

Executive Summary
**Intellectual Property
and Technology
Transfer for
COVID-19 Vaccines**
Assessment
of the Record





Executive Summary
**Intellectual Property
and Technology Transfer
for COVID-19 Vaccines**
Assessment
of the Record

Contents

Foreword	5
About the author and Acknowledgments	6
Executive Summary	7
1. The premise of inequitable distribution	7
2. The general IP and technology transfer framework	7
3. The case study approach	8
4. Distilling relevant factors	9
a. The customary role of IP and technology transfer	9
b. Multiple factors affecting development, production and distribution	9
c. Funder conditions	10
i. Price	11
ii. Access to technology	12
d. Patents and other IP	12
i. Patents	12
ii. Know-how and trade secrets	13
e. Counterfactual limitations	14
5. Better practices	14
6. Concluding observations	15

Foreword

Looking back at the global response to the COVID-19 pandemic, the role played by the advent, manufacturing and distribution of COVID-19 vaccines stands out as a crucial element in curbing the spread and impact of the virus as well as the global economic recovery. This present study, commissioned by WIPO and carried out by an independent expert, Professor Fredrick Abbott of Florida State University, is an effort to understand how various approaches to the licensing of IP rights, technology and know-how enabled, or curtailed, access to COVID-19 vaccines. Using a case-study methodology to provide an in-depth analysis of some of the different approaches adopted by various global vaccine manufacturers, this study constitutes a unique assessment of a broad range of licensing and funding structures and arrangements undertaken by developers and manufacturers of COVID-19 vaccines. The study's findings represent an array of recommendations alongside robust counterfactuals. An important take-away from these is that creating a better system for developing, manufacturing, and distributing vaccines that also addresses equity challenges requires a multi-pronged approach. By examining what worked well, and what worked less well, we can better prepare for the next pandemic and help countries around the globe to build back better.

Edward Kwakwa
Assistant Director General
World Intellectual Property Organization (WIPO)

About the author

Frederick Abbott is Edward Ball Eminent Scholar Professor at Florida State University College of Law, USA. He specializes in intellectual property, technology transfer, public health, competition, and trade law and policy. He has served as consultant and advisor to international organizations, governments and nongovernmental organizations. He is author of numerous publications, including studies and reports addressing policies and institutional frameworks for production and distribution of pharmaceutical and other health products. He has served as a dispute settlement panelist for the WIPO Arbitration and Mediation Center since 2000.

Acknowledgments

The author gratefully acknowledges research contributions by Samantha Longley and Amelia Naomi, JD candidates, Florida State University College of Law, class of 2024.

Executive Summary

The World Intellectual Property Organization (WIPO)'s Global Challenges Division commissioned an independent study on the role played by intellectual property (IP) and technology transfer in the development, production and distribution of vaccines used to address the COVID-19 pandemic. The study uses a case-study approach to provide an in-depth analysis of some of the different approaches adopted by ten different global vaccine manufacturers, with respect to their funding, procurement, vaccine development and IP strategies (including licensing, technology transfer and access provisions). These experiences and lessons learnt provide practical insights to guide global policy-making on IP, health and access issues.

1. The premise of inequitable distribution

This study starts with the premise that the global distribution of vaccines to address COVID-19 was inequitable in the sense that individuals and public health systems received vaccines in a sequence and in quantities that depended on the economic development level of the country or region in which they were situated, and that high- and upper middle-income countries (HICs and UMICs) were preferred over low- and middle-income countries (LMICs). One question addressed by the study is whether and how IP may have been a factor in this inequitable distribution, and whether there may be ways to improve the global response in the future.

2. The general IP and technology transfer framework

Since the study is directed toward a broad audience that may include non-experts in the fields of IP and technology transfer, it begins with a brief overview of technology (including IP) licensing and the terminology employed. This is followed by a description of the forms of IP relevant to vaccine development, production and distribution. Much attention has been devoted to the role that patents and patent licensing played in the development and manufacture of COVID-19 vaccines, and technology transfer licenses will typically identify the relevant patents that are being licensed. Beyond patents, technology transfer generally involves a broader range of "know-how" that is used by vaccine developers and manufacturers. The type of "know-how" covered by a technology license is usually defined in the agreement. It may be protected by a form of IP known as "trade secret," but it may also include information that is in the public domain.

An entire network of multilateral instruments administered by WIPO (26 multilateral treaties) deals with IP matters in terms of both substantive provisions and procedural aspects. Having said that, this study briefly reviews and focuses on relevant provisions of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement, since it is this agreement that contains specific substantive provisions on pharmaceutical-related subject matter. The TRIPS Agreement establishes minimum standards of IP protection, which include providing patent protection for pharmaceutical products (including vaccines). It also establishes certain rules regarding the protection of data submitted for regulatory purposes, and for protection of trade secrets. The TRIPS Agreement provides flexibilities that allow WTO members to override patent protection through limited exceptions and compulsory or government use licensing, and it includes flexibilities with

respect to regulatory data.¹ In 2001, WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health which confirmed important flexibilities, as well as that the agreement should be interpreted to promote access to medicines for all.

