

Intellectual Property and Technology Transfer for COVID-19 Vaccines

Assessment of the Record



WIPO

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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.

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Overview

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.

While there is a network of multilateral instruments regarding IP administered by WIPO, the focus of this study is on the World Trade Organization (WTO) legal instrument that addresses IP, the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement. It is this agreement that contains specific substantive provisions on pharmaceutical-related subject matter. 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.

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 study is relevant to those negotiations, though it does not make any specific proposals.

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.

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. 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. A synopsis of the case study findings is included as Section 4, with significantly greater detail provided in Annex 1. 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. There are examples of rapid and successful development of vaccines by companies such as Pfizer/BioNTech, Moderna and, with some qualification, AstraZeneca-Oxford.¹ Yet the case studies illustrate that many vaccine development and production efforts either were significantly delayed or were unsuccessful, based on the science of vaccine development as well as operational difficulties in scaling production.

The study 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 to enable them to invest in building up capacity prior to completing the development and obtaining approval for vaccines. The APAs basically resulted in the United States and Europe receiving vaccines before others.

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. PRC and Russian Federation government funders encouraged and supported technology transfer abroad by these entities.

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.

1 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. The SII was confronted with an export ban imposed by the Indian government which limited its supplies of AZD1222/Covishield to COVAX.

The AstraZeneca-Oxford case study most clearly suggests the potential benefit of the inclusion by funders of “access” conditions in their funding agreements. AstraZeneca was obligated to charge prices for its vaccine that were accessible and affordable, including through its licensing arrangement with the SII (with Gates Foundation funding),²

4. Counterfactual limitations

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. 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. If waiving IP rights would have added entrants to the vaccine race, these new entrants would have faced the same challenges as the vaccine developers identified in the case studies. We do not have a solid factual basis from which to determine whether development, production and distribution might have been constrained by shortages of materials,³ 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.⁴ 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 and other agreements, in order to enhance development of new vaccines or make their distribution more equitable.

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

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

2 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.

3 The Chief Executive Officer of Pfizer expressed the view that restricted capacity for the supply of the materials needed to produce vaccines was the principal reason that production levels could not be increased. Bourla, A., *An Open Letter from Pfizer Chairman and CEO to Colleagues*. 2021, www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines. <https://www.pfizer.com/news/announcements/open-letter-pfizer-chairman-and-ceo-colleagues>

4 Regarding the variety of constraints that generally impact the initiation of vaccine and pharmaceutical manufacturing, particularly in resource-limited environments, see Abbott, F. et al. (March 18, 2021), *Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Focus on the Role of Finance*, Final Report, Nova Worldwide, https://doi.org/10.33009/osf-php_report.

not facing pressures for return on investment in a financial sense, though they may face pressure for achieving adequate “social returns.”

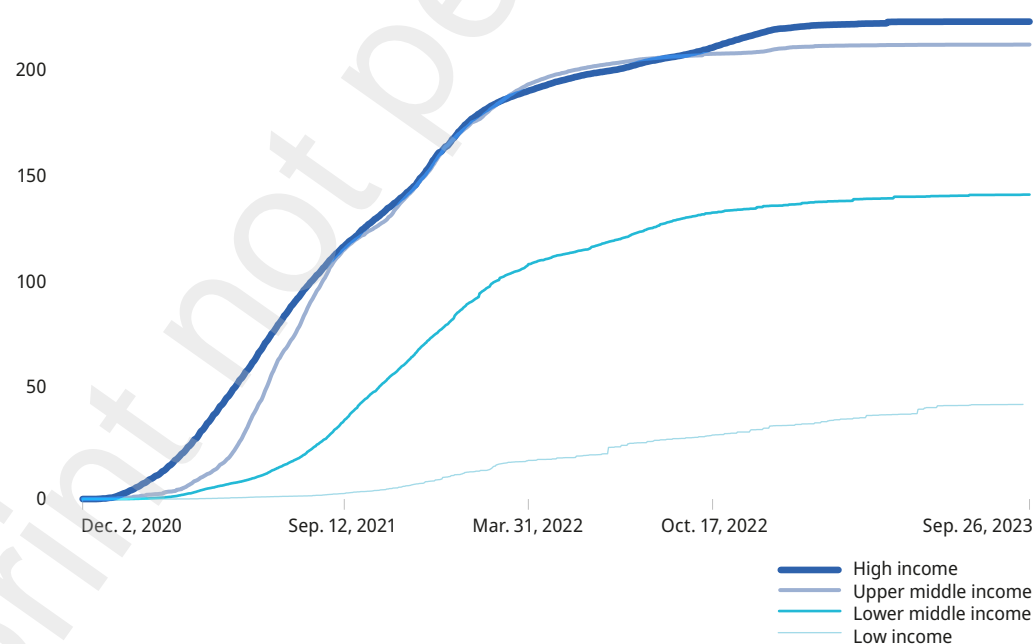
The private and public sectors each have advantages and disadvantages, and there is place for both in addressing present and future needs for pandemic vaccines. The response to the COVID-19 pandemic in terms of developing new vaccines and deploying them illustrated the value of capable and varied private sector actors, and likewise the important role of public funders and state-owned or state-controlled manufacturers. IP and technology transfer agreements helped to integrate the activities of the private and public sectors and to direct the benefits to protecting public health. As ever, striking the right balance between incentivizing research and development (R&D) and the building up of manufacturing and distribution capacity, on the one hand, and making the results accessible and affordable to the widest possible global public, on the other, was and remains the challenge.

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1. Addressing the challenges posed by the global pandemic response

It is common ground that vaccines to address COVID-19 were distributed unequally among countries and regions during the emergency phase of the pandemic, and that high- and upper middle-income countries (HICs and UMICs) generally received access to vaccines in advance of low- and lower middle-income countries (LMICs). This distributional inequality, and the potential to make more rapid and equal distribution of vaccines possible in the future, is the subject of ongoing discussion and negotiation in various forums, including at the World Health Organization (WHO), the World Bank, the World Trade Organization (WTO) and other multilateral institutions, including the World Intellectual Property Organization (WIPO). This study starts from the premise that the global response to the COVID-19 pandemic in terms of distribution of vaccines was inequitable in the sense of a wide disparity in addressing the public health needs of individuals living in different economic and social circumstances (see Figure 1).

Figure 1 COVID-19 vaccine doses administered per 100 people, by income group



Responding to the pandemic, public and private sector entities developed new vaccines. They manufactured them in substantial volume in response to the COVID-19 outbreak. The COVID-19 response witnessed the first use of mRNA-based vaccines, a significant scientific and technical achievement. Within three years of the initial outbreak in late 2019, about 15 billion vaccines were delivered worldwide.⁵ Yet throughout the course of the pandemic various governments and public interest groups expressed concern that private sector ownership and control of intellectual property (IP) rights, including patents and trade secrets, created or exacerbated an

inequitable distribution of vaccines and that a different approach to IP would have improved the global response. This governmental and public interest pressure manifested itself, among other ways, in a request at the WTO for a broad waiver of Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) rules to address the pandemic.

The Global Challenges Division at WIPO commissioned the consultant to prepare a study addressing the role that technology transfer and related IP played as the COVID-19 pandemic unfolded.⁶ Science and technology played a critical role in the pandemic response, and patent protection for scientific innovation is a long-standing feature of the international economic system. Much of the technology used during the COVID-19 pandemic vaccine response was covered in one way or another by patent or trade secret protection.

Licensing arrangements allocated IP among a variety of stakeholders participating in the pandemic response. For those enterprises that successfully developed, manufactured and distributed vaccines, IP ownership and licensing facilitated their activities. Moreover, foundations and other funding institutions promoted IP licensing and product distribution arrangements that required vaccine distribution at affordable prices. The question remains whether better approaches to IP might have been employed, and whether recommendations can be made for addressing pandemic preparedness and response moving forward.

There were a range of factors affecting how the pandemic response developed from the standpoint of vaccine development and distribution.⁷ Some serious impediments to rapid development and scaling up of vaccine production were prudential and regulatory, scientific and operational. On the prudential side, the time lag between identifying promising vaccine candidates and securing regulatory approval (based on clinical trials) 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,⁸ and that the approval timeframe was unusually short for new vaccines. From a scientific standpoint, while several important vaccine candidates proved successful, a significant proportion of the initially identified candidates failed for one reason or another, or were very substantially delayed, despite heavy public and private sector investment. On the operational side, significant manufacturing problems were confronted by at least two of the vaccines that were expected to play major roles, including in LMICs. These manufacturing problems delayed distribution. The full picture of the pandemic response from the perspective of vaccine development and rollout is multidimensional.

This study was undertaken as a series of case studies of specific vaccine development, manufacturing and distribution efforts. A substantial part of these efforts was led by private sector companies, though in each case with significant government support. Another important part of these efforts was undertaken by public sector companies, or mixed government-private enterprise. In addition to government financial support, in many cases foundations provided some part of the funding.

6 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. WIPO (2023), *COVID-19-Related Vaccines and Therapeutics: Insights Into Related Patenting Activity Throughout the Pandemic*. Geneva: WIPO. DOI: [10.34667/wipo.48015](https://doi.org/10.34667/wipo.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.

7 See detailed case study data, below sec. 4, and especially Annex 1 to this study.

8 US Food and Drug Administration (FDA) (2020), *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

2. Technology transfer

This study is directed to both expert and non-expert audiences in the field of IP and technology licensing. It begins with a brief introduction to the subject matter.

a. Licensing agreements

i. Assignment or licensing

Developing and manufacturing vaccines entails the use of technology or scientific information. Such technology may be developed by the party using it, in which case that party will typically (but not always⁹) have the legal authority to use it. Alternatively, the party seeking to use the technology may acquire it from a third party. Technology may be purchased outright, giving the acquiring party direct ownership and control. In legal terms, this is usually accomplished by an “assignment” from the seller to the buyer. In most cases, however, owners of technology prefer to authorize third parties to use it by “licensing” the technology.

A license is a form of contract that grants rights to use the covered subject matter (here technology) under defined terms and conditions. Those terms and conditions may vary quite widely depending on the objectives of the licensor and licensee. These may include typical business objectives such as earning a profit, but they may also include social objectives such as providing access to products at affordable prices. Technology licensing, just as IP systems more generally, may entail trade-offs between arrangements that provide more secure IP protection while maintaining restrictions on access to technology, and arrangements that provide more open access to IP and furnish less robust protection of IP owner interests. This study is aimed at identifying approaches to technology licensing that may establish an equitable balance of interests among stakeholders.

Technology licenses are often referred to by their role in the research and development (R&D), production or distribution chain. In the pharmaceutical and vaccine sector this is often referred to as the “value chain.”

ii. Upstream licenses

Technology licenses relating to the R&D elements of the value chain, which themselves are varied, are usually referred to as “upstream” licenses because they precede the steps involved in the direct commercialization of a product. Such upstream licenses may involve early-stage research such as to determine the biologic causal factors of a disease or condition, or how a compound or biological substance might prevent that causal factor from creating disease. The development of a new vaccine or pharmaceutical product involves a series of scientific inquiries

⁹ Although there are limited exceptions to this general rule, the owner of a patent has the right to exclude third parties from making, using or selling the corresponding invention even if a third party develops its version of the invention independently. Based on the initial filing and priority date of its application, the patent owner has exclusive rights to practice or to authorize third-party practice of its invention for the duration of the patent term.

and steps, including in vitro and in vivo testing of products,¹⁰ and submission for regulatory approval. These steps precede the direct commercialization of products, typically occurring after they have been approved. While there is no bright line division, licensing that involves steps prior to moving into commercialization are “upstream” licenses.

iii. Downstream licenses

When technology is being transferred for the purpose of allowing a third party to manufacture or distribute a vaccine or pharmaceutical product, this is typically referred to as “downstream” licensing. That is, the part of the value chain where a developed technology is moved from scientific concept into a physical product that is supplied and then used by health systems and individuals. So, for example, a license from the developer of a new vaccine to a contract manufacturing organization (or CMO) that is responsible for making the product, meeting good manufacturing practices (GMP)¹¹ and other regulatory requirements, and so forth, is a type of downstream license.

iv. Out-licensing, in-licensing, cross-licensing and pooling

When the owner or holder of a technology, such as a technology covered by a patent, licenses it to a third party, that practice is often referred to as “out-licensing” by the licensor. When a party is obtaining rights from a licensor, that practice is often referred to as “in-licensing.” Licensors “out-license”; licensees “in-license.” There are various arrangements in which independent parties are granting rights in technologies to each other in order to accomplish a common goal. This practice is often referred to as “cross-licensing.” There are arrangements under which two or more technology owners may decide to place their technology ownership or control rights into a central entity that may then out-license the technologies to participants in the arrangement, or to third parties, as well as receiving additional technology contributions. This type of arrangement is often referred to as a “pool” or a “pooling arrangement,” and technology pooling arrangements may take a variety of forms.

v. Common licensing terms and conditions

Technology licenses in the field of vaccines (and pharmaceuticals) are often quite complex, and such licenses are usually drafted and reviewed by lawyers who are trained and have experience with such complex contracts. There are certain core elements to such contracts, such as:

- identifying the parties and reciting the purpose of the agreement;
- identifying the technology that is to be transferred (e.g., patent rights and know-how);
- defining the obligations of the licensor with respect to providing materials (e.g., chemicals or biological materials) or training to the licensee in the use of the transferred technology;
- defining the scope of rights that the licensee is securing, such as whether the technology may be used worldwide or for a more limited geographic area, and whether the technology is authorized for use with respect to a specific type of vaccine, or is authorized for wider use;
- defining the financial terms of the arrangement, such as whether there are lump-sum or stage payments to be made in advance of, or in connection with, commercialization, and whether there will be ongoing obligations by the licensee to make payments in the form of royalties that are usually percentages of the revenues earned by the licensee from sales of the relevant product, and may vary according to various criteria;
- allocating responsibility for securing regulatory approval for the product in the relevant market, which may include providing licensee access and authority to use the regulatory dossier of the licensor; and

¹⁰ Per the US CDC Agency for Toxic Substances and Disease Registry, Glossary of Terms: “In vitro: In an artificial environment outside a living organism or body. For example, some toxicity testing is done on cell cultures or slices of tissue grown in the laboratory, rather than on a living animal. In vivo: Within a living organism or body. For example, some toxicity testing is done on whole animals, such as rats or mice.” www.atsdr.cdc.gov/glossary.html#print.

¹¹ WHO Health Products and Standards (2023), *Good Manufacturing Practices*; Per WHO Health products policy and standards: “Good Manufacturing Practices (GMP, also referred to as ‘cGMP’ or ‘current Good Manufacturing Practice’) is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.” Available from: www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp.

- defining the way in which technology that is developed by either the licensor or licensee during the performance of the agreement will be allocated between the parties, such as who will own the new technology and whether it becomes part of the ongoing licensing arrangement.

There are many other rights and obligations defined by complex licenses relating to the development, manufacture and distribution of vaccines, including provisions relating to joint management, product pricing responsibility, warranties of rights, responsibilities for injuries (and related indemnification), obligations to perform in accordance with relevant regulatory requirements, rights to sublicense, inspection and audit rights, allocation of tax responsibilities, currency conversion, confidentiality, the governing law and manner in which disputes will be settled, the term of the license, contingencies that may allow termination and so forth. In this study reference will be made to a variety of these types of provisions.

vi. Specific arrangements across the value chain

In order to engage a contract manufacturing organization, a vaccine developer needs to transfer the technology necessary to accomplish that to the manufacturer. The terms and conditions under which such technology will be transferred are incorporated into an agreement. Such an agreement covers matters beyond technology transfer, as such, since the contract manufacturer will have obligations and rights beyond a specific technology, such as the basic requirement to produce and deliver the product at a cost, at a time and place, and in conformity with applicable quality standards. Some CMOs have their own proprietary technology that also may be used in carrying out production, and to the extent such technology will be used that will also be subject to the terms of the relevant agreement.

There are various stages along the vaccine production process. These include manufacture of the material components of the vaccine, the production of the vaccine substance, and the “fill and finish” stage in which the vaccine is placed in a form that may be distributed and used. The CMOs at each stage enter into contracts that define rights and obligations with respect to technology, among other features.

As a general proposition, as confirmed by review of various agreements with CMOs, the impact of these agreements from a “technology access” standpoint is limited. The vaccine developer allows the CMO to use its technology to manufacture, but it does not typically confer rights on the CMO to make further upstream or downstream use of the technology. It allows the CMO to use the technology for the limited purpose of producing the product and providing it back to or distributing it on behalf of the contracting party that is paying for a service. The CMO is required to maintain the confidentiality of proprietary information, including know-how, transferred to it.

vii. Access terms

Among the various licensing conditions may be requirements placed on the licensee to meet certain social obligations, such as to provide the products covered by the license at prices that are affordable and accessible, including for individuals in lower-income circumstances.

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.

b. Types of IP and the public domain

i. Public domain

Scientific data or information is often in the “public domain,” meaning that it can be used by anyone that has access to it without additional permissions. Most of the accumulated knowledge of the human race is in the public domain, and the internet has revolutionized the way in which individuals and businesses are able to access that knowledge. Although it is not “protected,” a technology licensor may include provision of information in the public domain as part of its services, such as when a licensor provides training and related materials to assist a licensee. Even though the licensee could find the public domain information on their own, it may be easier to rely on a third party to assemble it. In that regard, licensors may include fees for public domain materials as part of the licensing agreement much as universities charge fees for instructing students with information in the public domain.

ii. Patents

The “patent” is a form of legal protection granted to the inventor of a new, useful and non-obvious (or inventive) product or process. A patent can cover only a certain part of a more complex 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. 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.¹²

These rights of exclusion may allow the patent owner to charge a higher than competitive market price for a product because third parties cannot offer the same, or a substantially identical, product without infringing on the rights of the patent owner. The “market power” of the patent owner depends on various factors, such as whether there are substitute products available on the market. While a substitute may not be “just as good” as the patented product, it may be good enough that consumers will remain with it, or switch to it, rather than paying a significant premium for the patented product. In other words, acceptable substitutes may limit market power.

Patents generally have a term of 20 years counted from the date the patent application is filed. However, in some jurisdictions the term of patents in the pharmaceutical sector may be extended for five years or so based on the time that was required to secure regulatory marketing approval; effectively the term of the patent becomes 25 years from the filing date. Such patent term extensions are not required by the TRIPS Agreement, and reflect a policy choice of the countries adopting them.

The scope of a patent is defined by the inventor’s “claims,” which are technical descriptions of the invention that establish its limits. Claims may be interpreted based on a written description and drawings of the invention included in the “specification,” forming part of the patent application.

Patents relating to the technologies used in creating new vaccines are often highly complex technical documents that are drafted and read by scientific and legal experts. They may recite sequences of genetic code, or formulas and structures of chemical compounds, that may not instruct a non-specialist even as to the particular product with which they are associated. Identifying the patents that cover a particular vaccine may be challenging.

Technology transfer licenses that include patents generally list the identification numbers of these patents, in addition to listing applications for patents not yet granted.¹³ Licenses often

¹² In general, a patent allows its owner to prevent others from making, using, offering for sale, selling or importing a covered product (or a product produced by a patented process) for the term or duration of patent protection.

¹³ The listing of patents for which license rights are granted is a feature common throughout the licensing agreements identified in the case studies. See Annex 1. In many cases the patent numbers in publicly available licenses are redacted, but the main body of the license expressly refers to the incorporated list, and the annex form (redacted) is attached. Other publicly available patent licenses, such as those entered into by MPP, routinely include patent number identifiers. See Medicines Patent Pool, Licensing for Public Health, <https://medicinespatentpool.org/what-we-do/licensing-for-public-health>, visited August 9, 2023.

provide that additional patents granted to the patent owner relevant to the product covered by the license will automatically become part of the licensed technology. In some cases additional payment is required for such new patents.

Patents are granted by IP authorities in each country for which protection is successfully sought. A patent granted in one country is “independent” of patents on the same invention granted in other countries. This means that decisions by patent authorities or courts in one country do not affect patents applied for or granted in other countries. Patents are generally understood to be “territorial” in the sense that the rights granted to a patent holder (e.g., to make, use and sell) are only enforceable in the country where the patent is granted and cannot be enforced in other countries.¹⁴ This means that an inventor must apply for patent protection in each country (or sometimes region) where it wishes to enjoy rights of exclusivity. An inventor wishing to block the importation of a patented vaccine, for example, must be the owner of patent rights in the country of importation. Exports are not the object of specific patent rights, but the right to prevent others from making and selling a patented product may also serve to preclude exports. WTO rules regarding compulsory and government use licensing establish some specific rules about exports. The waiver adopted at the WTO to address the COVID-19 pandemic relaxed the rules on compulsory licensing of vaccine patents for export.

In principle, a patent is granted to the inventor as a means to disseminate technical information to the public through the disclosure of information in the patent application. This is part of the “patent bargain” in which the inventor receives exclusive rights for a limited time in exchange for furnishing knowledge. However, patent documents generally are not “instruction manuals” that provide information sufficient to allow a party other than the patent owner to make the covered product (though, in some cases, they may). The patent owner is mainly trying to prevent someone else from entering the market with the same product, not teaching them how to do it. This is why reference is frequently made to the importance of technical “know-how” as a key component of licensing agreements, because it is this technical knowledge or information that allows the teaching of the patent to be transformed into a working product, such as a vaccine.

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 manufacturing its own vaccine may approach the patent owner for a license. 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.^{15, 16} 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.

The vaccines developed and used to address the COVID-19 pandemic were almost all covered by one or more patents that would prevent third parties from making those vaccines without the permission of the patent owners. The vaccine technology differed among the various vaccines, including mRNA-based, recombinant DNA-based, modified adenovirus, inactivated virus and others. While some of the patented technology being used was quite new, and understood by a relative handful of specialists, some of the technology was sufficiently well-established that the creation of alternatives based on similar underlying technology was possible, and might

14 Patent “territoriality” is not prescribed by the Paris Convention for the Protection of Industrial Property or the TRIPS Agreement, but it is one that is generally followed. There are certain circumstances in which extraterritorial activities are taken into account in the enforcement of patent rights.

15 WIPO (2022), *COVID-19-Related Vaccines and Therapeutics: Preliminary Insights on Related Patenting Activity During the Pandemic*, www.wipo.int/publications/en/details.jsp?id=4589.

16 WIPO (2023), *COVID-19 Vaccines and Therapeutics: Insights Into Related Patenting Activity Throughout the Pandemic*, www.wipo.int/publications/en/details.jsp?id=4658.

not be infringing.^{17, 18, 19} It is in all events important to note that during the “emergency phase” of the pandemic when new vaccines were being created and prepared for commercialization, there is no reported instance of a patent owner threatening to block a third party from making a vaccine. On the other hand, as vaccines became widely available, patent owners began suing each other for shares of the revenues from the sale of vaccines which they claimed they were entitled to receive. Such litigation is ongoing.

As will be discussed further in the study, some of the patents on technologies important to developing and producing vaccines, particularly the mRNA vaccines, covered basic or foundational discoveries. This refers to a type of technology that may be used across a broad range of new product developments, and regarding which lack of access might constitute a substantial impediment to a significant number of follow-on inventions (such as different vaccines to treat different conditions). In the case of COVID-19, the foundational technologies important to mRNA vaccines were out-licensed by their owners on a nonexclusive basis, and on present information there is no reason to conclude that companies were prevented from developing mRNA vaccines because of blocking patents. (This is a different issue than whether patent owners might have affirmatively taken steps to provide technology to third parties.) 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.

iii. Know-how and trade secret

Technology licenses covering vaccines, particularly those licenses authorizing the manufacture of vaccines, routinely include transfers of “know-how.” Know-how is typically a defined term in an agreement, covering matters such as production processes and methods, the chemicals or assays used in product testing, lists of machinery and equipment, the identities of material suppliers, computer software programs and so forth.

Some, but not necessarily all, know-how transferred by a licensor may be protected by a form of IP known as “trade secret.” A trade secret is commercially valuable information not generally known in the industry that its owner has taken reasonable steps to protect. Trade secrets are not the subject of government “registration” or approval. Trade secrets have value to the extent that they have not been made available to competitors or the public, or have not become generally known. A technology license typically requires that the recipient of trade secret information take reasonable steps to protect it from disclosure, which would otherwise destroy its trade secret character.²⁰

Trade secrets are of indefinite duration. They are protected as long as the owner maintains secrecy, or until a third party develops the information independently. Although trade secrets may be protected for much longer than patents, the reason that developers of vaccine and other pharmaceutical technologies secure patents is because once a product has been placed on the market there is nothing that prevents others from “reverse engineering” the product.

Going beyond trade secrets, technology licensing agreements often require the parties to maintain information shared by them “in confidence,” whether or not such information is trade secret. Technology licenses entered into during the course of the COVID-19 pandemic routinely required that the parties keep the terms and conditions of the license confidential, unless some government regulation required disclosure.

17 The technology underlying adenoviral vector vaccines has been in use for decades and many research organizations worked on vaccines based on adenoviruses during the COVID-19 pandemic. See, e.g., Mendonça, S.A., et al. (2021), Adenoviral vector vaccine platforms in the SARS-CoV-2 pandemic, *npj Vaccines*, 6:97, <https://doi.org/10.1038/s41541-021-00356-x>.

18 Lee, J. (2021), *Adenovirus: After 40 Years, a Call to Arms*. Cold Springs Harbor Laboratory, www.cshl.edu/adenovirus-after-40-years-a-call-to-arms/.

19 Norbert Pardi, et al. (2018), mRNA vaccines: a new era in vaccinology. *Nat Rev Drug Discov*, 17:4, 261-79, www.ncbi.nlm.nih.gov/pmc/articles/PMC5906799/pdf/nihms955599.pdf.

20 A third party may internally develop and keep the same “trade secret” provided it likewise protects it from public disclosure.

iv. Regulatory data and exclusivity

Although the specific requirements vary among jurisdictions, in order for a vaccine to receive approval for use from national or regional regulatory authorities, the vaccine developer must provide that authority with information regarding the conduct and outcome of clinical trials, as well as regarding manufacturing processes. The data submitted by the vaccine developer (the “originator”) is often held as confidential information by the regulatory authority, and third parties may not rely on that information as a basis for approval of another vaccine even if it is identical to the originator vaccine. There may be exceptions to these general rules, but this is generally the practice.

In addition, upon the initial approval of a vaccine (or pharmaceutical product) the originator may be granted a period of “market exclusivity” such that no other party may introduce the same vaccine for the duration of the exclusivity period. The length of the market exclusivity period may depend upon whether the vaccine is considered a “biologic” product or a chemical product. In either case, rules regarding market exclusivity, including duration, differ among national and regional jurisdictions.

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.

v. Other forms of IP

Other forms of IP may be relevant to vaccine distribution. In addition to their generic names (or international nonproprietary names, INNs),²¹ vaccines are often sold under “trademarks” by their originators. So, for example, Pfizer/BioNTech’s tozinameran (INN) vaccines are sold under the trademark “Comirnaty.” The licensee for production or distribution of a vaccine may or may not want to use the originator’s trademark, and the originator may or may not want to license its trademark. Because the vaccine originator may not have direct control over the licensee in terms of manufacturing oversight and quality compliance, the originator may be reluctant to allow a third party to use its trademark. These are business decisions by the licensor and licensee that should not affect the product itself, only the name by which it is called.

Copyright is generally intended to protect artistic expression, including in writings. However, pharmaceutical companies have from time to time asserted that information included in marketing literature and even product leaflets is protected from reuse by third parties through copyright. In addition, computer software (including custom software) may be protected by copyright (in addition to patent). Though it seems unlikely that copyright protection would substantially interfere with developing and distributing vaccines, the licensee might nevertheless assure that it has the rights it needs to effectively manufacture and sell its products.

There are other forms of IP such as design protection that conceptually might be relevant to a product such as an artistically designed vaccine vial, but we do not discuss further these more remote forms.

c. The WTO TRIPS Agreement

i. Relevant rules

The Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement, entered into force on Jan. 1, 1995.²² It is one of three principal agreements that form the WTO

21 Robertson, J. S., et al. (2022), International Nonproprietary Names (INN) for novel vaccine substances: A matter of safety, *Vaccine*, 40:1, 21–7, www.ncbi.nlm.nih.gov/pubmed/34844820.

22 See generally WHO, WIPO & WTO (2020), *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (2nd edn), www.wto.org/english/res_e/booksp_e/who-wipo-wto-2020_e.pdf.

rule system. The TRIPS Agreement establishes minimum substantive standards of protection for IP, as well as minimum standards for IP enforcement, by WTO members. The TRIPS Agreement requires that all WTO members provide patent protection in all fields of technology, which is generally understood to include pharmaceuticals (Article 27.1). In addition, the TRIPS Agreement establishes a minimum duration for patent protection (20 years from the application filing date) (Article 33), and it establishes rules governing the granting of “limited exceptions” to patent rights (Article 30) and for compulsory or government use licensing of patents (Article 31). In 2017, following an extended negotiation, transition and approval period, an amendment to the compulsory licensing rules came into effect broadening authority for such licenses for export under defined conditions (Article 31*bis*). The TRIPS Agreement establishes rules requiring the protection of data submitted in connection with approval of new pharmaceutical chemical products, which some WTO members interpret to require the granting of some term of market exclusivity (Article 39.3). Article 39.3 of the TRIPS Agreement includes certain in-built flexibilities such that, for example, data submitted for regulatory purposes can be disclosed where necessary to protect the public, and where data are protected against unfair commercial use.²³ As discussed earlier, trade secrets are relevant to technology transfer, and the TRIPS Agreement includes basic rules on protection of trade secrets (Article 39.1-2). There is no specific provision in the TRIPS Agreement addressing governmental authority to override trade secret protection or to compel the license or transfer of a trade secret from one party to another.

In November 2001, WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health. This Declaration confirmed the right of WTO members to use the flexibilities incorporated in the TRIPS Agreement, reaffirmed certain flexibilities, and insisted that the TRIPS Agreement be interpreted so as to promote access to medicines for all. The Doha Declaration negotiations led to the adoption of the first amendment to the TRIPS Agreement, adding Article 31*bis*.

The suggestion was made by public interest groups during the course of the COVID-19 pandemic that a government might compel a vaccine developer to provide third-party vaccine manufacturers with trade secret information useful or necessary to produce vaccines.²⁴ Provisions on compulsory licensing or transfer of trade secrets are not an ordinary feature of national IP laws, recognizing that businesses are required to provide trade secret information to governmental entities, among other things, for regulatory purposes, and governments are generally obligated to keep that information confidential (other than using it for governmental purposes). Governments typically have an inherent power under the national constitution to take private property for public purposes, combined with an obligation to provide adequate compensation to the property owner.²⁵ In principle, a government might take or direct a private entity to provide trade secret information to a third party, just as it might take over a manufacturing facility, for the purpose of manufacturing a vaccine. No such action appears to have been taken during the COVID-19 pandemic. However, vaccine developers and manufacturers that entered into development and supply agreements with governments, e.g., under Operation Warp Speed in the United States of America, provided extensive information to the government with respect to their manufacturing processes under conditions of confidentiality. The US government usually negotiated rights to step in and have a third-party manufacture vaccines in the event the originally contracting party defaulted. This would have effectively meant using trade secrets, though in a manner provided for by contract and related legislation. In addition, as discussed later in this study, the Coalition for Epidemic Preparedness Innovations (CEPI) incorporated a “public health license” and a related trigger in certain of its funding agreements that authorized it to transfer technology from the funding recipient to a third-party producer in the event of a default by the funding recipient. This would include transfer of trade secret information necessary to implement production.²⁶

23 This flexibility was effectively acknowledged in paragraph 4 of the waiver of TRIPS requirements adopted by WTO members in connection with the Twelfth Ministerial Conference (MC 12) on June 17, 2022. Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30, WT/L/1141, June 22, 2022.

24 Gurgula, O. & J. Hull (2021), Compulsory licensing of trade secrets: Ensuring access to COVID-19 vaccines via involuntary technology transfer, *Journal of Intellectual Property Law & Practice*, 18: 6, pp. 418–31, www.ncbi.nlm.nih.gov/pmc/articles/PMC8690222/.

25 See, e.g., *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984).

26 See Annex 1 to this study, sec. 5(ii).

The TRIPS Agreement, like the other principal agreements of the WTO, includes a national security exception that allows governments to take measures they consider necessary to protect their essential security interests in times of emergency in international relations (Article 73).²⁷ A number of members, including the United States, have argued that this exception is effectively “self-judging,” and that a member’s measures cannot be reviewed for WTO inconsistency when it invokes the national security exception. Although WTO dispute settlement panels have not gone so far as deciding that acts under the provision are completely a matter of national discretion, there is without doubt a significant deference given to governments that invoke the national security exception. Recall that WHO declared the COVID-19 pandemic a Public Health Emergency of International Concern (PHEIC), and the United Nations (UN) Security Council took cognizance of the pandemic. Some expert commentators on the TRIPS Agreement conclude that WTO member states would be justified in circumstances such as those surrounding the COVID-19 pandemic to invoke Article 73 to override TRIPS Agreement IP protection rules.

ii. The COVID-19 waiver

Provisions in multilateral agreements such as the TRIPS Agreement require implementation by WTO members in their national law to have effect within the domestic IP system. This includes implementation of modifications introduced by the recent TRIPS Agreement 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. Since the outset of the pandemic WTO members have had the authority to override patents and regulatory exclusivity based on the existing flexibilities in the TRIPS Agreement, including by issuing government use or compulsory licenses, and (according to some experts) by invoking the national security exception. Ultimately national law in each member governs patents and other IP. Members must take relevant steps within their national legal systems.²⁸

Finally, it is also important to point out that least developed country (LDC) members of the WTO are not under any obligation to protect IP with respect to pharmaceuticals (including vaccines) at least until 2033.²⁹ In this regard a WTO waiver may affect non-LDCs that are exporting to the LDCs. But the LDCs are not constrained with respect to what they may do within their own territories. Just as with other WTO members, it is up to the LDCs to address these matters within their internal legal systems.

d. WHO Pandemic Accord and International Health Regulations negotiations

An Intergovernmental Negotiating Body (INB) has been established within the framework of WHO to prepare a draft instrument (colloquially “Pandemic Accord”) to address pandemic prevention, preparedness and response.³⁰ This instrument would be open to adoption by member states. In parallel, WHO has established a Working Group on Amendments to the International Health Regulations (2005) (IHR). The IHR establish certain WHO member state rights and obligations with respect to surveillance and reporting of disease outbreaks, require the maintenance of certain core capacities for surveillance and response, and establish the framework through which the WHO Director General may declare a PHIEC.³¹ Each of these

27 Abbott, F.M. (2020), *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper 116. South Centre: Geneva, www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf.

28 Advocates of a WTO waiver argued that it is needed because of potential complications involved in complying with national compulsory licensing rules, and it may be that the patent laws of some countries include rules with respect to compulsory licensing that are challenging to navigate. But a WTO TRIPS waiver would not change these national rules. National parliaments or legislatures can do that, and they might have done it (and some did) in response to the pandemic.

29 Decision of 30 November 2015, Least Developed Country Members – Obligations Under Article 70.8 and Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WT/L/971, 2 December 2015; and Decision of the Council for TRIPS of 6 November 2015, Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/73, 6 November 2015. 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.

30 See generally WHO, Intergovernmental Negotiating Body, <https://inb.who.int/>.

31 See generally WHO, International Health Regulations, www.who.int/health-topics/international-health-regulations, and WHO, Fourth meeting of the Working Group on Amendments to the International Health Regulations (2005), [www.who.int/news-room/events/detail/2023/07/24/default-calendar/fourth-meeting-of-the-working-group-on-amendments-to-the-international-health-regulations-\(2005\)](http://www.who.int/news-room/events/detail/2023/07/24/default-calendar/fourth-meeting-of-the-working-group-on-amendments-to-the-international-health-regulations-(2005)).

negotiating groups is in the process of consultations with member states regarding the substance of the proposals, and each negotiating group has received a substantial number of drafting proposals from member states. For both the Pandemic Accord and IHR, considerable attention has been focused on enhancing the capacity of LMICs, in particular, for developing, manufacturing and distributing medical products – including vaccines – needed to prevent or respond to a pandemic outbreak or other health emergency. These proposals suggest mechanisms for facilitating transfer of technology, including by addressing potential constraints on “local production” that may be imposed by IP rights.³² While the subject negotiations are intended to produce results within a relatively short timeframe, at this early stage the draft negotiating texts reflect significant differences among member states regarding the preferred outcome.

This study is relevant to the WHO negotiations in the sense that it attempts to provide an objective view of the role that IP and transfer of technology played as governments and other stakeholders sought to develop, manufacture and distribute vaccines during the urgent phase of the COVID-19 pandemic. This study does not, however, make specific recommendations regarding the potential subject matter to be incorporated in the texts under negotiation at WHO.

e. Advanced purchase agreements

Parties entering into sale and purchase contracts are ordinarily doing so with some confidence or reasonable belief that the products themselves will exist as of the date of delivery.

In the course of the COVID-19 pandemic, a substantial number of the sale and purchase agreements between vaccine developers and purchasers (typically government-related entities) covered vaccine products that were not fully developed, tested or approved when the agreements were made. In addition to completing development of the vaccine products, sellers would be spending substantial sums to scale up manufacturing facilities. There was substantial uncertainty regarding whether vaccine development would be successful, and whether investments in manufacturing processes and facilities by any particular vaccine developer would be financially justified from the standpoint of routine commercial business.

In order to provide financial security to vaccine developers, government procurement authorities entered into so-called “advanced purchase agreements” (APAs) in which substantial amounts of funding were provided to the vaccine developers without customary assurance that products would be approved and available for delivery on a particular timetable, or at all.³³

APAs are not in themselves so unusual. They had previously been used as a means to finance completion of development of pharmaceutical products, including vaccines, by procurement entities such as Gavi, the Vaccine Alliance (GAVI). Such agreements would commit the purchaser to buying a certain quantity of the product (e.g., vaccine) when produced, notwithstanding what might then be the demand for the products. The intent was to encourage producers to participate in vaccine markets in which demand requirements could fluctuate quite significantly.

Although previously used, the APAs entered into during the COVID-19 pandemic were “atypical.” Government procurement authorities made very substantial payments to the vaccine developers before products had been developed, tested or approved, and without firm commitments by the developers to supply the products as of particular dates. In many cases, large advanced payments to vaccine developers were “non-refundable.” Even if products were never successfully developed or supplied, the vaccine developer did not need to return payments that had been made.

32 Such proposals address, among other things, potential IP waivers, technology pooling mechanisms and access provisions for funding agreements. These negotiations remain at an early stage and the inclusion of WHO member state proposals in draft texts constitute expressions of interest rather than agreed-upon terms.

33 Such APAs are identified and analyzed in many of the case studies. See Annex 1 to this study, e.g., Pfizer/BioNTech with United States, European Union, sec. 1(iv)(1-2); Moderna with the United States, sec. 2(i) and European Union, sec. 2(v); AstraZeneca with European Union, sec. 3(iii), Colombia, sec. 3(vii) and United States, sec. 3(viii); Novavax with United States, sec. 5(i), GAVI Alliance, sec. 5(iii), European Union, sec. 5(ix), Canada, sec. 5(x) and the United Kingdom, sec. 5(xi); CureVac with the European Union, sec. 6(ii). A number of the texts of the relevant agreements are linked to the Annex 1 footnotes.

From the standpoint of the vaccine developers or sellers, the risks associated with delivering approved vaccine products were very significant, and ranged across a variety of “contingencies” from whether the vaccine would work as intended, to the availability of the materials needed to produce the vaccine, to the process of securing regulatory approval, to whether manufacturing processes could be scaled up to produce required quantities. Advanced purchase funding was a mechanism for “de-risking” the process of completing development of vaccines and to facilitate investment in manufacturing when “time was of the essence.” Procurement authorities did not want vaccine developers to delay bringing vaccine manufacturing capacity online until vaccines had been approved. The objective was to make the quantities of vaccines needed to address the pandemic available as soon as possible following regulatory approval. APAs were effectively a form of subsidy that provided an incentive for vaccine developers and manufacturers to undertake R&D and scaling up. Subsidies have long been considered a means to promote R&D particularly to achieve an outcome identified in advance – a so-called “push” mechanism – and may serve as a substitute or complement to patent protection (the latter being a “pull” (*ex post facto*) mechanism since the patent is granted as a reward for completed innovation).³⁴ In this study several of the unusual aspects of the APA phenomenon during the COVID-19 pandemic will be identified.

³⁴ Governments often provide targeted R&D funding (subsidies) directed toward addressing specific technical problems, such as how to design military aircraft to avoid radar detection. Military budgets are replete with R&D subsidies, and military budgets include targeted biomedical research. Patent systems, on the other hand, leave the reward of exclusive rights open for solutions in all fields of technology, and individual inventors make choices about what technical problems they try to solve. Patents generally encourage innovation, but if a government needs to solve a particular problem it may want to specifically direct the research, rather than leave this open to inventor choice. Patents and subsidies are not mutually exclusive. A government may, but need not, allow the recipient of a subsidy to secure a patent. In some cases a government will allow the recipient of a subsidy to secure a patent, but require that the government be authorized to use it. The 1969 seminal work by William Nordhaus, *Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change* (MIT Press), explored the potential approaches to encouraging innovation, the principal alternatives being patents and subsidies. Because subsidies are usually granted to fund the work of inventors and are not fully contingent on a successful outcome, they are often referred to as a “push” mechanism. Patents, on the other hand, are rewarded after the fact based on success, and are often referred to as a “pull” mechanism. See, e.g., iavi, Incentives for Research and Development (2007), https://assets.publishing.service.gov.uk/media/57a08bfd40f0b652dd00103c/toolkit_incentives_for_research_and_development.pdf.

3. Case study approach

a. Developers and vaccines (or candidates)

This study focuses on the vaccines that were most widely distributed and used during the COVID-19 pandemic, as well as on a few vaccine development and supply efforts that were either unsuccessful or so substantially delayed as to not have made a substantial contribution in terms of supply volume. The consultant undertook 10 case studies. The vaccines are based on a variety of technologies, including mRNA-based (Pfizer/BioNTech, Moderna and CureVac/GSK), modified adenovirus (AstraZeneca-Oxford, Johnson & Johnson/Janssen), recombinant DNA protein (Novavax, Corbevax), inactivated virus (Sinopharm and Sinovac) and dual viral vector (Gamaleya).³⁵

The case studies illustrate that some vaccine development and supply efforts progressed relatively smoothly taking account of the built-in regulatory requirements.³⁶ From the private sector standpoint, the efforts of Pfizer/BioNTech and Moderna appeared to encounter the fewest unanticipated difficulties. While the AstraZeneca-Oxford effort ultimately resulted in wide distribution of a successful vaccine, early problems with manufacturing and clinical trials, and an export ban in India, delayed distribution. On the public sector side, the efforts by Sinopharm and Sinovac in the People's Republic of China (PRC) resulted in wide distribution of their vaccines, though public information regarding the mechanics of the rollout is limited.

The consultant's methodology for data collection and assembly is described in Annex 3.

b. Enterprise type and funding sources

The enterprises involved in the development, production and distribution of vaccines can be broadly categorized as predominantly private sector, mixed public-private and predominantly public sector, though these characterizations are subject to qualification.

i. Private sector (with subsidization)

Pfizer/BioNTech, Moderna, Johnson & Johnson/Janssen, Novavax and CureVac/GSK are private sector companies with securities traded on public exchanges. The funding for their R&D and for upgrading their manufacturing capabilities was in each case heavily subsidized, as will be described further. Pfizer/BioNTech did not receive US federal government support for vaccine development as such, but it secured large APA commitments that served as a form of subsidization. Various of these companies also received funding from foundations for different aspects of their work, as well as advanced purchase commitments from COVAX, among others.

35 These are: (a) Pfizer/BioNTech – Comirnaty (proprietary)/tozinameran (INN) vaccine (b) Moderna – Spikevax (proprietary)/elasomeran (INN) vaccine; (c) Oxford/AstraZeneca – Vaxzevria (proprietary) (Covishield in India), initially COVID-19 Vaccine 9ChAdOx1-S [recombinant] (INN), later AZD1222 COVID-19 vaccine; (d) Johnson & Johnson/Janssen – (proprietary) Jcovden, (INN) COVID-19 vaccine (Ad26.COV2-S [recombinant]); (e) Novavax – proprietary (Nuvaxovid) (Covovax in India), (INN) COVID-19 Vaccine (recombinant, adjuvanted); (f) CureVac – CVnCo2 (application for approval withdrawn); (CV2Co2) under development (with GSK); (g) Baylor College of Medicine/Texas Children's Hospital – Corbevax, in Indonesia as IndoVac; (h) Sinopharm – BIBP COVID-19 vaccine; (i) Sinovac – Sinovac-CoronaVac COVID-19 vaccine; (j) Gamaleya National Center of Epidemiology and Microbiology – Sputnik V (proprietary) or Gam-COVID-Vac (registration).

36 The case studies are generally described in sec. 4, below. Granular detail is set forth in Annex 1.

ii. Mixed public-private

AstraZeneca-Oxford combined vaccine development work at a public institution in the United Kingdom (albeit one with complex venture capital type investments) and a private sector publicly traded enterprise (i.e., AstraZeneca). This venture received significant financial support from CEPI, the Gates Foundation and Wellcome Trust, among others. Also, a significant part of the production and distribution of the AstraZeneca vaccine was undertaken through a licensing arrangement with the Serum Institute of India (SII), a privately held company that worked closely with the Indian government, and through a different arrangement with Brazilian public health entities. As will be discussed, this arrangement largely separated the supply of the AstraZeneca vaccine between HICs and LMICs, with AstraZeneca serving the HIC markets, and the SII and Brazil serving LMIC markets.

iii. State owned

For the PRC, Sinopharm is a predominantly state-owned and controlled enterprise based in the PRC, though a portion of its securities are publicly traded.³⁷ Sinovac is a privately held company based in the PRC (with shares formerly traded on the US NASDAQ exchange). As discussed below, Sinovac received PRC government support in the development and manufacture of its vaccine.

The Russian Federation's Gamaleya National Center of Epidemiology and Microbiology is part of the Health Ministry, and received financial support from the Russian Direct Investment Fund for its Sputnik V vaccine.

iv. University

Baylor College of Medicine and its affiliated Texas Children's Hospital are private institutions based in the United States. They are not reported to have received significant subsidy or external funding for the development of the Corbevax vaccine.

37 See WHO (2017), China Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health. Geneva: WIPO, at 27, www.who.int/publications/i/item/9789241512176.

4. The case studies

Table 1 identifies several parameters of the 10 vaccine developers and suppliers covered by the study, including the nature of the enterprise, the source of their funding, the underlying vaccine technology, their articulated access policies and the reported price of the vaccines they supplied during the COVID-19 pandemic.

Table 1 Parameters of the 10 vaccine developers and suppliers covered by the study

	Pfizer/ BioNTech	Moderna	AstraZeneca- Oxford – SII	Johnson & Johnson/ Janssen	Novavax	CureVac	Baylor/ Texas Children's Hospital	PRC – Sinovac; Sinopharm	Gamaleya/ Russian Federation
Type of entity	Private (securities market)	Private (securities market)	Private (securities market/ university)	Private (securities market)	Private (securities market)	Private (securities market)	University (private); hospital (private)	Private/ state owned	State owned
Source of funding	Private market plus APA	US gov't funded development and APA	Foundations (CEPI- Gates); US development and APA; UK development and APA; EU APA	US gov't development and APA	US gov't development and APA; CEPI development and APA	CEPI; German gov't; EU APA	Self-funded; CEPI (for Dynavax)	Self-funded and government supported	State funded
Vaccine technology	mRNA-based	mRNA-based	Modified adenovirus	Modified adenovirus	Recombinant DNA	mRNA-based (abandoned)	Recombined protein fragment	Inactivated virus	Dual adenovirus vector
Access provisions	Tiered pricing	No patent enforcement pledge	General intent on favorable access for developing countries	Supply at not-for-profit price	Affordable prices	Per CEPI equitable access guidelines	Unknown	Unknown	Unknown
Pricing	US gov't: USD 20–30/dose; EU: EUR 19.5; Peru, Albania, Colombia, Dom. Rep.: USD 12	US gov't: USD 15.25–25.36/dose; EU: USD 22.50, COVAX USD 7–10; Botswana: USD 28.88; Argentina: USD 21.50	EU: EUR 2.9/ dose; UK: (at cost); Brazil: USD 3.16–5.27; Colombia: USD 6, SII-CEPI USD 2.50	US: USD 10/ dose; EU: USD 8.50, COVAX USD 5–8	EU – Denmark: USD 20.90	EU: EUR 10/ dose	India: USD 1.75 (public), USD 3–10 (private)	PRC, both Sinovac and Sinopharm: USD 29.75; Zimbabwe: USD 7, Sinopharm; Hungary: USD 36, Sinovac; Indonesia: USD 17	From USD 9.75 (Guatemala) to USD 27.15 (Pakistan, private)

The findings of the case studies are summarized in this section, with substantially greater detail provided in Annex 1.

a. Pfizer/BioNTech³⁸

At the earliest stage of the pandemic outbreak, Pfizer, based in the United States, successfully negotiated to acquire rights to mRNA vaccine technology from BioNTech, based in Germany. Pfizer paid BioNTech nearly USD 1 billion for those rights, and agreed to a 50-50 split of gross profits from sales of a resulting vaccine. BioNTech's technology was protected by patents. Pfizer would distribute its vaccine (*Comirnaty*) to most of the world, with BioNTech retaining rights for Germany and Türkiye, and with BioNTech preserving a licensing agreement with a PRC biotechnology company, Fosun, on behalf of the partners (for which Fosun agreed to pay up to USD 85 million in fees and a 35 percent share of gross profits). For reasons which remain unclear, the Pfizer BioNTech vaccine was not introduced in the PRC until quite recently and in limited quantity.

Pfizer and BioNTech entered into a complex Collaboration Agreement that largely gave decision-making control to Pfizer, including with respect to pricing of the vaccines outside Germany and Türkiye. Each party would retain ownership of its solely developed IP, and the parties would jointly own collaboratively developed IP. BioNTech had previously in-licensed mRNA technology from the University of Pennsylvania/Cellscript and Acuitas, each of which received significant royalties based on sales of the vaccine.

