

13. VACCINE PATENTS IN TIMES OF CRISES: TIME TO RE-EVALUATE THE PATENT BARGAIN?

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ABSTRACT

While the global race for COVID-19 vaccines and related patents have resulted in many forerunners (Pfizer, Moderna and AstraZeneca), the equal accessibility of these has created further challenges. The forerunners' ability to develop an effective COVID-19 vaccine with unprecedented swiftness may be due to a multiplicity of factors, including the critical need to control a global pandemic, significant pumping of finances through public funds, and direct donations by private individuals and companies. In order to make vaccines urgently available, the standard approval processes needed to be expedited while granting liability exemptions for pharmaceutical companies, as demanded. Indemnifying Big Pharma is a significant factor that hinders access to COVID-19 vaccines (in addition to price, patent restrictions, and cold chains) as for many low and middle-income countries; this may not be a viable option. Moreover, the patent bargain that is commonly relied on to support the patenting of inventions seems to have taken a new turn, under the current pandemic conditions where the public is expected to trade-off more than usual, making the forerunners more potent than ever, making access to life-saving medicine even more difficult. This paper aims to examine to what extent the pandemic situation has shed new light on the traditional patent bargain. It further proposes the re-evaluation of the patent bargain through the introduction of appropriate responsibilities for Big

Pharma as the private monopoly holders for the vaccines to achieve an expected and appropriate balance in the patent bargain between the public and Big Pharma.

Keywords: *patents, COVID-19 vaccine, patent, bargain, justification, quid pro quo.*

1. INTRODUCTION

Since the COVID-19 outbreak was reported in late 2019, one of the biggest, if not the most significant, issues the world faced was to find a vaccine to prevent the wider spread of this highly contagious disease. While the race for a COVID-19 vaccine began soon after that and many successful and efficient COVID-19 vaccine development became a reality, and its progress was unfolding daily across the world, another complex set of issues surrounding the COVID-19 vaccines emerged. These varied from maintaining equal access to vaccines, limiting vaccine nationalism, improving vaccine confidence in the general public to minimise vaccine hesitancy.

Many initiatives locally and internationally were introduced and implemented to address some of these concerns to no avail. One of the most potent international initiatives suggested is by India and South Africa, commonly known as the TRIPS Waiver,¹ currently being discussed, although at a snail's pace since late 2020, at the World Trade Organization (WTO) to minimise the access issues through relaxing the vaccine patent restrictions. Big Pharma² is firmly blocking this initiative through the powerful countries³ of the Global North.⁴ Another promising initiative, COVAX,⁵ aimed to create unparalleled equal access to the vaccine, but that

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¹ 'Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and Treatment of COVID-19' Communication from India and South Africa, 2 October 2020, IP/C/W/669 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>> accessed on 22 June 2021.

² Cambridge dictionary defines Big Pharma as 'large and successful pharmaceutical companies considered a business group with important economic, political or social influence' <<https://dictionary.cambridge.org/dictionary/english/big-pharma>> accessed on 1 March 2022.

³ Durisch P, Hertig G, 'Big Pharma takes it all: How pharmaceutical corporations profiteer from their privileges – even in a global health crisis like COVID-19.' (*Public Eye*, March 2021) <<https://www.publiceye.ch/en/publications/detail/big-pharma-takes-it-all>> accessed on 22 June 2021.

⁴ Although the Biden administration, along with the European Parliament, has recently expressed some interest in supporting the TRIPS Waiver, it is yet to be seen whether this would be carried forward at the WTO.

⁵ Co-venued by Coalition for Epidemic Preparedness Innovation (CEPI), Gavi, the vaccine alliance and World Health Organization (WHO) – in partnership with the United Nations Children's Fund (UNICEF).

too was not a success due to the Global North bypassing COVAX and entering into bilateral agreements with Big Pharma.⁶ The lack of success in both the above initiatives is a consequence of the Pharma-Industrial Complex, a phenomenon where a substantial pharmaceutical industry has acquired great economic and political power, enough to influence public policy concerning life-saving medicines. Expectedly or unexpectedly, the current patent law, based on an illusory patent bargain, is a significant contributory factor in facilitating the engendering and the sustaining of the pharma-industrial complex. In the current COVID-19 climate, the consequence is the prediction that Big Pharma is to achieve a significant financial gain from the biggest disaster of the century, while millions of avoidable human deaths are left to happen – a hallmark of disaster capitalism.

Against this backdrop, this paper argues that a re-negotiation of the patent bargain could be considered an alternative mechanism to address some of the issues surrounding COVID-19 vaccines where the onus of addressing such issues is shared with Big Pharma. Firstly, this paper aims to add to the existing literature around the illusory nature of the concept of Patent Bargain that courts and intellectual property (IP) proponents continue to rely on by using COVID-19 vaccines as a case study. Moreover, the paper suggests ways in which the patent bargain could be renegotiated where the appropriate balance that the patent law promises could be achieved.

