ACCESS DENIED:
THE ROLE OF TRADE SECRETS
IN PREVENTING GLOBAL EQUITABLE ACCESS TO COVID-19 TOOLS

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EXECUTIVE SUMMARY[1]

Three years on, the COVID-19 pandemic has officially caused the deaths of over 7 million people (with excess mortality statistics putting the number at two to four times higher).[2] The pandemic disrupted global livelihoods and continues to have a devastating impact on communities without widespread access to health technologies. The world's response to the pandemic has re-emphasised the flaws in the existing global system for the research, development, and dissemination of health technologies. As of 30 September 2022, and despite 12.74 billion doses having been administered globally, 73% of the population in high income countries had been vaccinated with at least one dose, while only 24% had been vaccinated in low-income countries.[3]

The pandemic has been characterised by unprecedented progress in scientific research - including the rapid development of diagnostics, vaccines, and therapeutics. Public funding played a critical role in the research and development, manufacturing and distribution of COVID-19 tools. However, the governance of COVID-19 tools, including their distribution, pricing and manufacturing, has been dominated by narrow commercial or nationalistic motives rather than the interests of global public health. The pandemic exposed the power imbalance between the pharmaceutical industry, governments, and the public. Health technologies are an essential tool for our society's health and survival, yet important decisions around their research, manufacturing, and pricing happen behind closed doors.

Furthermore, the COVID-19 emergency has intensified a long-running debate over access to health technologies by illustrating the conflicts between intellectual property (IP) rules and global health objectives. While this debate has traditionally focused on patents, the pandemic brought to light concerns over other forms of IP such as trade secrets and other confidential information.

During the COVID-19 pandemic, the UK government made extensive reference to trade secret provisions as a way of restricting transparency during public procurement procedures. Pharmaceutical companies relied on trade secret protection to prevent other companies accessing manufacturing methods of COVID-19 vaccines and other commercially valuable information. In non-pandemic times, the UK government withholding certain procurement information, and private companies refusing to reveal trade secrets, may in limited circumstances be justifiable to protect commercially sensitive information. However, in the context of a global emergency such actions must be questioned.

This report provides a critical analysis of these issues, concluding that greater transparency is required in the public procurement process - especially in a time of emergency - to ensure a fair and equitable

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1 This paper is an edited version of a report published on 23 March 2023 by STOPAIDS on the role of trade secrets in preventing global equitable access to COVID-19 tools. The authors of this paper acted as experts who prepared the report. Please cite as O. Gurgula and L. McDonagh, *Access Denied: The Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools* (STOPAIDS, 2023).

2 https://covid19.who.int.

3 Our World in Data, 'Coronavirus (COVID-19) vaccination) <https://ourworldindata.org/covid-vaccinations> accessed 26 November 2022.

allocation of resources, and to guarantee accountability on the part of both the UK government and the pharmaceutical industry. We explain that the UK government prioritised trade secret protection over transparency during the public procurement of COVID-19 vaccines, and that pharmaceutical companies utilised trade secrecy strategies to prevent generic manufacturers from producing vaccines. We explore how this prevented good governance and denied equitable access to COVID-19 health products. We set out recommended legal and policy options to ensure that access to pandemic health tools is not denied again during emergency circumstances.

While the use of IP protection, such as patents and trade secrets, may play a part in stimulating innovation in the medical field, during emergencies access to life-saving technologies must be ensured. IP rights that maintain artificial scarcity may be counter-productive to bringing the emergency to an end. This is especially true where the development of such technologies is, in a large part, publicly funded.

Overall, while this report focuses on the COVID-19 pandemic in the UK, we conclude that the approach taken by the UK, other high-income states, and the pharmaceutical industry to protecting information related to COVID-19 vaccines has had a negative effect on low- and middle-income countries' ability to access vaccines. This unequal access may have played a role in the development of new variants of concern which have prolonged the pandemic. Therefore, our recommendations aim to prioritise the values of transparency and openness, which are crucial to the public interest, not only in the UK, but also for building global pandemic preparedness.

Part I. Transparency: Redacted information on Public Procurement of COVID-19 Vaccines

During 2020-21, the UK Government agreed major vaccine supply contracts with Oxford-AstraZeneca, Pfizer-BioNTech, Moderna, Johnson and Johnson (Janssen), Novavax, and Valneva (later cancelled). In every case only redacted versions of the contracts were made available on the UK Government contract finder website.[4] The UK Government redacted specific contractual information concerning the price of vaccine doses, the use of doses, liability rules, and ownership of IP, including industrial trade secrets. The lack of transparency over these aspects of the contract raises concerns about whether specific deals represent fair value to the UK public, as well as disquiet over the impact of secrecy on other countries. Moreover, there are gaps in transparency over the amount of funds the UK Government invested in R&D and manufacturing capacity building.

In its response to Freedom of Information requests the UK Government has, thus far, refused to fill in these gaps. We conclude that the Government's interpretation of the key laws – the Freedom of Information Act 2000 and the Public Contracts Regulations 2015 – has insufficiently protected the public interest, both in the UK and abroad. In all of the procurement agreements analysed, the UK Government took no stake in the IP generated through the R&D or production, regardless of the contribution made via public funds, nor did the UK Government use its funding leverage to mandate

[4] 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/

technology sharing with producers in other parts of the world.[5] The one exception was the Oxford-AstraZeneca partnership, which carried out a limited number of technology transfer agreements with certain global south producers, particularly the Serum Institute of India.[6]

Part II. Trade Secrets: Lack of Access to COVID-19 Vaccine Technologies During the COVID-19 Pandemic

During the COVID-19 pandemic, trade secrets have been relied upon extensively by pharmaceutical companies to prevent access to vaccine technologies. This includes valuable information held by pharmaceutical companies relating to safety, efficacy, and methods of manufacturing crucial to facilitating the rapid diversification and scaling up of vaccine production. Such information, had it been shared on an open basis, would have encouraged more widespread production of vaccines worldwide, therefore assisting in attaining widespread global coverage.[7] However, relying on strong IP protection, and trade secrets in particular, pharmaceutical companies refused to share such information with the WHO COVID-19 Technology Access Pool (C-TAP) and other similar initiatives. Companies also rejected offers to share their technologies with other pharmaceutical companies across the world that had the capacity to produce COVID-19 vaccines. Instead, pharmaceutical companies – the proprietors of COVID-19 technologies – focused production on their own manufacturing capacities, striking only limited bilateral deals with companies of their own choosing. Strong IP protection also allowed pharmaceutical companies to control prices and distribution of vaccines.

Over the course of the pandemic, a protectionist approach to IP, and trade secrets in particular, contributed to a significant limiting of the volume and regional spread of production capacity of COVID-19 vaccines, endangering global health efforts. This is despite the fact that the research underlying several of the vaccine technologies (Oxford-AstraZeneca, Pfizer-BioNTech, Moderna) was publicly funded.[8] Furthermore, in the early period of the pandemic public funding again played a key role, de-risking production of vaccines rapidly and at scale.[9]

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5 National Audit Office, *The rollout of the COVID-19 vaccination programme in England* (2022) at 29, fn 14, 'None of the contracts provided the UK with any rights to the intellectual property associated with the vaccines.'

6 Donato Mancini, 'AstraZeneca vaccine document shows limit of no-profit pledge' Financial Times (2020) - https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686

7 Ashleigh Furlong, Sarah Anne Aarup and Samuel Horti, 'Who killed the COVID vaccine waiver?' Politico (10 November 2022) –https://www.politico.eu/article/covid-vaccine-poor-countries-waiver-killed/

8 Samuel Cross et al., 'Who Funded the Research Behind the Oxford-Astrazeneca Covid-19 Vaccine?' (2021) BMJ Global Health, doi:10.1136/ bmjgh-2021-007321 ("Funders of ChAdOx platform research by grant mention in academic publications were 99% public and charitable bodies, of which 27.4% was overseas governments (including the European Union), 25.5% the UK government, 23.9% philanthropy, 19.6% research institution and 2.6% public–private partnership. Freedom of information (FOI) requests to the University of Oxford showed 97% public and charitable funding for the ChAdOx platform; the European Commission (34.0%), Wellcome Trust (20.4%) and Coalition for Epidemic Preparedness Innovations (17.5%) were the biggest funders of ChAdOx research until the start of the COVID-19 pandemic, but since January 2020, the UK government contributed 95.5% of identifiable R&D funding until October 2020"); Kayvan Bozorgmehr et al.,'Free licensing of vaccines to end the COVID-19 crisis' (2021) 397 The Lancet 1261 ('These pharmaceutical companies have benefited greatly from huge sums of public funding for research and development and advance purchase commitments, amounting to between US$2.2 billion and $4.1 billion (by Feb 1, 2021) from Germany, the UK, and North America combined').

9 Amnesty, *A Double Dose of Inequality: Pharma Companies and the Covid-19 Vaccines Crisis* (2021), available at https://www.amnesty.org/en/documents/pol40/4621/2021/en/

Given the global nature of the pandemic, and the need for several billion vaccine doses to be produced and distributed within an optimal timeframe, we conclude that the current set up of vaccine production proved insufficient during the key period of the emergency (2020-21). It remains problematic today. Such an inequitable response to the current pandemic calls for a reconsideration of the current structure of medical innovation and access, so that we in the UK, as part of a global community, can be better prepared for future pandemics.

At present several of these issues, concerning transparency, data sharing, technology sharing and IP flexibilities, are being discussed in the context of negotiations over the WHO Pandemic Treaty and reforms to the WHO International Health Regulations. As such, the UK government has an opportunity to take positive action at the domestic and international levels.

We therefore recommend the UK Government takes the following steps:

1. TRANSPARENCY

1.1. Regarding procurement, the UK Government should promote price transparency in the public interest. In the case of an emergency situation, such as the public procurement of COVID-19 vaccines, the UK public ought to be informed how large sums of public money are spent in terms of the per dose prices of each vaccine. This will provide complete transparency to UK taxpayers and will also help ensure fairness in negotiations between companies and other countries (e.g. low- and middle-income countries) to prevent them being over-charged.

1.2. The UK Government should publish the terms by which procured medical products, such as vaccines, may be used and transferred onward. In a global emergency, this will assist in ensuring doses are not wasted or allowed to expire, but can be donated to countries that require them.

1.3. The UK Government should inform the public of the liability responsibilities and indemnities that the Government has signed up to under contracts with private companies. This will help ensure public understanding and enhance confidence in mitigating the risks of procurement. Transparency on liability would assist the authorities in countering vaccine misinformation. Notably, this will also assist the UK Government and the governments of other states to ensure a smooth process of donation as liability rules will be clear.

1.4. The UK Government should promote transparency over public funds contributed to vaccine R&D and production.

2. TECHNOLOGY TRANSFER

2.1. When negotiating procurement contracts, the UK Government should facilitate voluntary technology transfers between pharmaceutical companies during emergencies, including to developing countries.

2.2. Advanced purchase agreements negotiated with manufacturers that involve substantial UK public funding for development and production, should include provisions enabling - and in emergency cases, mandating - the transfer of technology to other manufacturers, particularly those in the global south.

2.3. Further to this mandate, a new regime of compulsory licensing of trade secrets should be implemented in UK law to supplement the existing mechanism of compulsory licensing of patents. In an urgent health crisis, this would allow for more local production of generic and biosimiliar health technologies. These products could also be exported to meet demand in other countries and enable access to more affordably priced doses. A potential future benefit of having greater flexibilities within the IP system would be to facilitate increased competition among producers, which in the long term could help lower prices for the NHS.

2.4. In addition, a new compulsory licensing mechanism must be complemented by a data and marketing exclusivities waiver to allow the licensees under compulsory licences to obtain their marketing authorisations and launch their generic products before the normal end of exclusivity.

2.5. The UK Government should offer financial and political support for the WHO mRNA Vaccine Technology Transfer Hub.

2.6. For the ongoing WHO Pandemic Treaty and WHO International Health Regulations negotiation processes, the UK Government should support legal commitments mandating transparency, facilitating intellectual property waivers and requiring data sharing, particularly as part of conditions attached to public funding of research. The UK should also support measures aimed at increasing technology transfer and local production capacity in LMICs.

3. OWNERSHIP

3.1. As a matter of principle, where the UK taxpayers have funded research into specific health innovations, such public funding should be made contingent on the possibility of public access to the results of the research. The UK Government should introduce equitable access conditions across the R&D continuum. Equitable access conditions may include but should not be limited to mechanisms to ensure affordable pricing, norms around transparency, open access to data and results, pro-access intellectual property management strategies, technology transfer to independent and geographically diverse manufacturers, regulatory registration in low- and middle-income territories, and timely equitable supply of end products. We recommend placing compulsory clauses in research funding contracts which would provide a proportionate allocation of the IP ownership (i.e. proportionate to the amount of public funding provided) regarding the results of the research, as well as rules allowing such information to be shared with third parties in emergency circumstances (that can be domestically defined).

4. COMPETITION

4.1. The Competition and Markets Authority should engage in a rigorous investigation of various IP-related practices of pharmaceutical companies that may have a negative effect on access to e.g.

pandemic health technologies, such as tests and therapeutics, as well as on pricing of medicines. This investigation should include assessing the impact of patents and trade secrets.

5. OPEN INNOVATION

5.1. The UK Government should reconsider the current system of legal incentives for medical innovation and should facilitate the development of an open innovation model that ensures public funding for R&D is coupled with a policy of openness of technology within the pharmaceutical industry as a whole. We note the successful example of Corbevax, an open-source COVID-19 vaccine developed during 2020-21, which is an exemplar of this model.

5.2. The UK Government should assume the responsibility for UK pandemic preparedness by setting out a comprehensive research infrastructure plan aimed at sustainable production of medicines needed for health security. As part of this solution, the UK Government may consider exploring the creation of publicly funded and non-profit pharmaceutical facilities.

ACCESS DENIED: THE ROLE OF TRADE SECRETS IN PREVENTING GLOBAL EQUITABLE ACCESS TO COVID-19 TOOLS

Introduction

The COVID-19 pandemic has intensified a long-running debate over access to health technologies by illustrating the conflicts between intellectual property (IP) rules and global health objectives. While this debate has traditionally focused on patents, the pandemic brought to light concerns over other forms of IP such as trade secrets and other confidential information. This report investigates how the UK government prioritised trade secret protection over transparency during the public procurement of COVID-19 vaccines, and how pharmaceutical companies utilised trade secrecy strategies to prevent generic manufacturers from producing vaccines.

During the COVID-19 pandemic, the UK government made extensive reference to trade secret provisions as a way of restricting transparency during public procurement procedures. Pharmaceutical companies relied on trade secret protection to prevent other companies accessing manufacturing methods of COVID-19 vaccines and other commercially valuable information. In non-pandemic times, the UK Government withholding certain procurement information, and private companies refusing to reveal trade secrets, may in limited circumstances be justifiable to protect commercially sensitive information. However, in the context of a global emergency such actions can create significant problems, as we detail below.

Withholding information regarding the vaccine procurement deals made by the government prevented the public from assessing whether the public funds were spent responsibly, and led to uncertainty over use of doses and liability. As shown in this report, secrecy over contracts between the UK government and pharmaceutical companies had a negative effect on vaccine price negotiations undertaken by other governments, leading to higher prices paid in developing countries such as South Africa for e.g. the Oxford-AstraZeneca vaccine, as well creating uncertainty over when, and in what context, vaccine donations could be offered and received.[10]

It is important to emphasise that IP is a legal means of creating artificial scarcity for goods, including pharmaceutical products, that might otherwise be reproduced by rivals. During the COVID-19 pandemic, despite the need to swiftly accelerate the production of vaccines to inoculate populations worldwide, pharmaceutical companies prioritised maintaining secrecy over their COVID-19 vaccine technologies, which contributed to scarcity. Companies cited trade secret protections as a justification for refusing to share these technologies with other manufacturers or COVID-19 technology pools such as the WHO C-TAP scheme.[11] During the pandemic this contributed to limiting the number of vaccines

[10] Owen Dyer, 'Covid-19: Countries are learning what others paid for vaccines' (2021) BMJ 372:n281 doi:10.1136/bmj.n281

[11] Michael Safi, 'WHO platform for pharmaceutical firms unused since pandemic began' The Guardian (22 January 2021) <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began> accessed 26 November 2022; WEMOS 'Covid-19 Technology Access Pool (C-TAP)' <https://covid19response.org/c-tap/> accessed 26 November 2022 ("In November 2021, the Spanish National Research Council (CSIC) shared its intellectual property rights and know-how of its Covid-19 diagnostic tools globally through C-TAP, becoming the first one to do so. In May 2022, the US National Institutes of Health (NIH) announced licensing agreements with C-TAP for several therapeutics, early-stage vaccines and diagnostic tools… However, it lacks active support from governments where intellectual property and know-how is located.")

that could be manufactured. Such actions are hard to justify given the global nature of the virus, which continues its mutation post-Omicron amid a fragile pandemic recovery.