Pfizer came into the collaboration with a sophisticated manufacturing and distribution operation within the United States, and most of its manufacturing at least at the initial stages was undertaken in the United States. Unique among the major vaccine developers, Pfizer did not benefit from a technology development agreement with the US government, but it did receive an order for 300 million doses of its vaccine for a total price of USD 5.97 billion in March 2021 (a per dose price of USD 19.90). As of December 2022, the US government had paid more than USD 15 billion to Pfizer/BioNTech for about 655 million doses. As a consequence of going without a development subsidy, the US government did not secure typical Bayh-Dole "march-in" rights with respect to patents from Pfizer.

The European Union (EU) also entered into a large-scale APA in November 2020 with Pfizer/BioNTech, for up to 300 million doses at a price of EUR 19.5 per dose. Pfizer/BioNTech entered into a number of additional agreements to supply other countries, including Peru, Colombia, the Dominican Republic and Albania. The price per dose in each of these contracts was USD 12, without firm commitment on delivery schedule. Pfizer/BioNTech would retain ownership of all IP. Note that Pfizer's agreements with the US government did not require it to supply LMICs at preferential prices.

Pfizer's chief executive officer (CEO) objected to the proposal for a WTO TRIPS waiver, arguing that Pfizer was limited in its supply capacity by shortages of component materials, and that opening up the supply market to more potential producers would exacerbate the problem. He also suggested that LMICs were reluctant to purchase the mRNA vaccine because of cold chain storage limitations.³⁹

There is no evidence suggesting that Pfizer/BioNTech affirmatively threatened any party with patent infringement litigation intended to block production during the course of the pandemic. It is currently involved in litigation with Moderna, among others, regarding rights to patented technologies.⁴⁰ The litigation with Moderna – which Moderna initiated in the United States and Germany – has been extending to additional jurisdictions, including Belgium, Ireland and the United Kingdom. Pfizer and BioNTech have counterclaimed.⁴¹

³⁸ See Annex 1 to this study, sec. 1.

³⁹ See Albert Bourla, An Open Letter from Pfizer Chairman and CEO to Colleagues. 2021. www.pfizer.com/news/articles/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines, and; Albert Bourla On Ensuring Equitable Access to COVID-19 Vaccines, 2021. www.pfizer.com/news/articles/albert_bourla_on_ensuring_equitable_access_to_covid_19_vaccines.

⁴⁰ See Annex 1 to this study, sec. 2(vi).

⁴¹ See, e.g., Fraiser Kansteiner, Moderna mounts 2 new patent lawsuits against mRNA rivals Pfizer, BioNTech: report, for a general overview of the litigation, www.fiercepharma.com/pharma/covid-vaccine-patent-war-heats-moderna-mounts-additional-infringement-lawsuits-against. This study does not attempt to analyze the relative strength of the litigation claims and does not express an opinion on the merits.

Moderna is a biotechnology company based in the United States that has predominantly focused on development of mRNA therapeutic platforms. It undertook a successful initial public stock offering in 2018. Shortly following the pandemic outbreak, the US government entered into a development and purchase agreement with Moderna for what became its *Spikevax* vaccine, initially for USD 498 million, rising for procurement to approximately USD 10 billion by July 2022. The initial price per dose was approximately USD 16.80 per dose for the first 200 million doses.

The agreement with the US government required Moderna to produce its vaccines within the United States. Based on typical federal government procurement provisions, the US government would receive a nonexclusive license to practice the invention for its own purposes, and the US government secured “march-in” rights for patents secured based on US government funding. This gave the government the right to provide technology to third parties in the event Moderna did not supply vaccines on reasonable terms. (The US government has never exercised its “march-in” rights with respect to a pharmaceutical (including vaccine) product, despite being requested several times by public interest groups.)

Moderna in-licensed mRNA technology from the University of Pennsylvania, paying approximately USD 650 million in royalties (approximately 3.5 percent) by the end of 2021. In addition, Moderna recently agreed to pay USD 400 million (“delayed licensing” fee) to the US National Institutes of Health, Dartmouth College and Scripps Research for patented technology it used to stabilize mRNA-generated spike proteins.

Moderna entered into a large-scale contract manufacturing agreement with Lonza, a Swiss-based manufacturer, with production facilities in both the United States and Switzerland. Moderna licensed its IP to Lonza for purposes of manufacturing the mRNA vaccine, but each party otherwise retained rights in its own IP.

Moderna’s “access policy” consisted of announcing that it would not assert its patents in infringement actions against third parties, updating that policy in March 2022 to limit the pledge to 92 Gavi-COVAX Advanced Market Commitment countries.

In December 2020 Moderna concluded an APA with the EU for an initial 80 million doses, with option for an additional 80 million doses, at a price of USD 22.50 per dose, including a nonrefundable down payment of USD 360 million. The EU subsequently expanded that commitment. The EU agreed that it would not obtain any rights in Moderna IP, and it would not export doses outside of Europe without Moderna’s consent. Moderna engaged a Spanish manufacturer, ROVI, to perform fill and finish services in Europe, along with Lonza’s Swiss manufacturing operation.

Moderna was criticized for delivering only a small percentage of its vaccine doses outside high income countries. It eventually offered doses to COVAX at a tiered price of USD 7-10 per dose.

Moderna is currently involved in litigation with a number of companies regarding entitlement to patented technologies. Among other things, Moderna has asserted that for certain actions arising out of its supply of COVID-19 vaccines it can only be sued as a US government contractor in the Federal Court of Claims, and not otherwise in private civil infringement litigation.⁴³

42 See Annex 1 to this study, sec. 2.

43 See Annex 1 to this study, sec. 2(vi); Bultman, M. *Moderna Must Face Patent Claims Over US Government Vaccine Sales*, Nov. 2, 2022, www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X66THF2K000000?bna_news_filter=health-law-and-business#jcite; Yasiejko, C. *US Says It Must Be Target of Moderna Covid-Vaccine Patent Case*. Bloomberg Law News, 2023, www.bloomberglaw.com/bloomberglawnews/ip-law/XD849G4C000000?bwid=00000186-5637-d5e5-afae-de7763f60001&cti=LSCH&emc=bipnw_nl%3A3&et=NEWSLETTER&isAlert=false&item=read-text&qid=7422437®ion=digest&source=newsletter&uc=1320042232&udvType=Alert&usertype=External.

c. AstraZeneca-Oxford⁴⁴

Researchers at Oxford University developed a vaccine candidate based on a modified simian adenovirus shortly following the outbreak of COVID-19. That vaccine technology was previously patented by an Oxford entity used as a vehicle for commercialization of patents developed at the university. The developers of the vaccine initially planned to make it available for nonexclusive licensing for affordable and accessible vaccines, and initiated small-scale test production. The research at Oxford had been funded by the Gates Foundation and the Wellcome Trust, among others, and Oxford was persuaded that commercialization of the vaccine was better placed in the hands of an established multinational pharmaceutical firm. Oxford out-licensed its patents to AstraZeneca, which assumed control over subsequent development and out-licensing of the vaccine (leaving certain clinical trial work within Oxford). CEPI entered into a funding agreement with AstraZeneca that required AstraZeneca to make the vaccine – AZD1222 (*Vaxzevria*) – available at accessible and affordable prices for LMICs. AstraZeneca engaged a European CMO to produce the vaccine, but ran into difficulties as the initial batches of the vaccine contained the wrong dosage, which also led to difficulties with the conduct of clinical trials. This delayed the rollout of the vaccine.

AstraZeneca entered into a license agreement with the SII for production and distribution of the vaccine in India and other LMICs, preserving the high-income market for AstraZeneca. The SII successfully initiated production, offering the vaccine (under the name *Covishield*) for USD 3 per dose. It was the principal supplier to the Indian government and the large Indian population. CEPI agreed in June 2020 to purchase from the SII and supply 300 million doses to the COVAX facility for contract price of USD 750 million. The SII supplied vaccines to COVAX and LMICs, but deliveries were substantially delayed when the Indian government imposed an export ban as the country experienced a surge of COVID-19 infections. In November 2021, the SII reported that it had produced more than 1.25 billion doses of Covishield.

AstraZeneca entered into a sale and purchase agreement with the government of Brazil, as well as entering into a technology transfer agreement pursuant to which a Brazilian public entity (Fiocruz) would manufacture the vaccine for local supply to Brazil's Unified Health System, state and municipal governments. In each case, AstraZeneca would preserve its ownership rights in the patents it out-licensed. Fiocruz ultimately manufactured AZD1222, and the government also purchased supplies directly from AstraZeneca.

The EU entered into an advanced purchase commitment with AstraZeneca in August 2020 at a price of EUR 2.9 per dose, but it does not appear that a significant amount of AZD1222 was delivered to the EU. The UK government also purchased AZD1222, reporting that approximately 50 million doses were delivered under its agreement. The US government entered into a substantial development and procurement agreement with AstraZeneca with a potential combined value of USD 3 billion, but the amount paid remains uncertain because, among other things, the AstraZeneca vaccine was never approved for use in the United States.

d. Johnson & Johnson/Janssen⁴⁵

Johnson & Johnson developed a vaccine (*Jcovden*) based on a modified adenovirus in collaboration with Beth Israel Medical Center (which appears to own several of the patents that were relied on for the vaccine). Johnson & Johnson secured a USD 456 million development contract for the vaccine from the US government, and an additional USD 1 billion for initial deliveries. Johnson & Johnson retained rights in its IP. It also had the right to secure patents on technology developed under its development contract, subject to a limited form of “march-in” right in favor of the US government. Johnson & Johnson was obligated to supply its first 100 million doses to the US government, but could otherwise sell to third parties.

Johnson & Johnson initially relied on Emergent Biosolutions, based in the United States, to produce its vaccine. That contract manufacturer failed to comply with GMP standards, and its production was halted by the US government. Johnson & Johnson entered into alternative

⁴⁴ See Annex 1 to this study, sec. 3.

⁴⁵ See Annex 1 to this study, sec. 4.

manufacturing arrangements, including a fill and finish agreement with Aspen Pharmacare in South Africa. The latter invested in establishing a new facility but did not receive sufficient orders and the production line was shut down. CEPI/Gates and the SII agreed with Aspen to produce four other vaccines at the facility.

Throughout the course of the pandemic Johnson & Johnson took a public position strongly in favor of protection of its patent rights.⁴⁶ There is no public indication that Johnson & Johnson or Beth Israel granted rights to third parties outside their specific contract manufacturing.

Johnson & Johnson entered into an agreement with GAVI to supply COVAX but apparently fell far short of meeting its commitment. The companies are currently in litigation as GAVI-COVAX attempted to cancel deliveries, and Johnson & Johnson has demanded payment.

Johnson & Johnson concluded a purchase agreement with the EU at a reported price of USD 8.50 per dose. Deliveries were delayed, and it is not clear how many were eventually delivered. The EU refused to renew its contract.

Johnson & Johnson stated from the outset of the pandemic that it would supply its vaccine on a not-for-profit basis, and it appears that it charged USD 10 per dose or less, including a contract price with COVAX in the USD 5–8 range, bearing in mind that it did not make scheduled deliveries.

Johnson & Johnson reported that it booked a USD 1.5 billion charge in exiting its COVID-19 manufacturing operations. It appears to have received a total of approximately USD 4.6 billion in revenue from sales of its vaccine for 2021 and 2022, at least USD 1 billion of that coming from contracts with the US government.⁴⁷

e. Novavax⁴⁸

Novavax is a relatively small US-based vaccine development and production company with a vaccine, *Nuvaxovid* (*Covovax* in India), based on constructing polypeptides using recombinant DNA technology. In June 2020, Novavax received USD 1.6 billion in funding from the US government to conduct phase 3 clinical trials and to deliver 100 million doses of its vaccine. Novavax uses a proprietary antigen (Matrix M) that is derived from the bark of a tree primarily found in Chile. Novavax maintains a substantial patent portfolio covering its vaccine. In its agreement with the US government, Novavax retains ownership rights in its IP, and it grants the government a license for purposes of the vaccine project, retaining for Novavax rights to technology developed under the development agreement. In the event Novavax discontinues or abandons its work, it will provide the government with a license to make use of its IP so that a third party can carry out the agreement.

Novavax ran into substantial technical obstacles in developing its vaccine, which only received approval from the US FDA in July 2022. Ultimately the federal government ordered only 3.2 million doses, of which less than 80,000 were administered by February 2023. The US government and Novavax have not disclosed how much of the government's funding commitment was actually paid to Novavax.

Novavax received substantial funding (up to USD 399 million) from CEPI per an agreement of May 2020, of which USD 142.5 million is a forgivable loan. The funding, among other things, was to support clinical trials and manufacturing activities. The agreement allows Novavax to retain ownership of IP, both brought into the project and developed pursuant to it. Importantly, however, the project agreement includes what are effectively "march-in" rights in favor of CEPI drafted as a "Public Health License" along with "triggers" such that in the event Novavax fails

46 Johnson & Johnson media relations, *J&J Position on COVID-19 and Intellectual Property Rights*. 2022, www.jnj.com/about-jnj/policies-and-positions/our-position-on-covid-19-and-intellectual-property-rights; updated May 2023.

47 See Annex 1 to this study, sec. 4. Johnson & Johnson reported USD 1.5 billion in contracts with the US government, including about USD 450 million for vaccine development purposes. See also Jennifer Kates, Cynthia Cox & Josh Michaud, *How Much Could COVID-19 Vaccines Cost the U.S. After Commercialization?*, Table 4, Kaiser Family Foundation (KFF), March 10, 2023, www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/.

48 See Annex 1 to this study, sec. 5.

to perform adequately, CEPI may license Novavax technology to a third party, including the technology transfer needed to allow the third party to perform.

The agreement with CEPI obligates Novavax to supply first vaccines to populations at risk where they are needed at affordable prices, yet commercially sustainable to the manufacturer. It envisages that supply will go through COVAX. The agreement does not set a price, but it gives CEPI the right to audit Novavax's costs. In November 2022, Novavax announced the termination of its supply agreement with Gavi-COVAX on grounds that the latter had failed to purchase product, and indicated that it would not make refund of advance payments. The *New York Times* reported that Novavax "is refusing to refund ... \$700 million in advance payments for shots it never delivered," and that the parties are in arbitration.⁴⁹

Novavax also entered into a supply and license agreement with the SII which initially contemplated only fill and finish in India. The agreement was subsequently amended to include the SII's manufacture of the vaccine substance in India based on technology transferred from Novavax. That agreement provided that the SII would be the exclusive supplier of the product in India, and Novavax the exclusive supplier in HICs. The SII is obligated to pay Novavax 50 percent of its revenues on sales of products, although Novavax will pay the SII the same royalties for vaccines supplied by the SII on its behalf in "nonexclusive" territories. It appears that Novavax retains all its IP, and the SII committed not to reverse engineer the vaccine components.

Novavax entered into manufacturing agreements with SK Bioscience in Republic of Korea (also for supply to Thailand and Viet Nam), Fujifilm Diosynth in the United Kingdom and Takeda in Japan. It is not clear how many doses were manufactured or delivered under these agreements. Both Fujifilm and Takeda have canceled the arrangements, and Novavax agreed to pay Fujifilm USD 185 million for expenses that cannot be mitigated. Australia, Canada, the EU and the United Kingdom each entered into APAs with Novavax. It does not appear that substantial quantities of vaccines were delivered under these agreements.

Outside of the CEPI obligations with respect to affordable pricing, Novavax does not appear to have adopted a specific access policy. Other than with respect to its technology transfer agreements for manufacturing, there is no indication that Novavax offered to transfer its technology to third parties.

f. CureVac⁵⁰

CureVac failed to develop an approved COVID-19 vaccine. CureVac received funding from the Gates foundation well prior to the COVID-19 pandemic under a project agreement entitled "Rapid Response mRNA Vaccine Platform for Epidemic Preparedness." CureVac noted in its regulatory filings that it had received development funding from the German government, and that the government has "in the case of a special public interest, a nonexclusive and transferable right to use intellectual property generated as part of the funded work."

CureVac in-licensed patented LNP technology from Arcturus and Acuitas, which entails milestone and royalty payments. CureVac also entered into several agreements intended to allow for the scaling up of production for its anticipated vaccine. CureVac indicates that it owns a substantial patent portfolio relating to its vaccine technology.

Unfortunately, CureVac's principal vaccine candidate failed to demonstrate adequate efficacy in clinical trials.

Subsequent to this unsuccessful effort, CureVac has entered into a comprehensive collaboration arrangement with GSK, under which CureVac has supplied its vaccine technology, and has granted GSK rights to that technology for COVID-19 vaccine products. GSK paid CureVac EUR 75 million, as well as tiered royalties on certain products.

49 Stephanie Nolen, R.R., *Vaccine Makers Kept \$1.4 Billion in Prepayments for Canceled Covid Shots for the World's Poor*, *New York Times*, 2023, www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html.

50 See Annex 1 to this study, sec. 6.

CureVac had entered into an APA with the EU pursuant to which it received an upfront payment of EUR 450 million for development and supply. It was obligated to return unspent portions of the upfront payment. The EU agreed that it is not obligated to return any portion of that payment.

Subsequently, GSK and CureVac have entered into an agreement with the government of Germany, a Pandemic Preparedness Agreement pursuant to which GSK and CureVac agreed to maintain a facility in readiness to deliver 160 million doses of mRNA vaccine per year, either for COVID-19 or another health emergency, on demand.

g. Baylor College of Medicine/Texas Children's Hospital⁵¹

Dr. Peter Hotez, Dr. Maria Elena Bottazzi and colleagues at Baylor College of Medicine (BCM) developed a recombinant spike protein fragment vaccine based on work previously done in response to the SARS outbreak. The vaccine is called *Corbevax*. According to its developers, it is not covered by patent. There is no information regarding substantial external funding of the vaccine development effort, although BCM is a well-funded private institution.

BCM licensed its vaccine technology to Biological E. in India on terms which have not been disclosed. There are indications that BCM requires payment for technology transfer. *Corbevax* has been approved for use by the Indian drug regulatory authority (Central Drugs Standard Control Organisation, CDSCO).

Biological E. is reported to have sold doses to the government at approximately USD 1.75 per dose.⁵² It initially attempted to charge USD 10 per dose in the private market, but promptly lowered the price to USD 3.⁵³ It was reported in December 2022 that Biological E. had stockpiled 200 million doses of *Corbevax* for which it did not have buyers.⁵⁴

BCM also entered into a transfer of technology agreement with PT Bio Farma (a state-owned enterprise) in Indonesia where the vaccine is to be manufactured as a halal formulation (under the name IndoVac). PT Bio Farma planned to produce 20 million doses in 2022, and 100 million doses by 2024.

Although BCM refers to *Corbevax* as non-patented, the product formulation of Biological E. in India lists an adjuvant produced by Dynavax (CpG 1018). The contribution of that adjuvant to efficacy is not indicated. However, that adjuvant is covered by patent, and it may be that the *Corbevax* vaccine is not entirely free of patent restrictions.

h. PRC vaccine landscape⁵⁵

Sinovac and Sinopharm each developed an inactivated SARS-CoV-2 vaccine that was approved for use and widely distributed in the PRC and worldwide. Both vaccines received WHO Emergency Use Listing, Caribbean Regulatory System Emergency Use Recommendation, and are Africa Regulatory Task Force Endorsed (in addition to individual country drug regulatory approvals). Each of the vaccines appears to be covered by patents applied for by the Wuhan Inst of Biological Products Co. Ltd.⁵⁶

⁵¹ See Annex 1 to this study, sec. 7.

⁵² Livemint, *Biological E's Corbevax vaccine to cost ₹145 to govt, ₹990 in market*. mint, 2022. www.livemint.com/news/india/biological-e-s-corbevax-vaccine-to-cost-rs-145-to-govt-rs-990-in-market-11647439936440.html.

⁵³ Bharadwaj, S., *Biological E slashes Corbevax price in private market to Rs 250 per dose*, *Times of India*, 2022, <https://timesofindia.indiatimes.com/india/biological-e-slashes-corbevax-price-in-private-market-from-to-rs-250-per-dose/articleshow/91594281.cms>.

⁵⁴ Staff, *Biological E, Bharat Biotech together sitting on stockpile of 250 million COVID vaccine doses*, *Economic Times of India*, 2022, <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/biological-e-bharat-biotech-together-sitting-on-stockpile-of-250-million-covid-vaccine-doses/articleshow/96562417.cms>.

⁵⁵ See Annex 1 to this study, sec. 8.

⁵⁶ From Espacenet database: 1. CN111569058 (A) – 2020-08-25, SARS-CoV-2 inactivated vaccine and preparation method of vaccine, https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20200825&CC=CN&NR=111569058A&KC=A; 2. CN111569058 (B) – 2021-08-13, SARS-CoV-2 inactivated vaccine and preparation method of vaccine, https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210813&CC=CN&NR=111569058B&KC=B; See VaxPal for further details and www.vaxpal.org/?keywords=Sinovac&page=1

i. Sinovac⁵⁷

Sinovac reported at the end of 2021 that it had sold 848 million doses of its vaccine, *CoronaVac*, worldwide. At the end of 2022 it had reportedly shipped 2.9 billion doses globally. Sinovac received PRC government support for R&D and construction of a large domestic manufacturing plant.

Sinovac entered into a number of agreements with foreign research institutes, laboratories and companies throughout the development process, and the PRC government facilitated clinical trials in Brazil, Türkiye and Indonesia.⁵⁸ In June 2020, Sinovac entered into a clinical development collaboration agreement with Instituto Butantan, a state-owned producer of immunobiological products in São Paulo, Brazil. The agreement was reported to include transfer of technology for local manufacturing, which required the Brazilian entity to construct additional facilities. Initially the drug substance was imported. Instituto Butantan began local production. However, the production line was shut down as of October 2021 because of lack of demand.

In August 2020, Sinovac entered into agreements with PT Bio Farma in Indonesia for the supply, local production and technology licensing for *CoronaVac*. Drug substance concentrate was provided by Sinovac at least until the end of 2021. Sinovac entered into similar agreements with KEYMAN in Türkiye, and with entities in Chile (with the support of the PRC and Chilean governments). With respect to Chile, it was reported that construction of a vaccine facility in Quilicura, capable of producing 50 million doses of vaccine per year when completed, commenced in May 2022, with expected completion in early 2023. Sinovac entered into a fill and finish licensing agreement with Egypt's state-owned VASCERA, which produced its first batch of 1 million doses of vaccine in July 2021 using raw materials imported from the PRC. Sinovac and Colombia signed an MOU for fill and finish, with Sinovac announcing a USD 100 million investment for the project, including construction of a vaccine plant in Bogotá with capacity to package 60 million doses annually. Construction was set to commence in 2023. Sinovac entered into a fill and finish agreement with Pharmaniaga in Malaysia, with 20 million doses reported to have been supplied in Malaysia (as well as exported to Myanmar). In May 2022 Sinovac signed an MOU with the Cambodian Pharmaceutical Enterprise that included construction of a fill and finish plant in Cambodia reported to enable production of more than 100 million doses over three years.

United Nations Children's Fund (UNICEF) data reports an internal PRC price of USD 29.75 for the *CoronaVac* vaccine purchased by the PRC's health system. External prices are reported between USD 7 per dose for Zimbabwe and USD 32.50 per dose in Thailand's private market. As *CoronaVac* was provided free to PRC citizens, the internal USD 29.75 price presumably reflects a mechanism for internal subsidization of production.

ii. Sinopharm⁵⁹

Sinopharm is a state-owned enterprise based in the PRC, and its vaccine (*BIBP COVID-19 vaccine*) was the first PRC COVID-19 vaccine approved by WHO. Sinopharm is the leading supplier of vaccine donations by a PRC developer. Sinopharm entered into agreements with several foreign countries to produce vaccines, including at a new plant in Abu Dhabi, projected to have a production capacity of 200 million doses per year. While construction is ongoing, Gulf Pharmaceutical Industries was able to produce 2 million doses per year in the United Arab Emirates. Serbia, the PRC and the United Arab Emirates signed a trilateral agreement for construction of a domestic vaccine production facility near Belgrade, Serbia though as of November 2022 vaccines had not yet been produced. Sinopharm signed an MOU with Bangladesh for coproduction of vaccine by Incepta. Under this agreement, Incepta would provide raw materials and product formulation would be undertaken in the PRC. In July 2021, Morocco signed a fill and finish agreement with Sinopharm pursuant to which the domestic Moroccan firm Sothema would perform fill and finish services for 5 million doses per month.

⁵⁷ See Annex 1 to this study, sec. 8(i).

⁵⁸ See Annex 1 to this study, sec. 8(i) text for details on Sinovac arrangements.

⁵⁹ See Annex 1 to this study, sec. 8(ii) text for details on Sinopharm arrangements.

In May 2021 Sinopharm signed a preliminary agreement with an Argentinian pharmaceutical company, Sinergium Biotech. It is not clear whether this arrangement proceeded.

UNICEF pricing data showed the internal PRC price for the Sinopharm vaccine at USD 29.75, the same as for Sinovac, and external prices from USD 6.90 in Zimbabwe to USD 36 in Hungary.

i. Gamaleya National Center of Epidemiology and Microbiology (Sputnik V)⁶⁰

The Russian Federation's Gamaleya National Center is part of the Health Ministry. With backing from the Russian Direct Investment Fund (RDIF), Gamaleya developed the *Sputnik V* vaccine, which is adenovirus based, but uniquely among COVID-19 vaccines is a "dual vector" vaccine requiring two different shots. The Sputnik V vaccine has been approved for use in over 71 countries, but has not received approval by WHO or EMA. It appears that Sputnik V is covered by patents (with five applications reported by VaxPal),⁶¹ and the publicly available license agreements from RDIF refer to patent rights. RDIF is reported to have pursued a nonexclusive licensing approach with foreign manufacturers, including sharing regulatory dossier information.

Apparently the dual vector vaccine approach requires a complex manufacturing process with the doses isolated in different facilities. The doses were domestically produced in the Russian Federation by Pharmasintez, Generium, Binnopharm and Pharmstandard. Delays were reported in production and export. RDIF introduced a single dose vaccine under the name Sputnik Light to address the delays.

UNICEF does not list a domestic Russian Federation vaccine price. The vaccine is provided within the Russian Federation free to Russian Federation citizens.

RDIF entered into a series of transfer of technology and production agreements with entities in foreign countries, including Algeria, Argentina, Belarus, Brazil, Egypt, Germany, India, Iran (Islamic Republic of), Italy, Kazakhstan, Lebanon, Mexico, Pakistan, the PRC, the Republic of Korea, Serbia, Türkiye and Viet Nam.⁶² Certain of these arrangements were canceled as a consequence of the conflict between the Russian Federation and Ukraine. While information regarding anticipated volumes of foreign production of Sputnik V was reported, information regarding implementation of the technology transfer and production agreements is incomplete. There was significant media reporting of delays in delivery of Sputnik V vaccines and in the initiation of manufacturing operations outside the Russian Federation.

⁶⁰ See Annex 1 to this study, sec. 9.

⁶¹ From Espacenet database, see, e.g.: 1. WO2021002776 (A1) - IMMUNOBIOLOGICAL AGENT FOR INDUCING SPECIFIC IMMUNITY AGAINST SEVERE ACUTE RESPIRATORY SYNDROME VIRUS SARS-COV-2; APPLICANT FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTE [RU], https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210107&CC=WO&NR=2021002776A1&KC=A1; 2. WO2021076010 (A1) - PHARMACEUTICAL AGENT FOR INDUCING SPECIFIC IMMUNITY AGAINST SARS-COV-2; applicant FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTE [RU], https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210422&CC=WO&NR=2021076010A1&KC=A1; See VaxPal for additional details, www.vaxpal.org/?keywords=Gamaleya&page=1.

⁶² See Annex 1 to this study, sec. 9, for details regarding RDIF/Gamaleya arrangements.

5. Lessons learned

a. The role of technology licensing

The case studies make evident that technology transfer through IP licensing was widely employed while responding to the COVID-19 pandemic. IP licensing appears to have played its customary role in providing a framework by which enterprises shared their “proprietary” technology and products across the “value chain” from the in-licensing of innovations that were needed to develop vaccines (such as LNP technology) to the out-licensing of the technology embodied in approved vaccines to enable out-sourced production by CMOs.

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 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.

b. The variation in context

The developers of vaccines uniformly undertook to protect their patents, trade secrets and other confidential information in upstream and downstream license agreements, with the possible exception of BCM which apparently did not seek patent protection for its Corbevax vaccine (but which has not otherwise been transparent with respect to its technology transfer arrangements). Private vaccine developers such as Pfizer/BioNTech and Moderna, mixed entity developers such as AstraZeneca-Oxford, and state-owned or state-supported entities such as Sinopharm and Gamaleya, have maintained control over their IP. At the same time, under different types of arrangements, each of these entities has made their technology available for use by third parties in a way that has allowed the production and distribution of COVID-19 vaccines.

i. Private sector with government subsidy – Operation Warp Speed

Different approaches were taken by different countries and organizations to addressing the pandemic through the development and supply of vaccines. The US government chose to rely on private sector companies for vaccine development efforts, and it provided large-scale

subsidies (under Operation Warp Speed)⁶³ for them to pursue that (Pfizer/BioNTech, Moderna, Johnson & Johnson, Novavax, AstraZeneca-Oxford and Sanofi/GSK). Among the private companies, only Pfizer/BioNTech did not receive “development” funding, but Pfizer/BioNTech was awarded large-scale APA commitments that facilitated the ramping up of its manufacturing capacity. The US government contracted for the delivery of vaccines at a set price, in some cases subject to downward adjustment based on lower than anticipated costs (e.g., with Johnson & Johnson). In that regard, the government determined prices in the context of negotiation. The US government did not, however, impose price limitations on sales made by the funded entities outside the parameters of domestic supply.

The US government made COVID-19 vaccines available free to the public in the United States. From a domestic standpoint “affordability and access” was not a significant issue. More important in the United States was vaccine hesitancy combined with an anti-vaccine movement that limited the percentage of individuals who chose to be vaccinated.

Although not required to do so by the terms of arrangements with the US government, several private sector enterprises announced “access policies” during the pandemic that were not otherwise tied to a funding source.⁶⁴ Johnson & Johnson announced that it would sell its vaccines at a not-for-profit price during the pandemic.⁶⁵ And, while Johnson & Johnson encountered various scientific and operational problems that limited the role of its vaccine in the United States and globally, it appears to have charged a price that was uniformly at or below USD 10 per dose. Moderna made a pledge not to enforce its COVID-19 related vaccine patents during the course of the pandemic, though it eventually scaled back the geographic scope of this commitment.⁶⁶

ii. Public-private with foundation support

Oxford University is a public institution in the United Kingdom, and also maintains a patent portfolio and venture capital-type related entities that pursue commercial vaccine development.⁶⁷ Oxford vaccine researchers received substantial support from CEPI, the Gates Foundation and the Wellcome Trust in the development of their COVID-19 vaccine candidate, which ultimately became AstraZeneca’s AZD1222. AstraZeneca subsequently secured funding from CEPI/Gates that included a requirement that its vaccines be sold in LMICs at affordable and accessible prices. AstraZeneca subsequently entered into a licensing agreement with the SII, also a private sector company, for the manufacture and distribution of AZD1222 (under the name Covishield), and that license agreement is reported to have included a requirement of affordable and accessible prices. The AstraZeneca vaccine was produced and made widely available by the SII for LMICs at a price of USD 3 per dose, and AstraZeneca offered the vaccine at affordable prices (between USD 2.19 and USD 6 per the UNICEF COVID-19 Market Dashboard).

iii. State owned or state sponsored

The PRC’s vaccine development and supply program was undertaken through a combination of state-owned (Sinopharm) and privately owned (Sinovac) enterprises, with substantial

63 As explained by the US Government Accountability Office (GAO): “Operation Warp Speed (OWS)—a partnership between the Departments of Health and Human Services (HHS) and Defense (DOD)—aimed to help accelerate the development of a COVID-19 vaccine. GAO found that OWS and vaccine companies adopted several strategies to accelerate vaccine development and mitigate risk. For example, OWS selected vaccine candidates that use different mechanisms to stimulate an immune response (i.e., platform technologies ...). Vaccine companies also took steps, such as starting large-scale manufacturing during clinical trials and combining clinical trial phases or running them concurrently. Clinical trials gather data on safety and efficacy, with more participants in each successive phase.” USGAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*. 2021, www.gao.gov/products/gao-21-319. GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, GAO-21-319, Feb. 2021, www.gao.gov/assets/gao-21-319.pdf.

64 “Access policies” are guiding principles and implementing practices that are intended to assure that public health goods or services, whether research results (including new technologies) or end-products, are available in a way that promotes availability and affordability to the public.

65 Johnson & Johnson media relations, *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use*. 2020, www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use.

66 Moderna, *Moderna’s Updated Patent Pledge*, March 7, 2022; Available from: https://s29.q4cdn.com/435878511/files/doc_news/2022/03/07/Moderna-Patent-Pledge_7-March_Final.pdf.

67 See Annex 1 to this study, sec. 3.

government financial support to the private enterprise.⁶⁸ Sinovac reported as of April 2022 delivering over 2.8 billion doses of its vaccine worldwide.⁶⁹ Sinopharm has donated a substantial number of its vaccines outside the PRC.

The PRC government appears to have supported both companies in establishing technology transfer and production arrangements across a range of countries, including LMICs. There is limited public information regarding the progress of these joint production arrangements.

The price of the Sinovac and Sinopharm vaccines within the PRC is relatively high (USD 29.75), but as these vaccines are provided free to the public the price largely seems to be a government support transfer payment to the vaccine producers. The price of the Sinovac and Sinopharm vaccines outside the PRC appears to have varied significantly, although most of the reported prices were between USD 10 and USD 18. From a relative standpoint, this is substantially higher than the price for AstraZeneca/SII AZD1222.

The Russian Federation government provided Sputnik V to Russian Federation citizens free of charge, and there is no publicly reported internal Russian Federation price for the vaccine.⁷⁰ The Russian Federation government through RDIF pursued a policy of supporting technology transfer and manufacturing in a number of foreign countries. There is limited public information regarding the implementation of these arrangements. Reported pricing of the Sputnik V vaccine varied between USD 9.75 and USD 29.15. Sputnik V was not approved for use by WHO or the EMA.

c. Technology transfer arrangements and pricing

In a competitive market undistorted by subsidies and price controls, the price of a product, including a vaccine, will fluctuate as supply and demand increases or decreases. COVID-19 vaccines were not priced in an ordinary competitive market. Prices were determined by the nature of the funding and the conditions imposed (or not imposed) on vaccine developers and suppliers by funding sources.⁷¹ The US government, by way of example, might have required Pfizer/BioNTech and Moderna to charge cost-plus prices as a condition of its large purchase commitments.⁷² However, the 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.

Nevertheless, the US government might have required Pfizer/BioNTech and Moderna to charge lower prices to foreign purchasers. 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.

68 See Annex 1 to this study, sec. 8.

69 NY Times Coronavirus Vaccine Tracker, www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html#sinovac, visited April 24, 2023.

70 See Annex 1 to this study, sec. 9.

71 See case-by-case description and analysis of contractual arrangements in Annex 1 to this study, including pricing terms and conditions. The US government negotiated fixed price procurement agreements, though in the case of Johnson & Johnson with potential downward adjustment based on lower-than-anticipated costs (details regarding Johnson & Johnson Agreement are at sec. 4, Annex 1). CEPI negotiated funding agreements that required recipients to charge affordable and accessible prices. For example with Novavax CEPI's funding agreement does not set a price, but indicates that it shall be reasonable to achieve equitable access as well as an appropriate return on investment to make on-going supply commercially sustainable. CEPI is given the right to audit Novavax costs. See CEPI-Novavax details in Annex 1, sec. 5(ii), to this study.

72 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 J. Hopkins & D. Seal, Pfizer Expects Drop in Revenue as Covid Vaccine Demand Wanes, 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.

The best evidence of effective funder pricing restrictions on the ultimate accessibility and affordability of COVID-19 vaccines is seen in the pricing of the AstraZeneca/SII produced vaccine, which was sold in large quantities at about USD 3 per dose, compared to the USD 12–30 price for the Pfizer/BioNTech vaccine and the USD 7–28 price for the Moderna vaccine.

The consultant does not have information regarding the motivation of the PRC manufacturers or the PRC government for charging external prices in the mid-teens (in USD). These prices may reflect some increment over the cost of production in the PRC. The companies are reported to have charged an internal PRC price approximating USD 30, but that price may include an effective subsidization of development and other costs beyond the straightforward cost of manufacture.

It is difficult to correlate pricing decisions with respect to the COVID-19 vaccines and IP, whether patents, trade secrets or other IP. As previously discussed, there is no concrete evidence that third-party manufacturing of vaccines during the pandemic was inhibited by IP rights or that relaxing IP protections would have increased the volume of vaccine supply. Assuming hypothetically that waiving or relaxing IP rights would have resulted in additional third-party vaccine producers entering the market, overall expansion of supply presupposes that the originator vaccine developers would have continued to develop and manufacture without IP protection. Moreover, whether rapid expansion of supply was operationally feasible is an open question.

In summary, as a condition of product development or advance purchase commitments funders may have elected to impose pricing conditions on the recipients of funding. This was done in some cases. The funders that contractually limited prices saw the results manifested in lower vaccine prices. A question remains how far funders can go in limiting prices before disincentivizing developers and manufacturers from participating in the market.

d. Technology transfer arrangements and supply

i. Alternative financing arrangements

Funding sources for the development of vaccines generally did not require the recipients of the funds to make the technology generally available to third parties outside the scope of negotiated licenses. The funders did, however, include provisions requiring that technology already developed be made available to potential alternative suppliers on the default of the developer.⁷³ For example, the project agreement between CEPI and Novavax includes what may be described as “march-in” rights in favor of CEPI that allows it to take over and license the IP associated with the vaccine product in the event that Novavax either declines to meet CEPI’s request to expand the project, or (by mutual agreement) is unable to perform pursuant to the agreement, or there is a material breach which it has failed to cure.⁷⁴ This would also require Novavax to engage in technology transfer to the substitute performing party(ies) engaged by CEPI to perform in its place.⁷⁵

Might the funder of a new vaccine technology require that a funding recipient make its technology generally available to third parties once it is developed? This approach is technically feasible, but several issues must be addressed. First, at what stage in product development will the technology be open? If it is at an early developmental stage, steps such as formulating a usable product and subjecting it to clinical trials will remain, and this will entail the most significant financial commitment involved in new product development. Will enterprises undertake such investment without some assurance of market protection? If the technology is to be made “open” at a later stage, for example following regulatory approval of a vaccine, this will require the funding source to make larger and riskier commitment. CEPI-Gates provided financing throughout the development and regulatory approval processes, but did not generally “open” the relevant technology to third parties. Control over IP was retained.

73 See Annex 1 to this study, sec. 5(ii); Novavax_CEPI, Outbreak Response Funding Agreement (Step 2). 2020. www.sec.gov/Archives/edgar/data/1000694/000110465920092782/nvax-20200630xex10d1.htm.

74 Funding Agreement, id., section 13.4-5, “Public Health License” and “Public Health License Triggers,” respectively.

75 Id., section 13.7.

The challenge is finding funding sources that are willing to support the development of new technologies through a sufficient level where a great deal of additional investment is not needed to introduce a product on the market, and then to relinquish control over the technology.⁷⁶

ii. Capacity constraints

It was recognized at the very outset of the pandemic that global vaccine production capacity was constrained because of a long-term trend of major pharmaceutical companies to reduce their exposure to the vaccine market.⁷⁷ Moreover, there was a gap in information regarding precisely what vaccine capacity was available, where, and for what types of vaccines.

Pfizer/BioNTech and Moderna might have transferred technology to other developers and manufacturers that would have enabled them to proceed in parallel when both Pfizer/BioNTech and Moderna were working to complete development of their own vaccines – which were yet untested – and to bring online their own scale production facilities.⁷⁸ Given the scale of the investments made by the US government and private companies in establishing infrastructure in the United States, carrying out clinical trials and so forth, there is reason to question whether this type of parallel development might have worked. Pfizer/BioNTech has argued that limited availability of the components needed to manufacture its vaccine precluded a more rapid scaling of production (see note 3).⁷⁹ Moderna argued that it was using its internal resources to scale up its own production capacity and that during the emergency phase of the pandemic it did not have additional human resources that would have been necessary to support parallel operations.^{80, 81}

Suggestion was made by some public interest groups during the course of the pandemic that there existed a significant untapped pool of manufacturing facilities that could rapidly be engaged to produce substantial quantities of mRNA vaccines.⁸² One paper intended to demonstrate this referred to manufacturing plants capable of producing sterile liquid formulations located in various countries, including in LMICs. This paper effectively addressed the availability of fill and finish capacity, which was not a principal constraint on the production of mRNA vaccines, and revolved instead around the active drug substance, including its LNP delivery mechanism. While the paper represented an interesting proposal for a feasibility study, it did not demonstrate wide availability of manufacturing capacity for mRNA vaccines, including the question of constraint on material inputs.

The technology behind the manufacture of adenovirus vaccines is not simple or straightforward. Nonetheless, adenovirus vaccines had been successfully manufactured before the pandemic.⁸³ AstraZeneca was able to identify several CMOs to produce its vaccine, and the SII was able to ramp up production to a large scale in a relatively short period of time. As illustrated by the lead time required for the Brazilian health system to locally manufacture AZD1222, there might still be delay. Johnson & Johnson's initial CMO, Emergent Biosolutions, proved incapable of manufacturing its vaccine.

- 76 In the TRIPS waiver discussions, for example, there was an implicit assumption that relevant vaccine technology has already been developed, and the question is whether additional potential producers should have access to that technology.
- 77 Abbott, F.M. and J.H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*. *Journal of International Economic Law* (Oxford), 2020. 23(3): p. 535-561, <https://academic.oup.com/jiel/article/23/3/535/5909036>.
- 78 The mRNA vaccines developed and manufactured by Pfizer/BioNTech and Moderna were the “first of their kind” based on technology that had not previously been used for any approved vaccine. The science of the vaccines had not been tested successfully through human clinical trials, and considerable uncertainties surrounded manufacturing processes. An “installed base” of mRNA vaccine manufacturing facilities for production “at scale” did not exist before the pandemic, though companies such as BioNTech and Moderna were working on such facilities.
- 79 While the consultant has studied Pfizer’s explanation, and cross-referenced materials, this study has not developed an independent factual record regarding the availability of components.
- 80 Moderna declined to assist the WHO mRNA hub with technology transfer in later stages of the pandemic response.
- 81 Moderna. *Global Access to COVID-19 Vaccines*, April 28, 2022; Available from: https://s29.q4cdn.com/435878511/files/doc_news/2022/04/Access-Statement_4.28_817am.pdf.
- 82 Achal Prabhala and Alain Alsalhani, *Pharmaceutical manufacturers across Asia, Africa and Latin America with their technical requirements and quality standards to manufacture mRNA vaccines*. COVID-19 Technical Brief, Access IBSA, MSF, 2021, www.aerzte-ohne-grenzen.de/sites/default/files/2022-06/COVID19_TechBrief_Manufacturing-mRNA-Report-10DEC2021_EN.pdf.
- 83 Lowe, D., *How You Make an Adenovirus Vaccine*, *Science*, 2021, www.science.org/content/blog-post/how-you-make-adenovirus-vaccine.

Much of the attention on supply constraints has been focused on mRNA vaccines, with considerably less attention on why more modified adenovirus vaccines could not have been manufactured more rapidly. The vaccines developed by Oxford and transferred to AstraZeneca, by Johnson & Johnson, and by the Russian Federation's Gamaleya Institute, were each based on the use of a modified adenovirus "vector" to deliver the active substance intended to trigger antigenic response. Although the specific vaccines produced by each of these entities was and is covered by patent(s), there are different scientific routes to creating such vaccines and third parties may have been capable of developing alternatives.⁸⁴

iii. Incentivizing technology transfer

Assuming that enterprises such as Pfizer/BioNTech and Moderna have already developed new vaccine technologies, might there be some form of financial or other incentive that would induce them to share that technology with third-party producers?

As these enterprises are both profit-driven, shareholder owned companies, there is presumably a price at which they would share technology. Both COVID-19 vaccines earned their developer tens of billions of dollars so the licensing fee or the price of a buyout of the technology would presumably be high. With that said, there are ways of structuring a licensing arrangement that would divide markets geographically such that higher-income markets would be served by the large originator developers and LMIC markets would be served by licensed producers.

Vaccine developers may choose to maintain control over their IP while pursuing different types of access policies, with greater or lesser attention to equity. IP does not determine an access policy, although the presence of IP protection may play a role. CEPI, the Gates Foundation and other nongovernmental funders demonstrated during the COVID-19 pandemic that the provider of funding can incentivize the transfer of technology by providing developmental and purchase funding with conditions requiring affordability and access.

iv. Compelling technology transfer

A good deal of attention was paid from the outset of the COVID-19 pandemic to the possibility of compelling technology developers to share that technology with other developers and producers. The legal mechanisms for accomplishing such "compulsory" or "government use" licensing are by now well known, and are reflected in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health, and in other international instruments.

This study does not go into substantial detail regarding compulsory and government use licensing mechanisms. While a few countries (including HICs) modified their compulsory licensing legislation during the COVID-19 pandemic to facilitate addressing public health emergencies, compulsory licensing did not play a significant role during the pandemic. It was the subject of much discussion in the context of the request for a TRIPS waiver.

The question of whether or not to use compulsory licensing as a means to implement technology transfer policy is politically controversial. The development of new vaccines requires significant financial investment, and a program that requires innovators to transfer technology requires that they be compensated in a manner that will justify their investments. Also, as discussed throughout this study, there are multiple elements involved in successfully developing and manufacturing vaccines. Technology transfer may be an important component in accomplishing this, but the recipient of technology transfer must provide other elements of an enabling environment.

⁸⁴ Although the modified adenovirus vaccines may have been marginally less efficacious than the mRNA vaccines, the modified adenovirus vaccines had advantages in storage and distribution, and some manufacturing history.

6. Better practices

Another question is whether there are clauses for licensing and other vaccine development and procurement agreements recommended to promote a more globally equal distribution of vaccines in the event of emergency. Alternatively, are there clauses that should definitively be recommended against?

As noted earlier, various agreements entered into during the pandemic were “atypical,” presumably as a consequence of the pressures under which they were negotiated. Would it be possible to agree upon guidelines or rules regarding what may or may not be acceptable in a contract negotiated during a public health emergency?

a. Foundational building blocks

Consider the situation of “foundational technologies” such as the discovery that substitution of a nucleobase enables the successful development of mRNA vaccines, or of the foundational technologies underlying LNPs. From what we know, while the developers of these technologies have patented them, they have licensed them “nonexclusively.” Those wanting to develop mRNA vaccines can secure access to the foundational technologies.

There is an argument against permitting the exclusive licensing of foundational discoveries. There is even an argument against the patenting of foundational discoveries. However, this could work against the interests of universities, research institutions and other entities that fund their continuing research with royalties from such discoveries. Also, it may be difficult to identify “in advance” discoveries in science that need to be protected against monopolization such that access to them will allow a diversity of downstream innovation. This set of issues has been raised before.⁸⁵

Establishing sustainable production entails addressing conditions of competition, and in some circumstances exclusive licensing may be important to promoting investment in scaling up. Exclusive licensing may incentivize investment by right owners and encourage them to assume greater financial risk. While assessments of the preferred terms in a technology licensing arrangement might start with a baseline presumption for foundational technologies favoring nonexclusivity to encourage wider dissemination, a case-by-case assessment of competitive conditions may tilt the balance in favor of exclusive licensing in some circumstances.

b. Export or transfer restrictions

Some of the agreements reviewed in this study, including those negotiated by the EU, include restrictions against exporting purchase products outside the geographic territory where they are initially delivered. The supplier might (or might not) consent to such export.

For a vaccine, assuming the chain of custody preserves the integrity of the product, it is difficult to understand the grounds for preventing export of purchased and delivered product. One

could imagine a worry on the part of the supplier that the purchaser will be attempting to “make a market” in vaccine resales. Yet this would seem an odd sideline for the European Commission. Is it to prevent over-ordering on the theory that allowing surplus supplies to be resold promotes that?

There is a potential argument that has been used in opposition to parallel trade: producers (in this case of vaccines) wanting to sell at low prices to LMICs will not be able to do that unless they are assured that the vaccines will not be resold into higher-income markets.⁸⁶ However, such resales can be controlled by procurement authorities and recipient countries who are typically government health ministries.

The most likely consequence of export restrictions is to prevent vaccines from getting to those who need them, and potentially leading to expiration and destruction.

c. Liability and indemnity

The liability and indemnity provisions in many of the supply contracts examined relieve the vaccine producer from effectively all liability for injury from use of the vaccines unless the supplier is engaged in willful misconduct or gross negligence, or if it fails to comply with GMP.

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.

d. 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.⁸⁷ This appears to be a useful practice that may assist with establishing alternate sources of supply in the event of a default.

e. Insecure delivery schedule terms

It is understandable that suppliers of vaccines under development do not want to firmly commit to delivery schedules when there are substantial uncertainties surrounding when a product may actually be available for supply. On the other hand, suppliers should not be able to re-prioritize purchasers after the supply agreement is made because, for example, a subsequent purchaser has agreed to pay more, or otherwise has leverage to exercise against the supplier.

It might be wise to include in procurement agreements terms prohibiting the seller from adjusting the delivery priority between purchasers, particularly based on the potential for raising prices.

⁸⁶ This may help explain why the TRIPS Agreement waiver adopted in connection with the 12th Ministerial Conference, above note 23, at paragraph 3(c) required WTO members importing vaccines pursuant to a compulsory license prevent re-exports of those products.

⁸⁷ See, e.g., European Commission-AstraZeneca Advance Purchase Agreement (APA) of August 27, 2020, sec. 11.2, Annex 1 to this study, at sec. 3(iv); US_Army-J&J_Jansen, Annex 1 to this study, sec. 4, ns. 120-121; ATI-Novavax Statement of Work, sec. 10(b), Annex 1 to this study, sec. 5(i); Novavax-CEPI, 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).

f. 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.⁸⁸ 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 third-party research. The potential development of competitive vaccines may be inhibited.

g. 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.

h. Patent transparency

Redaction of the list of patents in the publicly available vaccine-related agreements brings back an issue that has been discussed at WIPO and other multilateral settings going back some decades, and was a major question during discussions of the Pandemic Influenza Preparedness Framework. This relates to "transparency." The lack of a listing of relevant patents, whether in the agreements or otherwise (e.g., a third-party database) makes it difficult for researchers to determine whether a particular avenue is worth pursuing. And even if researchers may overlook freedom to operate (FTO) analysis, parties willing to invest in the exploitation of new technology may be less willing to overlook potential future litigation.