2. PATENT BARGAIN

Granting exclusive property rights to innovations under the patent law has been most commonly justified under the 'reward theory' and 'contract theory', which often complement each other.⁷ While the former justifies the private monopoly rights as a reward for the innovative

contribution made, the latter, under the metaphorical patent bargain, justifies granting such rights as an exchange for the disclosure of the recipe of the invention. The patent bargain is expected to justify the granting of exclusivity for an invention in return for disclosing the said invention's recipe. The exclusivity is also a reward here since there is the assumption that the inventor may not disclose such innovations if not for the promised exclusivity, which may hamper the social and technical progression as a consequence.⁸ Thus, the bargain narrative has been seen as an appealing ground to support the granting of patents.

This section of the paper will attempt to dissect this contract theory-based patent bargain as a foundation for the later discussion concerning how the patent bargain functions in relation to the COVID-19 vaccines and whether a new patent deal is required where public health and access to medicine play an integral role in such negotiations.

Often referred to as '*quid pro quo*' in patent law cases,⁹ the bargain analogy provides an illusion of consensual agreement between the two contracting parties, i.e., the inventor (often a private company) and the public (executed through the State), where exclusivity is traded for disclosure. Thus, the *quid pro quo* has been viewed by courts as 'disclosure in sufficient detail to enable one skilled in the art to practice the invention'¹⁰ and at times as 'the benefit derived by the public from an invention with substantial utility'¹¹ in return for temporal and exclusive rights. However, the reality, more often, falls short of demonstrating a mutually beneficial contract between the two parties. This paper argues that such lack of balance is due to the many assumptions made when relying on a *quid pro quo* approach for patenting generally and patenting COVID-19 vaccines more specifically.

⁶ Usher AD, 'A beautiful idea: how COVAX has fallen Short' (2021) 397 (10292) World Report 2322.

⁷ Denicolo V, Franzoni LA, 'The Contract Theory of Patents' (2004) 23 Int. Rev. Law Econ. 365.

⁸ Ibid.

⁹ Ghosh S, 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred' (2004) 19 Berkeley Tech LJ 1315.

¹⁰ *Universal Oil Products Co. v. Globe Oil & Refining Co.* 322 US 471 (1944).

¹¹ *Brenner v Manson* 416 US 470, 485 (1974).

The first assumption made within a patent bargain narrative is to assume that the patentee always discloses the full recipe for the invention, enabling a person skilled in that specific field to recreate it in return for exclusivity. However, such disclosures have proven to be hardly enabling due to them being delayed,¹² inadequate¹³ or opaque¹⁴ disclosures¹⁵ preventing the very aim of knowledge sharing that the patent bargain proposes. Secondly, the bargain analogy seems to believe that the patentees prioritise their inventions to address societal needs. Such an assumption can be deduced from the often-made argument that the patents are utilitarian or have substantial utility to society. However, such views fail to explain the lack of cure available for Dengue when there is a cure for erectile dysfunction. Perhaps the utilitarian objectives need to be supported by their potentiality for financial benefit when prioritising investment in specific innovations. Thirdly, the patent bargain assumes that the patentee would use appropriate pricing for their products so the society could afford to benefit from them. But instead, the pricing seems to be based on the ground ‘whatever price the [Western] market will bear¹⁶ with no obligation for the industry to price their products at an affordable rate. Thus, the patent system and the illusory bargain that it relies on seems to support granting a **private monopoly without responsibility**¹⁷ to patent-holding companies.

Often the proponents of patent exclusivity for vaccines would argue that the existing TRIPS flexibilities around compulsory licensing (CL) schemes adequately serve the

purpose of maintaining the appropriate balance in the patent bargain. However, much ink has been spilt in highlighting the limits of TRIPS flexibilities due to the cumbersome nature of relying on CLs.¹⁸ These have resurfaced during the COVID-19 pandemic, particularly around the ‘TRIPS Waiver’ discourse. Being only applicable on an individual product and individual country basis, the potential for further restriction being imposed at the national level often leading to bureaucratic hurdles, regulatory obstacles such as data exclusivity and etc. do not make CLs a viable or appropriate method to maintain a patent bargain in a time of crisis.¹⁹ Thus this paper does not attempt to repeat such arguments but instead makes an effort to focus on the manner in which vaccines as specific innovation would work within the metaphorical patent bargain in times of crisis.

The paper will revisit the patent bargain metaphor to understand how it is performed concerning COVID-19 vaccines later, but firstly, the following section will examine vaccines as a particular patentable innovation more specifically to ascertain how the patent-reliant Big Pharma has perceived them.

3. VACCINES AS A POOR CONTENDER FOR MARKET-BASED PATENT INNOVATION

Since its introduction in the early 20th century, vaccines have played a crucial role in disease control, elimination, and eradication, resulting in the significant reduction of human morbidity and mortality.²⁰ Thus, it is not an

¹² Due to legal loopholes in publication requirements allowing postponement of disclosing the invention fully.