This report concludes that greater transparency is required in the public procurement process, especially in a time of emergency, to ensure a fair and equitable allocation of resources, and to guarantee accountability on the part of both the UK Government and the pharmaceutical industry. While the use of IP protection, such as patents and trade secrets, may play a part in stimulating innovation in the medical field, during emergencies access to life-saving technologies must be ensured: IP rights that maintain artificial scarcity may be counter-productive to bringing the emergency to an end. Access is a particularly pressing concern in circumstances where the development of such technologies was, in a large part, publicly funded. To varying degrees, the three major COVID-19 vaccines used in the UK – Oxford-AstraZeneca, Pfizer-BioNTech, Moderna – benefited from substantial public research funds (from the UK, EU and US governments) to bear the risk of early research and development (R&D).[12] Furthermore, in the initial period of the pandemic, public funding again played the key role to de-risk production of vaccines rapidly and at scale.[13]

While this report focuses on the COVID-19 pandemic in the UK, we conclude that the approach taken by the UK, other high-income states (HICs), and the pharmaceutical industry to protecting information related to COVID-19 vaccines had a negative effect on low- and medium-income countries' (LMICs) ability to access vaccines. The combination of vaccine hoarding by HICs and refusals by companies to share vaccine technology may have cost more than one million lives in LMICs, as well as increasing the risk of the development of new variants of concern, prolonging the pandemic.[14] Therefore, our recommendations aim to prioritise the values of transparency, access and openness, which are crucial to the public interest, not only in the UK, but also for building global pandemic preparedness.

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12 Samuel Cross et al., 'Who Funded the Research Behind the Oxford-Astrazeneca Covid-19 Vaccine?' (2021) BMJ Global Health, doi:10.1136/ bmjgh-2021-007321 ("Funders of ChAdOx platform research by grant mention in academic publications were 99% public and charitable bodies, of which 27.4% was overseas governments (including the European Union), 25.5% the UK government, 23.9% philanthropy, 19.6% research institution and 2.6% public–private partnership. Freedom of information (FOI) requests to the University of Oxford showed 97% public and charitable funding for the ChAdOx platform; the European Commission (34.0%), Wellcome Trust (20.4%) and Coalition for Epidemic Preparedness Innovations (17.5%) were the biggest funders of ChAdOx research until the start of the COVID-19 pandemic, but since January 2020, the UK government contributed 95.5% of identifiable R&D funding until October 2020"); Kayvan Bozorgmehr et al., 'Free licensing of vaccines to end the COVID-19 crisis' (2021) 397 The Lancet 1261 ('These pharmaceutical companies have benefited greatly from huge sums of public funding for research and development and advance purchase commitments, amounting to between US$2.2 billion and $4.1 billion (by Feb 1, 2021) from Germany, the UK, and North America combined').

13 Amnesty, *A Double Dose of Inequality: Pharma Companies and the Covid-19 Vaccines Crisis* (2021), available at https://www.amnesty.org/en/documents/pol40/4621/2021/en/

14 Heidi Ledford, 'Covid Vaccine hoarding might have cost more than a million lives' Nature (2 November 2022) - https://www.nature.com/articles/d41586-022-03529-3

Part I. Transparency: Redacted Information on Vaccine Development and Public Procurement of COVID-19 Vaccines

1.1 The Public Interest in Freedom of Information

The principle of freedom of information enhances transparency of government decisions, contributing to an informed debate on national interests such as public health, as well as promoting oversight of public expenditure. Transparency also creates space for enhanced accountability regarding possible deficiencies in government conduct or administration. UK law provides for freedom of information as a statutory principle of public law while simultaneously protecting commercially valuable information under private law (via the law of trade secrets/breach of confidence). The application of secrecy to public documents – the negation of transparency – can protect the financial interests of certain companies. As such, there are occasions when transparency and secrecy are in conflict.[15] As described below, the Freedom of Information Act 2000 and the Public Contracts Regulations 2015 are the relevant statutes providing for informational transparency in relation to procurement contracts, including the exceptions to the principle of freedom of information in the context of commercial trade secrets.[16] The UK Government relied on these provisions to redact crucial information from the publicly available vaccine procurement contracts, raising significant concerns, including on the use of public funds.

1.1.1. Legal provisions that regulate transparency of public procurement and relevant exceptions

a) The Freedom of Information Act 2000 (FOIA)

The Freedom of Information Act 2000,[17] including its various revisions,[18] provides public access to information held by public authorities in two ways:

- public authorities are obliged to publish certain information about their activities; and
- members of the public are entitled to request information from public authorities. [19]

At the same time, Section 43(1) provides an exemption from disclosure for information which is a trade secret.[20] Section 43(2) exempts information whose disclosure would, or would be likely to, prejudice

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15 There can also be convergence i.e., where the private law doctrine of breach of confidence, in the context of trade secrets, connects with public law as it relates to the withholding of state secrets from FOI requests. See David S. Levine, 'Secrecy and Unaccountability: Trade Secrets in our Public Infrastructure' (2007) 59 Fla. L. Rev. 135.

16 The UK National Security Bill, introduced in the House of Commons in 2022-23 refers to trade secrets - https://bills.parliament.uk/bills/3154

17 Freedom of Information Act 2000 (FOIA) - https://www.legislation.gov.uk/ukpga/2000/36/contents

18 Freedom of Information Law (2020 Revision) (FOI Law) and (2021 Revision) (FOI Revised Act). See also Freedom of Information (General) Regulations 2008 (FOI Regulations).

19 ICO, *Guide to Freedom of Information* - https://ico.org.uk/for-organisations/guide-to-freedom-of-information/what-is-the-foi-act/#9

20 Section 41 is also of relevance, whereby the publication of info held the public authority *can in some circumstances be considered* a breach of confidence. See also section 44.

the commercial interests of any legal person (an individual, a company, the public authority itself or any other legal entity). However, Section 43 provides only qualified exemptions. This means that if the requested information is considered as exempt from disclosure, the public authority must consider whether the public interest in maintaining the exemption outweighs the public interest in transparency. Courts have recognised the significance of the public interest in openness and transparency when the balancing exercise occurs.[21]

Defining what the public interest is in any given situation is open to interpretation, but the principles of the Information Commissioner's Office (ICO) offer guidance.[22] Moreover, such decisions are open to challenge, and the government does not always make the correct assessment. In 2021 the High Court of England and Wales found that the UK Government had not sufficiently given weight to the public interest in transparency in the context of procurement of several COVID-19 related contracts relating to personal protective equipment (PPE).[23] A 2022 judgment on the UK Government plan to send asylum-seekers to Rwanda held that the Government had not considered the public interest sufficiently, and ordered the release of several passages from internal government documents on the policy.[24] Similarly, a recent Upper Tier Tribunal case involving a complaint by a citizen against the Department of International Trade concerning negotiations over a free trade agreement led to the Tribunal ruling that the Government had erred in its interpretation of the FOIA in refusing to provide the requested information.[25]

b) Public Contracts Regulations 2015 (SI 2015/102) (PCR)

The primary piece of legislation that regulates public procurement in the UK is the Public Contracts Regulations 2015 (SI 2015/102) (PCR). According to Section 50(1) PCR a contracting authority 'shall submit for publication a contract award notice on the results of the procurement procedure' and that this should occur 'not later than 30 days after the award of a contract or the conclusion of a framework agreement, following the decision to award or conclude it'. However, Section 50(6) PCR also states that certain information on the award of the contract itself, or the conclusion of the framework agreement, may be withheld from publication where its release:

(a) would impede law enforcement or would otherwise be contrary to the public interest,
(b) would prejudice the legitimate commercial interests of a particular economic operator, whether public or private, or
(c) might prejudice fair competition between economic operators.

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21 *Hugh Mills v Information Commissioner* EA/2013/0263 (2 May 2014).

22 ICO, *Freedom of Information Act Awareness Guidance No. 12 - When is information caught by the Freedom of Information Act*? - https://ico.org.uk/media/1144/awareness_guidance_12_info_caught_by_foi_act.pdf

23 *R. (on the application of Good Law Project Ltd) v Secretary of State for Health and Social Care* [2021] EWHC 346 (Admin). On equal treatment see *R. (on the application of Good Law Project Limited, Everydoctor) v The Secretary of State for Health and Social Care v Crisp Websites Limited (t/a Pestfix), Clandeboye Agencies Limited, Ayanda Capital Limited* [2022] EWHC 46 (TCC).

24 *R (on the application of AAA & ors) v Secretary of State for the Home Department* [2022] EWHC 2191 (Admin). See also 'Rwanda Asylum Policy Passages Must Be Revealed, Judge Rules' The Guardian (17 August 2022) - https://www.theguardian.com/uk-news/2022/aug/17/rwanda-asylum-policy-passages-must-be-revealed-judge-rules

25 *Montague v The Information Commissioner and Department for International Trade* [2022] UKUT 104 (AAC) - https://assets.publishing.service.gov.uk/media/6273a6ec8fa8f57a41d53ee9/UA_2020_000324_000325_GIA.pdf

Sub-sections 50(6)(b) and (c) offer the Government a legal justification for withholding information from the public sphere where it may prejudice commercial interests or undermine fair competition. However, this must be balanced with the overall principle of freedom of information under the FOA.

1.2 Procurement of Covid-19 Vaccines by the UK Government

During 2020-21, the UK Government agreed major vaccine supply contracts with Oxford-AstraZeneca,[26] Pfizer-BioNTech,[27] Moderna,[28] Johnson and Johnson (Janssen),[29] Novavax,[30] and Valneva (later cancelled).[31] There is a lack of transparency over these contracts. In every case only redacted versions of the contracts have been made available on the UK Government contract finder website.[32] The UK Government has cited trade secrets and confidential information protection as a justification for refusing to allow complete transparency over the contracts relating to vaccines.[33] Our analysis is therefore based on the publicly available (redacted) contracts and other government publications such as the National Audit Office reports.

1.2.1. Vaccine Supply Contracts

In published contracts the UK Government redacted specific contractual information concerning several crucial issues, including the price of vaccine doses, the use of doses, liability rules, and the ownership of IP and industrial trade secrets.[34] As detailed later on in this sub-section, the lack of transparency over

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26 The UK-AZ supply agreement is accessible at <https://www.contractsfinder.service.gov.uk/notice/2ce928f2-0e8b-48cd-b0e7-bccff514d281?origin=SearchResults&p=1>

27 The UK-Pfizer supply agreements are accessible at <https://www.contractsfinder.service.gov.uk/notice/846275db-46ef-47b3-8300-979c00896f82?origin=SearchResults&p=1>, <https://www.contractsfinder.service.gov.uk/notice/f6adf3ca-59a4-4976-95e6 27a62a2a4c6e?origin=SearchResults&p=1>, https://www.contractsfinder.service.gov.uk/notice/13d7b712-2d29-4c10-ba76-3aa7b221c3db?origin=SearchResults&p=1.

28 The UK-Moderna supply agreements are accessible at <https://www.contractsfinder.service.gov.uk/notice/a3df05e8-9916-4c12-90c3-0c28611cf48e?origin=SearchResults&p=1>, <https://www.contractsfinder.service.gov.uk/notice/b2d73286-4939-4120-b1fd-bf44d559b4e0?origin=SearchResults&p=1>, https://www.contractsfinder.service.gov.uk/notice/8930d6c5-354d-44d0-8540-c134fe59aa0a?origin=SearchResults&p=1.

29 The UK-Janssen supply agreement is accessible at <https://www.contractsfinder.service.gov.uk/notice/c97f8992-b918-4973-9e38-9eb42e6f73a8?origin=SearchResults&p=1>.

30 The UK Novavax supply agreements are at <https://www.contractsfinder.service.gov.uk/notice/c1ed715e-9a39-4263-961f-dc8166a81216?origin=SearchResults&p=1>, <https://www.contractsfinder.service.gov.uk/notice/440445d9-888f-4b09-8fdf-465f913b7ca0?origin=SearchResults&p=1>.

31 The UK-Valneva supply agreement is accessible at <https://www.contractsfinder.service.gov.uk/notice/cd5013be-e8b8-4e57-82bc-d40301e55ab5?origin=SearchResults&p=1>.

32 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/

33 Public Services and Procurement Canada, A-2020-000666 (June 2021). The Canadian government made redactions to contracts before making them available to the public.

34 Beyond procurement, as we discuss further below, in the particular case of the Oxford-AstraZeneca vaccine the UK government has not provided adequate transparency over the use of public funds invested in R&D and manufacturing capacity building.

price per dose, use of doses, and liability had significant consequences relevant to global equitable distribution of vaccines.[35]

Despite the FOI requests made by the authors, and others, the UK Government has refused to fill in the gaps in public knowledge. The Government's interpretation of the key laws – the Freedom of Information Act 2000[36] and the Public Contracts Regulations 2015[37] – has not protected the public interest adequately, whether considered by reference to the UK or globally.[38] It is arguable that the procurement contracts favoured the rights of suppliers over states and the public.[39] For example, with respect to the UK-Moderna vaccine contract,[40] the following justification was given by the UK Government for redacting elements of the contract:

> *Information on contract value is being withheld due to commercial sensitivity under Regulation 50(6)(b) and (c) as the publication of the price may enable competitors to calculate cost per dose. This will (i) commercially prejudice the supplier in its ongoing negotiations with other national governments; (ii) commercially prejudice the contracting authority in its ongoing negotiations with other vaccine vendors and (iii) impact fair competition between vaccine vendors. Contract end date is being withheld on grounds that release of the information would be contrary to public interest under Regulation 50(6)(a). The contract end date is variable based on production and delivery of the requirement. There are significant challenges to overcome and the end date may not be a true reflection, setting unrealistic expectation for the public and in the market. This information is also being withheld on due to commercial sensitivity under Regulation 50(6)(b) and (c) as there is significant competition to develop and bring to the market a successful vaccine. Provision of the contract term may provide valuable information to competitors that may impact negotiations or future competition in the market.*
>
> *Sub-contractor details are being withheld on grounds that release of the information would be contrary to public interest under Regulation 50(6)(a). This information is very sensitive given potential for targeting and disruption of the activities at the facilities which would be contrary to public interest as these activities are critical to success and delivery of the requirement.*

In response to the FOI request for the unredacted vaccine procurement contracts made by the authors of this report, the Government responded:

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35 Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang and Graham Dutfield, 'Addressing vaccine inequity during the COVID-19 pandemic: the TRIPS intellectual property waiver proposal and beyond' (2022) 81 Cambridge Law Journal 384. See also Matthew Malone, 'Trade Secrets, Big Data, and the Future of Public Interest Litigation Over Artificial Intelligence in Canada' (2020 35 Canadian Intellectual Property Review 6; Orly Lobel, 'The New Cognitive Property: Human Capital Law and the Reach of Intellectual Property' (2015) 93 Tex L Rev 789; and Hannah Bloch-Wehba, 'Access to Algorithms' (2020) 88 Fordham L. Rev. 1265.

36 Sections 41 and 43 FOIA.

37 This is particularly so with respect to the section 50(6)(a-c) exceptions

38 Peter S. Menell, 'Tailoring a Public Policy Exception to Trade Secret Protection' (2017) 105 California Law Review 62. See also Charles T. Graves and Sonya Katyal, 'From Trade Secrecy to Seclusion' (2019) 109 *The Georgetown Law Journal* 1337; Don Weisner and Anita Cava, 'Stealing Trade Secrets Ethically' (1988) 47 Maryland L. Rev. 1076; Amy Kapczynski, 'The Public History of Trade Secrets' (2022) 55 UC Davis Law Review 1367.

39 Alison Slade and Naomi Hawkins, 'Intellectual Property Rights and Advance Purchase Agreements in a Crisis' (2023) Intellectual Property Quarterly 1.