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 FTO), or to encourage third-party developers to seek licenses from the patent owners.

i. Equitable access policies and provisions

Governments, privately funded foundations and other sources made efforts to provide access to vaccines that avoided the national-interest-first allocation that resulted from subsidization and private pharmaceutical industry control over decisions regarding allocation. There were several different areas in which this effort at equalizing distribution was undertaken. Private foundations, most notably CEPI, included provisions in funding agreements that required recipients to provide vaccines to low-resource environments at cost or other preferential prices. In the case of CEPI, these requirements flowed from Board-Adopted Access Policies,⁸⁹ including an updated policy adopted in the context of the pandemic.⁹⁰ Among the specific provisions required in the CEPI-negotiated agreements was a requirement that, in the event of some type

⁸⁸ 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 grant back 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.

⁸⁹ CEPI, *Equitable Access Policy*. 2019, <https://cepi.net/wp-content/uploads/2019/01/Equitable-Access-Policy.pdf>.

⁹⁰ CEPI, *Enabling Equitable Access to COVID-19 Vaccines: Summary of equitable access provisions in CEPI's COVID-19 vaccine development agreements*. 2022, <https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v8-14-February-2022.pdf>.

of default in supply by the funding recipient, CEPI or its designee could step in and take over responsibilities for supply, including with access to patents or other IP rights.⁹¹

j. Introducing time- and cost-efficient dispute resolution mechanisms

Out-of-court dispute resolution procedures such as deal mediation can offer practical, time- and cost-effective solutions for life sciences stakeholders in resolving existing disputes and catalyzing contract negotiations. Such mechanisms offer more flexibility in finalizing the terms and conditions of an agreement while adding an element of confidentiality to ongoing disputes. For example, parties may jointly appoint a mediator with relevant expertise during the deal negotiation phase. The mediator can assist parties in identifying their reasons for the collaboration by assessing their business interests and expectations in the commercial venture, strictly confidentially. Further, the mediator may assist parties in determining the scope and use of confidential information (such as know-how) revealed during negotiations. Finally, the appointed mediator facilitates negotiations between the parties to conclude a formal contract. The same mediator may later be appointed to resolve potential disputes between the parties more expediently.

As part of the WIPO COVID-19 Support Package, the WIPO Arbitration and Mediation Center has recently developed and launched new ADR options specifically tailored to life sciences disputes, particularly mediation to facilitate contract negotiation (deal mediation) and resolving disputes that may arise throughout long-term collaborations between parties in a confidential manner, with the view to causing minimal disruption in their business relationship.

k. Technology transfer licensing resources

In addition to considering what may be better practices in terms of technology transfer licensing for vaccines, it may be useful to consider establishing training programs for attorneys and business executives involved with entities conducting research on new vaccines or contemplating creating manufacturing capacity. While most of the licensing arrangements examined in this study involved large and well-capitalized enterprises with sophisticated business and legal negotiating capacity at their disposal, in countries and regions where such expertise is not as widely available, and may be too costly to outsource, assisting with the development of skills capacity may be as valuable as identifying specific better-practice terms and conditions.⁹²

⁹¹ As a general matter with respect to CEPI, the high-level Access Policies remained to be translated into specific provisions in individual contractual arrangements. There was flexibility in respect to how the different contracting parties were treated. The lack of specificity in the Access Policies was identified as problematic in a study of the CEPI Access Policies, and the appointment of a coordinating officer for implementing those Policies was suggested. O'Neill Institute, *Equitable Access Review of CEPI's Covid-19 Vaccine Development Agreements*. 2022, https://cepi.net/wp-content/uploads/2022/05/EQUITABLE-ACCESS-REVIEW-OF-CEPI-2022-05-VACCINE-DEVELOPMENT-AGREEMENTS-Final_April-2022.pdf.

⁹² 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. See, e.g., WIPO, Intellectual Property and Technology Transfer, www.wipo.int/technology-transfer/en/.

7. Concluding observations and the way forward

Technology licensing facilitated the movement of needed information across the value chain during the COVID-19 pandemic. Throughout the pandemic, technology flowed between different entities involved in different stages of developmental activities and out to manufacturers responsible for producing vaccines.⁹³ This flow was accomplished through licensing agreements of various kinds. Commercial enterprises that had invested in technology would have been reluctant to share it even with their development and manufacturing partners if it would not be protected from uncompensated disclosure.

When the pandemic emerged and the urgent need for vaccines became evident, patents and other IP rights did not stand in the way of governments, especially the US government, subsidizing research or procuring vaccines. Pfizer, by way of example, received large government procurement contracts because it owned (through acquisition of rights from BioNTech) valuable vaccine technology necessary to manufacture new vaccines. Some other biotechnology company might have developed and manufactured the vaccines if they had acquired the technology. But Pfizer also brought a large and established manufacturing and distribution system into its arrangement. It produced and supplied vaccines within a tight timeline. Moderna could have been substituted with some other biotechnology company, even though it had been at the forefront of mRNA research. Well-capitalized biopharmaceutical companies such as CureVac also had access to mRNA technology. Yet CureVac was not successful despite large-scale subsidization.

Large enterprises that acquired third-party patented technology and know-how to rapidly develop and scale manufacturing of vaccines paid substantial amounts of money in that acquisition process. That expense was not likely within the means of most enterprises in LMICs, and local governments were not in a position to provide the type of large-scale subsidization or access to capital markets that was employed in ramping up production. Companies with existing networks of internal and external (contract) production were more effective in scaling vaccine production. Even then, some of those networks failed.

What this may suggest in terms of addressing future pandemics is that financial resources must be made available that allow a wider group of actors to in-license the technology that is needed to create and manufacture new vaccines. At the least, this would allow a wider group of actors to compete with the large private sector industry actors in gaining access to the necessary technologies and, by providing for compensation, without depriving universities, teaching hospitals and smaller startup biotechnology companies that rely on royalties and stage payments to fund future research.

The applicant for a patent is required to disclose technical information sufficient to demonstrate enablement of the invention, and in principle this disclosure should permit a third party to reproduce the invention without undue experimentation. In practice, as illustrated by the COVID-19 pandemic, the technical data included within a patent may not be sufficient to instruct prospective third-party developers and manufacturers to replicate a patented vaccine without

supplementary know-how that may be protected by trade secret. A pledge by a vaccine patent owner not to enforce a patent may be “necessary but insufficient” to allow additional producers to produce and supply a vaccine product. Technology licensing that encompasses the sharing of trade secrets and other necessary information is important to expanding capacity.

In addition, as reflected in the recent agreement between the German government and GSK/Curevac, some vaccine manufacturing facilities should be maintained in an operational state in the “inter-pandemic” period.⁹⁴ This also requires a commitment of financial resources. One approach to maintaining standby capacity in a cost-effective way may be through the establishment of regional vaccine production hubs.

Among “potential entrants” into mRNA production are the South African firms Biovac and Afrigen that are being assisted in terms of transfer of technology by the recently established WHO mRNA Technology Hub.⁹⁵ While these firms have not been threatened with litigation for patent infringement, they have suggested that Moderna’s LNP technology, some of which is trade secret, would assist with their development of vaccines. Moderna has indicated that it will not provide such assistance, but rather intends to establish its own mRNA production facility somewhere in Africa.⁹⁶

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.⁹⁷ 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 the contribution of a product-ready vaccine technology during the emergency phase of the COVID-19 pandemic.⁹⁸ On Aug. 29, 2023, C-TAP and MPP announced the conclusion of their first license for an approved COVID-19 vaccine with Medigen Vaccine Biologics.⁹⁹

There is further question as to whether the international community is at risk of overconcentration of ownership of critical technologies needed to address existing and emerging pathogenic outbreaks. This is something that might be looked at from a competition law perspective. That is: (1) are there dominant actors in the field and, if yes, (2) is that dominance being abused? Moreover, the question of whether there might be some type of limitation for patents regarding foundational technology was raised. These are complex and challenging subject matters that may merit further inquiry.

The COVID-19 pandemic is fresh in the mind and a wide range of stakeholders are debating how to prevent, prepare for and respond to future pandemic outbreaks and other public health

94 See Annex 1 to this study, sec. 6(ii), at n. 467. This is a complex arrangement. According to GSK/CureVac, “On April 8, 2022, we received a letter from the Federal Republic of Germany’s counsel confirming that the Consortium [consisting of CureVac and GSK] is awarded with the Pandemic Preparedness Agreement. Pursuant to the Pandemic Preparedness Agreement, the Consortium will have to achieve, within a two years’ time frame beginning from the signing of the Pandemic Preparedness Agreement, a state in which it is considered qualified to provide manufacturing capacities in Germany for one hundred and sixty (160) million doses of mRNA vaccine per year, including procurement of the required nonproduct specific manufacturing licenses and insurances and to have achieved ‘pandemic preparedness.’”

95 See WHO, The mRNA vaccine technology transfer hub, Visited Aug. 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.”

96 Loftus, P., *Moderna to Build Vaccine-Manufacturing Plant in Africa*. 2021, www.wsj.com/articles/moderna-to-build-vaccine-manufacturing-plant-in-africa-11633586400.

97 WHO mRNA Hub, above note 95.

98 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.

99 See WHO initiative signs new licensing agreements on COVID-19 technologies, WHO Press Release, Aug. 29, 2023, www.who.int/news/item/29-08-2023-who-initiative-signs-new-licensing-agreements-on-covid-19-technologies.

emergencies. The technological advances that were operationalized during the COVID-19 pandemic provide reason to hope that new scientific discoveries will make it possible to develop vaccines with broad scopes of potential application within pathogen classes and so, with comprehensive inoculation programs, to prevent or minimize catastrophic outbreaks. There is likewise reason to expect that continuing research on new therapeutics will make it possible to reduce the ill effects of outbreaks should they take place.

It is difficult to anticipate where scientific discoveries will emerge. They may come from researchers working within universities, from private sector laboratories, from public research institutes or from individual scientific “tinkers.” From wherever these new developments may emerge, it is important to encourage them with adequate funding and other support.

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.

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 appreciate the importance of building 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 the 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.

Annex 1: The case studies

1. Pfizer/BioNTech

Pfizer/BioNTech Comirnaty (proprietary)/tozinameran (INN) vaccine is based on a then-novel mRNA vaccine technology.¹⁰⁰ Pfizer recognized very early following the reported outbreak of SARS-CoV-2 infection in the People's Republic of China (PRC) that developing and distributing an effective vaccine represented an important commercial opportunity. It did not possess the technological capability to rapidly undertake that development process, and it promptly initiated negotiations with BioNTech – which did have that technological capability – to substantially expand their previously existing collaborating relationship. Pfizer invested a significant amount of financial capital (overall approximately USD 1 billion) to acquire the technological capacity from BioNTech (including patent rights) that was needed and agreed to a 50-50 split of the gross profits earned from sales of a resulting vaccine¹⁰¹ (see Box 1).

Box 1: Terms of Pfizer-BioNTech Collaboration Agreement

On April 9, 2020, we signed a global agreement with BioNTech to co-develop a mRNA-based coronavirus vaccine program, BNT162b2, aimed at preventing COVID-19 infection. In connection with the April 2020 agreement, we made an upfront cash payment of \$72 million and an equity investment in the common stock of BioNTech of \$113 million. ... BioNTech became eligible to receive potential milestone payments of up to \$563 million for a total consideration of \$748 million. Under the terms of this agreement, we and BioNTech share gross profits and development costs equally after approval and successful commercialization of the vaccine ... On January 29, 2021, we and BioNTech signed an amended version of the April 2020 agreement. Under the January 2021 agreement, BioNTech paid us their 50 percent share of prior development costs in a lump sum payment during the first quarter of 2021. Further R&D costs are being shared equally. We have commercialization rights to the vaccine worldwide, excluding Germany and Turkey where BioNTech markets and distributes the vaccine under the agreement with us, and excluding China, Hong Kong, Macau and Taiwan, which are subject to a separate collaboration between BioNTech and Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ...

We made an additional investment of \$50 million in common stock of BioNTech as part of an underwritten equity offering by BioNTech, which closed in July 2020. As of December 31, 2021, we held an equity stake of 2.5% of BioNTech.

Pfizer's Fiscal Year 2020 SEC Form 10-K, at 69¹⁰²

100 *Alnylam v. Pfizer*. DC Del, Case 1:22-cv-00924-UNA. Complaint filed July, 12, 2022

101 Amended and Restated Collaboration Agreement by and between Pfizer Inc. and BioNTech SE, March 17, 2020 (hereinafter "Collaboration Agreement"), https://www.sec.gov/Archives/edgar/data/1776985/000156459021016723/bntx-ex444_416.htm; Section 4.9 Gross Profit Sharing.

102 Pfizer, SEC Form 10-K for Fiscal Year Ended December 31, 2020. 2021. <http://www.sec.gov/Archives/edgar/data/78003/000007800321000038/pfe-20201231.htm>

Pfizer approached COVID-19 vaccine development with a well-established business infrastructure in place, including its own manufacturing capacity and outsourcing capability, that enabled it to implement a vaccine program rapidly. It had the financial reserves and creditworthiness to make a rapid decision to invest hundreds of millions of dollars principally to acquire technology. Such a combination of capacity is not widely distributed.

The mRNA vaccines developed and sold by Pfizer/BioNTech (Comirnaty) and Moderna (Spikevax) were the result of long years of basic research that were needed to solve two fundamental problems.^{103, 104, 105, 106, 107} The first was to identify a mechanism for modifying mRNA in a way that would decrease anti-RNA immune response. This first problem was solved by two researchers at the University of Pennsylvania some years prior to the pandemic. This involved replacement of the nucleoside, uridine.^{108, 109, 110} This solution was patented by the University of Pennsylvania and out-licensed.¹¹¹ The second problem was to identify a mechanism by which fragile mRNA strands could be introduced into the cells where they are needed to code for the proteins imitating pathogenic SARS-CoV-2 viruses and providing a prophylactic. This second problem was solved by development of lipid-based delivery systems (lipid nanoparticles or LNPs) that could be used to deliver mRNA into cells while preserving the integrity of the mRNA code. This technology was patented by at least one smaller biotech research company and out-licensed.¹¹²

Pfizer effectively acquired the technology portfolio of BioNTech (including among its leaders one of the co-inventors at University of Pennsylvania) (see note 101)¹¹³ the latter having advanced the technology for creating benign mRNA chemical code. Moderna asserts that it developed its own mRNA sequencing technology and LNP delivery mechanism that was not dependent on earlier patented discoveries. Moderna nonetheless paid substantial licensing fees to the University of Pennsylvania/Cellscript.

i. Technology and licensing terms

From a commercial standpoint – putting aside the emergency characteristics of the pandemic – the licensing terms and conditions employed by Pfizer and BioNTech in their Collaboration Agreement are largely common to such agreements. The 50-50 gross profits split is more in the nature of joint venture allocation than the type of running royalty that usually accompanies licensing, and consequently the dollar amounts ultimately shared are high as a consequence of the substantial revenues from vaccine sales (see note 72). The patent licenses granted to each other conferred exclusive rights,^{114, 115} except in those cases where previously in-licensed technology from third parties was on a nonexclusive basis.¹¹⁶ The parties did not publicly disclose the patents that were being relied upon. They agreed to keep commercial information

103 Perhaps the most comprehensive and accessible description of the technologies and the competing interests at stake in the development of the mRNA vaccines are included in the litigation documents among the rival complainants, which incorporate annexes with substantial scientific background.

104 *ModernaTX v Pfizer, ModernaTX Complaint for Patent Infringement, Case 1:22-cv-11378-RGS, filed Aug. 8, 2022 (D. Mass).*

105 *Pfizer, Answer, Affirmative Defenses, and Counterclaims to ModernaTX, id., filed Dec. 5, 2022.*

106 Angelica Peebles, et al., *Pfizer, Moderna Sued by Alnylam in New Fight Over Covid Shots*, in *Bloomberg Law*. 2022. <https://news.bloomberglaw.com/ip-law/pfizer-moderna-sued-by-alnylam-in-new-fight-over-covid-shots>

107 Zipkin, M. *New vaccine approaches present new possibilities, but new challenges*. *Nature*. www.nature.com/articles/d43747-021-00079-x

108 In the Pfizer and Moderna vaccines, uridine is replaced with pseudouridine (Ψ). Uridine is a nucleoside that consists of uracil and ribose, and forms a part of RNA.

109 Kellie D. Nance and Jordan L. Meier, *Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines*. *ACS Science Central*, 2021. 7, 748–756.

110 Pedro Morais, Hironori Adachi and Yi-Tao Yu, *The Critical Contribution of Pseudouridine to mRNA COVID-19 Vaccines*. *Frontiers in Cell Development and Developmental Biology*, 2021. 9. www.frontiersin.org/articles/10.3389/fcell.2021.789427/full

111 Pallas, N., *Penn researchers receive royalties of \$750 million for breakthrough vaccine development*, in *The Daily Pennsylvanian*. 2022. www.thedp.com/article/2022/06/penn-royalties-mrna-covid-vaccines

112 *Acuitas Therapeutics v. Genevant Sciences et al., Complaint for Declaratory Judgment of Non-infringement and Invalidity Case 1:22-cv-02229, filed Mar. 18, 2022 (SDNY).*

113 Collaboration Agreement, above note 101.

114 Collaboration Agreement Section 3.4.1: "License from BioNTech to Pfizer. Subject to the terms and conditions of this Agreement, BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer an exclusive (even as to BioNTech) license under the BioNTech Technology to Commercialize and have Commercialized Products within the Pfizer Commercialization Territory in any indication."

115 Collaboration Agreement Section 3.4.2 "License from Pfizer to BioNTech. Subject to the terms and conditions of this Agreement, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a license under the Pfizer Technology to Commercialize and have Commercialized (a) Products within the BioNTech Commercialization Territory in any indication, which license shall be granted on a sole basis; and (b) products identical to any Product within the Field but outside the Territory by BioNTech or by Fosun or its Affiliates pursuant to the Fosun Agreement."

116 See U Penn./Cellscript and Acuitas license agreements with BioNTech, below.

confidential,¹¹⁷ except in those cases where government regulation would require disclosure. For the most part, Pfizer was given exclusive authority to distribute the vaccine products, reserving to BioNTech its home country of Germany, and Türkiye.¹¹⁸

The Collaboration Agreement between Pfizer and BioNTech included detailed provisions on joint management,¹¹⁹ with Pfizer generally maintaining ultimate decision-making authority;¹²⁰ pricing;¹²¹ responsibilities for securing regulatory approvals;¹²² methodologies for accounting for costs;¹²³ allocation of tax burdens;¹²⁴ warranties and indemnifications;¹²⁵ mechanisms for addressing disputes;¹²⁶ allocation of rights in intellectual property developed in the course of the arrangement;¹²⁷ and the other elements common to joint ventures and technology transfer arrangements.

While the publicly available text of the Collaboration Agreement redacts a general statement regarding ownership of the Product Technology, additional detailed terms indicate that the parties have not transferred ownership of pre-existing patents or other intellectual property to each other, and their respectively licensed rights are generally defined by authority to commercialize the vaccine. Each party will own its “improvements,” and they will jointly own “Joint Technology,” with rights to grant third-party licenses without seeking consent.

The VaxPal database lists at least 14 patent applications relevant to the Pfizer/BioNTech vaccine. Three of those have application dates following the emergence of the SARS-CoV-2 virus,¹²⁸ and for one of those the applicant is Acuitas.¹²⁹

The negotiating parties foresaw an extensive list of potentially damaging contingencies, ranging from vaccine candidate failure,¹³⁰ to responsibility for patient injury,¹³¹ to intervening force majeure,¹³² and so on. Few of these adverse contingencies appear to have materialized, leaving aside the ongoing litigation with various rival claimants to patents and other intellectual property.

Pfizer was ultimately responsible for control of pricing decisions, except with respect to the territories reserved to BioNTech.¹³³ Pfizer (and BioNTech) agreed to sell vaccines to the

117 See Collaboration Agreement definition of Confidential Information, Section 1.38 and Section 12.1: Confidentiality.

The terms and conditions of the Collaboration Agreement itself are to be maintained in confidence, except as required by government regulation and filings, Section 12.3.

118 See, e.g., Collaboration Agreement Section 1.10: “BioNTech Commercialization Territory’ means (a) Germany and Turkey, until such time, on a country by country basis, a BioNTech Territory Exit Option is exercised by BioNTech in respect of one or both of those countries and (b) those countries, on a country by country basis, which become Pfizer Exit Countries (if any).”

119 See id. Section 6, Contract Governance.

120 See id. e.g., Section 9.2: Pfizer Commercialization Responsibilities.

121 See id. Section 9.6.2: “Pricing Meetings, Submissions & Negotiations. Subject to Section 8.2, the Commercializing Party having rights to Commercialize in a specific country or region of its Commercialization Territory will be solely responsible for conducting all meetings and negotiations with, and the preparation of all materials and submissions for, national and local Governmental Authorities, health insurance providers (e.g., managed care, sickness fund), retail and hospital pharmacies, other formulary segments (e.g., sub-national and local payors) and other Third Party payors relating to any pricing, tenders, direct procurement contracts, inclusion on formularies, coverage or reimbursement with respect to Products in each such country or region, and shall have the right to hold in its name and control all applications, registrations, licenses, authorizations, approvals required for such purposes.”

122 Pfizer to lead in USA, BioNTech in the EU. Id. Section 8.1.1 and 8.2.1.

123 Id. e.g., Section 4.4.

124 Id. Section 4.11. Generally each party is responsible for its own income tax.

125 Id. Section 13 and 16.

126 Id. Section 17.11.

127 Id. Section 11.

128 From Espacenet database: 1.WO2021213924 (A1) - CORONAVIRUS VACCINE; applicant BIONTECH, https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20211028&CC=WO&NR=2021213924A1&KC=A1; 2. WO2021030701 (A1) - IMPROVED LIPID NANOPARTICLES FOR DELIVERY OF NUCLEIC ACIDS; applicant ACUITAS THERAPEUTICS INC [CA], https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210218&CC=WO&NR=2021030701A1&KC=A1; 3. WO2021214204 (A1) - RNA CONSTRUCTS AND USES THEREOF; applicant BIONTECH SE [DE], https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20211028&CC=WO&NR=2021214204A1&KC=A1; See VaxPal, www.vaxpal.org/?keywords=Pfizer&page=1, for further details.

129 See Acuitas licensing discussed below.

130 See Collaboration Agreement, e.g., Section 4.15.3: “Neither Party makes any representation, warranty or covenant, either express or implied, to the other Party that (a) it will successfully Develop, Manufacture, Commercialize or continue to Develop, Manufacture or Commercialize any Product in any country, (b) it will secure Regulatory Approval for the Product in any country in the Territory, (c) if Commercialized, that any Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (d) it will devote, or cause to be devoted, any level of diligence or resources to Developing, Manufacturing or Commercializing any Product in any country, or in the Territory.” See also Section 9.14.

131 See id. Section 8.3: Pharmacovigilance and Pharmacovigilance Agreement.

132 Id. Section 17.3.

133 See id. note 121, above.

US government at a relatively low price during the initial phase of the pandemic¹³⁴ and at a somewhat higher price to the EU. Neither company was specifically bound to do this by the terms of their Collaboration Agreement. Nor were they contractually bound to sell to any particular group of countries at a favorable price.¹³⁵ A unique feature of the arrangement between Pfizer and BioNTech is that BioNTech was authorized to continue with a development and distribution arrangement with Fosun Pharmaceuticals,¹³⁶ a PRC-based company, on behalf of the collaboration.¹³⁷ For reasons which remain unclear, that latter Fosun-PRC arrangement did not result in an introduction of the Pfizer/BioNTech vaccine in the PRC until very recently, and then in only limited quantities.

The Pfizer/BioNTech collaboration is somewhat unique among the major vaccine candidates in that most received funding for development from government sources (and BioNTech did receive some funding from the government of Germany), and such development contracts with the governments generally included some type of pricing/access obligation, though not necessarily extending to foreign countries. Funding agreements entered into by other companies with private foundations such as CEPI included commitments with respect to providing access for low-income environments. By and large, unlike most of the actors in this space, Pfizer was able to charge the price to foreign country procurement authorities which “the market would bear,” and to determine the “place in line” of the recipient of the vaccines. The Collaboration Agreement does not include obligations with respect to establishing preferential terms and conditions for LMICs or low-income individuals elsewhere.

ii. The supply chain network and technology licensing

Pfizer/BioNTech engaged an array of upstream and downstream enterprises to create, manufacture and distribute the Comirnaty vaccine.¹³⁸ On the upstream side, it appears that the two most important agreements were entered into by BioNTech with the (1) University of Pennsylvania/Cellscript and (2) Acuitas.¹³⁹

The BioNTech-University of Pennsylvania license addresses the foundational mRNA technology developed at the University and out-licensed to Cellscript, among others, that further sublicensed the patents. BioNTech in its financial reporting to the US SEC avoids identifying the amount of royalties it has paid to the University of Pennsylvania.¹⁴⁰ However, it is reported that the University of Pennsylvania has earned approximately USD 1 billion in licensing fees with respect to COVID-19 vaccines. Moderna has disclosed payments of approximately USD 600 million. We might reasonably deduce that BioNTech on behalf of itself and Pfizer has paid a roughly equivalent amount, which is consistent with third-party reporting (see note 111). It is

134 Lupkin, S., *Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, in NPR. 2020. www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections

135 See Section 9, Collaboration Agreement.

136 Shanghai Fosun Pharmaceutical, *Overseas Regulatory Announcement: Agreement with BioNTech*. 2020

137 Collaboration Agreement, Section 1.36 “Competitive Product” means a pharmaceutical product that incorporates an immunogenic composition comprising RNA in the Field that is intended to be, has been, or is being Exploited by a Third Party. For avoidance of doubt, Competitive Product does not include Product (a) Commercialized by or on behalf of BioNTech in the BioNTech Commercialization Territory pursuant to this Agreement; or (b) Commercialized outside of the Territory in accordance with the terms of the Fosun Agreement. According to a Fosun filing with the Hong Kong stock exchange of March 15, 2020. “Fosun Pharmaceutical Industrial shall pay to BioNTech the licensing fee (including upfront payment, clinical development, registration and sales milestone payments) in the aggregate amount of not exceeding USD85 million, and pay the sales royalty at the rate of 35% of annual gross profit during the term of sales royalty.”

138 See Neubert, J., *Exploring the Supply Chain of the Pfizer/BioNTech and Moderna COVID-19 vaccines*. 2021–2022.

<https://blog.jonasneubert.com/2021/01/10/exploring-the-supply-chain-of-the-pfizer-biontech-and-moderna-covid-19-vaccines/>

139 Acuitas BioNTech, *Non-Exclusive License Agreement*. 2020. www.sec.gov/Archives/edgar/data/1776985/000177698522000019/acuitasbiontechnon_exclu.htm

140 U. Penn-BioNTech 2018 License (Amended and Restated (2d)) Dec. 2022, https://www.sec.gov/Archives/edgar/data/1776985/000177698522000019/penn_biontechxamd2xfully.htm: “Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for in vivo uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties. BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately USD 26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.” BioNTech Form 20-F for fiscal year 2021 (2022), at 182, <https://investors.biontech.de/static-files/50d0cafc-b2c1-4392-a495-d252f84be105>

important to note that the BioNTech-University of Pennsylvania license¹⁴¹ is nonexclusive such that in principle there is nothing to preclude another party seeking to develop and produce mRNA vaccines from licensing the same patents and related technology. It is further of interest to note that while Moderna (see discussion below) claims to have developed its own mRNA technology, and has sued Pfizer for infringement, it is nevertheless (like Pfizer) paying the University of Pennsylvania for foundational mRNA patents.

The second important in-license for BioNTech is with Acuitas. This license concerns patents covering lipid nanoparticle (LNP) technology that is used for encapsulation of the active biological substance of the vaccine. The commercial terms of this license are set forth in BioNTech's 2021 Form 20-F.^{142, 143}

Acuitas (see note 112) and Pfizer (see note 104) are each involved in patent infringement litigation with respect to their use of LNP technology, as is Moderna. The parties with whom they are disputing include Arbutus,^{144, 145} Alnylam (see note 100) and Genovant,¹⁴⁶ each of which stakes a claim to having developed the LNP technology being used in the approved mRNA vaccines.

iii. Manufacturing

Pfizer owns and operates its own vaccine manufacturing facilities in the United States of America, at St. Louis, Missouri and Andover, Massachusetts.¹⁴⁷ BioNTech operates or contracts with manufacturing facilities in Europe. Components of the vaccines are sourced from various locations. Lipids apparently are produced in Alabama, USA. LNPs may be assembled in the United States using technology in-licensed from, among other parties, Acuitas, and also transferred from Polymun Scientific based in Austria.^{148, 149} In the United States, Pfizer's fill and finish operations are carried out at a facility in Kalamazoo, Michigan, where the vaccines are also stored at ultra-low temperature as they await shipment. BioNTech operates several manufacturing facilities in Europe, including a facility it acquired from Novartis in Marburg, Germany. In addition, Sanofi was contracted to fill and finish the Pfizer-BioNTech vaccine at a site in Frankfurt, Germany. Outside the United States, Pfizer shipments of Comirnaty are sent from its facility in Puurs, Belgium (see note 93).

Because Pfizer's manufacturing operations in the United States are primarily in-house, these presumably do not involve licensing agreements.¹⁵⁰

141 The text above refers to the University of Pennsylvania, taking note that some of the technology/patents is indirectly licensed through, e.g., Cellscript.

142 BioNTech 2021 Form 20-F, above note 140, at 182 - "Acuitas License Agreement: In April 2020 we entered into a Non-Exclusive License Agreement with Acuitas, or the Acuitas License Agreement. Under the Acuitas License Agreement Acuitas grants us a non-exclusive worldwide license, with the right to sublicense (subject to certain conditions) under Acuitas's LNP technology to develop, manufacture and commercialize licensed products directed to the SARS-CoV-2 surface glycoprotein. We have the option to convert the nonexclusive licenses to exclusive licenses subject to certain additional financial obligations. Under the Acuitas License Agreement, we must pay Acuitas up to between approximately USD 1.6 million and USD 2.45 million in development milestone payments, USD 2.5 million and USD 3.75 million in regulatory milestone payments and USD 2.5 million and USD 3.75 million in commercial milestone payments upon the occurrence of certain milestone events. We are further required to pay Acuitas a low single-digit tiered percentage royalty on net sales of licensed products, subject to certain potential customary reductions. The amount of fees and royalties that Pfizer/BioNTech have paid to Acuitas has not been publicly disclosed. However, as the royalty levels (low single-digit tiered) are roughly comparable to what has been publicly reported with respect to the University of Pennsylvania (3.5 percent) it seems reasonable to assume that payments have been in the several hundreds of millions of dollars. While BioNTech's initial agreement with Acuitas (which preceded COVID-19) gave it the option to convert the license to an exclusive license, there is no indication that that option was ever exercised. In addition, though not directly relevant to Pfizer's COVID-19 vaccine, in 2022 Pfizer announced its own broader agreement with Acuitas for technology relating to vaccine or therapeutic development."

143 Pfizer_media_relations, *Pfizer Enters into Agreement with Acuitas Therapeutics for Lipid Nanoparticle Delivery System for Use in mRNA Vaccines and Therapeutics*. 2022.

144 Arbutus and Genovant v. Moderna, *Complaint for Patent Infringement D.Del., Case 1:22-cv-00252-UNA, filed Feb. 28, 2022*. 2022.

145 Wolfe, J. *Moderna loses challenge to Arbutus patent on vaccine technology*. July 23, 2020; Available from: www.reuters.com/article/us-moderna-patent-idUSKCN2402XY.

146 *Acuitas v. Genovant and Arbutus*. SDNY Case 1:22-cv-02229, filed Mar. 18, 2022.

147 Johnson, C.Y., *A vial, a vaccine and hopes for slowing a pandemic — how a shot comes to be*, in *Washington Post*. 2020. www.washingtonpost.com/health/2020/11/17/coronavirus-vaccine-manufacturing/

148 *The Austrian firm Polymun has been playing a key role in developing a vaccine*. 2023; Available from: www.advantageaustria.org/lv/news/20201230_Polymun.en.html.

149 Pancevski, B., *If One Leading Coronavirus Vaccine Works, Thank This Tiny Firm in Rural Austria*, in *Wall St J*. 2020. www.wsj.com/articles/if-one-leading-coronavirus-vaccine-works-thank-this-tiny-firm-in-rural-austria-11604664001

150 There may be reasons relating to corporate internal structuring, taxation and so forth, that would result in the generation of an intra-corporate licensing agreement. If so, it is unlikely that such agreements would be made publicly available.

Although the specific terms and conditions of BioNTech's outsourced manufacturing operations are not publicly disclosed, and similarly with Pfizer's non-US outsourced production, there is no reason to expect that the relevant agreements give the manufacturers any rights in the IP of these two companies, nor would they have any control over the destinations for distribution.¹⁵¹

iv. Sales and distribution

1. United States

As of March 31, 2021, the US government had placed orders for 300 million doses of the Comirnaty vaccine at a total price of USD 5.97 billion,¹⁵² giving a per dose price of USD 19.90.¹⁵³ Kaiser Family Foundation (KFF) analysis indicates that as of December 2022, the US government had paid USD 15.272 billion to Pfizer/BioNTech for 655 million doses, including of the more recent bivalent vaccine. The average price was USD 23.32, including the more costly bivalent at USD 30.48 per dose. (See Annex 4.)

The initial July 21, 2020 procurement agreement was characterized as a developmental phase agreement. As this was a US government contract it incorporated various standard government procurement provisions. However, it expressly excluded according any rights to intellectual property in favor of the government pursuant to the Bayh-Dole Act or related legislation acknowledging that Pfizer had not received R&D funding from the government in connection with development of the vaccine.¹⁵⁴ The publicly available versions of the initial contract and the subsequent contract of December 22, 2020 do not expressly require Pfizer to place delivery to the US government ahead of non-US purchasers. However, some terms are redacted.^{155, 156.} ¹⁵⁷ That said, since BioNTech produced and supplied vaccines from European locations, it is doubtful that the EU would have been affected by an internal US priority with the exception perhaps of certain raw materials.

2. Europe

The European Union entered into an advance purchase agreement with Pfizer and BioNTech on November 11, 2020 for an initial 200 million doses with an option to request an additional

151 As is evidenced in the publicly available Moderna-Lonza Manufacturing Agreement discussed in the next section of the Study, the contract manufacturer is obligated to make and deliver a product on a defined timetable under specific conditions (e.g., cGMP manufacturing). BioNTech may well be supplying the contract manufacturers with manufacturing technology, and the manufacturers may have and maintain their own technology, but these agreements typically are not designed to share ownership of that technology. These manufacturers may be relying on in-licensed technology going into the development and even manufacturing process for the vaccines.

152 Siddalingaiah, S.V., *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*. 2020, Congressional Research Service. <https://crsreports.congress.gov/product/pdf/IN/IN11560>

153 C.1.1: "As part of DHHS preparedness and response activities, DHHS seeks to purchase 500M doses of the EUA authorized (or Biologics License Application (BLA) approved) BNT162b2 vaccine, enough to vaccinate the entire American population." US Dept. Defense/HHS-Pfizer, *Production of COVID-19 BNT162b2 Vaccine in Support of National Emergency Response to Coronavirus 2019 (COVID-19)*. 2020. www.hhs.gov/sites/default/files/vaccine-production-contract-with-pfizer.pdf. An initial contract for 100 million doses was awarded on July 21, 2020, at a total cost of USD 1.97 billion. An additional contract was executed on December 22, 2020 for an initial additional 100 million doses at a total cost of USD 2,011,282,500, with an additional 100 million doses ordered by March 31, 2021. The total contract price of the December 22, 2020 procurement agreement was USD 10,016,418,500 inclusive of all options, and this contract is reported to have been nearly fulfilled, so for a total of 500 million doses (apparently inclusive of the initial 100 million doses). US Army-Pfizer, *Vaccine Procurement*. 2020. www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf. On July 29, 2022, the US government announced an additional agreement for 105 million doses of bivalent vaccine at a price of USD 3.2 billion, with an option for an additional 195 million doses. *Pfizer media relations, Pfizer and BioNTech Announce New Agreement with U.S. Government to Provide Additional Doses of COVID-19 Vaccine*. 2022. www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-new-agreement-us-government

154 See Section 7.1 of the July 21, 2020 Agreement. "Inventions ... Notwithstanding the foregoing, and as set forth more fully in Section 1.1.2, the Government acknowledges that it is not funding the research or development of the vaccine, or CMC/process development in respect thereof. As such, neither Pfizer nor the Government anticipate the conception or reduction to practice of any Subject Inventions. The Government acknowledges that the Bayh-Dole Act does not apply to or govern this Agreement. Given that the Government will not fund the conception or reduction to practice of Background Inventions or Subject Inventions hereunder, this Agreement shall neither (i) give the Government any rights to "march-in," as that term is defined in 35 U.S.C. § 203, nor (ii) subject Pfizer to the manufacturing requirements of 35 U.S.C. § 204."

155 The agreements otherwise incorporate a substantial number of national emergency-related priority terms by reference – mainly relating to the Defense Production Act – so it is difficult to draw a firm conclusion about whether explicit priority or export restrictions were included.

156 Aime William and Kiran Stacey, *Is there a ban on Covid vaccine exports in the US?* 2021. www.ft.com/content/82fa8fb4-a867-4005-b6c2-a79969139119

157 Chad P. Bown and Chris Rogers, *The US did not ban exports of vaccine supplies. But more help is needed*. 2021. www.piie.com/blogs/trade-and-investment-policy-watch/us-did-not-ban-exports-vaccine-supplies-more-help-needed

100 million doses.^{158, 159} The price paid per dose was not disclosed by the Commission, but reports indicate that the updated price was EUR 19.50¹⁶⁰ The advance purchase agreement provided that the quantities allocated to the individual member states would be subsequently agreed among EU members. This latter process apparently did not go smoothly.¹⁶¹

As part of the advance purchase agreement, the EU agreed that vaccines would not be exported without the consent of the supplier.¹⁶² Although many of the relevant provisions were redacted from the publicly available version, there appears to have been a concerted effort to relieve the manufacturer of liability from use of the vaccine based on the emergency circumstances.

The European Union has entered into a number of subsequent amendments and further purchase commitments with Pfizer and BioNTech. These arrangements are subject to continuing criticism within and outside the EU for a lack of transparency, including by the European Court of Auditors.¹⁶³

Vaccine procurement agreements are not directed toward patents or other intellectual property rights “as such.” However, they raise the issue of the extent to which the market power of the suppliers is dependent on IP. The argument from the side of the manufacturers is that pricing power during the pandemic was largely a consequence of supply constraints, and the supply constraints were substantially a function of the extended ramp-up periods for bringing new production online. This does not answer questions regarding whether more open access to IP including know-how might have ameliorated the supply constraints. The CEO of Pfizer has expressed the view that restricted capacity for the supply of the materials needed to produce vaccines was the principal reason that production levels could not be increased.¹⁶⁴ But he also argues that a waiver of IP would have resulted in an unproductive competition for scarce input materials, suggesting at least that there may have been third-party capacity that could have been brought online.

3. Rest of world

Pfizer entered into a substantial number of additional procurement agreements with countries outside the United States and Europe. Representative examples of those agreements indicate that Pfizer made no enforceable commitment to deliver vaccines in specific quantities or along a specific schedule. In addition, the agreements insulated the supplier against liability.¹⁶⁵ In

158 Pfizer_European_Union, *Advance Purchase Agreement (“APA”) for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member*. 2020 EU Advance Purchase Agreement.

159 Pfizer_media_relations, *Pfizer and BioNTech Reach an Agreement to Supply the EU With 200 Million Doses of Their BNT162b2 mRNA-Based Vaccine Candidate Against SARS-CoV-2*. 2020. www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-reach-agreement-supply-eu-200-million

160 “The new price for a Pfizer shot was €19.50 against €15.50 previously, according to portions of the contracts seen by the Financial Times.” Donato Paolo Mancini, Hannah Kuchler and Mehreen Khan, *Pfizer and Moderna raise EU Covid vaccine prices*. 2021. www.ft.com/content/d415a01e-d065-44a9-bad4-f9235aa04c1a

161 Michael Peel, et al., *EU leaders clash over vaccine distribution in tense summit*, in *Financial Times*. 2021. www.ft.com/content/486a65fe-0608-4230-b9d5-c990f10d5be8

162 EU Advance Purchase Agreement: “I.6.16 Diversion issues ... All Product delivered to a Participating Member State shall be: (a) stored securely by the Participating Member State; and (b) without prejudice to Article I.6.2, distributed by the Participating Member State in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) or unauthorised resale or export out of the Participating Member State, and to protect and preserve the integrity and efficacy of the Product.”

163 Kansteiner, F. *EU ignores information request in probe over massive Pfizer COVID-19 vaccine order*. 2022. www.fiercepharma.com/pharma/investigation-eus-biggest-covid-19-vaccine-contract-pfizer-met-silence

164 Bourla, A., *An Open Letter from Pfizer Chairman and CEO to Colleagues*. 2021. www.pfizer.com/news/articles/why-pfizer-opposes-the-trips-intellectual-property-waiver-for-covid-19-vaccines; Bourla, A., *Albert Bourla on Ensuring Equitable Access to COVID-19 Vaccines*. 2021. www.pfizer.com/news/articles/albert_bourla_on_ensuring_equitable_access_to_covid_19_vaccines

165 As for example, from the Binding Term Sheet with the government of Peru: “Indemnification by Government. Government hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, subcontractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development or manufacture of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing (‘Indemnitees’), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including reasonable attorneys’ fees and other expenses of an investigation or litigation) whether sounding in contract, tort, intellectual property or any theory, and whether legal, statutory, equitable or otherwise (collectively, ‘Losses’) arising out of, relating or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, distribution, marketing, promotion, sale, purchase, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine.” Pfizer-Peru, *Binding Term Sheet*. 2020. <https://ghiaa.org/wp-content/uploads/2021/06/Peru-Pfizer-Binding-Term-Sheet-1.pdf>

addition, the representative agreements made clear that the purchasers were not acquiring rights in Pfizer's intellectual property: "Suppliers will be the sole owners of all intellectual property they generate during the development, manufacture and supply of the Vaccine or otherwise related to the Vaccine." (Peru) Pfizer's price to Peru in the above-referenced agreement was USD 12 per dose (USD 118,800,000 for 9,900,000 doses).

A draft supply contract between Pfizer and Albania also employs a price of USD 12 per dose. As with Pfizer's contract with the European Union, it explicitly prohibits export of the product (Section 4.6). Pfizer owns all of the relevant intellectual property (Section 7). The indemnity provision is the same as that incorporated in the Peru Term Sheet (Section 8.1). The parties are obligated to maintain information in confidence (Section 10.1). Disputes are to be settled pursuant to arbitration in accordance with the rules of the International Chamber of Commerce (Section 12.2). Procurement agreements between Pfizer and Colombia¹⁶⁶ and between Pfizer and the Dominican Republic¹⁶⁷ appear to be to the same effect. Pfizer employed a template, and a procedure that involved first the negotiation of a term sheet, and subsequently a finalized agreement.

Although the above-referenced agreements are from a customary standpoint one-sided in the sense that the supplying party is making very few firm commitments, while being relieved of potential liability, these agreements were negotiated under highly unusual circumstances in which the subject products were themselves the subject of considerable scientific and commercial uncertainty. In addition, the terms are not in practical effect different from those accepted by the European Union. It may be that because of paying a higher price and exercising more direct political power over the suppliers that the European Union would receive its vaccine doses sooner, this is not so much a question of contract terms. The United States was in a different position because Pfizer is situated in the United States and ordinarily is the recipient of significant funding from the US government in terms of NIH R&D funding and so on, so there was a reason for the United States to stand first in line for Pfizer, including based on the size of the government procurement contracts. While LMICs were required to accept contract terms that they might not accept "in the ordinary course," they were negotiating the best terms available to them under the circumstances.

Finally, it should be acknowledged that Pfizer and BioNTech were themselves dealing in a very uncertain environment, including with respect to liability. They were manufacturing and distributing a vaccine based on a technology that had never been used at commercial scale before, and they were planning to distribute these products for use by substantial part of the global population. The potential liability in a non-emergency context would effectively be "unlimited." A private sector company would foreseeably seek to limit its potential liability. One might argue that bankruptcy would be a reasonable consequence of introducing a dangerous vaccine to the world population. And well it might be. But corporate executives might also be wary of taking that risk.

v. Access terms

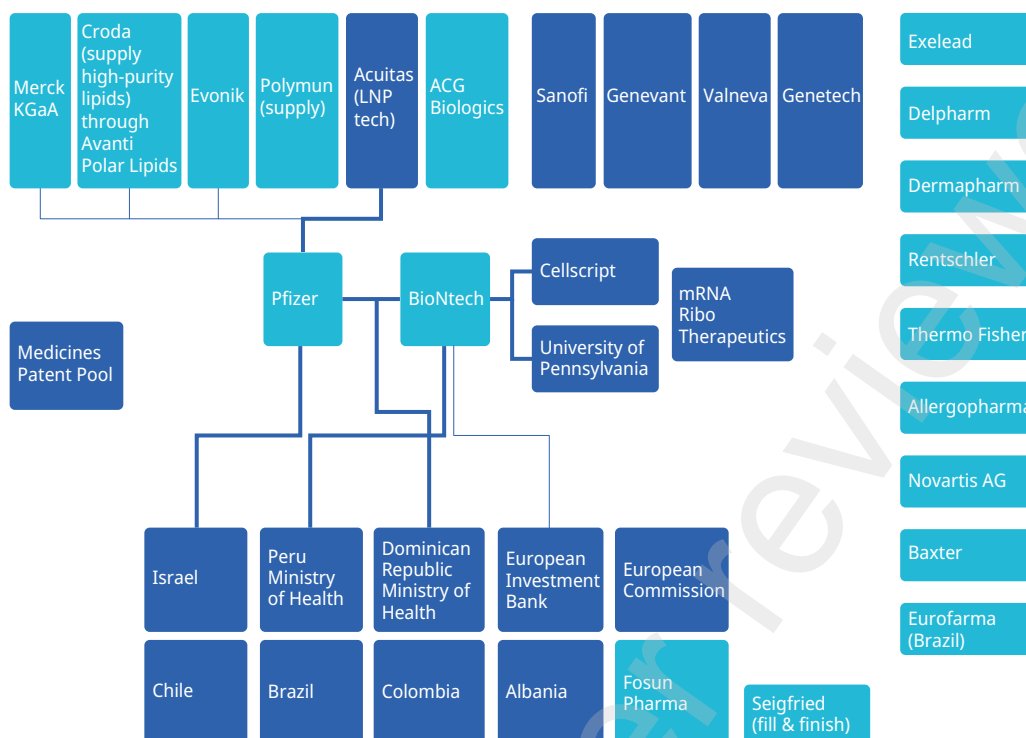
As the United States and European Union generally made vaccines available without charge to individuals living within those areas, this should not have been a significant barrier to access in those countries. However, considerable controversy surrounded access in other countries/regions. In response to these concerns, Pfizer issued public statements explaining its policies and practices.¹⁶⁸

¹⁶⁶ Pfizer-Colombia, *Manufacturing and Supply Agreement between Pfizer and FNGRD (Colombia)*. 2021

¹⁶⁷ Dominican Republic-Pfizer, *Binding Term Sheet*. 2021

¹⁶⁸ Pfizer_media_relations. *Pfizer works toward equitable and affordable access to COVID-19 vaccines and treatments around the world*. 2021; Available from: www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/story/working-to-end-the-pandemic/ (see note 3).

Pfizer mapping



Summary: Pfizer/BioNTech

- Pfizer acquires BioNTech mRNA vaccine technology for about USD 1 billion plus 50-50 split of revenues (BioNTech retains Germany/Türkiye), plus Fosun arrangement for the PRC (35% revenue from Fosun)
- BioNTech has previously in-licensed fundamental mRNA nucleobase substitution (for uracil) from U Penn/Cellscript and lipid nanoparticle encapsulation (LNP) from Acuitas (pending litigation) – royalties approx. 3.5% each plus lump sums
- Pfizer does not accept US development funding
- Pfizer brings in existing manufacturing and supply/distribution chain – mostly based in United States – but requiring some foreign (e.g., Austrian) components
- Vaccine (Comirnaty) proves highly efficacious and safe
- First ever mRNA vaccines (with Moderna) – scientific success
- Ultra-cold storage requirement
- US government priority recipient of vaccines
- Pfizer/BioNTech retains control of IP
- Local production preference
- No explicit access policy
- Large advance purchase with EU
- Sales to LMICs on “flexible delivery” terms

2. Moderna

Moderna Spikevax (proprietary)/elasomeran (INN) vaccine

i. Operation Warp Speed

Shortly following the outbreak of SARS-CoV-2 virus (April 2020), the US Department of Health and Human Services (HHS) and the Biomedical Advanced Research and Development Authority (BARDA), further to Operation Warp Speed, entered into an agreement with Moderna for the

development of an mRNA vaccine to address it.^{169, 170} Moderna had spent a number of years developing its mRNA platform, made a successful initial public offering (IPO) in 2018, and was considered a leader in the development of mRNA therapeutics technology.¹⁷¹ The initial agreement provided for payments totaling USD 498 million by the US government, which included funds both for conducting R&D and for the procurement of vaccines. US vaccine procurement from Moderna was increased on several occasions up to approximately USD 10 billion by July 2022 (see Annex 4).¹⁷²

Moderna's agreement with the US government committed it to an extensive schedule of deliverables, including undertaking of clinical studies,¹⁷³ assuring manufacturing capacity (including with third-party subcontractors), using Moderna patents, committing Moderna to maintaining confidentiality (including with subcontracting third parties), assuring that the US government would be the priority recipient of vaccines,¹⁷⁴ the requirement to keep detailed cost records, and agreement by the government not to reverse engineer confidential data.¹⁷⁵ It appears that the government paid Moderna's USD 16.80 per dose of the 200 million doses delivered under the first tranche of the agreement.¹⁷⁶

The agreement required that manufacturer of vaccines be conducted within the United States.¹⁷⁷

Moderna would not be acting as an agent of the US government.¹⁷⁸

With respect to intellectual property rights, the agreement provides:

The parties agree that data generated prior to entering in to or outside the scope of the agreement will, when delivered to the USG, be considered be limited rights data subject to the restrictions covered under FAR Clause 52.227-14 Alt II paragraph (g)(3).¹⁷⁹ The government will obtain unlimited rights to data funded under this contract pursuant to FAR Clause 52.227-14. The parties rights to subject inventions developed during performance of this contract will be governed by the terms of FAR Clause 52.227-11.^{180, 181, 182, 183}

169 HHS_BARDA. *Moderna Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2*. 2020; Available from: <https://ghiaa.org/wp-content/uploads/2021/01/Moderna-%E2%80%93BARDA-Agreement-Contract-No.75A50120C00034-for-Development-of-an-mRNA-Vaccine-for-Sars-Cov-2.pdf>. HHS_BARDA-Moderna.

