered by those governments to their population.[28] Alternatively, vaccines are also procured by international organisations and delivered by those organisations to individuals through (often UN administered) vaccination programmes.[29] An important mechanism for the procurement of vaccines to alleviate epidemic and pandemic diseases is Advance Purchase Agreements.

APAs can be utilised to incentivise technological development by contractually securing the market for a future product. In this role, they serve to increase the incentive to both develop and commercialise a product, and also to increase manufacturing capacity. This is achieved by either guaranteeing the price to be paid or guaranteeing the volume to be purchased, or a combination of both. Procurers are protected by conditions in the agreement which usually require that the product in question is licensed by a specified regulatory authority,[30] meets technical criteria or some other specified development milestone.[31] APAs can, therefore, be seen to address three market objectives: first, they reduce uncertainty or risk for product developers and manufacturers; second, they secure the availability of the product for the procurer; and third, if concluded with several suppliers, they hedge against R&D and manufacturing risk.[32] They act as a 'pull' incentive – a reward for those who successfully bring a product to clinical use by increasing or ensuring future revenues.[33] From an early point in the COVID-19 pandemic, pull incentive strategies were proposed,[34] of which APAs were the primary mechanism put forward.

While APAs and IP rights are normally thought of as alternative 'pull' strategies, they can both be operational in incentivising the development and manufacture of COVID-19 vaccines. States have a national interest in incentivising production of an effective vaccine, and the bilateral APAs which they enter into, as well as the national IP rights which they grant, are operating to support this interest. There is also an international interest in incentivising vaccine production. The impacts caused by the spread of the disease will not be fully controlled until there is international access to the vaccine. These national and global interests support the development of effective vaccines.

Consequently, the APAs are for the supply of vaccines which are also the subject of a web of intersecting IP rights.[35] At the time of signing the APAs, several vaccine producers had made price pledges, promising not to extract the full value from their IP rights, at least in the short term.

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[28] Advance purchase agreements for vaccines are common for neglected infectious diseases and they have also been used for vaccines against other threats in higher income countries, including, for example, avian flu. See for example: Webber and Kremer, "Perspectives on Stimulating Industrial Research and Development for Neglected Infectious Diseases"; Turner, "Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1." For a discussion of the UK's COVID-19 vaccine procurement programme see Chris Baraniuk, "Covid-19: How the UK Vaccine Rollout Delivered Success, so Far" (2021) 18 BMJ 372.

[29] UNICEF Supply Division, "COVAX: Ensuring Global Equitable Access to COVID-19 Vaccines" https://www.unicef.org/supply/covax-ensuring-global-equitable-access-covid-19-vaccines.

[30] For example, in Europe, COVID-19 vaccines are approved by the European Medicines Agency: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines.

[31] Thornton, *et al, "*"No Regrets' Purchasing in a Pandemic: Making the Most of Advance Purchase Agreements".

[32] Thornton, *et al, "*"No Regrets' Purchasing in a Pandemic: Making the Most of Advance Purchase Agreements"; Rachel Glennerster and Michael Kremer, "A Better Way to Spur Medical Research and Development" (2000) 23 Regulation 34.

[33] J Cama, *et al*, "To Push or to Pull? In a Post-COVID World, Supporting and Incentivizing Antimicrobial Drug Development Must Become a Governmental Priority" (2021) 7 ACS Infectious Diseases 2029.

[34] Christopher M Snyder, *et al,* "Designing Pull Funding for a COVID-19 Vaccine" (2020) 39 Health Affairs 1633.

[35] WIPO, "Patent Landscape Report: COVID-19-Related Vaccines and Therapeutics: Preliminary Insights on Related Patenting Activity during the Pandemic" 24; Gaviria and Kilic, "A network analysis of COVID-19 mRNA vaccine patents."

However, these commitments were temporary and limited in scope.[36] As an alternative, the APAs presented an opportunity for governments, in return for financing and de-risking the development process, to extract a broader and sustainable legally binding commitment from producers. Some of the practical considerations that should have been at the forefront of state considerations when negotiating APAs, and which can be hindered by the uncontrolled application of IP rights, include ensuring national manufacturing capacity is safeguarded in the immediate and longer term; securing access to technology in the event of the termination or abandonment of production by the supplier; and facilitating global distribution as a complement to meeting local demand. As will be discussed in detail below, these issues have not been completely ignored within these agreements. However, there is clear indication from our analysis that the full implications of the arrangements for IP rights and related rights were insufficiently considered. It may be that the need to secure quick delivery of a safe and effective vaccine trumped all other considerations during negotiations, or that other priorities were at play. However, this study will highlight areas of contractual weakness in relation to IP rights arising from the development of the vaccine, with the aim of ensuring that the wider public interest is better safeguarded going forward.

The content of the Covid-19 vaccine APAs

Preliminary observations

The private law nature of contract law means there is, in general, a lack of transparency as to the terms of procurement agreements.[37] This can be problematic for, for example, oversight by legislatures, that may be denied access, and for governments who wish to make informed choices based on existing contractual arrangements.[38] While there are moves to enhance the openness of agreements related to medical technologies,[39] in most cases these agreements are not made public, with pharmaceutical companies reluctant to have their contracting arrangements the subject of public scrutiny. Lack of transparency surrounding the APAs has been the subject of much criticism, with many calling for far greater accountability and traceability of public funds.[40] However, the significant public attention given to COVID-19 procurement and vaccine availability in the UK, Europe and internationally has resulted in a number of APAs becoming publicly available, either through government release or in some cases by unofficial leaks. Yet, many of those that are accessible have been heavily redacted making the process of public scrutiny more difficult. Increased transparency in

[36] Jorge L Contreras, *et al,* "Pledging Intellectual Property for COVID-19" (2020) 38 Nature Biotechnology 1146.
[37] Guidance on public sector procurement is available at https://www.gov.uk/guidance/public-sector-procurement-policy. The policy operates on a presumption in favour of disclosure, with commercial confidentiality being the exception rather than the rule. Yet, given the variation between the redacted agreements, there is clearly uncertainty on what can and should be excluded from public scrutiny.
[38] Transparency International & WHO Collaborating Centre for Governance, Accountability, and Transparency in the Pharmaceutical Sector, "For Whose Benefit? Transparency in the Development and Procurement of COVID-19 Vaccines" 17.
[39] For example, in 2019, 194 Member States of the WHO adopted the 'Transparency Resolution' that encourages Member States to publicly share information on the net prices of health products, to support the sharing of data and costs from human subject clinical trials (while ensuring patient confidentiality), to improve reporting by suppliers (e.g. reports on sales revenue, prices, units sold, etc), to facilitate public reporting of patent and marketing approval status, and to improve open and collaborative research and development of health products. World Health Assembly, "Improving the Transparency of Markets for Medicines, Vaccines and other Health Products" (WHA72.8, 28 May 2019) https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf.
[40] See for example, Salvatore Sciacchitano and Armando Bartolazzi, "Transparency in Negotiation of European Union with Big Pharma on COVID-19 Vaccines" (2021) 9 Frontiers in Public Health Article 647955; Transparency International & WHO Collaborating Centre for Governance, Accountability, and Transparency in the Pharmaceutical Sector, "For Whose Benefit? Transparency in the Development and Procurement of COVID-19 Vaccines"; Katrina Perehudoff, "European Governments should Align Medicines Pricing Practices with Global Transparency Norms and Legal Principles" (2022) 16 Lancet Regional Health – Europe 100375.

relation to procurement of medicines, vaccines and diagnostics is regarded as vital to the question of access to essential medicines, and this message is one we support.[41] Our study, therefore, is not based on complete unfettered access to all the APAs. Nevertheless, the material that is publicly available has provided sufficient data for us to make supported observations on the nature and scope of the IP and IP-related provisions included in the APAs.

Study

Our study analysed eleven publicly accessible advanced purchase agreements which were signed in 2020, i.e. prior to an approved vaccine being available, five concluded by the UK government[42] and six by the EU Commission.[43] The agreements analysed are as follows (in chronological order of the date they were signed):[44]

EU & AstraZeneca (27 August 2020) – unredacted.[45]

UK & AstraZeneca (28 August 2020) – redacted.[46]

UK & Valneva (13 September 2020) – redacted.[47]

EU & Sanofi/GSK (16 September 2020) – redacted.[48]

UK & Pfizer/BioNTech (12 October 2020) – redacted.[49]

EU & Janssen (21 October 2020) – redacted.[50]

UK & Novavax (22 October 2020) – redacted.[51]

EU & Pfizer/BioNTech (11 November 2020) – redacted.[52]

UK & Moderna (16 November 2020) – redacted.[53]

EU & CureVac (17 November 2020) – redacted.[54]

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[41] Boulet *et al,* "Advanced Purchase Agreements for COVID-19 Vaccines: Analysis and Comments"; Transparency International & WHO Collaborating Centre for Governance, Accountability, and Transparency in the Pharmaceutical Sector, "For Whose Benefit? Transparency in the Development and Procurement of COVID-19 Vaccines".

[42] According to the report undertaken by the National Audit Office published on the 14 December 2020, as of the 8 December 2020 the UK government had concluded five agreements with potential vaccine suppliers. National Audit Office, "Investigation into Preparations for Potential COVID-19 Vaccines" (14 December 2020) https://www.nao.org.uk/reports/investigation-into-preparations-for-potential-covid-19-vaccines/.

[43] For access to relevant documents related to the EU Vaccines Strategy see https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en.

[44] Links have been provided to each agreement below. Copies of each agreement are also on file with the authors of this paper and available on request.

[45] This agreement has been unofficially made available in unredacted form via several media outlets and is currently accessible here https://www.rai.it/dl/doc/2021/02/19/1613725900577_AZ_FIRMATO_REPORT.pdf. The authors also retain a copy on file, which is available on request.

[46] https://www.contractsfinder.service.gov.uk/Notice/SupplierAttachment/77bb967f-0194-452a-bdae-9999aecc753d

[47] https://www.contractsfinder.service.gov.uk/notice/cd5013be-e8b8-4e57-82bc-d40301e55ab5

[48] https://ec.europa.eu/info/sites/default/files/apa_with_sanofi_gsk.pdf

[49] https://www.contractsfinder.service.gov.uk/notice/f6adf3ca-59a4-4976-95e6-27a62a2a4c6e.

[50] https://ec.europa.eu/info/sites/default/files/jj_apa_202005071550.pdf.

