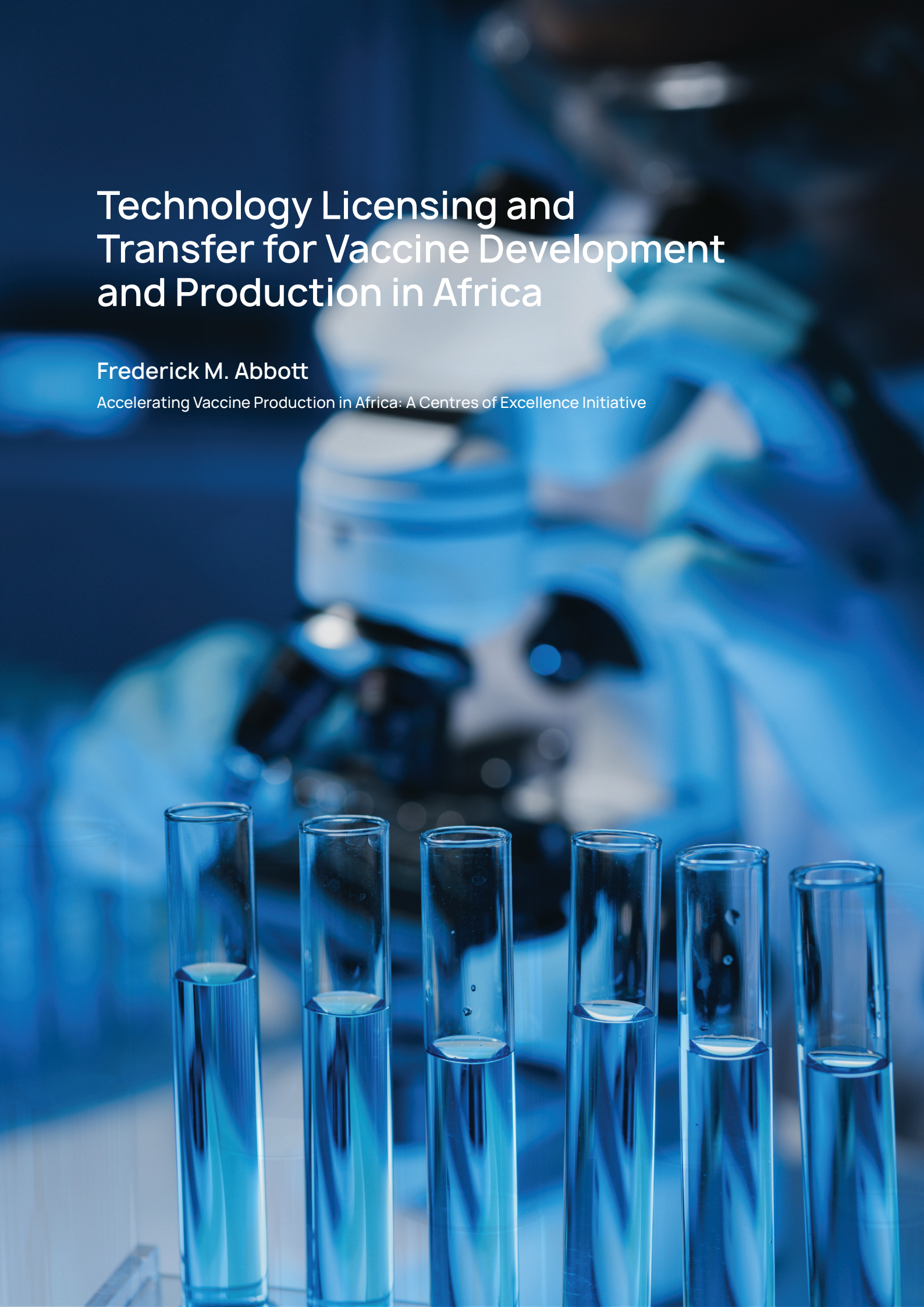
Technology Licensing and Transfer for Vaccine Development and Production in Africa

Frederick M. Abbott

Accelerating Vaccine Production in Africa: A Centres of Excellence Initiative



Technology Licensing and Transfer for Vaccine Development and Production in Africa

Frederick M. Abbott

Accelerating Vaccine Production in Africa: A Centres of Excellence Initiative

About the Accelerating Vaccine Production in Africa: A Centres of Excellence Initiative

Improving the pharmaceutical sector's ability to innovate is dependent in a large part on robust university-industry collaborations and a strong African public sector that focuses on translational research for medicines, vaccines and diagnostics. Skills building at universities is not just about creating science capacity. New discoveries in basic and applied research need to be learned and applied in a pharmaceutical ecosystem. Natural science should be considered in light of advancements in the social science field to promote a better understanding of pharmaceutical innovation and production systems, and help to measure gaps. We also must measure the extent of capacity that exists in the sector presently, identify technology gaps and critical tipping points.