170 Moderna. *Moderna Announces Award from U.S. Government Agency BARDA for up to \$483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus*. 2020; Available from: www.sec.gov/Archives/edgar/data/1682852/000119312520109482/d870934dex991.htm.

171 Terry, M. *Moderna Therapeutics Sets Record for Biggest Biotech IPO* | BioSpace. BioSpace, 2018. www.biospace.com/article/moderna-therapeutics-biggest-ipo-in-biotech-history/

172 Initially: "2. Modification to Contract ... This modification adds \$471,596,459 to CUN 0002 and increases the total contract value from \$483,298,520 to \$954,894,979. [***]" HHS_BARDA-Moderna. See also KFF data in table above.

173 Phase 3 Pivotal Study: (WBS 1.4.3.1) - Updated: "Approximately 30,000 subjects will be enrolled according to 1:1 randomization (active: placebo). Primary objectives will be 1) to demonstrate the efficacy of mRNA-1273 to prevent COVID-19 and 2) to evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart. (***)". HHS_BARDA-Moderna.

174 See id., e.g., Section B.4.1. Also: "This is a rated order certified for national defense use and you are required to follow all provisions of the Defense Priorities and Allocations System regulations (15 CFR part 700)."

175 See id., Sec. B.4.13.

176 The price per dose is not expressly set forth in the agreement, but can be inferred from the agreement amount and the number of doses to be delivered. Barron's reports: "[T]he federal government paid \$3.3 billion for 200 million doses, or \$16.50 per dose" for vaccines delivered in June 2021. "Moderna spokesman Chris Ridley told Barron's that the price is set by the U.S. government." Nathan-Kazis, J., *Moderna Lands \$1.7 Billion Deal with Government. Pfizer Is Getting More Per Dose*. 2023. www.barrons.com/articles/moderna-pfizer-covid-vaccine-sale-51659110407

177 See, HHS_BARDA-Moderna e.g., sec. B.1, B.4.10, C.1.

178 See, id., Sec. C.2.

179 US_FAR. *52.227-14 Rights in Data-General*. | Acquisition.GOV. 2014; Available from: www.acquisition.gov/far/52.227-14.

180 US_FAR Clause 52.227-11 ... "(b) Contractor's rights. (1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause. ... (2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. ... (2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.... (h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award." US_FAR. *52.227-11 Patent Rights-Ownership by the Contractor*. 2014; Available from: www.acquisition.gov/node/32149/printable/pdf.

181 *35 USC § 203. March-in rights*. 1981. www.govinfo.gov/content/pkg/USCODE-2021-title35/pdf/USCODE-2021-title35-partII-chap18-sec203.pdf

182 *35 USC § 210. Precedence of chapter*. 1981. www.govinfo.gov/content/pkg/USCODE-2021-title35/pdf/USCODE-2021-title35-partII-chap18-sec210.pdf

183 *37 CFR § 401.6 Exercise of march-in rights*. Current. www.ecfr.gov/current/title-37/chapter-IV/part-401/section-401.6

That clause that is part of the implementation of the Bayh-Dole Act grants to recipients of federal R&D funding a right to secure patents in their own names, provided that a nonexclusive license to practice is granted back to the government, and it also subjects the patent owner to “march-in rights.” Those march-in rights permit the government to step in and grant nonexclusive licenses under the patent to third parties when certain conditions are met, principally that the patent owner has not made the invention available on reasonable terms.¹⁸⁴ Such march-in rights have never been granted by the US government with respect to a pharmaceutical or vaccine product, despite a number of requests from civil society organizations.

Moderna is seeking to defend itself against claims of patent infringement in litigation with Arbutus on grounds that it was acting as a government contractor in producing its vaccine, and therefore may only be sued for reasonable compensation before the Federal Court of Claims.¹⁸⁵

ii. University of Pennsylvania/Cellscript

Well before the arrival of SARS-CoV-2, Moderna entered into a licensing agreement with Cellscript, which is a licensee of the Trustees of the University of Pennsylvania, for the use of mRNA related patents and technology that had been developed by individuals at the University of Pennsylvania School of Medicine.¹⁸⁶ One of those individuals, Dr. Katalin Kariko, went on to become a senior executive at BioNTech.¹⁸⁷ It was the researchers at the University of Pennsylvania who discovered the technique of substituting specific nucleosides in mRNA strands that reduced immunogenicity. This discovery was patented by the University of Pennsylvania, and it is fundamental to the successful development of mRNA vaccines.

The license agreement between Cellscript and Moderna provides the latter with nonexclusive worldwide rights to use patents and technical know-how for the development of new products. The commercial terms of the license and the resulting contractual payments from Moderna to Cellscript are outlined in Moderna’s 2021 10-K.¹⁸⁸ It would appear that the royalty rate would be in the low single digits.¹⁸⁹ As Moderna sold USD 17.7 billion¹⁹⁰ worth of COVID vaccine in 2021 for 807 million doses and paid roughly USD 641 million in royalties (milestone payments included), it appears that Moderna paid approximately 3.5 percent royalties to Cellscript, which would be consistent with low single digits.

The revenue per dose of vaccine for Moderna in 2021 would appear to be about USD 22.

184 Congressional_Research_Service, *March In Rights Under the Bayh Dole Act*. 2016. www.everycrsreport.com/files/20160822_R44597_6e41fed24de1621cbcefcc04ca20b41845db44cb.pdf

185 *Arbutus v. Moderna - USG Statement of Interest*, Case No. 22-252 (MSG), D. Del, filed Feb. 14, 2023.

186 Cellscript_Moderna. *Patent Sublicense Agreement*. 2017; Available from: www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473dex108.htm.

187 Wikipedia Entry. *Katalin Kariko - Wikipedia*. 2023; Available from: https://en.wikipedia.org/wiki/Katalin_Karik%C3%B3.

188 “Patent sublicense agreements with Cellscript and mRNA RiboTherapeutics ...Together, the Cellscript-MRT Agreements grant us a worldwide, sublicensable sublicense to the Penn Modified mRNA Patents to research, develop, make, and commercialize products covered by the Penn Modified mRNA Patents, or licensed products, for all in vivo uses in humans and animals, including therapeutic, prophylactic, and diagnostic applications. The Cellscript-MRT Agreements are non-exclusive, although Cellscript and MRT are subject to certain time restrictions on granting additional sublicenses for in vivo uses in humans under the Penn Modified mRNA Patents.... We paid Cellscript and MRT aggregate sublicense grant fees of \$28 million upon entering into the Cellscript-MRT Agreements, \$25 million in early 2018, and \$22 million in early 2019. Cellscript and MRT are collectively eligible to receive, on a licensed product-by-licensed product basis, milestone payments totaling up to \$0.5 million upon the achievement of certain regulatory-based events for diagnostic products, and milestone payments totaling up to \$1.5 million upon the achievement of certain development and regulatory-based events for either therapeutic or prophylactic products, and up to \$24 million upon the achievement of certain commercial-based events for either therapeutic or prophylactic products. The Cellscript-MRT Agreements require us to pay royalties based on annual net sales of licensed products at rates in the low single digits for therapeutic, prophylactic, and diagnostic uses, and royalties based on annual net sales of licensed products sold for research uses at rates in the mid-single digits, subject to certain reductions, with an aggregate minimum floor. Following the first commercial sale of licensed products under a Cellscript-MRT Agreement, we are required to pay Cellscript or MRT, as applicable, minimum annual royalties ranging from \$10,000 to \$400,000 depending on the use of such licensed product, with all such payments creditable against earned royalties on net sales. In 2021, we paid \$641 million in royalties and milestone payments to Cellscript in connection with sales of our COVID-19 vaccine.” (at 10-K pp. 45–46) [underlining added] Moderna. *2022 Form 10-K (for fiscal year 2021)*. 2022; Available from: <https://d18rn0p25nwr6d.cloudfront.net/CIK-0001682852/ffa50947-bd8a-4758-890d-ccbbf7648.pdf>.

189 Since the Moderna Spikevax vaccine was sold for therapeutic purposes.

190 “COVID-19 Commercial, Manufacturing and Supply Updates...Commercial sales of our COVID-19 vaccine accounted for \$17.7 billion in revenues for the year ended December 31, 2021, based upon the delivery of approximately 807 million doses of the vaccine, accounting for all of our commercial revenues.” (2022 10-K, above note 188, at p. 19).

Separately from the University of Pennsylvania/Cellscript, in February 2023, Moderna agreed to pay the US National Institutes of Health, Dartmouth College and Scripps Research a total of USD 400 million as delayed licensing payments for their patented technology used in stabilizing mRNA generated spike proteins.¹⁹¹

iii. Manufacturing

Moderna manufactures Spikevax at its own facilities located in the United States, and also contracts for production outside the United States.¹⁹²

Moderna committed to developing the technology for and manufacturing COVID-19 vaccine products in its own US facility, recalling that its agreement to supply the US government included a requirement for domestic manufacturing. Moderna does not specify a breakdown of the quantities that are produced at each facility in the United States or worldwide. It has entered into a significant manufacturing outsourcing agreement with Lonza which is headquartered in Switzerland, but which also has production facilities in the United States.

1. The Lonza Manufacturing Agreement¹⁹³

The Global Long Term Agreement (GLTA) between Moderna and Lonza involves the transfer of manufacturing know-how from Moderna to Lonza,¹⁹⁴ and other technology (including patents) as broadly defined.¹⁹⁵ Lonza commits to avoiding the use of its own proprietary technology in the manufacturing process, unless that use is specifically agreed.¹⁹⁶ In other words, Moderna wants to avoid dependence upon Lonza-owned technology for subsequent manufacturing.

191 Mueller, B., *After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique*, in *NY Times*. 2023. www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html.

192 The following is its description of its manufacturing operations with respect to COVID-19: "The MTC [Moderna Technology Center] campus has been designed with a high level of automation and state-of-the-art digital integration to handle manufacturing execution, product testing and release, and regulatory filings. In addition, substantial manufacturing capabilities are realized via CMO relationships in the United States and abroad, providing drug substance and fill-finish capacity for the COVID-19 vaccine. Much of the production for our COVID-19 vaccine supply for the U.S. market is completed at the MTC campus, with additional production by Lonza Ltd. (Lonza). We have also partnered with Lonza to complete production in Switzerland of our COVID-19 vaccine for markets outside the United States, as well as with National Resilience, Inc. to manufacture drug substance at its facility in Ontario, Canada for distribution worldwide. Fill-finish services for our COVID-19 vaccine are provided by Catalent Inc., Thermo Fisher Scientific, Sanofi and Baxter BioPharma Solutions in the United States, and by ROVI (in Spain), Recipharm (in France) and Samsung Biologics (in Republic of Korea) outside the United States. We have also partnered with other CMOs for the production of and fill-finish services of our COVID-19 vaccine, and expect that we will enter into additional collaborations as we continue to scale. In April 2021, we announced additional investments in manufacturing to increase supply at our owned and partnered manufacturing facilities, with the goal of increasing our global 2022 capacity for COVID-19 vaccine production. In May 2021, we announced the planned expansion of the MTC, which we expect to more than double the space at the MTC and allow us to continue to optimize our mRNA products as we explore new pharmaceutical delivery forms such as prefilled syringes and lyophilized products. Additionally, in February 2022, we announced new collaborations with ROVI and Thermo Fisher Scientific (Thermo Fisher) for manufacturing capabilities. With ROVI, we agreed to a ten-year collaboration to increase manufacturing capacity at ROVI's facilities in Spain. In addition to producing our COVID-19 vaccine, we expect that ROVI's platform may be utilized to service other vaccine candidates in the future. With Thermo Fisher, we agreed to a fifteen-year collaboration to enable dedicated large-scale manufacturing in the United States of our COVID-19 vaccine and other investigational mRNA medicines in our pipeline In addition, during 2021 we announced agreements in principle with the governments of Canada and Australia to establish mRNA manufacturing facilities in those countries. These agreements are subject to final negotiation, but we envision entering into long-term supply agreements with these countries for the supply of mRNA vaccines. By establishing manufacturing facilities locally, we will also provide these governments with direct access to rapid pandemic response capabilities. We are in active discussions with other governments to provide similar manufacturing capabilities in other geographies.... We have further committed to building a state-of-the-art mRNA facility in Africa to provide a local source of mRNA medicines for the continent, in part to prepare for future pandemics. We expect to invest up to \$500 million in this facility and anticipate that once fully operational, it will be capable of producing up to 500 million doses of vaccines annually at the 50 µg dose level." (2022 Form 10-K, above note 188, at p. 33)

193 Moderna_Lonza, *Global Long Term Agreement*. 2020. www.sec.gov/Archives/edgar/data/1682852/000168285220000023/lonzamodernagltafullye.htm GLTA

194 GLTA, "MODERNA Manufacturing Know-How" means Know-How Controlled by MODERNA or its Affiliates which is maintained in confidence by MODERNA or its Affiliates, relating to the manufacturing of a given Product, including documentation constituting material support, performance advice, shop practice, specifications as to materials to be used, control methods, standard operating procedures, protocols, descriptions of the manufacturing process and related know how, development reports, analytical methods, equipment size/name/customizations/components, validation reports, cleaning methods and batch records and any other information, in each case, that is (a) necessary or reasonably useful to manufacture such Product in accordance with the applicable Specifications or (b) disclosed to LONZA or its Affiliates by or on behalf of MODERNA or its Affiliates in connection with this Agreement, including any Statement of Work."

195 Id., "Technology" means all patents, patent applications, inventions, trade secrets, copyrights, know-how, methods, processes, techniques, improvements, data, technical documentation, manuals, regulatory submissions, specifications, SOPs, instructions, and other intellectual property of any kind (whether or not protected or protectable under patent, trademark, copyright or similar laws)."

196 Id., at 1.b.

The parties agree to maintain information exchanged under the agreement in confidence.¹⁹⁷

Lonza's basic responsibilities include assuring that the vaccine products are produced in accordance with good manufacturing practices (cGMP), that the regulatory approvals necessary for undertaking manufacturing are complied with, and that the products are produced pursuant to the agreed timetable. Lonza is responsible for securing materials that are not specifically proprietary to Moderna.

The parties make clear that it is not their intention that either acquires an ownership interest in the technology of the other.¹⁹⁸

iv. Moderna's policy statements regarding intellectual property¹⁹⁹, non-assertion pledges²⁰⁰ and access²⁰¹

Moderna and other vaccine manufacturers based in high income countries, and particularly in the United States, faced substantial pressure to address the apparent inequity of allocating supplies to a single country, or a small group of countries, before extending supplies to LMICs and international supplier groups such as COVAX. Part of that pressure manifested itself in proposals from LMICs to waive rights and patents and other intellectual property so as to permit manufacturing by third parties in these countries. In response to these pressures,

197 *Id.*, Definition. "'Confidential Information' means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, specifications, data, results and other material, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, and any tangible embodiments of any of the foregoing, and any scientific, manufacturing, marketing and business plans, any financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business, that has been disclosed by or on behalf of such Party or such Party's Affiliates to the other Party or the other Party's Affiliates either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement."

198 *Id.*, "INTELLECTUAL PROPERTY... Ownership... i. Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Technology of the other Party. Except as expressly otherwise provided herein, ownership of any Technology that is developed, conceived, invented, first reduced to practice or made in connection with the performance under this Agreement shall follow inventorship all as determined under Applicable Laws. ii. Subject to LONZA's right, title and interest in and to any and all LONZA Improvements, MODERNA shall own all right, title, and interest in and to any and all MODERNA Improvements. LONZA hereby assigns to MODERNA (or its designee), without additional compensation, all of LONZA's right, title and interest in and to such MODERNA Improvements. LONZA shall promptly disclose to MODERNA in writing all MODERNA Improvements. LONZA shall execute, and shall require its personnel as well as its Affiliates, or other contractors or agents and their personnel involved in the performance of this Agreement to execute, any documents reasonably required to confirm MODERNA's ownership of MODERNA Improvements, and any documents required to apply for, maintain and enforce any patent or other right in the MODERNA Improvements. Notwithstanding the foregoing, and subject to the license granted in Section 11.2.2, LONZA shall own all right, title and interest in and to any and all LONZA Improvements.... a. License Grants... i. During the Term, MODERNA hereby grants to LONZA a fully paid-up, non-exclusive license, without the right to grant sublicenses, under any and all MODERNA Technology, MODERNA Manufacturing Know-How, and MODERNA Improvements that are necessary for LONZA to perform its obligations under this Agreement for the sole and limited purpose of LONZA's performance of its obligations under this Agreement and the relevant Statements of Work, including, without limitation, the development of the Process (if and to the extent applicable in the relevant Statements of Work) and the Manufacture of Product for MODERNA as set forth in the relevant Statements of Work. Except as set forth in this Section 11.2.1, LONZA shall not by virtue of this Agreement acquire any right, license or title in or to any MODERNA Technology, MODERNA Manufacturing Know-How, MODERNA Improvements, Products or Process.... ii. LONZA hereby grants to MODERNA a non-exclusive, world-wide, fully paid-up, perpetual, transferable (subject to the assignment provisions) license, including the right to grant sublicenses, under the LONZA Technology and LONZA Improvements, to use, sell, offer to sell, import and export the Product Manufactured under this Agreement, including any Statement of Work. ... c. Prosecution of Patents... i. LONZA will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming LONZA Technology or LONZA Improvements at LONZA's expense... ii. MODERNA will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming MODERNA Technology or MODERNA Improvements at MODERNA's expense. LONZA will cooperate with MODERNA to file, prosecute and maintain patent applications and patents claiming MODERNA Technology or MODERNA Improvements."

199 Moderna. *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic*. 2020 [October 8, 2020]; Available from: https://s29.q4cdn.com/435878511/files/doc_news/2020/10/08/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic.pdf.

200 Moderna. *Moderna's Updated Patent Pledge*. 2022 March 7, 2022]; Available from: https://s29.q4cdn.com/435878511/files/doc_news/2022/03/07/Moderna-Patent-Pledge_7-March_Final.pdf.

201 Moderna. *Global Access to COVID-19 Vaccines*. 2022 April 28, 2022]; Available from: https://s29.q4cdn.com/435878511/files/doc_news/2022/04/Access-Statement_4.28_817am.pdf.

Moderna issued a general policy statement regarding access to vaccines during the pandemic, as well as making specific pledges regarding non-assertion of patents in infringement actions.²⁰²

While the publicly available texts of licensing agreements entered into by Moderna generally redact the patent identification numbers, Moderna has provided at least an illustrative list of those patents. As noted in the above quoted statement, Moderna has made available on its corporate website a list of representative patents that it claims are relevant to its Spikevax vaccine.²⁰³ Because the list is not said to be “comprehensive,” there likely are additional patents that need to be examined by third parties in order to establish freedom to operate. However, the 10 patents listed on its website should provide a useful roadmap to third parties to the extent that patent applications often cross-reference related patents that may be relevant.

VaxPal identifies at least 18 patents relevant to SpikeVax, although only three applications post-date the emergence of SARS-COV-2, and the applicant on one of those is Acuitas.²⁰⁴

More generally, Moderna has responded to criticism of its product allocation decisions with an explanation that relies in part on the difficulties at LMICs confront in effectively using vaccines that require deep cold chain storage (see note 201).²⁰⁵

v. Supply agreements

1. The European Union

On December 4, 2020, the European Union (through the Commission) concluded an Advanced Purchase Agreement with Moderna for 80 million doses, with an option for an additional 80 million doses. The purchase obligation was conditional on Moderna’s vaccine being approved by the EMA, and approval which took place on January 6, 2021.²⁰⁶ EMA data shows the vaccine

202 “As the pandemic surged in October 2020, we voluntarily committed that, ‘while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic’ At that time, as a biotech company still working to develop its first commercial products, we understood that our portfolio of intellectual property was – and still is – an important asset[1] [fn 1: A summary of our intellectual property can be found here. A selection of representative issued U.S. patents relevant to our mRNA-1273 vaccine against COVID-19 is available here.] that allowed us to attract investment. Such private investment made our mRNA technology possible. Further, that very intellectual property and associated rights protect and enhance our ability to continue to develop innovative medicines. Nevertheless, we felt and continue to believe that we have a special obligation to remove any perceived impediments created by our intellectual property rights so that the world could be vaccinated during the pandemic. That is why we have also licensed our patents to several manufacturing partners and raised more than \$1.9 billion in private capital to scale up our manufacturing capacity so that we can now make billions of doses of our vaccine each year.... To underscore our commitment to low-and middle-income countries, Moderna is now updating our patent pledge to never enforce our patents for COVID-19 vaccines against companies manufacturing in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries. ... In non-AMC 92 countries, vaccine supply is no longer a barrier to access. In these countries, the Company expects those using Moderna-patented technologies will respect the Company’s intellectual property. Moderna remains willing to license its technology for COVID-19 vaccines to manufacturers in these countries on commercially reasonable terms. Doing so enables Moderna to continue to invest in research to develop new vaccines, prepare for the next pandemic, and meet other pressing areas of unmet medical need.” Moderna’s Updated Patent Pledge, above note 200.

203 Moderna. *Moderna’s Patents and pending patent applications*. 2023; Available from: www.modernatx.com/en-US/patents/

204 From the Espacenet database: 1. WO2021030701 (A1) - IMPROVED LIPID NANOPARTICLES FOR DELIVERY OF NUCLEIC ACIDS; applicant ACUITAS THERAPEUTICS INC [CA] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210218&CC=WO&NR=2021030701A1&KC=A1; 2. WO2021154763 (A1) - CORONAVIRUS RNA VACCINES; applicant MODERNATX INC [US] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210805&CC=WO&NR=2021154763A1&KC=A1; 3. WO2021262909 (A3) - LNP COMPOSITIONS COMPRISING MRNA THERAPEUTICS WITH EXTENDED HALF-LIFE; applicant MODERNATX INC [US] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20220421&CC=WO&NR=2021262909A3&KC=A3 - See VaxPal for further details: www.vaxpal.org/?keywords=Moderna&page=1

205 Saying, among other things: “Beginning in the summer of 2020, the Moderna team was engaged with Gavi, the Vaccine Alliance, on behalf of the COVAX Facility, hoping to secure a commitment from them to procure a significant number of Moderna COVID-19 vaccines. An agreement was not reached until April 2021, though we were pleased to commit up to 500 million doses to COVAX – a number that was subsequently increased to 650 million doses. Similarly, we were proud to reach an agreement with the African Union to supply 110 million doses, which we were prepared to start delivering as early as the fourth quarter of 2021. In each case, we offered these vaccines at our lowest price, and in the latest agreements the price for each of these organizations was \$7 per 100 µg dose.... Despite our efforts, ultimately COVAX and the African Union deferred or declined hundreds of millions of doses of Moderna’s vaccine. While we were prepared to deliver tens of millions of doses to the African Union in December 2021, they asked us to delay delivery, noting that they did not have the means of distributing them. They also declined to exercise an option for 60 million doses that were available to them in the second quarter of this year. Moderna Global Access, above note 201.

206 European_Medicines_Agency, *Spikevax (previously COVID-19 Vaccine Moderna)*. 2023. www.ema.europa.eu/en/medicines/human/EPAR/spikevax

had proven to be highly efficacious.²⁰⁷ The European Union agreed to pay USD 22.50 per dose, including a non-refundable down payment of USD 360 million (recoverable on purchase, and unspent amounts potentially recoverable depending on grounds of termination).²⁰⁸ The total price for 80 million doses would be USD 1.8 billion.²⁰⁹ The EU would not obtain any rights in Moderna intellectual property,²¹⁰ although Moderna warranted that it had rights to the intellectual property used in the vaccine.²¹¹ The vaccines were for delivery within the EU and EEA area, although they might be exported outside Europe for donation with the consent of Moderna, or resold for delivery within Europe with the consent of Moderna.²¹² The EU agreed to indemnify Moderna for claims arising out of delivery and use of the vaccine, except in the case of willful misconduct, gross negligence, or failure to comply with good manufacturing practice.²¹³ In an annex to the agreement, the parties indicate that Moderna plans to engage ROVI, a Spanish manufacturer, to perform fill and finish services intended to supply markets in Europe and other markets outside of the US.²¹⁴ It also notes that Moderna has engaged Lonza, based in Switzerland, as its contract manufacturing partner to which Moderna made a substantial upfront financial commitment to assure capacity.

On March 1, 2021, the European Union (through the Commission) entered into an additional Purchase Agreement with Moderna to secure 150 million doses of the vaccine, with an option for another 150 million doses.²¹⁵ The price is redacted from the publicly available version of the agreement. As with the earlier Advanced Purchase Agreement, Moderna retains all intellectual property in the vaccines.²¹⁶ Reporting indicates that the EU also reserved the rights to donate doses to LMICs.²¹⁷

2. UNICEF and COVAX

Moderna has been subject to criticism for prioritizing vaccine supplies to high income countries while allocating a small portion of it supplies to LMICs.²¹⁸ That criticism includes charging prices to LMICs as high or higher than the prices charged to high income countries. In April 2022, Moderna was reported to have delivered only eight percent of doses that had been ordered by LMICs, and to have donated 14 percent of its production.²¹⁹ Precise data is difficult to come by, but as of October 17, 2022, Moderna reported that it had supplied through Gavi nearly 70 million doses of its vaccine to COVAX Advanced Market Commitment (AMC) low and middle income countries “in addition to the Company facilitating the donation of more than 100 million doses to these countries.” As of that date in 2022, Gavi and Moderna agreed to cancel an existing supply agreement and to put in place a new agreement pursuant to which Gavi could purchase up to 100 million doses of variant specific vaccines in 2023, “with all doses offered at Moderna’s lowest-tiered price.”²²⁰ UNICEF’s data compilation shows Moderna’s prices to COVAX as low as

207 EMA Information Sheet: “... the vaccine demonstrated a 94.1% efficacy in the trial. The trial also showed 90.9% efficacy in participants at risk of severe COVID-19, including those with chronic lung disease, heart disease, obesity, liver disease, diabetes or HIV infection.” (European Medicines Agency 2023)

208 Commission-Moderna, Advance Purchase Agreement, Dec. 4, 2020, e.g., Section I.4.2; Section II.19.1.

209 The vaccines would be subject to apportionment among the EU member states based on internal decisions regarding allocation. Member states would provide purchase orders.

210 Commission-Moderna 2020, Section I.10: “The Commission and the Participating Member States acknowledge and agree that the contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the ‘Vaccine IP Rights’). The contractor shall be entitled to exclusively exploit the results of the APA and any such Vaccine IP Rights. Except as expressly set forth in this APA, the contractor does not grant to the Commission or any of the Participating Member States by implication, estoppel or otherwise, any right, title, license or interest in or to the results of the APA, the Vaccine IP Rights or the contractor’s Pre-existing rights. All rights not expressly granted by the contractor hereunder are reserved by the contractor.”

211 Id., Section II.12.

212 Id., Section I.4.6.

213 Id., Section II.5.1.

214 Id., Annex IV: Description of the Contractor’s Intended Utilization of the Down Payment.

215 European Commission-Moderna, *Purchase Agreement*. 2021. https://paginaum.pt/wp-content/uploads/2023/01/SANTE_2021_C3_010.pdf

216 Id., Purchase Agreement, Section I.10.

217 Staff, *EU concludes discussions with Moderna for COVID-19 vaccine*. PMLive, 2020. DOI: 1347308. www.pmlive.com/pharma_news/eu_concludes_discussions_with_moderna_for_covid-19_vaccine_1347308

218 Robbins, R., *Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor*, *NY Times*. Oct. 9, 2021, updated Nov. 9, 2021. www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html

219 Dangor, G. *Moderna And Pfizer Have Fulfilled Slim Share Of Covid-19 Vaccine Orders From Lower Income Countries*. *Forbes*, updated Apr. 21, 2022. www.forbes.com/sites/graisondangor/2021/10/09/moderna-and-pfizer-have-fulfilled-slim-share-of-covid-19-vaccine-orders-from-lower-income-countries/

220 Gavi_media_relations, *Gavi, Moderna update COVAX supply agreement; agree on access to variant-containing vaccines for lower-income countries*. 2022. www.gavi.org/news/media-room/gavi-moderna-update-covax-supply-agreement-agree-access-variant-containing-vaccines

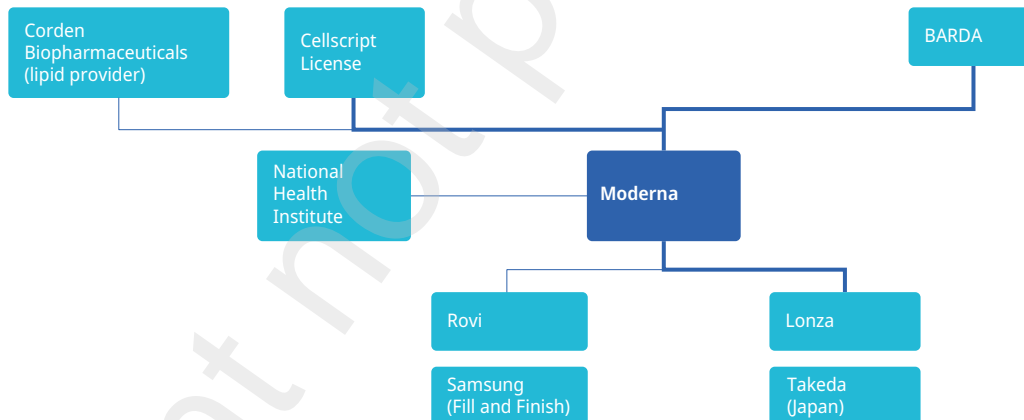
USD 7 per dose in 2022, and otherwise at USD 10 per dose to COVAX.²²¹ The same table shows prices of USD 28.88 per dose to Botswana, USD 21.50 to Argentina and USD 40 to Kuwait.

vi. Litigation

Moderna is engaged in significant litigation with respect to allegations that it infringed the patents of developers of technologies used in its vaccine. It has sued Pfizer for infringing what it claims are patents on the basic underlying technology of its mRNA vaccines, or at least the specific components in Spikevax.²²² Pfizer has pointed out in its reply and counterclaim and counterclaim that it is somewhat difficult to explain Moderna's failure to reference the predecessor Cellscript licensed patents and their inventors in light of (as noted above) Moderna's substantial payment of licensing fees to Cellscript.²²³ Moderna and Pfizer are also battling over LNP patents.²²⁴

Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") have sued Moderna for patent infringement based on their asserted patents on LNP technology.²²⁵ Moderna attempted to defend by asserting that the parties had improperly sued Moderna in federal district court as opposed to the Federal Court of Claims which hears suits regarding claims for compensation based on 28 USC §1498 that precludes suits for injunction for US government use of patents, directing claims to compensatory actions. Moderna asserts that it acted as a government contractor/supplier and is therefore immune from suit for infringement. The District Court judge in Delaware in November 2022 rejected Moderna's request to deny jurisdiction pending full adjudication of the merits of that assertion.²²⁶ The US government in February 2023 filed a brief in the case supporting Moderna's position by confirming that the company was acting for the government under its contract.²²⁷ It is not yet clear how Moderna would intend to approach the question of party liability if a suit was removed to the Court of Claims which at the present time the ordinary federal trial court has not allowed.

Moderna mapping



Summary: Moderna

- Moderna receives major Warp Speed funding for development and advanced purchase
- Prior R&D with mRNA, but also in-licensing nucleobase substitution from UPenn/Cellscript (paid more than USD 600 million to Upenn + NIH/Scripts settlement)
- Litigation re: source of LNP technology

²²¹ UNICEF, *Moderna Pricing*, 2023. www.unicef.org/supply/covid-19-market-dashboard

²²² *ModernaTX, Inc. et al v. Pfizer Inc. et al*, United States District Court for the District of Massachusetts. Case 1:22-cv-11378-RGS, filed Aug. 26, 2022 (D. Mass).

²²³ See Pfizer Reply, paras. 7-10, id., filed Dec. 5, 2022.

²²⁴ E.g., id., paras 11-12.

²²⁵ *Arbutus Biopharma Corporation et al v. Moderna, Inc. et al*. Case 1:22-cv-00252-UNA, filed Feb. 28, 2022 (D. Del.)

²²⁶ Bultman, M. *Moderna Must Face Patent Claims Over US Government Vaccine Sales*. 2022 Nov. 2, 2022; Available from: www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X66THF2K000000?bna_news_filter=health-law-and-business#jcite.

²²⁷ Yasiejko, C. *US Says It Must Be Target of Moderna Covid-Vaccine Patent Case*. Bloomberg Law News, 2023. www.bloomberglaw.com/bloomberglawnews/ip-law/XD849G4C000000?bwid=00000186-5637-d5e5-afae-de7763f60001&cti=LSC&emc=bipnw_nl%3A3&et=NEWSLETTER&isAlert=false&item=read-text&qid=7422437®ion=digest&source=newsletter&uc=1320042232&udvType=Alert&usertype=External.

- Enters into contract manufacturing agreement with Lonza (US and Europe) (CMO)
- Major advance purchase agreement with EU
- Retains IP both with US government (Bayh-Dole) and subcontractors, EU
- Vaccine proves highly efficacious and safe (Spikevax)
- Ultra-cold storage requirement
- Moderna issues “no patent enforcement” pledge
- Moderna does not have LMIC concessionary pricing policy
- Moderna delivers small part of production to COVAX-LMICs
- Moderna refuses to provide assistance to Biovac/Afrigen
- Announces plan for African manufacturing

3. AstraZeneca-Oxford

The AstraZeneca-Oxford, Vaxzevria (proprietary), COVID-19 Vaccine 9ChAdOx1-S (recombinant) (INN), AZD1222, appears to have been used in the largest number of countries.

Researchers at Oxford University rapidly developed a modified simian adenovirus vaccine following release of genomic sequence data from the PRC. It appears that the technology is covered by one or more patents.

Oxford University operates through an internal licensing department in connection with offshoots that permit the faculty to license technology to startup companies, and otherwise to obtain patent rights. After University researchers had created a vaccine candidate based on previous research regarding modified adenovirus vaccines, those researchers and their Oxford based spinoff company attempted to move the product to the conduct of clinical trials, to the development of manufacturing processes (both of smaller and larger scale) and into the manufacture of batches. However, it appeared that the resources necessary for large-scale production would be difficult to assemble, and the researchers were persuaded by some of their funding sources to collaborate with a major integrated vaccine manufacturer, which ultimately turned out to be AstraZeneca.^{228, 229, 230, 231, 232, 233}

Oxford University and AstraZeneca entered into a Research Collaboration and Exclusive Worldwide Patent and Know-How License for a COVID-19 vaccine on May 17, 2020.²³⁴ As the title suggests, pursuant to this Collaboration Agreement, Oxford granted to AstraZeneca an exclusive worldwide license on its patent portfolio related to the vaccine candidate it had developed, as well as with respect to related know-how. The agreement refers to the intention of the parties that favorable access terms will be made available for developing countries (as defined by reference to a Gavi vaccine alliance 2019 list), and that further discussions will take place regarding access with CEPI,²³⁵ but there are no firm commitments in the Collaboration Agreement.²³⁶ Oxford will remain responsible for at least some additional parts of the clinical

228 Jenner_Institute_Media_Relations. *Development of the ChAdOx vaccine platform – The Jenner Institute*. [Web Page] 2022 2022-08-11T09:01:05+00:00; Available from: www.jenner.ac.uk/about/the-oxford-astrazeneca-covid-19-vaccine/ChAdOx-platform.

229 Jenner_Institute_Media_Relations. *Clinical trials – The Jenner Institute*. [Web Page] 2022 2022-08-11T09:00:37+00:00; Available from: www.jenner.ac.uk/about/the-oxford-astrazeneca-covid-19-vaccine/clinical-trials.

230 Jenner_Institute_Media_Relations. *Manufacturing a COVID-19 vaccine mockup*. 2022; Available from: www.cbf.ox.ac.uk/our-involvement-in-manufacturing-a-covid-19-vaccine/manufacturing-a-covid-19-vaccine-mockup.

231 Jenner_Institute_Media_Relations. *Large-scale manufacturing and industry partnerships – The Jenner Institute*. [Web Page] 2022 2022-07-15T14:16:20+00:00; Available from: www.jenner.ac.uk/about/the-oxford-astrazeneca-covid-19-vaccine/large-scale-manufacturing.

232 Garrison, C. *How the “Oxford” Covid-19 vaccine became the “AstraZeneca” Covid-19 vaccine | Medicines Law & Policy*. 2020. <https://medicineslawandpolicy.org/2020/10/how-the-oxford-covid-19-vaccine-became-the-astrazeneca-covid-19-vaccine/>.

233 Erin Banco, A.F.L.P., *How Bill Gates and partners used their clout to control the global Covid response – with little oversight*, in *Politico*. 2022. www.politico.com/news/2022/09/14/global-covid-pandemic-response-bill-gates-partners-00053969.

234 Oxford-University-AstraZeneca, *Research Collaboration and Exclusive Worldwide Patent And Know-How Licence for ChAdOx nCoV-19 Vaccine Against SARS-CoV-2*. 2020. Oxford-AZ Collaboration Agreement. www.whatdotheyknow.com/request/668542/response/1802897/attach/3/Oxford%20AZ%20Covid19%20Vaccine%20Licence%20Redacted%20Version%20FINAL.pdf?cookie_passthrough=1.

235 Oxford-AZ. Collaboration Agreement, Section 1.22.

236 Id. “Section 2.3 The Parties have a strong desire for any vaccine against SARS-CoV-2 in humans developed pursuant to this Agreement to be a positive component in the global response to the SARS CoV-2 pandemic. As such, AstraZeneca intends to participate in good faith in the global efforts to meet global demand for manufacture and supply of such vaccine. 2.4 The Parties agree that it will be necessary for both Parties to participate in negotiations and discussions with CEPI to help finalise arrangements regarding funding and global access to the Licensed Product and so both Parties shall participate accordingly.”

trials, and will assist AstraZeneca with others.²³⁷ While Oxford will be granting AstraZeneca an exclusive license with respect to its patents and know-how, the parties will continue to own their own IP save for any which is jointly developed under the Collaboration, which IP rights they will share as joint tenants.²³⁸ The commercial terms of the license are redacted from the publicly available version, but it is reported that Oxford will not earn royalties during the course of the pandemic, but will be paid royalties thereafter (through an affiliated entity).^{239, 240, 241}

The Collaboration Agreement effectively turns over decision-making and distribution to AstraZeneca. Among other things, AstraZeneca received a major development and purchase commitment from the US government, and it was initially perceived as a front runner in the race to establish large-scale vaccine supply.

Mistakes were made.^{242, 243, 244} An initial vaccine production run by AstraZeneca's contract manufacturer produced a batch of products for which the potency was difficult to determine, and clinical trials were conducted using a half dose vaccine candidate. Efficacy results were not comparable to the mRNA vaccines under development by Pfizer and Moderna. Subsequently, it appeared that better efficacy of the AstraZeneca vaccine was achieved by using an initial half dose, followed by a full dose, a result that was difficult to explain. As a consequence, US FDA approval under an emergency use authorization was continuously delayed. At the same time, regulatory authorities outside the United States approved the vaccine for human use, and it moved into large-scale production. The largest quantities were produced by the licensee Serum Institute of India, and the vaccine became the foundation of India's vaccination program. Ultimately, the AstraZeneca vaccine was very widely used.

i. In-licensing

Oxford University maintains a large patent portfolio based on research conducted within its various scientific institutes.²⁴⁵ The modified adenovirus COVID-19 vaccine candidate developed by researchers within Oxford University relied on patents previously secured with respect to modified adenovirus platforms. It appears that the relevant holding company for patents relevant to AZD1222 is Vaccitech, which was formed at the initiative of two Oxford researchers, and which in-licensed the foundational adenovirus IP portfolio from Oxford University Innovation Ltd. (OUI).

The VaxPal database identifies 2 patents relevant to the AZD1222 vaccine, neither of which post-dates the emergence of SARS-CoV-2.²⁴⁶

²³⁷ Id., Section 3.

²³⁸ Id., "17.7 Any Joint Activities IP shall be owned by the Parties as tenants in common in equal undivided Shares ... 17.8 To the extent Clause 17. 7 does not of itself cause the Joint Activities IP to be co-owned by the Parties as tenants in common in equal undivided shares, the Parties shall without charge, execute such documents and do such other things as may be necessary or desirable to vest the Joint Activities IP in the joint names of the Parties as tenants in common in equal undivided shares....17.9 Subject to the licences granted under this Agreement, each Party shall be entitled to exploit and to license third parties to exploit the Joint Activities IP with or without the consent of the other Party."

²³⁹ Research has not uncovered the royalty rate.

²⁴⁰ Hancock, Jay. *Oxford's COVID vaccine deal with AstraZeneca raises concerns about access and pricing*. 2020. <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>.

²⁴¹ Strasburg, J., *If Oxford's Covid-19 Vaccine Succeeds, Layers of Private Investors Could Profit*, in *Wall St. J.* 2020. www.wsj.com/articles/if-oxfords-covid-19-vaccine-succeeds-layers-of-private-investors-could-profit-11596373722.

²⁴² See, e.g., Robert Fortner, *AstraZeneca's COVID-19 (mis)adventure and the future of vaccine equity*, *BMJ* 2022;379:o2592, <http://dx.doi.org/10.1136/bmj.o2592>, November 11, 2022.

²⁴³ Rebecca Robbins, Sharon LaFraniere, Noah Weiland, David D. Kirkpatrick and Benjamin Mueller, *Blunders Eroded U.S. Confidence in Early Vaccine Front-Runner*, in *New York Times*. 2021. www.nytimes.com/2020/12/08/business/covid-vaccine-oxford-astrazeneca.html.

²⁴⁴ Fortner, R., *AstraZeneca's covid-19 (mis)adventure and the future of vaccine equity*. *BMJ*, 2022; p. 379:o2592. <http://dx.doi.org/10.1136/bmj.o2592>.

²⁴⁵ It generally holds and manages these patents through an entity known as Oxford University Innovation Ltd. (OUI). Oxford University researchers may file for and secure patents through OUI, which will then license those patents to entities the researchers establish (i.e. spinoff companies). The details of the various arrangements are difficult to sort through as individual patents may be relevant to multiple ventures, and ownership of spinoff companies may vary. Those patents were "in-licensed" from an entity previously established by Oxford University researchers (with minority shareholder stakes), along with Oxford Sciences Innovation (OSI) – a related venture capital firm – and various private and state-owned investment firms.

²⁴⁶ From Espacenet database: 1. WO2012172277 (A4) - SIMIAN ADENOVIRUS AND HYBRID ADENOVIRAL VECTORS; applicants ISIS INNOVATION[GB]; DICKS MATTHEW DOUGLAS JAMES [GB]; COTTINGHAM MATTHEW GUY[GB]; HILL ADRIAN VIVIAN SINTON[GB]; GILBERT SARAH[GB] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20130404&CC=WO&NR=2012172277A4&KC=A4; 2. WO2020043869 (A3) - METHODS AND COMPOSITIONS FOR PRODUCING A VIRUS, applicant UNIV OXFORD INNOVATION LTD[GB] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20200409&CC=WO&NR=2020043869A3&KC=A3 - See VaxPal for further details: www.vaxpal.org/?keywords=AstraZeneca&page=1.

The Oxford researchers who founded Vaccitech initially sought to pursue the development and production of what became AZD1222 through nonexclusive not-for-profit internal development and licensing. But, as previously noted, they were persuaded to grant AstraZeneca an exclusive worldwide license for their patents and know-how. The terms and conditions of the licensing between Vaccitech and OUI, and thereafter to AstraZeneca, have not been publicly disclosed, and the lack of transparency has been the subject of heavy criticism from public interest groups. However, it is widely reported that royalties on the patent portfolio will not be paid by sublicensees producing and distributing AZD1222 “during the pandemic.” It is not known how the existence of the pandemic is defined in the licensing agreement(s).²⁴⁷ Part of the public interest criticism is directed toward the prospect that Vaccitech and Oxford may earn substantial revenues from their patents if and when AZD1222 is produced and distributed once the pandemic is considered over.

Oxford and its related institutes are dependent on CEPI, the Gates Foundation, and the Wellcome Trust, for ongoing funding of their research initiatives, and the access policies of those groups help to shape the downstream relationship with the Serum Institute in India, which was the primary producer of the AstraZeneca vaccine. The Serum Institute claimed to be operating on a not-for-profit basis during the pandemic with respect to production of the vaccine.

ii. Serum Institute of India

In June 2020 it was announced that AstraZeneca and the Serum Institute of India (SII) had reached agreement to supply 1 billion doses of AZD1222 (“Covishield” in India) to LMICs, including India.^{248, 249, 250} The quantity figure in the announcement may have been premature as in September 2020, the SII announced that a total of 200 million doses, plus potentially an additional 100 million doses, were agreed to be delivered in 2021 at a maximum price of USD 3 per dose.²⁵¹

SII was forced to halt clinical trials of AZD1222 in September 2020 when concerns had been raised, initially in Europe, about the safety of its vaccine trials.²⁵² Subsequently, COVAX was unable to secure deliveries of the vaccine when India banned the export of domestically produced vaccines as its internal demands were strained by the pandemic.²⁵³ Finally, SII halted production of AZD1222 and destroyed between 100 and 200 million doses when demand fell precipitously (among other things, because of concerns that it was not effective against Omicron).²⁵⁴ In the final analysis, it is difficult to report a robust figure regarding how many doses of AZD1222 were produced by SII, and of those doses how many were exported. In late November 2021, SII said “Total number of COVISHIELD doses produced now surpasses 1.25bn mark” (see note 253). As of February 10, 2022, AstraZeneca reported that 2.5 billion doses of its

247 A paper by Christopher Garrison on behalf of Medicines Law and Policy provides extensive details regarding what is and is not known about the licensing arrangements. (Garrison, above note 232, 2020)

248 AstraZeneca Press Release June 4, 2020: “Agreements with CEPI and Gavi and the Serum Institute of India will bring vaccine to low and middle-income countries and beyond Global supply capacity to exceed two billion doses AstraZeneca has taken the next steps in its commitment to broad and equitable global access to the University of Oxford’s COVID-19 vaccine, following landmark agreements with the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance, and the Serum Institute of India (SII).... The Company today reached a \$750m agreement with CEPI and Gavi to support the manufacturing, procurement and distribution of 300 million doses of the vaccine, with delivery starting by the end of the year. In addition, AstraZeneca reached a licensing agreement with SII to supply one billion doses for low and middle-income countries, with a commitment to provide 400 million before the end of 2020.... AstraZeneca recently agreed to supply 400 million doses to the US and United Kingdom after reaching a licence agreement with Oxford University for its recombinant adenovirus vaccine, formerly ChAdOx1 nCoV-19 and now known as AZD1222.”

249 Rajagopal, D. *AstraZeneca & Serum Institute of India sign licensing deal for 1 billion doses of Oxford vaccine*. 2020; Available from: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/astrazeneca-serum-institute-of-india-sign-licensing-deal-for-1-billion-doses-of-oxford-vaccine/articleshow/76202016.cms>.

250 AstraZeneca media relations, *AstraZeneca takes next steps towards broad and equitable access to Oxford University’s COVID-19 vaccine*. 2020. www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html.

251 Serum_Institute_Media_Relations, *Serum Institute of India to Produce up to an Additional 100 Million COVID-19 Vaccine Doses for India and Low- and Middle-Income Countries in 2021*. 2020. www.seruminstitute.com/news_sii_gavi_bmgf.php.

252 Staff, *Serum Institute of India gets DCGI nod to resume clinical trial of Oxford Covid-19 vaccine*, in *Times of India*. 2020. <https://timesofindia.indiatimes.com/india/serum-institute-of-india-gets-dcgi-nod-to-resume-clinical-trial-of-oxford-covid-19-vaccine/articleshow/78136760.cms>

253 Serum_Institute_Media_Relations, *Serum Institute of India (SII) re-starts COVAX exports; passes 1 billion COVISHIELD dose milestone*. 2021. www.seruminstitute.com/press_release_sii_261121.php.

254 Liu, A. *With 200M unused doses, AstraZeneca’s COVID vaccine partner Serum Institute halts production*. 2022. www.fiercepharma.com/pharma/200m-unused-doses-astrazenecas-covid-vaccine-partner-serum-institute-halts-production.

vaccine had been released for supply around the world, but that figure does not break out the quantity produced by SII.²⁵⁵

iii. European Union

On August 27, 2020, the European Commission on behalf of the European Union entered into an Advance Purchase Agreement (APA) with AstraZeneca.^{256, 257} This agreement was entered into before clinical trials or regulatory approval for AZD1222 were completed, and the agreement is drafted in a contingent manner depending on AstraZeneca success in completing the approval process, and relieving AstraZeneca of liability in the event regulatory approval was not forthcoming. The agreement provides that AstraZeneca will use its “best reasonable efforts” to manufacture the vaccine at sites within the EU (which for purposes of the agreement only includes the United Kingdom).²⁵⁸ The agreement says that the estimated cost of that at the time of contracting is EUR 870 million for the initial EU doses.²⁵⁹ The agreement further provides that the price of the initial 300 million doses will be EUR 2.9 per dose, subject to adjustment based on actual costs.²⁶⁰ If it turns out there are excess doses for a participating member state, it reserves the possibility to donate them to LMICs or public institutions, or to resell to other European countries that no profit. The participating member states may also resell to non-EU member states at no profit. AstraZeneca is required to secure regulatory approval for its vaccine. The agreement provides that all relevant IP is and will remain the property of AstraZeneca.²⁶¹

The provision on intellectual property further provides that if AstraZeneca abandons its vaccine project, that AstraZeneca will provide a license allowing third party to carry out development and distribution.²⁶² Each party has the right to terminate the agreement in the event clinical trials in development are unsuccessful, which in the case of AstraZeneca would require it to return “unspent” funding. The agreement includes an indemnification provision that requires the participating member states to indemnify AstraZeneca and all its related parties from any damages or liability resulting from performance of the agreement or use of the vaccine, unless such losses are the result of “willful misconduct,” or a finding of a competent court that AstraZeneca failed to comply with cGMP or EMA pharmacovigilance regulations.²⁶³ In the same vein, the agreement waives any liability on the part of AstraZeneca should the vaccine lacked safety or efficacy, provided that AstraZeneca has complied with relevant regulatory requirements.²⁶⁴ The parties are generally obligated to keep information confidential.²⁶⁵

Controversies subsequently suddenly arose within the EU regarding allocation of vaccine supplies, prompted in part by AstraZeneca’s failure to deliver doses on the schedule that had

255 AstraZeneca_media_relations, *Full-year and Q4 2021 results*. 2022. www.astrazeneca.com/media-centre/press-releases/2022/full-year-2021-and-q4-results.html.