¹³ Deliberately withholding information and know-how to prevent efficient recreation of the invention.

¹⁴ Disclosing the information in a manner that is difficult for another to understand and thus, limiting the possibility of its recreation by a third party.

¹⁵ Roin BN, ‘The Disclosure Function of the Patent System (Or Lack thereof)’ (2005) 118(6) Harv. L. Rev. 2007.

¹⁶ Abbott FM, ‘Rethinking Patents: From ‘intellectual property’ to ‘private taxation scheme’ in Drahos P, Ghidini G, Ullrich H (eds), *KRTIKA: Essays on Intellectual Property* Vol. 1 (Edward Elgar 2015) 7.

¹⁷ Ibid 3.

¹⁸ Ragavan S, Vanni A (Eds.), *Intellectual Property Law and Access to Medicine: TRIPS Agreement, Health, and Pharmaceuticals* (Routledge, 2021). See also Aginam O, Harrington J, Yu PK (Eds.), *The Global*

Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines (Edward Elgar, 2013), Gaviria M, Kilic B, ‘A network analysis of COVID-19 mRNA vaccine patents’ 39 *Nature Biotechnology* (2021) 546. McMahon A, ‘Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance’ 47 *Journal of Medical Ethics* (2021)142.

¹⁹ McMahon A, ‘Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance’ 47 *Journal of Medical Ethics* (2021)142. Thambisetty S, McMahon A, McDonagh L, Yoon Kang H, Dutfeld G, (2021) *The TRIPS intellectual property waiver proposal: creating the right incentives in patent law and politics to end the COVID-19 pandemic*. LSE Legal Studies Working Papers (06/2021).

²⁰ Rappuoli R, Miller HI, Falkow S, ‘The Intangible Value of Vaccination’, (2002) 297 *Science* 937.

exaggeration to identify vaccines as the most effective public health intervention. Nevertheless, the distinctive characteristics of vaccine innovation seem to be threatening its continued use and development in an era where medicinal innovation seems to be controlled based on the financial gain by Big Pharma as gatekeepers, and the rest of the world is constantly kept at their mercy.

The multifaceted benefits of vaccinations have been identified beyond controlling targeted infectious diseases worldwide to include a more comprehensive societal advantage.²¹ They have proven to be helpful in preventing related diseases to the targeted disease²² as well as preventing the development of cancer.²³ Reduction of infant deaths through perinatal and early infancy inoculations²⁴ further empowers women as they need to have many children in case some may not reach adulthood is reduced, which has further social, educational, and economic benefits.²⁵ While inoculation programmes have contributed to the reduction of morbidity and mortality rates in the world population, what often goes less regarded is the economic efficacy of such methods and their contribution towards the achievement of health equity²⁶ in a society where the financially able and the financially vulnerable can both be equally protected.

Regardless of these multiple benefits of vaccines, they have become less enticing for Big Pharma and their

research and development (R&D) priorities.²⁷ The specific characteristics of vaccines, their market economies coupled with the patent-driven innovation systems relied on by Big Pharma, seemed to have made vaccines unattractive as a biotechnological investment.²⁸ Such factors include the inability or difficulty to quantify the overall economic savings that vaccines provide by preventing the broader dissemination of an infectious disease than medicines that cure disease.²⁹ Thus, the successful outcome of the former is considered a non-event. However, the successful outcome of the latter is considered a tangible benefit. The long-term immunity that most vaccines can provide with a single dose also makes them unattractive as they are therefore less profitable for Big Pharma compared with other medicines that require lifelong use in the long run.³⁰ The barriers to maintaining a cold chain when delivering vaccines to remote parts of a country/the world while sustaining its efficacy compared to the ease of distributing conventional drugs also make vaccines to be seen as a less attractive investment.³¹ Such difficulties often mean the target market could get significantly reduced, or the high cost of delivery would drastically increase the price, making them unaffordable for some populations and particularly people in the Global South.³² This has become visible during the current COVID-19 crisis, where Moderna and Pfizer vaccines require cold chain

²¹ Andre FE, Booy R, Bock HL, Clemens J, Datta SK, *et al.*, 'Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide' (2008) 86 BULL. WORLD HEALTH ORG. 140.

²² For Example, Measles vaccination can protect from multiple complications such as dysentery, bacterial pneumonia, keratomalacia and malnutrition, as mentioned in Strebel PM, Papania MJ, Halsey NA, 'Measles vaccine' in Plotkin SA, Orenstein WA, (eds) *Vaccines*, 4th ed. (WB Saunders 2004) 389.

²³ For example, reduction of cervical cancer with the use of HPV vaccine against stereotypic 16 and 18, as per Harper DM, Franco EL, Wheeler CM, Moscicki AB, Romanowski B, Roteli-Martins CM, *et al.*, HPV Vaccine Study Group. 'Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial' 15 April 2006, *Lancet* 367.