[51] https://www.keionline.org/misc-docs/UK-Novavax-Supply-Agreement-22Oct2020.pdf.

[52] https://ec.europa.eu/info/sites/default/files/redacted_advance_purchase_agreement_biontech-pfizer_0.pdf.

[53] https://www.contractsfinder.service.gov.uk/notice/a3df05e8-9916-4c12-90c3-0c28611cf48e.

[54] https://ec.europa.eu/info/sites/default/files/curevac_-_redacted_advance_purchase_agreement_0.pdf

EU & Moderna (4 December 2020) – unredacted.[55]

Our analysis is based upon this regionally defined subset of publicly accessible APAs. We selected these agreements on the basis that the underlying legal frameworks for the grant and regulation of IP rights are closely aligned. Although the contracts themselves are governed by the laws of different jurisdictions,[56] all of the agreements studied here regulate a broadly common set of IP rules.

We undertook qualitative content analysis of the agreements, using NVivo.[57] We coded all clauses in each agreement and, for the purposes of this study, selected for academic analysis clauses that impact upon the suppliers' ability to exert any IP rights that arise from the development of the vaccines.[58] The clauses identified for analysis in this paper are those concerning the definitions of IP and confidential information; IP ownership and exploitation; test data; access to IP rights following abandonment; location of manufacture; and redistribution of excess doses. Outside of issues related to local manufacture and the redistribution of excess doses, we do not consider the relevance of any IP rights existing on underlying background technologies.[59]

Although this study is limited by the number of redactions made to most of the agreements, significant conclusions can be drawn. While variation between the agreements is notable, in many instances the clear similarity of objective allows us to draw certain conclusions between redacted and unredacted clauses. Therefore, despite the limitations noted, this study has generated important knowledge which can be used to further understand the role of APAs as an IP policy strategy, provide a basis for calls for improved IP policy, and more fully appreciate the value of critical oversight.

To assist the reader, we have summarised the relevant clauses from each agreement and grouped the information into tables according to the categories of clauses identified above.[60] The tables are available to view and download on ORDA, the University of Sheffield's open access data repository.[61]

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[55] This agreement has been unofficially made available in unredacted form and is currently accessible here https://www.rai.it/dl/doc/2021/04/17/1618676613043_APA%20Moderna__.pdf. The authors of this paper also retain a copy on file, which is available on request.

[56] The UK government agreements are governed by the laws of England and Wales. The applicable laws for the EU agreements are that of Belgium.

[57] NVivo Pro 1.6.1 is a Computer Assisted Qualitative Data Analysis (CAQDAS) software package. CAQDAS broadly refers to software designed to assist the analysis of qualitative data through the identification and coding of theses in order to build or enlarge theories or explanations: A Lewins and C Silver, *Using software in qualitative research: a step-by-step guide* (Sage, Los Angeles 2007) 7. In this study, NVivo was used as a tool to manage data to enable analysis.

[58] We approach this analysis primarily from an academic perspective, rather than that of a commercial party or a practitioner. Accordingly, we note the theoretical, doctrinal, and ethical aspects, and recognise that there may be commercial imperatives operating that we have not explored in detail.

[59] Most APAs expressly warrant that they will deliver the vaccine free from any third-party IP rights that might encumber use of the product– See Table 12 (Naomi Hawkins and Alison Slade "Covid-19 Vaccine Advance Purchase Agreements in the UK and EU - compilation and analysis of intellectual property provisions." The University of Sheffield. Dataset. https://doi.org/10.15131/shef.data.21583323.v1). The clause on 'Warranties of either party' has been redacted in the EU/Pfizer agreement and, in the EU/Janssen agreement, Janssen is leveraging its own technologies and know-how to develop a COVID-19 vaccine which may explain the lack of any direct reference to third-party technologies. In the EU/AstraZeneca APA there is no express warranty, but the agreement does acknowledge that AstraZeneca has pre-existing obligations to its upstream licensor.

[60] The tables also provide detailed referencing to allow the reader to identify the relevant clause in each specific agreement.

[61] Naomi Hawkins and Alison Slade "Covid-19 Vaccine Advance Purchase Agreements in the UK and EU - compilation and analysis of intellectual property provisions." The University of Sheffield. Dataset. https://doi.org/10.15131/shef.data.21583323.v1

The subject matter of the APAs

To place the following information and analysis into context it is important that the subject matter of each agreement is established (see Table 1).[62] By their 'advanced' nature, the above APAs help fund the development process necessary to create and manufacture a product that meets safety and market requirements by providing significant *upfront* financing.[63] While many of the agreements define the contracted subject matter as the manufacture and supply of a vaccine, at the date the agreements were signed the vaccines in question were at various stages of clinical development with most still undergoing Phase IIb or III trials (Table 2).[64] Consequently, in every agreement considered, the upfront payments provided by the state/s financed aspects of the development of the product, the clinical trials, the market authorisation process, plus the establishment and/or expansion of the manufacturing capacity necessary to quickly supply the product. They are therefore, in substance, the sort of pull incentive discussed above, not agreements purely for the supply of an existing product.

This upfront financing is accompanied by relatively weak payback clauses (Table 3).[65] While some of the information on termination and payback has been redacted, especially in the UK initiated APAs, it is clear from the majority of the EU agreements that, should the contracted party be unable to deliver on their obligations, the amount refundable is limited to any unspent down-payment, and any unused raw materials/components and manufacturing capacity purchased with the upfront payments. A somewhat stronger payback obligation is found in the EU/Janssen APA, which makes the down payment non-refundable except where Janssen decides to abandon its development programme in respect of the vaccine candidate.[66] Also, in all situations, Janssen is required to return all equipment, materials and property that has been supplied by the Commission.[67]

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[62] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[63] According to the special report produced by the European Court of Auditors, "In return for securing future vaccine supplies, part of the development costs faced by vaccine producers was financed by down payments from the EU budget" and that "by the end of 2021, the Commission had paid more than €2.55 billion in down payments to vaccine manufacturers." European Court of Auditors, "Special Report – EU COVID-19 Vaccine Procurement" [04]-[05].

[64] The EU & Moderna agreement was signed on 4 December 2020, the latest of the agreements examined in this paper. The Moderna vaccine received conditional marketing authorisation in the EU on 6 January 2021 and phase III clinical trials were still underway at the date of signing of the agreement.
Further information about the trials conducted for COVID-19 vaccines, including Phase IIb or III trials and what is involved, is available at COVID-19 vaccines: development, evaluation, approval and monitoring https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring.

[65] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[66] Clause I.6.4. The extent to which the "Refundability" clause favours Janssen is somewhat uncertain. In situations outside of abandonment, Janssen is required to credit the Commission's down payment against the cost of the end product to Member States (clause I.6.2). Should it deliver some or all of the contracted doses prior to completion or termination of the agreement some or all of the down payment would have been recovered by the EU.

[67] Clause II.16.4. The implication of this provision is far from clear. We assume the Commission to have directly supplied minimal if any "equipment, materials and property". Thus, like the other agreements we take this to require Janssen to return unused raw materials/components that have been purchased with the down payment. Yet, we cannot be sure whether it would also require the return of purchased services, such as manufacturing capacity.
An apparent outlier to the weak payback obligations is the UK/Valneva agreement. In this APA several clauses expressly state that Valneva shall be responsible for its own costs and expenses related to the development and manufacture of the product. However, the impact of these clauses on who bears the financial burden is unclear given the heavy redactions made to the clause concerning the "Consequences of Termination" (Clause 26) and the complete redactions made to the pricing and payment clauses/schedules. We, therefore, treat this apparent exception with some scepticism, especially as it is impossible to make a direct comparison with the other UK government APAs.

Also of significance for the IP focus of this study is that when accounting to the EU for the 'costs, expenses and liabilities' directly or indirectly incurred, many suppliers can deduct expenses related to IP or legal costs in general (Table 4).[68] Without any express terms to the contrary, this could extend to legal costs for professional services related to registration of rights, for example the filing and prosecution of patent applications.[69] Thus, not only are the EU Commission and Member States funding the development of the vaccine and manufacturing technology that will form the subject matter of various IP rights, in some agreements, they may also be contributing to the legal processes that gives rise to these rights.

The lack of any meaningful commitment to repay state funding in the event of failure, or even success, significantly reduces the financial risks borne by the companies in developing the vaccine. Weak repayment obligations also mean that the upfront payments can be lost to the state should no effective vaccine emerge. The result is the gifting of manufacturing facilities and, subject to other safeguards, the technologies and other IP assets financed with those upfront payments.[70] Of note in this context is the EU Commission's mandate to conclude APAs on behalf of its Member States.[71] As part of that mandate, negotiations with pharmaceutical companies were to be conducted according to a set of 'negotiating directives', one of which requires the Commission "to promote related questions with the pharmaceutical industry regarding IP sharing, especially when such IP has been developed with public support."[72] The rest of the analysis, therefore, will focus on the IP and related clauses to examine the extent to which they offer suitable controls over the vaccine technology arising from the public financing provided by the APAs.

Provisions on nature, scope and proprietorship of IP and related rights

In this section, we first consider the provisions that define the nature, scope, and proprietorship of the IP rights arising from the performance of these agreements. We then move on to consider other relevant terms and conditions that have the potential to either further restrict or facilitate access to IP rights and the products/services protected by those rights.

IP definitions

As discussed above, the APAs are directed at incentivising significant innovative activity, i.e., the development of the vaccine and suitable manufacturing/delivery/storage processes. Valuable technological developments which would potentially be the subject of IP rights are a likely consequence of that activity. Every APA examined expressly includes provisions directly related to 'Intellectual property rights', see Table 5.[73] As expected, each agreement includes a 'Definitions'

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[68] With the exception of the Sanofi/GSK and Janssen APAs, the EU agreements include a clause that appears to include IP costs as a legitimate expense to be covered by the upfront payments. Unfortunately, under all four UK agreements what can be attributed to the "costs of the product/goods" has been heavily redacted. Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[69] While regulated by different laws, it is of note that several agreements concluded by the US government do expressly state that, unless otherwise agreed, the filing party bears expenses relating to filing, prosecuting and maintaining any patent rights that may arise from performance of the agreement. See for example, the US contract W15QKN2191003 signed on 28 October 2020 between the DoD and AstraZeneca, Article 9 'Intellectual Property Rights', clause F. https://www.keionline.org/misc-docs/DoD-AstraZeneca-OTA-W15QKN2191003-28Oct2020.pdf

[70] Boulet *et al,* "Advanced Purchase Agreements for COVID-19 Vaccines: Analysis and Comments" 37.