The AVPA Centers of Excellence Initiative is built on a strong collaborative effort among different participating institutions throughout Africa that act as nodes of learning and interaction. Various research, training and policy engagement activities bring together private, public, and academic sectors to build a strong vaccine ecosystem in the region that trains talent and increases returns on innovation investments in Africa.

The AVPA Initiative is financed through the German Development Cooperation and brings together the University of Johannesburg (South Africa), the Centre of Excellence for Vaccines, Immunisation and Health Supply Chain Management (RCE-VIHSCM), University of Rwanda (Rwanda), with other select centres in Nigeria and Ghana.

Acknowledgements

This brief was originally prepared in 2024 as a background paper for the AVPA Initiative. This version has not been copy-edited. Any queries on the program or the paper should be addressed to the AVPA Program.

Table of Contents

1. A Brief History

A. Technology Licensing

Technology, patented and otherwise, is often developed across a series of research steps and frequently involves different entities, public and/or private. Licensing and associated technology transfer provides the mechanism through which ownership and/or control of technology can be moved among enterprises without entering the public domain. Parties owning patents or trade secrets are often not situated to exploit the technology themselves, such as through the establishment of manufacturing facilities. They may elect to commercialize their technology by allowing others to use it for a fee or other considerations. This can be accomplished through an agreement authorizing third party use of patents, trade secrets and other know-how.

Patents, which are creatures of government legislative and regulatory process, may be owned by government and/or public entities, but they are usually owned by private entities, whether individuals or businesses. Patents may cover technologies that are needed for governmental functions, such as for military/defense purposes or to address public health needs. Governments typically reserve the right to make use of patents for public purposes through the grant of government (or Crown) use or compulsory licenses.

Technology licensing is a long-standing phenomenon. The Paris Convention for the Protection of Industrial Property, which has continuously evolved since its adoption in 1883, establishes rules relevant to patent licensing, as well as for protection against unfair competition. In the late 1960s and through the mid-1980s, there was a political movement at the international level pursued by low- and middle-income countries (LMICs) toward creating a more even level of technological development with the high-income countries (HICs). This political movement, referred to as the New International Economic Order (or NIEO), foresaw establishing weakened standards of intellectual property protection to allow LMICs to make use of technology that had been developed in the HICs. Efforts toward a NIEO were pursued at the United Nations Conference on Trade and Development (UNCTAD) and at the World Intellectual Property Organization (WIPO). The net result of these efforts was to encourage the HICs to pursue stronger IP protection at the World Trade Organization (WTO) through adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which entered into force on January 1, 1995.[2] The TRIPS Agreement establishes common rules for the protection of patents, copyrights, trade secrets and regulatory data, among other IP fields, that are relevant to technology licensing and the establishment of pharmaceutical and vaccine manufacturing facilities. These rules are generally permissive with respect to contracting for transfers of technology, and they establish certain standards regulating government use and compulsory licensing.

In the "ordinary course of business" an enterprise seeking to produce and distribute pharmaceuticals and vaccines will be relying on legal rules established by national law that govern contracts and protection of intellectual

[1] Frederick M. Abbott, Public-Private Partnerships as Models for New Drug Development: The Future as Now, in THE CAMBRIDGE HANDBOOK OF PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT, pp. 29-45, eds. M. Chon, P. Roffe & A. Abdel-Latif (Cambridge Univ. Press 2018), available at SSRN: https://ssrn.com/abstract=3298428

[2] See generally RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT, UNCTAD-ICTSD (2005), https://www.iprsonline.org/unctadictsd/ResourceBookIndex.html.

property (IP). The fact that these national rules may incorporate requirements established at the WTO, WIPO or other institutions generally does not affect the negotiation, conclusion or implementation of technology licenses. The international rules form a background that may come into play as governments assess activities taking place within their own national, or in foreign, jurisdictions.