Some members of the WTO proposed that the organization adopt a waiver of the main TRIPS Agreement IP protection and enforcement obligations to better enable them to address the COVID-19 pandemic. Contentious negotiations followed, resulting in a waiver, more limited than that initially proposed, that relaxes conditions on compulsory or government use licensing for export of vaccines, with negotiations regarding therapeutics and diagnostics to continue.

Provisions in multilateral agreements such as the TRIPS Agreement require implementation by WTO members in their national law to have effect within their domestic IP systems. This includes implementation of modifications introduced by the TRIPS Agreement recent waiver. As noted above, the TRIPS Agreement incorporates various flexibilities (predating the waiver) regarding the way in which WTO members implement rights and obligations. It is for WTO members to choose whether and how to implement these flexibilities in their national IP systems.

Least developed WTO members (LDCs) are generally exempt from implementing and enforcing TRIPS Agreement obligations until 2033/34 based on decisions of the TRIPS and General Councils of the WTO. Notwithstanding WTO exemptions, LDCs nevertheless generally establish and maintain domestic IP legal systems.

Member states of the World Health Organization (WHO) are engaged in parallel negotiations with respect to a proposed Pandemic Accord and amendments to the International Health Regulations (IHR). Working groups addressing both instruments have received a substantial number of proposals directed toward enhancing the capacity of WHO member states, and particularly LMICs, to develop and manufacture health products, including vaccines, to prevent, prepare for and address pandemics and other health emergencies. This may include addressing potential IP barriers, with some WHO member states having proposed waivers of IP based on WHO instruments. This study is relevant to those negotiations, though it does not make any specific proposals.

The study also briefly describes advanced purchase agreements (APAs). These agreements were employed by the United States of America, the European Union (EU) and other countries seeking to provide financial support and assurance to vaccine developers and manufacturers so as to enable them to invest in building up capacity prior to completing the development and obtaining approval for vaccines. The APAs negotiated during the pandemic were unusual in terms of the large aggregate advance payments, the non-refundable character of those payments, the lack of firm delivery commitments, and limitations on developer or manufacturer liability. They predominantly left IP in the hands of the developers or suppliers. One consequence of these heavily funded APAs was that the providers of funds received “front of line” positions for the delivery of vaccines. The APAs appear largely to have fulfilled their purpose in terms of providing financial support for initial vaccine development and production, but they raise questions regarding their impact on equity and whether there may be preferable ways to design these mechanisms for the future. WHO Pandemic Accord and IHR Amendment negotiating proposals include financing mechanisms intended to support more equitably distributed capacity to develop and produce vaccines.

3. The case study approach

The study reports on the efforts of the developers and producers of the COVID-19 vaccines that were used most extensively during the emergency phase of the pandemic, as well as on efforts of some developers that received significant financial support yet whose efforts fell short. The developers or producers that are subjects of the case studies are Pfizer/BioNTech,

1 In addition, the TRIPS Agreement provides a national security exception that broadly permits members to override IP to protect their essential security interests in an international emergency, which, according to some experts, would include a pandemic recognized by the WHO.

Moderna, AstraZeneca-Oxford, Johnson & Johnson/Janssen, Novavax, CureVac, Baylor College of Medicine/Texas Children's Hospital, Sinovac, Sinopharm and Gamaleya National Center of Epidemiology and Microbiology.

COVID-19 vaccine development and production efforts can largely be broken down among private sector (with subsidy), mixed public-private and predominantly state-owned entities. There was one private university effort (Baylor College of Medicine/Texas Children's Hospital).

The technology underlying the vaccine development efforts differed. These technologies included mRNA, recombinant DNA, modified adenovirus and inactivated virus.

Most of the study is devoted to the details of the vaccine development, production and distribution efforts.²

4. Distilling relevant factors

a. The customary role of IP and technology transfer

The case studies indicate that IP and technology transfer agreements played their customary role during the COVID-19 pandemic, which was to enable technology developers to secure and move technical information across the development, manufacturing and distribution value chain. In the absence of legally enforceable agreements, investors in technology would likely have tried to maintain technology within their own enterprises and would not have benefited from the ability to in-license scientific contributions from third parties or to out-license to contract manufacturing organizations. This would have resulted in substantial inefficiencies and almost certainly would have delayed the introduction and distribution of vaccines.