[71] EU Commission, "Decision of 18.6.2020 approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures" C(2020) 4192 final.

[72] EU Commission, "Annex to the Commission Decision on approving the agreement with Member states on procuring Covid-19 vaccines on behalf of the Member States and related procedures" C(2020) 4192 final, 6.

[73] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

section which defines intellectual property rights for the purposes of the contract. There is noted similarity between many of the clauses, suggesting that this may be a standard 'boilerplate' definition. Where variation does occur, as for example in the UK/Pfizer and EU/Janssen agreements, this does alter the fact that all definitions are broad in their reach, covering all IP rights including registered and unregistered rights, and know-how. Most agreements expressly define IP to include applications as well as rights to apply for IP rights, and the geographical reach of the defined rights is also global.

Unsurprisingly, each agreement also provides extensive coverage of the obligations arising in relation to confidential information of the other party (Table 6).[74] The definitions of 'confidential information' are again broad in their scope and create an overlap with the agreements' definition of IP rights. Confidential information is defined to include all business, commercial or technical information concerning the contract and its performance and includes know-how, software, sources of supply (in whatever form) and also includes physical items such as compounds and components. The definition in each agreement is also broad enough to capture test data arising from the pre-clinical and clinical trials.[75]

Having defined what falls to be protected as confidential information, the agreements go on to set out the non-disclosure obligations of each party in relation to these assets. By way of what appear to be standard clauses, each party is required to treat the confidential information of the other party with at least the same care and in the same manner as its own secret and valuable information – i.e., ensure the same level of protection to the other parties' confidential information that it would afford its own and take appropriate steps to keep it secure from theft or unauthorised use or disclosure. The information is only to be used as permitted under the agreements, with parties reserving the right to disclose information to its staff, affiliates, representatives to enable performance of the APA, but it is not to be disclosed to any third party without authorisation. Most agreements also include a survival clause that defines how long the non-disclosure obligation lasts following the expiry or termination of the agreement. There is significant variation, with terms ranging from three to ten years, or "as long as the information or documents remain confidential."[76]

Certain narrow exceptions are provided for disclosures necessary to comply with freedom of information requests, codes of practice disclosures, environmental regulations, and regulatory authority conditions/requests, among other things.[77] It is also noteworthy that all UK contracts, apart from the Pfizer APA, provide for the publication of the APAs themselves, subject to agreed redactions.[78]

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[74] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[75] The EU/AstraZeneca APA is the only one to provide a definition of know-how. This definition captures all practical knowledge associated with the development and manufacture of the vaccine and expressly covers pre-clinical and clinical trial data. "Know-How means (a) inventions, technical information, know-how, show-how, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), formulae, assays, sequences, discoveries, procedures, processes, practices, protocols, methods, techniques, results of experimentation, knowledge, trade secrets, designs, skill, experience, and/or (b) information embodied in compounds, compositions, materials (including chemical or biological materials), formulations, dosage regimes, apparatus, devices, specifications, samples, works, regulatory documentation and submissions pertaining to, or made in association with, filings with any regulatory authority." Clause 1.34.

[76] EU/CureVac, clause 11.6.4; EU/Janssen, clause II.8.3(a) & (b); EU/Pfizer, clause II.9.9.

[77] These exceptions are often subject to a) the request being notified to the disclosing party, b) that only relevant information is disclosed and c) reasonable efforts are made by the receiving party to prevent disclosure of the pharmaceutical companies' confidential information. See for example, EU/Janssen, clause ii.8.3(c), EU/Pfizer, clause 11.9.3.

[78] The implications of the redactions for our study, as well as a discussion of how this study relates to broader questions of transparency is discussed at the section entitled, "The content of the Covid-19 vaccine APAs, Preliminary observations" above.

IP ownership & exploitation

While there is similarity between the provisions defining IP and confidential information, there are clear differences in wording between the provisions related to ownership and exploitation of IP rights – see Table 7.[79] Four of the EU agreements expressly state that the pharmaceutical company will be the sole owner of all "vaccine/product IP rights" and thereby retain the exclusive right to exploit those rights subject to the limits provided under the agreements (discussed in more detail below). All six EU agreements also directly exclude the Commission or Member States from gaining any rights, title, licence or interest in the vaccine IP rights by implication, estoppel or otherwise.

In contrast, this express declaration of ownership over the IP rights arising from performance of the agreement is missing from the EU/Janssen, EU/Pfizer and all UK agreements. Nevertheless, they do confirm that neither party gains rights of ownership or use of the IP owned by the other. It can be assumed that this covers both rights existing prior to the signing of the agreement and those arising during its performance.[80] With IP ownership vesting in the inventor/creator's employer when the invention/creation is made in the course of the normal duties of the employee,[81] the same practical result is achieved - i.e. ownership of any resulting IP rights is reserved to the relevant pharmaceutical company. A possible exception is found in the UK/AstraZeneca agreement where the UK government is named as a third-party beneficiary of certain rights granted in its favour under the original licence agreement between AstraZeneca and Oxford University Innovation. However, without access to this original licence agreement it is impossible to determine the nature of the rights granted.[82]

In the AstraZeneca, Pfizer and Moderna agreements, the UK is granted permission to utilise IP for the purposes of "receiving and using the goods" and/or "for the purpose of illustrating and describing the vaccine in product catalogues".[83] These 'use' rights would extend to IP relevant for marketing purposes, such as trade marks and technical information concerning product specification and administration. The EU/Moderna APA also indirectly refers to the use of product marks and related rights. While no express permission is granted, the inclusion of several conditions on the use of these marks necessarily anticipates some use by the Commission and/or Member States. In contrast, the EU/Pfizer APA expressly requires permission to be sought before any use can be made of trade marks, trade names, etc for publicity, advertising or any other publication.[84]

Despite some limited rights of access to certain product marks and technical information for marketing and illustration purposes, the clear and unambiguous provisions on IP ownership and the broad definition of the rights covered in the APAs highlight the control that the pharmaceutical companies have maintained over valuable IP assets, including confidential information, that have been developed through the state funding provided via the APAs. The question is whether these

[79] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1
[80] A large section of the IP clause in the UK/Pfizer APA is redacted. While we can't be certain, we assume that the redacted sections cover controls on the use of the IP rights mentioned in the following paragraph, rather than any further clarification on the ownership of IP rights The EU/Pfizer agreement is also heavily redacted on the "Exploitation of the Results of the APA".
[81] To selectively paraphrase patent ownership under the UK Patents Act 1977, section 7(2) states that a patent for an invention will be granted to the inventor(s) unless an invention is made in the course of the normal duties of the employee, in which case the invention belongs to his employer (section 39(1)(a)). Similar provisions on employee ownership in IP rights be found in the Copyright, Designs and Patents Act 1988, s11(2) and the Registered Designs Act 1949, s2(1B).
[82] Samuel Cross *et al,* "Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine?" (2021) 6 BMJ Global Health e007321.
[83] These rights may also be present in the UK/Valneva APA, but large sections of text have been redacted from the clause that may cover this issue – Clause 19.
[84] Clause II.10.

strong IP rights for companies are balanced by appropriate controls to protect the public interest. Based on the discussion above, these terms excessively favour the interest of companies over that of the public when considered on their own. Therefore, the following analysis will seek to determine the extent to which this imbalance is remedied by other provisions included in the APAs.

Provisions related to access

Access to test data[85]

As discussed above, the APAs provide a funding stream for product development, including clinical trials in relation to the vaccine. It is also of note that in the UK/Novavax agreement, the UK government is committed to using commercially reasonable efforts to assist Novavax's Phase III clinical trials in the UK by facilitating access to the National Institute of Health Research in order to access trial sites, principal investigators, lab facilities, and institutional review boards, and to facilitate streamlined regulatory approvals via introductions to the Health Research Authority and MHRA.[86] Yet, despite this direct funding and assistance during the clinical trials process, there are very few provisions in the agreements governing the collection and use of test data associated with the vaccines (Table 8).[87]

Pre-clinical and clinical test data falls under the broad definition of IP, being protected under data exclusivity regulation and laws protecting confidential information, and ownership is expressly reserved to the company in all APAs. The majority of APAs do provide limited rights of access by placing an obligation on the supplier to provide the state/Commission with updates on test results and the progress of clinical development of the product. In addition, it also appears that many of the agreements make access to clinical trial data a condition of indemnification for liability should the use of the vaccine cause injury or loss. However, many of the indemnification clauses are partially or completely redacted, so it is impossible to say whether this right of access was granted under all agreements examined. It is also possible that the UK government may have been granted access to test data under the original upstream licensing agreement between AstraZeneca and Oxford University Innovation. The introduction to the UK/AstraZeneca APA notes that the UK has acquired some rights under the AZ/OUI agreement, but no detail is provided.

Nevertheless, the real value of test data is in ensuring the safe administration of the vaccine to the relevant population. These data provide information about the groups to whom the vaccine is administered and adverse reactions, among other matters. They are valuable for the originator company in securing market authorisation for their pharmaceutical product. Yet, they are also valuable to any subsequent manufacturer who would wish to avoid the costly and time-consuming process of replicating the original test results. Current data exclusivity laws in the UK and Europe provide up to 8-years of protection for regulatory data on most medical products, and market authorisation rules require consent from the authorisation holder before the original filed data can be used by another applicant during this period.[88] Despite the importance of access to test data for

[85] The agreements also include some boilerplate provisions on the collection and use of personal data, for GDPR compliance. However, these do not have any particular relevance to the collection of research data, and we therefore do not consider them in any detail here.
[86] UK & Novavax APA, clause 4.7.
[87] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1.
[88] Data and market exclusivity rules in the EU and UK follow an 8+2+1 approach. Data exclusivity protection provides exclusive rights over preclinical and clinical test data for 8 years. Market protection laws provide an additional 2 years when the generic or biosimilar product cannot be marketed, even if it has been approved by the relevant regulatory authority. A further 1 year of market protection is granted to "new therapeutic indications" that provide "significant clinical benefit". Regulations (EC) no. 726/2004 of 31 March 2004 laying

subsequent manufacturers, the agreements are mostly silent on questions of who collects data about the use and administration of the vaccine, questions of control and use of that data, as well as questions of post-marketing surveillance and use of the vaccine.[89] A notable exception is found in the EU/AstraZeneca agreement where, on reasonable notice, "AstraZeneca shall enable the Commission … to access all clinical trial data … and all data relevant to the manufacturing of the vaccine" (provided it is permitted to share such information).[90] Yet, the use of such data will be severely restricted by the obligations related to confidential information and thus would do little to facilitate access for the any global manufacturing and distribution effort.