40 An equivalent text is found on the website for the other contracts.

Some information in these contracts has been redacted and is being withheld under section 43(2) of the Act. Section 43(2) exempts information from release if its disclosure would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it). The information you have requested falls into this category of commercially sensitive information. The use of section 43(2) is subject to a public interest test. We recognise that there is a general public interest in the disclosure of information relating to vaccines, as greater transparency makes Government and decision making in this policy area more open and accountable. However, against this there is a public interest in ensuring that the commercial interests of external companies are not damaged or undermined by disclosure of information which is not common knowledge, and which could adversely impact on future business.

It is important that companies are able to share commercially sensitive information with Government in the confidence that that information will not then enter the public domain and damage their wider commercial interests and opportunities. Disclosure of the requested information in this case would be contrary to legitimate expectations of confidentiality and would be likely to damage the commercial interests of the companies. The commercial sensitivities mean that on this occasion we consider that the public interest would not be served by its release.

As shown in the above UK Government statements, there remains unwillingness to provide full transparency and accountability with regard to UK Government funding of vaccines and their procurement.[41] Rather than facilitating openness, the lack of transparency has led to a 'drip feed' of information that has come into the public domain only after leaks and releases of contract information by other governments, such as the EU. As explained further below, crucial information on terms regarding price, use of doses (donations), and liability/indemnity has not been made available, hindering policy assessments by LMIC governments, and exacerbating global inequalities.

Yet, as a basic principle, the Information Commission Office (ICO) guidance suggests that it is in the public's interest to know how the government spends money (during e.g. the pandemic). In terms of balance, this could outweigh commercial interests (by applying the balancing exercise provided in the ICO guidance). As explained in the Information Commissioner Guidance:

Public authorities spend money collected from taxpayers, and make decisions that can significantly affect many people's lives. Access to information helps the public make public authorities accountable for their actions and allows public debate to be better informed and more productive.[42]

In the case of public procurement of COVID-19 vaccines, the public ought to know how large sums of public money were spent in terms of e.g. funding the research, the prices of vaccines, how ownership of IP on the products generated by the research was allocated, and on liability responsibilities.[43] As

41 WIPO/INN/GE/19/INF/3, "WIPO Symposium on Trade Secrets and Innovation" (March 9, 2020).

42 ICO, *Guide to Freedom of Information* - https://ico.org.uk/for-organisations/guide-to-freedom-of-information/what-is-the-foi-act/#9

43 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) - https://www.transparency.org.uk/publications/whose-benefit-transparency-development-and-procurement-covid-19-vaccines

outlined below, a lack of openness regarding trade secrets relevant to manufacturing vaccines hindered efforts to scale up global production during the apex of the pandemic in 2020-21.

1.2.2. Lack of Transparency Regarding Procurement Contracts: Negative Consequences

a) Regarding the price of vaccines

Typically, vaccine dose buying for most countries involved a 'buy down' (i.e. deposit) committing countries to a certain number of doses;[44] but the deposit was only fully paid for part of that number, while the other part was only partially paid for (an optional number of additional doses).[45] For each vaccine the UK kept the agreed price per dose confidential, redacting this information from all contracts. Keeping the price confidential has meant that UK taxpayers remain unaware of how much public funding was used for each particular vaccine. In February 2022, the UK National Audit Office published figures on the total amount spent on vaccines up to October 2021 (£2.9bn) as well as an estimate of the average price per dose (£15.02 per dose).[46] Moreover, the UK Government made some public announcements during 2021 regarding price and volume of specific deals reached with pharmaceutical companies.[47] Nonetheless, to date the Government has refused to publish the unredacted versions of the vaccine contracts with the actual agreed prices per dose. This means that UK taxpayers are unaware of how much public funding was used to procure each particular vaccine.[48] In the case of the Pfizer-BioNTech vaccine, this includes the relatively high price of the mRNA vaccines when compared with the Oxford-AstraZeneca vaccine (a point noted by the National Audit Office, even though the exact price per dose remains unpublished).[49] This raises concerns about whether specific deals represent fair value to the UK public, and causes disquiet over the impact of secrecy on other countries.

Through confidentiality clauses, which are themselves redacted, pharmaceutical companies insisted upon significant restrictions on transparency over price. At time of agreement, the UK public was unable to access information on price, or the conditions attached to the issue of price. Instead, the public had to rely on leaks and investigative journalism. For example, in early 2021 it was reported that vaccine manufacturers 'included clauses in their supply contracts that allow them to suspend deliveries if countries reveal the price'.[50] The inclusion of such terms demonstrates the significant power such companies held over governments during the COVID-19 emergency.

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44 Pascale Boulet, Ellen 't Hoen, Katrina Perehudoff, Kaitlin Mara & Ernest Tan, 'Advanced Purchase Agreements for COVID-19 Vaccines: Analysis and Comments' *Study for The Left in the European Parliament* (July 2021) - https://medicineslawandpolicy.org/2021/07/new-analysis-advanced-purchase-agreements-for-covid-19-vaccines/

45 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.

46 National Audit Office, *The rollout of the COVID-19 vaccination programme in England* (2022) at 18, figure 2.- https://www.nao.org.uk/reports/the-roll-out-of-the-covid-19-vaccine-in-england/

47 Andrew Gregory, 'UK ministers secure 114m more Covid vaccines for next two years' The Guardian (2021) - <https://www.theguardian.com/world/2021/dec/01/uk-ministers-secure-114m-more-covid-vaccines-for-next-two-years>.

48 Jon Ungoed-Thomas, 'Wall of Secrecy in Pfizer Contracts as Company accused of Profiteering' The Guardian (2021) - https://www.theguardian.com/uk-news/2021/dec/05/wall-of-secrecy-in-pfizer-contracts-as-company-accused-of-profiteering
See also Zain Rizvi, 'Pfizer's Power' Public Citizen (2021) - https://www.citizen.org/article/pfizers-power/

49 National Audit Office, *The rollout of the COVID-19 vaccination programme in England* (2022) at 18, figure 2.- https://www.nao.org.uk/reports/the-roll-out-of-the-covid-19-vaccine-in-england/

50 'Vaccine Secret Contract Prices' The New York Times (28 January 2021) - https://www.nytimes.com/2021/01/28/world/europe/vaccine-secret-contracts-prices.html - noting that a Belgian

Critically, a lack of transparency on dose pricing in the UK and other high-income countries (HICs) had consequences elsewhere: early in the pandemic some developing countries (e.g. South Africa) were charged a higher price for the Oxford-AstraZeneca doses than the UK or EU governments were. LMIC negotiators did not know what other countries were paying – it was later revealed that the European Commission had paid $2.19 per Oxford-AstraZeneca dose, whereas South Africa had paid $5.25 per dose (the exact UK price remains redacted but is thought to be approximately $3).[51]

That LMICs lacked leverage in negotiations on vaccine dose price was a partial consequence of the lack of transparency of pricing elsewhere.[52] This raises a concern about the ability of private companies to dictate terms to the UK Government that may not be in the public interest, whether at home or abroad. In the specific case of Oxford-AstraZeneca, it remains puzzling as to why the UK Government agreed to maintain secrecy over price given AstraZeneca's promise to sell doses at 'cost price'.[53]

b) Regarding the use of doses

The terms of use agreed by the UK are also of great importance. The absence of full transparency caused great uncertainty about the conditions by which countries could donate unused doses. In early 2021 concerns were raised in the media that some countries were prohibited under contract from donating or reselling doses.[54] Subsequently, it was acknowledged that, even amidst a pandemic, companies such as Moderna had insisted upon contractual restrictions on state purchasers of vaccines that prevented them from donating or reselling doses.[55] Indeed, a term of the UK-Moderna agreement is worded to prevent redistribution to countries to which Moderna already supplies doses, a point which may have hindered global distributive equity.[56]

official had 'mistakenly revealed a price list', which showed that United States taxpayers were paying $19.50 per dose for the Pfizer vaccine, while Europeans paid $14.70'.

51 Owen Dyer, 'Covid-19: Countries are learning what others paid for vaccines' (2021) BMJ 372:n281 doi:10.1136/bmj.n281

See also Stephanie Nolen and Rebecca Robbins, 'Vaccine Makers Kept $1.4 Billion in Prepayments for Cancelled Covid Shots for the World's Poor' The New York Times (1 Feb 2023). - https://www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html?smid=nytcore-ios-share&referringSource=articleShare

52 Amnesty, *A Double Dose of Inequality: Pharma Companies and the Covid-19 Vaccines Crisis* (2021), available at https://www.amnesty.org/en/documents/pol40/4621/2021/en/

53 Donato Mancini and Clive Cookson, 'Vaccine deal allows AstraZeneca to take up to 20% on top of costs' Financial Times (2020) - https://www.ft.com/content/e359159b-105c-407e-b1be-0c7a1ddb654b

54 "Available documents, however, suggest that drug companies demanded and received flexible delivery schedules, patent protection and immunity from liability if anything goes wrong. In some instances, countries are prohibited from donating or reselling doses, a ban that could hamper efforts to get vaccines to poor countries." in 'Vaccine Secret Contract Prices' The New York Times (28 January 2021) - https://www.nytimes.com/2021/01/28/world/europe/vaccine-secret-contracts-prices.html

55 'Germany may miss COVID-19 vaccine donation goal, blames manufacturers' Reuters (2021) - https://www.reuters.com/world/europe/exclusive-germany-may-miss-covid-19-vaccine-donation-goal-blames-manufacturers-2021-10-19/

56 Clause 3.11. UK-Moderna contract.

Outside of the UK, contractual restrictions played a role in holding up EU donations of the Moderna vaccine until this restriction was lifted in November 2021.[57] With regard to the Pfizer-BioNTech contracts, in October 2022 the Prime Minister of Albania admitted that the Italian Foreign Minister Luigi Di Maio had violated Pfizer's contractual terms by transferring doses on humanitarian grounds from Italy to Albania during early 2021.[58] The contract Pfizer agreed with Brazil contained a similar clause, according to which Pfizer claimed the right to give permission before donations could occur.[59] These terms, which remain redacted in UK contracts, were a factor that contributed to delays in global donations, exacerbating a shortage of mRNA vaccines in many developing countries during 2021.[60] There is a danger such rules could become standardised - the UK has accepted a similarly restrictive condition in the recent supply agreement with Bavarian Nordic for the monkeypox vaccine.[61] Contractual restrictions have also been reported in relation to the US government's contracts with Moderna – scientists at the National Institutes of Health (NIH) who assisted Moderna in the creation of the COVID-19 vaccine have had to seek special permission from Moderna for use of the vaccine in research studies that were not expressly allowed under the initial contract.[62]

c) Regarding liability

Shielding manufacturers from liability for harm caused by the vaccines (or if the vaccines failed to work) was obviously an important issue to cover under contract. We acknowledge that companies were working to an accelerated time-line in an unprecedented situation to produce vaccine doses. There is a legitimate argument that companies needed a reasonable amount of liability protection in this circumstance. Yet, it is not evident why the contracts did not provide transparency on all information on the circumstances by which companies or governments could be held liable for any problems that recipients faced, or on what the repercussions would be for affected people. Furthermore, the absence of transparency on liability, and related concerns, also affected the willingness of countries to make, or accept, donations at the apex of the pandemic, as several reports made clear during 2021.[63]

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57 'Germany may miss COVID-19 vaccine donation goal, blames manufacturers' Reuters (2021) - https://www.reuters.com/world/europe/exclusive-germany-may-miss-covid-19-vaccine-donation-goal-blames-manufacturers-2021-10-19/

'Moderna says EU to donate over 70mln doses of its COVID-19 vaccine' Reuters (2022) - https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-says-eu-donate-over-70-mln-doses-its-covid-19-vaccine-2021-11-16/

58 'Premier albanese Rama: fatto contrabbando vaccini con Di Maio senza consenso Pfizer' SkyIt (9 October 2022) - https://tg24.sky.it/mondo/2022/10/09/covid-vaccini-contrabbando-rama-di-maio-video

59 Zain Rizvi, 'Pfizer's Power' Public Citizen (2021) - https://www.citizen.org/article/pfizers-power/

60 KEI, 'Covid-19 Contracts' (2022) - https://www.keionline.org/coronavirus

61 Clause 6.12.13. UK- Bavarian Nordic contract - https://www.contractsfinder.service.gov.uk/notice/6b0a5974-3a1d-4718-a75f-099eb7ca26e4?origin=SearchResults&p=1

62 Benjamin Mueller, 'The End of Vaccines at "Warp Speed" The New York Times (18 November 2022) - www.nytimes.com%2F2022%2F11%2F18%2Fhealth%2Fcovid-nasal-vaccines-warp-speed.html&usg=AOvVaw0TZxhI5pCftdOKW6sIQuwu

63 'Germany may miss COVID-19 vaccine donation goal, blames manufacturers' Reuters (2021) - https://www.reuters.com/world/europe/exclusive-germany-may-miss-covid-19-vaccine-donation-goal-blames-manufacturers-2021-10-19/

d) Regarding IP ownership in vaccine procurement contracts

It is important to distinguish between advance order contracts that are tied to vaccine development and production, and procurement contracts that relate solely to dose purchasing. The most extensive advance order and developmental relationship between the UK Government and industry concerns the University of Oxford and AstraZeneca. As such the Oxford-AstraZeneca partnership forms the main case study of this report. We also note that the UK provided funds for local manufacture of the Novavax vaccine.

The underlying technology of the Oxford-AstraZeneca vaccine (ChAdOx) arose from research funded by the EU and UK governments, as well as charities such as the Wellcome Trust, who supported work undertaken at the Jenner Institute at the University of Oxford, as well as at the Oxford University Innovation spin-out company Vaccitech.[64] Cross et al. state that the total R&D amount disclosed via FOI requests was £104,226,076, of which £69,313,380 was provided before 1 January 2020 and £34,912,696 on, or after, that date.[65] However, from their own study of the literature, Cross et al. estimate the entire funding figure at £228,466,771. This disparity highlights the difficulty of apportioning costs accurately within a somewhat opaque research funding system. For the sake of clarity, we use their breakdown of the FOI figure. Based on the FOI figure, prior to January 2020, the largest funders of the R&D into the technology were foreign public funders (37.9%), of which the largest was the EU, and charitable funders (31.0%), of which the largest was the Wellcome Trust.[66] Public-private partnership funders such as the Coalition for Epidemic Preparedness Innovations (CEPI) provided 18.7%.[67] The UK Government contributed 8%. Private industry funding accounted for just 2.8%.[68]

As the early days of the pandemic unfolded in December-January 2020, the research team led by Prof. Sarah Gilbert and Prof. Adrian Hill worked to apply this underlying technological platform to the novel Coronavirus/COVID-19. From January 2020 the UK Government became the largest funder of the R&D associated with the Oxford-AstraZeneca vaccine, contributing £33,354,469 (95.5%).[69] By March 2020 it was evident that the Oxford researchers had produced a potentially viable vaccine candidate. Initially, Oxford considered issuing only non-exclusive licences – akin to a purported 'open source' approach – but by the end of April 2020 Oxford had agreed an exclusive licence with AstraZeneca.[70] One rationale behind this decision to go for exclusivity was that Oxford needed a partner that possessed experience of running clinical trials. On their side of the agreement AstraZeneca committed to providing the vaccine on a 'not-for-profit basis for the duration of the pandemic, and in perpetuity to low- and

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64 S. Cross et al., 'Who Funded the Research Behind the Oxford-Astrazeneca Covid-19 Vaccine?' (2021) BMJ Global Health, doi:10.1136/ bmjgh-2021-007321 - https://gh.bmj.com/content/6/12/e007321

65 Ibid.

66 Ibid.

67 Ibid.

68 Ibid.

69 Ibid.

70 The relevant press release is available here - https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html#modal-historic-confirmation

middle-income countries'.[71] Meanwhile, it was reported in April 2020 that, on the basis of a 'gentlemen's agreement' (rather than a strict contract), Oxford researchers had provided the Serum Institute of India (Serum) with a sample of the vaccine candidate.[72] Later this agreement was supplanted by a formal contract between AstraZeneca and Serum.[73]

In addition to investing into an underlying technology and the development of a COVID-19 vaccine, part of the overall UK negotiations with AstraZeneca involved the UK Government investing in manufacturing capacity, to effectively de-risk rapid development and production.[74] The UK Government secured 100m doses of the Oxford-AstraZeneca vaccine. AstraZeneca received its estimated costs, plus an additional cushion of 20%.[75]

As with AstraZeneca, in the case of Novavax the UK Government provided funds for manufacturing in the UK, with an expected supply of 60m doses (though production delays hampered the actual rollout of this vaccine in the UK and elsewhere).[76] The 2022 NAO report does not give a breakdown of fund allocation per vaccine, but it shows that the UK Government spent overall sums of £140m on vaccine clinical trials and £322m on 'onshoring' of manufacturing, i.e. producing and fill/finishing doses in the UK, the majority of which would have related to AstraZeneca and Novavax.[77] Initially, the UK Government also planned for UK local manufacture of the Valneva vaccine, but this was later cancelled.[78] Thus, in the case of Oxford-AstraZeneca and Novavax, significant public funding was spent on research, development and manufacture of the vaccines.