Recognizing the important role of IP and technology transfer in the process of developing, manufacturing and distributing vaccines, stakeholders expressed a variety of perspectives regarding whether voluntary initiatives encouraging technology transfer, such as for the purpose of expanding capacity for local production of vaccines, were adequate to address concerns regarding equitable access during the COVID-19 pandemic.³ This study endeavors to shed light on this question in the context of the COVID-19 pandemic.

b. Multiple factors affecting development, production and distribution

The case studies illustrate there were multiple reasons why vaccine development, production and distribution were not more rapid. Vaccines could not be delivered and administered until they were subject to clinical trials and approved by drug regulatory authorities. This delayed the introduction of vaccines by about one year from the outset of the pandemic, notwithstanding that initial approvals were typically granted through accelerated emergency use authorizations,⁴ and that the approval timeframe was unusually short for new vaccines. This was not a

- 2 WIPO prepared a well-researched preliminary landscape report identifying the vaccine (and therapeutic) technologies being studied and patented prior to and during the COVID-19 pandemic (up to September 2021), including scientific explanations and glossary of key terms. World Intellectual Property Organization (WIPO) (2022), COVID-19-related vaccines and therapeutics: Preliminary insights on related patenting activity during the pandemic, Geneva: WIPO. This report was updated with data up to September 2022. World Intellectual Property Organization (WIPO) (2023). COVID-19-related vaccines and therapeutics: Insights into related patenting activity throughout the pandemic. Geneva: WIPO. DOI: 10.34667/tind.48015. The present study is directed more specifically to the role that IP (including patents), technology licensing and transfer played in the development, manufacture and distribution of the vaccines that were predominantly used in response to the pandemic, as well as in select unsuccessful development efforts, and it considers the extent to which IP and licensing may have contributed to or constrained the response. This study is not intended as a vaccine patent landscape. Relevant patents are identified in the case studies from a variety of sources, including enterprise disclosures (including licenses), the Vaxpal and Espacenet databases, and Google Patents.
- 3 The importance of local production to promoting access to quality, safe, effective and affordable medicines and other health technology was reaffirmed by WHO member states in Resolution WHA74.6 on strengthening local production of medicines and other health technologies to improve access. Seventy-Fourth World Health Assembly, Seventh plenary meeting, May 31, 2021 – Committee A, third report), WHA74/2021/REC/1.
- 4 US Food and Drug Administration, *FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*. FDA. 2020. www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; US Food and Drug Administration, *COVID-19 Vaccines*. FDA. 2023. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>; WHO, *COVID-19 Vaccines with WHO Emergency Use Listing*. 2021. <https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued>

consequence of IP protection or transfer of technology. Instead, it reflected legitimate concerns regarding safety and efficacy.

There are examples of rapid and successful development of vaccines by companies such as Pfizer/BioNTech, Moderna and, with some qualification, AstraZeneca-Oxford.⁵ Yet the case studies illustrate that many of the vaccine development and production efforts either were significantly delayed, or were unsuccessful, based on the science of the vaccine development or operational difficulties in scaling production. Johnson & Johnson developed its vaccine fairly rapidly, but experienced failure of its prime manufacturing contractor.⁶ The use of its vaccine was subsequently limited based on safety concerns. CureVac's primary vaccine candidate failed to demonstrate adequate efficacy and was abandoned.⁷ Novavax experienced delays in securing adequate supplies of vaccine components, obtaining regulatory approval and effectively assembling a manufacturing network.⁸ The Russian Federation's Sputnik V vaccine deliveries were delayed by operational concerns within the Russian Federation, as well as slow implementation of arrangements with foreign manufacturers.⁹

AstraZeneca-Oxford successfully partnered with the Serum Institute of India (SII), but AstraZeneca's vaccine was delayed because of startup manufacturing problems, and subsequent clinical trial issues.¹⁰ SII was confronted with an export ban imposed by the Indian government which limited its supplies of AZD1222/Covishield to COVAX.¹¹

If Johnson & Johnson had not confronted substantial manufacturing delays, and if AstraZeneca likewise had not suffered manufacturing and clinical trial delays, the volume of vaccines available for distribution may have been substantially greater at an earlier stage in the pandemic, and consequently the global rollout of vaccines may well have been more equitable. This would still have depended on the effective establishment of appropriate arrangements for worldwide distribution. Such arrangements likewise suffered from organizational difficulties during the pandemic.

c. Funder conditions

Agreements to provide funding at the various stages of vaccine development, manufacture or distribution may include conditions intended to assure that funding recipients make outputs – whether research results (including new technologies) or end-product vaccines – available in a way that promotes the wide availability of vaccines to the public. There are a wide range of potential funding sources, including national (or regional) governments, foundations, charitable institutions and multilateral organizations (including development banks). A common type of “access condition” is a requirement that the funding recipient offer its product (e.g., a vaccine) at an affordable price in identified markets. There are various ways an affordable price might be determined (e.g., fixed price, or cost plus a reasonable increment). A vaccine technology developer might be required to charge reduced royalties or stage payments to certain categories of licensees (e.g., in low-income countries). There are a broad range of potential access conditions, and of circumstances in which they may be deployed.