Access to IPRs and abandonment

The APAs ensure that the pharmaceutical companies maintain complete control over valuable vaccine related IP rights. However, questions arise in relation to access should the supplier not continue to develop the vaccine. This may occur for several reasons, including unsatisfactory clinical trial results in terms of efficacy or safety, and/or an inability to obtain market authorisation. While, as detailed above, all agreements provide for some form of accounting of money expended and the payback of unspent amounts, only the EU/AstraZeneca agreement expressly provides for the licensing or sublicensing of the vaccine IP rights in the case of abandonment – see Table 9.[91] This type of right of access is commonly referred to in the literature as a 'march-in' right.[92] As stated in the agreement, the purpose of this march-in right is "to enable the Commission to continue the development efforts for the vaccine for the EU market". However, this is subject to permission of the upstream licensor. The agreement expressly states that AstraZeneca has pre-existing obligations to its upstream licensor that must be satisfied to ensure the product is delivered free of any third-party IP rights. Yet, it does not follow from the APA that the Commission, or any appointed third-party, would be automatically entitled to assume that licence or acquire a sublicence to allow the vaccine development to continue. Thus, without any upstream licensing commitment, the value of this type of march-in right is greatly reduced. It seems clear that Oxford University, the upstream licensor in this case, is committed to the wider public interest, and is unlikely to have prevented a third party from continuing to develop the vaccine.[93] However, it is certainly possible that the University might have objected, for varied and potentially reasonable and valid reasons, to the grant of a licence to a company of the Commission's choosing.

Location of manufacture

Knowledge dissemination through technology transfer is a key pillar of the IP system. The grant of IP rights can partly be justified on the basis that IP protection facilitates increased technology transfer by encouraging cooperation and the sharing of important technical, process and business knowledge with

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down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ l136/1, article 14(11); Human Medicines Regulation 2012 (2012/1916).

[89] Several of the EU agreements do provide that if post-marketing studies are required by the EMA the cost shall be borne by the Member states. EU/AstraZeneca, clause 10.3; EU/Sanofi/GSK, clause I.6.6.

[90] EU/AstraZeneca, clause 4.2(b).

[91] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[92] Such 'march-in rights' are included in many UK Government research funding agreements. For example, NIHR grant terms include such rights in clauses 16 and 17: https://www.nihr.ac.uk/documents/nihr-research-contract-global-health-research-example/27845. For a recent discussion of march in rights in the US under the Bayh-Dole Act see Robert Cook-Deegan, Aaron S Kesselheim & Ameet Sarpatwari, "Updating the Bayh-Dole Act" (2022) 327 JAMA 923.

[93] The approach of Oxford University Innovation, the technology transfer arm of the University of Oxford, to expedite access to COVID-19 related IP is set out at https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/.

others. IP rights are the basis for the licensing of protected technology and the accompanying transfer of associated know-how.[94] The effectiveness of these rights in increasing technology transfer, especially at the international level, has been the subject of much debate.[95] Nevertheless, there is little doubt that local and/or regional manufacturing of Covid-19 vaccines is vital to ensuring rapid delivery to local populations. Without increased sharing of protected information to local contract manufacturing organisations (CMOs) the ability of the state to control when the product is delivered is much reduced.

It is not surprising, therefore, that the majority of agreements place significant obligations on the vaccine suppliers to use and/or establish local manufacturing facilities, especially for the production of the initial doses (Table 10).[96] Unfortunately, detail regarding specific manufacturing sites and third-party contractors has been redacted in most APAs. Nevertheless, from the EU initiated agreements it appears that the Commission sought to ensure, as far as possible, that manufacturing of the vaccine took place in Europe. AstraZeneca is obliged to use best reasonable efforts to manufacture the vaccine at sites located within the EU.[97] The geographical restriction is broader in the CureVac, Moderna and Sanofi/GSK agreements. CureVac and Moderna may not manufacture at sites outside the EU[98], EEA or Switzerland, with the Sanofi/GSK manufacturing locations being "predominantly" within the "European territory". With consent of the Commission, additional manufacturing sites may be used by most manufacturers if necessary to accelerate production and supply. The EU/Pfizer agreement is heavily redacted, making it impossible to be certain if any territorial restrictions have been placed on manufacturing. And while the EU/Janssen APA does not appear to include any express requirement for local manufacture, the "tentative availability schedule" does state that Janssen is scaling up manufacturing capacity in various European Member States with a view to making available vaccine volume from its European manufacturing sites.[99]

The UK agreements have similar geographical restrictions.[100] Valneva is committed to achieving a manufacturing facility within "the United Kingdom of Great Britain and Northern Ireland",[101] and manufacturing facilities in the AstraZeneca and Novavax agreements are defined in terms of a "UK supply chain." While each agreement is heavily redacted on this issue, AstraZeneca's obligation to ensure that the market authorisation granted will cover both the UK supply chain and *"the other manufacturing facilities in Europe"* suggests regional rather than national restrictions on manufacture. The same European regional restriction can be seen in the Novavax agreement with its validation of manufacturing sites extending to those outside of the UK but within the EEA. Finally, Pfizer commits to the UK government that the supply of goods will be made from Pfizer sites within the EEA, which

[94] Robert M Sherwood, "Global Prospects for the Role of Intellectual Property in Technology Transfer" (2002) 42 IDEA 27.
[95] Carlos M Correa, "Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?" in *International Public Goods and Technology Transfer under a Globalised Intellectual Regime* (CUP 2005); Daniel J Gervais, "Intellectual Property, Trade & Development: The State of Play" (2005) 74 Fordham L. Rev. 505, analysing whether increased IP protection in developing countries has led to increased FDI and trade flow.
[96] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1
[97] There is some uncertainty in clause 5 as to whether the UK is part of the EU for the purposes of manufacture of the "initial" doses (clause 5.1) or only the "optional" or "additional' doses. On a strict reading of the terms, the definition in 5.4, that the EU shall include the UK, is "for the purpose of this section 5.4 only" and thus not applicable to the definition of the "manufacture [of] the Initial Europe doses within the EU" in clause 5.1.
[98] In the CureVac agreement the UK is expressly considered a suitable manufacturing location. However, the UK is not expressly mentioned in the EU/Moderna APA.
[99] Exhibit A "Tentative Availability Schedule", (a). The Commission and Member States acknowledge that Janssen will rely on additional manufacturing capacity within its worldwide network, in particular in the United States.
[100] The only exception is the UK/Moderna agreement that, while heavily redacted, does not appear to include a local manufacturing obligation.
[101] Clause 3.2.2.

includes the UK. Many of these agreements also hint at the potential use of manufacturing facilities outside Europe and/or the EEA, but much of this information is redacted. It is fair to assume that, where necessary and with approval of the state, alternative locations may be sought to produce the product quickly.

In summarising the commitments towards local or regional manufacture, it is not clear how much is driven by the suppliers' manufacturing locations, the need for speed of delivery by removing risks associated with importation,[102] or any real aim to increase technology transfer to secure future manufacturing capacity in the UK and Europe. [103] It is probably fair to assume that all three played a role. This commitment to having the product produced as close as possible to its recipients was clearly a factor in the fast rollout of the vaccines in Europe, allowing the UK and EU member states to prioritise their health commitments to their own citizens. However, the local manufacturing obligation, while avoiding risks associated with a reliance on importation, has reinforced the problem of vaccine nationalism and has done little to increase the global manufacturing capacity. As observed by CEPI,

> "The Covid-19 pandemic has shone a light on some of the challenges within vaccine manufacturing and the overall vaccine ecosystem…For example, few nations currently have end-to-end capacity to translate basic research into vaccine products within their borders as they lack the manufacturing capacity to scale-up production for large-scale testing and distribution. This has meant these regions have become dependent on shipment of Covid-19 vaccines produced on other countries to inoculate their own populations – and they cannot always guarantee they will be first in line to receive these urgently needed doses."[104]

Redistribution of excess doses

In contrast to the conditions on local manufacturing, any provisions on the distribution of excess doses have greater potential to positively impact global vaccine supply.[105] In the agreement between the Commission and Members States on the procurement of vaccines there is a clear intention to ensure that, "Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort."[106] However, the IP rights associated with the vaccine technology, patents and trade marks in particular,

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[102] The risks associated with a reliance on imports is exemplified by the situation in India in March 2021. The Indian government blocked the Serum Institute from exporting its vaccine (the main supplier of COVID vaccine to the WHO's COVAX programme) in order to prioritise local vaccinations. Stephanie Findlay, Michael Peel and Donato Paolo Mancini, "India blocks vaccine exports in blow to dozens of nations" *Financial Times* (25 March 2021) https://www.ft.com/content/5349389c-8313-41e0-9a67-58274e24a019.

[103] In the Annex to the Commission decision on procuring vaccines for the Member states, it does state that a factor in the decision to award an APA is the "capacity to supply through development of production capacity within the EU" and "*possible flexible future use of capacity funded".* This suggests that consideration was given to facilitating technology transfer for the purposes of ensuring future pharmaceutical manufacturing capacity in Europe. EU Commission, "Annex to the decision on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures".

[104] CEPI, "Vaccine production efforts across key regions mapped ion first-of-its-kind study to prepare for future pandemics" https://cepi.net/news_cepi/vaccine-production-efforts-across-key-regions-mapped-in-first-of-its-kind-study-to-prepare-for-future-pandemics/.

[105] Jeffrey Lazarus *et al* estimate that vaccine wastage is running as high as 30% in some countries. The UK has reported vaccine expiration of 600,000 doses. They propose that "closed vial" wastage could be improved by better tracking and more timely redistribution of surplus vaccines. Jeffrey V Lazarus, *et al,* "COVID-19 Vaccine Wastage in the Midst of Vaccine Inequity: Causes, Types and Practical Steps" (2022) BMJ Global Health 7:e009010.