By contrast, the initial supply contract agreed by the UK Government with Moderna was for procurement of only 7m doses. It does not appear the UK contributed development funds to Moderna – in fact, Moderna was almost entirely funded via the US Government's Operation Warp Speed, which led to the US getting priority on Moderna doses for 2021.[79] The UK's initial supply contract with Pfizer-BioNTech was for 40m doses. It does not appear the UK Government provided any R&D capital to

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71 Asher Mullard, 'How COVID vaccines are being divvied up around the world' Nature (20 November 2020) - https://www.nature.com/articles/d41586-020-03370-6; See also Oxford Innovation Policy at https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/

72 'An Indian Firm starts mass producing an unproven Covid-19 Vaccine' The Economist (28 April 2020) - https://www.economist.com/business/2020/04/28/an-indian-firm-starts-mass-producing-an-unproven-covid-19-vaccine

73 The relevant press release is available here - https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html#modal-historic-confirmation

74 UK Vaccine Taskforce, *UK Vaccine Taskforce 2020 Achievements and Future Strategy - End of year report* (2020) - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027646/vtf-interim-report.pdf

75 Donato Mancini and Clive Cookson, 'Vaccine deal allows AstraZeneca to take up to 20% on top of costs' Financial Times (2020) - https://www.ft.com/content/e359159b-105c-407e-b1be-0c7a1ddb654b

76 UK Vaccine Taskforce, *UK Vaccine Taskforce 2020 Achievements and Future Strategy - End of year report* (2020) - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027646/vtf-interim-report.pdf

77 National Audit Office, *The rollout of the COVID-19 vaccination programme in England* (2022) at 18, figure 2.- https://www.nao.org.uk/reports/the-roll-out-of-the-covid-19-vaccine-in-england/

78 Ibid.

79 'Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials' US Congressional Research Service (2021) - https://crsreports.congress.gov/product/pdf/IN/IN11560

BioNTech, although the German and the EU governments did provide substantial public funding prior to, and subsequent to, the emergence of COVID-19.[80]

In all these agreements the UK Government took no stake in the IP generated through the R&D or production, even where it was a substantial funder of both R&D and manufacturing costs.[81] Nor did the UK use its funding leverage to encourage or mandate technology sharing with producers in other parts of the world. The one exception was Oxford-AstraZeneca, which carried out some technology transfer agreements with a number of global south producers, not just Serum, as discussed above, but also to e.g. Fiocruz in Brazil and Siam Therapeutics in Thailand.[82] Even here, however, it was Oxford scientists, acting alone, who were responsible for the early sharing of the cell cultures crucial to the vaccine with Serum – the researchers shipped the vaccine samples to Serum without the permission of AstraZeneca, fearing that the company might stop them on IP grounds.[83]

1.2.4 Lack of Transparency: the Oxford-AstraZeneca Licence Agreement

Despite repeated requests made to Oxford and AstraZeneca from civil society organisations, the specific terms of the licence were not made public. One organisation – Universities Allied for Essential Medicines (UAEM) – submitted FOI requests to Oxford for all agreements between the University of Oxford, Vaccitech, and AstraZeneca referencing the vaccine, including contracts, licence agreements, and MOUs.[84] Eventually, a redacted version of the agreement was published.[85] This text did not provide details on costs or on licence terms.

Even without publication, we know some details of typical AstraZeneca licence terms because a subsequent agreement between AstraZeneca and Fiocruz (Brazil) was leaked, with several notable details falling into the public domain.[86] Crucially, this included the date by which AstraZeneca expected the 'pandemic period' to be over, and therefore when a profit price could be charged. Indeed,

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80 'BioNTech chief: EU R&D funds helped develop Covid-19 vaccine' Research Professional (2021) - https://researchprofessionalnews.com/rr-news-europe-horizon-2020-2021-1-biontech-chief-eu-r-d-funds-helped-develop-covid-19-vaccine/

81 National Audit Office, *The rollout of the COVID-19 vaccination programme in England* (2022) at 29, fn 14, 'None of the contracts provided the UK with any rights to the intellectual property associated with the vaccines.'

82 Donato Mancini, 'AstraZeneca vaccine document shows limit of no-profit pledge' Financial Times (2020) - https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686

83 Donato Mancini, 'Vaccine patents battle intensifies as poor nations struggle in war on coronavirus' Financial Times (16 August 2021) -

https://www.ft.com/content/cf12e1ba-ee25-4a0a-870d-53f5b66b0996

84 Details of the UAEM campaign are accessible at https://cherwell.org/2020/05/30/student-campaign-for-affordable-access-to-oxford-covid-19-vaccine/ and

https://studentsforglobalhealth.org/universities-allied-of-essential-medicines-uaem-2/

85 Although an unredacted version of the UK-AstraZeneca contract is unavailable, an unredacted version of the EU-AstraZeneca contract is available here - https://www.whatdotheyknow.com/request/668542/response/1802897/attach/3/Oxford%20AZ%20Covid19%20Vaccine%20Licence%20Redacted%20Version%20FINAL.pdf?cookie_passthrough=1

86 Donato Mancini, 'AstraZeneca vaccine document shows limit of no-profit pledge' Financial Times (2020) - https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686

AstraZeneca did change its policy during late 2021, to allow the price to be raised with a view to profiting.[87]

Overall, we conclude that the failure to disclose the terms of IP licence agreements can have an impact on prices in procurement contracts - and that a lack of transparency in either legal form can have negative consequences on access. By contrast, promoting transparency can assist in creating a model for what a voluntary licence agreement should consist of in a public health emergency. A good example is demonstrated by the UN Medicines Patent Pool (MPP). As a matter of standard operation MPP publishes its licence agreements in order to help develop best practices for the supply of medicines for global public health needs.[88]

Part II. Trade Secrets: Lack of Access to COVID-19 Vaccine Technologies During the COVID-19 Pandemic

2.1. The current set-up of vaccine production proved to be inadequate to swiftly combat the COVID-19 pandemic

When the COVID-19 outbreak began in late 2019 – and with the WHO declaring the COVID-19 outbreak a global pandemic on 11 March 2020 – the world faced a number of serious challenges. The first enormous task was to swiftly develop vaccines against the coronavirus. While the development of a vaccine typically requires significant time,[89] this challenge was successfully overcome within a relatively short period.[90] This was possible because of international collaboration on an unprecedented scale. The open publication of the genetic sequence of COVID-19 virus in early January 2020 by a team of Chinese and Australian researchers made this information freely available for access by researchers worldwide.[91] The subsequent development of life-saving vaccines would not have been possible without this collaborative research.[92] It is important not to take this for granted. In prior coronavirus crises, such as SARS and MERS, patents had been a barrier to rapid sharing of the genetic viral

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87 Julia Kollewe and Mark Sweney, 'AstraZeneca signs new Covid contracts in shift away from not-for-profit pledge' The Guardian (12 November 2021) - https://www.theguardian.com/business/2021/nov/12/astrazeneca-sells-22bn-of-covid-vaccine-in-first-nine-months

88 A list of MPP licences is here with links to the full documents - https://medicinespatentpool.org/progress-achievements/licences. See also - https://msfaccess.org/voluntary-licenses-access-medicines

89 Hilde Stevens et al., 'Vaccines: Accelerating Innovation and Access. Global Challenges Report' WIPO (2017) at 14 <https://www.wipo.int/publications/en/details.jsp?id=4224> ("While the pace of vaccine development has increased throughout history, there is still a time lag of more than a decade between the discovery of a vaccine candidate and its translation into a safe and effective product…In spite of technological progress, the vaccine development pathway remains lengthy|").

90 William Petri, 'COVID-19 vaccines were developed in record time – but are these game-changers safe?' The Conversation (2020) <https://theconversation.com/covid-19-vaccines-were-developed-in-record-time-but-are-these-game-changers-safe-150249> ("The Pfizer-BioNTech and the Moderna COVID-19 messenger RNA vaccines <…> have been developed in less than a year.")

91 Mukhisa Kituyi, Secretary-General, UNCTAD, 'Covid-19: Collaboration is the engine of global science – especially for developing countries' World Economic Forum (2020) <https://www.weforum.org/agenda/2020/05/global-science-collaboration-open-source-covid-19/>.

92 J. Contreras, 'How the "Patent Eligibility Restoration Act" Would Harm American Businesses and Endanger Global Health by Reintroducing 'Pathogen Patents' Patently-O Blog (2023). J Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA*(Algonquin Books, 2021).

sequences, because the researchers who had sequenced the viruses first claimed patents on these sequences, holding up research by others.[93] Due to the widespread ending the practice of allowing patents on genetic sequences following a crucial US case in 2013, the COVID-19 virus was shared openly.[94] As discussed below, there is a stark contrast between the open approach to the sharing of the genetic sequence of the virus, and the subsequent attitude taken by pharmaceutical companies to the vaccine technologies.

As outlined above, another important aspect that facilitated the successful development of COVID-19 vaccines was significant public funding of research and development into the vaccines;[95] i.e. government funding for promising vaccine candidates removed much of the risk for pharmaceutical companies.[96] As stated by the OECD, '[t]he development of vaccines for COVID-19 has been a powerful demonstration of how substantial public funding, intense focus, and unprecedented levels of scientific collaboration can help spur innovation to address global public needs in a very short time.'[97] By 2 December 2020, less than one year since the release of the genetic sequence of the virus, the UK Medicines and Healthcare Products Regulatory Agency had approved the Pfizer-BioNTech COVID-19 vaccine, making the United Kingdom the first country to provide emergency authorisation to such a coronavirus vaccine.[98] The approval of other vaccines, including Oxford-AstraZeneca and Moderna, subsequently followed.[99]

Once viable vaccine candidates emerged, the next significant hurdle in combating the pandemic concerned the manufacture and distribution of the COVID-19 vaccines across the globe in a speedy, equitable and affordable manner. The global scientific community expressed the view that the most

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93 J. Contreras, 'How the "Patent Eligibility Restoration Act" Would Harm American Businesses and Endanger Global Health by Reintroducing 'Pathogen Patents' Patently-O Blog (2023). J Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA*(Algonquin Books, 2021).

94 J. Contreras, 'How the "Patent Eligibility Restoration Act" Would Harm American Businesses and Endanger Global Health by Reintroducing 'Pathogen Patents' Patently-O Blog (2023). J Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA*(Algonquin Books, 2021).

95 Samuael Cross et al., 'Who Funded the Research Behind the Oxford-Astrazeneca Covid-19 Vaccine?' (2021) BMJ Global Health, doi:10.1136/ bmjgh-2021-007321 ("Funders of ChAdOx platform research by grant mention in academic publications were 99% public and charitable bodies, of which 27.4% was overseas governments (including the European Union), 25.5% the UK government, 23.9% philanthropy, 19.6% research institution and 2.6% public–private partnership. Freedom of information (FOI) requests to the University of Oxford showed 97% public and charitable funding for the ChAdOx platform; the European Commission (34.0%), Wellcome Trust (20.4%) and Coalition for Epidemic Preparedness Innovations (17.5%) were the biggest funders of ChAdOx research until the start of the COVID-19 pandemic, but since January 2020, the UK government contributed 95.5% of identifiable R&D funding until October 2020"); Kayvan Bozorgmehr et *al*, 'Free licensing of vaccines to end the COVID-19 crisis' (2021) 397 The Lancet 1261.

96 Claire Klobucista, 'A guide to COVID-19 vaccine efforts' Council of Foreign Relations (2022) <https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts>.

97 OECD, 'OECD Policy Responses to Coronavirus (COVID-19). Enhancing public trust in COVID-19 vaccination: The role of governments' (2021) <https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/>.

98 Nasir Abbas and Zaheer-Ud-Din Babar, 'Marketing authorization of COVID-19 vaccines across UK, EU, and the US: fact-checking and the implications for future research' (2021) 14 Journal of Pharmaceutical Policy and Practice 110*;* Heidi Ledford, David Cyranoski and Richard Van Noorden, 'Covid Vaccines: What Scientists Now Want to Know' Nature (2020) <https://media.nature.com/original/magazine-assets/d41586-020-03441-8/d41586-020-03441-8.pdf >.

99 NHS, 'Coronavirus (COVID-19) vaccine) <https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/>; 'COVID-19 vaccine tracker' <https://www.covid-19vaccinetracker.org/> (As of August 2022, 24 vaccines are or were in use, 109 are or were in clinical testing and 276 vaccines are or were in development worldwide.)

effective way to end the COVID-19 pandemic would be through the mass vaccination of populations around the world.[100] Given the global dimension of the pandemic, billions of vaccine doses need to be produced and distributed worldwide to contain the rapid spread and mutation of the virus across the globe. In 2021, at the apex of the pandemic, companies were simply unable to produce enough vaccines to inoculate the majority of the world population within an optimal period to contain and combat the pandemic.[101]

Although scarcity of vaccines was particularly acute during 2021, and overall supply had improved by mid-2022, vast inequalities remain today, particularly with respect to access to the most effective mRNA vaccines and Omicron-targeting bivalent boosters.[102] As of 30 September 2022, over two years into the pandemic, and despite 12.74 billion doses having been administered globally,[103] 72,54% of the population in high income countries had been vaccinated with at least one dose, while only 24,27% had been vaccinated in low-income countries.[104] The failure to achieve vaccine equity has contributed to the prolonging of the COVID-19 pandemic. As reported by Nature, the hoarding of vaccine doses and technologies by HICs like the UK may have led to more than one million lives lost in LMICs.[105]

The problem of global vaccine inequity was predictable. Anticipating the inadequacy of the vaccine development and manufacturing systems, numerous calls for sharing vaccine technologies to boost the production of vaccines were made early on, starting in May 2020 with the WHO COVID-19 Technology Access Pool (C-TAP).[106] C-TAP initiated a call for action within the global community, and most importantly by pharmaceutical companies, to voluntarily share knowledge, intellectual property and data necessary to combat COVID-19. However, C-TAP attracted no contributions from major vaccine producers, as pharmaceutical companies refused to share their vaccine technologies with this scheme or other similar initiatives such as the WHO mRNA Hub in South Africa.[107] Despite production levels falling short, pharmaceutical companies rejected vaccine technology licensing

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100 OECD, 'OECD Policy Responses to Coronavirus (COVID-19). Enhancing public trust in COVID-19 vaccination: The role of governments' (2021) <https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/> accessed 26 November 2022.

101 Sarah Newey, 'Pharmaceutical leaders admit 'we dismally failed' at global Covid vaccine rollout' The Telegraph (16 December 2021) <https://www.telegraph.co.uk/global-health/science-and-disease/pharmaceutical-leaders-admit-dismally-failed-global-covid-vaccine/> accessed 26 November 2022.

102 Olga Gurgula and Wen Hwa Lee, 'How can governments end the COVID-19 pandemic?' Oxford Martin School blog (28 May 2021) <https://www.oxfordmartin.ox.ac.uk/blog/how-can-governments-end-the-covid-19-pandemic/> accessed 26 November 2022.

103 Our World in Data, 'Coronavirus (COVID-19) vaccination) <https://ourworldindata.org/covid-vaccinations> accessed 26 November 2022.

104 UNDP, 'Global Dashboard for Vaccine Equity' (2022) <https://data.undp.org/vaccine-equity>/ accessed 26 November 2022.; see also WHO Coronavirus (COVID-19) Dashboard <https://covid19.who.int/> accessed 26 November 2022.

105 Heidi Ledford, 'Covid Vaccine hoarding might have cost more than a million lives' Nature (2 November 2022) -

106 WHO, 'WHO COVID-19 Technology Access Pool' <https://www.who.int/initiatives//covid-19-technology-access-pool> accessed 26 November 2022.