Many of the terms and conditions employed in the technology transfer licenses reviewed in the case studies are common among vaccine or pharmaceutical development, production

5 See Annex 1 to this study (hereinafter Annex 1), secs. 1–3.

6 Id., sec. 4. Weiland, N., *High Hopes for Johnson & Johnson's Covid Vaccine Have Fizzled in the U.S.*, in *NY Times*. 2021. www.nytimes.com/2021/06/18/us/politics/johnson-johnson-covid-vaccine.html

7 Annex 1, id., sec. 6.; Cohen, J., *What Went Wrong With CureVac's Highly Anticipated New mRNA Vaccine for COVID-19?* AAAS. *Science*. 2021. www.science.org/content/article/what-went-wrong-curevac-s-highly-anticipated-new-mrna-vaccine-covid-19; Zimmer, C., *CureVac Has Withdrawn Its Covid Vaccine Application to European Regulators*, in *NY Times*. 2021. www.nytimes.com/2021/10/12/health/curevac-covid-vaccine-europe.html

8 Annex 1, id., sec. 5; Tribble, S.J. and R. Pradhan, *Novavax's Effort to Vaccinate the World, From Zero to Not Quite Warp Speed*. KHN. 2021. <https://khn.org/news/article/covid-vaccine-novavax-vaccination-effort-from-zero-to-not-quite-warp-speed/>

9 Ivanova, P. and P. Nikolskaya, *Big Promises, Few Doses: Why Russia's Struggling to Make Sputnik V Doses*. Reuters. 2021. www.reuters.com/business/healthcare-pharmaceuticals/big-promises-few-doses-why-russias-struggling-make-sputnik-v-doses-2021-05-14/

10 Rebecca Robbins, Sharon LaFraniere, Noah Weiland, David D. Kirkpatrick and Benjamin Mueller, *Blunders Eroded U.S. Confidence in Early Vaccine Front-Runner*, in *NY Times*. 2021. www.nytimes.com/2020/12/08/business/covid-vaccine-oxford-astrazeneca.html

11 Roy, Rajesh and Vibhuti Agarwal, *India Suspends Covid-19 Vaccine Exports to Focus on Domestic Immunization*, in *Wall St. J.* 2021. www.wsj.com/articles/india-suspends-covid-19-vaccine-exports-to-focus-on-domestic-immunization-11616690859

and distribution agreements. However, there are terms and conditions negotiated during the pandemic that are “atypical” of IP licensing and technology transfer agreements. These include large-scale government funding of new product development that relinquishes potential government claims to rights in IP created pursuant to the agreement; large non-refundable advance purchase payments; contingent or imprecise product delivery schedules; substantial elimination of potential liability or indemnifying the product supplier except in cases of deliberate wrongdoing; and limitations on the resale or export of products. These atypical terms and conditions were the result of unusual circumstances prevailing at the time of negotiation, and they were accepted among high-income and low-income contracting parties.

The AstraZeneca-Oxford case study most clearly suggests the potential benefit of the inclusion by funders of access conditions in their funding agreements. AstraZeneca agreed to charge prices for its vaccine that were accessible and affordable, including through its licensing arrangement with the SII (with Gates Foundation funding). This resulted in a price for AZD1222 of about USD 3 per dose.¹² This price appears to have allowed large-scale procurement by the government of India and other LMICs (including through COVAX).

The success of the AstraZeneca-Oxford arrangement raises the question whether other funders of vaccine development might have imposed similar conditions, and whether those conditions may have improved the pace at which vaccines were introduced, the volume of vaccines produced or affordability.¹³

i. Price

The US government was the largest funding source for private sector vaccine development. The US government negotiated prices with Pfizer/BioNTech, Moderna, Johnson & Johnson and others for delivery of vaccines to the US government.¹⁴ The Johnson & Johnson price was intended as a not-for-profit price. Pfizer/BioNTech and Moderna each negotiated higher prices that do not appear to have been tied to the cost of production, and the US government might have negotiated more aggressively. However, the US government presumably intended that “higher than necessary” prices served as a strong incentive to proceed rapidly given the threats to public health and the economy, and that the expenditures could be accommodated within the US budget. Since the US government provided the resulting vaccines without charge to individuals within the country, this did not affect “affordability” within the United States. There is no indication that supplies of mRNA vaccines in the United States were limited based on pricing concerns.

The US government might have required Pfizer/BioNTech and Moderna to charge lower prices to foreign purchasers.¹⁵ Such an approach would be complicated. If the EU price were lower than the price within the US market, this might not be politically viable within the United States. As an alternative, the US government could have mandated some type of global allocation formula for Pfizer/BioNTech, Moderna and the other vaccine developers receiving government funding (including through purchase agreements). Instead, it allowed the companies to negotiate separately with foreign purchasers and to obtain what was in effect an open market price.

It is not apparent that reducing the price of the Pfizer/BioNTech vaccine (by way of illustration) would have increased production volume by Pfizer/BioNTech. There would be a number of variables to consider. It is not unreasonable to suggest that one impact of requiring Pfizer/

¹² See Annex 1 to this study, sec. 3(ii).

¹³ See, e.g., proposals by various WHO member states in Pandemic Accord negotiations to promote inclusion of technology sharing conditions in funding agreements. Intergovernmental Negotiating Body (INB) Zero Draft version of April 4, 2023, at Art. 9.

¹⁴ For Pfizer procurement agreements, see Annex 1 to this study, sec. 1(iv)(1); for Moderna procurement agreements, see id., sec. 2(1), and for prices paid and aggregate US government purchase from these suppliers, see Annex 4 to this study (with Kaiser Family Foundation data). For Johnson & Johnson/Janssen procurement agreements, see Annex 1 to this study, sec. 4, including references to not-for-profit commitment. Note that Johnson & Johnson agreed to downward price adjustment if its costs were lower than initially anticipated.