This research paper addresses a key question: what is the appropriate public policy for promoting the development and manufacture of vaccines on the African continent from the standpoint of encouraging local R&D and transfer of technology? It begins by briefly reviewing policies and legislative measures with respect to technology transfer mainly from the United States and Europe. It then looks at the technology transfer mechanisms used during the COVID-19 pandemic and the role played by them, including the IP elements. There is then a discussion of some of the technology licensing arrangements in the process of implementation in Africa. Finally, it suggests certain policy measures to consider for future implementation.

B. Regulation by Competition/ Antitrust Law

Technology licensing at the national and regional level is generally regulated through a variety of different types of policy and legal measures. Private actors typically have substantial leeway to negotiate and enter into technology licensing agreements among themselves and to establish the terms and conditions of doing business.

[3] The U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) jointly issued the "Antitrust Guidelines for the Licensing of Intellectual Property", January 12, 2017 to provide guidance on how they evaluate the potential competitive effects of licensing agreements involving intellectual property (IP) such as patents, copyrights, and trade secrets, https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf

The primary regulatory focus may be the rules on competition that seek to assure that licensing agreements are not used as a mechanism for restricting the entry of new products or technologies onto the market and to preserve the vibrancy of the competitive research space. This involves approaches that seek to prevent or remedy a single enterprise from dominating a product or technology market, and that seek to prevent groups of enterprises from entering or implementing agreements that may have anticompetitive effects. The United States Department of Justice and Federal Trade Commission maintain Guidelines on Intellectual Property Licensing.[3] These Guidelines address markets for products made and distributed under technology licenses, as well as technology markets such as R&D markets. For example, under the DOJ/FTC Guidelines a technology license that will not give combining parties in a product market more than a 20% combined market share is presumed to be compliant with the antitrust laws, although this presumption is not conclusive.[4] The Competition Commission of the European Union has adopted the Technology Transfer Block Exemption Regulation (TTBER).[5]

[4] Section 4.3: "Absent extraordinary circumstances, the Agencies will not challenge a restraint in an intellectual property licensing arrangement if (1) the restraint is not facially anticompetitive and (2) the licensor and its licensees collectively account for no more than twenty percent of each relevant market significantly affected by the restraint…."

Regarding potential effects in a research and development market, the Agencies, absent extraordinary circumstances, will not challenge a restraint in an intellectual property licensing arrangement if (1) the restraint is not facially anticompetitive and (2) four or more independently controlled entities in addition to the parties to the licensing arrangement possess the required specialized assets or characteristics and the incentive to engage in research and development that is a close substitute of the research and development activities of the parties to the licensing agreement." (DOJ-FTC Guidelines on IP)

[5] Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union (TFEU) to categories of technology transfer agreements, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0316

This regulation provides a safe harbor for certain types of technology transfer agreements, exempting them from Article 101 of the TFEU if they meet specific conditions. It covers agreements such as patent and know-how licenses and technology pooling arrangements. The TTBER is accompanied by a detailed set of Guidelines regarding their application.[6] The basic presumptions of the US Antitrust Guidelines and the TTBER regulations are similar, with the EU also presuming that a combined post-license market share of competitive companies of 20% or less does not raise competition concerns.[7] The TTBER and related Guidelines also include certain "hardcore" prohibitions against certain terms and conditions, such as licenses that fix prices among horizontal competitors.

To the extent that one seeks to define a technology licensing regulatory program in the United States or the European Union this would mainly focus on the antitrust/competition rules which essentially set out the limits of private party flexibility in the negotiation of licensing terms and conditions, as well as the degree to which markets are permitted to become concentrated. The underlying premise of the rules in both jurisdictions is that technology licensing predominantly serves a positive competition- enhancing function by encouraging the entry of new products onto the market and challenging structural rigidity, providing benefit to consumers in the form of improved products. At the same time, rules in both jurisdictions recognize that technology developers and owners may attempt to exercise control over technologies in ways intended to capture more than a fair share of the market, injuring consumers by preventing the introduction of improved products and/or unjustifiably raising prices.

C. Government Use and Compulsory Licensing

New technologies are often protected by IP, principally patent and trade secret. Historically, concerns have been expressed regarding the potential for these IP protections to inhibit economic development and social welfare, particularly for developing countries. As noted earlier, such concerns were prevalent during the late 1960s and early 1970s and resulted in a push for a NIEO. The concerns escalated during the HIV-AIDS epidemic that started in the 1980s and represented a major threat to public health and welfare in Africa in the late 1990s and early 2000s. This concern gave rise to considerable interest in whether non-voluntary licensing of pharmaceutical technology, in particular, could help solve problems surrounding lack of adequate access to HIV antivirals. Although the "compulsory licensing" of patents ultimately played a minor role in terms of enhancing access to HIV medicines through the actual grant of licenses, the potential grant of such licenses may have acted as a restraint on pricing behaviors by patent owners.