107 Michael Safi, 'WHO platform for pharmaceutical firms unused since pandemic began' The Guardian (22 January 2021) <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began> accessed 26 November 2022; WEMOS 'Covid-19 Technology Access Pool (C-TAP)' <https://covid19response.org/c-tap/> accessed 26 November 2022 ("In November 2021, the Spanish National Research Council (CSIC) shared its intellectual property rights and know-how of its Covid-19 diagnostic tools globally through C-TAP, becoming the first one to do so. In May 2022, the US National Institutes of Health (NIH) announced licensing agreements with C-TAP for several therapeutics, early-stage vaccines and diagnostic tools… However, it lacks active support from governments where intellectual property and know-how is located").

requests from several pharmaceutical manufacturers,[108] including manufacturers in Canada, Bangladesh, and Denmark.[109] Instead, pharmaceutical companies – particularly mRNA vaccine technology holders Moderna and Pfizer-BioNTech – prioritised keeping a tight grip on IP, concentrating on their own manufacturing capacities, and only striking limited bilateral deals.[110] These companies continue to take a restrictive approach. In late November 2022, it was reported that Pfizer-BioNTech and Moderna were withholding mRNA vaccine samples that could allow researchers at Yale University to develop new COVID-19 vaccines. Dr Iwakai (Yale) has been developing a nasal vaccine that aims to boost immunity in those who had received mRNA vaccine shots. However, he has not been able to obtain Pfizer-BioNTech or Moderna vaccine samples in order to do comparative studies in monkeys.[111]

Fundamentally, this pandemic has shown that the current system of medical innovation and access to medicines is not designed to tackle such extraordinary situations as the COVID-19 pandemic.[112] In normal times, the IP system is supposed to balance the private interests of companies and the public interest in access to health technologies (although the adequacy of this balance has been increasingly questioned as prices have risen dramatically in recent years).[113] A lesson of the COVID-19 pandemic is that during emergencies, this system should be rebalanced with the public interest in protecting (global) public health taking precedence over private financial interests of pharmaceutical corporations.

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108 Carlos M. Correa, 'Expanding the production of COVID-19 vaccines to reach developing countries' (2021) 91 South Centre Policy Brief <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf> accessed 26 November 2022 ("Some companies - Incepta from Bangladesh, Biolyse from Canada, Getz Pharma from Pakistan, Teva from Israel - have reported that current vaccine producers have dismissed or not even responded to requests to obtain licenses for production"); Arianna Schouten, 'Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low Income Countries, may test Canada's compulsory licensing for export law' KEI (12 March 2021) <https://www.keionline.org/35587> accessed 26 November 2022. (Referring to the Biolyse-Bolivia example - J&J refused to license its technology to Biolyse).

109 Brook K. Baker, 'Third-Way Proposals from Big Pharma and the WTO are the Same-Old Way – Commercial Control of Supply, Price, and Distribution' (2021) The People's Vaccine Policy Brief - https://healthgap.org/wp-content/uploads/2021/05/Baker.The-Third-Way-is-the-Same-Old-Way-Final1.pdf

110 Aisling Irwin, 'What it will take to vaccinate the world against COVID-19' Nature (2021) <https://www.nature.com/articles/d41586-021-00727-3> accessed 26 November 2022; K M Gopakumar, Chetali Rao and Sangeeta Shashikant, 'Trade secrets protection and vaccines: The role of medicine regulatory agencies' (2021) Third World Network Briefing Paper - ('the current approach of the multinational pharmaceutical industry to production and supply of vaccines is mainly premised on expanding internal capacity, establishing secretive contract manufacturing agreements with selected contractors and artificially constraining production and supply').

111 Benjamin Mueller, 'The End of Vaccines at "Warp Speed" The New York Times (18 November 2022) - www.nytimes.com%2F2022%2F11%2F18%2Fhealth%2Fcovid-nasal-vaccines-warp-speed.html&usg=AOvVaw0TZxhI5pCftdOKW6sIQuwu

112 E. Richard Gold, 'What the COVID-19 pandemic revealed about intellectual property' (2022) 40 Nat Biotechnol 1428 https://doi.org/10.1038/s41587-022-01485-x accessed 26 November 2022.

113 Olga Gurgula, 'Drug Prices, Patents and Access to Life-Saving Medicines: Changes Are Urgently Needed in the COVID-19 Era' (2021) 43 European Intellectual Property Review 381.

2.2. IP as a barrier for accessing vaccine technologies and the inadequacy of the current legal system in facilitating technology transfer

Within the IP system, trade secrets include various types of information that give an economic or competitive advantage to the owner because such knowledge is not generally known by rivals.[114] In relation to vaccines, trade secrets may include industrial secrets concerning complex manufacturing processes, as well as information about specific (unpatented) medical formulae ('recipes'), cell lines, genomic information and other biological materials. It may also include information about dead ends, trials and errors.[115]

Trade secrecy was relied upon extensively by pharmaceutical companies to prevent access to COVID-19 vaccine technologies. Pharmaceutical companies rejected the voluntary sharing of COVID-19 vaccine technologies with C-TAP and/or the WHO mRNA hub, and, as noted above, also refused licensing offers from several other manufacturers with production capacities. The result was that knowledge critical to facilitating the rapid diversification and scaling up of vaccine production was kept secret by pharmaceutical companies; whereas, had it been shared on an open basis, this would have encouraged more widespread production of vaccines worldwide, therefore assisting in attaining widespread global coverage.[116]

This failure of voluntary engagement led to proposals for alternative mechanisms. To overcome the problem of insufficient production of COVID-19 vaccines in, and for, countries in the global south, two key proposals were put forward at the World Trade Organisation (WTO) level. One of them was the proposal by South Africa and India to temporarily waive IP rights relating to COVID-19 vaccines, treatments and diagnostics under the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[117] In May 2021 this proposal was partially supported by the US.[118] To counter this proposal, on 4 June 2021, the EU advanced its own proposal to merely clarify the currently available flexibilities in TRIPS[119] in the form of compulsory licensing.[120] The final WTO Ministerial Decision

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114 For a detailed discussion on the main characteristics of trade secrets related to COVID-19 vaccines see Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer' (2021) 16 Journal of Intellectual Property Law & Practice 1242.

115 Michael Risch, "Why Do We Have Trade Secrets?" (2007) 11 Intellectual Property Law Review 1.

116 Ashleigh Furlong, Sarah Anne Aarup and Samuel Horti, 'Who killed the COVID vaccine waiver?' Politico (10 November 2022) –https://www.politico.eu/article/covid-vaccine-poor-countries-waiver-killed/

117 Communication from India and South Africa, 'Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19' (2 October 2020) IP/C/W/669. A revised proposal was submitted on 21 May 2021. See 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. Revised Decision Text' <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True> accessed 26 November 2022.

118 Andrea Shalal, Jeff Mason and David Lawder, 'U.S. reverses stance, backs giving poorer countries access to COVID vaccine patents' Reuters (5 May 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/> accessed 26 November 2022.

119 WTO Agreement on Trade-Related Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, as amended on 23 January 2017.

120 Communication From the European Union to the Council for TRIPS, 'Urgent Trade Policy Responses to the Covid-19 Crisis: Intellectual Property' Brussels (4 June 2021) <https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf> accessed 26 November 2022.

on these proposals was adopted on 17 June 2022 at the 12th Ministerial Conference of the WTO.[121] The latter decision is considered to be an inadequate solution to the global pandemic, as it simply clarifies and waives certain provisions regarding the grant of compulsory licences of patents, and relates to COVID-19 vaccines only (rather than also including treatments and diagnostics).[122]

As detailed in the following sections, the legal mechanisms at the international and national levels - in the form of compulsory licensing of patents, as well as pharmaceutical regulations and the FOIA - provide inadequate solutions for the involuntary transfer of lifesaving COVID-19 vaccine technologies. Resolving this is important not just for this pandemic, but for building resilience into the legal system as part of global pandemic preparedness.

2.2.1. Current legal mechanisms are inadequate to facilitate involuntary technology transfer

a) Compulsory licensing of patents

Patents provide the exclusive rights to their owners to prevent others from using a protected invention, but the exercise of such rights may be limited in view of the public interest, including to protect public health.[123] International and national laws contain specific mechanisms, such as 'compulsory licences' and 'government use for non-commercial purposes' that facilitate restrictions on the exercise of exclusive rights under the patent. Put simply, a compulsory licence is an authorisation granted by a state authority that allows the person who receives it to use the invention without the consent of the patent holder.[124] To help governments in securing sufficient amounts of , for example, COVID-19 medicines, a special type of a compulsory licence can be utilised. This is called 'government use'[125] under which the state grants an authorisation for its *own use,* meaning that such authorisation is given to a state agency or department, or even to a private entity.[126] These mechanisms are bound by the terms of Article 31 TRIPS.[127] In November 2001, the Doha Declaration on the TRIPS Agreement and Public Health[128] confirmed that the granting of compulsory licences is one of the flexibilities under TRIPS, which all

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121 WTO, Draft Ministerial Decision on the TRIPS AGREEMENT, WT/MIN(22)/W/15/Rev.2, 17 June 2022 <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True> accessed 26 November 2022.

122 See Carlos M. Correa and Nirmalya Syam, 'Analysis of the Outcome Text of the Informal Quadrilateral Discussions on the TRIPS COVID-19 Waiver' (2022) 110 South Centre Policy Brief.

123 Carlos M. Correa, 'Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents' (2020) 107 South Centre Research Paper.

124 See the Patents Act 1977 (sections 46 – 54).

125 For example, UK law contains 'Crown use'. Under section 55 of The Patents Act 1977, any government department, or person authorised in writing by a government department, may, for the services of the Crown, perform certain acts in the UK without the consent of the proprietor of the patent. Such acts consist of: (i) making, using, importing/keeping the product or selling or offering to sell the product where doing so would be ancillary to making, using importing or keeping it; or (ii) selling or offering to sell the product for foreign defence purposes or for the production or supply of specified drugs and medicines. Section 59 of The Patents Act 1977 provides for Crown use during a period of emergency and extends the powers provided under Section 55.

126 Medicines Law & Policy. Research and resources on intellectual property and health <https://medicineslawandpolicy.org/tools/> accessed 26 November 2022.

127 Article 31 of the TRIPS Agreement. This provision applies to both compulsory licenses and government use.

128 WT/MIN(01)/DEC/W/2, 14 November 2001, available from www.wto.org.

WTO members have the right to use if necessary.[129] These mechanisms have been implemented in the majority of jurisdictions worldwide, including in the UK, and may be used to address public health needs.[130]

While compulsory licensing of patents can be used to improve the production of COVID-19 treatments and medicines to various degrees,[131] this mechanism is not sufficient, by itself, to boost the production of vaccines. This is because vaccines are complex biologics, and their manufacture is challenging. Complex biologics differ from small-molecule drugs. The latter are relatively easy for generic manufacturers to reverse-engineer and reproduce, without the generic manufacturers needing to know a specific manufacturing process used by the original producer. However, with a vaccine, the knowledge of how to manufacture it may be of critical importance.[132] Vaccine production involves complex processes and requires tailored facilities, specific equipment, and specialist knowledge and experience.[133] Access to this know-how is vital, otherwise it may take a lot of time and effort for new manufacturers to develop such knowledge themselves,[134] delaying the increase in the production of vaccines. As noted above, such knowledge is typically not only protected by patents, but also by trade secrets.[135] For this reason, Searle argues that in the field of vaccines, a manufacturing process itself is somewhat akin to a product.[136]

Therefore, relying solely on compulsory licensing of patents would be insufficient. The compulsory licensing mechanism does not provide an option or mandate to compel pharmaceutical companies to share know-how with other manufacturers. This gap leaves power with the private companies, resulting in both developed and developing countries relying on such companies to provide a sufficient number of vaccines. When companies fall short, as they did during the apex of the COVID-19 pandemic during

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129 Doha Declaration on the TRIPS Agreement and Public Health: 'Sub-paragraph 5 (b) 5. Accordingly, and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: … b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.'

130 Carlos M. Correa, 'Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents' (2020) 107 South Centre Research Paper.

131 For a critique of this mechanism see Olga Gurgula, 'Compulsory Licensing vs. the IP Waiver: What Is the Best Way to End the COVID-19 Pandemic?' (2021) 104 South Centre Policy Brief <https://www.southcentre.int/policy-brief-104-october-2021/> accessed 26 November 2022.

132 Aisling McMahon, 'Patients, access to health and COVID 19 – the role of compulsory and government-use licensing in Ireland' (2020) 71 Northern Ireland Legal Quarterly 331; Sara Eve Crager, 'Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer and Regulatory Pathways' (2014) 104 Am Jo Pub Health, e87 (arguing that for a successful vaccine access strategy '[a]ccess to manufacturing process information protected by trade-secret law, as well as access to technology and know-how held by the innovator company, will likely be necessary').

133 John Smeaton and Lydia Harriss, 'Manufacturing COVID-19 vaccines' UK Parliament (14 January 2021) <https://post.parliament.uk/manufacturing-covid-19-vaccines/> accessed 26 November 2022; Derek Lowe, 'COVID_19: Myths of Vaccine Manufacturing' Science Translational Medicine blog (2 February 2021) <https://blogs.sciencemag.org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing> 26 November 2022.

134 Aisling McMahon, 'Patients, access to health and COVID 19 – the role of compulsory and government-use licensing in Ireland' (2020) 71 Northern Ireland Legal Quarterly 331.

135 Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer' (2021) 16 Journal of Intellectual Property Law & Practice 1242.

136 Nicola Searle, 'The process may (or may not) be the product: trade secrets and COVID research' The IPKat blog (3 August 2020) <https://ipkitten.blogspot.com/2020/08/the-process-may-or-may-not-be-product.html > accessed 26 November 2022.

2020-21, this negatively affects countries' abilities to adequately protect public health.[137] This power imbalance is glaring given that, as was mentioned above, the R&D and production of the vaccines was heavily subsidised by public funding from the UK, EU and US governments.[138]

The following sections will provide an outline of the alternative legal pathways currently available in UK law which could provide a route to accessing information about a vaccine beyond the publicly available patent documentation. However, as will be explained, these mechanisms may not be sufficient – and are certainly not optimal – to enable a third party to produce a generic vaccine, which means reform is required.

b) Disclosure of data contained in a marketing authorisation dossier by a marketing authorisation body

As noted above, a compulsory licence of a patent may not, by itself, provide sufficient information to manufacture a vaccine in generic form. One possible route to accessing such information is via the regulatory data stored by public authorities. Before a vaccine can be used, a marketing authorisation body must assess all the data from preclinical and clinical trials and decide on its quality, safety and efficacy. In the UK, the grant of a marketing authorisation is governed by the Human Medicines Regulations 2012 that were implemented to consolidate the law pertaining to the authorisation and production of medical products under EU Directive 2010/84/EU. The authority responsible for granting marketing authorisation of medical products, including COVID-19 vaccines, is the Medicines and Healthcare products Regulatory Agency (MHRA).

The information supplied by a pharmaceutical company that accompanies an application for a marketing authorisation includes, among other things, the results of the pharmaceutical tests, pre-clinical tests and clinical trials.[139] It also includes a description of methods of manufacturing relevant to the medicinal product.[140] Some authors suggest that providing access to such information to other (generic) manufacturers may help in replicating a vaccine.[141] In this view, access to a marketing authorisation dossier could help a generic manufacturer to obtain know-how about the production of a

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137 Michael Safi, 'WHO platform for pharmaceutical firms unused since pandemic began' The Guardian (22 January 2021) <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began> accessed 26 November 2022 **(**explaining that the C-TAP has attracted zero contributions since it was established in May 2020**)**; Grace Ren, 'Progress on COVID-19 Technology Pool Inches Along as Sister Initiative to Pool Vaccine Procurement Accelerates' Health Policy Watch (25 August 2020) <https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/> accessed 26 November 2022 ("…unlike the COVAX Facility, which has received broad industry support, the COVID-19 Technology Access Pool has been dismissed by the pharmaceutical industry, which holds much of the rights to the technology, data, and research that the Pool would aim to more freely distribute").

138 Kayvan Bozorgmehr et al., 'Free licensing of vaccines to end the COVID-19 crisis' (2021) 397 The Lancet 1261.

139 Para 11, Schedule 8 of the Human Medicines Regulations 2012. See also EU Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use Text with EEA relevance - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0084

140 Para 5, Schedule 8 of the Human Medicines Regulations 2012.

141 K M Gopakumar, Chetali Rao and Sangeeta Shashikant, 'Trade secrets protection and vaccines: The role of medicine regulatory agencies' (2021) Third World Network Briefing Paper, ("…the dossier contains crucial information that could allow non-originator manufacturers to replicate the product without the cooperation of the originator").

vaccine, given that the dossier is likely to contain useful information beyond that disclosed in the patent specification (for a patent under a compulsory licence).[142]

However, from the wording of the relevant medicines regulation provision it is not clear how precise the disclosure of a 'method of manufacture' by the marketing authorisation applicant must be.[143] It is not clear whether a manufacturer must disclose to the MHRA the details of a particular piece of machinery, or a physical element of the process, which is critical in the production of a vaccine. In some cases, the method of manufacture provided in the dossier may not contain sufficient details to allow a generic manufacturer to produce a vaccine to the required level of perfection and purity. Nevertheless, the combination of the publicly available patent specification(s) and the provision of access to the regulatory dossier, would provide a generic manufacturer with a greater amount of useful information than the mere patent documents alone.