¹⁵ Pfizer/BioNTech and Moderna each earned record-breaking revenues and profits from the sale of COVID-19 vaccines, with Pfizer generating USD 37.8 billion in revenues from Comirnaty in 2022, and Moderna generating USD 18.4 billion in revenues. See Hopkins J., and D. Seal, *Pfizer Expects Drop in Revenue as Covid Vaccine Demand Wanes*, in *Wall St. J.*, Jan. 31, 2023, and Kevin Dunleavy, *Moderna Reaped \$18.4B in COVID Vaccine Sales Last Year, Projects at Least \$5B in 2023*, *FiercePharma*, Jan. 9, 2023. Neither company reported product-specific profits, but each reported record-breaking earnings per share. This suggests that Pfizer/BioNTech and Moderna may have profitably supplied their vaccines at lower prices.

BioNTech to charge lower prices would have been to reduce the profits made by Pfizer/BioNTech from vaccine sales during the pandemic. What is not clear is whether this would have changed the overall global level of production or the distribution destinations of the vaccines.

ii. Access to technology

A technology development funder might have imposed a condition on the private sector recipient of funding that it make its technology generally available to third parties for purposes of their own development, manufacturing or distribution. None of the case studies illustrates the use of this approach. The Coalition for Epidemic Preparedness Innovations (CEPI) included in its funding agreements with at least some recipients a form of “march-in” right that would allow CEPI to designate an alternative developer or manufacturer in the event of a default by the funding recipient. But this technology transfer to a third party required a “trigger” event such as abandonment of the project by the funding recipient.

Sinovac, Sinopharm and Gamaleya are state owned or were significantly state supported and they out-licensed their technology to a number of producers in foreign countries. Government funders encouraged and supported the technology transfer.

The new WHO mRNA Technology Hub, supported by various governments, illustrates a mechanism for technology transfer that is intended to address concerns with respect to affordability and access.¹⁶ The Technology Hub may help pave the way for better addressing future pandemic vaccine requirements in LMICs. The Medicines Patent Pool (MPP) is an established framework through which owners of patents can license their technology for sublicensing to manufacturers. Such sublicensee manufacturers may then supply products at affordable and accessible prices, usually to a defined set of LMICs. The MPP did not secure licenses of patents on approved vaccines during the emergency phase of the COVID-19 pandemic. The WHO Covid 19 Technology Access Pool (C-TAP) program was established as a platform for receiving and coordinating the voluntary licensing of COVID-19-related technologies, including for vaccines. C-TAP did not receive contribution of a product-ready vaccine technology during the emergency phase of the COVID-19 pandemic.¹⁷ On August 29, 2023, C-TAP and MPP announced the conclusion of their first license for an approved COVID-19 vaccine with Medigen Vaccine Biologics.¹⁸

d. Patents and other IP

i. Patents

The owner of a patent has the right to prevent others from using the protected invention in the manufacturing or commercialization of products or when providing services. A patent can cover only a certain part of a product, and the same product may be covered by several patents. Moreover, a certain complex technology may be covered by various IP rights, as discussed in this study.

Each of the case studies shows that the technology used by the vaccine developer was covered by patents (except in the case of Baylor College of Medicine), in some cases in-licensed from third parties. Absent some type of pledge or agreement on non-enforceability of patents, in principle third parties were not permitted to manufacture and sell vaccines identical or substantially similar to those produced by the patent owners. If a vaccine was covered by a patent in a prospective importing country, in principle importation might have been blocked by the patent owner.

16 See WHO, The mRNA vaccine technology transfer hub, visited August 7, 2023. www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub: “Announced on 21 June 2021, the objective of the technology transfer hub is to build capacity in low- and middle-income countries to produce mRNA vaccines through a centre of excellence and training (the mRNA vaccine technology hub). ... The Hub and partners create a global common good for the benefit of all by providing a range of services along the entire vaccine value chain.”

17 The US National Institutes of Health (NIH) out-licensed certain early-stage technology relating to vaccines and diagnostics to foreign researchers through an arrangement with MPP/C-TAP. See, e.g., *NIH Licenses COVID-19 Research Tools and Early-Stage Technologies to WHO Program*, HHS Press Release, May 12, 2022. www.hhs.gov/about/news/2022/05/12/nih-licenses-covid-19-research-tools-early-stage-technologies-who-program.html

18 See *WHO Initiative Signs New Licensing Agreements on COVID-19 Technologies*, WHO Press Release, August 29, 2023. www.who.int/news/item/29-08-2023-who-initiative-signs-new-licensing-agreements-on-covid-19-technologies

At a basic level, there is no evidence that any of the vaccine developers in the case studies threatened third parties with suits for patent infringement, or threatened to block imports or exports, during the emergency phase of the pandemic. While some litigation has started more recently, no patent owner has sought to “enjoin” or prevent vaccine production. If inquiry is limited to whether any of the vaccine developers identified in the case studies affirmatively sought to prevent a third party from developing, producing or importing a vaccine, there is no available evidence of that.