²⁴ Shearley AE, 'The societal value of vaccination in developing countries' (1999) 17 *Vaccine* 109; Ruff TA, Gertig DM, Otto BF, Gust ID, Sutanto A, Soewarso TI, *et al.*, 'Lombok Hepatitis B Model Immunisation Project: Toward universal infant hepatitis B immunisation in Indonesia' (1995) 171 *J Infect Dis* 290; Martinez J, Paul VK, Bhutta ZA, Koblinsky M, Soucat A, Walker N, *et al.*, 'Neonatal survival: a call for action' (2005) 365 *Lancet* 1189.

²⁵ See Andre FE, *et al.* (n 18) and Shearley AE (n 21).

²⁶ Flannery B, Schrag S, Bennett NM, Lynfield R, Harrison LH, Reingold A, *et al.*, 'Impact of childhood vaccination on racial disparities in invasive *Streptococcus pneumoniae* infections' (2004) 291 *JAMA* 2197; Bishai D, Koenig M, Ali Khan M, 'Measles vaccination improves the equity of health outcomes: evidence from Bangladesh' (2003) 12 *Health Econ* 415.

²⁷ Plotkin SA, *et al.*, 'Establishing a Global Vaccine-Development Fund' (2015) 373 *NEW ENG. J. MED.* 297.

²⁸ Rutschman AS, 'The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks' (2019-2020) 118 *Mich L Rev Online* 170.

²⁹ Rappuoli R, *et al.* (n 17).

³⁰ See 'Varicella Vaccine Effectiveness and Duration of Protection', Centres For Disease Control & Prevention <<https://www.cdc.gov/vaccines/vpd-vac/varicella/hcp-effective-duration.htm>> accessed 22 June 2021; Danzon PM, *et al.*, 'Vaccine Supply: A Cross-National Perspective' (2005) 24 *HEALTH AFF.* 706.

³¹ Kartoglu U, Milstien J, 'Tools and Approaches to Ensure Quality of Vaccines Throughout the Cold Chain' (2014) 13 *EXPERT REV. VACCINES* 843.

³² *Ibid.*

distribution.³³ Thus, regardless of the more comprehensive public health benefits and health equity vaccines could deliver, they are generally considered unappealing within a patents-based pharma-industrial complex.

Since vaccines are generally considered a non-lucrative form of innovation, the following section will explore whether the COVID-19 vaccine innovation was considered similarly or differently and the reasons for such considerations.

4. THE RACE FOR A VACCINE, LIKE NO OTHER

Since the World Health Organization (WHO) declared COVID-19 as a public health emergency of international concern in January 2020,³⁴ the race for a COVID-19 vaccine was in full force, providing the first few efficient vaccines available much earlier than anticipated. Currently, more than a dozen vaccines have started to be rolled out across the world.³⁵ While it was a welcome outcome to have such vaccines available in an expedient manner to control this highly infectious disease when reflecting on the vaccine development in other recent infectious disease outbreaks and the delay in developing an effective vaccine for them, some contributing factors for such disparity is vital to be identified for this paper.

As discussed in the previous section, although vaccine development is generally underfunded (for the reasons considered therein) with COVID-19, substantial financial donations were awarded to Big Pharma by private philanthropists,³⁶ as well as by the public³⁷ through various governments in the Global North. All three forerunners of COVID-19 vaccines benefited from generous financial contributions. For Moderna vaccine, while the country singer Dolly Parton donated USD one million to Vanderbilt University,³⁸ significant donations appear to have been made by the US government as direct financial support and indirectly through the National Institute of Health with whom Moderna Inc. developed this vaccine, coined as ‘people’s vaccine’ by public interest groups due to this very reason.³⁹ More than 97% of research funding that went into the development of the AstraZeneca vaccine too is attributable to public funding,⁴⁰ while Pfizer vaccine development benefited from direct funding of USD 445 million from the German government.⁴¹ Thus, it is no secret that COVID-19 vaccines, unlike other vaccines generally, have received significant funding for their R&D.

While the public money is being pumped towards Big Pharma from one end, they also demanded exemption from any public liability claims for any vaccine-related injuries.⁴² While Pfizer vaccine was provided with such statutory indemnity by the UK government in

³³ Fischetti M, ‘The COVID Cold Chain: How a Vaccine Will Get to You’ (*Scientific American*, 19 November 2020) <<https://www.scientificamerican.com/article/the-covid-cold-chain-how-a-vaccine-will-get-to-you/>> accessed 22 June 2021.

³⁴ ‘Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)’ *WHO News* (30 January 2020) <[https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov))> accessed 22 June 2021.

³⁵ ‘The COVID-19 vaccine race – weekly update’ (*Gavi The Vaccine Alliance*, 16 June 2021) <<https://www.gavi.org/vaccineswork/covid-19-vaccine-race>> accessed 22 June 2021.