[106] EU Commission, "Annex to the Commission Decision on approving the agreement with Member states on procuring Covid-19 vaccines on behalf of the Member States and related procedures" 6.

have the potential to limit redistribution of the vaccine. IP rights are territorial in nature and can be asserted in each territory in which they apply to prevent the importation of infringing products, including the importation of products put on the market in another state by the IP holder.[107]

That being said, the principle of exhaustion of rights operates to limit the IP holders' ability to prevent redistribution. The principle of exhaustion is a policy-based limitation on IP rights in the interest of facilitating trade and the preservation of the autonomy of the owner of the physical property.[108] The law establishes that where products have been placed on the market within a specified territory with consent of the IP rights holder those rights can no longer be asserted to stop further resale or distribution of the goods within that territory.[109] The IP right to control further distribution is said to be 'exhausted' on the lawful 'first sale' of the goods, and it is not possible to exclude the principle of exhaustion, where applicable, by contractual agreement.[110] At the time of signing these agreements, the UK and EU operated under a system of regional IP exhaustion rules whereby IP rights on goods placed on the market in the UK, EU or EEA by or with consent of the IP holder would be considered exhausted within that territory.[111] Questions related to international exhaustion, where IP rights are exhausted globally on legitimate first sale anywhere in the world, are not provided for under UK/EU law and are generally left to be considered as part of the contractual arrangements between trading parties.

In our analysis we observed a range of approaches, and some inconsistency within the agreements on the issue of redistribution of excess doses (Table 11).[112] For example, the EU/Sanofi and GSK agreement on the one hand places an obligation on Sanofi and GSK to endeavour to provide at least 200 million doses to the Access to Covid-19 Tools (ACT) Accelerator, while simultaneously placing limitations on the EU Member states' ability to redistribute excess doses to countries in need.

The EU APAs all provide for the resale of excess doses to other EU and EEA member states.[113] With the exception of the EU/Janssen agreement, all EU APAs also provide for donation to EU and EEA states. The EU/Janssen agreement limits acts of donation to low- or middle-income countries and to supranational/international organisations or NGOs.[114] Many of the UK agreements also provide for

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[107] All agreements warrant that the vaccine will be delivered free from any third-party IP rights – See Table 12 https://doi.org/10.15131/shef.data.21583323.v1. While the EU/AstraZeneca agreement does not make an express warranty in this regard, clause 11.1 does acknowledge that AstraZeneca has pre-existing obligations to its upstream licensor.

[108] Justine Pila and Paul Torremans, *European IP Law* (2nd Ed OUP 2019), [2.4.2.1.3].

[109] *Deutsche Grammophon v Metro*, Case 78/70 [1971] E.C.R. 487; *Merck & Co. v Stephar*, Case 187/80 [1981] E.C.R. 2063; *Centrafarm v Sterling Drug*, Case 15/74 [1974] E.C.R. 1147; *Centrafarm v Winthrop*, Case 16/74 [1974] ECR 1183. While most national laws define the geographical scope nationally or regionally, it is possible for rights to be exhausted internationally – i.e., where IP rights are exhausted on legitimate first-sale anywhere in the world.

[110] *Peak Holding AB v Axolin-Elinor AB,* C-16/03 [2004] E.C.R. I-11313.

[111] Post-BREXIT, the UK currently continues to recognise and apply the EEA regional exhaustion regime, thus IP rights associated with goods placed on the market in the UK, EU or EEA by or with consent of the IP holder will be considered exhausted in the UK and thus allowed to be 'parallel' imported into the UK. A consultation on the future direction of UK exhaustion rules was conducted by the IPO, concluding in August 2021, but a decision has not yet been forthcoming. However, as of the end of the BREXIT transition period, 31 December 2020, EU law no longer incorporates the UK. All of these agreements were concluded before the end of the transition period and it may be assumed that the UK will still be considered part of the EU for the purposes of EU exhaustion. If not, the result is that goods protected by IP rights and lawfully placed on the market within the UK are not exhausted within the EU, and EU vaccine IP rights can potentially be enforced to prevent the importation into the EU from the UK.

[112] Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[113] The EU/AstraZeneca agreement only expressly covers donation and resale to EU states (plus public organisation and low to middle income countries): see Table 11, Hawkins and Slade, Dataset. https://doi.org/10.15131/shef.data.21583323.v1

[114] Clause I.4.7.2.

the resale or donation of the vaccine to other European countries, including non-EEA states, except for the UK/Pfizer and UK/Valneva agreements. The Valneva agreement states that, "the product may be made available to *developing countries* around the world to help control the pandemic".[115] The Pfizer APA restricts redistribution to acts of "donation" and only to those countries "in-need" or public institutions contributing to the global vaccine distribution effort. Further acts of resale or donation to countries other than those "in need" are only possible to the extent permitted by law. This is taken to include reference to the rules governing IP exhaustion discussed above, and thus subject to these rules, redistribution of doses by the UK within the EEA would be possible.[116]

The principle of exhaustion that facilitates parallel trade within the EEA does not extend to redistribution outside of this territory and many developing states have not legislated for the exhaustion of IP rights.[117] Consequently, the IP rights could be asserted to prohibit parallel imports to the states that most need access.[118] The redistribution of vaccines to countries outside the UK, EU and EEA is, therefore, very dependent upon the terms, both express and implied, in the APAs.

The UK agreements mostly provide for the redistribution of doses to any country outside the EEA and to organisations contributing to the global distribution effort, such as the ACT Accelerator. However, the clauses are heavily redacted making it impossible to comment on any conditions placed on redistribution outside the EEA. We note that the UK/Valneva and UK/Pfizer agreements, however, reserve redistribution to "developing countries" or countries 'in need", and the UK/Moderna agreement prevents redistribution to countries to which Moderna already provides product[119]. In the EU/AstraZeneca agreement, EU Member States reserve the right to determine the best use of excess doses, including the right to donate them to lower or middle-income countries or public institutions. The EU agreements with Sanofi/GSK, CureVac, Janssen and Moderna all require express permission to be sought from the vaccine supplier before redistribution outside the EEA can occur. While the most agreements state that consent is not to be unreasonably withheld, there are a significant number of clauses that could be relied upon to justify *reasonably* denying permission. Some of these clauses are also applicable to redistribution within the EEA.

For example, most agreements require the receiving state to be bound by the indemnification clauses in the original APAs, and any resale cannot be for profit.[120] In addition, any EU state that redistributes excess doses must agree to reimburse the Commission the upfront/down payment made to the supplier in relation to the doses being resold. Furthermore, and unique to the EU/Sanofi and GSK agreement, is the requirement that any receiving state or international organisation must have already concluded a vaccine purchase order with Sanofi and GSK. If not, then any redistribution or donation will be subject to notification to and approval of Sanofi and GSK. Finally, the EU/Janssen agreement allows Janssen to influence the volume of vaccine to be donated to third countries. Although, the

[115] Clause 28.1.
[116] Practical guidance on parallel importation and the legal restrictions can be found at LexisPSL "Practice Note on Parallel Imports" (2022).
[117] This is despite the Agreement on Trade Related Aspects of Intellectual Property Rights, art 6 allowing Member States significant flexibility to adopt their own rules on exhaustion and parallel trade.
[118] For a comparative study on the rules related to IP exhaustion and parallel importation of pharmaceutical products see Irene Calboni, "IP Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review" in *Access to Medicines and Vaccines: Implementing Flexibilities under Intellectual Property Law* (Springer 2022).
[119] Clause 3.11. The UK/Moderna agreement also prevents redistribution to organisations or countries identified as "restricted persons" e.g., the target of sanctions or identified by the US government as not to be commercially engaged with.
[120] The redistribution clauses in the UK agreements are subject to redactions. We assume the redactions prevent access to the conditions placed upon redistribution which we suspect includes similar restrictions to those found in the EU agreements. The EU/CureVac appears to reserve the right to sell "for profit" to other EU, EEA states, as it only expressly excludes "for profit" sales outside the EU, EEA and Switzerland, clause I.10.3.

optimisation of worldwide allocation of a vaccine is a significant factor in reaching a mutually agreeable decision.

While not expressly restricting redistribution, several additional clauses could also frustrate any redistribution effort. The later agreements concluded by the EU with CureVac and Moderna both state that the donating EU Member State or receiving country is to assume responsibility for regulatory/quality/good manufacturing practice/good distribution practice processes. Any obligation placed on Moderna to obtain market authorisation in the receiving country is grounds to withhold consent to redistribute, and CureVac have only agreed to support or execute the implementation of these processes in the case of donation or resale to another EU, EEA state or Switzerland. In all other instances, the donating EU state or recipient country, and not CureVac, shall assume all responsibility for these requirements. These limitations indicate an unwillingness to share clinical trial data and associated manufacturing and distribution know-how.

The following table provides a visual representation of the contractual data on the redistribution of excess doses. Please note, however, that there is significant variation between the agreements. And while we have grouped the contractual conditions on redistribution into related themes, in doing so, some of the more nuanced differences have not been captured:

APAs	*Resale*	*Donation*	*Permission of supplier required*	*EU Commission to be reimbursed for related payments*	*Recipient to be bound by APA obligations/Offer indemnification*	*Supplier will(+)/will not(-) support regulatory, quality, GMP, GDP processes*	*Recipient to have(+)/or not to have(-) concluded a vaccine order with supplier.*
EU/AZ	●♦	●♦	-	●♦	●♦	-	-
UK/AZ	●♦	●♦	?	n/a	?	?	?
UK/Valneva	♦	♦	?	n/a	?	?	?
EU/Sanofi/ GSK	●♦	●♦	♦	●♦	●♦	-	●♦(+)
UK/Pfizer	●	●♦	?	n/a	?	?	?
EU/Janssen	●♦	♦	●♦	●	●?	●(-)	?
UK/Novavax	●♦	●♦	-	n/a	●♦	●(-)♦(-)	-
EU/Pfizer	●♦	?	?	●♦	?	?	?
UK/Moderna	●♦	●♦	♦	n/a	?	●(-)♦(-)	● ♦(-)
EU/CureVac	●♦	●♦	♦	●♦	●♦	●(+)♦(-)	-
EU/Moderna	●♦	●♦	♦	●♦	●♦	♦(-)	-

• Indicates redistribution to EU and/or EEA member state/s (EU/CureVac also includes Switzerland).

♦ Indicates redistribution to recipient countries outside the EU/EEA/Switzerland.

? Indicates that redactions make it impossible to establish if such a clause exists.