But would the situation for potential third-party developers or manufacturers of vaccines have been better if patent rights had been waived or opened up?

It is difficult to answer this “counterfactual” question. Patents are by definition open technical documents, and third parties contemplating the use of patented technology can examine patent documents whether the patent owner has waived its rights to enforce or not. A third party that identifies a technology in a patent document that it considers necessary for developing and manufacturing its own vaccine may approach the patent owner for a license. The case studies did not identify specific unsuccessful approaches of this nature.

Note, however, that patent disclosures typically “lag” the filing date by around 18 months, and the latest developments might not be promptly identified. There is evidence that public disclosures from new patent applications may have been accelerated during the COVID-19 pandemic, including through patent office adoption of accelerated review mechanisms for COVID-19-related patent applications. As the case studies illustrate, a significant part of the technology used in successful vaccines, even the novel mRNA vaccines, was based on patents predating the pandemic with disclosure having previously taken place.

While it is possible that some third-party vaccine developers refrained from pursuing a vaccine because of fear of a patent infringement lawsuit, there is no concrete evidence of that. Likewise, while it is possible that a potential third-party vaccine manufacturer decided against commencing production because of fears regarding patent-based restrictions in potential importing countries, there is no concrete evidence of that. In the absence of such evidence of patent-based impediments, there is not a sound basis for predicting whether a waiver of patents or relaxation of potential inhibitions on importation (or corresponding exportation) would have materially affected distributional outcomes.

In the timeframe of the emergency phase of the pandemic, without cooperation from the vaccine technology or patent owner, a third-party vaccine developer would still need to develop and formulate a vaccine candidate, subject the candidate to clinical trials, and develop a manufacturing process and suitable facilities. Such a vaccine would need to be approved for use by regulatory authorities within potential importing countries, and suitable storage and distribution arrangements made.

ii. Know-how and trade secrets

Patents are not the only form of IP relevant to vaccine development and production. Trade secrets and other technical “know-how” are typically needed to instruct third parties on the effective use of technology, and transfer of the subject matter is usually included within technology transfer agreements. Because trade secrets are by definition “secret,” either trade secret information needs to be voluntarily transferred by the trade secret owner, or some authority needs to compel its transfer. As noted in the study, national laws do not typically provide mechanisms for compulsory licensing of trade secrets, although governments have inherent powers to take property needed for public purposes (with compensation). In certain contexts, such as for allowing use of previously submitted originator regulatory data for purposes of approving “generic” versions of pharmaceutical products, the TRIPS Agreement (Article 39.3) provides flexibility regarding use of “undisclosed information” to protect the public. This may allow a regulator’s use of previously submitted confidential regulatory data to approve a third-party version of a vaccine.

Just as with respect to patents, there is no evidence from the case studies that a vaccine developer threatened to initiate litigation against a third party for making use of a trade secret during the emergency phase of the pandemic.

As enterprises in countries such as South Africa initiated efforts to develop and produce their own mRNA vaccines, Moderna was approached for assistance with know-how involving lipid nanoparticle (LNP) and other technology, and Moderna rejected these approaches. It announced instead its intention to establish an mRNA manufacturing facility in Africa. Even with assistance from Moderna, end-to-end local production at scale of mRNA vaccines in South Africa may have been difficult within the emergency phase of the COVID-19 pandemic given clinical trial and regulatory review requirements, as well as the need for constructing or retrofitting manufacturing facilities. Yet these events illustrate that access to trade secret information and know-how must be considered as an important part of ongoing discussions regarding improvements to the framework for global vaccine development and production.

e. Counterfactual limitations

This study does not suggest a conclusion regarding whether waiving patents and trade secret protections of vaccine manufacture would have resulted in a more rapid development and rollout of vaccines during the emergency phase of the pandemic. There is insufficient information basis to develop a robust counterfactual. There were multiple factors that delayed the development and scaling up of vaccine production, and more companies failed than succeeded to develop or deliver vaccines in a timely way. If waiving IP rights would have added entrants to the vaccine race, these new entrants would have faced challenges similar to those faced by the vaccine developers identified in the case studies. Data regarding global availability and distribution of material inputs and other resources needed to create and produce different types of vaccines was and remains limited. It is difficult to assess whether development, production and distribution might have been constrained by shortages of materials, by the need to modify or construct manufacturing facilities and to obtain good manufacturing practices (GMP) approval for such facilities, by the availability of adequately trained technical personnel to operate them, by infrastructure limitations and by other factors. If starting from the point of developing a new vaccine candidate, the degree of difficulty and potential for delay are greater.