There are limitations to how effective this approach may be. For one thing, under the current law obtaining access to such information may not be possible. This is because the marketing authorisation body may point to trade secret protection and refuse to disclose this information to a third party.[144] In such a scenario, the most feasible way for third parties to seek to obtain access to the information contained in a MHRA marketing authorisation dossier would be under the Freedom of Information Act 2000 (FOIA), mentioned above. As a government agency, the MHRA is subject to the FOIA and assesses each FOIA request on its merits, deciding the level of disclosure needed to comply. The MHRA also takes under advisement the Heads of Medicines Agency (HMA)/European Medicines Agency (EMA) guidance on disclosure of documents contained within the marketing authorisation dossier.[145] According to the HMA/EMA guidance, personal data, confidential information and commercially sensitive information may be redacted from the documents disclosed. In line with the HMA/EMA guidance, information encompassing non-clinical and clinical development of the medicinal product, and the subsequent assessment by a competent authority, is not considered commercially confidential *per se* (although some information can be redacted, e.g. where innovative study designs and/or innovative analytical methods have been used).[146] Yet, information related to the details of the

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142 Christopher Morten, 'Publicizing Corporate Secrets' (Forthcoming, 2022) 171 University of Pennsylvania Law Review <https://ssrn.com/abstract=4041556 or http://dx.doi.org/10.2139/ssrn.4041556> accessed 26 November 2022.

143 For example, according to Annex 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended '[t]he description of the manufacturing method accompanying the application for marketing authorization pursuant to Article 8(3)(d), shall be drafted in such a way as to give an adequate synopsis of the nature of the operations employed'.

144 Hilde Stevens et al., 'Vaccines: Accelerating Innovation and Access. Global Challenges Report' WIPO (2017) at 20 <https://www.wipo.int/publications/en/details.jsp?id=4224> accessed 26 November 2022 ('In most sectors, companies can protect commercially sensitive data through trade secrecy laws, but the requirement for vaccine manufacturers to disclose data to regulators puts them at a competitive disadvantage. Clinical test data protection thus ensures that competitors cannot gain regulatory approval and enter the market via reliance on an innovator's test data before the innovator has had an opportunity to recoup the costs of compiling it.'); Kristina Lybecker, 'When patents aren't enough: Why biologics necessitate data exclusivity protection' (2014) 40 Wm. Mitchell L. Rev. 1427.

145 Heads of Medicines Agencies/ European Medicines Agency, *HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the Marketing Authorisation (MA) application – Release of the Information after granting of a Marketing Authorisation* (November 2012)

https://www.ema.europa.eu/en/documents/other/heads-medicines-agencies/european-medicines-agency-guidance-document-identification-commercially-confidential-information_en.pdf

146 ibid, para 3.2.

manufacturing process is likely to be classed as commercially confidential, and thus is unlikely to be disclosed by the EMA or MHRA as a normal matter of practice.[147]

Section 41(1) FOIA sets out an exemption from the 'right to know' where the information was provided to the public authority in confidence.[148] The provision states that information is exempt information if: (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public <…> by the public authority holding it would constitute a breach of confidence actionable by that or any other person. When determining whether to release the dossier under Section 41, the MHRA would need to consider whether there would be a public interest defence to the disclosure i.e. public health.

Another relevant provision is Section 43 FOIA. As explained above, Section 43 FOIA contains a qualified exemption.[149] This means that if the requested information is exempt from disclosure (either because the information is a trade secret or because of prejudice to commercial interests), the authority that holds the protected information must consider whether the public interest in maintaining the exemption outweighs the public interest in its disclosure.[150] In an emergency circumstance, such as a pandemic, the public interest could be invoked, with disclosure to a third party viewed as necessary to protect public health.

Given that no third-party generic manufacturer made such a FOIA request during the COVID-19 pandemic, this approach is untested.[151] If such a request were made in future, the MHRA would need to balance the claim by the original pharmaceutical manufacturer that the information in the marketing authorisation dossier ought to be kept confidential with the need, in an emergency, to allow generic production of a vaccine. On the one hand, by sharing such information with a generic manufacturer, the MHRA would arguably be devaluing the originator company's valuable asset in a way which would be difficult to compensate. In this vein, the MHRA would consider the pharmaceutical companies' interest in limiting the disclosure of information relating to products they are marketing, or are planning to place on the market.[152] On the other hand, the MHRA would need to look at the public health and public interest arguments, i.e. would it be right to disclose the requested information given a (global) emergency? During an emergency circumstance, such as a pandemic, the public interest argument in allowing access to information which would help to protect public health could be compelling..

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147 ibid, para 3.1.

148 ICO, 'Information provided in confidence (section 41)' <https://ico.org.uk/media/for-organisations/documents/1432163/information-provided-in-confidence-section-41.pdf> accessed 26 November 2022.

149 ICO, 'Section 43 – Commercial Interests' <https://ico.org.uk/for-organisations/guidance-index/freedom-of-information-and-environmental-information-regulations/section-43-commercial-interests/> accessed 26 November 2022.

150 ibid.

151 See the 2022 ICO case where a complainant (not a prospective generic manufacturer) made a FOIA request for all COVID-19 vaccine data held by the MHRA. The MHRA refused to issue the information and the ICO upheld this decision, after the MHRA followed the HMA/EMA guidance and the FOIA. See *Freedom of Information Act 2000 (FOIA) Decision notice IC-167627-X2Z0* (18 November 2022). The ICO case officer stated: 'However, it is precisely because of the volume and complexity of information in the scope of the request that has led the Commissioner to accept that the burden placed on the MHRA in complying with it is a grossly oppressive one.'

https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4022928/ic-167627-x2z0.pdf

152 ibid.

Yet, a further challenge in relying on this mechanism is that even if the information contained in the marketing authorisation dossier were sufficient to produce a vaccine, and the MHRA were to agree to disclose it, such a disclosure would certainly lead to further legal challenges by the company. As the MHRA is a public body, there would be a process of judicial review, which in normal times would be lengthy, though the courts may decide to expedite it in an emergency.

Finally, it is notable that if the MHRA were to decide to authorise the disclosure of the required information to a third party, the MHRA would not be acting as a licensor, and the third party would not be a licensee, as the MHRA has no equivalent power to act as a compulsory licensor comparable with that under the Patents Act 1977; the latter, as was explained above, establishes a specific process for compulsory licensing of patents in certain circumstances. Due to a lack of legislative provision, it is unclear what conditions the MHRA could attach to the third-party usage of the information disclosed. This adds further complications to the process of providing access to information and balancing private and public interests.

Overall, the current domestic legal routes for a third party to obtain additional information on vaccine manufacture through accessing a marketing authorisation dossier are uncertain and sub-optimal. At present, UK law does not go far enough to resolve the problem of inadequacy of compulsory licensing of patents. As will be outlined below, reform is necessary.

c) Article 39(3) TRIPS and the public interest

It is worth commenting on whether disclosure of a dossier held by the MHRA could be a breach of the TRIPS Agreement. On this, it is arguable that the disclosure of the information contained in the marketing authorisation dossier would be in line with TRIPS. Article 39 TRIPS is drafted in terms of protection against unfair competition, but it is not silent on the public interest.[153] It requires members to protect undisclosed information '[i]n the course of ensuring effective protection against unfair competition as provided in Article *10bis* of the Paris Convention (1967)'. The regime of unfair competition essentially protects against unfair commercial practices. Similarly, Article 39(3) TRIPS requires WTO members to protect test data submitted to regulatory authorities against *unfair commercial use*.[154] In particular, this provision states that:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.

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153 International Chamber of Commerce, 'Protecting Trade Secrets - Recent EU and US Reforms' (2019) 8 <https://iccwbo.org/content/uploads/sites/3/2019/04/final-icc-report-protecting-trade-secrets.pdf> accessed 26 November 2022; Tanya Aplin, 'Right to Property and Trade Secrets' in *Research Handbook on Human Rights and Intellectual Property,* Christopher Geiger, ed, (Edward Elgar, 2015) 422.

154 Paris Convention for the Protection of Industrial Property (1883) – Article 10bis2 – '[a]ny act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition'. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) art. 39. Several 'TRIPS+' agreements protect trade secrets.

This provision serves as a basis for test data protection in many jurisdictions, including in the UK.[155] However, while Article 39(3) TRIPS mandates Members to protect such data against disclosure, it contains two exceptions, when disclosure is allowed: (a) where it is necessary to protect the public, or (b) when steps are taken to ensure that the data are protected against unfair commercial use. Therefore, disclosure of information contained in a dossier by a marketing authorisation body to a third party in order to accelerate the production of medicines during an emergency would appear to meet the exceptions of Article 39(3) TRIPS, and thus the disclosure would not breach the provision.[156] Disclosure would be necessary for the protection of the public (i.e. protection of public health); and would be unlikely to be considered an unfair commercial use in the context of a global emergency. This bolsters the argument provided above that under domestic law that a FOIA request to the MHRA for disclosure would be feasible (though not optimal).

d) A deferral of, or an exception to, marketing exclusivities would be necessary to allow the production of biosimilars of COVID-19 vaccines under a compulsory licence

One of the barriers that would also need to be overcome to enable generic vaccine manufacture relates to legal rights pertaining to data and marketing exclusivities (eight and two years respectively) that protect clinical test data submitted by the originator to the MHRA. This type of exclusivity aims to prevent rival pharmaceutical companies from utilising such data during the term of protection to, for example, obtain a marketing authorisation for their generic or biosimilar version of the originator's medicine via an abridged procedure. Therefore, such exclusivity would need to be deferred, waived or exempted, such as via legislative action, to allow the licensees under compulsory licences to obtain their marketing authorisations and launch their generic products before the normal end of exclusivity.[157] This is yet another gap in the legal architecture that needs to be filled via reform.

In the following sub-section we provide greater detail on the protection of trade secrets and map out the need for legislative reform.

2.2.2. An additional mechanism that must be implemented by the UK Government to enable effective involuntary technology transfer: compulsory licensing of trade secrets

a) UK Law of Trade Secrets

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155 Hilde Stevens et al., 'Vaccines: Accelerating Innovation and Access. Global Challenges Report' WIPO (2017) at 20 <https://www.wipo.int/publications/en/details.jsp?id=4224> accessed 26 November 2022 ('In most sectors, companies can protect commercially sensitive data through trade secrecy laws, but the requirement for vaccine manufacturers to disclose data to regulators puts them at a competitive disadvantage. Clinical test data protection thus ensures that competitors cannot gain regulatory approval and enter the market via reliance on an innovator's test data before the innovator has had an opportunity to recoup the costs of compiling it.'); Kristina Lybecker, 'When patents aren't enough: Why biologics necessitate data exclusivity protection' (2014) 40 Wm. Mitchell L. Rev. 1427.

156 Pires de Carvalho, *The TRIPS Regime of Antitrust and Undisclosed Information* (Kluwer Law International 2007) at paras 39.2.102 – 39.3.115 and 39.3.195 – 39.3.207.

157 A detailed analysis of this aspect is beyond the scope of this report, which focuses on trade secrets. For stellar analysis see Ellen t'Hoen et al., 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation' (2017) 10 Journal of Pharmaceutical Policy and Practice 1; Carlos M. Correa, 'Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents (World Health Organisation 2009).

Trade secrets, like other forms of IP, are territorial, protected under the laws of the country in which the owner is based, or of the country where an infringement action is pursued.[158] Under Article 39 TRIPS, signatory countries are obliged to provide protection to trade secrets as part of their national laws.[159] Some countries do so by unfair competition laws; others by a combination of tort, contract and employment statutes or codes.[160] The UK, and other countries which follow the common law, base their protection predominantly on case law and the development of the breach of confidence action.[161] In June 2018, the UK adopted the Trade Secrets (Enforcement, etc.) Regulations 2018,[162] implementing the 2016 EU Trade Secrets Directive that harmonised national laws across the European Union.[163]

b) Compulsory licensing of trade secrets: a proposal for a new mechanism

From the above discussion, it is evident that the information contained in a patent specification under a compulsory licence, even when combined with a marketing authorisation dossier (assuming it is shared by MHRA), may not be enough to enable a compulsory licensee of a patent to manufacture generically a complex vaccine.[164] Ideally, the generic producer would to be provided with detailed knowledge of

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158 Trade secret laws differ from country to country and no attempt is made here to provide detailed source material - Trevor Cook, *Trade Secret Protection: A Global Guide* (Globe Law and Business 2016) and Sharon K.Sandeen and Elizabeth A.Rowe, *Trade Secrets and Undisclosed Information* (Edward Elgar 2014). See also WIPO, 'Trade secrets' <https://www.wipo.int/tradesecrets/en/> accessed 26 November 2022.

159 Article 39 of the TRIPS Agreement reads as follows:

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

160 Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer' (2021) 16 Journal of Intellectual Property Law & Practice 1242.

161 *Coco v A.N.Clark (Engineering) Ltd*. [1969] RPC 41. Generally: Tanya Aplin et al*., Gurry on Breach of Confidence* (2nd edn, OUP 2012). The UK has implemented the 2016 EU Trade Secrets Directive - see the Trade Secrets (Enforcement etc) Regulations SI 2018/597.

162 Relevant EU law provides civil law remedies for breach of trade secrets, but also subjects trade secrets to the public interest assessment - The Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (hereinafter 'the EU Trade Secrets Directive'), 1(2)(b) states:

'This Directive shall not affect: [...] the application of Union or national rules requiring trade secret holders to disclose, for reasons of public interest, information, including trade secrets, to the public or to administrative or judicial authorities for the performance of the duties of those authorities.'

163 ibid.

164 In some scenarios, however, vaccine replication may be possible. The successful experience of the WHO hub, explored below in 2.3.1, in replicating the Moderna vaccine in the absence of Moderna's agreement, indicates there is some

the precise method of manufacture of the relevant vaccine and other know-how.[165] As acknowledged above, such knowledge is typically protected by the law of trade secrets. Nonetheless, although the emphasis is on secrecy, confidential information is often transferred to third parties via contract. In fact, companies voluntarily license the use of their trade secrets as a matter of common practice, i.e. when they make technology transfer agreements with other companies, such as when Oxford-AstraZeneca transferred vaccine know-how to Serum and Fiocruz during 2020-21. Trade secrets, including tacit know-how, usually forms part of such agreements. Where voluntary technology transfer occurs, this can be beneficial to all concerned. However, a lesson of the COVID-19 pandemic, and the Monkeypox crisis, is that relying on private companies to act voluntarily to achieve equitable health outcomes is risky, with the greatest harm from this risk falling on LMICs. Notably, in the early stages of the pandemic, several HICs, such as Germany, altered their domestic compulsory licence provisions to make it easier to deal with any projected shortages.[166] In the end, HICs such as the UK and Germany were able to access vaccines, and did not have to resort to compulsory means. However, this may not be the case in the next pandemic – indeed, the UK has suffered shortages of the Monkeypox vaccine, which is only made by one company in Denmark.[167]

The flexibility of compulsory licensing, as envisaged in the Patents Act 1977, was intended to balance strong proprietary patent rights with public health concerns. However, this flexibility is in grave danger of having no utility in practice. Crucially, where private companies refuse to engage in voluntary technology transfer of vaccine know-how, national governments such as the UK lack adequate legal mechanisms to compel them to do so. Furthermore, as TRIPS is silent about compulsory licensing of

cause for optimism in this regard - Amy Maxmen, 'South African scientists copy Moderna's COVID vaccine' Nature (3 February 2022) - https://www.nature.com/articles/d41586-022-00293-2

165 John Smeaton and Lydia Harriss, 'Manufacturing COVID-19 vaccines' UK Parliament (14 January 2021) <https://post.parliament.uk/manufacturing-covid-19-vaccines/> accessed 26 November 2022; Derek Lowe, 'COVID_19: Myths of Vaccine Manufacturing' Science Translational Medicine blog (2 February 2021) <https://blogs.sciencemag.org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing> accessed 26 November 2022.