256 AstraZeneca, E.C.-*Advance Purchase Agreement*. 2020. Commission-AZ APA. www.rai.it/dl/doc/2021/02/19/1613725900577_AZ_FIRMATO_REPORT.pdf.

257 The APA is characterized as an agreement entered into by the EU on behalf of participating member states that ultimately will have responsibility for placing orders, receiving and paying for vaccines, according to an allocation formula that will be subsequently agreed within the EU. *Id.*, e.g., sec. 2.2.

258 *Id.*, sec. 5.

259 *Id.*, sec. 9.1. AstraZeneca will be paid an initial fixed amount of EUR 336 million toward that estimated cost. The balance of EUR 534 million is stated as the estimate for fill/finish/packaging costs for the product.

260 *Id.*, sec. 5.4. If AstraZeneca is unable to fulfill its manufacturing commitments, the Commission or the participating member states may recommend to AstraZeneca contract manufacturing organizations (CMOs) within the EU capable of carrying out the manufacturing. The Commission and the participating member states commit to providing AstraZeneca with adequate funding to procure the materials needed to produce the vaccines, and; *Id.*, sec. 7.4. Performance by AstraZeneca is subject to audit. The Commission undertakes to deliver a final and binding written allocation of initial Europe doses between the participating member states within 30 days following the effective date of the agreement. *Id.*, sec. 8.3.

261 The Commission-AZ APA states as follows: “11. Intellectual property... 11.1. Ownership. The Commission acknowledges that AstraZeneca has pre-existing obligations to its upstream licensor and throughout the term of this agreement, may incur obligations to its CMOs and other contractors in respect of patents, know-how and other intellectual property rights relating to the Vaccine. The Commission acknowledges and agrees that as between the Parties, (i) AstraZeneca shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Vaccine, including all Know-How (collectively, the ‘Vaccine IP Rights’), and (ii) AstraZeneca shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this Agreement, AstraZeneca does not grant to the Commission by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by AstraZeneca hereunder are reserved by AstraZeneca.”

262 *Id.*, sec. 11.2.

263 *Id.*, sec. 14.1.

264 *Id.*, sec. 15.1.

265 *Id.*, sec. 16. The courts of Brussels will be used to resolve disputes. *Id.*, sec. 18.5.

been anticipated. The EU ultimately sued AstraZeneca, and the matter was ultimately settled in September 2021.²⁶⁶

iv. United Kingdom

By agreement dated August 28, 2020, the UK government agreed to purchase 100 million doses²⁶⁷ of AZD1222 from AstraZeneca priced at AstraZeneca's cost.²⁶⁸ The agreement does not purport to modify AstraZeneca's rights to intellectual property in the vaccine.²⁶⁹ Vaccine supplied by AstraZeneca will be delivered into the Territory,²⁷⁰ which is defined to encompass the United Kingdom.²⁷¹ As with other COVID-19 vaccine supply agreements, AstraZeneca's obligations to deliver are contingent on its ability to obtain regulatory approval.²⁷²

As of January 2022, the British government reported that around 50 million doses of AZD1222 had been administered in the United Kingdom, presumably delivered under the aforementioned supply contract.²⁷³

v. Brazil

On June 1 2021, AstraZeneca entered into a technology transfer agreement with the Oswaldo Cruz Foundation in Brazil that envisaged the local production of AZD1222.²⁷⁴ The agreement included the transfer of both rights in patents²⁷⁵ protocols, methods, techniques, results of experimentation, knowledge, trade secrets, designs, skill, experience; and/or and know how. Pursuant to the agreement,

266 According to AstraZeneca's press release: "AstraZeneca and the European Commission have reached an agreement that ends legal proceedings over the execution of the Advance Purchase Agreement for the delivery of the COVID-19 vaccine Vaxzevria (ChAdOx1-S [Recombinant]). Under the agreement, AstraZeneca commits to deliver 60 million doses of the vaccine by the end of the third quarter 2021, 75 million by the end of the fourth quarter 2021 and 65 million by the end of the first quarter 2022. Member States will be provided with regular delivery schedules, and capped rebates will apply in the event of any delayed doses." AstraZeneca_media_relations, *AstraZeneca and European Commission reach settlement agreement over vaccine supply, ending litigation*. 2021. www.astrazeneca.com/media-centre/press-releases/2021/astrazeneca-and-european-commission-reach-settlement-agreement-over-vaccine-supply-ending-litigation.html

267 *Supply Agreement for AstraZeneca-UK Secretary, AZD1222*. 2020. AZ-UK Supply. <https://ghiaa.org/wp-content/uploads/2021/05/AZD1222-Supply-Agreement-REDACTED.pdf>. Quantity at Section 5.1.

268 Price at cost per Section 11.1, id.

269 Recognizing that certain of those rights have been in-licensed from Oxford University Innovation Limited (i.e. Section 16.1, "Neither Party will gain any rights of ownership to or use of any property or Intellectual Property Rights owned by the other (whether by virtue of this Supply Agreement, by implication or otherwise).") Id.

270 Id., Section 1.1: Delivery Location means the Purchaser's nominated facility in the Territory as notified to AstraZeneca by the Purchaser.

271 Although the agreement specifies numerous rights and obligations with respect to the Territory (e.g., regulatory approval, compliance, delivery), it does not (in the redacted version) appear to specifically preclude exports outside the Territory. There is provision for indemnification (Section 8), but terms are not publicly available. Id.

272 See, id., e.g., Sections 10.4 & 22.3.

273 The British government reported that as of that date 2.5 billion doses of the vaccine had been distributed at cost to more than 170 countries, with almost two-thirds having gone to LMICs, including 30 million doses donated by the British government. It further indicated an intention to donate an additional 20 million doses to "countries in need." According to the government: • UK government funding for the Oxford/AstraZeneca vaccine: • To date the UK government has invested over £88 million in funding to develop and manufacture the vaccine. This includes £2.6 million through NIHR and UKRI for research of the vaccine, £20 million for clinical trials and £65.5 million for early manufacturing of the vaccine. • The government also invested £8.75 million to set up the rapid deployment facility at Oxford Biomedica to manufacture the vaccine at scale. • The UK government has invested in the Oxford team and their technology since 2016, and in their COVID specific vaccines since March 2020. GOV. UK *One year anniversary of UK deploying Oxford-AstraZeneca vaccine*. 2022. www.gov.uk/government/news/one-year-anniversary-of-uk-deploying-oxford-astrazeneca-vaccine.

274 Among the objectives: "make the Licensed Product available in the in Territory at affordable prices the country of use and use Best Efforts (as defined below) to ensure that Licensed Product pricing does not prevent the health authorities in any country from being able to obtain sufficient quantities of the Licensed Product to meet requirements in that country"; ... Section 1.38: "'Licensed Product' means the Vaccine Product for the prevention of SARS-CoV-2 in humans containing one or more of the Head Licensor's ChAdOx1-S CoV-19 construct also referred to by AstraZeneca as AZD1222." AstraZeneca-Oswaldo_Cruz_Foundation, *Technology Transfer Agreement*. 2020. AZ-OC Foundation Agreement. https://ghiaa.org/wp-content/uploads/2021/11/Fiocruz_AZ-COVID19-Vaccine-Technology-Transfer-Agreement.pdf.

275 Section 1.30: "'Intellectual Property Rights' means patents, Patent Term Extensions, registered designs, applications for any of the foregoing (including continuations, continuation applications, continuations-in-part, continuation-in-part applications, divisional applications and national or international patent applications anywhere in the world that claim priority solely from such patent applications and/or any of their priority filings), the right to apply for any of the foregoing, copyrights, design rights, moral rights, and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world.... Section 1.33 'Know-How' means (a) inventions, technical information, know-how, show-how, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), formulae, assays, sequences, discoveries, procedures, processes, practices, protocols, methods, techniques, results of experimentation, knowledge, trade secrets, designs, skill, experience; and/or (b) any information embodied in compounds, compositions, materials (including unpatented chemical or biological materials), formulations, dosage regimens, apparatus, devices, specifications, samples, works, regulatory documentation and submissions pertaining to, or made in association with, filings with any Regulatory Authority." Id.

'Territory' means the Brazilian public market to meet the needs of Brazilian Unified Health System ('SUS'), State and Municipal governments in Brazil, provided that the Parties may, upon mutual agreement, discuss the manufacturing of an exceeding production of the Licensed [sic] pursuant to separate terms, provided that the parties hereby agree that Licensee shall give priority to meet the demand within the Territory." The agreement provides that the technology transfer is intended to allow authorization, manufacture and supply of the licensed product in the Territory as just defined. AstraZeneca will be providing the starting material (e.g., seed lots and working cell banks) needed to produce the drug substance in manufacturing quantities.²⁷⁶ The agreement specifically precludes exploiting the licensed product outside the territory, or for sale in the private market in Brazil.²⁷⁷

The agreement does not automatically provide to Fiocruz developments such as other viral agents, although it gives to Fiocruz a right of first refusal to negotiate such an extension with AstraZeneca.²⁷⁸ Fiocruz is responsible for obtaining regulatory authorization for the vaccine within Brazil.²⁷⁹ AstraZeneca agrees to provide personnel support in respect to transfer of technology.²⁸⁰ In general, Fiocruz bears the responsibility for manufacturing and distributing the product in Brazil within the scope of the territory.²⁸¹ There is express provision pursuant to which AstraZeneca may approve sales outside Brazil for humanitarian purposes.²⁸² Fiocruz will own manufacturing improvement technologies that it develops.²⁸³ There is broad agreement to protect confidential information exchanged under the agreement.²⁸⁴ The "Agreement shall continue in effect until the Know-How Period has expired for Brazil."²⁸⁵ The parties agreed to keep this license and its terms confidential.²⁸⁶ The agreement is governed by Brazilian law and Brazilian courts, other than with respect to the validity of patents which are determined in the country where granted.²⁸⁷

The Technology Transfer Agreement enabled Fiocruz to produce the AZD1222 vaccine starting from the cell banks provided by AstraZeneca. The release of the first fully locally produced batches was announced on February 22, 2022.²⁸⁸ According to Fiocruz, the cost of a locally-produced dose was USD 5.27. Overall Brazilian supplies of the AZD1022 vaccine appear to have involved a combination of vaccine supplied by AstraZeneca, and the locally produced vaccines.²⁸⁹

Data from UNICEF indicates a per dose price of the AstraZeneca vaccine in Brazil in 2020 was USD 3.16 per dose, cross-referencing a Fiocruz press release of November 3, 2020.²⁹⁰ This price appears to predate local manufacture of the vaccine.

276 See, id., e.g., Sections 1.71-1.73., and 2.03 (Transfer of Technology).

277 Id., Section 2.01.

278 Id., Section 2.05. The agreement provides for a division of responsibilities mainly allocating to AstraZeneca ultimate decision making authority with respect to matters involving its agreement with Oxford and the conduct of clinical trials. Fiocruz has ultimate decision-making authority with respect to other matters. Section 3.05.

279 Id., e.g., Section 4.05.

280 Id., e.g., Section 4.07.

281 Id., e.g., Section 5.01, 5.05.

282 Id., Section 5.03.

283 Id., Section 5.08. "All manufacturing process improvements and all Licensees Know How derived from the manufacturing process will at all times be owned by Licensees."

284 Id., Section 8.

285 "[P]rovided, however, the entirety of this Agreement shall terminate if the Head License [i.e., with Oxford] expires or is terminated." Section 11.01. Various provisions address potential acts of default and rights of termination. While warranties and representations are provided by the parties as to their rights to undertake this agreement, there is no express provision for indemnification. See, id., Sections 11 and 14.

286 Id., Section 15.09.

287 Id., Section 15.04.

288 Fiocruz_News_Agency, *Fiocruz releases first 100% Brazilian COVID-19 vaccine*. 2022. <https://portal.fiocruz.br/en/news/fiocruz-releases-first-100-brazilian-covid-19-vaccine>

289 Berti, L. *AstraZeneca becomes the most-used vaccine in Brazil*. The Brazilian Report, 2021. <https://brazilian.report/liveblog/2021/07/05/astrazeneca-surpassing-coronavac/>

290 Fiocruz_media_relations, *Covid-19 vaccine: Fiocruz discloses its Technological Order Agreement with AstraZeneca*. 2020. <https://portal.fiocruz.br/en/news/covid-19-vaccine-fiocruz-discloses-its-technological-order-agreement-astrazeneca>

vi. CEPI-Gates

On June 4, 2020 AstraZeneca reached agreement with CEPI to manufacture and supply 300 million doses of AZD1222 to the COVAX facility (see note 250)^{291, 292} The total reported contract price was USD 750 million, yielding a per dose price of USD 2.50 (see note 250). Subsequent reporting raised questions concerning the schedule and delivery of AstraZeneca doses to COVAX, recognizing that the Serum Institute also entered into a commitment to deliver AZD1222 to COVAX, at least in part funded by the Gates Foundation (see above). The SII-COVAX delivery schedule also suffered from delays, including because of the decision by the Indian government to block exports during a surge of infection within the country.

Texts of agreements between CEPI and the Gates Foundation, on one side, and AstraZeneca, COVAX and SII, on the other side, have not been made publicly available.^{293, 294} Given the extent of public benefits CEPI and the Gates Foundation enjoy through tax exemptions and government funding of procurement the lack of transparency is notable. As noted below, contracts involving CEPI, on one side, and CureVac and Novavax, on the other side, are publicly available (with redactions) as a consequence of US Securities and Exchange Commission material transaction reporting requirements.

vii. Colombia

On December 15, 2020, the government of Colombia entered into an Advance Purchase Agreement with AstraZeneca foreseeing the supply of 9,984,000 doses of AZD1222 at a per dose price of USD 6 for “distribution within the Territory” which is defined as Colombia.²⁹⁵ The APA places a “best reasonable efforts” obligation on AstraZeneca to obtain regulatory approval, manufacture and deliver the vaccines. Colombia will not acquire any intellectual property ownership rights under the agreement.

A first shipment of 244,800 doses arrived from AstraZeneca in Colombia on March 20, 2021.²⁹⁶ Although data is spotty, it appears that Colombia received most of its AZD1222 through the COVAX facility, as compared with the bilateral agreement with AstraZeneca.²⁹⁷

291 From CEPI Summary (pp. 11–12) CEPI, Enabling Equitable Access to COVID-19 Vaccines: Summary of equitable access provisions in CEPI's COVID-19 vaccine development agreements. 2022. <https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v8-14-February-2022.pdf>. “CEPI and AstraZeneca UK Limited (AZ) entered into a partnership on 4 June 2020 to support the manufacture of 300 million doses of the AZ's AZD1222 vaccine candidate. AZ is a publicly traded, multi-national corporation headquartered in Cambridge, UK. The agreements build upon CEPI's initial seed funding for this vaccine candidate, which supported the University of Oxford both for manufacturing development and to manufacture clinical trial materials. Following that initial investment by CEPI, Oxford partnered with AZ in a global development and distribution agreement for the vaccine. The funded project will result in greater manufacturing capacity and up to 300 million doses of vaccine to the COVAX Facility, with Gavi supporting the procurement. If the vaccine is approved by regulatory authorities, the aim is to provide initial doses in early 2021. CEPI has agreed to fund AZ's technology transfer of vaccine production to additional manufacturing sites, the purchase of manufacturing materials, and the reservation of manufacturing slots. If AZ is unable to use the reserved manufacturing capacity, that capacity may be used at CEPI's direction for another CEPI project. The total funding amount is up to \$383m of which up to \$338 is shared risk and recoverable on product sales.... Where will the vaccine be made? Asia and Europe.... How much vaccine will be supplied to the COVAX Facility? AZ will offer to sell up to 300 million doses of vaccine to the COVAX Facility. An additional agreement between Gavi, the Bill & Melinda Gates Foundation and the Serum Institute of India secures additional doses of vaccine from the Serum Institute of India under licence from AZ for COVAX for LMICs.... How will be the price be determined? AZ will sell on a no-profit, no loss basis during the COVID-19 pandemic. CEPI has the right to audit to ensure compliance.... How will results support the research community? AZ has agreed to abide by the guidance provided by WHO, Wellcome, and additional CEPI obligations in the agreement regarding access to data, and to meet in good faith CEPI's requirements on open publication of research results.”

292 CEPI media relations, *CEPI Partners with AstraZeneca to manufacture 300 million globally accessible doses of COVID-19 vaccine*. 2020, CEPI. https://cepi.net/news_cepi/cepi-partners-with-astrazeneca-to-manufacture-300-million-globally-accessible-doses-of-covid-19-vaccine/.

293 Scourse, R., *Access to information in COVID-19 contracts and agreements: Oxford/AstraZeneca vaccine case study*. 2022. www.keionline.org/wp-content/uploads/MSF-RS-KEI-webinar-transparency-20sep2022.pdf.

294 Rizvi, Z., *COVAX's Choices*, in *Access to Medicines Program*. 2020. www.citizen.org/wp-content/uploads/Covax-choices-embargoed-Nov-16.pdf.

295 Colombia Ministry of Health, *Colombia Received 912,000 Doses of AstraZeneca Vaccines*, Apr. 25 2021. <https://minsalud.gov.co/English/Paginas/Colombia-Received-912,000-Doses-of-AstraZeneca-Vaccines.aspx>.

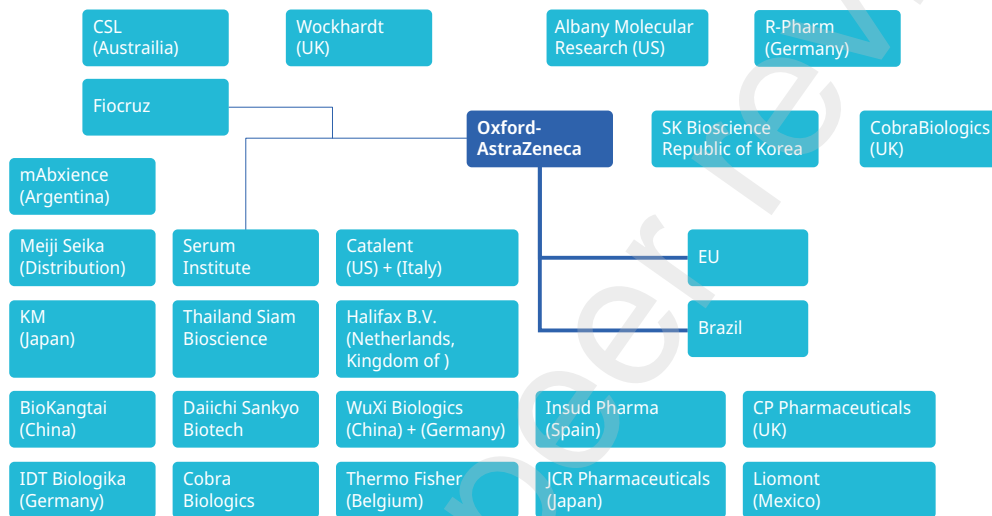
296 Colombia Ministry of Health, *First AstraZeneca Doses Arrive in the Country*, March 20, 2021, <https://www.minsalud.gov.co/English/Paginas/First-AstraZeneca-Doses-Arrive-in-the-Country.aspx>.

297 Colombia Ministry of Health, *Colombia Received 912,000 Doses of AstraZeneca Vaccines*, Apr. 25 2021. <https://minsalud.gov.co/English/Paginas/Colombia-Received-912,000-Doses-of-AstraZeneca-Vaccines.aspx>.

viii. United States

On October 28, 2020 the US government (through the US Army) awarded two contracts to AstraZeneca.²⁹⁸ These agreements referred to development work as well as procurement of 300 million doses of what was then AstraZeneca's vaccine candidate. AstraZeneca retained relevant IP. Although it is difficult to estimate the per dose price based on the redacted agreements, the Congressional Research Service reported that the combined value of these contracts was USD 3 billion, implying a USD 10 per dose price. The US government never approved the AstraZeneca vaccine, and while it was reported that the United States was planning to donate some quantity of that vaccine abroad, it is not clear whether this ever happened because the announcement of intention was combined with the need for federal approval (which never happened).²⁹⁹

Oxford-AstraZeneca mapping



Summary: AstraZeneca-Oxford

- Oxford rapidly develops modified adenovirus candidate based on prior patented research – complex Oxford internal patent VC and licensing system
- Inventors initially contemplate non exclusive concessionary licensing
- Funding from Gates/CEPI for development
- Begins internal development but persuaded by Gates to out-license exclusively to AstraZeneca (AZ) – no royalty during pandemic but yes afterward, rate undisclosed
- Licensing agreement requires AZ to provide concessionary/access pricing for incipient COVAX and developing country supply
- AZ runs into trouble during development/clinical trial phase as CMO provides half-dose and trials must be re-run
- SII in-licenses AZD1222 vaccine with rights for India, COVAX and LMICs, in India “Covishield”
- SII successfully ramps production and India DRA grants EUA, but has been delayed – price approx. USD3 per dose

²⁹⁸ One contract “requires AstraZeneca to Conduct Phase 3 clinical trials and demonstrate the ability to manufacture and distribute 100 Million (M) doses of the ChAdOx 1 nCoV-19 vaccine (now referred to as AZD1222... This action has a total Firm Fixed Price value of \$1,208,933,813.79. It is not anticipated that the total value of this action will increase during the definitization process.” US-Oxford Project Agreement. Contract W15QICN2191003, Oct. 28, 2020, US-AZ No. W15QKN2191003. The other “requires AstraZeneca to manufacture and distribute 200 Million (M) doses of the ChAdOx1 nCoV-19 vaccine (now referred to as AZD1222) to the United States Government to prevent the general population from developing symptoms of the COVID-19 infection...This action has a total Firm Fixed Price value of \$286,927,159.00. It is not anticipated that the total value of this action will increase during the definitization process.” US-AstraZeneca Supply Contract, W15OKN-21-C-0003, Oct. 28, 2020. This implies per dosage price of USD 12 under the first agreement, and only USD 1.43 under the second agreement, but the Congressional Research Service reports that the total value of these two contracts was USD 3 billion, yielding a per dose price of USD 10. It is not clear from the redacted agreements where the additional USD 1.7 billion is identified. Article 9: Intellectual Property Rights.

²⁹⁹ Tyler Pager, Annie Linskey and Emily Rauhala, *U.S. to share up to 60 million vaccine doses amid pressure to aid desperate countries*. 2021. www.washingtonpost.com/politics/us-to-share-up-to-60-million-doses-of-astrazeneca-coronavirus-vaccine-with-other-countries-official-says/2021/04/26/b2dab8a0-a694-11eb-bca5-048b2759a489_story.html.

- Widely used in India and exported by SII subject to period when government imposes export ban due to scale of need in India – COVAX deliveries suffer
- AZ offers low-price to Brazil public health authority with license for local production
- Approved and extensively used in Brazil – combination of AZ supplies and local production

4. Johnson & Johnson/Janssen

Johnson & Johnson is the parent company of Janssen Pharmaceuticals. For the sake of convenience, we generally refer to Johnson & Johnson, recognizing that many of the contractual arrangements regarding its vaccine Ad26.COV2.S – Viral Vector Vaccine for COVID-19, are entered into by Janssen.

The Johnson & Johnson vaccine uses a technology similar to that of the AstraZeneca vaccine; that is a modified adenovirus.³⁰⁰ Because this vaccine is based on stable DNA molecules it is less sensitive to degradation than the mRNA vaccines in terms of storage and administration. The Johnson & Johnson vaccine, while requiring refrigeration, does not require the intense cold chain storage of the first mRNA vaccines, making it more suitable for use in many LMICs.

The Johnson & Johnson vaccine was developed in collaboration with Beth Israel Medical Center which appears to have been the assignee on various patents covering the technology for modifying adenovirus.^{301, 302, 303} The text of the agreements between Johnson & Johnson and Beth Israel are not publicly available.

Johnson & Johnson received an initial USD 456 million from BARDA to develop its COVID-19 vaccine.³⁰⁴ This was accomplished through a set of amendments to a previously existing development agreement (amendments nos. 6, 7 and 8).^{305, 306, 307, 308}

The agreements have been closely guarded by the federal government that has provided redacted versions pursuant to US Freedom of Information Act requests. However, these texts are so heavily redacted that little meaningful information can be derived from them.³⁰⁹ Because these agreements were entered into under a special “Other Transactions Authority” it is expected that they limit federal government authority with respect to intellectual

300 Jonathan Corum, C.Z., *How the Johnson & Johnson Vaccine Works*, in *NY Times*. 2020. www.nytimes.com/interactive/2020/health/johnson-johnson-covid-19-vaccine.html.

301 Johnson&Johnson_media_relations, *Johnson & Johnson Announces Collaboration with the Beth Israel Deaconess Medical Center to Accelerate COVID-19 Vaccine Development*. 2020. www.jnj.com/johnson-johnson-announces-collaboration-with-the-beth-israel-deaconess-medical-center-to-accelerate-covid-19-vaccine-development.

302 Johnson&Johnson_media_relations, *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use*. 2020. www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use.

303 Saltzman, J., *Beth Israel is working with Johnson & Johnson on a coronavirus vaccine - The Boston Globe*. 2020, Boston Globe. www.bostonglobe.com/2020/03/12/business/beth-israel-is-working-with-johnson-johnson-coronavirus-vaccine/.

304 Johnson&Johnson_media_relations, *Johnson & Johnson Announces Collaboration with U.S. Department of Health & Human Services to Accelerate Development of a Potential Novel Coronavirus Vaccine*. 2020. <https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/johnson-johnson-announces-collaboration-us-department-health>.

305 The initial agreement was entered into on August 15, 2017, at a total of USD 43.6 million, and directed toward influenza viruses. An additional USD 41.3 million was awarded on December 27, 2018. The agreement is described: “HHSO100201700018C is a Cost Sharing Federal Contract IDV Award. It was awarded to Janssen Pharmaceuticals, Inc. on Aug 15, 2017. The indefinite delivery contract is funded by the Office of the Assistant Secretary for Preparedness and Response (HHS). The potential value of the award is \$1,261,139,514.00. The NAICS Category for the award is 541711 - Research and Development in Biotechnology. The PSC Category is 6505 - Drugs And Biologicals; Our Summary, ASPR-17-03390 - Janssen Influenza Portfolio - Advanced Development Candidates (Other Transactional Authority) <https://govtribe.com/award/federal-idv-award/indefinite-delivery-contract-hhs0100201700018c>.... The purpose of these agreements as described by an organization tracking U.S. Federal government expenditures. P00008 Supplemental Agreement for work within scope \$456.2m 3/27/20; Addition of New Vaccine Asset for 2019 Novel Coronavirus (COVID-19) P00007 Supplemental Agreement for work within scope \$148.4m, 3/20/20; Addition of New Antiviral / Therapeutic Asset for 2019 Novel Coronavirus (COVID-19) P00006 Supplemental Agreement for work within scope \$0, 2/11/20; Addition of New Asset for 2019 Novel Corona Virus (COVID), Budget Restructure to Fund New Asset from Existing UNIFLU Funding, Addition of Program Management Lead for New Asset. <https://govtribe.com/award/federal-idv-award/indefinite-delivery-contract-hhs0100201700018c>

306 US_HHS_BARDA-Janssen_Research, *Amendment of Other Transaction Agreement (OTA) - No. 6*. 2020

307 US_HHS_BARDA-Janssen_Research, *Amendment of Other Transaction Agreement (OTA) - No. 7*. 2020

308 US_HHS_BARDA-Janssen_Research, *Amendment of Other Transaction Agreement (OTA) - No. 8*. 2020

309 Rowland, C., *Trump administration makes it easier for drugmakers to profit from publicly funded coronavirus drugs, advocates say*, in *Wash. Post*. 2020. www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump/.

property, including patents, such as narrowing march-in rights.³¹⁰ That would be consistent with the subsequent procurement agreement (see below), though the contexts are somewhat different.³¹¹

The VaxPal database identifies more than 20 patents relevant to the Johnson & Johnson/Janssen vaccine. One of the applications post-dates the emergence of SARS-CoV-2.³¹²

Janssen subsequently received a USD 1 billion plus contract for an initial delivery of 100 million doses of its vaccine.³¹³ The agreement for 100 million doses specified a maximum price of USD 10 per dose (regimen),³¹⁴ and this was subject to adjustment downward if it turned out that Johnson & Johnson's costs were lower, as Janssen had publicly promised a not-for-profit arrangement on these vaccines.

Pursuant to the USD 1 billion Procurement Agreement, Janssen maintains close control over patents, trade secrets and other intellectual property,³¹⁵ and grants the government limited rights to use the technology for purposes of distributing and administering the vaccine. To the extent that Janssen develops new patentable technology in the course of its work under the agreement, it will have the right to secure patents on that technology, providing the government with non-exclusive license to practice the technology for its purposes, and not allowing the government to license the invention to third parties for commercial purposes.³¹⁶ Only in the event that Janssen elects not to seeking patent protection may the government apply for and obtain patents.³¹⁷ With respect to Janssen patents that are secured based on work undertaken pursuant to the agreement, the government retains specified march-in rights in the event of non-performance by Janssen.³¹⁸ The terms suggest that Janssen will negotiate the terms of the march-in licenses.³¹⁹ The agreement imposes strict confidentiality requirements on uses of Janssen information.³²⁰ Janssen's performance is contingent upon successfully obtaining authorization for the vaccine.

The agreement provides that Johnson & Johnson is obligated first to supply the US government with the contracted 100 million doses,³²¹ but thereafter it appears that Johnson & Johnson would be able to supply its products elsewhere.

310 Love, J. *KEI receives seven new contracts for COVID 19 research from BARDA and DOD, including five using "Other Transactions Authority" that weaken or eliminate Bayh-Dole and FAR Safeguards - Knowledge Ecology International*. 2020. www.keionline.org/covid19-ota-contracts.

311 A product development agreement logically contemplates the creation of patentable technology, whereas a production and procurement agreement may not so specifically contemplate that. The patent numbers for Johnson & Johnson's intellectual property used for the US government are redacted from the publicly available version of its agreements. Johnson & Johnson in the procurement agreement refers to its own patents and to patents for which it has rights. Presumably, the Beth Israel patents are among those included in the listing. Apparently in some cases Janssen may have been included as an assignee of the patents perhaps as part of some pre-existing funding agreement with Janssen.

312 From the Espacenet database: 1. WO2021064688 (A1) - ADENOVIRUS VECTORS AND USES THEREOF; applicants JANSSEN VACCINES & PREVENTION BV[NL]; BATAVIA BIOSCIENCES BV[NL]; UNIV COURT UNIV OF EDINBURGH; NIKLAS ARNBERG KONSULT AB[SE] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210408&CC=WO&NR=2021064688A1&KC=A1.

313 US Army-J&J Janssen, *P00081 Modification to MCDC OTA No. W150KN-16-9-1002*. 2020. US Army-Janssen Project.

314 See, id., e.g., Section 1.2 Milestones/Payments.

315 Id., Section IX.1: "Janssen asserts full title to all background intellectual property relevant to its performance of this statement of work and listed at Attachment 1. Janssen hereby conveys a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States to the 'Licensed Patents' throughout the world for the prevention, diagnosis and treatment of COVID-19 caused by Severe Respiratory Syndrome-Coronavirus-2 (SARS CoV-2)."

316 Id., Section IX.3.

317 Id., Section IX.4.

318 Id., Section IX.8.

319 Id., Section IX.8(c): "Where the circumstances described in Article IX, Section 8(a) and/or (b) are met, Janssen will act promptly to negotiate in good faith with the responsible US-based third party a non-exclusive license on terms that are reasonable under the circumstances under the SI Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States."

320 Id., Section VII.

321 Id., Milestones/Payments: "Janssen's current production plan contemplates 100% of release of finished Regimens in 2020 and January and February of 2021 will occur in the United States. If Janssen changes this plan in any substantial way, it will discuss with the Government adjustments to this Project Agreement that are consistent with the principles established in this section."

i. Outsourced manufacturing

Johnson & Johnson had initially relied on Emergent Manufacturing (Emergent BioSolutions) as prime subcontractor for producing its vaccine,³²² but Emergent failed to perform in accordance with appropriate cGMP standards and its production was halted by the US government.³²³ Johnson & Johnson's ill-fated manufacturing agreement with Emergent BioSolutions gave Johnson & Johnson tight control over its IP, including broadly defined confidential information.³²⁴

Under the terms of the agreement Johnson & Johnson provides the cell line to be used by Emergent for the manufacturing process.³²⁵ Other than the cell line and related attenuated virus, Emergent is responsible for the materials and equipment used to manufacture the vaccine.³²⁶ As this is outsourced contract production (CMO), there is no provision for Emergent to otherwise sell or distribute vaccines produced under the agreement, and Emergent is responsible for complying with applicable terms of Johnson & Johnson's agreement with the federal government. In 2022, Janssen initiated arbitration against Emergent for alleged breach of the aforementioned manufacturing agreement.³²⁷

Johnson & Johnson entered into manufacturing agreements with Catalent for its facility in Bloomington, Indiana³²⁸ and (subsequently) in Anagni, Italy,³²⁹ and GRAM for its facility in Grand Rapids, Michigan^{330, 331} It subsequently entered into an arrangement with Merck to make use of its production capacity,^{332, 333} and with Takeda using its production facility in Germany (IDT Biologika).³³⁴ Johnson & Johnson also entered into a fill and finish manufacturing

322 J&J_Janssen-Emergent, *Manufacturing Services Agreement*. 2020. Janssen-Emergent.

323 Jeong, A., *U.S. cancels multimillion-dollar deal with coronavirus vaccine maker whose plant ruined Johnson & Johnson doses*. 2021. www.washingtonpost.com/business/2021/11/05/coronavirus-vaccine-emergent-biosolutions-cancel/.

324 Janssen-Emergent, "Section 8.1 Nothing in this Agreement shall affect a Party's rights to its Intellectual Property nor imply grant of any license to a Party's Intellectual Property unless expressly set forth herein. Each Party agrees not to decompile, disassemble or otherwise reverse engineer any or all of the other Party's Background IP... 8.2 Manufacturer acknowledges and agrees that all Foreground IP shall be and shall at all times remain the sole and exclusive property of Buyer. Manufacturer and/or its agents, consultants, subcontractors and employees shall, without delay, inform Buyer of any Foreground IP and hereby assign or shall cause to be assigned free of any restrictions and/or additional remuneration and charges, to Buyer or its designee all rights to the Foreground IP. In the event that such assignment is not possible, for whatever reason, Manufacturer hereby grants, or shall grant, or cause to be granted, as the case may be, to Buyer an exclusive, worldwide, perpetual, irrevocable, unlimited, royalty-free and transferable license, with a right to sublicense, to Foreground IP. [**]. ... 9.3 Restrictions on Use and Disclosure. The Receiving Party shall not, except as otherwise provided below (a)use or reproduce the Disclosing Party's Confidential Information for any purpose other than as required to perform the obligations or exercise the rights granted in connection with this Agreement ..."

325 See, id., e.g., Section 1.11.

326 See, id., e.g., Section 3.2.

327 From J&J Form 10-K for fiscal year 2022 (filed 2023): "In June 2022, Janssen Pharmaceuticals, Inc. filed a Demand for Arbitration against Emergent Biosolutions Inc. et al ('EBSI') with the American Arbitration Association, alleging that EBSI breached the parties' Manufacturing Services Agreement for the Company's COVID-19 vaccine.... In July 2022, Emergent filed its answering statement and counterclaims." <https://johnsonandjohnson.gcs-web.com/static-files/06bc3388-603b-4768-bf95-e6d43fda9fd3>.

328 Catalent_media_relations, *Catalent Signs Agreement with Johnson & Johnson to be U.S. Manufacturing Partner for Lead COVID-19 Vaccine Candidate* | *Business Wire*. businesswire, 2020. www.businesswire.com/news/home/20200429005148/en/Catalent-Signs-Agreement-Johnson-Johnson-U.S.-Manufacturing.

329 Catalent_media_relations, *Catalent Expands Partnership with Johnson & Johnson for COVID-19 Vaccine*. 2021. www.catalent.com/catalent-news/catalent-expands-partnership-with-johnson-johnson-to-significantly-increase-capacity-for-sterile-manufacturing-and-packaging-of-covid-19-vaccine-in-italy/.

330 GRAM Press Release, Sept. 5, 2020: "The agreement includes the technical transfer and fill and finish manufacture of Johnson & Johnson's SARS-CoV-2 vaccine candidate. Together, teams from both companies are working diligently to transfer the manufacturing process to GRAM's new, state-of-the-art facility, and are swiftly p GRAM is expanding domestic fill/finish capacity for COVID-19 vaccines and therapeutics for companies that have agreements with the federal government to meet its Operation Warp Speed goals. The GRAM expansion is funded, in part, by the Biomedical Advanced Research and Development Authority (BARDA) part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, in collaboration with the Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND).... The Johnson & Johnson vaccine candidate being manufactured at GRAM is being developed, in part, with funding from BARDA. BARDA, in collaboration with JPEO-CBRND, also is funding a demonstration of manufacturing capability that is expected to result in 100 million doses of the investigational vaccine which the federal government will own."

331 Grand_River_Aseptic_Manufacturing_media_relations, *GRAM Partners with Johnson & Johnson on Manufacturing in Fight Against COVID-19*. 2020. www.prnewswire.com/news-releases/gram-partners-with-johnson-johnson-on-manufacturing-in-fight-against-covid-19-301137966.html

332 Merck_media_relations, *Merck to Help Produce Johnson & Johnson's COVID-19 Vaccine; BARDA to Provide Merck With Funding to Expand Merck's Manufacturing Capacity for COVID-19 Vaccines and Medicines* - Merck.com. 2021. www.merck.com/news/merck-to-help-produce-johnson-barda-to-provide-merck-with-funding-to-expand-mercks-manufacturing-capacity-for-covid-19-vaccines-and-medicines/.

333 "In October 2022, Janssen Pharmaceuticals, Inc. filed a Demand for Arbitration against Merck Sharp & Dohme Corp. with the American Arbitration Association pursuant to the Parties' agreements relating to production of drug substance and drug product for the Company's COVID-19 vaccine. Also in October 2022, Merck filed its answer and counterclaims." Johnson & Johnson Form 10-K, above note 237.

334 Takeda_media_relations, *Takeda and IDT Support Manufacturing of Johnson & Johnson's COVID-19 Vaccine*. 2021. www.takeda.com/newsroom/newsreleases/2021/takeda-and-idt-support-manufacturing-of-johnson-johnsons-covid-19-vaccine.

agreement with Aspen Pharmacare in South Africa.^{335, 336, 337} This was seen as a major step towards increasing local production within Africa. However, although Aspen spent considerable resources in establishing a new facility on the Eastern Cape,³³⁸ that facility never received the orders it anticipated and ultimately shut down the production line.³³⁹ It subsequently announced an agreement with CEPI, the Gates Foundation and the Serum Institute of India to produce “four routine vaccines in Africa — Pneumococcal, Rotavirus, Polyvalent Meningococcal, and Hexavalent — with technology transfer activities initiating in early 2023.”³⁴⁰

Johnson & Johnson ultimately entered into supply and manufacturing agreements with enterprises outside the United States, including for delivery of vaccines outside the United States.³⁴¹

Johnson & Johnson’s manufacturing problems were compounded by adverse reaction to the vaccine in the form of blood clotting that caused the FDA first to require a warning, and subsequently limited its emergency use authorization.³⁴² As a consequence of the various difficulties, the Johnson & Johnson vaccine did not achieve the initially anticipated major role in global vaccination efforts.³⁴³

ii. Licensing agreements

Throughout the course of the pandemic, Johnson & Johnson took a public position strongly in favor of protection of its patent rights, and its agreements are consistent with protection of IP against third-party use.³⁴⁴ As noted previously, Janssen relied on a collaboration with Beth Israel Medical Center for the development of its modified adenovirus vaccine. There are numerous patents listening researchers at Beth Israel,³⁴⁵ including Janssen as assignee, broadly identifying this technology.³⁴⁶ There is no public indication that Janssen or Beth Israel granted rights in their patent portfolio to third parties to make and distribute the Johnson & Johnson

335 Burton, P. *South Africa's Aspen Inks Deal to Manufacture J&J's COVID-19 Vaccine*. 2020. <https://pharmaboardroom.com/articles/south-africas-aspen-inks-deal-to-manufacture-jjs-covid-19-vaccine/>.

336 Dunleavy, K. *A \$200M injection from the U.S. will allow Aspen to produce more Johnson & Johnson COVID-19 vaccines for Africa*. Fierce Pharma, 2021. www.fiercepharma.com/pharma/a-200m-injection-from-u-s-will-allow-aspen-to-produce-more-johnson-johnson-covid-19-vaccines.

337 Fernsby, C. *Siemens South Africa and Aspen join forces to enhance vaccine production for Africa*. Post_Online_Media, 2022. www.poandpo.com/companies/siemens-south-africa-and-aspen-join-forces-to-enhance-vaccine-production-for-africa/.

338 Burton (2020), see note 335 above: “Aspen said it had invested around USD 190 million into the facility, which has the capacity to produce more than 300 million doses annually and will be used to manufacture state-of-the-art sterile drugs and vaccines, packaged into vials, ampoules and pre-filled syringes.”

339 CGTN_Africa *South Africa's Aspen to halt COVID-19 vaccine production*. 2022. <https://africa.cgtn.com/2022/08/11/south-africas-aspen-to-halt-covid-19-vaccine-production/>.

340 CEPI_media_relations, *Aspen, CEPI and the Bill & Melinda Gates Foundation expand commitments to improve access to vaccines in Africa*. 2022. https://cepi.net/news_cepi/aspen-cepi-and-the-bill-melinda-gates-foundation-expand-commitments-to-improve-access-to-vaccines-in-africa/.

341 According to its form 10K filing for the fiscal year 2021: “The Company continues to evaluate and monitor both its internal and external supply arrangements, including its contract with Emergent BioSolutions and related production activities at its Bayview, Maryland facility. The Company has established a global vaccine supply network, where, in addition to its internal manufacturing site in Leiden, the Netherlands, ten other manufacturing sites will be involved in the production of vaccine across different countries and continents.” Form 10-K for 2021, at p. 38.

342 FDA News Release, *Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals*, May 5, 2022.

343 Carl Zimmer, J.C.S.-L.W.M.K., *Coronavirus Vaccine Tracker*, in *NY Times*. 2020. www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.

344 Johnson&Johnson_media_relations, *J&J Position on COVID-19 and Intellectual Property Rights*. 2022. www.jnj.com/about-jnj/policies-and-positions/our-position-on-covid-19-and-intellectual-property-rights.

345 See, e.g., US Patent 10106781B2, <https://patents.google.com/patent/US10106781B2/en> (Recombinant adenoviruses and use thereof), Inventor: Dan H. Barouch, Herbert Virgin, IV, Peter ABBINK, Current Assignee: Beth Israel Deaconess Medical Center Inc, Washington University in St Louis WU STL. Generally re Janssen, Justia Patents, Patents Assigned to Janssen Vaccines & Prevention B.V., <https://patents.justia.com/assignee/janssen-vaccines-prevention-b-v>, including, e.g., Adenovirus vectors and uses thereof, Patent number: 11459583, Abstract: Provided herein are chimeric adenoviral vectors. The provided chimeric adenoviral vectors can be used to induce a protective immune response in a subject. Type: Grant, Filed: October 30, 2018, Date of Patent: October 4, 2022, Assignee: Janssen Vaccines & Prevention B.V., Inventors: Taco Gilles Uil, Soumitra Roy, Jort Vellinga, Selina Khan, Jerome H. H. V. Custers; Adenovirus and uses thereof. Patent number: 11236361, Abstract: Provided herein are adenoviral nucleic acid sequences and adenoviral vectors comprising said nucleic acid sequences. The provided adenoviral vectors can be used to induce a protective immune response in a subject. Type: Grant, Filed: October 30, 2018, Date of Patent: February 1, 2022, Assignee: Janssen Vaccines & Prevention B.V., Inventors: Taco Gilles Uil, Soumitra Roy, Selina Khan, Jérôme H. H. V. Custers. The above references are the result of a basic Google search for illustration of patent portfolio purposes only. There is no suggestion that these are directly related to the Johnson & Johnson vaccine. See also VaxPal - COVID-19 vaccines patent landscape, www.vaxpal.org/?page=1.

346 See, e.g., Silbersher (2020): “J&J has developed a candidate – AD26.CO2-S – along with Beth Israel Deaconess Medical Center, which is part of Harvard Medical School. The candidate is developed from the AD26 adenoviral vector. Janssen, which is J&J’s pharmaceutical division, has numerous patents covering different aspects of AD26. For instance, Janssen has a patent (U.S. Patent No. 9,701,718) covering an AD26 vaccine for Ebola, and Janssen has a pending patent application covering large-scale production of recombinant adenovirus 26 (U.S. Patent Publication No. 2018/0080010.) It would therefore not be surprising if J&J has pending patent applications, which have not yet been made public, that are specifically directed to its AD26 adenoviral vector for a COVID-19 vaccine.”

vaccine, other than rights granted to third parties to practice the invention under limited scope manufacturing agreements.

iii. Supply

On May 21, 2021 Johnson & Johnson entered into an agreement to supply Gavi with 200 million doses of its vaccine to be distributed through the COVAX facility.³⁴⁷ It appears that about 37 million doses of the Johnson & Johnson vaccine were eventually delivered to LMICs under the COVAX facility.³⁴⁸ According to Gavi, by the end of 2021 Johnson & Johnson had delivered only four million doses to it, and the companies are locked in a dispute over the deliveries COVAX attempted to cancel but for which Johnson & Johnson is demanding payment.³⁴⁹

On October 8, 2020, Johnson & Johnson announced the conclusion of an agreement with the European Union for the supply of 200 million doses of its vaccine with an option for an additional 200 million doses. The agreement reportedly set a per dose price of USD 8.50.³⁵⁰ Johnson & Johnson ran into supply chain difficulties, and notified the EU of prospective delays in delivery. It is not clear how many doses were eventually delivered by Johnson & Johnson to the European Union, which did not renew its contract after prolonged delays.^{351, 352}

It is difficult to put a positive spin on the Johnson & Johnson vaccine development and manufacturing experience. In its latest Form 10-K submission to the US SEC it reports costs of approximately USD 1.5 billion in exiting its COVID-19 vaccine manufacturing operations.³⁵³ It booked a total USD 4.564 billion in revenues from the vaccine for 2021 and 2022, presumably at least USD 1.5 billion of that total came from the agreements initially entered into with the US government, including both procurement and R&D. And, with its price of USD 10 per dose under the US government contract it purported to be selling at cost. While we do not know the price charged to COVAX/Gavi (see below), the contract was for 200 million doses, and the figures just quoted may help explain why it is trying to collect for product that COVAX ordered but ultimately did not want to take.

iv. Access policies

As noted above, Johnson & Johnson expressed a firm commitment to the protection of intellectual property rights throughout the course of the pandemic. Although it entered into manufacturing and distribution agreements with third parties, these agreements protected Johnson & Johnson's technology.

Johnson & Johnson committed from the outset of the pandemic to provide its vaccines at a not-for-profit price (see notes 355-356).³⁵⁴ Its initial agreement with the United States provided for a USD 10 per dose price, subject to downward adjustment if costs were lower. The European Union reportedly paid USD 8.50 per dose (see note 350), and there is some indication that its prices to COVAX and LMIC purchasers were lower, apparently in the USD 5–8 range.³⁵⁵ This would make the Johnson & Johnson vaccine more costly than the AstraZeneca vaccine for LMICs, which was reported at approximately USD 3 per dose. Reports have not suggested that Johnson & Johnson

347 Gavi_media_relations, *Gavi signs agreement with Johnson & Johnson for supply of its COVID-19 vaccine to COVAX*.

2021. www.gavi.org/news/media-room/gavi-signs-agreement-johnson-johnson-supply-its-covid-19-vaccine-covax

348 Reuters_Staff Factbox: *Vaccines delivered under COVAX sharing scheme for poorer countries*. 2022. www.reuters.com/business/healthcare-pharmaceuticals/vaccines-delivered-under-covax-sharing-scheme-poorer-countries-2022-01-03/

349 Stephanie Nolan and Rebecca Robbins, *Vaccine Makers Kept \$1.4 Billion in Prepayments for Canceled Covid Shots for the World's Poor*, in *NY Times*. 2023. www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html

350 Boseley, S., *Belgian minister tweets EU's Covid vaccine price list to anger of manufacturers*, in *The Guardian*. 2020.

www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list

351 Sagonowsky, E. *Johnson & Johnson runs into vaccine supply issues in Europe, threatening 2nd-quarter delivery pledge*: Reuters. Fierce Pharma, 2021. www.fiercepharma.com/pharma/johnson-johnson-runs-into-vaccine-supply-issues-europe-threatening-second-quarter-delivery

352 Reuters_Staff *EU Commission to end AstraZeneca and J&J vaccine contracts at expiry - paper*. Reuters, 2021.

www.reuters.com/article/us-health-coronavirus-eu-vaccines-idUSKBN2C10MU

353 Johnson & Johnson, Form 10-K for fiscal year 2022, above note 357, e.g., page 81.

354 Johnson&Johnson_media_relations, *Johnson & Johnson Announces Advance Purchase Agreement with the African Vaccine Acquisition Trust for the Company's COVID-19 Vaccine Candidate*. 2021. www.prnewswire.com/news-releases/johnson-johnson-announces-advance-purchase-agreement-with-the-african-vaccine-acquisition-trust-for-the-companys-covid-19-vaccine-candidate-301257348.html

355 Manas Mishra, C. O'donnell, *J&J forecasts \$2.5 bln in 2021 COVID-19 vaccine sales, sets lower production target*. Reuters, 2021. www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-forecasts-25-bln-2021-sales-covid-19-shot-2021-07-21/

departed from its not-for-profit pledge during the pandemic. Its access policy therefore can be summarized as a “supply vaccines at a not-for-profit price.” Some reports suggested that Johnson & Johnson was planning to shift to a for-profit model once the pandemic emergency was over.³⁵⁶ However, Johnson & Johnson appears to have made a decision to largely exit the COVID-19 vaccine market, and plans for a for-profit shift have not been recently reported.