³⁶ Snapes L, ‘Dolly Parton partly funded Moderna Covid vaccine research’ *The Guardian* (17 November 2020) <<https://www.theguardian.com/music/2020/nov/17/dolly-parton-partly-funded-moderna-covid-vaccine-research>> accessed 22 June 2021.

³⁷ Stone J, ‘The People’s Vaccine-Moderna’s Coronavirus Vaccine Was Largely Funded By Taxpayer Dollars’ (*Forbes*, 3 December 2020) <[https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-](https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/)

[dollars/](https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded)> accessed 22 June 2021; Safi M, ‘Oxford/AstraZeneca COVID-19 vaccine research ‘was 97% publicly funded’ *The Guardian* (15 April 2021) <<https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded>> accessed 22 June 2021; Griffin R, Armstrong D, ‘Pfizer Vaccine’s Funding Came From Berlin, Not Washington’ *Bloomberg* (9 November 2020) <<https://www.bloomberg.com/news/articles/2020-11-09/pfizer-vaccine-s-funding-came-from-berlin-not-washington>> accessed 22 June 2021.

³⁸ Snapes, (n 33).

³⁹ ‘Statement: Moderna Vaccine Belongs to the People’ *Public Citizen* (Washington, D.C., 16 November 2020) <<https://www.citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/>> accessed 22 June 2021.

⁴⁰ Safi, (n 34).

⁴¹ Griffin, Armstrong (n 34).

⁴² TRIPS Waiver Communications by The Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe on 15 January 2021, IP/C/W/672 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W/672.pdf&Open=True>> accessed 22 June 2021.

December 2020,⁴³ AstraZeneca⁴⁴ and Moderna,⁴⁵ too, have included such indemnity clauses in their vaccine contracts. Such indemnity provision for Big Pharma has compelled the respective governments to absorb or address such potential civil liability claims.⁴⁶ For example, in the UK, COVID-19 is added to the Vaccine Damages Payment Act, which grants a meagre amount of GBP 120,000 if one were to suffer severe disability as a consequence of taking a listed vaccine in the said Act.⁴⁷ Any lesser level of harm would not make one eligible for any damages. While vaccine indemnity provision is not necessarily limited to COVID-19 vaccines, given the significant public funding received by Big Pharma for its development, it is questionable whether the public should also absorb the subsequent costs relating to the COVID-19 vaccines. It seems that Big Pharma is socialising the risks but privatising the profits.⁴⁸

Expedited approval of COVID-19 vaccines is another significant difference compared with other vaccine approvals. For example, it has been reported that the European Medicine Agency (EMA) approved a COVID-19 vaccine within 70 days compared to the average approval time of 210 days.⁴⁹ When compared with another recent infectious disease crisis of Ebola, where the vaccine against it had been developed and awaiting clinical trials

more than 10 years before its outbreak in 2014-2016,⁵⁰ and only approved by the FDA in December 2019,⁵¹ one can see the rate of rapidity at which COVID-19 vaccines have been approved at. While the nature of the current crises meant that an accelerated approval process was a necessity for the benefit of the public, it is also worth noting that Big Pharma, too, benefit from such expedited approval as a swifter approval can contribute towards their brand promotion.

Due to the pandemic, governments bid for many hundreds of millions of COVID-19 vaccines, even during their development stage. For example, as Kate Bingham, the Chair of the UK's Vaccine Task Force, confirms, the UK has not only supported the clinical trials and development of specific vaccines but had secured 400 million doses⁵² of vaccines.⁵³ Similarly, the US had offered to buy 600 million doses of Pfizer vaccine alone,⁵⁴ another 500 million doses from Moderna⁵⁵, and 300 million doses of AstraZeneca.⁵⁶ This level of guaranteed sales for the vaccines at such early stages of their development is also a unique position that COVID-19 vaccine developers benefited from. While the Global North hoarded up COVID-19 vaccines multiple times of the required amount, the Global South countries struggled to have access to any.⁵⁷ Such nationalistic

⁴³ Lintern S, 'Coronavirus vaccine: Pfizer given protection from legal action by UK government' (*Independent*, 2 December 2020) <<https://www.independent.co.uk/news/health/coronavirus-pfizer-vaccine-legal-indemnity-safety-ministers-b1765124.html>> accessed 22 June 2021.

⁴⁴ Burger L, Aripaka P, 'AstraZeneca to be exempt from coronavirus vaccine liability claims in most countries' (*Reuters*, 30 July 2020) <<https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability-idUSKCN24V2EN>> accessed 22 June 2021.

⁴⁵ Sigalos M, 'You can't sue Pfizer or Moderna if you have severe Covid vaccine side effects. The government likely won't compensate you for damages either' *CNBC* (17 December 2020) <<https://www.cnn.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html>> accessed 22 June 2021.

⁴⁶ While governments of the Global North may consider this option with limited occasions for such damages being granted, the Global South governments may not, creating vaccine inequity during a pandemic.