The inclusion of contractual conditions on redistribution is of significance. First, they have the potential to undermine the EU exhaustion principle by allowing suppliers to rely on contractual provisions, rather than IP law, to control parallel importation. This is despite the commitment that permission to redistribute is not to be unreasonably withheld. Establishing whether the other party acted unreasonably in exercising its discretion places a significant burden on the party challenging such a decision.[121] It is important to note that the EU Member State/Commission, as a contracting party, will be subject to EU rules on the free movement of goods, making any contractual term that undermines EU exhaustion principles subordinate to legal principles that protect free movement, including competition law.[122] Nevertheless, any contractual restriction, whether legally enforceable or not, is still likely to have a chilling effect on states' behaviour when considering whether to redistribute excess doses.

Second, for redistribution outside the EEA, the contractual conditions prevent the international exhaustion of IP rights being implied into the contract. For example, under English law, the concept of 'common law exhaustion' or, more properly, 'implied licence' is dependent upon the terms, or lack of terms, in the contract. Unless it is 'brought home' to the purchaser that there are restrictions on further use of the patented goods, then they take them free of patent restrictions, and further disposal is unrestricted by the patent right.[123] Absent any rules in the receiving state, the extent of the principle of international exhaustion is, therefore, left to contract law and the concept of implied terms and any implied terms can always be supplanted by express terms in that contract. Therefore, in the case of the APAs, the limitations on further redistribution are permitted within the bounds of contract law, giving the IP holder the right to impose conditions on further dealing in the wider international market through contract in this way.[124]

Consequently, while there is substantial variation between the agreements, they do appear to signal some attempt to indirectly leverage IP rights to extract a further benefit, despite the patented goods being put on the market through this initial agreement; or, at the very least, they endeavour to control the further distribution of the patented vaccines. This can be construed as merely an attempt to ensure

[121] For example, under English law, the question of reasonableness in the exercise of contractual discretion has been the subject of significant scrutiny from the Appellate courts in recent years. The general obligation is that the decision-making power is to be exercised honestly, rationally and in good faith. However, the burden firmly rests on the party challenging the decision and what amounts to 'unreasonableness' may differ according to the context. For a more detailed discussion, see *Chitty on Contracts (34th Ed.),* Chapter 2, Section 4 – "Good Faith, Contractual Fairness and Reasonableness".

[122] The legal principle of horizontal *direct effect* of treaty provisions does not readily extend to horizontal contractual relationships that hinder the free movement of goods, see *Sapod Audic*, C-159/00 [2002] ECR I-5031 [74]. However, where one of the parties is an EU Institution or EU state actor, e.g., in a procurement contract, the legal principles of free movement of goods are applicable to the enforcement of the contract. *Commission v Ireland (Dundalk Council)*, Case 45/87 [1988] ECR 4929. See also Gareth Davies, "Freedom of Movement, Horizontal Effect, and Freedom of Contract" (2012) 3 European Review of Private Law 805, 818-820.

[123] *Roussel Uclaf S.A. v. Hockley Int'l Ltd.,* (1996) R.P.C. 441 (P.C.) 445; *Betts v. Willmott* (1871) LR 6 Ch. 239; *National Phonograph Co of Australia Ltd v Menck* [1911] A.C. 336.

[124] *National Phonograph Co of Australia Ltd v Menck* [1911] A.C, 336, 349-350.

legitimate and appropriate use, but the potential of these provisions to extend beyond such reasonable controls is clear.

Beyond any legal restrictions on the application of contractual limitations, we question the underlying policy reasons for their inclusion. What purpose is served by including these limitations on the further distribution and use of excess doses? Concerns over responsibility for product recalls and pharmacovigilance, etc. appear to be covered by requiring the receiving state to be bound by the obligations contained within the original APA.[125] Pharmaceutical companies may have commercial reasons to limit redistribution, to ensure that they can sell to these markets. However, we query whether such motivations are reasonable in a pandemic. At the time of these agreements and for many months following, there was a pressing global shortage of vaccines, and any spare doses would have contributed to the global vaccination effort. Perhaps more importantly, why have governments, who should be motivated by public policy concerns, agreed to these conditions which limit the global redistribution of much needed vaccines? Surely governments should have exercised their bargaining rights to remove, or limit the impact of, these clauses from the agreements.

Summary analysis of the IP provisions of the APAs

The APAs examined in this study are all in substance providing pull incentives for the development of the vaccines, rather than merely agreements for the supply of an existing product. Technological developments by these companies, and their associated intellectual property protection, were therefore an inevitable consequence of the agreements, and the IP provisions of those agreements are therefore key. All agreements examined provide a definition of IP rights, with noted similarities. All definitions are broad and cover all registered and unregistered rights, technical knowledge, and data. All agreements also provide extensive obligations to the other party in relation to confidential information, with associated non-disclosure obligations.

Although there is variation in the terms of the APAs in relation to the ownership and exploitation of IP rights arising by virtue of the performance of the agreement, as outlined above, what is consistent across all agreements is the control that the pharmaceutical companies have maintained over these valuable IP rights. Although there was clear public interest in rapid vaccine development, there also must be accountability in public spending and procurement. As noted above, these favourable IP terms secure control in favour of the pharmaceutical companies and, in doing so, minimise the importance of other public interest considerations.

The remaining provisions of the agreements fail to adequately redress this imbalance. Provisions around access to test data fail to secure acceptable government or public access to enable research and the future development of related or other vaccines. Insufficient contractual guarantees are provided to ensure march-in rights in the case of abandonment. The provisions on location of manufacture seem focused on ensuring local access to vaccines themselves, but do not ensure wider technology transfer or sharing of know how. Finally, provisions which provide restrictions on the redistribution of excess doses appear to frustrate the policy objectives of enabling the sharing of vaccines beyond the UK and EU.

Overall, the APAs evidence strong IP protections for pharmaceutical companies, but weak safeguards and protections for the government parties, with resultant lack of regard to and protection of the public interest. The following explores the implications of this imbalance, in the light of incentive-based theories of IP law and policy.

[125] Pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem." European Medicines Agency https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview

Justifying contractual controls over IPRs

In this section, we argue that the APAs should be viewed not merely as administrative procurement agreements but rather as policy levers to protect the wider public interest. Taken together, the basic economics of supply and demand, the duty of the state to protect its citizens, and the legal principle of freedom of contract might combine to forgive governments for failing to play close attention to IP rights early in the pandemic. At the time these contracts were concluded, governments were under immense pressure to act, and pharmaceutical companies held the key to controlling the impact of COVID-19. Yet, beyond matters of relative bargaining power, the circumstances outlined in the paper reveal questions fundamental to why states grant and protect IP in the first place.

There are numerous discipline specific arguments that can be advanced to support the state securing favourable terms in relation to IP rights arising over vaccine technology, including those from public health, economics, and political perspectives and the need to foster innovation. We touch upon several of these in our discussion below. Nevertheless, we link our arguments back to the primary rationales that justify the grant of IP rights, that of incentive-based theories of IP law. We accept the value of IP and its significance in incentivising risk-taking and development. However, where the incentivisation effect of IP either fails and/or is offset by further state intervention, the scope of IP rights must be questioned. Absent any truly effective statutory mechanisms that provide appropriate safeguards, that role must ultimately pass to the contractual arrangements concluded by the state.

The diminished logic of incentive-based theories for IPRs

The state is actively involved in encouraging valuable research activity through both 'push' and 'pull' incentivisation strategies.[126] The former, commonly in the form of public research grants or tax credits on R&D, aim to reduce the costs and risks associated with early R&D, and they do so irrespective of the success or failure of the research activity. Pull strategies, on the other hand, seek to provide rewards to those who successfully develop a useful end-product, by enhancing or securing a future revenue stream.[127] IP rights and data exclusivity protection are examples of well-established regulatory pull strategies that indirectly support an economic environment that incentivises R&D. Nevertheless, in some instances the returns promised by the IP system are insufficient to entice companies to undertake the necessary R&D to bring a product to market (or to clinic). The risks and unpredictability involved in the research, development, and commercialisation of certain pharmaceutical products forces governments to look beyond traditional IP incentive structures to offer more direct support.[128] Healthcare situations where alternative incentive strategies have been required include financing for the development of antibiotics and antifungals for the treatment of antimicrobial

[126] Use of the terms 'push' and 'pull' incentives is more usually associated with the development of treatments where a limited market exists for the end product. For example, pharmaceutical companies have been reluctant to invest in developing new antibiotics that are only intended to be used sparingly. Elias Mossialos *et al,* "Policies and Incentives for Promoting Innovation in Antibiotic Research" 2010 European Observatory on Health Systems and Policies, https://apps.who.int/iris/bitstream/handle/10665/326376/9789289042130-eng.pdf; Pedro Henrique D Batista, *et al,* "IP-Based Incentives Against Antimicrobial Crisis: A European Perspective" (2019) 50 IIC 30; Pascale Boulet *et al,* "Advanced Purchase Agreements for COVID-19 Vaccines: Analysis and Comments".

[127] These alternative pull or "supply side response mechanisms" include, for example, prizes for innovation, orphan drug incentives, patent buyouts, and, importantly in our case, APAs.

[128] Jonathan J Darrow, Michael S Sinha & Aaron S Kesselheim, "When Markets Fail: Patents and Infectious Disease Products" (2018) 73 Food and Drug Law Journal 361. For a recent and detailed overview of R&D in the pharmaceutical sector and factors influencing R&D spending, including the impact of government policy decisions on funding, tax, regulations, etc see Congressional Budget Office, "Research and Development in the Pharmaceutical Industry' (April 2021) https://www.cbo.gov/publication/57126.

resistant diseases where the end-products are to be used sparingly;[129] and the development of treatments for neglected diseases where both market failures and inadequate public health policies undermine R&D in this area.[130]

As the rest of this section will demonstrate, both push and pull strategies are operational in the context of COVID-19 vaccines and their use alters the incentive-based rationale for IP rights. Therefore, we argue that restrictions on their use are justified.