5. Better practices

The case studies suggest several areas where additional consideration may be given to improving licensing terms or supply terms in APAs or other agreements in order to enhance development of new vaccines or make their distribution more equitable. These include the following:

- **Foundational building blocks:** the foundational mRNA vaccine technology developed at the University of Pennsylvania and by Acuitas (among others) appears to be important for a broad range of future vaccines and other therapeutic products. The case studies indicate that these technologies were out-licensed on a nonexclusive basis, and this helps to assure that the technology will remain available to other researchers and developers. In principle, nonexclusive licensing of foundational technology allows a wider range of research than exclusive licensing. Exclusive licensing may, however, incentivize investment by right owners and encourage them to assume greater financial risk.
- **Export or transfer restrictions:** a number of the APAs identified in the case studies included restrictions on exports or resales of vaccines following delivery. Acknowledging that there would need to be assurances of appropriate storage and chain of custody, permitting exports of delivered products would increase global availability of supply.
- **Liability and indemnity:** the agreements identified in the case studies typically provided broad waivers of liability for the vaccine developers and producers, except in circumstances of deliberate wrongdoing. They also required that purchasers indemnify suppliers in the event of claims. Potential product liability for developers and producers of health products ordinarily serves as an important incentive for attention to safe practices and products. If such potential liability is waived, alternative mechanisms for safeguarding the interests of the public may include strong contractual requirements to carefully monitor, test and audit production to assure product safety.
- **Nonrefundable payments:** the APAs identified in the case studies typically provided that the amounts paid to vaccine developers and suppliers in advance of delivery would be “nonrefundable.” A number of these APAs required the developer or supplier to provide the covered technology to the purchaser or a designated alternative developer or producer if it

did not meet its contractual obligations.¹⁹ This appears to be a useful practice that may assist with establishing alternate sources of supply in the event of a default.

- **Insecure delivery schedule terms:** although it is understandable that a vaccine developer may want to avoid committing to a firm delivery schedule when a vaccine has not yet been approved, vaccine developers should not be allowed to reallocate “places in line” of vaccine purchasers for reasons such as receipt of better offers.
- **Exclusive technology grantbacks:** a number of APAs require that the purchaser must grant back to the supplier an exclusive right to use IP the purchaser develops with respect to the vaccine. Exclusive grantbacks are generally understood to constitute a disincentive to innovation by licensees.²⁰ It is difficult to identify a potential justification for an exclusive grantback in the context of an APA, which instead should encourage innovation by the receiving party or licensee. Exclusive grantbacks may discourage improvements to existing vaccines by reducing incentives for licensee research. They may also discourage the development of new vaccines by foreclosing out-licensing by licensees of newly developed technology that may otherwise aid in third-party research. The potential development of competitive vaccines may be inhibited.
- **Pricing:** if a funder of vaccine production or distribution is seeking to promote affordability of a vaccine product for identified parties (such as procurement authorities in low-income countries), a funding agreement should include conditions that obligate the funding recipient to carry out the funder’s objectives (such as through a defined pricing formula). Similarly, if a funder is seeking to make newly developed vaccine technologies affordable in certain environments (e.g., for low-income country licensees), the funding recipient should be obligated to adopt concessionary royalty rates or stage payments for relevant licensees.
- **Patent transparency:** the developers of vaccines used to prevent or mitigate pandemics or other urgent circumstances should publicly identify patents (and patent applications) they consider to cover technologies used in their vaccines in order to aid potential third-party developers to avoid committing resources to infringing products (i.e., helping to define the freedom to operate), or to encourage third-party developers to seek licenses from the patent owners.
- **Quick and efficient dispute resolution procedures:** during a pandemic, a dispute between stakeholders could influence the speed of development, production and distribution of vaccines. Efficient dispute resolution procedures focused on maintaining and restoring long-term collaborations and business relationships between life sciences parties might usefully be included in agreements.
- **Technology transfer licensing resources:** just as important as the specific terms mentioned above, more developmental resources should be spent on training programs for lawyers and business managers to negotiate complex vaccine licensing agreements.

6. Concluding observations

The study starts by identifying the inequitable distribution of vaccines during the COVID-19 pandemic as a significant global problem. The case studies reflect “the world as it was” during the emergency phase of the pandemic, and do not inherently contain a solution regarding the best way forward. However, the case studies suggest that creating a better system for developing, manufacturing and distributing vaccines that reduces inequity requires addressing multiple factors. These include improving the speed at which vaccines can be developed and approved by regulatory authorities, the establishment of manufacturing capacity that can be

19 See, e.g., European Commission-AstraZeneca Advance Purchase Agreement (APA) of August 27, 2020, sec. 11.2, Annex 1 to this study, sec. 3(iii); US NIH & BARDA – Janssen Research, Supplemental Agreements of Feb.–Mar. 2020, Annex 1 to this study, sec. 4, ns. 306-308; US Advanced Technology International – Novavax, Project Agreement, July 6, 2020, sec. 10(b), Annex 1 to this study, sec. 5(i); CEPI-Novavax, Outbreak Response Funding Agreement (Step 2), May 11, 2020, Section 13.4–5, “Public Health License” and “Public Health License Triggers,” respectively, Annex 1 to this study, sec. 5(ii).