⁴⁷ UK Vaccine Damage Payment <<https://www.gov.uk/vaccine-damage-payment>> accessed 22 June 2021.

⁴⁸ Durisch P, Hertig G (n 3).

⁴⁹ Thirstrup S, 'Accelerated approval of COVID-19 vaccines' *NDA* (14 January 2021) <<https://ndareg.com/news/accelerated-approval-of-covid-19-vaccines/>> accessed on 22 June 2021.

⁵⁰ Grady D, 'Ebola Vaccine, Ready for Test, Sat on the Shelf' *The New York Times* (23 October 2014) <<https://perma.cc/RF4V-RPK2>> accessed 22 June 2021.

⁵¹ 'First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response' (*The US Food and Drug Administration*, 19 December 2019) <<https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>> accessed 22 June 2021.

⁵² When the UK population is less than 70,000,000, i.e., more than five times of the country's population.

⁵³ Bolzen DS, Guerrera A, 'Kate Bingham: Why UK strategy on Covid vaccines has been a great success' *la Repubblica* (7 February 2021) <https://www.repubblica.it/cronaca/2021/02/07/news/kate_bingham_interview_vaccines_covid_astrazeneca_uk_coronavirus_johnson-286384093/> accessed on 22 June 2021.

⁵⁴ Griffin, Armstrong (n 34).

⁵⁵ Sandler R, 'US To Buy 100 Million Doses Of Moderna Coronavirus Vaccine' (*Forbes*, 11 August 2020) <<https://www.forbes.com/sites/rachelsandler/2020/08/11/us-to-buy-100-million-doses-of-moderna-coronavirus-vaccine/?sh=6c8414ae6ab7>> accessed on 22 June 2021.

⁵⁶ Akash B, Faulconbridge G, Holton K, 'US secures 300 million doses of potential AstraZeneca COVID-19 vaccine' *Reuters* (21 May 2020) <<https://www.reuters.com/article/us-health-coronavirus-astrazeneca-idUSKBN22X0J9>> accessed on 22 June 2021.

⁵⁷ Bhutto F, 'The world's richest countries are hoarding vaccines. This is morally indefensible' *The Guardian* (17 March 2021)

approaches to an international crisis that led to vaccine nationalism, which further contributed to the failure of initiatives such as COVAX and delaying the TRIPS Waiver, may have contributed to millions of preventable human deaths in the Global South.

As clearly evaluated in this section, the unprecedented support Big Pharma received in developing a COVID-19 vaccine, the accelerated approval from regulatory bodies, guaranteed sales even before the approval stages were completed meant that they were in a far better position financially with COVID-19 vaccines. As predicted in January 2021 by some WTO Members⁵⁸ and confirmed by subsequent reports, the forerunners of the COVID-19 vaccines have reaped⁵⁹ or are expected to gain⁶⁰ significant financial returns even before the pandemic has ended. When the public has provided extensive support towards the development of COVID-19 vaccines while having to purchase such vaccines back, Big Pharma is only accountable for a (limited) disclosure for enjoying exclusive monopoly rights to these vaccines and gaining significant financial benefit does not, this paper argues, even provide a semblance of an appropriate bargain between the Big Pharma and the public.

5. BALANCING THE SCALE: A NEW PATENT DEAL?

As discussed previously, the public, from their side of the bargain, provided substantial financial contribution for COVID-19 vaccine development, facilitated accelerated vaccine approval, granted private monopoly rights over such vaccines with no limitation on pricing, and subsequently not only bought back such vaccines from Big Pharma but also indemnified them from potential injury claims. In return, the public is only expected to receive the disclosure of the vaccine recipe, which is not

timely, adequate or proper disclosure, making such disclosure irrelevant or almost non-existent.

It is no secret then that the patent bargain needs re-evaluating, and there is no time like the present pandemic to understand this need clearly and lobby for necessary changes in finding a new, better patent deal. A deal where the bargain is based on the interests of the public rather than Big Pharma and strengthening the pharma-industrial complex further. A proper *quid pro quo*. This section of the paper will hint at how the patent bargain could be renegotiated so that the public is not worse off when granting exclusive monopoly rights to big pharma.

The experiences of the COVID-19 crisis made it clear that the 'private monopoly without responsibility' approach in patenting does not work for the benefit of the public, highlighting the terrible nature of the illusory patent bargain. This position becomes apparent when examining the current COVID-19 vaccine crisis closely. Thus, this paper proposes that introducing some responsibilities into the patent bargain could be assistive in balancing the scale to an appropriate level.