State 'push' financing for COVID-19 vaccines

There is widespread recognition of the role that 'push' funding plays in early stage 'blue skies' research, which is far upstream of commercialisable outcomes. For example, both the mRNA and viral vector platforms utilised by the key COVID-19 vaccine producers were the subject of many years of research prior to the outbreak of the COVID-19 pandemic, with much of the ground-breaking activity undertaken by publicly funded institutions, such as universities and research institutes.[131] When the pandemic struck, state push funding strategies moved beyond supporting 'blue skies' research, or, more plainly, research for its own sake, to incentivise the development of identifiable technologies, such as vaccines.[132]

Where significant amounts of public money are used to directly fund background and/or follow-on technology, it is reasonable to expect appropriate safeguards on the exploitation of any existing and

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[129] Elias Mossialos *et al, "*Policies and Incentives for Promoting Innovation in Antibiotic Research". For a discussion of IP incentives in relation to antimicrobials, see Pedro Henrique D Batista, *et al,* "IP-Based Incentives Against Antimicrobial Crisis: A European Perspective" (2019) 50 IIC 30.

[130] Frank Mueller-Langer, "Neglected infectious diseases: Are Push and Pull incentive mechanisms suitable for promoting drug development research?" (2013) 8 Health Economics, Policy and Law 185.

[131] In a detailed investigation into the financing behind the Oxford/AstraZeneca vaccine, Samuel Cross *et al* estimate that state and charitable funding accounted for between 97-99% of the funding received to develop the chimpanzee adenovirus-vectored vaccine technology (ChAdOx): Samuel Cross *et al,* "Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine?". Furthermore, the underlying mRNA technology utilised by both Moderna and BioNTech/Pfizer has its origins in the research undertaken by several universities and publicly funded research institutions, including the Universities of Pennsylvania and British Columbia: Gaviria & Kilic, "A network analysis of COVID-19 mRNA vaccine patents".

[132] For example, in 2020, Moderna received approximately $955 million from the US government's Biomedical Advanced Research and Development authority (BARDA) to develop their vaccine (CureVac, "CureVac expected to receive up to 252 million Euros from the German Federal Ministry of Research for further COVID-19 vaccine development and production expansion capacity" (Press release, 2 September 2020) https://www.curevac.com/en/curevac-expected-to-receive-up-to-252-million-euros-from-the-german-federal-ministry-of-research-for-further-covid-19-vaccine-development-and-production-capacity-expansion/) CureVac was promised €252 million by the German Federal Ministry of Research to directly support the development of its vaccine. This was in addition to a €300 million investment into the company made by the German Federal Government in June 2020. The Sanofi/GSK vaccine collaboration and Novavax were together awarded over $3.5 billion by the US government under Operation Warp Speed, much of which was to directly support the development (rather than mere supply) of their proposed COVID vaccines, Sanofi, "Sanofi and GSK selected for Operation Warp Speed to supply the United States government with 100 million doses of COVID-19 vaccine" (Press release, 31 July 2020) https://www.sanofi.com/en/media-room/press-releases/2020/2020-07-31-11-00-00-2071010; Novavax, "Novavax announces $1.6 billion funding from Operation Warp Speed" (Press release, 7 July 2020) https://ir.novavax.com/2020-07-07-Novavax-Announces-1-6-Billion-Funding-from-Operation-Warp-Speed. And, while Pfizer have repeatedly denied the acceptance of public funding for the development of their COVID vaccine, this is only true to the extent that they did not accept direct funding for this purpose. The German government provided €375M in funding to Pfizer's partner, BioNTech, to support vaccine development (BioNTech, "BioNTech to receive up to €375m in funding from German Federal Ministry of Education and Research to support COVID-19 vaccine program BNT162" (Press release, 15 September 2020) https://investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-funding-german-federal-ministry).

arising IP rights, in favour of the state, and to improve access to the end product.[133] Traditional push funding strategies often require the imposition of IP related safeguards – such as conditions over ownership rights to generated IP, the right to impose licensing restrictions, or an obligation on the licensee and subsequent sublicensees to make royalty payments.[134] Examples of these IP control mechanisms can be found in university tech transfer agreements and university/business collaboration contracts.[135] There is much debate about whether IP and the related restrictions are a positive means of protecting the public interest, or whether they amount to unreasonable and unhelpful restrictions which chill further research or which limit options for commercialisation and technology transfer.[136] That debate is beyond the scope of this work. Nevertheless, the objective of an equitable funding system is to ensure that law and policy provide a fair and justifiable way of rewarding those who invest, in terms of time and money, in the process of innovation by fairly regulating the exploitation of that investment.

The push funding model, therefore, is one that supports two related assertions. First, where public resources have played a central role in the development of technologies, IP safeguards are accepted as necessary to protect the wider public interest, including to secure a return on public investment and to ensure public access to publicly funded outputs.[137] Second, this constraint on the use of exclusive IP rights by contractual arrangement on the authority of the state is, by implication, acknowledgement that the incentivisation rationale for granting IP rights is diminished where the state has played an active role in financing development.

State 'pull' financing for COVID-19 vaccines

It has long been recognised that public procurement can form an important part of a state's innovation policy and a means to drive demand for new products and services where business investment in R&D is weak.[138] The move away from viewing procurement as a mere administrative function and

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[133] Statutory measures such as compulsory licensing and, in the UK, Crown use do exist to facilitate access to patented technologies in limited circumstances. However, the calls for an amendment of the WTO TRIPS Agreement to provide a waiver of patent for COVID technologies is testament to the inability of current legal safeguards to address the access problem in many situations. For an analysis of the reforms thought necessary to the Patents Act 1977 see Johnathon Liddicoat and James Parish, "Ironing out the Wrinkles: Reforms to Crown use and compulsory licensing to help prepare the Patents Act 1977 for the next health crises".

[134] See for example, the National Institute for Health and Care Research "approach to intellectual property' https://www.nihr.ac.uk/researchers/manage-your-funding/manage-your-project/intellectual-property.htm; The NIHR Research Contract – Global Health Research Example, in particular clauses 11, 16 and 17 https://www.nihr.ac.uk/documents/nihr-research-contract-global-health-research-example/27845; Wellcome, "Consent and Revenue and Equity Sharing Policy" https://wellcome.org/grant-funding/guidance/intellectual-property-guidance/consent-revenue-equity-sharing-policy.

[135] Thi-Yen Nguyen, Mohammad Shahzad, Juliana Veras, "Recent Experience in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America: Identifying Key Provisions to Promote Global Access to Health Technologies" (2019) Les Nouvelles Online https://www.lesi.org/publications/les-nouvelles/les-nouvelles-article-of-the-month/les-nouvelles-article-of-the-month-archives/les-nouvelles-article-of-the-month-february-2019.

[136] Michael A Heller and Rebecca S Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698; Jorge L Contreras, "In the Public Interest – University Technology Transfer and the Nine Points Document – An Empirical Assessment" (2022) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3990450#; Karen Walsh *et al*., "Intellectual Property Rights and Access in Crisis" (2021) 52 IIC 379; Hawkins, *Patenting Biotechnical Innovation: Eligibility, Ethics and Public Interest;* Claude Henry and Joseph E. Stiglitz, "Intellectual Property, Dissemination of Innovation and Sustainable Development" (2010) 1 Global Policy 237-251.

[137] For a review of this debate in the US context see Bhaven N Sampat and Kenneth C Shadlen, "The COVID-19 Innovation System" (2021) 40 Health Affairs 400.

[138] Jakob Edler and Luke Georghiou, "Public Procurement and Innovation: Resurrecting the Demand Side" (2007) 36 Research Policy 949, 952.

towards harnessing its research and innovation impact is clearly evident in the context of COVID-19 vaccine development, where alternative pull funding strategies in the form of advanced purchase agreements were adopted by governments around the world to expedite development and production of a safe and effective vaccine for the disease.

Justification for the use of APAs can be found in the extensive literature which debates the incentivisation value of IP protection in particular fields, including health.[139] Much of the writing in this area promotes the use of alternative 'pull' funding strategies, such as prizes, to finance pharmaceutical innovation where consumer demand and/or the ability to pay is limited, thereby reducing the market-driven motivation to innovate. For the purposes of this analysis, we accept this argument in principle and acknowledge APAs as a valuable mechanism that could be utilised to expedite innovation in times of crisis.

In line with the previous discussion on state facilitated push funding, the public purse equally demands from APAs an appropriate return on its investment. But when framed in these terms, this argument can be used to support a whole range of applicable benefits, including price discounts, robust payback obligations for non-delivery, and priority distribution. And while we acknowledge that governments are under an obligation to protect their citizens, it might even extend to justifying a policy of vaccine nationalism. We resist that interpretation, and instead employ the rationale behind incentive-based theories of IP law to justify restrictions on private property rights in this context.

It must be remembered that these alternative 'pull' incentive systems are just that – replacements for IP protection where the incentive effect of IP fails to deliver results. Before we advance this 'alternative incentive strategy' argument to justify controlling the application of IP rights on COVID-19 vaccines, it is first necessary to understand why states felt it necessary to use APAs to advance COVID-19 vaccine development. Clearly the market-driven incentives to provide a viable vaccine were significant.[140] An effective vaccine product would have global reach and be approved for immediate use by virtually the whole adult population. Thus, because there was no pipeline crisis *per se,* the market incentives of IP rights did not fail – the monopoly profits secured by the rights would be vast.[141] The use of APAs was not, therefore, as a response to market failures but to expedite the innovation process, i.e., not just to incentivise companies to act, but to incentivise them to act more quickly. APAs achieved this by de-risking the development process for pharmaceutical companies.