Compulsory licensing has typically been viewed as a form of exceptional measure that can be exercised when specific problems of access to technology are in evidence. It is not clear that compulsory licensing is an effective basis for a technology development program in Africa or elsewhere for several reasons. First, the developers and owners of patented technology tend to be quite resistant to the grant of

[6] Communication from the Commission, 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), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0328(01).

[7] See, e.g., Recitals,

"(10) For technology transfer agreements between competitors it can be presumed that, where the combined share of the relevant markets accounted for by the parties does not exceed 20 % and the agreements do not contain certain severely anti-competitive restrictions, they generally lead to an improvement in production or distribution and allow consumers a fair share of the resulting benefits."

compulsory licenses and maintain influence within their host country governments. Interfering with these private rights can result in political and economic pushback that presents a cost to the country using the mechanism. Second, the effect of deployment of technology involves a substantially broader range of input than simply access to patent information. It requires not only expertise in the building and operation of manufacturing facilities, but also a range of "know-how" including that protected by trade secret, that is more effectively transferred through cooperative efforts such as voluntary licensing within or outside of joint venture arrangements. Third, although an individual compulsory license may not have a negative investment consequence, a policy of compulsory licensing would likely discourage investment in R&D as individuals and enterprises are less able to obtain sufficient return on investment to compensate for risk. The development and deployment of pharmaceutical technology is a capital intensive process, and the pool of investors that are willing to fund R&D without an expectation of licensing royalties or other returns on investment is shallow. Governments in Africa do not have unlimited resources to commit to R&D projects.

Recognizing these caveats, national governments typically reserve for themselves the right to use patented technologies for government purposes, recognizing an obligation to compensate the patent owner in some measure. National patent legislation often reduces or eliminates the bureaucratic steps that are needed in order for the government to secure patented technologies through government use licensing as compared to private sector directed compulsory licensing. This is at least in part in recognition that technologies may be needed for military defense purposes, or in cases of particular urgency, such as in a public health crisis.

With respect to government authority to make use of technology developed and owned by private sector enterprises, the United States has a broadly permissive arrangement. The US government or its contractors are permitted to make use of any patent without notice to the patent owner, subject to the payment of reasonable compensation as may be prescribed pursuant to suit brought by the patentee in the Federal Court of Claims. This system is not part of the US Patent Act, but is implemented through a federal statute that prohibits suits to enjoin the US government from use of a patent, and it prescribes the potential for monetary recourse to the Court of Claims. This is 28 USC §1498. [8]

This system is used by the US government with respect to military defense contracting. Clauses recognizing the potential government use of patents are routinely inserted in government contracts,[9] and decisions by the US Federal Trade Commission imposing blocking orders on infringing importation of patented goods routinely exclude the federal government from the effects of such orders.[10]

Many of the agreements entered into by the US government regarding the development and distribution of COVID-19 vaccines included clauses acknowledging the potential for government use of patents.[11] Moderna, creator of the mRNA Spikevax vaccine is defending

[8] 28 U.S.C. §1498. Patent and copyright cases. See, e.g., Amy Kapczynski & Aaron S. Kesselheim, "'Government Patent Use': A Legal Approach to Reducing Drug Spending," Health Affairs 35 (2016).

[9] See, e.g., March-in Rights, 35 USC 203; US Federal Government, "Title 37 Chapter IV Part 401 § 401.6 Exercise of march-in rights.," ed. Department of Commerce National Institute of Standards and Technology (Code of Federal Regulations). https://www.ecfr.gov/current/title-37/chapter-IV/part-401/section-401.6.

[10] Frederick M. Abbott, Thomas Cottier and Francis Gurry. International Intellectual Property in an Integrated World Economy, Aspen Casebook Series. 4th ed.: Wolters Kluwer, 2019.