Summary: Johnson & Johnson/Janssen

- Major Warp Speed development and contracts procurement
- Johnson & Johnson retains IP
- Vaccine candidate developed rapidly through collaboration with in-licensed technology (patented) from Beth Israel Hospital (Jcovden)
- Modified adenovirus
- Because only refrigeration required considered more suitable for LMICs
- Relies on US government funded Emergent Biosolutions for production
- Johnson & Johnson expresses strong IP protection position
- Vaccine trials initially show safety and efficacy (though below Pfizer/Moderna)
- Johnson & Johnson access policy to sell at no-profit price during pandemic
- Emergent Biosolutions production fails, halted by US FDA
 - Johnson & Johnson pursues backup manufacturers – delays
 - Fill and finish arrangement with Aspen (South Africa); shuts down for lack of demand
- Adverse effects emerge – US eventually limits EUA

5. Novavax

Novavax is a relatively small (less than USD 1 billion market capitalization) vaccine development and production company based in the United States.³⁵⁷ Novavax received very substantial funding from the US government and CEPI to develop and produce a protein-based vaccine against COVID-19. In the course of development, Novavax entered into a number of licensing and other agreements with third-party producers and suppliers of materials within and outside the United States, including a licensing agreement with the Serum Institute of India. It also agreed to supply a significant quantity of vaccine to COVAX. While ultimately Novavax succeeded in developing a vaccine – Nuvaxovid (Covovax in India) – that was approved by regulators in various countries, it completed that process later than anticipated, and encountered manufacturing bottlenecks, such that its vaccine was not heavily deployed in comparison to other approved vaccines. Recently (February 2023) the US government extended a procurement agreement to Novavax for up to 1.5 million doses, apparently for the purpose of keeping its production facilities operational.³⁵⁸ Stock market share prices may not be a good indicator of success in addressing public health needs, yet it is interesting to note that the Novavax share price rose above USD 300 in February 2021 as the pandemic surged in the United States, and the same shares as of April 2023 are selling at less than USD 10.³⁵⁹ Companies and investors take risks in addressing pandemic medicines requirements.

Novavax has secured patent protection for its COVID-19 vaccine in the United States, stating: “We pursue patents related to NVX-CoV2373, our COVID-19 vaccine candidate.”^{360, 361} The VaxPal

356 Pagliarulo, N. *J&J foresees end to not-for-profit sales of coronavirus vaccine*. BioPharmaDive, 2021. www.biopharmadive.com/news/johnson-johnson-vaccine-not-for-profit-price/608477/

357 Novavax, *2021 Novavax Annual Report*. 2022. <https://ir.novavax.com/reports-financials>

358 Novavax_media_relations, *U.S. Government and Novavax Extend Partnership, Securing Up to 1.5 Million Additional Doses of Novavax' COVID-19 Vaccine*. 2023. <https://ir.novavax.com/2023-02-13-U-S-Government-and-Novavax-Extend-Partnership-Securing-Up-to-1-5-Million-Additional-Doses-of-Novavax-COVID-19-Vaccine>

359 Fidelity NVAX price chart Feb. 10, 2021 \$315.18 at open. April 21, 2023, NVAX \$8.68 at close.

360 Gail Smith, Michael J. Massare, Jing-Hui Tian, *Coronavirus Vaccine Formulations*, USPTO. 2021, Novavax, Inc.: USA. <https://patentimages.storage.googleapis.com/4d/45/36/e8872e9b08700a/US10953089.pdf>

361 Per Novavax, “Our applications include PCT/US2021/015220 and U.S. Serial No. 16,997,001, which the U.S. Patent Office has allowed.” Novavax 2021 Annual Report, above note 357. The US patent was granted as US 10,953,089 B1, to Novavax as assignee, for “Coronavirus Vaccine Formulations.” “The present disclosure is generally related to non-naturally occurring coronavirus (CoV) Spike (S) polypeptides and nanoparticles and vaccines comprising the same, which are useful for stimulating immune responses. The nanoparticles provide antigens, for example, glycoprotein antigens, optionally associated with a detergent core and are typically produced using recombinant approaches. The nanoparticles have improved stability and enhanced epitope presentation. The disclosure also provides compositions containing the nanoparticles, methods for producing them, and methods of stimulating immune responses.” Smith, et al., id.

database lists 6 patents relevant to the Novavax vaccine period. Two of the applications post-date the emergence of SARS-CoV-2.³⁶²

The Novavax vaccine is based on a substantially different technology than the mRNA vaccines developed by Pfizer/BioNTech, Moderna, or the modified adenovirus vaccines developed by AstraZeneca and Johnson & Johnson. The Novavax vaccine constructs polypeptides by using recombinant DNA formulation designed to be sufficiently similar to the SARS-CoV-2 spike protein to trigger an immune response, and by delivering those polypeptides to the target cells.³⁶³ Recognizing that mRNA technology was novel when first applied to vaccines in the COVID-19 pandemic, those funding Novavax presumably considered it important to simultaneously work with alternative technologies to assure that at least one of them worked.³⁶⁴

i. Operation Warp Speed

On July 6, 2020, Novavax secured funding of USD 1.6 billion from Operation Warp Speed for undertaking phase 3 clinical trials and producing an initial 100 million doses of its vaccine. The Statement of Work (referred to within the Statement as the “Project Agreement”) supplemented a 2018 Base Agreement (see below) and was executed on the part of the United States by a party referred to as “Advanced Technology International” or “ATI” that defined itself as a consortium of US government agencies.³⁶⁵

Consistent with USG objectives, the ‘prototype project’ under this agreement is defined as the manufacture and delivery of 100M doses of a SARS-CoV-2 vaccine, NVX-CoV2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the ‘prototype project’ will effectively demonstrate Novavax’s ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

One of the concerns addressed in the Project Agreement was assuring adequate supply of the proprietary antigen (Matrix-M) derived from the bark of the *Quillaja saponaria* (Soapbark) tree primarily found in Chile. In terms of intellectual property, Novavax recites that it brings substantial previously developed proprietary IP into the project, including manufacturing processes, and it provides a listing (redacted) of that IP. The Project Agreement states: “The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.”³⁶⁶ Novavax grants a fully paid nonexclusive license to the government to use that background IP for purposes of the project, but not to provide it to third parties without Novavax consent.³⁶⁷ The Project Agreement goes on to provide Novavax with all right title and interest to intellectual property conceived, made or reduced to practice in connection with activities funded under the agreement.³⁶⁸ Novavax grants the government a license to use that IP for purposes of the agreement. In addition, Novavax owns all right title and interest to all data generated as a result of work performed under the agreement, granting the government the right to use the data for purposes of carrying out the agreement.³⁶⁹

362 From the Espacenet database: 1. WO2021154812 (A8) - CORONAVIRUS VACCINE FORMULATIONS; applicant NOVAVAX INC [US] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20220224&CC=WO&NR=2021154812A8&KC=A8; 2. WO2021163365 (A1) - SARS-COV-2 VACCINE; applicants US HEALTH [US]; UNIV TEXAS [US]; DARTMOUTH COLLEGE[US] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210819&CC=WO&NR=2021163365A1&KC=A1 - See VaxPal for further details, www.vaxpal.org/?keywords=Novavax&page=1

363 See the patent referenced in note 361 above.

364 Sarah Jane Tribble and Rachana 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/>

365 ATI-Novavax, *Statement of Work For Rapid (W F10) Advanced Research & Development to Large Scale Manufacturing of NVX CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus*. Statement of Work. 2020. www.keionline.org/misc-docs/DOD-ATI-Novavax-Technical-Direction-Letter-W15QKN1691002-6July2020-HHSRR.pdf

366 Id., Section 7.1(a).

367 Id., Section 7.1(b). Similarly the US government grants Novavax a right in its IP for purposes of carrying out the agreement.

368 Id., Section 7.2(a).

369 Id., Section 8.

Novavax agrees to keep the government informed with respect to its communications with the FDA in the process of regulatory approval, and to grant the government a “right of reference” should the US government require some regulatory approval from the FDA.³⁷⁰ In the event that Novavax decides to discontinue or abandon its work under this Project Agreement, Novavax will provide the government with a license to make use of its IP so that a third party can carry out the project.³⁷¹ All specific patent information is redacted from the publicly-available version of the agreement.

The July 2018 Base Agreement between ATI and Novavax (extended on June 25, 2020) includes provision for march-in rights with respect to patents developed under that agreement.³⁷² It appears that the July 6, 2020 Project Agreement discussed above is generally subject to the terms and conditions of the Base Agreement but that in the event of a conflict the Project Agreement governs.³⁷³ This is important point because the Base Agreement would give the government the right to require the contractor to grant a nonexclusive license to a third party on reasonable terms, or for the government to take a license itself if, for example “Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees” (Section 10.10(2) March-in Rights). However, the Project Agreement includes a more limited set of rights on behalf of the government (discussed above).

The US government provided Novavax with a very substantial amount of money for purposes of R&D and improving production processes, and it allowed Novavax to own and control the resulting intellectual property. This is not inconsistent with the US government’s ordinary practice under the Bayh-Dole Act which allows funding recipients to secure patents in their own names, and limits the government to non-exclusive licenses to practice for itself, and to march-in rights which it historically does not exercise.³⁷⁴

The US Food and Drug administration did not approve the Novavax vaccine until July 2022,³⁷⁵ and at that point the federal government ordered only 3.2 million doses, of which only 77,500 were administered by February 2023.³⁷⁶ The federal government and Novavax have not disclosed what portion of the USD 1.6 billion provided for in the initial funding agreement has been paid to Novavax given the low level of procurement. In its third quarter 2022 financial report, Novavax indicated that it had globally delivered a total of 94 million doses of its vaccine.^{377, 378}

ii. CEPI

On May 11, 2020, Novavax entered into an agreement with the Center for Epidemic Preparedness Innovations (CEPI) to undertake a Project.³⁷⁹ According to published information from CEPI, it has

invested up to \$399m to accelerate the development and manufacture of Novavax’s NVX-CoV2373 vaccine candidate against COVID-19. \$142.5m of this funding is a forgivable loan which is recoverable on product sales. This investment will support preclinical studies

370 *Id.*, Section 9(b).

371 *Id.*, Section 10(b).

372 ATI-Novavax, *Base Agreement*. 2018. www.keionline.org/misc-docs/DOD-ATI-Novavax-Contract-W15QKN1691002-25June2020.pdf

373 Statement of Work, Section 1.5: “If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.”

374 “The federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government retains a ‘nonexclusive, nontransferable, irrevocable, paid-up license’ for its own benefit. The Bayh-Dole Act also provides federal agencies with ‘march-in rights,’ codified at 35 U.S.C. §203. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a ‘nonexclusive, partially exclusive, or exclusive license’ to a ‘responsible applicant or applicants.’ If the patent owner refuses to do so, the government may grant the license itself. No federal agency has ever exercised its power to march in and license patent rights to others.” (Congressional Research Service 2016)

375 US FDA, *Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted* | FDA. 2022. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted

376 Choi, J. *US government buying another 1.5M doses of Novavax COVID vaccine* | *The Hill*. 2023. <https://thehill.com/homenews/3855673-us-government-buying-another-1-5m-doses-of-novavax-covid-vaccine/>

377 Novavax_media_relations, *Third quarter 2022 financial results & operational highlights*. 2022. <https://ir.novavax.com/investor-hub>

378 “Over 19 million doses delivered to date by strategic partners (Serum Institute of India, SK bioscience and Takeda),” *Third Quarter 2022 Results*.

379 Novavax_CEPI, *Outbreak Response Funding Agreement (Step 2)*. 2020. Novavax-CEPI. www.sec.gov/Archives/edgar/data/1000694/000110465920092782/nvax-20200630xex10d1.htm

and phase 1 and phase 2 clinical trials as well as manufacturing activities. Operation Warp Speed is funding the pivotal trial.³⁸⁰

The forgivable loan is referenced by amount in the Project Agreement described below, but the other funding is not specifically disclosed.

The Project Agreement provides that Novavax will retain ownership of its intellectual property existing as of the effective date of the agreement, and further provides that Novavax will own all IP resulting from the Project Agreement.³⁸¹ Novavax is responsible for conducting clinical trials,³⁸² as well as pursuing regulatory approval of a product developed under the Agreement.³⁸³ The Project Agreement includes what may be described as “march-in rights” in favor of CEPI that allows it to take over and license the IP associated with the product in the event that Novavax either declines to meet CEPI’s request to expand the project, or (by mutual agreement) is unable to perform pursuant to the agreement, or is a material breach which it has failed to cure.³⁸⁴ This will also require Novavax to engage in technology transfer to the substitute performing party(ies) engaged by CEPI to perform in its place.³⁸⁵

The Project Agreement includes a provision addressing “Equitable Access” that recites CEPI’s commitment that a Project Vaccine “is available first to populations at risk when and where they are needed at affordable prices” and “that the price of a Project Vaccine shall be commercially sustainable to the manufacturer.”³⁸⁶ The Project Agreement anticipates that there will be established a Global Allocation Body (envisioning COVAX) and that Novavax will negotiate in good faith a separate supply agreement with that entity. The specific quantity of vaccines to be provided to the Global Allocation Body are redacted from the publicly available agreement, but it provides that Novavax will not supply vaccines to third parties if it conflicts with its supply obligations under the Project Agreement.

With respect to pricing, the agreement does not set a price, but indicates that it shall be reasonable to achieve Equitable Access “as well as an appropriate return on investment for vaccine manufacturers that make on-going supply commercially sustainable.”³⁸⁷ CEPI is given the right to audit Novavax costs.³⁸⁸

As part of the arrangement under the Project agreement, CEPI agrees to fund Novavax manufacturing related expenses, including reservation fees to secure future production capacity and to obtain raw materials, initially making available USD 142,500,000. If and when Novavax secures payment for the Project Vaccines, it is obligated to repay the loan amount “in excess of” its corresponding cost of goods.³⁸⁹ The agreement provides that generally CEPI is required by its funders to obtain a share of Novavax “Commercial Benefits” from the agreement, but it waives that requirement to the extent that Novavax has complied with the equitable access provisions.³⁹⁰

Novavax agrees to indemnify and hold harmless CEPI and its affiliates, officers, directors, third-party contractors and employees “from and against any and all claims, damages, and liabilities asserted by third parties (including claims for negligence)” which arise from Novavax activities under the Agreement, except in the case of CEPI’s negligence or intentional misconduct.³⁹¹ The terms of a liability cap are redacted.

380 CEPI, *Enabling Equitable Access to COVID-19 Vaccines: Summary of equitable access provisions in CEPI’s COVID-19 vaccine development agreements*. 2022. <https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v8-14-February-2022.pdf>

381 Novavax-CEPI, Section 5 defines ownership of Intellectual Property. Section 1.13: “Intellectual Property” is defined as “the intangible property rights claiming or covering the discoveries, inventions and materials as well as works of authorship made by Awardee under the Project, such as copyrights, patents and trademarks.”

382 Id., Section 6.

383 Id., Section 7.

384 Id., Section 13.4-5, “Public Health License” and “Public Health License Triggers,” respectively.

385 Id., Section 13.7.

386 Id., Section 14.1.

387 Id., Section 14.6

388 Id., Section 14.9.

389 Id., Section 14.14. Put another way, to the extent that Novavax would “profit” from sales, it must first pay back the loan amount from prospective profits.

390 Id., Section 15.

391 Id., Section 17.2.

The parties agreed to keep Novavax cost of goods, pricing and sales confidential, except to the extent that CEPI may use that information in an anonymized way.³⁹² The agreement provides for the arbitration of disputes, but redacts the type of arbitration.

The specifics of the Project Agreement Vaccine Product development plan are not included in the redacted public version of the agreement.

iii. GAVI/COVAX

On May 5, 2021, Novavax entered into an Advance Purchase Agreement (APA) with the GAVI ALLIANCE (“Gavi”) pursuant to which Gavi agreed to purchase up to 350 million doses of the Novavax vaccine on behalf of the COVAX facility.³⁹³ This quantity would supplement the purchases by Gavi/COVAX of vaccines from the Serum Institute of India (SII) to which Novavax granted a license to manufacture and supply the vaccine, among other things, to COVAX (see discussion below). Although the Agreement does not specify the purchase price or the total purchase amount in the redacted version, presumably the amount of the APA commitment is reflected in the funding amount under the CEPI Project Agreement. Of principal interest from the point of view of this Study is that this agreement expressly leaves ownership of all relevant intellectual property in the hands of Novavax,³⁹⁴ but the performance of Novavax is subject to the IP rights march-in clause included in the CEPI Project Agreement.³⁹⁵ The agreement provides for arbitration of disputes, but redacts the specifics associated with that process. In that connection, the parties waive a right of review by courts.³⁹⁶

On November 23, 2022, Novavax announced the termination of the APA with Gavi stating that Gavi had failed to purchase the contracted vaccines before the end of 2022 notwithstanding Novavax readiness to deliver. Novavax indicated that the advance payments made to it are not refundable and that it does not expect to incur any penalties in connection with the termination.³⁹⁷ In February 2023, the New York Times reported that Gavi has sought a refund from Novavax: “Another drug company, Novavax, is refusing to refund another \$700 million in advance payments for shots it never delivered.”³⁹⁸ Note above that the parties had agreed to arbitration of disputes in the APA.

iv. Serum Institute of India

On July 30, 2020, Novavax entered into a Supply and License Agreement with the Serum Institute of India (SII).³⁹⁹ That initial agreement provided for Novavax to supply vaccine components to SII for fill and finish in India. However, that agreement contemplated and the parties shortly thereafter (September 15, 2020) signed an agreement under which SII would manufacture the antigen component of the vaccine in India based on technology transferred from Novavax.⁴⁰⁰ ⁴⁰¹ When announcing the manufacturing agreement, Novavax indicated that its total global manufacturing capacity would exceed 2 billion doses per year, and that SII would manufacture up to 1 billion doses per year.

The supply and license agreement provided that SII would be the exclusive supplier of the vaccine product in India, that Novavax would be the exclusive supplier of the product in high

³⁹² Id., Section 18.1.

³⁹³ GAVI-Novavax, *Advance Purchase Agreement for purchase of Covid-19 vaccines*. 2021. GAVI-Novavax. www.sec.gov/Archives/edgar/data/1000694/000155837020013462/nvax-20200930xex10d4.htm

³⁹⁴ Id., Section 16.2: “Intellectual Property... No rights or obligations in respect of a Party’s Intellectual Property Rights are granted, or are implied to be granted, to the other Party by this Agreement. In particular, Novavax will be the sole owners of all Intellectual Property Rights generated during the development, manufacture and supply of the Vaccine or otherwise related to the Vaccine, and nothing in this Agreement shall affect Novavax’s ownership of such rights.”

³⁹⁵ Id., Section 13.5 (“Public Health License”).

³⁹⁶ Id., Sections 14.1-2.

³⁹⁷ Novavax_media_relations, *Termination of COVID-19 Vaccine Purchase Agreement with Gavi*. 2022. <https://ir.novavax.com/Termination-of-COVID-19-Vaccine-Purchase-Agreement-with-Gavi>

³⁹⁸ Stephanie Nolen and Rebecca Robbins, *Vaccine Makers Kept \$1.4 Billion in Prepayments for Canceled Covid Shots for the World’s Poor*, in *NY Times*. 2023. www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html

³⁹⁹ Serum Institute of India-Novavax, *Supply and License Agreement*. 2020. SII-Novavax. www.sec.gov/Archives/edgar/data/1000694/000155837020013462/nvax-20200930xex10d4.htm

⁴⁰⁰ The text of the manufacturing agreement has not been made publicly available. It does not appear that the adjuvant produced by Novavax would be produced by SII.

⁴⁰¹ Novavax_media_relations, *Novavax Announces COVID-19 Vaccine Manufacturing Agreement with Serum Institute of India, Increasing Novavax’ Global Production Capacity to Over 2 Billion Doses Annually*. 2020. <https://ir.novavax.com/2020-09-15-Novavax-Announces-COVID-19-Vaccine-Manufacturing-Agreement-with-Serum-Institute-of-India-Increasing-Novavax-Global-Production-Capacity-to-Over-2-Billion-Doses-Annually>

income countries, and that the parties would share nonexclusive rights elsewhere. SII is obligated to pay Novavax 50 percent of its revenues under the Supply and License Agreement.⁴⁰² Novavax is obligated to pay SII 50 percent of its revenues on sales of products manufactured by SII and supplied in the nonexclusive territories.⁴⁰³ Novavax is licensing its technology to SII solely for the purpose of manufacturing and distributing the product in the exclusive and nonexclusive territories, and SII commits to not reverse engineer the vaccine components.⁴⁰⁴ Although the publicly available Supply and License Agreement redacts various terms with respect to intellectual property, it appears that Novavax retains ownership to all IP associated with the vaccine product.⁴⁰⁵ Novavax commits to a broad transfer of technology under the Supply and License Agreement.⁴⁰⁶ SII is responsible for obtaining regulatory approval for the vaccine in India and elsewhere in the nonexclusive territory.⁴⁰⁷ Each party grants the other a right of reference with respect to regulatory approvals.⁴⁰⁸

It is difficult to determine how many doses of the Novavax vaccine, referred to as Covovax by SII, have been delivered by SII in India or elsewhere. Unlike with respect to the AstraZeneca vaccine, it does not appear that SII overproduced Covovax, and SII has not publicly announced a plan to discontinue production.

Novavax and SII entered into a separate agreement (“Supply Agreement”) dated October 25, 2021 that defined the terms pursuant to which Novavax could order the vaccine product for delivery to Novavax customers either in the Novavax exclusive territory or the SII/Novavax nonexclusive territory.⁴⁰⁹ The terms of that agreement are consistent with the Supply and License Agreement of July 30, 2020.

v. SK Bioscience – Republic of Korea

By agreement dated December 23, 2021, Novavax and SK Bioscience agreed to amend the terms of an initial Collaboration and License Agreement of February 12, 2021, which contemplated the manufacture by SK Bioscience pursuant to technology transfer from Novavax of a substantial quantity of vaccines to be supplied to the Republic of Korea’s government (up to 40 million doses).⁴¹⁰ The amended agreement would extend the quantity available to the Republic of Korea’s government by 5 million doses, and also make provision for supply of the vaccine by SK to the governments of Thailand and Viet Nam.

The agreement addresses intellectual property both for an original antigen product, as well as for a variant antigen product under development.⁴¹¹ As under the initial agreement, SK will manufacture antigen based on technology transferred from Novavax, but Novavax will continue to supply its proprietary adjuvant so that the vaccine product may include components both from Novavax and SK. Pursuant to the Collaboration and License Agreement, including as amended, Novavax maintains ownership of the intellectual property embodied in the vaccine product. Novavax grants a nonexclusive royalty-bearing license to SK, although the royalty rates are not specified in the publicly-available agreement.⁴¹² However, the relevant data can be found

402 SII-Novavax, Section 6.1(a).

403 Id., Appendix B.

404 Id., Section 2.

405 Id., See, e.g., Section 9.1(d): “9.d For the sake of clarity all Intellectual Property Rights in relation to the Vaccine Components and the Licensed Know-How, shall be the exclusive proprietary concern of Novavax.”

406 Id., Section 5.1.

407 Id., See, e.g., Section 2.5.

408 Id., Section 4.5.

409 Novavax-SII and Serum Life Sciences Limited, *Supply Agreement*. 2021. www.sec.gov/Archives/edgar/data/1000694/000100069422000004/nvax-20211231xex1037.htm

410 Novavax_media_relations, *Novavax and SK bioscience Expand Manufacturing Agreement*. 2021. Novavax--SII Supply. <https://ir.novavax.com/2021-12-23-Novavax-and-SK-bioscience-Expand-Manufacturing-Agreement>

411 Collaboration and License Agreement between SK Bioscience and Novavax, Feb. 12, 2021 (hereinafter “SK Collaboration”), <https://www.sec.gov/Archives/edgar/data/1000694/000100069421000008/nvax-20210331xex101.htm>, Section 3.1.

412 Id., Section 12.4.1; Amended agreement, Section 12.4.1.

in Novavax form 10Q quarterly report for the period ended March 31, 2022, referring to the SK royalty “in the low to middle double-digit range.”⁴¹³

vi. Fujifilm

Novavax also entered into a contract manufacturing agreements with Fujifilm Diosynth Corporation on June 30, 2020 and August 30, 2021 which Novavax is reported in October 2022 to have terminated, and for which it will pay Fujifilm up to USD 185 million for Fujifilm’s expenses that could not be mitigated.⁴¹⁴

vii. Takeda

In September 2021, Japan’s Ministry of Health announced that it would purchase 150 million doses of Novavax vaccine to be manufactured by Takeda Pharmaceutical Company in Japan.⁴¹⁵ On February 10, 2023, Takeda reported that the Ministry of Health had cancelled the arrangement having received less than 10 million doses from Takeda.⁴¹⁶

viii. Australia

By agreement dated December 31, 2020, the Department of Health of Australia entered into an Advanced Purchase Agreement with Novavax.⁴¹⁷

The agreement provides for a nonrefundable advance payment (amount unspecified in publicly available agreement).⁴¹⁸ The agreement makes clear that Australia does not acquire any interest in Novavax intellectual property, other than for the purpose of distributing the vaccine in the territory.⁴¹⁹ The agreement provides that in the eventuality the customer (Australia) does generate intellectual property, that intellectual property will immediately vest in Novavax.⁴²⁰ Three million doses of the vaccine were reported to have arrived in Australia on February 7, 2022, with another 48 million doses “expected to arrive over the coming weeks.”⁴²¹ It is not clear when and whether the additional doses arrived.

ix. European Union

An Advance Purchase Agreement entered into between the European Commission and Novavax, for a minimum 20 million doses and maximum 100 million doses, reserved all IP rights to

413 Per the 10-Q: “SK bioscience, Co., Ltd.: The Company has a collaboration and license agreement with SK bioscience, Co., Ltd. (‘SK bioscience’) to manufacture and commercialize NVX-CoV2373 for sale to the governments of Republic of Korea, Thailand and Viet Nam. SK bioscience pays a royalty in the low to middle double-digit range. Additionally, the Company has a manufacturing supply arrangement with SK bioscience under which SK bioscience supplies the Company with the antigen component of NVX-CoV2373 for use in the final drug product globally, including product to be distributed by the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies.” Novavax 10-Q for period ended Mar. 31, 2022, <https://www.sec.gov/Archives/edgar/data/1000694/000100069422000009/nvax-20220331.htm>

414 Stanton, D. *Novavax axes Fujifilm CDMO vaccine contract - BioProcess Insider*. 2022. <https://bioprocessintl.com/bioprocess-insider/facilities-capacity/novavax-to-pay-fujifilm-up-to-185m-after-axing-vaccine-contract/>

415 Takeda_Media_Relations, *Takeda to Manufacture and Provide 150 Million Doses of Novavax’ COVID-19 Vaccine Candidate to the Government of Japan*. 2021. www.takeda.com/newsroom/newsreleases/2021/takeda-to-manufacture-and-provide-150-million-doses-of-novavax-covid-19-vaccine-candidate-to-the-government-of-japan

416 Takeda_Media_Relations, *Cancellation of the Purchase Schedule of Nuvaxovid® Intramuscular Injection by the Japanese Government*. 2023. www.takeda.com/announcements/cancellation-of-purchase-schedule-of-nuvaxovid

417 Novavax-Australia-Dept_of_Health, *Advanced Purchase Agreement*. 2020. www.sec.gov/Archives/edgar/data/1000694/000100069421000004/exhibit1036.htm

418 Id., Section 5.1.

419 Id., Section 6.

420 Id.

421 ABC_News_Staff *First batch of the Novavax COVID vaccine arrives in Australia - here’s what happens next*. ABC News, 2022. www.abc.net.au/news/2022-02-08/novavax-lands-in-australia-vaccine/100812276

Novavax, including any IP developed by a participating Member State.⁴²² Deliveries to the European Union were reported to have started in February 2022, although the number of doses ultimately delivered by Novavax is not reported. A price per dose for a purchase by Denmark was reported at USD 20.90.⁴²³

x. Canada

Novavax entered into an Advanced Purchase Agreement with Canada on January 19, 2021.⁴²⁴ The agreement established a commitment for Canada to purchase 52 million doses, and a right for Candidate to purchase an additional 24 million doses.⁴²⁵ Canada was limited to use of the doses within its territory, but was authorized to donate vaccines outside Canada.⁴²⁶ Canada committed to a nonrefundable advance payment, although the amount of said payment and the price of the vaccines is redacted from the publicly available version.⁴²⁷ With respect to intellectual property, Canada agreed that all intellectual property relevant to the vaccine was and is owned by Novavax, and that any IP developed by Canada with respect to the vaccine would be owned by Novavax.⁴²⁸ In addition, Canada agrees to indemnify and hold harmless Novavax from any injuries it may suffer as a result of performance under the agreement, and the publicly released version of the agreement does not exclude negligence or willful misconduct by Novavax.⁴²⁹ The agreement includes a statement with acknowledgment by Novavax that it will work toward establishing a mutually beneficial contract manufacturing relationship in Canada for one or more Novavax vaccines, including for drug substance manufacturing and/or final formulation, filling and finishing.⁴³⁰ Disputes are to be settled by binding arbitration.⁴³¹

On March 31, 2022 it was reported that the first 3.2 million doses of Nuvaxovid had arrived in Canada.⁴³² On December 7, 2022, Novavax reported that its vaccine would be manufactured at the Biologics Manufacturing Centre in Montreal beginning in early 2023.⁴³³ As of January 29, 2023, official Canadian statistics indicate that 30,722 doses of the Novavax vaccine had been administered in Canada out of a total of approximately 97 million doses administered

422 Per the EU APA: "1.9.Vaccine IP rights... The Commission and the Participating Member States acknowledge and agree that the Contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the 'Vaccine IP Rights'). The Contractor shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this APA, the Contractor does not grant to the Commission or any of the Participating Member States by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by the Contractor hereunder are reserved by the Contractor. To the extent a Participating Member State, directly or indirectly, creates, discovers, reduces to practice or otherwise generates intellectual property relating to the composition or method of use of the Product and in connection with the activities contemplated by this APA, such intellectual property will be solely owned by the Contractor. The Participating Member State shall assign, and hereby does assign, to the Contractor all such intellectual property, and will take reasonable actions requested by the Contractor, at the Contractor's expense, to record and confirm the Contractor's ownership thereof, including signing formal documentation evidencing the Contractor's ownership thereof." EU Commission-Novavax, Advance Purchase Agreement, SANTE/2020/C3/087 - SI2.854725, <https://www.sec.gov/Archives/edgar/data/1000694/000100069421000020/nvax-20210930xex108.htm>

423 Kollwe, J. *Covid-19 vaccines: the contracts, prices and profits*. The Guardian, 2021. www.theguardian.com/world/2021/aug/11/covid-19-vaccines-the-contracts-prices-and-profits

424 Novavax-Canada, *Advanced Purchase Agreement*. 2021 Novavax-Canada. www.sec.gov/Archives/edgar/data/1000694/000100069421000004/exhibit1037.htm

425 Novavax-Canada, Section 2 and Exhibit A.

426 Id., Section 2.3.1.

427 Id., Section 5.

428 Id., Section 7: "Customer hereby acknowledges and agrees that all rights, title and interests in, to and under any intellectual property that relate to the Product are and shall remain the sole and exclusive property of Novavax. This Agreement does not grant Customer and right, title or interest in, to or under any such intellectual property or any other intellectual property owned or controlled by Novavax. To the extent Customer, directly or indirect creates, discovers, reduces to practice or otherwise generates intellectual property relating to Product in connection with the activities contemplated by this Agreement, such intellectual property will be solely owned by Novavax. Customer shall assign, and hereby does assign, to Novavax all such intellectual property, and will take reasonable actions requested by Novavax [***] to record and confirm Novavax's ownership thereof, including executing formal documentation evidencing Novavax's ownership thereof."

429 Id., Section 9.3.1: "By Customer. Notwithstanding any contrary provision of this Agreement and to the fullest extent not prohibited by applicable laws, Customer will defend, indemnify and hold harmless Novavax and its affiliates and its or their respective officers, directors, employees, agents and contractors (each a 'Novavax Indemnitee') from and against any and all claims, demands, causes of action, damages, losses, liabilities, costs, expenses (including legal fees and litigation expenses), penalties, fines, settlements and judgments (collectively, 'Losses') resulting from a claim (each, a 'Claim') arising out of or in connection with any one or more of [***]. Notwithstanding any provision of this Agreement to the contrary, the provisions of this Section 9.3.1 shall apply and be binding on Customer regardless of whether any defect in the Product causing any Losses originates from the testing, development, manufacture, delivery, export, import, distribution sale, offer for sale, administration, use or deployment of the Product."

430 Id., Section 15.

431 Id., Section 14.6.1. Key terms are redacted.

432 Parkhill, M. *COVID-19 vaccine: Novavax deliveries arrive in Canada* | CTV News. CTVNews, 2022. www.ctvnews.ca/health/coronavirus/novavax-deliveries-arrive-in-canada-1.5843358

433 Novavax_media_relations, *Novavax Nuvaxovid COVID-19 Vaccine Approved in Canada for Use as a Primary Series in Adolescents*. 2022. <https://ir.novavax.com/2022-12-07-Novavax-Nuvaxovid-COVID-19-Vaccine-Approved-in-Canada-for-Use-as-a-Primary-Series-in-Adolescents>

(of which about 64 million were from Pfizer and 29 million from Moderna).⁴³⁴ This fairly raises question whether there is adequate demand for the Novavax vaccine to sustain production within Canada.

xi. United Kingdom

Novavax entered into an agreement with the United Kingdom for the supply of its vaccine on October 22, 2020. That initial agreement was amended and replaced on July 1, 2022.⁴³⁵ The amended agreement contemplated a significant preference for manufacture of the Nuvaxovid vaccine to take place within the United Kingdom by a facility operated by Fuji.⁴³⁶ However, it did not require UK manufacturing. Under the terms of the agreement, Novavax retains ownership of its intellectual property in the vaccine.⁴³⁷ The parties agree to maintain information in confidence.⁴³⁸ As noted above, Novavax terminated at least a portion of its manufacturing agreements with Fuji as of October 2022. Though there has been some reporting of at least preliminary manufacturing steps taking place in the United Kingdom, it was not clear whether scale production was subsequently ramped.⁴³⁹ Moreover, only in September 2022 did Novavax indicate that it had delivered the first 1 million doses of its vaccine in the United Kingdom.⁴⁴⁰ Data on the number of Novavax vaccine doses actually administered in the United Kingdom is difficult to ascertain.

xii. Novavax vaccine access policy

Novavax received funding from CEPI which contemplated delivery of substantial quantities of vaccine to COVAX (through Gavi), and the funding from CEPI was conditional on provision of vaccines to COVAX at cost, with commercialization rights of Novavax elsewhere reserved. Novavax licensed its technology and provided proprietary material inputs to the Serum Institute which offered low-priced access of the vaccine to LMICs. Novavax received large-scale funding from the US government and entered into a significant supply agreement, although the price per dose under that agreement has not been made publicly available, and few doses were actually delivered.

Outside the CEPI-funded agreements, there is no report of special concessionary pricing offered by Novavax, and its agreements with third parties tightly restrict access to and use of its technology.

Because COVAX and the Serum Institute would be providing the Novavax vaccine at a low price to LMICs, and the Serum Institute had the expertise to manufacture at scale, it is not apparent that LMICs were adversely impacted by intellectual property insofar as the Novavax vaccine goes. There were significant delays having to do with approvals and limits on the quantity of adjuvant materials that affected scaling manufacturing lines, but IP does not appear to have been a major factor in this.

While in the end Novavax developed a vaccine that has been approved for use in a significant number of countries, and may have certain advantages compared with other offerings (e.g., storage at ordinary temperatures), the overall effort was not successful in terms of addressing the pandemic emergency. It is possible that if Novavax had opened up its technology to any party wanting to use it that some third party would have more successfully introduced the vaccine through a manufacturing network. Because the US government and CEPI provided very substantial funding for completing the development and clinical trials of the vaccine, it may have required the cooperation of these parties in agreeing that the technology would be opened.

434 Public_Health_Agency_of_Canada, *COVID-19 vaccine doses administered in Canada - Canada.ca*. 2023. <https://health-infobase.canada.ca/covid-19/vaccine-administration/>

435 Novavax-United Kingdom, *Amended and Restated SARS-CoV-2 Vaccine Supply Agreement as of 1 July 2022*. 2022.

436 *Id.*, see Section 5.

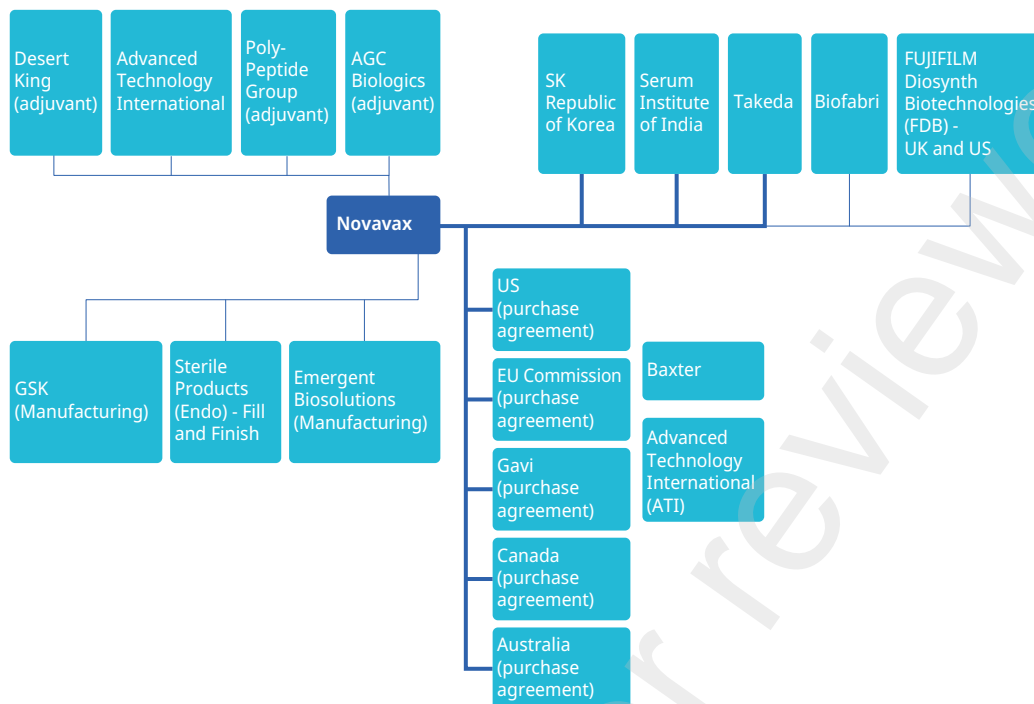
437 *Id.*, Section 19.1: "Neither Party will gain any rights of ownership to or use of any property or Intellectual Property Rights owned by the other whether by virtue of this Agreement, by implication or otherwise."

438 *Id.*, Section 20.

439 NEPIC *Production of the Novavax vaccine gets under way in Billingham - Nepic*. 2022. www.nepic.co.uk/blog/memberposts/production-of-the-novavax-vaccine-gets-under-way-in-billingham/

440 Novavax_media_relations, *Novavax Makes One Million Doses of Nuvaxovid™ Available for Use in the United Kingdom*. 2022. <https://ir.novavax.com/2022-09-27-Novavax-Makes-One-Million-Doses-of-Nuvaxovid-TM-Available-for-Use-in-the-United-Kingdom>

Novavax mapping



Summary: Novavax

- Smaller vaccine developer without approved vaccine
- Major development and advance purchase funding from Operation Warp Speed
- Funding from CEPI requires cost-plus reasonable access price for LMICs
- Recombinant DNA vaccine candidate – patented
- Novavax retains IP with US march-in rights
- Uses Matrix M Chilean tree bark derived adjuvant
- No ultra-cold chain storage required
- Limited pre-existing manufacturing or supply chain structure
- Subcontracting globally
- Enters into manufacturing and distribution license with SII
- APA with EU, United Kingdom and others
- No vaccine approved until July 2022
- Limited demand, manufacturing contracts terminated with expenses paid
- Novavax seeks payment for cancelled doses from COVAX and others
- In arbitration
- Small maintenance contract with US government
- Novavax stock price rose above USD 300/share at height of pandemic; today around USD 7/share

6. CureVac

CureVac does not presently have an approved COVID-19 vaccine on the market. In October 2021 it withdrew its application regarding its initial vaccine candidate in Europe and elsewhere.⁴⁴¹

441 Zimmer, C., *CureVac has withdrawn its Covid vaccine application to European regulators*. (Published 2021), in *NY Times*. 2021. www.nytimes.com/2021/10/12/health/curevac-covid-vaccine-europe.html

CureVac is presently engaged in clinical trials of a vaccine candidate developed in collaboration with GSK and using a different technology.⁴⁴²

While CureVac more recent approach to vaccine development technology may yield an efficacious vaccine, in theory preferable to some other comparable vaccines, the principal focus of this report is on the extent to which intellectual property may have facilitated or inhibited the global response to the COVID-19 pandemic. Almost certainly there will be a demand for continued vaccinations to address some variation of the SARS-CoV-2 virus. This appears likely to be a highly competitive market (public and private) in which the major pharmaceutical companies will vie to capture market share, and more typical of the “non-emergency” global pharmaceutical market. IP is going to play a role in that market (public or private).

CureVac received funding from the Gates foundation well prior to the outbreak of the COVID-19 pandemic pursuant to a Global Access Commitments Agreement of February 13, 2015,⁴⁴³ and less than a year before the outbreak of the pandemic CureVac had received funding from CEPI for research involving mRNA platform technology pursuant to a Framework Partnering Agreement dated February 15, 2019.⁴⁴⁴ The project funded under that CEPI agreement was called “Rapid Response mRNA Vaccine Platform for Epidemic Preparedness.” CEPI refers to that Framework as the basis for an initial USD 15.3 million funding relating to COVID-19.

The follow-on development agreement between CEPI and CureVac is not publicly available. However, CureVac has described its terms in some detail in its fiscal 2021 SEC Form 20-F filing.⁴⁴⁵

442 Described by CureVac as follows: “CV0501 is the first COVID-19 vaccine candidate applying chemically modified mRNA from the COVID-19 vaccine program developed in collaboration with GSK. It is based on CureVac’s advanced second-generation mRNA backbone. CV0501 encodes the prefusion stabilized full-length spike protein of the SARS-CoV-2 Omicron variant BA.1 and is formulated with lipid nanoparticles (LNPs). As for all vaccine candidates applying the second-generation mRNA backbone, CV0501 was designed with specifically optimized non-coding regions aiming to deliver improved mRNA translation for increased and extended protein expression compared to the first-generation mRNA backbone....The ongoing Phase 1 dose-escalation study is assessing the safety, reactogenicity and immunogenicity of CV0501 as a booster vaccination in the dose range of 12 to a potential maximum of 200µg in the predefined age groups of 18-64 years and ≥65 years. It is expected to also test additional cohorts at a 3 and 6µg dose level. The study is being conducted in the U.S., Australia, and the Philippines and is expected to enroll up to 180 healthy participants.” CureVac Press Release, CureVac Announces Positive Data on Joint COVID-19 and Flu mRNA Vaccine Development Programs, Jan. 30, 2023, <https://www.curevac.com/en/curevac-announces-positive-data-in-older-adults-from-covid-19-and-flu-mrna-vaccine-development-programs/>

443 Gates_Foundation-CurVac, *Global Access Commitments Agreement*. 2015. Global Access Commitments Agreement. https://www.sec.gov/Archives/edgar/data/1809122/000110465920089179/tm2016252d8_ex10-7.htm

444 CEPI (2022): “CEPI and CureVac had previously entered into an agreement to develop their mRNA platform technology, and that agreement served as the basis for extending that previous program toward the development of a vaccine against COVID-19, based on the mRNA platform. This expanded program includes additional initial funding of up to \$15.3 million by CEPI for the accelerated vaccine development, manufacturing and phase 1 clinical trial.”

445 As follows: “Coalition for Epidemic Preparedness Innovations Framework Partnering Agreement: In February 2019, we entered into a framework partnership agreement with CEPI, which as amended we refer to as the CEPI Agreement, to develop our RNA Printer using certain intellectual property controlled by us covering the development and manufacture of mRNA products as well as certain additional intellectual property licensed to us. In connection with the CEPI Agreement ... we entered into a work package for the preclinical development and a Phase 1 clinical trial for our first-generation SARS-CoV-2 vaccine, CVnCoV....We are required to use reasonable efforts to achieve certain development milestones and are responsible for conducting certain clinical trials. We are required to share clinical trial data with CEPI, subject to the terms of specific work packages entered into in connection with the CEPI Agreement. In the event of an infectious disease outbreak, where such outbreak can be addressed by a ... SARS-CoV-2 or future vaccine developed under the CEPI Agreement, we must manufacture such vaccine for use in the area affected by the outbreak on economic terms that satisfy CEPI’s equitable access guidelines or otherwise allow CEPI or a third-party to supply such vaccine in the affected area. For the initial term of the CEPI Agreement and for a certain period thereafter, in the event of an outbreak that cannot be addressed by a vaccine already developed under the CEPI Agreement, CEPI may request, and we may agree, that we will develop a product targeted against such outbreak, or we will assist CEPI to develop a candidate product against such outbreak. In the event we decline to enter into such a development agreement, we will grant CEPI the right to develop and stockpile such vaccines under certain of our background intellectual property and intellectual property developed under the CEPI Agreement. We are additionally required to use reasonable efforts, at CEPI’s request, to submit certain optimized antigen nucleotide sequences for up to three specified pathogens in order for CEPI to start its own product development program. We have a right of first refusal to manufacture any pharmaceutical products developed by CEPI using the antigen nucleotide sequences we provide. In certain scenarios, including if we fail to provide ... SARS-CoV-2 or future vaccines developed under the CEPI Agreement at prices that comply with CEPI’s equitable access guidelines, we must grant CEPI a license under certain of our background intellectual property and intellectual property developed under the CEPI Agreement to, among other things, develop our automation solution for use in treating such infectious diseases and to develop, manufacture and market such pharmaceutical products for use in geographic areas where there is a disease outbreak....In connection with a December 2020 amendment to the CEPI Agreement, we agreed to provide CVnCoV to organizations operating under the COVAX Facility, a global collaboration to accelerate the development, production and equitable access to SARS-CoV-2 tests, treatments and vaccines. Under this amendment, we agreed to supply a certain percentage of our total capacity for distribution of CVnCoV to organizations participating in the COVAX Facility....CEPI agreed to contribute up to \$34 million in funding for projects undertaken under the CEPI Agreement and an additional \$15.3 million in connection with development of CVnCoV. ... We solely own all intellectual property developed under the CEPI Agreement but are required to obtain CEPI’s consent prior to exploiting any intellectual property developed under the CEPI Agreement if such exploitation is in conflict with or goes against CEPI’s mission or policies....The CEPI Agreement terminated in February 2022, except with respect to certain ongoing projects, which are contemplated to be completed in March 2023.” CureVac, *SEC form 20-F for 2021*. 2022. <https://www.curevac.com/wp-content/uploads/2022/06/Annual-Report-2021-CureVac-N.-V.-on-Form-20-F.pdf>.

In its corporate disclosure filings, CureVac noted that with respect to certain of its technologies developed with funding from the German government, including with respect to a SARS-CoV-2 vaccine candidate, the government has “in the case of a special public interest, a nonexclusive and transferable right to use intellectual property generated as part of the funded work.”⁴⁴⁶

CureVac has in-licensed patented technology relating to lipid nanoparticles (LNPs) from Arcturus and Acuitas. The Arcturus Agreement involves an initial commitment payment, and additional payments depending on CureVac’s decision to reserve certain targets.^{447, 448} The Acuitas Agreement involves milestone and royalty payments, and provides CureVac nonexclusive rights to use the relevant LNP technology.^{449, 450} Recall that Acuitas is involved in licensing with Pfizer/BioNTech, and is also involved in litigation with Genevant and Arbutus.⁴⁵¹

CureVac entered into a number of arrangements intended to permit the scaling up of production of its initial vaccine candidate “CVnCoV.” This included agreements with Bayer, Wacker and Fareva. The agreement with Bayer was “for infrastructure in areas such as clinical operations, regulatory affairs, pharmacovigilance, medical information, supply chain performance as well as support in selected countries.”⁴⁵² The agreement with Wacker foresaw the production of the mRNA drug substance at Wacker’s biotech facility in Amsterdam.⁴⁵³ The agreement with Fareva was for fill and finish in France.⁴⁵⁴

446 Regarding Germany: “We would be entitled to compensation in the event a use order is issued with respect to our owned or in-licensed patents; however, such compensation may be less than what we could otherwise receive and any such use order could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.” CureVac also noted: “... a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit, without consent or compensation, inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in countries that Russia has deemed unfriendly. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.” Id., Form 20-F.

447 CureVac-Arcturus, *Co-development and Co-commercialization Agreement*. 2018. www.sec.gov/Archives/edgar/data/1566049/000156459018013460/arct-ex413_1676.htm

448 The Collaboration Agreement has been amended several times: “We paid Arcturus an up-front fee of \$5 million in connection with the Arcturus Agreement and must pay an extension fee of \$1 million if we exercise our option to extend the initial term of the Arcturus Agreement beyond July 2023. We are further required to reimburse Arcturus for certain costs incurred in connection with development activities and provide certain FTE funding. ... Under the Arcturus Agreement, Arcturus granted us a worldwide, non-exclusive license under its LNP technology for research and preclinical development. We granted Arcturus a worldwide, non-exclusive license under our mRNA technology solely to enable Arcturus to perform development activities in connection with the Arcturus Agreement....The Arcturus Agreement will expire in July 2023 unless earlier terminated or extended for an additional 18-month term.” CureVac Form 20-F, above note 445.