166 See the activities of the German government in the early stages of the pandemic – Thomas Musmann, 'German Government Plans Possibilities to Limit Patents In View of Corona Pandemic' Kluwer Patent Law Blog (24 March 2020) - http://patentblog.kluweriplaw.com/2020/03/24/german-government-plans-possibilities-to-limit-patents-in-view-of-corona-pandemic/

167 Nicola Davis, 'UK trials smaller doses of monkeypox vaccine as supplies run low' The Guardian (22 August 2022) - https://www.theguardian.com/world/2022/aug/22/uk-trials-smaller-doses-of-monkeypox-vaccine-as-supplies-run-low

trade secrets, while at the same time encouraging technology transfer,[168] it is logical that countries should be able to implement such a provision in their national IP laws to protect the public interest.[169]

Therefore, we recommend the implementation of a new legal mechanism that would supplement compulsory licensing of patents, and facilitate compulsory access to, and transfer of, the relevant trade secrets that e.g. protect COVID-19 vaccine technologies. This preferred approach would ensure that the UK Government has all the legal tools it needs to effectively facilitate access to medicines in an emergency: the powers to grant compulsory licensing on both patents and trade secrets when needed.

Legislating for a new mechanism would build resilience into the UK's pandemic preparedness. Without such an additional mechanism, compulsory licensing of patents may become even more of a shallow and ineffective tool, given that an increasing number of new medicines, including COVID-19 vaccines, are complex biologics, protected not only by patents but also by trade secrets.

c) The complex nature of a compulsory licence of trade secrets and its key elements

One legislation is in place, compulsory licensing of trade secrets would be feasible via governmental order (similar to government, or Crown, use of patents). This order would oblige vaccine producers to disclose and provide access to all the information, including trade secrets, required to manufacture a vaccine.[170] However, in contrast to compulsory licensing of patents, where the patent owner can regain

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168 TRIPS encourages technology transfer to developing countries that lack manufacturing capacity. In particular, in the context of Article 31*bis* TRIPS, it states that:

"Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS."

169 In recent years, several jurisdictions, including the EU and Brazil, have discussed making amendments to their IP laws, which would require patent owners to transfer corresponding know-how to compulsory licensees of relevant patents. On the 7th July 2022 the European Commission launched an EU consultation: 'Intellectual property – revised framework for compulsory licensing of patents'. The questionnaire included a question on whether a compulsory licence should apply not only to patents but also to trade secrets (see question 5) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents/public-consultation_en> (accessed 26 November 2022). On the 11th August 2021, the Brazilian Senate approved a Compulsory Licensing Bill (#12/2021), which amends the Brazilian Patent Statute (Law #9,279/96). The amendments require the patent or patent application holder to provide the necessary and sufficient information (e.g. know-how, technical aspects, biological material, test results and other data) for the effective reproduction of the object protected by the patent or patent application. On the 2nd September 2021, the bill was affected by vetoes made by Brazilian President Bolsonaro when he signed the law 14.200/2021. The President vetoed the provisions regarding sharing such information by the owner of technology as part of a compulsory licence (see Casimir Jones SC, 'Compulsory Licensing in Brazil: Updates and Perspectives' Lexology (17 August 2021) <https://www.lexology.com/library/detail.aspx?g=4adf38aa-3a49-4230-b129-82b3f750993e> accessed 26 November 2022; Louis Lozouet, 'Brazil: New Compulsory Licensing Rules For Patents In Brazil' Mondaq, (September 2021) <https://www.mondaq.com/Article/1111706> accessed 26 November 2022).

170 For a detailed analysis of the substance and elements of a compulsory licence of trade secrets see Olga Gurgula and John Hull, 'Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer' (2021) 16 Journal of Intellectual Property Law & Practice 1242; Olga Gurgula, 'Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer' (2021) 102 South Centre Policy Brief <https://www.southcentre.int/policy-brief-102-september-2021/> 26 November 2022.

the full right to utilise their patent rights after the emergency has passed and the licence has been terminated, compulsory licensing of trade secrets would raise additional issues.

Patents are public documents held at searchable databases via patent offices – their value is in the exclusive intellectual property rights the owner holds to that publicly disclosed information. The value of a trade secret, on the other hand, is precisely in it remaining secret; once such information ceases to be secret, and becomes public, much of its value may be lost. In this sense, compulsory licensing of trade secrets would need to differ from the comparable mechanism already developed for patents. Such a compulsory licence for trade secrets would need to balance the interests of the IP-holding company with the public interest in, for example, increased vaccine production. To this end, the licence must ensure that the transfer of trade secrets is limited only to the company that seeks to produce the product e.g. the vaccine. Specifically, to preserve the fairness of this mechanism, a compulsory licence must do two things. On the one hand, it must ensure full access to a vaccine technology necessary for production. On the other hand, it ought to mandate that the licensee would protect the transferred trade secrets from public disclosure, since such disclosure would deprive the secrets of their value, potentially harming the owner's business.

To achieve this, there are a number of elements that a compulsory licence of trade secrets must contain. These elements are divided between those that would be equivalent to terms typically included in a voluntary licensing and technology transfer agreement; and those that would reflect the compulsory nature of the licence. The two key elements of such a compulsory licence would be (i) the scope of the transfer and (ii) confidentiality. On the first of these, the licence must identify – and thus limit - the scope of the technology transfer so that it includes only the range of information necessary to enable production, such as precise technical assistance that would be needed to enable the licensee to make effective use of the technology. To maintain discretion the licence must also contain a confidentiality clause imposing strict obligations on the party to whom the trade secrets are being transferred, including a responsibility to observe security over the information transferred under the licence. This would follow the pattern of a typical voluntary technology transfer agreement, whereby the recipient of the technology is bound under contract from disclosing the confidential information received.

Finally, since this is a compulsory licence, the royalties paid to the licensor should be set by the UK government at a level that, on the one hand, would not impede the rationale of such a compulsory licence and, on the other hand, would adequately compensate the owner for the use of its technology.[171] The royalties should be calculated following the approach taken to calculate royalties with respect to compulsory licensing of patents.[172]

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171 During the COVID-19 pandemic Jamie Love suggested governments could attempt to buy out know-how and other information protected by trade secrets - Jamie Love, 'Buying Out Know-how to Scale Vaccine Manufacturing' Medium (20 March 2021) available at https://jamie- love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36 (last accessed 14 November 2022).

172 For example, according to WHO guidance, this should typically be a rate of 2%–4% based on generic product price - James Love, 'Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies' (2005) World Health Organization and United Nations Development Programme <https://apps.who.int/iris/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf?sequence=1&isAllowed=y> accessed 21 May 2021.

2.3. Case Studies on Open Innovation for Vaccines

To bolster our argument on the value of transparency and openness in the sphere of public health, in this section we highlight two examples of successful open innovation in the field of COVID-19 vaccines – first, the open source Corbevax model developed by Baylor College of Medicine (BCM) and the Texas Children's Center; and second, the WHO mRNA vaccine technology transfer hub.

2.3.1. The Open-Source Model of Vaccine Production – Corbevax

In contrast to the traditional model of closed or semi-closed innovation based on strong IP protection, the vaccine developed by Baylor College of Medicine (BCM) and the Texas Children's Center (Texas) is an example of a successful open-source model. This success belies the notion put forward by some in industry that protecting trade secrets is essential to the provision of safe, reliable vaccines. Notably, the BCM-Texas researchers who developed the Corbevax vaccine have gone beyond the more restrictive Oxford-AstraZeneca approach – the BCM-Texas scientists have published all of their engineering, process development and scale up procedures on an open access basis. For instance, the BCM-Texas researchers have published (openly) eight scientific publications about laboratory development of the BCM-Texas Children's CVD recombinant protein COVID-19 vaccine.[173] This means that manufacturers, researchers or partners can read the documents and conduct research into the manufacturing processes. As a normal practice, the BCM-Texas researchers do not utilise the law of trade secrets to protect their know-how.[174]

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173 See Wen-Hsiang Chen et al., 'Genetic modification to design a stable yeast-expressed recombinant SARS-CoV-2 receptor binding domain as a COVID-19 vaccine candidate' (2021) Biochim Biophys Acta Gen Subj Jun;1865(6):129893. doi: 10.1016/j.bbagen.2021.129893. Epub 2021 Mar 14. PMID: 33731300; PMCID: PMC7955913.

See also Jungsoon Lee et al., 'Process development and scale-up optimization of the SARS-CoV-2 receptor binding domain-based vaccine candidate, RBD219-N1C1' (2021) Appl Microbiol Biotechnol. May;105(10):4153-4165. doi: 10.1007/s00253-021-11281-3. Epub 2021 May 7. PMID: 33959781; PMCID: PMC8102132.

See also Jeroen Pollet et al., 'SARS-CoV-2 RBD219-N1C1: A yeast-expressed SARS-CoV-2 recombinant receptor-binding domain candidate vaccine stimulates virus neutralizing antibodies and T-cell immunity in mice.' (2021) Hum Vaccin Immunother. Aug 3;17(8):2356-2366. doi: 10.1080/21645515.2021.1901545. Epub 2021 Apr 13. PMID: 33847226; PMCID: PMC8054496.

See also Maria Pino et al., 'A yeast expressed RBD-based SARS-CoV-2 vaccine formulated with 3M-052-alum adjuvant promotes protective efficacy in non-human primates' (2021) Sci Immunol. Jul 15;6(61):eabh3634. doi: 10.1126/sciimmunol.abh3634. PMID: 34266981; PMCID: PMC9119307.

See also Etsuro Nanishi et al., 'Alum:CpG adjuvant enables SARS-CoV-2 RBD-induced protection in aged mice and synergistic activation of human elder type 1 immunity' (2021) bioRxiv [Preprint]. May 21:2021.05.20.444848. doi: 10.1101/2021.05.20.444848. PMID: 34031655; PMCID: PMC8142652.

See also Jeroen Pollet et al., 'Receptor-binding domain recombinant protein on alum-CpG induces broad protection against SARS-CoV-2 variants of concern' (2022) Vaccine. Jun 9;40(26):3655-3663. doi: 10.1016/j.vaccine.2022.05.007. Epub 2022 May 8. PMID: 35568591; PMCID: PMC9080055.

See also Wen-Hsiang Chen et al., 'Yeast-expressed recombinant SARS-CoV-2 receptor binding domain RBD203-N1 as a COVID-19 protein vaccine candidate' (2022) Protein Expr Purif. Feb;190:106003. doi: 10.1016/j.pep.2021.106003. Epub 2021 Oct 21. PMID: 34688919; PMCID: PMC8529586.

See also Peter Hotez and Maria Bottazzi, 'Whole Inactivated Virus and Protein-Based COVID-19 Vaccines' (2022) Annu Rev Med. Jan 27;73:55-64. doi: 10.1146/annurev-med-042420-113212. Epub 2021 Oct 12. PMID: 34637324

174 This was confirmed by the Corbevax researcher Maria Bottazzi in an email response to a query from the authors of this report (email on file with authors).

If the BCM-Texas researchers need to agree a contract with a specific partner to conduct further experimentation, or if for any reason more specialised documentation is required – such as regulatory enabling reports – then they utilise standard academic material transfer agreements (MTAs), or standard research collaboration frameworks. These set guiding principles of accountability, the scope of the work, and the approach to joint publications. These, and other measures they have taken, have enabled the production and subsequent administration of millions of Corbevax vaccine doses in India and Botswana.[175]

2.3.2. The WHO mRNA Vaccine Technology Transfer Hub

The WHO mRNA Vaccine Technology Transfer Hub was set up during the COVID-19 pandemic after it became clear that very little vaccine production was taking place in the global south, particularly on the African continent, which left much of the global south in an insecure position with regard to vaccine access.[176] The central firm is a biotechnology company – Afrigen Biologic and Vaccines – located in Cape Town, South Africa. As noted above, even in the context of the COVID-19 pandemic, Moderna and Pfizer-BioNTech refused to grant licences and share technology with the WHO mRNA hub. Thus, Afrigen had no choice but to reverse-engineer the vaccine without Moderna's know-how, data or technology transfer. As outlined above, reverse-engineering a vaccine, without technology transfer assistance, is no easy feat. Despite this immense challenge, in February 2022 Afrigen announced it was at the end stages of developing an mRNA vaccine comparable to the Moderna vaccine.[177] Key to this effort was assistance from scientists from around the world, including at the US National Institutes of Health (NIH). Due to the fact that NIH had co-developed the COVID-19 vaccine with Moderna during 2020, NIH's assistance was vital to Afrigen during 2021-22, though it is unclear whether NIH disclosed information to Afrigen that could be considered a Moderna trade secret.[178] NIH remains determined to continue to assist the WHO hub in its ongoing activities and has also begun to cooperate with C-TAP.[179]

Moderna and Pfizer-BioNTech's refusal to license the mRNA technology undeniably delayed the Afrigen development process by many months. In addition, without shared regulatory data from Moderna (or as argued above, from government agencies such as the UK MHRA, the EMA or the US FDA), the prediction is that it could take up to 12–18 months longer for Afrigen to roll out the vaccine than if such data were shared.[180]

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175 Mbongeni Mguni, 'Botswana Approves Corbevax Covid Vaccine, Plans Local Output' Bloomberg (28 March 2022) https://www.bloomberg.com/news/articles/2022-03-28/botswana-approves-corbevax-covid-vaccine-plans-local-output.

176 Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang and Graham Dutfield, 'Addressing vaccine inequity during the COVID-19 pandemic: the TRIPS intellectual property waiver proposal and beyond' (2022) 81 Cambridge Law Journal 384.

177 Amy Maxmen, 'South African scientists copy Moderna's COVID vaccine' Nature (3 February 2022) - https://www.nature.com/articles/d41586-022-00293-2.

178 Amy Maxmen, 'The radical plan for vaccine equity' Nature (13 July 2022) - https://www.nature.com/immersive/d41586-022-01898-3/index.html.

179 ibid.

180 Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang and Graham Dutfield, 'Addressing vaccine inequity during the COVID-19 pandemic: the TRIPS intellectual property waiver proposal and beyond' (2022) 81 Cambridge Law Journal 384.

Afrigen's accomplishment demonstrates that LMIC firms can replicate mRNA vaccines. Notwithstanding the assertions of IP rightsholders, the relative lack of licensing and technology-transfer agreements between mRNA companies and LMIC producers is not because LMICs lack competence or capacity.[181] During the COVID-19 emergency, rather than agreeing licensing deals with LMICs that would help deal with vaccine inequity, Moderna and Pfizer-BioNTech prioritised protectionist control over mRNA, seeing it as a technological platform that may offer them profitable income in the future. By contrast, the hub's LMIC researchers are adamant their countries need access to mRNA technology. One Indonesian researcher remarked: "High-income countries have all of the new technology, but low- and middle-income countries need it, too."[182] Another LMIC researcher stated: "We don't know how this pandemic will change with new variants, and if there is another pandemic, we need to be able to prepare our own weapons to defend us from a new disease."[183]

Although the WHO mRNA hub was established to combat COVID-19, the intention is that it could be useful for dealing with other diseases that tend to have a particularly deleterious impact on LMICS e.g., HIV, Zika, malaria etc. Aside from its centre at Afrigen, the hub aims to transfer mRNA technology to 15 institutions in LMICs:[184] Argentina (Sinergium Biotech); Brazil (Bio-Manguinhos); Egypt (BioGeneric Pharma S.A.E); Kenya (facility tbd); Nigeria (Biovaccines Nigeria Limited); Senegal (Institut Pasteur de Dakar); Tunisia (Institut Pasteur de Tunis); Bangladesh (Incepta Vaccine Ltd); Indonesia (Biofarma); India (BiologicalE (Bio E)); Pakistan (National Institute of Health); Serbia (Institut Torlak); South Africa (Biovac); Ukraine (Darnitsa); and Vietnam (Polyvac).

There are more than 80 known patents on mRNA COVID-19 vaccine technology.[185] The hub is unlikely to be the subject of legal action while it is merely making research use to work the mRNA technology in the lab.[186] Nevertheless, a greater possibility of patent infringement actions will arise if and when the hub attempts to bring a vaccine product to the market. Moderna has filed several mRNA patents in South Africa, and it remains unclear whether the company will eventually enforce these patents, as well as whether other mRNA IP rightsholders will take legal action.[187]

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181 Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang and Graham Dutfield, 'Addressing vaccine inequity during the COVID-19 pandemic: the TRIPS intellectual property waiver proposal and beyond' (2022) 81 Cambridge Law Journal 384.