20 Per the Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements: (2014/C 89/03), para. 129: “An obligation to grant the licensor an exclusive licence to improvements of the licensed technology or to assign such improvements to the licensor is likely to reduce the licensee’s incentive to innovate since it hinders the licensee in exploiting the improvements, including by way of licensing to third parties.” Exclusive grantbacks are “excluded” from the EC’s block exemption for technology transfer licenses. Id. para. 130. The stronger the position of the licensor, the more likely it is that exclusive grantback obligations will have restrictive effects on competition in innovation. While they may be acceptable under competition law in some circumstances, exclusive grantbacks are disfavored and particularly so when the licensor enjoys market power.

brought online and scaled up promptly, and assuring that countries have the financial means needed to procure the necessary supplies.

Work on these elements is ongoing. For example, the case studies describe the establishment by the government of Germany of a program that includes the maintenance of vaccine manufacturing facilities that can be rapidly brought online in the event of a pandemic or other public health emergency.²¹ Research groups are working on vaccine platforms that can be rapidly adapted to new viruses and other pathogens.²² The World Bank, among others, is working on financing mechanisms.²³ WHO member states are working on a Pandemic Accord and amendments to the IHR that envision improvements in LMIC vaccine development and manufacturing capacity.²⁴ WIPO prepares detailed studies of the vaccine research environment, maintains an accessible global database of patenting activity, and sponsors workshops and other training activities with respect to technology licensing and transfer.²⁵

IP is generally governed by national law, and to the extent governments consider it important to facilitate access to IP in cases of emergency, they can and should ensure that they have appropriate legislation in place to facilitate that. TRIPS Agreement flexibilities are implemented at the national level. National IP legislation can be designed to provide rapid special pathways for uses that avoid bureaucratic delays. This is the case for provisions relating to access to given technologies or knowledge in emergency situations, such as provisions on compulsory licensing in the case of vaccine-related patents or confidential information protected under provisions governing regulatory authorization processes.

Licensing and technology transfer, including relevant IP, is a necessary element to the effective development and manufacturing of vaccines. No single inventor or company developed and produced a COVID-19 vaccine without cooperation or collaboration, and this cooperation or collaboration can and should be improved. Vaccine technology is developed with public and private resources; often through a combination of both. Private sector pharmaceutical companies (including vaccine developers) are generally obliged to pursue financial results that benefit their shareholders if for no other reason than that they compete with other industry sectors for investor capital. Private sector pharmaceutical companies pursue positive contributions to public health, yet face pressures to generate attractive returns on investment, which affects the pricing and access to their products. Public or non-profit funders are typically not facing pressures for return on investment in a financial sense, though they may face pressure for achieving adequate “social returns.” Public or non-profit funders may be in a better position to address concerns regarding affordability and access for vaccines as achieving these objectives will generate positive social returns.

This study of the COVID-19 pandemic response has illustrated the value of diverse approaches to pursuing innovation. Overall, with government support, private sector initiatives rapidly created new and effective vaccines and put them into production. Predominantly government- and foundation-supported initiatives paid greater attention to addressing conditions of access. The results of this study do not strongly point in a direction of emphasizing a preference for one type of innovation resource (e.g., private or public) over another.

21 See Annex 1 to this study, sec. 6(ii), at n. 447.

22 See, e.g., CEPI, Platform Technologies. https://cepi.net/research_dev/technology/, visited August 7, 2023.

23 See, e.g., World Bank, *Preventing, Preparing for, and Responding to Disease Outbreaks and Pandemics: Future Directions for the World Bank Group*. 2023, Washington, DC. <https://openknowledge.worldbank.org/bitstreams/2189d4e8-7d41-599f-8196-55dc1fc353b2/download>

24 See WHO Intergovernmental Negotiating Body, <https://inb.who.int/>, and WHO, International Health Regulations: amendments, www.who.int/news-room/questions-and-answers/item/international-health-regulations-amendments, visited August 7, 2023.

25 See, e.g., WIPO, Intellectual Property and Technology Transfer, www.wipo.int/technology-transfer/en/

IP protection has been singled out by some stakeholders as a primary reason why the global response to the COVID-19 pandemic was inequitable. This study suggests that there were a variety of factors that led to the conditions of an inequitable response that are not IP related. IP protection may have played a role in limiting wider distribution of vaccine production and distribution, but on present evidence there is no reason to single out patents or trade secrets as the primary cause of inequity in the COVID-19 response. This does not mean that mechanisms for improving access to technology, particularly among LMICs, are not important. To the contrary, the record strongly suggests the value of initiatives to encourage wider geographic distribution of vaccine production capacity to reduce inequity moving forward. Establishing wider geographic distribution of production capacity entails improved access to technology. It is also important that WIPO member states build IP-related safeguards into their national legislation so that they are prepared to take necessary measures in a public health emergency.

On present evidence, IP most likely will continue to be used to establish and maintain control over vaccine technology, and licensing is and will remain essential to providing access to that technology. The fundamental questions revolve around the terms and conditions under which access can and should be provided. This suggests an ongoing role for WIPO to assist stakeholders in exchanging views, and in developing and recommending forms of agreement that can be used to facilitate technology sharing to improve equity.