449 CureVac-Acuitas, *Development and Option Agreement*. 2016. www.sec.gov/Archives/edgar/data/1809122/000110465920086354/tm2016252d12_ex10-11.htm

450 “Acuitas Non-exclusive License Agreements: For each option we have exercised under the Acuitas Agreement, we have entered into a non-exclusive license agreement with Acuitas with respect to such optioned product, all based on the same form agreement, which we collectively refer to as the Acuitas License Agreements. Under the Acuitas License Agreements, Acuitas grants us a non-exclusive, non-transferable, sublicensable (subject to certain conditions) worldwide license under Acuitas’s LNP technology to develop, manufacture and commercialize licensed products directed to the optioned targets. We may convert the non-exclusive licenses to exclusive licenses subject to certain additional financial obligations....We must pay Acuitas up to between USD 1.1 million and USD 1.6 million in development milestone payments, USD 1.3 million and USD 1.8 million in regulatory milestone payments and USD 1.3 million and USD 1.8 million in commercial milestone payments under each Acuitas License Agreement upon the occurrence of certain milestone events. We additionally are obligated to pay Acuitas annual fees ranging from USD 5,000 to USD 10,000 for any additional protein targeted by a vaccine product licensed under an Acuitas License Agreement after a certain milestone event. We are further required to pay Acuitas a low single-digit tiered percentage royalty on net sales of licensed products, subject to certain potential customary reductions. Our royalty obligations continue under each Acuitas License Agreement on a country-by-country and product-by-product basis until the later of the expiration of the last-to-expire licensed patent claim covering such licensed product in such country, expiration of any regulatory exclusivity period for such product in such country and 10 years following the first commercial sale of such product in such country. As of December 31, 2021, we have made USD 100,000 in development milestone payments to Acuitas with respect to the license agreement relating to Rabies RAV-G, and we have made USD 1.4 million in development milestone payments (Phase I, Phase II and Phase III milestone payments) to Acuitas with respect to the license agreement relating to the SARS-CoV-2 Spike protein S and have not made any royalty payments....Each Acuitas License Agreement will continue on a product-by-product and a country-by-country basis until there are no more payments owed to Acuitas for such product in such country.” CureVac Form 20-F, above note 445.

451 Jacob Plieth, E.E. *Curevac muddies the Moderna/Arbutus waters further*. Evaluate Vantage, 2020. www.evaluate.com/vantage/articles/news/patents-and-litigation/curevac-muddies-modernaarbutus-waters-further

452 Bayer_media_relations, *CureVac and Bayer join forces on COVID-19 vaccine candidate CVnCoV*. 2021. www.bayer.com/media/en-us/curevac-and-bayer-join-forces-on-covid-19-vaccine-candidate-cvncov/

453 Wacker_media_relations, *CureVac and WACKER Sign Manufacturing Contract for CureVac’s COVID-19 Vaccine Candidate: CVnCoV*. 2023. www.wacker.com/cms/en-us/about-wacker/press-and-media/press/press-releases/2020/detail-150656.html

454 CureVac_media_relations, *CureVac and Fareva Sign Agreement For Fill & Finish Manufacturing of Curevac’s COVID-19 Vaccine Candidate, CVnCoV - joint press release - CureVac*. 2020. www.curevac.com/en/curevac-and-fareva-sign-agreement-for-fill-finish-manufacturing-of-curevacs-covid-19-vaccine-candidate-cvncov-joint-press-release/

CureVac indicates that it owns a substantial patent portfolio.⁴⁵⁵ It does not specifically identify which of its patents cover its COVID-19 vaccine candidates, whether in its redacted license agreements, corporate disclosure filings or on its website. The VaxPal database identifies 10 patents relevant to Curevac's unsuccessful first-generation vaccine candidate (CVnCoV). Only one application post-dates the emergence of SARS-CoV-2, and that application is owned by Acuitas.⁴⁵⁶

Unfortunately, the initial vaccine candidate ran through clinical trials just did not perform well. Its efficacy rate in the large trial prior to withdrawal from application for approval was 48 percent,^{457, 458} compared with the mRNA vaccines of Pfizer and BioNTech which were above 90 percent.

The foregoing narrative does not suggest that the poor performance of the CureVac vaccine candidate was specifically influenced by intellectual property rights. Although there does not appear to be a definitive answer to why the vaccine did not work, it appears to be a matter of decision-making regarding application of the relevant science, not a failure to acquire rights to any particular science. Of course, we do not have a "counterfactual" in which the CureVac vaccine would have been developed in an environment without IP.

i. CureVac-GSK

CureVac persists in pursuing a successful COVID-19 vaccine in collaboration with GSK. The parties have entered into a series of agreements in July 2020, April 2021⁴⁵⁹ and March 2022.^{460, 461} The basic concept of the ongoing CureVac-GSK collaboration is that each becomes the exclusive partner of the other with respect to the development of COVID-19 vaccines, though leaving to

455 "We have built an intellectual property portfolio in the United States, Europe and other major geographies. As of March 23, 2022, we own approximately 1,056 issued patents worldwide, including 85 issued U.S. patents, 62 issued European patents (which have been validated in various European countries resulting in a total of approximately 682 national patents in European countries), and 227 issued patents in other foreign countries, 130 pending U.S. patent applications, 78 pending European patent applications, 282 pending patent applications in other foreign countries and 27 pending PCT patent applications. Our patent portfolio includes claims relating to our RNA technology platform, our CVCV delivery system, our proprietary LNP technology and our CV8102, CV7202, CV-SSIV, and our SARS-CoV-2 product candidates." CureVac Form 20-F, above note 445.

456 From the Espacenet database: 1.WO2021030701 (A1) - IMPROVED LIPID NANOPARTICLES FOR DELIVERY OF NUCLEIC ACIDS; applicant ACUITAS THERAPEUTICS INC[CA] https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210218&CC=WO&NR=2021030701A1&KC=A1 - See VaxPal for additional details, www.vaxpal.org/?keywords=Curevac&page=1

457 Cohen, J. *What went wrong with CureVac's highly anticipated new mRNA vaccine for COVID-19?* | *Science* | AAAS. Science, 2021. www.science.org/content/article/what-went-wrong-curevac-s-highly-anticipated-new-mrna-vaccine-covid-19

458 CureVac_media_relations_CureVac_Final_Data_from_Phase_2b/3_Trial_of_First-Generation_COVID-19_Vaccine_Candidate_CVnCoV_Demonstrates_Protection_in_Age_Group_of_18_to_60. 2021. www.curevac.com/wp-content/uploads/2021/06/20210630_PR_CV_Final-analysis-of-Phase-2b-3-clinical-trial-for-CVnCoV_EN_Final.pdf

459 CureVac-GSK, *COVID Collaboration and License Agreement*. 2021. https://ghiaa.org/wp-content/uploads/2021/09/CureVac_GSK_COVID-Collaboration-and-License-Agreement.pdf

460 CureVac, *SEC Form 6-K*. 2022. <https://curevac.gcs-web.com/static-files/99832a38-27e0-4cf7-b22a-e114624b851f>

461 CureVac SEC Form 6-K May 2022: "In March 2022, CureVac AG and GlaxoSmithKline Biologicals SA amended and restated the 2020 GSK agreement and the GSK COVID Agreement in connection with GSK entering into a direct agreement with Novartis for use of Novartis as a CMO at the same time as CureVac exits its CMO agreement with Novartis. Additionally, under the restated agreement, CureVac is entitled to further compensation by GSK...."

CureVac further pursuit of its first generation (unsuccessful) vaccine.⁴⁶² CureVac brings with it the technology it has in-licensed with respect to LNP.⁴⁶³

ii. Supply agreements

On November 30, 2020, CureVac announced that it had entered into an advance Purchase Agreement with the European Commission.^{464, 465} The agreement provided for delivery of 225 million doses, with an option for an additional 180 million doses. CureVac reported that it received an upfront payment of EUR 450 million, which was to be used for development and supply. CureVac would be required to return unspent portions of the upfront payment. However, when it withdrew its application for approval by the EMA of its first-generation vaccine (CVnCoV), that had the effect of automatically terminating the APA. CureVac reported that it had reached

⁴⁶² CureVac-GSK Collaboration, above note 459, Section 2.

⁴⁶³ Id., Section 2.8. In its Form 20-F filing for 2021 (filed 2022), above note 445, CureVac has provided a summary of its arrangement with GSK going forward: "GlaxoSmithKline COVID Collaboration and License Agreement. In April 2021, we entered into a new collaboration agreement with GSK, which we refer to as the GSK COVID Agreement, pursuant to which we are collaborating with GSK to research, develop and manufacture next-generation mRNA vaccines targeting the original SARS-CoV-2 strain as well as emerging variants, including multivalent and monovalent approaches, such as our second-generation COVID-19 vaccine candidate, CV2CoV. These vaccine candidates may either be used to protect unvaccinated individuals or to serve as boosters in the event that SARS-CoV-2 immunity gained from an initial vaccination reduces over time....Under the terms of the GSK COVID Agreement, we granted GSK a worldwide, exclusive, sublicensable (subject to certain conditions) license under certain of our intellectual property relating to mRNA-based vaccines targeting SARS-CoV-2 and a non-exclusive license under certain LNP technology to develop, manufacture and commercialize certain SARS-CoV-2 pathogen vaccine products, or the GSK COVID Products, for use in connection with the prevention or treatment of diseases caused by the SARS-CoV-2 pathogen. The GSK COVID Products consist of (i) next-generation SARS-CoV-2 pathogen vaccine products (other than CVnCoV), (ii) vaccine products targeting coronaviruses other than SARS-CoV-2 for which GSK exercises its exclusive option pursuant to the 2020 GSK Agreement and where we elect to develop and commercialize such product on a cost and profit split basis under the GSK COVID Agreement and (iii) next-generation SARS-CoV-2 pathogen vaccine products (other than CVnCoV) that also target one or more pathogens that the parties are targeting under the 2020 GSK Agreement, which we refer to as Combination Products. In the event we obtain rights to any intellectual property controlled by a third-party that is useful for the development, manufacture or commercialization of the GSK COVID Products, but which is not necessary to obtain freedom to operate with respect to the use or exploitation of our technology or know-how, we must, at GSK's election, use commercially reasonable efforts to obtain a sublicense to such rights on behalf of GSK. Under the terms of the GSK COVID Agreement, GSK granted us a royalty-free, non-exclusive license under certain GSK-controlled technology to perform certain development and manufacturing activities under the GSK COVID Agreement. Under the September 2021 Amendment, each party also granted the other party a royalty-free, perpetual, worldwide, non-exclusive, sublicensable license under certain inventions created by such party to freely practice, use and exploit such inventions in any field....GSK and its affiliates and sublicensees and we and our affiliates are prohibited from, subject to certain exceptions, developing, manufacturing or commercializing, directly or indirectly, any mRNA-based vaccine or mRNA-based antibody products targeting the SARS-CoV-2 pathogen, other than a GSK COVID Product as contemplated under the GSK COVID Agreement or CVnCoV. The exclusivity obligations remain in effect until the expiration or termination of the GSK COVID Agreement...We and GSK are required to complete certain development activities with respect to the GSK COVID Products set forth in various development plans. ... At GSK's request, we are required to transfer to GSK all know-how necessary for GSK's development activities under the GSK COVID Agreement and all know-how necessary for the manufacture of the GSK COVID Products. GSK is responsible for the commercialization of GSK COVID Products in all countries other than Austria, Germany and Switzerland and is required to use diligent efforts to commercialize approved GSK COVID Products in certain major market countries. At our request, we and GSK will negotiate and agree in good faith to a distribution agreement pursuant to which we will have the exclusive right to commercialize GSK COVID Products in Austria, Germany and Switzerland. We and GSK are required to provide development data to the other party through a joint steering committee....Under the GSK COVID Agreement, GSK paid us an upfront payment of €75 million. Upon GSK's exercise of its option to add CVnCoV and boosters for such vaccine as GSK COVID Products, GSK is required to compensate us for certain development costs. We and GSK agreed to equally share all development costs for GSK COVID Products, subject to certain exceptions. We and GSK will share all net profits generated from sales of GSK COVID Products, other than Combination Products, under profit sharing arrangements that in certain cases vary depending upon the GSK COVID Product in question, the time of sale, the number of doses sold and the party to whom the sale is made. We are eligible to receive tiered royalty payments ranging from a sub-teen percentage to a mid-teens percentage on net sales of Combination Products, subject to certain customary reductions. We will pay GSK a high-teen percentage royalty on net sales of all Combination Products in Austria, Germany and Switzerland....Upon expiration, the licenses granted to GSK under the GSK COVID Agreement will become fully paid-up, perpetual and non exclusive....The CureVac-GSK Consortium submitted an application and offer under the Tender Procedure for the award of a Pandemic Preparedness Agreement. The CureVac-GSK Consortium entered into a Pandemic Preparedness Agreement with the Federal Republic of Germany to supply mRNA vaccines. Following a setup period of a maximum of two years, the Pandemic Preparedness Agreement grants the government access to manufacturing capacity until 2029, enabling availability of 80 million mRNA-based vaccine doses. Under the contract, the government will pay the CureVac-GSK Consortium an annual standby fee after successful completion of the setup period, which requires the companies to maintain manufacturing capacity at constant readiness."

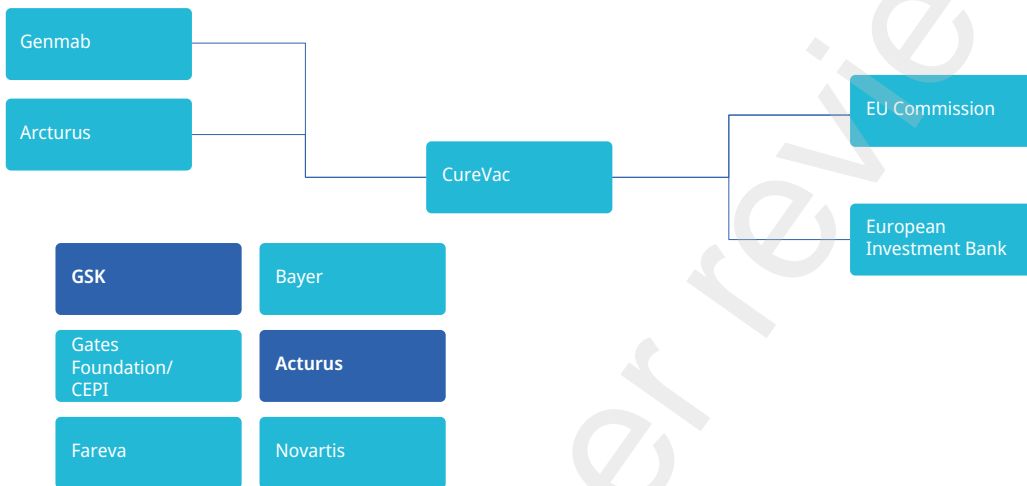
⁴⁶⁴ Last year, on November 30, 2020, CureVac entered into an Advanced Purchase Agreement (APA) with the European Commission (EC), which was acting on behalf and in the name of all Member States of the European Union to deliver 225 million doses of CVnCoV. In order to support our accelerated efforts to develop a safe and effective vaccine, the EC structured the APA to share the financial risk with CureVac and to support the development of CureVac's operations in the form of an upfront payment of EUR 450 million. Upon notification of the EC of the withdrawal of CureVac's regulatory approval application for CVnCoV in October 2021, the APA automatically terminated. According to the EU APA, in such case of termination, CureVac must return only the unspent amount of the prepayment. CureVac is in the process of submitting to the EC a report of qualified expenditures incurred or committed to using the upfront payment and do not expect that it will be required to return any portion of it. CureVac_media_relations, *CureVac Announces Financial Results for the Third Quarter and First Nine Months of 2021 and Provides Business Update*, 2021.

⁴⁶⁵ CureVac-European Commission, *Advance Purchase Agreement*, 2020. https://ghiaa.org/wp-content/uploads/2021/01/Curevac_-_redacted_advance_purchase_agreement.pdf

agreement with the EU that it was not required to return any portion of the upfront payment.⁴⁶⁶ Although neither the redacted agreement nor CureVac disclosures provided the price per dose, a leaked document showed the price per dose as EUR 10 (see note 350).

The only other “material” supply agreement entered into by CureVac (and GSK) is a Pandemic Preparedness Agreement with the federal government of Germany which is said to require it to be prepared to deliver 160 million doses of mRNA vaccine per year, either to address COVID-19 or another health emergency.⁴⁶⁷

CureVac mapping



Summary: CureVac/GSK

- German smaller biotech receives substantial funding from CEPI/Gates and Germany
- Uses mRNA platform different from Pfizer, Moderna
- Substantial patent portfolio
- In-licenses from Acuitas and others
- Substantial APA with EU
- Contracts for manufacturing in Europe
- Primary vaccine candidate fails (48% efficacy) – reason unknown
- Enters into complex Joint Venture with GSK for second generation mRNA
- Receives large standby facility funding contract from German government

466 Form 20-F for 2021: “On March 8, 2022, we received a letter signed by the EC acknowledging and outlining that we will not be required to return any portion of the up-front payment. Due to the termination of the APA, we will not receive any further payments related to the APA.”

467 Form 20-F for 2021: “On April 8, 2022, we received a letter from the Federal Republic of Germany’s counsel confirming that the Consortium (consisting of us and GSK, see above) is awarded with the Pandemic Preparedness Agreement. Pursuant to the Pandemic Preparedness Agreement, the Consortium will have to achieve, within a two years’ time frame beginning from the signing of the Pandemic Preparedness Agreement, a state in which it is considered qualified to provide manufacturing capacities in Germany for one hundred and sixty (160) million doses of mRNA vaccine per year, including procurement of the required nonproduct specific manufacturing licenses and insurances and to have achieved ‘pandemic preparedness,’ which means that we maintain the GMP IV facility in a stand-by mode that can be activated for manufacture of a so-called selected vaccine at any time and that the Consortium, inter alia, is complying with the material requirements set out in the Pandemic Preparedness Plan (in particular with the requirements regarding the assurance of a supplier network and the availability of the particularly critical supplier products and the critical supplier products)....If qualification and pandemic preparedness is achieved the Consortium will receive a certain pandemic preparedness fee / a pandemic preparedness fee, which will be shared between us and GSK in accordance with the GSK Consortium (see above). The phase during which pandemic preparedness is to be maintained is for five years, it being understood that this term may be extended by mutual agreement up to three (3) times for a subsequent one (1)-year renewal term....At any time during the pandemic preparedness phase, in case there is a public health emergency, the Federal Republic of Germany may exercise its preferred purchase right and/or its preferred manufacturing right. If the preferred purchase right is exercised we will have to deliver up to eighty (80) million doses of our mRNA vaccine, and if the preferred manufacturing right is exercised we will have to act as a contract manufacturer and manufacture a third-party’s vaccine in our GMP IV facility. However, there are strict and narrow requirements to be fulfilled before the Federal Republic of Germany may exercise the preferred manufacturing right.”

7. Baylor College of Medicine/Texas Children's Hospital

A substantial amount of public attention has been devoted to a vaccine developed at the Texas Children's Hospital and Baylor College of Medicine (operating through BCM Ventures) by Dr. Peter Hotez and colleagues. This vaccine relies on the use of a recombinant spike protein fragment isolated from the SAR-CoV-2 virus and designed to trigger an immune response.⁴⁶⁸ The Corbevax vaccine is described by its developers as being free from patents.

The formulated vaccine – as manufactured by Biological E. in India – includes an adjuvant, CpG 1018, developed and supplied by Dynavax, a company based in Emeryville, California.⁴⁶⁹ Dynavax is assignee of a number of patents surrounding CpG 1018.⁴⁷⁰ CEPI provided funding for building-up of supplies of the adjuvant by Dynavax.^{471, 472} Pursuant to a funding agreement with CEPI, Dynavax supplies its adjuvant to Biological E. at access-oriented prices for onward Corbevax supply to COVAX countries.⁴⁷³ Some vaccine developers (e.g., Novavax, GSK) stress the contribution of the proprietary adjuvant component of their COVID-19 vaccine. The use of the Dynavax adjuvant in Corbevax is acknowledged by its developer, but its contribution to efficacy is not identified (see note 477). It may be that the procurement of a patented component is important to the efficacy of the Corbevax vaccine such that it may not be free of patents in a literal sense.

The VaxPal database does not identify any patents relevant to Corbevax.

The know-how embodied in the Corbevax vaccine is controlled by BCM Ventures, and it is reported that BCM ventures requires substantial fees for the transfer of technology needed to produce the Corbevax vaccine. Details are not public, and those fees could involve vaccine cell lines or other starter materials. Although Baylor indicated that it was involved in negotiations with the WHO C-TAP program to provide its technology for out-licensing, these negotiations did not progress, although Baylor has more recently attempted to restart these discussions.

Corbevax was approved by the Indian Central Drugs Standard Control Organization (CDSCO) in June 2022 as a booster.⁴⁷⁴ The initial approvals were subject to some question as they were based on a small clinical trial cohort.⁴⁷⁵ The cohort was expanded in subsequent trials, and it received emergency authorization for primary use in patients aged five years and above.^{476, 477, 478}

468 Peter J. Hotez and Maria Elena Bottazzi, *Whole Inactivated Virus and Protein-Based COVID-19 Vaccines*. Annual Review of Medicine, 2022(73): p. 55-64. www.annualreviews.org/doi/pdf/10.1146/annurev-med-042420-113212

469 Dynavax. *CpG 1018 | toll-like receptor 9 (TLR9) agonist adjuvant | Dynavax Technologies*. 2023; Available from: www.dynavax.com/science/cpg-1018/.

470 Justia. *Patents, Patents Assigned to Dynavax Technologies Corporation - Justia Patents Search*. 2023. <https://patents.justia.com/assignee/dynavax-technologies-corporation>

471 CEPI Summary of Agreement with Dynavax: "Scale-up of manufacturing; Supply of vaccine adjuvant: Dynavax is a public company with its headquarters in Emeryville, CA USA. CEPI and Dynavax entered into an agreement on September 8, 2020 to fund scale-up of the manufacturing capacity for Dynavax's CpG 1018 vaccine adjuvant and subsequently announced an agreement on 1 February 2021 to secure CpG 1018 adjuvant in 2021 by way of an interest free, forgivable loan of up to \$99m to Dynavax which is recoverable upon product sales. Under an expansion of the agreement announced on 7 May 2021, CEPI will increase funding by \$77m to a total of \$176m which will increase the available volume of adjuvant in 2021. This adjuvant investment is fully fungible between CEPI-funded COVID-19 vaccine development programmes and represents a key strategic investment to increase overall 2021 dose availability from the R&D Portfolio... How much adjuvant will be supplied to the COVAX Facility? Secured adjuvant will first be made available to CEPI-funded COVID-19 vaccine development programmes. These vaccine development programmes will offer to sell the vaccine produced with CEPI's investment to the COVAX Facility...How will be the Price be determined? The CEPI-funded vaccine developers will enter into direct Commercial Supply Agreements with Dynavax to set a price per adjuvant dose based upon their program needs. The pricing to CEPI-funded vaccine developers will be tiered according to country economic level with supply available to all levels and must be consistent with the pricing agreed in the agreement between CEPI and Dynavax with respect to the material funded by CEPI...How will results support the research community? CEPI-funded vaccine development partners have agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in their agreements." CEPI. *Enabling Equitable Access (2022)*, above note 90.

472 CEPI-Dynavax, *Project Agreement*. 2021. https://ghiaa.org/wp-content/uploads/2022/01/CEPI_Dynavax-adjuvant-supply-agreement.pdf

473 Dynavax-Biological E., *Supply Agreement*. 2021. www.sec.gov/Archives/edgar/data/1029142/000156459021040926/dvax-ex107_312.htm

474 Staff *Biological E's Covid-19 vaccine Corbevax gets DCGI approval as booster dose*. Pharmaceutical Technology, 2022. www.pharmaceutical-technology.com/news/biological-e-corbevax-dcgi-approval/

475 Pulla, P. *India's speedy approvals of COVID-19 vaccines come under fire*. Science, 2022. www.science.org/content/article/india-s-speedy-approvals-covid-19-vaccines-come-under-fire

476 It is difficult to cite precise efficacy data with respect to Corbevax because the available data uses comparison against similar vaccines, and not for example against mRNA vaccines.

477 Biological_E, *Corbevax Data Sheets*. 2023. www.biologicale.com/Vaccines_Biologics/products.html

478 Texas_Childrens_Hospital_media_relations, *Texas Children's Hospital and Baylor College of Medicine Covid-19 Vaccine Technology Secures Emergency Use Authorization in India*. 2021. <https://www.texaschildrens.org/texas-children%E2%80%99s-hospital-and-baylor-college-medicine-covid-19-vaccine-technology-secures-emergency>.

The license agreement from BCM Ventures to Biological E. is not publicly available.

Biological E. first set the private market price of Corbevax at approximately USD 10 (840 Rs), but it soon sharply reduced the private market price to approximately USD 3 (250 Rs).⁴⁷⁹ It is reported that Biological E. Delivered 100 million doses of Corbevax to the Indian government by March 2022 for local distribution. The government appears to have paid approximately USD 1.75 (Rs 145) per dose. In December 2022, it was reported that Biological E. had stockpiled 200 million doses for which it did not have buyers.⁴⁸⁰

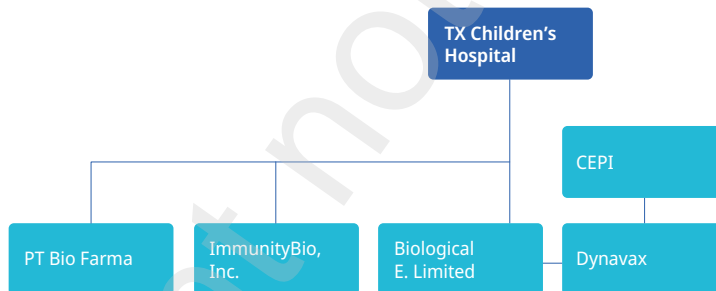
Corbevax has also been approved for primary use in Indonesia where it is to be manufactured as a halal vaccine formulation by PT Bio Farma – the holding company for state-owned pharmaceutical companies in Indonesia – under the name “IndoVac.” PT Bio Farma announced plans to produce 20 million doses in 2022, and 100 million doses by 2024.^{481, 482}

The third country to grant regulatory approval to Corbevax is Botswana.⁴⁸³ The President of Botswana indicated that the vaccine would be manufactured locally at a plant called Pula Corbevax.

The individual behind the Corbevax vaccine refers to it as a proof of concept that pandemic vaccine development and production can take place without the type of large-scale investment undertaken by companies such as Pfizer and Moderna, and with better results for low-resource environments. We do not have data regarding the investment that was needed to create the laboratory environment at Baylor Medical Center where the vaccine was developed. The research team at Baylor had been working on coronavirus vaccines for more than a decade when SARS-CoV-2 emerged⁴⁸⁴. The production of the adjuvant used in the vaccine by Biological E was financially supported by CEPI and there is reason to believe that the Dynavax adjuvant is protected by patent.

The process used to develop and manufacture Corbevax is a model that illustrates an alternative. It seems premature to suggest that it is *the* model that should be used for future vaccine development and deployment, even in low-resource environments.

TX Children's Hospital mapping



479 Bharadwaj, S., *Biological E slashes Corbevax price in private market to Rs 250 per dose* | *India News - Times of India*, in *Times of India*. 2022. <https://timesofindia.indiatimes.com/india/biological-e-slashes-corbevax-price-in-private-market-from-to-rs-250-per-dose/articleshow/91594281.cms>

480 Staff, *Biological E, Bharat Biotech together sitting on stockpile of 250 million COVID vaccine doses*, in *Economic Times of India*. 2022. <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/biological-e-bharat-biotech-together-sitting-on-stockpile-of-250-million-covid-vaccine-doses/articleshow/96562417.cms>

481 Hackett, D.W. *Texas-Developed COVID-19 Vaccine Technology Receives 2nd Authorization*. Precision Vaccinations, 2022. www.precisionvaccinations.com/2022/09/30/texas-developed-covid-19-vaccine-technology-receives-2nd-authorization

482 Texas_Childrens_Hospital_Media_Relations, *Texas-Developed Patent-Free COVID-19 Vaccine Technology Receives Emergency Use Authorization In Indonesia* | *Texas Children's Hospital*. 2022. www.texaschildrens.org/about-us/news/releases/texas-developed-patent-free-covid-19-vaccine-technology-receives-emergency-use-authorization

483 Mguni, M. *Botswana Approves Corbevax Covid Vaccine, Plans Local Output*. 2022. www.bloomberg.com/news/articles/2022-03-28/botswana-approves-corbevax-covid-vaccine-plans-local-output

484 See, e.g., Mike Hixenbaugh, *Scientists were close to a coronavirus vaccine years ago. Then the money dried up*, NBC News, Mar. 5, 2020, <https://www.nbcnews.com/health/health-care/scientists-were-close-coronavirus-vaccine-years-ago-then-money-dried-n1150091>

Summary: Baylor/Texas

- Peter Hotez et al. develop Corbevax (recombinant spike protein fragment) based on early research on SARS at Baylor
- No patent on drug substance, but formulation at Biological E. uses Dynavax adjuvant CpG 1018 (patented) – Dynavax funded by CEPI
- Out-licenses to Biological E., terms undisclosed but understood to require technology transfer fees
- Clinical trials delay introduction (some issues with cohort size)
- Biological E. sells to Indian government at low price; tries USD 10/dose private market price but soon reduces to USD 3
- Limited demand – Biological E. reports surplus doses
- Licenses to Indonesia (PT Bio Pharma) – uses “Indovac”
- Announces significant production ramp plan – no further information
- C-TAP negotiations do not progress
- Non-transparent

8. PRC vaccine landscape

As of the end of 2022, eight vaccines have been approved for use in the PRC. Two vaccine developers stand out among the PRC developers, Sinovac and Sinopharm. Their vaccines have been approved for emergency use in 56 and 93 countries respectively. Both vaccines are inactivated whole virus vaccines. Sinopharm and Sinovac have been the most prominent PRC manufacturers of COVID-19 vaccines sold and donated worldwide. In addition to receiving country specific approval, both vaccines received WHO Emergency Use Listing, Caribbean Regulatory System Emergency Use Recommendation, and are Africa Regulatory Taskforce Endorsed.⁴⁸⁵

VaxPal data indicates that the Sinovac and Sinopharm vaccines are covered by at least two patents granted in the PRC on COVID-19 Vaccines, with corresponding PCT filings.^{486, 487} The applicant for these is Wuhan Inst of Biological Products Co. Ltd., and the same patents appear to cover the vaccines of both companies. The consultant does not have access to specific licensing texts for Sinovac and Sinopharm. It appears reasonable to assume that manufacturing and supply arrangements discussed for each of the companies includes rights as needed to practice these patents. Whether and what additional rights might be conveyed remains for further inquiry.

The PRC government provides the Sinovac and Sinopharm vaccines to the public within the PRC free of charge.⁴⁸⁸

i. Sinovac

As of the end of 2021 Sinovac reported that it had sold 848 million doses of their vaccine CoronaVac. Sinovac made approximately 774.2 million deliveries of their vaccine worldwide, with 492 million going to countries in Asia Pacific, 200 million countries to Latin America, 42 million to countries Africa, and 40 million to countries in Europe. Indonesia is the country that received the most deliveries of COVID-19 vaccines from the PRC. At the end of 2022, Sinovac reported that it had shipped 2.9 billion doses of CoronaVac globally.⁴⁸⁹

485 *China COVID-19 Vaccine Tracker*. 2022; Available from: <https://covid19.trackvaccines.org/country/china/>.

486 From Espacenet database: 1. CN111569058 (A) – 2020-08-25, SARS-CoV-2 inactivated vaccine and preparation method of vaccine https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20200825&CC=CN&NR=111569058A&KC=A; 2. CN111569058 (B) – 2021-08-13, SARS-CoV-2 inactivated vaccine and preparation method of vaccine https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210813&CC=CN&NR=111569058B&KC=B - See VaxPal for further details, www.vaxpal.org/?keywords=Sinovac&page=1, and www.vaxpal.org/?keywords=Sinovac&page=1

487 Medicines_Patent_Pool. *VaxPal - COVID-19 vaccines patent database MPP*. 2023; Available from: <https://medicinespatentpool.org/what-we-do/vaxpal>.

488 Reuters_Staff *China to provide COVID-19 vaccines free of charge - official*. 2021. www.reuters.com/article/us-health-coronavirus-china-idUSKBN29E04B

489 Reuters_Media. *Relations, SINOVAC's COVID-19 Vaccine Obtains the Official Pharmaceutical Product Registration in Hong Kong*. 2022.

Sinovac received government assistance to be able to construct facilities and manufacture vaccines domestically. A state-driven collaborative approach has played a role throughout the COVID-19 vaccine R&D process in the PRC. The municipal government in Beijing unconditionally funded Sinovac's acquisition of a 69,000-square-meter vaccine manufacturing plant and related facilities that enabled Sinovac to produce 300 million COVID-19 vaccine doses annually.⁴⁹⁰

In addition to domestic production of their vaccine CoronaVac, Sinovac entered into several agreements with foreign research institutes, laboratories, and companies throughout the development process. The central government of the PRC assisted PRC vaccine companies, including Sinovac, to facilitate phase 3 clinical trials including trials in Brazil, Türkiye and Indonesia.

In June 2020, Sinovac entered into a clinical development collaboration agreement with Instituto Butantan. Instituto Butantan is a state-owned producer of immunobiologic products in Sao Paulo, Brazil. The agreement was to advance the clinical trials of CoronaVac to phase III. Instituto Butantan sponsored the phase III clinical trials in Brazil. The collaboration agreement is said to include technology licensing, market authorization and commercialization of CoronaVac. CoronaVac uses inactivated SARS-CoV-2 virus, a technological approach that Butantan had experience with from the production of rabies and dengue vaccines (Batista, 2020). The initial stage features the local laboratory importing the drug substance and completing the manufacturing process locally, with an expectation that Butantan will also move to producing the drug substance. When the agreement was entered into Instituto Butantan did not have capacity for manufacturing this vaccine at scale, so there were expectations that Butantan would need to convert existing facilities and also construct additional facilities to accomplish what was agreed.⁴⁹¹ Initially, the purchasing commitment involved coverage in the state of Sao Paulo, with the possibility of expanding it nationally.⁴⁹² Instituto Butantan finished construction and opened the additional facility intended to locally produce COVID-19 vaccines, and Sinovac CoronaVac vaccines were produced at this site for a period of time.⁴⁹³ In late June 2022, Butantan reported that it has officially ended production of the CoronaVac vaccine as of October 2021 due to a lack of demand.⁴⁹⁴

In August 2020, Sinovac signed two agreements with PT Bio Farma, an Indonesian state-owned enterprise, for the supply, local production and technology licensing in respect of CoronaVac. Under these agreements, Sinovac committed to supply Bio Farma with a million doses of a COVID-19 vaccine concentrate that would allow PT Bio Farma to produce at least 140 million doses of CoronaVac in Indonesia. Bio Farma was expected to increase its manufacturing capacity to 250 million doses by the end of 2020. Before mass production, the COVID-19 vaccine concentrate was required to pass a series of tests and register with the Indonesian Food and Drug Monitoring Agency. Sinovac agreed to continue to supply the required amounts of its bulk vaccine candidate to Bio Farma after March 2021, until the end of 2021. The collaboration between Sinovac and Bio Farma leaves open the possibility for biopharmaceutical development in the future, beyond the production and technology licensing of the COVID-19 vaccine.^{495, 496, 497, 498}

In November 2020, Sinovac reported having signed two agreements with KEYMEN Ilac Sanayi. Ve Tic. A.S. ("KEYMEN"), a Turkish entity, for the supply, local production and technology and

490 Hu, Y. and S. Chen, *What can we learn from COVID-19 vaccine R&D in China? A discussion from a public policy perspective*. Journal of Travel Medicine, 2021. 28(4). <https://academic.oup.com/jtm/article-pdf/28/4/taab026/41825888/taab026.pdf>

491 Sinovac. *2022 Form 20-F (for fiscal year 2021)*. 2022.

492 Fonseca, E.M.D., K.C. Shadlen, and F.I. Bastos, *The politics of COVID-19 vaccination in middle-income countries: Lessons from Brazil*. Soc Sci Med, 2021. 281: p. 114093

493 Simões, E., *Exclusive: Brazil to buy 20 million more doses of China's CoronaVac, governor says*. 2021. www.reuters.com/article/us-health-coronavirus-brazil-vaccines-ex-idUSKBN2A50EP

494 Berti, L., *CoronaVac vaccines will no longer be produced in Brazil*. 2022. <https://brazilian.report/liveblog/2022/06/27/coronavac-vaccines-production/>

495 Rahadiana, R. *Indonesia Signs Agreement With Sinovac for Covid-19 Vaccine (1)*. 2020 2020-08-

22; Available from: www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X4GDVFQ000000?bna_news_filter=health-law-and-business#cite

496 *Indonesia's Sinovac rollout sets high stakes for China's vaccine diplomacy | East Asia Forum*. 2021. www.eastasiaforum.org/2021/02/06/indonesias-sinovac-rollout-sets-high-stakes-for-chinas-vaccine-diplomacy/

497 Hung, J. *Sinovac, Bio Farma Indonesia collaborate on Covid-19 Vaccine CoronaVac*. 2020 2020-08-26; Available from: www.ns-healthcare.com/news/sinovac-bio-farma-indonesia-coronavac/

498 Sinovac_Media_Relations, *SINOVAC Expands Strategic Partnership with Bio Farma, Bolstering Indonesia's Vaccine Supply*, July 28, 2023. <http://www.sinovac.com/news/1686-en.html>

know-how licensing of CoronaVac. Under the terms of the agreements, Sinovac and KEYMEN will cooperate to enable local filling and packaging from bulk vaccine supplied by Sinovac in designated facilities in Türkiye.⁴⁹⁹

In August 2021, Sinovac formed a partnership with the Innovation Center of the Pontifical Catholic University of Chile, with the support of the PRC and Chilean governments and the Millennium Institute, for the planned construction of a fill and finish site near Santiago, a R&D research center in the Antogafasta region and office space for scientists in the University. Sinovac kicked off construction of a vaccine factory in Quilicura, Chile in May 2022, with an expectation of completion in early 2023. The factory, which covers 21,000 square meters, will be able to produce 50 million doses of vaccine per year once completed, while the R&D center will benefit future development and production of other vaccines.⁵⁰⁰ Sinovac claimed that the facility would be devoted to packaging and producing vaccines for COVID-19, as well as for hepatitis A and flu and help Chile to industrialize local vaccines production.⁵⁰¹ The partnership between Sinovac and the University of Chile includes clinical trials to be conducted in Chile, with the support of State capacity and public sector funding, as well as contributions from the Confederation of Production and Commerce (CPC) and the University.⁵⁰²

Under an agreement with Sinovac, Egypt's state-owned VACSERA company was able to produce its first batch of 1 million doses of the VACSERA-Sinovac vaccine in July 2021 using raw materials from the PRC.⁵⁰³ In January 2022, they also signed a new cooperation agreement for the construction of an automated vaccine cold storage facility at VACSERA that is projected to be able to hold 150 million vaccine doses.⁵⁰⁴ The deal was signed by the CEO of Sinovac Biotech Weidong Yin and VACSERA Chief Heba Wali in the presence of Egypt's acting Health Minister Khaled Abdel-Ghaffar. The construction of the facility started in April and was completed and in operation on September 25, 2022. The facility is 2,800 square-foot and fully automated.⁵⁰⁵ On the day construction was complete, 10 million doses of Sinovac vaccines gifted by the PRC became the first batch handled by the cold storage facility, part of the PRC's pledge to provide 1 billion doses of the vaccine to Africa.

In August 2021, the Ministry of Science, Technology and Innovation in Colombia and Sinovac signed an MoU for the packaging and filling of vaccines following selection of a suitable plant. The MoU includes plans for future production of other vaccines over the next two years as part of a long-term plan to help Colombia rebuild its vaccine industry. In May the following year, Sinovac announced a USD 100 million investment for the project, including the construction of a vaccine plant in Bogotá with the capacity to package 60 million doses annually. In an announcement made by the Vice President of Sinovac, the project will be divided into three sub-projects, the first of which will be initiated in 2023.⁵⁰⁶

Pharmaniaga in Malaysia entered into a contractual agreement with Sinovac to supply 12 million doses of the Sinovac COVID-19 fill and finish vaccines from its high-tech plant Pharmaniaga LifeScience Sdn Bhd (PLS). The contract obligates Pharmaniaga to supply the vaccines within seven months, beginning in May 2021. As of November, over 20 million doses have

499 *Sinovac provides license to Turkey to produce its vaccines - Türkiye News*. 2021 2021-05-12; Available from: www.hurriyetdailynews.com/sinovac-provides-license-to-turkey-to-produce-its-vaccines-164677.

500 Shumei, L., *Sinovac starts building vaccine factory in Chile, to provide 50 million shots per year - Global Times*. 2022. www.globaltimes.cn/page/202205/1265608.shtml

501 Shumei, Leng, *Sinovac starts building vaccine factory in Chile, to provide 50 million shots per year*, May 14, 2022, <https://www.globaltimes.cn/page/202205/1265608.shtml>.

502 *Government Meets With Sinovac For First Covid-19 Vaccine Clinical Trial In Chile*. 2020 2020-10-13; Available from: www.gob.cl/en/news/government-meets-sinovac-first-covid-19-vaccine-clinical-trial-chile/.

503 *Egypt establishes largest coronavirus vaccine factory in Middle East*. 2021. www.al-monitor.com/originals/2021/09/egypt-establishes-largest-coronavirus-vaccine-factory-middle-east

504 *Egypt's VACSERA, China's Sinovac Biotech sign new cooperation agreement - Health - Egypt*. 2022 2022-01-19; Available from: <https://english.ahram.org.eg/News/456590.aspx>.

505 Xiaoyu, W., *Vaccine storage boosts African supply chain*. 2022. www.chinadaily.com.cn/a/202209/27/WS63325084a310fd2b29e79e5e.html

506 *SINOVAC, ready to invest USD 100 million in its vaccine production facility in Colombia | Investinbogota.org | Invest in Bogotà*. 2022. <https://en.investinbogota.org/news/sinovac-invest-usd-100-million-in-colombia/>

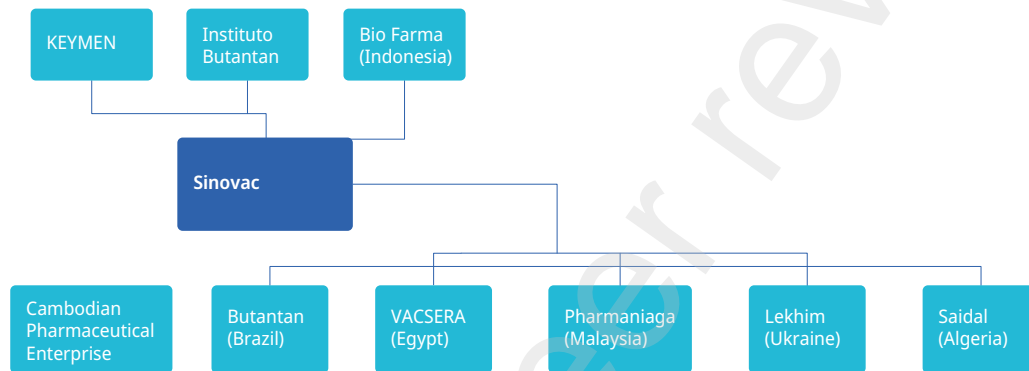
been supplied to the National Immunisation Programme in both manufactured (by Sinovac) and fill and finished form, and the vaccine has been exported overseas to Myanmar.^{507, 508}

In May 2022, Sinovac signed an MoU with the Cambodian Pharmaceutical Enterprise that included the construction of a vaccine packaging facility and license to fill and finish Sinovac vaccines in Cambodia. The facility is said to enable Cambodia to produce more than 100 million doses of the vaccine in the next three years.⁵⁰⁹

Pricing

UNICEF's COVID-19 data tracker shows a range of prices for Sinovac's CoronaVac vaccine, going from USD 7 per dose in Zimbabwe to USD 32.52 in Thailand's private market, and with a price of USD 29.75 in the PRC.⁵¹⁰

Sinovac mapping



ii. Sinopharm

The Sinopharm COVID-19 vaccine, also referred to as BBIBP-CorV or COVILO is an inactivated vaccine made of virus particles grown in culture and lacking disease-producing capability. The vaccine was developed by China National Pharmaceutical Group Co., Ltd., also referred to as Sinopharm, a state-owned enterprise, and the Beijing Institute of Biological Products Co. in 2020. The vaccine was approved by WHO in May of the following year for emergency use, making it the first PRC COVID-19 vaccine approved for international use.^{511, 512}

Sinopharm has been the leading supplier of vaccine donations by a PRC developer, supplying 103 million doses of donated vaccines to 79 countries.⁵¹³

In addition to domestic product of its vaccine, Sinopharm entered into agreements with several foreign countries to produce the vaccine abroad. Sinopharm and the United Arab Emirate's (UAE) G42 launched a joint venture to locally package the Sinopharm vaccine as "Hayat-Vax" in March 2021. A new plant built in the Khalifa Industrial Zone of Abu Dhabi will manufacture the

507 *Pharmaniaga First to Complete Government's COVID-19 Vaccine Requirement and Sinovac Is Still an Approved Vaccine for the Nation*. 2021, Pharmaniaga. <https://pharmaniaga.com/wp-content/uploads/2021/07/News-Release-Pharmaniaga-The-First-Company-Completed-Vaccine-Supplies.pdf>

508 *Pharmaniaga National Institute of Biotechnology Malaysia to Co-Operate In RD On Vaccines*. 2021, Pharmaniaga. <https://pharmaniaga.com/wp-content/uploads/2021/11/News-Release-I-PHARMANIAGA-NATIONAL-INSTITUTES-OF-BIOTECHNOLOGY-MALAYSIA-TO-CO-OPERATE-IN-RD-ON-VACCINES-011121-DZ.pdf>

509 Sreylin, Y., *Cambodia to produce more than 100 million doses of Covid-19 vaccine for use in 2024-2026 - Khmer Times*. 2022. www.khmertimeskh.com/501086173/cambodia-to-produce-more-than-100-million-doses-of-covid-19-vaccine-for-use-in-2024-2026/

510 UNICEF COVID-19 Market Dashboard, www.unicef.org/supply/COVID-19-market-dashboard, visited April 23, 2023.

511 Sinopharm, or the China National Pharmaceutical Group Co., Ltd., is a large healthcare group directly under the State-owned Assets Supervision and Administration Commission (SASAC) of the State Council. Sinopharm owns over 1,100 subsidiaries and 6 listed companies including Sinopharm Group Co., Ltd. (Sinopharm Holding), China National Medicines Corporation Ltd., China National Accord Medicines Corporation Ltd., Beijing Tiantan Biological Products Co., Ltd., Shanghai Shyndec Pharmaceutical Co., Ltd., and China Traditional Chinese Medicine Holdings Co., Ltd. *Sinopharm - About Us*. 2023; Available from: <http://www.sinopharm.com/en/1398.html>.

512 *Sinopharm COVID-19 Vaccine (BBIBP-CorV)*. 2022. www.precisionvaccinations.com/vaccines/sinopharm-covid-19-vaccine-bbibp-corv

513 Bridge Consulting, *Tracking China's COVID-19 Vaccine Distribution*, Dec. 28, 2022. <https://bridgebeijing.com/our-publications/our-publications-1/china-covid-19-vaccines-tracker/>.

vaccine, the site will have a production capacity of 200 million doses a year with three filling lines and five automated packaging lines. While the facility was being modified to increase capacity, Gulf Pharmaceutical Industries PSC, also known as Julphar, produced the vaccine in the UAE, this initial site has a smaller capacity, able to produce 2 million doses per month. The vaccine produced by G42 under the name Hayat-Vax has already been exported to several countries including Viet Nam and Kazakhstan. At the outset of 2022 there were discussions between the UAE Ambassador to the PRC and the president of Sinopharm for future collaborations.⁵¹⁴

In July 2021, Serbia, the PRC, and the United Arab Emirates signed a memorandum of understanding and cooperation to build a domestic facility near Belgrade for the production of the Sinopharm vaccine. As of November 2022, the plant had yet to produce vaccines.^{515, 516}

Sinopharm signed an agreement with Bangladesh for co-production of its vaccine. Under the Memorandum of Understanding (MoU) signed between the governments in August 2021, Sinopharm and Bangladesh's Incepta pharmaceutical firm, Incepta agreed to supply five million doses of the vaccine a month from its plant in Savar to the capital Dhaka. According to the triparty MoU, the parties agreed that the raw materials would be supplied by Incepta and the actual manufacturing would be performed by the Beijing Bio-Institute of Biological Products Company Limited. Incepta retained the right to fill and finish in Bangladesh. Incepta agreed to provide bulk and bottling, labeling and finishing of the vaccine. Once produced, the Government of Bangladesh agreed to purchase these vaccines and administer them to its citizens free of cost. However, from what is known from the terms of the MoU, the extent of technology transfer from the PRC to Bangladesh is unclear.^{517, 518}

On July 5, 2021, Morocco signed a fill and finish agreement with Sinopharm. The agreement grants a domestic pharmaceutical firm, Société de Thérapeutique Marocaine (Sothema), a fill and finish license under which Sothema would be able to produce 5 million doses of Sinopharm vaccine per month. There is limited additional information regarding the agreement with Morocco.^{519, 520}

In May 2021, Sinopharm and Sinergium Biotech, an Argentinian pharmaceutical company, preliminarily agreed to produce vaccines in Argentina with further discussions on technology transfer anticipated. In February the following year, Argentina's President met with directors of Sinopharm. Negotiations suggested that that the Sinergium would be able to deliver up to a million doses of the vaccine per week. No further information on this arrangement has been identified.⁵²¹

Pricing

UNICEF's COVID-19 data tracker shows a range of prices for Sinopharm vaccine going from 6.90 US dollars in Zimbabwe to USD 36 in Hungary, and with a price of USD 29.75 in the PRC.⁵²²

iii. Observations

Sinovac and Sinopharm appear to be using technology patented by the Wuhan Institute of Biological Products in the preparation of their vaccines. Each has entered into manufacturing

514 Barrington, L., *Abu Dhabi launches new COVID-19 vaccine plant with China's Sinopharm*. 2021. www.reuters.com/article/us-health-coronavirus-emirates-china-idUSKBN2BL0DS

515 Dragojlo, S. *Work Starts in Serbia on Chinese Sinopharm Vaccines Factory*. 2021 2021-09-09; Available from: <https://balkaninsight.com/2021/09/09/work-starts-in-serbia-on-chinese-sinopharm-vaccines-factory/>.