Such responsibilities that ought to be added to this new patent deal could commence by restoring the disclosure responsibility as envisaged when the patent bargain was first relied on. The need for a disclosure that is timely, adequate, and clear. Disclosure of the full recipe. Moreover, it is reasonable to expect that big pharma needs to play an active role in improving vaccine confidence in the public, given that their demand for indemnity and lack of transparency can often be seen as contributory factors to vaccine hesitancy. Finally, some accountability levels in maintaining equal access to vaccines and limiting vaccine nationalism need to be built

<<https://www.theguardian.com/commentisfree/2021/mar/17/rich-countries-hoarding-vaccines-us-eu-africa>> accessed on 22 June 2021.

⁵⁸ TRIPS Waiver communication IP/C/W/672 (n 39).

⁵⁹ Robbins R, Goodman PS, 'Pfizer reaps Hundreds of Millions of Profits from Covid Vaccines' *The New York Times* (5 April 2021) <<https://www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html>> accessed on 22 June 2021.

⁶⁰ Kollwe J, 'From Pfizer to Moderna: who's making billions from COVID-19 vaccines?' *The Guardian* (6 March 2021) <<https://www.theguardian.com/business/2021/mar/06/from-pfizer-to-moderna-whos-making-billions-from-covid-vaccines>> accessed 22 June 2021.

into the bargain with appropriate sanctions for failing to do so since no one is safe until everyone is safe during a pandemic. Incorporating the above as primary responsibilities in return for a private monopoly may provide a glimpse of a balanced patent bargain.

6. CONCLUSIONS

This paper closely examined the patent bargain justification in vaccines generally and COVID-19 vaccines more specifically to highlight the lack of balance in this bargain between the public and Big Pharma. While the public seemed to have borne much of the onus of COVID-19 vaccine innovation by making considerable financial contributions, providing efficient and accelerated approval for vaccines, purchasing them back, and even offering indemnity for the Big Pharma, it seemed to suggest that the time has undoubtedly come to renegotiate the patent deal.

In that regard, this paper proposes firstly to identify and confront the various assumptions made when relying on this contract-theory justification where expected disclosure is hardly provided, financial gain rather than public or societal needs being central to innovation schemes and pricing based on 'what the market can bear' rather than what the public can afford. In essence, a private monopoly is given with no responsibility expected from Big Pharma in return.

Thus, in making the patent bargain a more balanced one, this paper proposes the re-evaluation of it by relying on COVID-19 vaccines as a case study and reflecting on potential and reasonable responsibilities that could be built into the patent bargain to work towards achieving an appropriate quid pro quo between the public and the Big Pharma.

BIBLIOGRAPHY

Brenner v Manson 416 US 470, 485 (1974).

Universal Oil Products Co. v. Globe Oil & Refining Co. 322 US 471 (1944).

Abbott FM, 'Rethinking Patents: From 'intellectual property' to 'private taxation scheme' in Drahos P, Ghidini G, Ullrich H (eds), *KRTIKA: Essays on Intellectual Property* Vol. 1 (Edward Elgar 2015) 7.

Andre FE, Booy R, Bock HL, Clemens J, Datta SK, *et al.*, 'Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide' (2008) 86 BULL. WORLD HEALTH ORG. 140.

Bishai D, Koenig M, Ali Khan M, 'Measles vaccination improves the equity of health outcomes: evidence from Bangladesh' (2003) 12 Health Econ 415.

Burger L, Aripaka P, 'AstraZeneca to be exempt from coronavirus vaccine liability claims in most countries' (*Reuters*, 30 July 2020) <<https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability-idUSKCN24V2EN>> accessed 22 June 2021.

Danzon PM, *et al.*, 'Vaccine Supply: A Cross-National Perspective' (2005) 24 HEALTH AFF. 706.

Denicolo V, Franzoni LA, 'The Contract Theory of Patents' (2004) 23 Int. Rev. Law Econ. 365.

Durisch P, Hertig G, 'Big Pharma takes it all: How pharmaceutical corporations profiteer from their privileges – even in a global health crisis like COVID-19.' (*Public Eye*, March 2021) <<https://www.publiceye.ch/en/publications/detail/big-pharma-takes-it-all>> accessed 22 June 2021.

Fischetti M, 'The COVID Cold Chain: How a Vaccine Will Get to You' (*Scientific American*, 19 November 2020) <<https://www.scientificamerican.com/article/the-covid-cold-chain-how-a-vaccine-will-get-to-you/>> accessed 22 June 2021.

Flannery B, Schrag S, Bennett NM, Lynfield R, Harrison LH, Reingold A, *et al.*, 'Impact of childhood vaccination on racial disparities in invasive *Streptococcus pneumoniae* infections (2004) 291 JAMA 2197.

Ghosh S, 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred' (2004) 19 Berkeley Tech LJ 1315.

Grady D, 'Ebola Vaccine, Ready for Test, Sat on the Shelf' *The New York Times* (23 October 2014) <<https://perma.cc/Rf4V-RPK2>> accessed 22 June 2021.

Griffin R, Armstrong D, 'Pfizer Vaccine's Funding Came From Berlin, Not Washington' *Bloomberg* (9 November 2020) <<https://www.bloomberg.com/news/articles/2020-11-09/pfizer-vaccine-s-funding-came-from-berlin-not-washington>> accessed 22 June 2021.