State 'de-risking' of private R&D

State funding strategies are an effective means to 'de-risk' private R&D. Push strategies do so by providing early-stage funding for risky and speculative research with no guaranteed reward. Pull funding, in the form of APAs, functions to both incentivise pharmaceutical development activity by

[139] See for example Webber and Kremer, "Perspectives on Stimulating Industrial Research and Development for Neglected Infectious Diseases".
[140] Mark Eccleston-Turner, "The Economic Theory of Patent Protection and Pandemic Influenza Vaccines: Do Patents Really Incentivise Innovation in the Field" (2016) 42 AM. J. L. & Med. 572, 584 noting that in a pandemic a viable market for a successful vaccine will exist. Demand for the vaccine will outstrip supply, with governments hoping to secure as much of the finite resource as they can, and compulsory licenses or government use authorisations are not viable access tools.
[141] The recent financial returns of the pharmaceutical companies behind the approved vaccines have shown this to be the case. See for example, Jamie Smyth, "Pfizer raises 2021 sales forecast for Covid vaccine to $36bn" *Financial Times* (2 November 2021) https://www.ft.com/content/5054863d-2c1e-4e2b-89ab-5d1a4a2ff0f8; Hannah Kuchler, "Covid vaccine helps push AstraZeneca to record revenues" *Financial Times* (London, 10 February 2022) https://www.ft.com/content/2227262f-b240-407c-b02c-597f481cc121; Hannah Kuchler, "BioNTech beats forecast on back of Covid vaccine demand" *Financial Times* (9 May 2022) https://www.ft.com/content/99f0f75a-e24b-4e98-8de3-1d326a28a093.

guaranteeing the end market, and also to reallocate the risks associated with product development to the state, which is better able to bear the burden.[142] As declared by the EU Commission in June 2020,

> "[Advance purchase agreements] will de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain which is required for a rapid deployment of sufficient doses of an eventual vaccine in the EU and globally."[143]

Given the financial risks involved in drug/vaccine development,[144] pharmaceutical companies traditionally limit their exposure by developing products in sequential steps, reassessing the results of each staged trial in order to evaluate efficacy and commercial viability before progressing to the next.[145] This approach, while sound from both a financial and safety perspective, means that the established vaccine development model is protracted, taking around ten years from initial conception to market authorisation.[146] Nevertheless, despite a natural predisposition towards risk minimisation, the financial security provided by the APAs allowed vaccine developers to undertake "preclinical and phase I, II and III trials, as well as manufacturing, in parallel instead of sequentially."[147] This de-risking of the development process succeeded in incentivising companies to act with unprecedented speed.[148]

Yet, risk reallocation, which is a natural consequence of alternative 'pull' funding strategies, also reduces the justification for the strong monopoly rights of the IP system. It is widely accepted that IP rights, particularly patents, exist to encourage an inventor to innovate by providing a means, arising by way of an awarded monopoly, to generate an income based on the innovation.[149] Where risks have been taken during the development of the invention into a marketable product, then the patents system

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[142] Boulet *et al,* "Advanced Purchase Agreements for COVID-19 Vaccines: Analysis and Comments" 10.
[143] EU Commission, "EU Strategy for COVID-19 Vaccines" (Communication) COM (2020) 245 final [2.2].
[144] A 2018 study estimated that the cost of advancing a single epidemic infectious disease vaccine candidate from preclinical to the end of phase IIb trials can cost $31-68 million, assuming no failure. The total cost was significantly higher if the probability of success of the vaccine was a factored into the analysis – e.g., 11 to 21 preclinical candidates would be required for at least one to progress to the end of phase 11b. Dimitrios Gouglas *et al,* "Estimating the cost of vaccine development against epidemic infectious diseases: A cost minimisation study" (2018) 6 Lancet Global Health e1386, e1390.
[145] See for example the explanation of the Covid vaccine development and approval process as contrasted with standard vaccine development and approval outlined by the European Medicines Agency: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring.
[146] EU Vaccination Informational Portal, "Approval of Vaccines in the European Union" https://vaccination-info.eu/en/vaccine-facts/approval-vaccines-european-union.
[147] A quote from Rino Rappuoli, chief scientist at GlaxoSmithKline's vaccines division in Siena, Italy. Philip Ball, "The lightning-fast quest for COVID vaccines – and what it means for other diseases" (2020) Nature News Feature https://www.nature.com/articles/d41586-020-03626-1.
[148] The mRNA and viral vector platforms utilised by the key vaccine producers had been the subject of many years of investment prior to the outbreak of the COVID-19 pandemic. Nevertheless, the speed at which the vaccines were developed was unprecedented. See for example, McKinsey, "Fast-forward: Will the speed of COVID-19 Vaccine Development Reset Industry Norms?" https://www.mckinsey.com/industries/life-sciences/our-insights/fast-forward-will-the-speed-of-covid-19-vaccine-development-reset-industry-norms.
[149] As observed by Frederic M Scherer, "Governments have chosen to grant exclusive patent rights on inventions for three main reasons: to promote invention, *to encourage the development and commercial utilization of inventions*, and to encourage inventors to disclose their inventions to the public". Frederic M Scherer, *Industrial Market Structure and Economic Performance* (3rd edn, Houghton Mifflin 1990) 440 [emphasis added].

has the effect of rewarding the taking of that risk.[150] Exclusive property rights seek to compensate the holder for the promotion of scientific and technological progress and the risks undertaken in doing so.[151] When the risks of both invention and subsequent innovation, i.e. the investment risks in bringing an invention to market, are lessened or even removed through both push and pull state funding strategies, the weakening of the innovator's position in relation to acquiring/acquired IP rights should be a natural consequence. Other 'pull' strategies such as rewards, prizes and patent buyout schemes, are often rationalised on the basis that societies' return for governments' shouldering the economic risks is that "innovations would pass immediately into the public domain, becoming freely available to all."[152] This may come about through a general lack of renewal or enforcement by the IP right holder, because the protected technology has limited market value, or because the state or institution behind the alternative pull mechanism demands disclosure. If we apply the same rationale to APAs, it therefore follows that APAs should, at the very least, include safeguards to ensure that patent and other IP rights do not unreasonably restrict fair and equitable access in the healthcare context, nor permit excessive rewards to accrue to IP right holders.

Today these alternative systems of financing innovation are all too often supplements rather than alternatives to the existing IP system.[153] They exist in addition to IP rights, with both incurring costs for the consumer in terms of higher taxes used to fund innovation, and also higher costs associated with accessing IP protected products.[154] However, their purpose as alternatives to IP rights is not only to encourage innovation but also to facilitate access in ways not easily achieved by the IP system alone. Therefore, as a minimum, these alternative mechanisms used to fund vaccine innovation should provide significant IP controls to protect the public interest. The nature of this state intervention, in our opinion, fundamentally alters the rationale for the grant and unfettered exploitation of IP rights.

Time to redress the diminished logic

As our analysis of the agreements above has shown, there are no significant safeguards in the APAs to address the access concerns highlighted earlier in the paper. Many of the agreements do touch upon measures that could, if drafted differently, contribute to appropriate controls of IP rights. Yet, the provisions included in the APAs we examined provide limited leverage in this regard. In fact, there are clauses which are actively counter to the global access initiative, and have no reasonable justification, such as the provisions that control the redistribution of excess doses. In the absence of

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[150] Jay Kesan, "Economic Rationales for the Patent System in Current Context" (2015) 22 Geo. Mason L. Rev. 897.F Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions" (2001) 85 Minnesota Law Review 697. As noted by Adam Smith, "[Patents can'] be vindicated [as] the easiest and most natural way in which the state can recompense [inventors] for *hazarding a dangerous and expensive experiment*, of which the public is afterward to reap the benefit". Adam Smith, "An Inquiry into the Nature and Causes of the Wealth of Nations" (London: W. Strahan and T. Candell 1776) as highlighted by Benjamin N Roin, "IP Versus Prizes: Reframing the Debate" (2014) 81 U Chi. L. Rev. 999, 1028 [emphasis added].

[151] The 'reward' theory of patent law is not to be seen in isolation. Patent rights provide compensation/reward for the inventors' risk of failure, thereby promoting further inventive activity.

[152] Michael Kremer, "Patent Buyouts: A Mechanism for Encouraging Innovation" (1998) 113 Quarterly Journal of Economics 1137, 1138; Steven Shavell & Tanguy van Ypersele, "Rewards versus IP Rights' (2001) 44 Journal of Law & Economics 525, 525.

[153] See, for example, the 2008 study conducted by Knowledge Ecology International which highlights that prizes are regularly not structured as replacements for IP rights. Knowledge Ecology International, "Selected Innovation Prizes and Reward Programmes" (2008) KEI Research Note 1 http://www.keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf.

[154] This "paying twice" argument is one advanced by many public interest groups and the media. See for example, Public Citizen, "Paying Twice for a Vaccine: Moderna is Taking Taxpayers for a Ride" (5 August 2020) https://www.citizen.org/news/paying-twice-for-a-vaccine-moderna-is-taking-taxpayers-for-a-ride/; Quartz, "In the push for new vaccines, taxpayers keep paying and paying" (12 May 2021) https://qz.com/2006390/taxpayers-are-paying-twice-or-more-for-the-covid-19-vaccine/.

external safeguards, such as through legislative intervention, such safeguards must be included in these types of agreements in the future.

This argument finds traction in the theoretical foundations of the IP system itself. It is hard to justify the maintenance of unconstrained exclusionary property rights when their function, the incentivisation of technological and informational development, is being performed by other mechanisms – in this case APAs. IP rights are not immune to curbs on their exploitation where other policy objectives take priority. Statutory exceptions to IP rights and other legislative controls such as competition regulation are useful examples, but the adaptation of statutory regimes to deal with new or unexpected challenges is slow. Procurement contracts, therefore, provide the ideal opportunity to safeguard or implement protection for specific interests, especially when speed is of the essence. Given that States are one of two parties to these agreements, and hold significant bargaining power, in our view this bargaining power must be fully leveraged to include necessary safeguards for the public interest.

Conclusion

The COVID-19 pandemic has once again brought into sharp focus the two sides to the innovation ecosystem. On the one hand, the pace of development of the COVID-19 vaccine was unprecedented, with a vaccine being available for roll-out very quickly, compared to the normal timeline for development. At the same time, the pandemic has highlighted the obstacles which IP rights can pose for the global dissemination of and access to important medical technologies. This paper has sought to address questions around the role of IP rights in the development and dissemination of vaccine technologies through examination of the IP terms in the APAs.

In so doing, we have argued that the nature and scope of the IP and IP-related contractual clauses included in the APAs concluded by the UK government and EU Commission provide strong rights in favour of the suppliers, with limited safeguards in favour of states. By drawing on incentive-based theories of IP rights, we contend that APAs act as *alternatives* to IP rights, through incentivising research and development in areas where the market-based incentives of IP rights fail to achieve state policy objectives, and because they also reallocate risk away from the IP owner. We therefore argue that their use justifies restricting IP rights in those agreements beyond the limitations currently provided for in statutory IP regimes.

Vaccine procurement contracts and APAs provide the perfect opportunity for the state to insist on public interest safeguards to be included as part of the agreement. Such safeguards can be implemented easily, with no legislative changes required, and can potentially have important impacts in terms of ensuring wider access, not only in individual states but also globally. In light of the vital role played by vaccination in bringing the COVID-19 pandemic under control, and the essential nature of both IP rights and procurement to enable the delivery of the vaccination programme, greater attention to procurement contracts and the role of IP safeguards in them, is important to ensure that in any future pandemic, the balance in favour of the public interest is better safeguarded.