182 Amy Maxmen, 'The radical plan for vaccine equity' Nature (13 July 2022) - https://www.nature.com/immersive/d41586-022-01898-3/index.html.

183 ibid.

184 https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

185 Mario Gaviria and Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' (2020) 39 Nature Biotechnology 546 – https://www.nature.com/articles/s41587-021-00912-9

186 Medicines Patent Pool, 'MPP position statement on patents with regards to the mRNA vaccine technology transfer hub' (2021) - https://medicinespatentpool.org/news-publications-post/mpp-position-statement-on-patents-with-regards-to-the-mrna-vaccine-technology-transfer-hub

187 Amy Maxmen, 'The radical plan for vaccine equity' Nature (13 July 2022) - https://www.nature.com/immersive/d41586-022-01898-3/index.html.

2.4. Monitoring pharmaceutical companies' IP-related practices during the COVID-19 pandemic by the Competition and Markets Authority (CMA)

To supplement our research into trade secrets, we provide a short comment here on market competition. Intellectual property (IP) law is closely intertwined with competition law. IP rights confer upon their owners' certain exclusivities that enable them to behave in a particular way. For example, patents provide exclusive rights to their holders, allowing them to prevent their competitors from marketing a product protected by the patent.[188] This, in turn, allows them to charge supra-competitive prices for a limited period.[189] Similarly, trade secret protection confers owners the right to prevent the information lawfully within their control from being disclosed, acquired or used by others without their consent in a manner contrary to honest commercial practice.[190] While preventing competitors from using the IP-protected technologies and thus gaining a competitive advantage is typically considered to be a lawful exercise of the IP rights, some IP-related practices may be considered anti-competitive to the extent that they significantly impede competition and harm consumer welfare.

In recent times, pharmaceutical companies have been accused of exploiting the IP system to delay or even block generic competition.[191] Such practices have attracted the attention of the European Commission, which discussed them in its 2009 Pharmaceutical Sector Inquiry Report.[192] The Commission identified a series of patent strategies which it described as aiming 'to extend the breadth and duration of [originators'] patent protection'[193] and 'to delay or block the market entry of generic medicine'.[194] These include, *inter alia*, such practices as 'pay-for-delay' agreements, life-cycle management strategies, sham litigation, divisional patent applications and strategic patenting.[195] These practices have the capacity not only to increase drug prices, making them unaffordable for patients, but also may affect dynamic competition by stifling innovation of both originators and generic companies.[196]

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188 See e.g. EGC, Case T-321/05 *AstraZeneca AB v. European Commission* (2010) EU:T:2010:266, para 362 (the possession of an exclusive right 'normally results in keeping competitors away, since public regulations require them to respect that exclusive right').

189 OECD, 'Licensing of IP Rights and Competition Law' DAF/COMP (2019) 3, 8.

190 WHO, 'Frequently Asked Questions: Trade Secrets' <https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html#:~:text=What%20are%20the%20rights%20conferred,contrary%20to%20honest%20commercial%20practice> accessed 26 November 2022; David-Levine, 'covid-19 Trade Secrets and Information Access: An Overview' (*InfoJustice*, 10 July 2022) <https://infojustice.org/archives/42493> accessed 26 November 2022 (trade secret law generally operates to empower the owners of trade secrets to control if, when, and how their secrets are shared.)

191 European Commission, 'Pharmaceutical Sector Inquiry Final Report' (2009) 181-202, 351-368 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 26 November 2022.

192 ibid.

193 European Commission, 'Executive Summary of the Pharmaceutical Sector Inquiry Report' (8 July 2009) 10 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf> accessed 26 November 2022.

194 ibid.

195 Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062.

196 ibid, 1071.

In the aftermath of its 2009 Pharmaceutical Sector Inquiry, the European Commission launched several investigations against originators and generic companies for entering into pay-for-delay agreements,[197] alleging violations of Articles 101 and 102 TFEU.[198] The Commission concluded that these agreements caused consumer harm by delaying generic entry and maintaining unjustifiably high prices.[199] More recently, in March 2021, the European Commission opened a formal investigation to assess whether the pharmaceutical company Teva illegally delayed the market entry of generic medicines that compete with its blockbuster multiple sclerosis drug Copaxone.[200] One of the strategies under investigation relates to a potential abuse of the patent system. In particular, the Commission is investigating whether, following the expiry of a compound patent, Teva engaged in practices to artificially prolong the market exclusivity of Copaxone by strategically filing and withdrawing divisional patents, and thus repeatedly delaying the entry of its generic competitor who was obliged to file a new legal challenge each time.[201]

Competition is also relevant where there is a failure to license. In normal times, the principle of freedom of contract guides the technology owner's right to choose whether to license a technology to a third party. However, where IP owned by a dominant company is indispensable to consumers and impossible for other competitors to replicate, or acquire, the refusal to license such an IP-protected technology may restrain and even hamper market competition, thus negatively affecting consumer welfare. In such circumstances, competition authorities may play an important role in protecting the market and consumer welfare.[202] A relevant example of a competition authority asserting its duties during the COVID-19 pandemic is shown by the actions by the Dutch competition authority regarding potential abuse by Roche. In March 2020 the Dutch competition authority launched an investigation into

197 These agreements are typically entered into to settle patent litigation between the originator company (the patent holder who alleges patent infringement) and the generic company (the potential competitor who asserts that the patent is invalid or not infringed). A salient element of these agreements is that they involve some kind of consideration flowing from the originator to the generic company (hence the 'reverse payment', as normally it is the alleged infringer who pays the patent holder) in exchange for the promise by the latter to refrain from entering the market.

198 For example, in 2014, the European Commission fined Servier EUR 330 million and several producers of generic medicines EUR 97 million for delaying the market entry of generic perindopril, a medicine used to treat high blood pressure. In 2013, it fined Johnson & Johnson and Novartis EUR 16 million for delaying the market entry of generic pain-killer fentanyl.

199 The UK Competition and Market authority has also investigated such practices. For example, in 2021 the CMA found that GlaxoSmithKline and several generic suppliers of the anti-depressant paroxetine infringed competition law. 'CAT upholds infringement decision for pay for delay pharma deals' (10 May 2021) <https://www.gov.uk/government/news/cat-upholds-infringement-decision-for-pay-for-delay-pharma-deals>.

200 ' Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine' (4 March 2021) <https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1022> accessed 26 November 2022.

201 This new investigation is significant because it assesses a novel 'theory of harm'. Specifically, the Commission explores whether Teva's patent filing practices, i.e. the filing and selective withdrawal of divisional patents, abuse its dominant position as prohibited under Article 102 TFEU.

202 In the UK, there have been a number of different vaccine producers, therefore, the refusal to licence doctrine may not be entirely appropriate (although this argument may be useful for other countries, including developing countries). See e.g. T-201/04 *Microsoft Corp v Commission* [2007] ECR II-3601; [2006] 4 CMLR 311. See also, *FTC v Mallinckrodt Ard Inc*, 'Stipulated Order for Permanent Injunction and Equitable Monetary Relief', Case Number: 1:17-Cv-120 EGS (20 January 2017, US District Court for the District of Columbia) <https://www.ftc.gov/system/files/documents/cases/stipulated_order_for_permanent_injunction_mallinckrodt.pdf> (in which the US Federal Trade Commission imposed a compulsory licence on a pharmaceutical company Mallinckrodt ARD Inc, according to which the company had to share its technology related to a biologic drug, adrenocorticotropic hormone (ACTH), including patents and trade secrets, with a designated third-party licensee).

allegations against Roche.[203] The majority of laboratories in the Netherlands depended on Roche's test kits, while the company was only able to supply 30 percent of the outstanding orders.[204] Despite that Roche refused to release its secret recipe for a solution used in its COVID-19 tests – the so-called lysis buffer – which was needed for the tests. With the recipe, laboratories would be able to quickly make their own solution and improve their testing capability.[205] The Dutch competition authority closed the investigation after Roche agreed to share the recipe with the government and committed 'to doing everything it can (and what can be reasonably expected from it) to enable hospitals and laboratories to carry out as many tests as possible and to eliminate any obstacles as much as possible'.[206]

The UK CMA should engage in rigorous monitoring and enforcement activities to deal with potential competition concerns, paying a special attention to the risk of coordination and tacit collusion of pharmaceutical companies. The CMA should be vigilant in monitoring such practices so that IP rights do not create artificial barriers resulting in an unjust delay in accessing the market for generic vaccines or treatments - whether for this pandemic or the next one.[207]

To improve competitiveness within the market, and facilitate technology sharing, the UK Government could also consider developing an alternative approach outside of competition law. A an alternative approach was followed in the US with the Hatch-Waxman Act.[208] This Act introduced a system that encourages the manufacture of generic drugs by the pharmaceutical industry, establishing the modern system of governmental generic drug regulation in the US, making it easier for generic drug companies to make new abbreviated drug applications.[209] More recently, the European Parliament adopted a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on contestable and fair markets in the digital sector ('Digital Markets Act').[210] The Act is designed to tackle

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203 Authority for Consumers & Markets, 'ACM has confidence in commitments made by Roche to help solve problems with test materials' (2020) <https://www.acm.nl/en/publications/acm-has-confidence-commitments-made-roche-help-solve-problems-test-materials> accessed 26 November 2022.

204 Eelke Van Ark And Jan-Hein Strop, 'Roche releases recipe after European Commission considers intervention due to lack of coronavirus tests' Follow the Money (2020) <https://www.ftm.eu/articles/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test> accessed 26 November 2022.

205 ibid.

206 Authority for Consumers & Markets, 'ACM has confidence in commitments made by Roche to help solve problems with test materials' (2020) <https://www.acm.nl/en/publications/acm-has-confidence-commitments-made-roche-help-solve-problems-test-materials> accessed 26 November 2022.

207 Carlos M. Correa, 'Expanding the production of COVID-19 vaccines to reach developing countries' (2021) 91 South Centre Policy Brief <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf> accessed 26 November 2022; Communication from South Africa, 'Examples of IP Issues and Barriers in Covid-19 Pandemic' (WTO, 23 November 2020), IP/C/W/670; Cynthia Koons, 'The Vaccine Scramble Is Also a Scramble for Patents' Bloomberg 12 (August 2020) <https://www.bloomberg.com/features/2020-covid-vaccine-patent-price/>; Achal Prabhala and Ellen 't Hoen, 'We'll find a treatment for coronavirus – but drug companies will decide who gets it' The Guardian (15 April 2020) (" …there is every indication that treatments for coronavirus may soon emerge, the mere fact of their existence is no guarantee that people will be able to access them. In fact, Covid-19 is more likely to end in the same way that every pandemic ends: treatments and vaccines will be buried in a thicket of patents – and pharmaceutical companies will ultimately make the decisions about who lives and who dies…Remdesivir, a medicine developed for Ebola by the biotechnology company Gilead, has major patents across the world that last until 2038") all accessed 26 November 2022.

208 The Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act of 1984.

209 Hatch-Waxman Letters (2 March 2022) <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters> accessed 26 November 2022.

210 European Parliament Legislative Observative, ''Digital Markets Act' (2020/0374(COD) - 05/07/2022) <https://oeil.secure.europarl.europa.eu/oeil/popups/summary.do?id=1710475&t=e&l=en> accessed 26 November 2022.

some of the perceived weaknesses in EU antitrust enforcement by imposing a broad range of obligations on the so-called 'gatekeepers' by way of ex-ante regulation.[211] A similar mechanism could be developed for the pharmaceutical sector that would facilitate competition between vaccine producers.

CONCLUSION AND RECOMMENDATIONS

This report has attempted to draw lessons from the UK's development of and procurement of vaccines during the COVID-19 Pandemic. Despite the perceived success of the domestic rollout, our conclusion is that there were significant failings – notably, a lack of transparency, insufficient technology transfer, a failure to consider apportionment of IP ownership for public goods, inadequate competition, and a lack of support for open innovation models. Therefore, we recommend that the UK Government should take the following steps.

RECOMMENDATIONS:

1. TRANSPARENCY

1.1. Regarding procurement, the UK Government should promote price transparency in the public interest. In the case of an emergency situation, such as the public procurement of COVID-19 vaccines, the UK public ought to be informed how large sums of public money are spent in terms of the per dose prices of each vaccine. This will provide complete transparency to UK taxpayers and will also help ensure fairness in negotiations between companies and other countries (e.g. low- and middle-income countries) to prevent them being over-charged.

1.2. The UK Government should publish the terms by which procured medical products, such as vaccines, may be used and transferred onward. In a global emergency, this will assist in ensuring doses are not wasted or allowed to expire, but can be donated to countries that require them.

1.3. The UK Government should inform the public of the liability responsibilities and indemnities that the Government has signed up to under contracts with private companies. This will help ensure public understanding and enhance confidence in mitigating the risks of procurement. Transparency on liability would assist the authorities in countering vaccine misinformation. Notably, this will also assist the UK Government and the governments of other states to ensure a smooth process of donation as liability rules will be clear.

1.4. The UK Government should promote transparency over public funds contributed to vaccine R&D and production.

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211 Sharon Malhi et al., 'The European Parliament approves the final text of the Digital Markets Act (6 July 2022) <https://technologyquotient.freshfields.com/post/102hsfg/the-european-parliament-approves-the-final-text-of-the-digital-markets-act> 26 November 2022.

2. TECHNOLOGY TRANSFER

2.1. When negotiating procurement contracts, the UK Government should facilitate voluntary technology transfers between pharmaceutical companies during emergencies, including to developing countries.

2.2. Advanced purchase agreements negotiated with manufacturers that involve substantial UK public funding for development and production, should include provisions enabling - and in emergency cases, mandating - the transfer of technology to other manufacturers, particularly those in the global south.

2.3. Further to this mandate, a new regime of compulsory licensing of trade secrets should be implemented in UK law to supplement the existing mechanism of compulsory licensing of patents. In an urgent health crisis, this would allow for more local production of generic and biosimiliar health technologies. These products could also be exported to meet demand in other countries and enable access to more affordably priced doses. A potential future benefit of having greater flexibilities within the IP system would be to facilitate increased competition among producers, which in the long term could help lower prices for the NHS.

2.4. In addition, a new compulsory licensing mechanism must be complemented by a data and marketing exclusivities waiver to allow the licensees under compulsory licences to obtain their marketing authorisations and launch their generic products before the normal end of exclusivity.

2.5. The UK Government should offer financial and political support for the WHO mRNA Vaccine Technology Transfer Hub.

2.6. For the ongoing WHO Pandemic Treaty and WHO International Health Regulations negotiation processes, the UK Government should support legal commitments mandating transparency, facilitating intellectual property waivers and requiring data sharing, particularly as part of conditions attached to public funding of research. The UK should also support measures aimed at increasing technology transfer and local production capacity in LMICs.

3. OWNERSHIP

3.1. As a matter of principle, where the UK taxpayers have funded research into specific health innovations, such public funding should be made contingent on the possibility of public access to the results of the research. The UK Government should introduce equitable access conditions across the R&D continuum. Equitable access conditions may include but should not be limited to mechanisms to ensure affordable pricing, norms around transparency, open access to data and results, pro-access intellectual property management strategies, technology transfer to independent and geographically diverse manufacturers, regulatory registration in low- and middle-income territories, and timely equitable supply of end products. We recommend placing compulsory clauses in research funding contracts which would provide a proportionate allocation of the IP ownership (i.e. proportionate to the amount of public funding provided) regarding the results of the research, as well as rules allowing such information to be shared with third parties in emergency circumstances (that can be domestically defined).

4. COMPETITION

4.1. The Competition and Markets Authority should engage in a rigorous investigation of various IP-related practices of pharmaceutical companies that may have a negative effect on access to e.g. pandemic health technologies, such as tests and therapeutics, as well as on pricing of medicines. This investigation should include assessing the impact of patents and trade secrets.

5. OPEN INNOVATION

5.1. The UK Government should reconsider the current system of legal incentives for medical innovation and should facilitate the development of an open innovation model that ensures public funding for R&D is coupled with a policy of openness of technology within the pharmaceutical industry as a whole. We note the successful example of Corbevax, an open-source COVID-19 vaccine developed during 2020-21, which is an exemplar of this model.

5.2. The UK Government should assume the responsibility for UK pandemic preparedness by setting out a comprehensive research infrastructure plan aimed at sustainable production of medicines needed for health security. As part of this solution, the UK Government may consider exploring the creation of publicly funded and non-profit pharmaceutical facilities.