Harper DM, Franco EL, Wheeler CM, Moscicki AB, Romanowski B, Roteli-Martins CM, *et al.*, HPV Vaccine Study Group. 'Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial' (2006) 15 April, *Lancet* 367.

Kartoglu U, Milstien J, 'Tools and Approaches to Ensure Quality of Vaccines Throughout the Cold Chain' (2014) 13 EXPERT REV. VACCINES 843.

Lintern S, 'Coronavirus vaccine: Pfizer was given protection from legal action by UK government' (*Independent*, 2 December 2020) <<https://www.independent.co.uk/news/health/coronavirus-pfizer-vaccine-legal-indemnity-safety-ministers-b1765124.html>> accessed 22 June 2021.

Martines J, Paul VK, Bhutta ZA, Koblinsky M, Soucat A, Walker N, *et al.*, 'Neonatal survival: a call for action' (2005) 365 *Lancet* 1189.

Olin JM, 'The Disclosure Function of the Patent System (Or Lack thereof)' *Harvard Law Review*, (2005) 118(6) *Harv. L. Rev.* 2007.

Rappuoli R, Miller HI, Falkow S, 'The Intangible Value of Vaccination', (2002) 297 *Science* 937.

Ruff TA, Gertig DM, Otto BF, Gust ID, Sutanto A, Soewarso TI, *et al.*, 'Lombok Hepatitis B Model Immunisation Project: Toward universal infant hepatitis B immunisation in Indonesia' (1995) 171 *J Infect Dis* 290.

Rutschman AS, 'The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks' (2019-2020) 118 *Mich L Rev Online* 170.

Safi M, 'Oxford/AstraZeneca Covid vaccine research 'was 97% publicly funded' *The Guardian* (15 April 2021) <<https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded>> accessed 22 June 2021.

Shearley AE, 'The societal value of vaccination in developing countries' (1999) 17 *Vaccine* 109.

Shubha G, 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred' (2004) 19 Berkeley Tech LJ 1315.

Sigalos M, 'You can't sue Pfizer or Moderna if you have severe Covid vaccine side effects. The government likely won't compensate you for damages either' *CNBC* (17 December 2020) <<https://www.cnn.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html>> accessed 22 June 2021.

Snapes L, 'Dolly Parton partly funded Moderna Covid vaccine research' *The Guardian* (17 November 2020) <<https://www.theguardian.com/music/2020/nov/17/dolly-parton-moderna-covid-vaccine>>

lly-parton-partly-funded-moderna-covid-vaccine-research> accessed 22 June 2021.

Plotkin AS, *et al.*, 'Establishing a Global Vaccine-Development Fund' (2015) 373 NEW ENG. J. MED. 297.

Strebel PM, Papania MJ, Halsey NA, 'Measles vaccine' in Plotkin SA, Orenstein WA, (eds) *Vaccines*, 4th ed. (WB Saunders 2004) 389.

Stone J, 'The People's Vaccine-Moderna's Coronavirus Vaccine Was Largely Funded By Taxpayer Dollars' (*Forbes*, 3 December 2020)
<<https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/>> accessed 22 June 2021.

Thirstrup S, 'Accelerated approval of COVID-19 vaccines' *NDA* (14 January 2021)
<<https://ndareg.com/news/accelerated-approval-of-covid-19-vaccines/>> accessed 22 June 2021.

Usher AD, 'A beautiful idea: how COVAX has fallen Short' (2021) 397 (10292) *World Report* 2322.

'Varicella Vaccine Effectiveness and Duration of Protection', Centres For Disease Control & Prevention, <<https://www.cdc.gov/vaccines/vpd-vac/varicella/hcp-effective-duration.htm>> accessed 22 June 2021.

'Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)' *WHO News* (30 January 2020)
<[https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov))> accessed 22 June 2021.

'The COVID-19 vaccine race – weekly update' (*Gavi The Vaccine Alliance*, 16 June 2021)
<<https://www.gavi.org/vaccineswork/covid-19-vaccine-race>> accessed 22 June 2021.

'Statement: Moderna Vaccine Belongs to the People' *Public Citizen* (Washington, D.C., 16 November 2020)
<<https://www.citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/>> accessed 22 June 2021.

'Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and Treatment of COVID-19' Communication from India and South Africa, 2 October 2020, IP/C/W/669
<<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>> accessed 22 June 2021.

TRIPS Waiver Communications by the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela, and Zimbabwe on 15 January 2021, IP/C/W/672
<<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W672.pdf&Open=True>> accessed 22 June 2021.

UK Vaccine Damage Payment
<<https://www.gov.uk/vaccine-damage-payment>> accessed 22 June 2021.

'First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response' (*The US Food and Drug Administration*, 19 December 2019)
<<https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>> accessed 22 June 2021.