516 Chastand, J.-B. *From miracle to mirage: Serbia's vaccine factories*. 2022 2022-11-18; Available from: www.lemonde.fr/en/europe/article/2022/11/18/from-miracle-to-mirage-serbia-s-vaccine-factories_6004810_143.html.

517 Burua, S., *China-Bangladesh Covid vaccine co-production deal a game-changer in combating pandemic*. 2021. www.southasiamonitor.org/china-watch/china-bangladesh-covid-vaccine-co-production-deal-game-changer-combating-pandemic

518 Khatun, F., *The Covid-19 Vaccination Agenda in Bangladesh: Increase Supply, Reduce Hesitancy* | ORF. 2021. www.orfonline.org/research/covid-19-vaccination-agenda-in-bangladesh/

519 *Le Maroc fabriquera ses propres vaccins anti-Covid: conventions signées devant le Roi - Médias24*. 2021-07-05; Available from: <https://medias24.com/2021/07/05/le-maroc-fabriquera-les-vaccins-anti-covid-convention-signee-devant-le-roi/>

520 Zhang, Y., et al., *Real-world study of the effectiveness of BBIBP-CorV (Sinopharm) COVID-19 vaccine in the Kingdom of Morocco*. BMC Public Health, 2022. 22(1): p. 1-7. <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-022-14016-9>

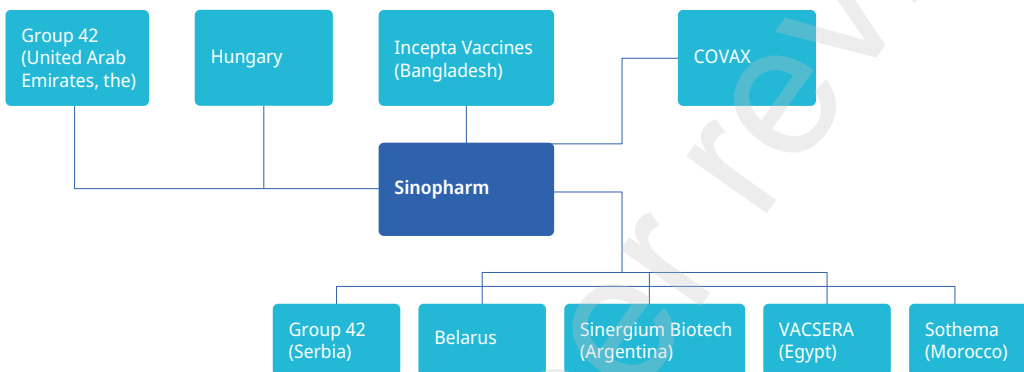
521 *Argentina closer to producing Sinopharm vaccine locally*. 2022. <https://en.mercopress.com/2022/02/05/argentina-closer-to-producing-sinopharm-vaccine-locally>

522 UNICEF COVID-19 Market Dashboard, www.unicef.org/supply/COVID-19-market-dashboard, visited April 23, 2023.

and distribution agreements with foreign vaccine producers. The consultant does not have access to the texts of those agreements. The extent of rights beyond those needed for manufacturing and distribution conveyed to the licensees is unknown. That said, there is nothing in the public record to suggest that a third party has been inhibited from making and selling either the Sinovac or Sinopharm vaccine based on difficulties accessing the technology covered by the patents.

Pricing data available from UNICEF for each of the Sinovac and Sinopharm vaccines suggests that they were sold at relatively high prices to the PRC health system, and at substantially different prices to other country health systems, generally in the low to mid-teens in US dollars. In this regard, by way of comparison, the Sinovac and Sinopharm prices were generally higher than for the AstraZeneca/SII vaccine.

Sinopharm mapping



Summary: PRC

- Sinopharm and Sinovac major producers and exporters to LMICs
- Substantial number of foreign licensing and production arrangements announced
- Follow-up information limited
- Includes Argentina, Brazil, Bangladesh, Egypt, India, Indonesia, etc.
- Sinopharm and Sinovac each covered by two patents owned by Wuhan Institute of Biological Products
- Inactivated whole virus vaccines
- EUA from WHO

9. Gamaleya National Center of Epidemiology and Microbiology (Sputnik V)

The vaccine developed by the Russian Federation Health Ministry's Gamaleya Institute is adenovirus vector, with the Russian Direct Investment Fund (RDIF) as the main investor in development and production of the vaccine. Sputnik V is the first COVID-19 vaccine to use a heterogeneous boosting approach using two different vectors for two different shots. Sputnik V has been approved for use in over 71 countries. The vaccine has yet to receive either WHO or EMA approval. Over 50 countries worldwide have placed orders for the vaccine. The vaccine is produced both at domestic sites within the Russian Federation, as well as at sites that the RDIF has entered into agreements with abroad.⁵²³

VaxPal data indicates that at least five patent applications surrounding the Sputnik V vaccine have been filed, with initial filing in the Russian Federation and corresponding PCT applications.

523 *More Countries Line Up for Russia's Sputnik V Coronavirus Vaccine - The Moscow Times*. 2020. www.themoscowtimes.com/2020/11/13/more-countries-line-up-for-russias-sputnik-v-coronavirus-vaccine-a72042

It is not clear what patents may have been granted and where.⁵²⁴ Publicly available supply agreements refer to patent rights.⁵²⁵ The RDIF reportedly pushed an “open-license” approach to manufacture of Sputnik V, adopting a non-exclusive approach to sharing technology and know-how with foreign manufacturers. The RDIF is said to have shared regulatory dossier information with multiple manufacturers.⁵²⁶

In August 2020, the Russian Federation introduced the Sputnik V COVID-19 vaccine for domestic use. Russian Federation officials claimed first-to-approval success as compared with Western counterparts. However, questions arose regarding the methodologies by which the vaccine was assessed, and as of this Study Sputnik V has not received approval from the WHO.⁵²⁷

The RDIF is reported to have failed to meet promised deliveries of the vaccine hampered by supply chain mismanagement and production problems. Some challenges relate to the formula of the vaccine itself. Sputnik V uses two different vectors unlike other adenovirus vaccines, with the second dose being more difficult to manufacture.⁵²⁸ The first dose of the vaccine uses the adenovirus Ad26 while the second dose uses Ad5. Producing the second adenovirus is time consuming because of the low yield of quality virus that can be grown at a time. RDIF has marketed a single dose of the vaccine under the name “Sputnik Light” using the first component which is easier for manufactures to produce. Several countries demanded payments be returned because of undelivered supply and pricing issues.⁵²⁹ The vaccine has also been affected by Russian Federation’s own population being hesitant to get vaccinated. In May 2021, the Russian Federation had only produced 33 million doses of the 800 million for which it had made commitments. In August 2022 the Russian Federation reported delivery of more than 400 doses of Sputnik V and Sputnik light, becoming the most exported vaccine in the Russian Federation’s history.⁵³⁰

i. Domestic collaborations within the Russian Federation

On November 3, 2020, Gamaleya Federal Research Center entered into a manufacturing agreement with Pharmasintez for manufacturing of Sputnik V. Under the terms of the agreement, Pharmasintez agreed to provide dose manufacturing services to Gamaleya for COVID-19 vaccine candidate in the form of solution and lyophilized products from its Saint Petersburg, Nord factory facility. Sputnik V combines two separately produced shots. This requires different manufacturing facilities and twice as many people to make. The shots must be produced separately due to the risk of contamination. Pharmasintez agreed to produce the second component of the Sputnik V vaccine.^{531, 532}

Generium entered into a manufacturing agreement with the RDIF to produce Sputnik V. Generium provided active pharmaceutical ingredient (API), dose, and packaging manufacturing services to RDIF for Sputnik V from its site in Vladimir, Russian Federation. Under the agreement, Generium would produce 60 to 100 million doses of Sputnik V per year. Generium

524 From Espacenet database, see, e.g.: 1. WO2021002776 (A1) - IMMUNOBIOLOGICAL AGENT FOR INDUCING SPECIFIC IMMUNITY AGAINST SEVERE ACUTE RESPIRATORY SYNDROME VIRUS SARS-COV-2; applicant FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTE[RU], https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210107&CC=WO&NR=2021002776A1&KC=A1; 2. WO2021076010 (A1) - PHARMACEUTICAL AGENT FOR INDUCING SPECIFIC IMMUNITY AGAINST SARS-COV-2; applicant FEDERAL STATE BUDGETARY INSTITUTION NATIONAL RES CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTE[RU], https://worldwide.espacenet.com/publicationDetails/biblio?DB=worldwide.espacenet.com&II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20210422&CC=WO&NR=2021076010A1&KC=A1 - See VaxPal for additional details, www.vaxpal.org/?keywords=Gamaleya&page=1

525 RDIF Human Vaccine LLC-Hungary Public Health Center, *Supply Agreement*. 2020. www.nnk.gov.hu/attachments/article/1052/Szputnyik%20V_Supplementary%20Agreement.pdf

526 Vijay, S.L., *Russia Pushes Ahead With Open License Approach To Sputnik V - Despite WHO Concerns Over Manufacturing Practices* - Health Policy Watch. 2021. <https://healthpolicy-watch.news/russia-pushes-ahead-with-open-license-approach-to-sputnik-v-despite-who-concerns-over-manufacturing-practices/>

527 Hoffman, M. *Sputnik Vaccine Efficacy Data Published In Lancet Are “Statistically Impossible”* - Health Policy Watch. 2022. <https://healthpolicy-watch.news/sputnik-vaccine-efficacy-data/>

528 Ivanova, P. and P. Nikolskaya, *Big promises, few doses: why Russia’s struggling to make Sputnik V doses*. 2021. www.reuters.com/business/healthcare-pharmaceuticals/big-promises-few-doses-why-russias-struggling-make-sputnik-v-doses-2021-05-14/

529 Kier, G. and P. Stronsk, *Russia’s Vaccine Diplomacy Is Mostly Smoke and Mirrors*. 2021. <https://carnegieendowment.org/2021/08/03/russia-s-vaccine-diplomacy-is-mostly-smoke-and-mirrors-pub-85074>

530 *Sputnik V becomes most exported medicine in Russia’s history - RDIF*. 2022. <https://tass.com/world/1492239>

531 *Pharmasintez will produce the COVID-19 Sputnik V vaccine*. 2020 2020-11-06; Available from: <https://pharmasintez.com/en/press-center/news/pharmasintez-will-produce-the-covid-19-sputnik-v-vaccine/>

532 Nikolskaya, P., *Some Russian drugmakers focus on export-oriented Sputnik Light shot*. 2021. www.reuters.com/business/healthcare-pharmaceuticals/some-russian-drugmakers-focus-export-oriented-sputnik-light-shot-2021-06-08/

is the first company to be able to complete the whole cycle of vaccine production from active pharmaceutical ingredients (API) to the finished product. The site was operational in February, 2021 producing several million doses a month with plans to scale up.⁵³³

In September 2020, RDIF also entered into a manufacturing agreement with Biocad for production of the Sputnik V vaccine. Under this agreement, Biocad provided dry, lyophilized and liquid vaccine manufacturing services to RDIF for the vaccine at the Biocad facility in Saint Petersburg. In November 2020, Biocad had already released 3 million doses of the Sputnik V vaccine with plans to expand to produce 5-6 million doses by the summer of the same year.^{534, 535}

In August 2020, RDIF entered into a manufacturing agreement with Binnopharm for production of Sputnik V. Under the terms of this agreement, Binnopharm would provide dose manufacturing services to RDIF at its facility in Moscow. Binnopharm expected 500 million doses of the vaccine to be made in the first 12 months of productions. In June 2021, Binopharm, RDIF, and Bahrain's Mumtalakat Holding Company, and Binnopharm Group signed a Memorandum of Understanding (MoU). The MoU is to establish a new vaccine production facility in Bahrain to manufacture and distribute Sputnik V across the Middle East and North Africa (MENA) region.⁵³⁶

RDIF also entered into a manufacturing agreement with Pharmstandard for Sputnik V. Under this agreement, Pharmstandard will provide injectable manufacturing services to RDIF for Sputnik V at its facility Vladimir, Russian Federation. Included in the agreement, Pharmstandard agreed to provide manufacturing and ampoule filling services from its Ufa facility.⁵³⁷

Pricing

The UNICEF COVID-19 Market Dashboard does not list an internal price for Sputnik V within the Russian Federation. The vaccine is understood to be supplied domestically free of charge to Russian Federation citizens.⁵³⁸

ii. Foreign production of Sputnik V

The Russian Direct Investment fund is responsible for agreements to produce the Sputnik V vaccine outside the Russian Federation and has signed agreements with more than a dozen sites with plans to make the vaccine available in those markets. Information regarding implementation of the various agreements is sparse.

1. Mexico

RDIF entered into a manufacturing agreement with Laboratorios de Biologicos y Reactivos de Mexico (BIRMEX), a state-run pharmaceutical corporation, for production and packaging of the vaccine in October 2021.^{539, 540}

533 Generium. *Russia shows off new Covid-19 vaccine factory even as its people hesitate to get the shot*. 2023; Available from: www.generium.ru/en/news/russia-shows-off-new-covid-19-vaccine-factory-even-as-its-people-hesitate-to-get-the-shot/.

534 *Biocad plans to produce up to 6 million doses of Sputnik V vaccine per month* | GxP News. 2021. <https://gxpnews.net/en/2021/04/biocad-plans-to-produce-up-to-6-million-doses-of-sputnik-v-vaccine-per-month/>

535 Naczyk, M. and C. Ban, *The Sputnik V moment: biotech, biowarfare and COVID-19 vaccine development in Russia and in former Soviet satellite states*. <https://doi.org/10.1080/21599165.2022.2121117>, 2022. www.tandfonline.com/doi/full/10.1080/21599165.2022.2121117

536 Shipilova, E. *Binnopharm Group, RDIF and Mumtalakat agree to establish production of the Sputnik V coronavirus vaccine in Bahrain - Sistema*. 2021 2021-06-03; Available from: <https://sistema.com/press/pressreleases/binnopharm-group-rdif-and-mumtalakat-agree-to-establish-production-of-the-sputnik-v-coronavirus-vacc>.

537 *Sputnik V Vaccine*. 2023 2023-02-13; Available from: www.precisionvaccinations.com/vaccines/sputnik-v-vaccine.

538 Russian_Service_RFERL *Vaccination With Russia's Sputnik-V To Cost "Less Than \$20"*. 2020. www.rferl.org/a/vaccination-with-russia-s-sputnik-v-to-cost-less-than-20-/30966577.html

539 Under the terms of this agreement, BIRMEX would provide test batch of the Russian Federation Sputnik V vaccine from its Mexico facility. BIRMEX had the ability to package approximately 2 million doses of the vaccine per month, but the goal of the agreement was transfer of technologies for production of a substance for the vaccine to Mexico. However, in March 2022 both parties had yet to fulfil their part of the agreement: the Russian Federation failed to transfer vaccine technology and BIRMEX had not built the promised production facility. *Mexico to sign agreement with Russia on Sputnik V production - newspaper*. 2021. <https://tass.com/economy/1347409>

540 Stronski, P., *In Mexico, the Window on Russia's Vaccine Diplomacy Is Closing*. 2022. <https://carnegieendowment.org/2022/04/28/in-mexico-window-on-russia-s-vaccine-diplomacy-is-closing-pub-87013>

2. Brazil

RDIF entered into an agreement with Uniao Quimica for the manufacture and supply of 10 million doses of Russian Federation Sputnik V vaccine in the first quarter of 2021. In June the same year, Anvisa approved the vaccine with conditions giving the go ahead to import the COVID-19 vaccine.^{541, 542}

3. Argentina

RDIF entered into an agreement with Laboratorios Richmond for the manufacturing of Sputnik V. Under the terms of this agreement, Laboratorios Richmond will provide formulation and filling for Sputnik V vaccine with USD 60–90 million funding from RDIF for construction of new manufacturing facility at Pilar, Argentina and technology transfer to Laboratorios Richmond. In August 2021, the parties delivered the first batch of Sputnik V produced in Argentina to the Ministry of Health. It is not clear, however, if construction of the promised facility has commenced.⁵⁴³

4. Algeria

On April 7, 2021, RDIF entered into a dose manufacturing agreement with Groupe Sidal in the company's city of Constantine site. The site was said to begin production of the vaccine in September 2021. The production is said to be facilitated by transfer of technology provided by the Russian Federation vaccine developer.^{544, 545}

5. Egypt

RDIF and Minapharm in Egypt agreed to initially supply 40 million doses of the Sputnik V vaccine per year. Under this agreement, production is said to take place in Minapharm's biotech facility in Cairo for global distribution. The agreement is reported to include technology transfer provision.⁵⁴⁶ There is little information regarding whether domestic production has occurred.

6. Germany

In April 2021, RDIF entered into an agreement with R-Pharm for the manufacture and supply of 8–10 million doses Sputnik V vaccine from its plant in Bavaria. Production was not forecasted to begin until the third and fourth quarters of the year. However, as of February 2022 production of the Russian Federation vaccine in Bavaria was blocked, citing the actions of the Russian Federation in Ukraine.⁵⁴⁷

541 As part of the agreement with União Química, RDIF agreed to actively facilitate the transfer of technology to launch the production of Sputnik V in Brazil, including the provision of documents and biomaterials. The RDIF and Uniao Quimica applied for an emergency use authorisation for Sputnik V in Brazil in January 2021. Health regulators Anvisa initially rejected regulatory approval for the vaccine in April 2021 because of the presence of an adenovirus that could reproduce. The RFID challenged this ruling and threatened to bring legal action for defamation. *Russia, Brazil's Uniao Quimica to supply 10 million doses of Sputnik V vaccine to Brazil*. 2021. www.reuters.com/article/us-health-coronavirus-russia-brazil-vacc-idINKBN29I2EO

542 McGeever, J. and L. Paraguassu, *Brazil's Anvisa approves Russian Sputnik V vaccine, with conditions*. 2021. www.reuters.com/world/americas/brazil-health-regulator-technical-staff-recommend-conditions-any-approval-2021-06-04/

543 *Laboratorios Richmond delivers the first batch of over 1 million doses of the Sputnik V vaccine produced in Argentina to the country's Ministry of Health*. <https://sputnikvaccine.com/newsroom/pressreleases/laboratorios-richmond-delivers-the-first-batch-of-over-1-million-doses-of-the-sputnik-v-vaccine/>

544 *Algeria to start Russia's Sputnik V vaccine production in September*. 2021. www.reuters.com/article/us-algeria-russia-vaccine-idUSKBN2BU3HG

545 Lamptey, E., et al., *COVID-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production*. *Clin Exp Vaccine Res*, 2022. 11(1): p. 82–88

546 *Minapharm to manufacture Sputnik V in Egypt*. 2021. <https://enterprise.press/stories/2021/04/22/minapharm-to-manufacture-sputnik-v-in-egypt-39004/>

547 *Bavaria freezes Sputnik V production in Germany citing sanctions against Russia*. 2022. www.reuters.com/business/healthcare-pharmaceuticals/bavaria-freezes-sputnik-v-production-germany-citing-sanctions-against-russia-2022-02-23/

7. Italy

RDIF signed an agreement for manufacturing with Adienne Pharma & Biotech. Under this agreement, Adienne Pharma agreed to manufacture the vaccine near Milan.^{548, 549}

8. Serbia

RDIF entered into a manufacturing agreement with Institute of Virology Vaccines and Sera Torlak for the Sputnik V vaccine to provided services from its Belgrade, Serbia facility. Serbia started production of the vaccine in June, 2021.^{550, 551}

9. Belarus

RDIF has entered into a manufacturing agreement with Belmedpreparaty RUE for the Sputnik V vaccine. Under the terms of their agreement, Belmedpreparaty will utilize technology transferred by the Russian Federation company Generium for the production of Sputnik V vaccine in Belarus. Production of the vaccine in Belarus was announced in February 2021, and mass production began in March.⁵⁵²

10. Türkiye

Turkish pharmaceutical company Viscoran İlaç and RDIF agreed to cooperate on the production of the coronavirus vaccine Sputnik V in Türkiye. As part of the agreement between the two, Viscoran İlaç agreed to provide assistance in establishing partnerships with other leading local pharmaceutical producers. RDIF entered into a manufacturing agreement with CinnaGen İlaç for Sputnik V production in Türkiye. Under this agreement, CinnaGen will provide technology transfer, active pharmaceutical ingredient (API), and dose manufacturing services to RDIF.^{553, 554}

11. Kazakhstan

A memorandum on the supply of 2 million doses of the Sputnik V COVID vaccine was signed by Kazakhstan's Ministry of Health and RDIF. In January 2021 an experimental batch of the vaccine was manufactured by Karaganda Pharmaceutical Complex and sent to the Russian Federation for approval by the Gamaleya National Center of Epidemiology and Microbiology for quality testing as per the agreement between the parties. The vaccine was launched for use in Kazakhstan in February 2021.⁵⁵⁵

12. Lebanon

RDIF is said to have entered into a manufacturing agreement with Arwan Pharmaceutical for the Sputnik V vaccine.^{556, 557}

548 *Italian-Swiss Adienne Pharma & Biotech to produce Sputnik V vaccine*. 2021. <https://pharma-industry-review.com/italian-swiss-adienne-pharma-biotech-to-produce-sputnik-v-vaccine>. At the time the agreement was signed the vaccine was still being assessed by the European Medicines Agency, but parties were optimistic that production could begin in early July 2021. However, there is little information as to whether the vaccine was produced as Sputnik V has yet to receive authorization from the EMA, and is unlikely to receive it at this time.

549 Smith, J., *Europe Shuns Russian Covid-19 Vaccines as Ukraine War Continues*. 2022. www.labiotech.eu/trends-news/sputnik-v-russia-europe/

550 Under the terms of this agreement, Torlak agreed to provide services in two phases. The first phase of production includes the transport of the substance from the Russian Federation, filling into ampoules, packaging and distribution of the vaccine. The second phase includes the full production cycle of the vaccine.

551 Xinhua, *Serbia officially starts to produce Russia's COVID-19 vaccine*. 2021 2021-06-05; Available from: www.xinhuanet.com/english/2021-06/05/c_139989827.htm.

552 Hackett, D.W. *Belarus Launches Sputnik V Vaccine Production*. 2021 2021-03-27; Available from: www.precisionvaccinations.com/2021/02/27/belarus-launches-sputnik-v-vaccine-production.

553 *Turkey to produce Russia's Sputnik V COVID-19 vaccine - statement*. 2021. www.reuters.com/world/middle-east/turkey-produce-russias-sputnik-v-covid-19-vaccine-statement-2021-04-26/

554 *Turkey to produce Russian virus vaccine Sputnik V - Türkiye News*. 2021 2021-04-26; Available from: www.hurriyetdailynews.com/turkey-to-produce-russian-virus-vaccine-sputnik-v-164255.

555 *Kazakhstan to produce 2 mln doses of Sputnik V vaccine by June 2021*. 2021. <https://tass.com/world/1254115>

556 Yassine, H., *Lebanese Factory Can Now Produce COVID-19 Vaccines*. 2021. www.the961.com/lebanese-factory-covid-19-vaccines-lebanon/

557 Under the terms of this agreement, Arwan Pharmaceutical would provide 30 to 60 million doses of vaccine from its Sidon, Lebanon facility. The agreement was said to be signed in mid-June 2021. In August of the same year, it was announced that the factory was soon to begin production. There is little information on detailed terms of the agreement.

13. Islamic Republic of Iran

RDIF entered into a license agreement with Actoverco in Islamic Republic of Iran for the production of Sputnik V. Actoverco provided a test batch of the Russian Federation Sputnik V from its Islamic Republic of Iran facility and the two parties actively cooperated in the technology transfer process.⁵⁵⁸

14. Uzbekistan

RDIF entered into a manufacturing agreement with Jurabek Laboratories for production of the Russian Federation vaccine. RDIF organized the technology transfer for production of the vaccine in the Republic of Uzbekistan. Validation batches have been shipped to the Gamaleya Center for quality control and Sputnik V was certified in the country in February 2021.⁵⁵⁹

15. India

The RDIF entered into several agreements with corporations in India to produce Sputnik V. RDIF entered into a manufacturing agreement with Morepen Laboratories for vaccine production. Under the terms of the agreement, Morepen would provide dose manufacturing services from its facility in Solan. The first test batch was shipped to Gamaleya Center for quality control. RDIF and Morepen Laboratories signed a cooperation agreement in June 2021 to implement the technology transfer.⁵⁶⁰ RDIF also entered an agreement with Hetero Drugs for the manufacture and supply of 100 million doses of Sputnik V vaccine the production was intended to begin early 2021 (see note 564).

Dr. Reddy's Laboratories (DRL) signed a manufacturing agreement with Shilpa Medicare for Sputnik V vaccine. Under the three years agreement, Shilpa Biologicals subsidiary of Shilpa Medicare would provide active pharmaceutical ingredient (API) and dose manufacturing services to Dr. Reddy's for Sputnik V from its biologics R&D and manufacturing center at Dharwad, Karnataka, India. DRL agreed to facilitate the transfer of the Sputnik technology to Shilpa Biologicals. DRL is said to be responsible for distribution and marketing of the Sputnik V vaccine in its marketing territories.⁵⁶¹

In July 2021, RDIF provided Panacea Biotech with a manufacturing license to produce the Sputnik V vaccine. Per the terms of the licenses Panacea would produce the vaccine using ready to fill drug substance provided by Generium and to supply the quantity produced to Dr. Reddy's Laboratory for distribution within India.⁵⁶²

RDIF also signed an agreement with Serum Institute of India for the manufacture and supply of 300 million doses of its vaccine. The technology transfer process began in 2021 and the Serum Institute began the cultivation process after receiving cell and vector samples from the Gamaleya Center subsequent to approval by the Drug Controller General of India.⁵⁶³

RDIF entered an agreement with Gland Pharma for the manufacture from its Hyderabad facilities and supply of 252 million doses of its COVID-19 vaccine. Under this agreement, Gland Pharma would undertake technology transfer of API followed by manufacturing of dose and filling into vials under aseptic conditions.⁵⁶⁴

558 Sinaiee, M., *Officials Clash Over Made-In-Iran Russian Covid Vaccines*. 2021. <https://old.iranintl.com/en/world/officials-clash-over-made-iran-russian-covid-vaccines>

559 *Russia's focus on domestic pharma production could shield it from sanctions' effects*. 2022. www.pharmaceutical-technology.com/comment/russia-pharma-production/

560 Russian Direct Investment Fund, *RDIF and Morepen Laboratories announce production of the test batch of Sputnik V in India*. 2021. www.prnewswire.com/in/news-releases/rdif-and-morepen-laboratories-announce-production-of-the-test-batch-of-sputnik-v-in-india-805616964.html

561 RDIF, *RDIF and Dr. Reddy's to cooperate on clinical trials and supply of 100 million doses of Sputnik V vaccine to India*. 2020. www.prnewswire.com/news-releases/rdif-and-dr-reddys-to-cooperate-on-clinical-trials-and-supply-of-100-million-doses-of-sputnik-v-vaccine-to-india-301132146.html

562 Xinhua, *India's Panacea Biotech to manufacture Russia's Sputnik V vaccine*. 2021 2021-08-05; Available from: www.xinhuanet.com/english/asiapacific/2021-08/05/c_1310110344.htm.

563 Kumar, N.R., *Serum Institute to produce Russia's Sputnik V vaccine*. 2021. www.thehindu.com/business/Industry/serum-institute-to-produce-russias-sputnik-v-vaccine/article35297586.ece

564 *India's Gland Pharma to make up to 252 million Sputnik V vaccine doses*. 2021. www.reuters.com/article/health-coronavirus-russia-vaccine-india-idUSKBN2B8125

RDIF entered an agreement with Virchow Biotech for the manufacture and supply of 200 million doses of the vaccine. The technology transfer was expected to be completed in the second quarter of 2021 and to be followed by commercial production of Sputnik V.⁵⁶⁵

RDIF also entered into an agreement with Stelis Biopharma for the manufacturing and supply of 200 million doses. Production was intended to commence from the third quarter of 2021. The production was intended to be conducted at the Stelis Bengaluru facility.⁵⁶⁶

16. PRC

RDIF also entered into several agreements to produce Sputnik V in the PRC. In April 2021, RDIF entered an agreement with Hualan Biological Bacterin, a subsidiary of Hualan Biological Engineering Inc., for the manufacture and supply of 100 million doses of Sputnik V.

RDIF also entered into an agreement with TopRidge, a subsidiary of the PRC's Tibet Rhodiola Pharmaceutical Holding, for the manufacture and supply of 100 million doses of Sputnik V. TopRidge Pharma was said to be able to distribute the vaccine in mainland PRC as well as in Hong Kong, Macao and Taiwan subject to all appropriate regulatory approvals. RDIF further entered into an agreement with Shenzhen Yuanxing for the manufacture and supply of 60 million doses of the vaccine, the commercial production of this vaccine was said to begin in May 2021.^{567, 568, 569}

17. Republic of Korea

RDIF signed a manufacturing agreement with ISU ABXIS for production of the vaccine. RDIF, GL Rapha and ISU ABXIS entered the first trilateral contract for technology transfer and production of Sputnik V vaccine in the Korean consortium. RDIF also entered into an agreement with Hankook Korus for the manufacture and supply of 150 million doses of the Russian Federation vaccine. Further, RDIF signed an agreement with Prestige BioPharma in which the Korean company could produce 2.6 billion doses of the first vaccine dose of Sputnik V.⁵⁷⁰ In March 2022, Huons Global of which Prestige Biopharma is a member, announced that it was ending the contract to manufacture Sputnik V. Huons Global cited the impacts of the Russian Federation–Ukraine war and the Russian Federation sanctions against the Republic of Korea as the basis for the decision.⁵⁷¹

18. Viet Nam

The Russian Direct Investment Fund has signed an agreement with Polyvac in Viet Nam to manufacture and supply 50 million doses of Sputnik V. Under this agreement the Russian Federation would transfer semi-finished products along with instructions to the Ministry of Health's Polyvac Center.⁵⁷²

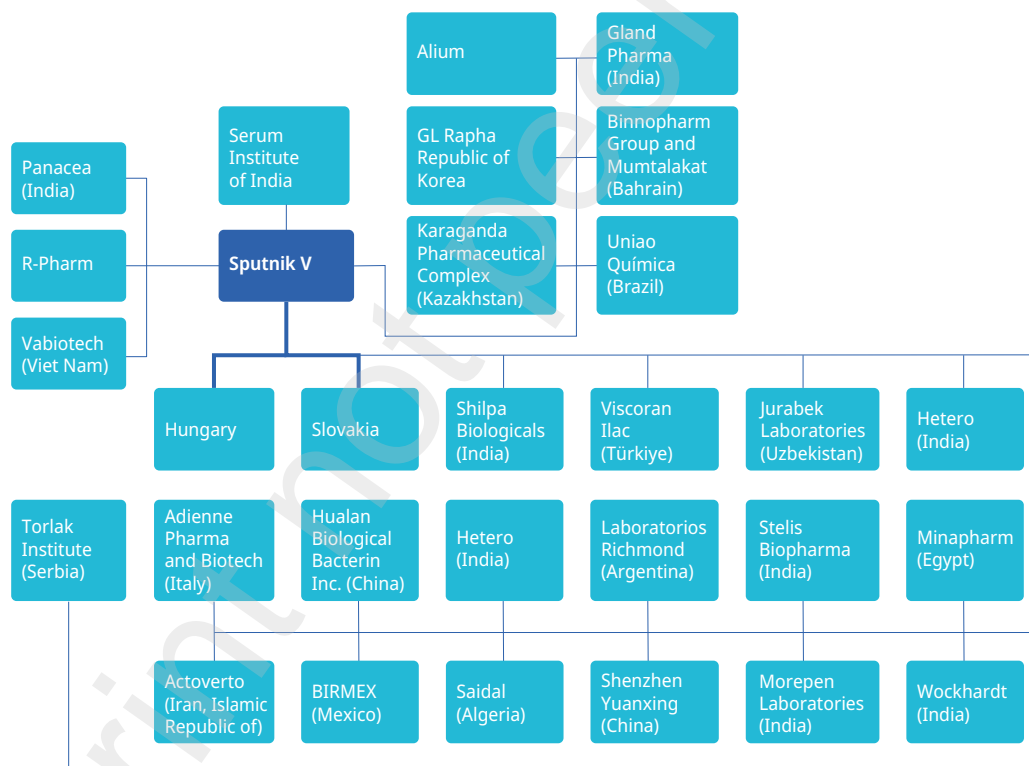
- 565 Bharadwaj, S., *Hyd's Virchow Biotech to make 200 million doses of Sputnik V | India News - Times of India*. 2021. <https://timesofindia.indiatimes.com/vaccine/hyds-virchow-biotech-to-make-200-million-doses-of-sputnik-v/articleshow/81634147.cms>
- 566 Reuters Staff, *India's Stelis Biopharma to make 200 million doses of Sputnik V vaccine*, Mar. 19, 2021. <https://www.reuters.com/article/health-coronavirus-russia-vaccine-india-idUSKBN2BB0ST>.
- 567 Xinhua, *Russia to cooperate with China on production of Sputnik V vaccine*. 2021. www.chinadaily.com.cn/a/202105/08/WS6095e6f7a31024ad0babca39.html
- 568 *RDIF and Hualan Biological Bacterin agree to produce over 100 million doses of the Sputnik V vaccine in China*. 2021. www.bloomberg.com/press-releases/2021-04-19/rdif-and-hualan-biological-bacterin-agree-to-produce-over-100-million-doses-of-the-sputnik-v-vaccine-in-china
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UNICEF's COVID-19 data tracker shows a range of prices for Sputnik V vaccine going from USD 9.75 in Guatemala to USD 27.15 in Pakistan's private market.⁵⁷³

iii. Observations

The consultant considers that there is insufficient information regarding the Russian Federation's effort to develop, manufacture and distribute vaccines to draw meaningful conclusions regarding the subject matter of the study. The publicly available supply agreements entered into by the Russian Federation (through RDIF), for example with Hungary, indicate that the Sputnik V vaccine is patented (see note 524). The Russian Federation has entered into a number of nonexclusive manufacturing and distribution licenses which presumably include rights to use those patents. However, there are substantial questions regarding the manufacturing technology that was provided, the efficacy of the vaccine, the conditions under which manufacturing has taken place, and the extent to which promises of delivery and technology transfer with respect to Sputnik V were carried out.⁵⁷⁴ The Sputnik V effort does not without more complete information suggest a model moving forward. In any case, there is nothing to suggest that inability to access patents or other IP inhibited producers within or outside the Russian Federation from making and supplying Sputnik V.

Sputnik V mapping



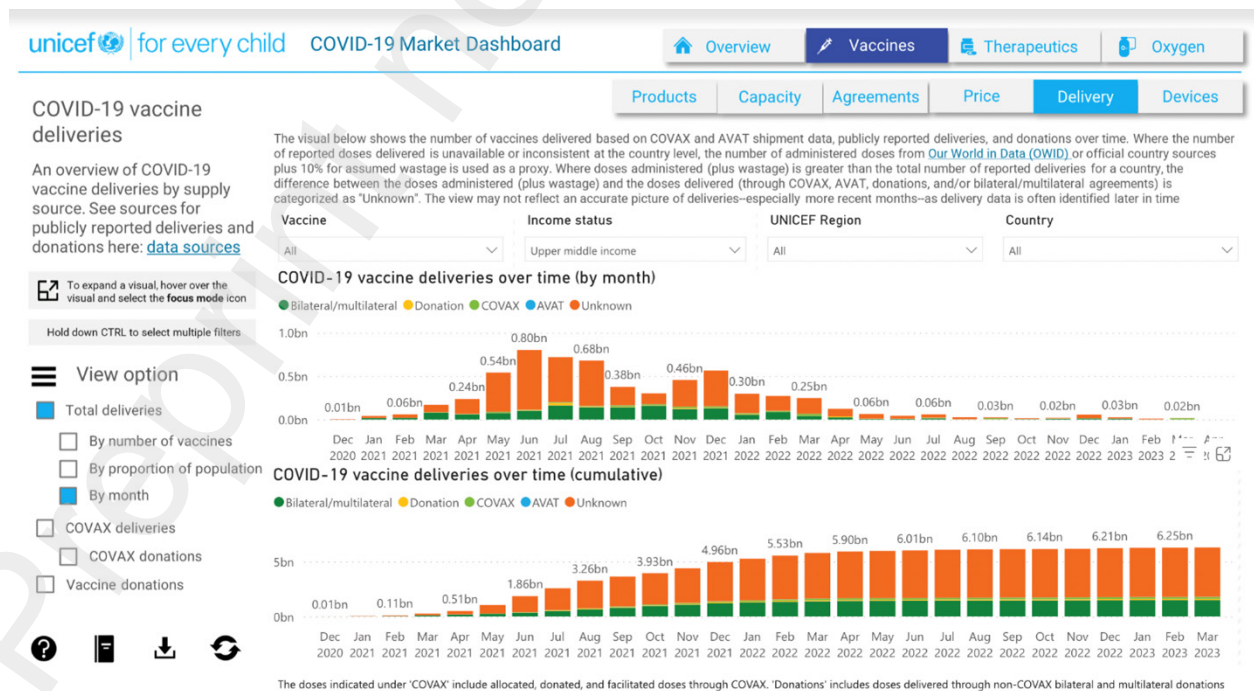
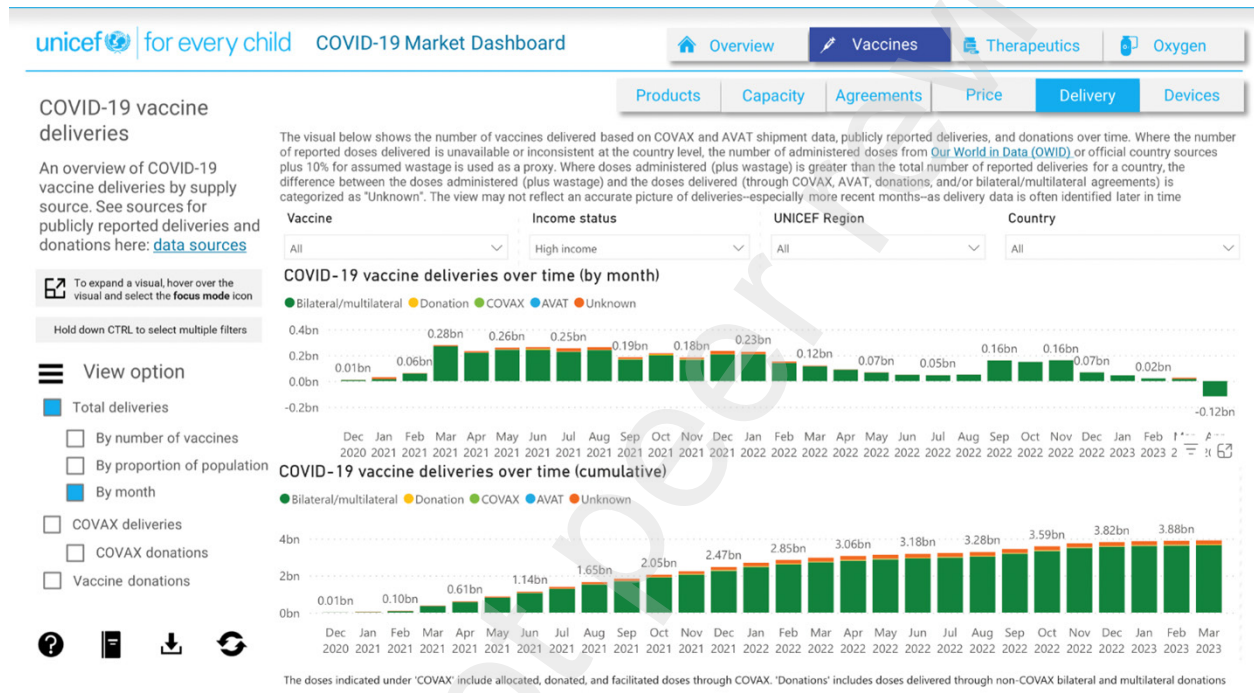
573 UNICEF COVID-19 Market Dashboard, www.unicef.org/supply/COVID-19-market-dashboard. A price of USD 3 is listed for Sputnik V manufactured by Uniao Quimica Farmaceutica Nacional (Brazil) for Latin America. However, the cited source for that price refers to it as a "hope" of the CEO. There is no indication that Sputnik V was provided by anyone at that price.

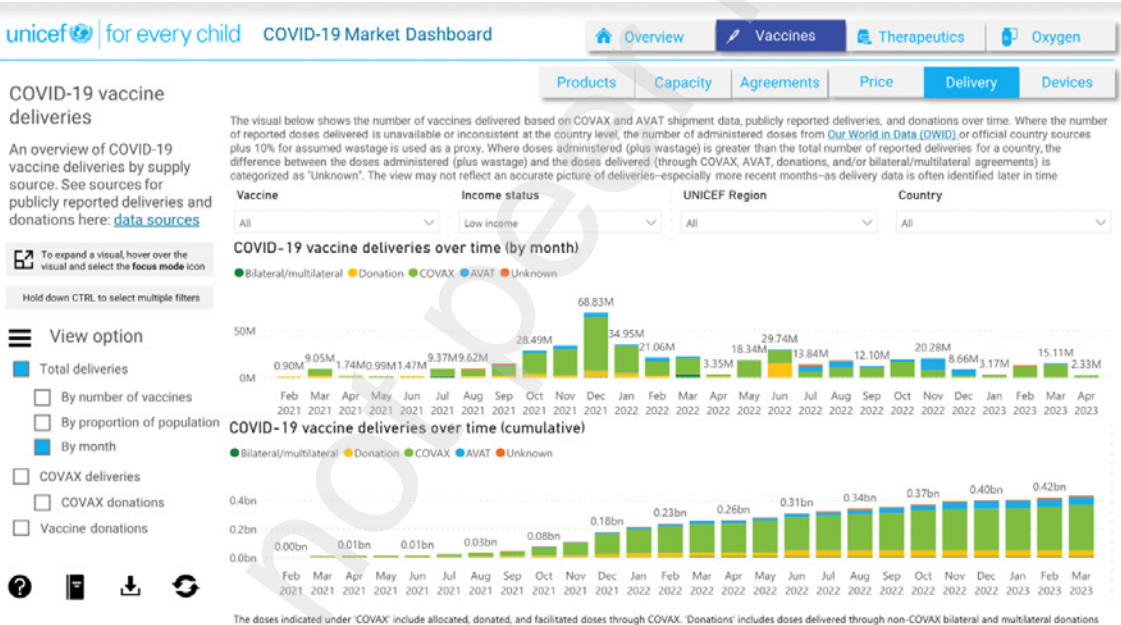
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Summary: Gamaleya (Sputnik V)

- Early development of adenovirus vector vaccine using two different vectors in separate doses
- Difficult to manufacture consistently in large volume
- Introduces one dose Sputnik Light
- Mainly produced in and for the Russian Federation, but many external licensing arrangements announced
- Problems with clinical trials and approvals: neither WHO nor EMA approve
- Several patents
- Limited information on progress of external ventures

Annex 2: UNICEF data





Annex 3: Data and methodology

The consultant was able to assemble a substantial body of data and agreements that formed part of the operational environment addressing the COVID-19 pandemic. A body of licensing, development collaboration, manufacturing and supply agreements are publicly available based on statutorily mandated disclosure for securities markets, most notably (but not exclusively) directed toward the United States Securities and Exchange Commission and its EDGAR database. Publicly traded enterprises disclosing agreements may redact what in their view are commercial terms the disclosure of which may adversely affect their competitive position, such as specific licensing royalty rates. But, other disclosure documents, including quarterly and annual financial filings often describe those licensing terms, both in terms of stage payments and royalty rates, although royalty rates are sometimes referred to in approximate terms (e.g., “in the low single digits”). By cross-referencing revenue disclosures, the specific rates may be ascertained or approximated. Patent number identifiers are typically not disclosed in published agreements, but there are alternative ways to identify certain important patents, including through patent searches, corporate websites, news and public-interest group reporting and litigation documents. Searchable databases such as those maintained by the Medicines Patent Pool (i.e., VaxPal – vaxpal.org) are specifically tailored to provide information regarding patents relevant to vaccines. This study is not a “patent landscape” or analysis as such, or a “freedom to operate” analysis, and specific patent identifiers generally are not critical to describing the operating environment. In litigation concerning the COVID-19 patent environment a number of key patents and their owners are identified. Regarding vaccine prices, a substantial portion of publicly disclosed agreements redact specific pricing terms, but the prices have generally become publicly available through a variety of other routes. Sometimes the pricing data may be approximate.

In addition to the work by this consultant, public interest groups have attempted to identify and publish technology-oriented and distribution agreements entered into during the course of the pandemic. The identified agreements may be affected by redactions but, in general, the redactions do not preclude an understanding of the role and potential effect of the agreements.

There is more complete public information available with respect to the activities of publicly traded private companies than is available regarding the operation of foundations, universities, intergovernmental procurement and supply organizations, and other entities not legally required to make public disclosures. While the consultant was able to assemble data regarding them, entities such as CEPI, the Gates Foundation, Gavi and COVAX published limited information regarding their working arrangements. University technology offices are substantially less transparent than publicly traded companies. Some university technology centers earned substantial royalties from vaccines produced during the COVID-19 pandemic, and the specific terms of their licenses are “closely held”. Nevertheless, there is information in the public domain sufficient to allow for identify essential terms. It is paradoxical that the parties espousing public benefit restrict information. As evidenced by available terms, the publicly interested organizations are no less protective of patents, trade secrets and other information used in developing and producing vaccines than are private sector enterprises.

A threshold question in undertaking this study was how best to secure additional documentation from the entities involved in developing, producing and distributing the vaccines used in addressing COVID-19. The consultant believes that sufficient information has been identified for at least a preliminary description and analysis. The consultant welcomes additional information, including from the parties whose activities are addressed in this study.

Annex 4: Kaiser Family Foundation data for Pfizer and Moderna

How much could COVID-19 vaccines cost the US after commercialization? (Jennifer Kates, Cynthia Cox Josh Michaud), KFF, December 7, 2022

The federal government has so far purchased 1.2 billion doses of Pfizer and Moderna COVID-19 vaccines combined, at a cost of USD 25.3 billion, or a weighted average purchase price of USD 20.69 per dose. In mid-2020, months before any COVID-19 vaccine was yet authorized or had even completed clinical trials, the federal government purchased an initial 200 million vaccine doses from Pfizer and Moderna (100 million each), at a price of USD 19.50 per dose and USD 15.25 per dose, respectively. This guaranteed an advance market for these vaccines, should they prove safe and effective and receive emergency use authorization (EUA) from the Food and Drug Administration (FDA), as each did in December 2020. In total, the federal government has made six different bulk purchases from Pfizer, totaling 655 million doses, and five bulk purchases from Moderna, totaling 566 million doses, for a total of 1.2 billion doses. Subsequent federal government purchases were made at a higher price per dose, with a weighted average across these purchases of USD 20.69. (See figure below.)

The federal price paid per dose has generally increased over time, with the highest price paid for the most recent bivalent, or updated, boosters. The most expensive price per dose paid by the government was for the recent purchase of bivalent booster doses from each manufacturer, including 105 million doses at USD 30.48 per dose from Pfizer and 66 million doses at USD 26.36 per dose from Moderna (or a weighted average price per dose of USD 28.89) (See Table 1 below). This represented a 56 per cent increase in the price per dose for Pfizer, compared to the initial Pfizer purchase price, and a 73 per cent increase for Moderna. In total, the US has purchased 171 million doses of the bivalent booster at a cost of USD 4.9 billion.

Table US government purchases of Pfizer COVID-19 vaccines

Purchase	Date	Amount paid	Number of doses	Price/dose
1	7/22/2020	\$1,950,000,000	100,000,000	\$19.50
2	12/23/2020	\$2,011,282,500	100,000,000	\$20.11
3	2/11/2021	\$2,011,282,500	100,000,000	\$20.11
4	7/23/2021	\$4,869,750,000	200,000,000	\$24.35
5	10/22/2021	\$1,230,000,000	50,000,000	\$24.60
6*	6/29/2022	\$3,200,000,000	105,000,000	\$30.48
TOTAL	—	\$15,272,315,000	655,000,000	\$23.32

Source: KFF analysis

Figure Federal purchases of Pfizer and Moderna COVID-19 vaccines have totaled USD 25.3 billion at an average price of USD 20.69 per dose (costs in USD)

Federal Purchases of Pfizer and Moderna COVID-19 Vaccines have Totaled \$25.3 Billion at an Average Price of \$20.69 per Dose

Date	Manufacturer	Amount Paid (\$ Billions)	Number of Doses (Millions)	Price per Dose (\$)
Jul '20	Pfizer	\$1.95 B	100 M	\$19.50
Dec '20	Pfizer	\$2.01 B	100 M	\$20.11
Feb '21	Pfizer	\$2.01 B	100 M	\$20.11
Jul '21	Pfizer	\$4.87 B	200 M	\$24.35
Oct '21	Pfizer	\$1.23 B	50 M	\$24.60
Jun '22	Pfizer (bivalent)	\$3.20 B	105 M	\$30.48
Aug '20	Moderna	\$1.53 B	100 M	\$15.25
Dec '20	Moderna	\$1.67 B	100 M	\$16.67
Feb '21	Moderna	\$1.75 B	100 M	\$17.50
Jun '21	Moderna	\$3.30 B	200 M	\$16.52
Jul '22	Moderna (bivalent)	\$1.74 B	66 M	\$26.36
Total	Both	\$25.26 B	1,221 M	\$20.69

Source: KFF analysis

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