[11] See, e.g., HHS/BARDA-Moderna Development Agreement, Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2, SEC Edgar database (19/01/2021).

itself in patent litigation brought by a third party on grounds that it was acting as a contractor for the federal government which effectively authorized it to use third party patents without permission. [12]

Although the United States government is expressly authorized to use private party patents upon the payment of compensation as described above, this authorization does not extend to use of trade secret information such as might be necessary to more effectively implement a patent license. During the COVID-19 pandemic, the advanced purchase agreements (APAs) entered into by the United States with private sector pharmaceutical companies typically included clauses providing that if the supplier failed to carry out its responsibilities the government could appoint a third party to fulfill the contract and the government would be authorized to provide confidential information, including trade secrets, needed for that party to fulfill its "stand in" role. The initially contracted supplier would have previously provided information to the government regarding how its vaccine was manufactured. Pursuant to the Fifth Amendment of the US Constitution, private sector companies are protected against appropriation without compensation of trade secrets by the federal government.[13] This does not prevent the government from "taking" trade secrets when circumstances warrant, but it does require the government to pay adequate remuneration. No such situation materialized in the United States during the COVID-19 pandemic.

A new European Union-wide compulsory licensing statute, proposed in April 2023, would provide a mechanism for government use of patents.[14] It aims to ensure the rapid deployment of patent-protected inventions in times of crisis or emergency. The proposed regulation introduces a new instrument called the "Union compulsory license," which allows the European Commission to grant licenses of EU-wide validity for patents in specific crisis situations. The license may cover patents, patent applications, supplementary protection certificates, and utility models. The Commission can grant such a license if certain conditions are met, including the existence of an EU-wide crisis, the failure of voluntary licensing negotiations, and the necessity of the invention to address the crisis. The patent holder is entitled to "adequate remuneration" for the use of their invention. The regulation also establishes rules and procedures for granting Union compulsory licenses and supervising the law's implementation. The proposal is in the legislative process and might undergo changes before final adoption.

Until a EU wide compulsory licensing scheme is put in place to address emergencies, the member states of the EU are governed by national law in terms of the granting of compulsory licenses. The individual member states take different approaches to the grant of compulsory patent licenses.[15] As noted by the European Patent Academy: "Most European countries have integrated the regime of granting compulsory licences into their IP legislations, although possible grounds for grant may differ between them. The competent authorities vary as does the procedural framework leading to the grant of a compulsory licence as this depends on the national civil or administrative procedures." (Patent Academy, at 3). A number of European countries, including France and Germany, amended their compulsory licensing legislation during the COVID-19

[12] Matthew Bultman, Moderna Must Face Patent Claims Over US Government Vaccine Sales, Bloomberg News, Nov. 2, 2022.

[13] Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).

[14] Commission proposal for a Regulation of the European Parliament

15 European Patent Academy, Compulsory licensing in Europe: A country-by-country overview, European Patent Office 2018, /https://link.epo.org/elearning/compulsory_licensing_in_europe_en.pdf

pandemic to facilitate the grant of authorization.[16]

Some non-European countries also enhanced the flexibility of their approaches to government use and compulsory licensing during the course of the COVID-19 pandemic.[17]

The United States and European Union have in place, or are in the process of adopting, measures that facilitate the use of patented technologies in the context of public health emergencies. There is no evident reason why African governments should not do the same.[18]

There is, however, a distinction between the policy role that compulsory or government use licensing can and should play in the context of urgent situations, and the role that compulsory or government use licensing can or should play in the development and implementation of broader national or regional technology development and licensing policy. The broader policy context requires attention to the need for capital formation and longer term investment for which security of rights may be a significant factor.

[16] During the COVID-19 pandemic, both France and Germany made significant amendments to their compulsory licensing legislation, primarily aimed at facilitating access to essential medicines and medical technologies required to combat the public health crisis.

France
France introduced a new article, L.3131-15, into the Public Health Code through the emergency law no. 2020-290 of 23 March 2020. This amendment empowered the Prime Minister to:

- Order the requisition of any goods and services necessary to combat the health crisis, including medicines.
- Take all necessary measures to make appropriate medicines available to patients for the eradication of the health crisis.

While the law didn't explicitly mention compulsory licenses, it provided a legal framework for the government to potentially utilize compulsory licensing mechanisms if needed to ensure access to essential medicines.

Germany
Germany supplemented Section 13 of the German Patent Act with Section 5, paragraph 2, no. 5 of the Infection Protection Act. This amendment allowed the government to order the use of a patented invention without the consent of the patent holder in cases of public interest, particularly during epidemics. It expanded the existing provisions for compulsory licensing to specifically address public health emergencies.

Both countries' amendments aimed to prioritize public health needs during the pandemic. The amendments broadened the scope of existing compulsory licensing provisions or provided alternative legal frameworks for the government to intervene in patent rights. While neither country explicitly granted compulsory licenses during the pandemic, the legal changes signaled a willingness to utilize such measures if necessary.

[17] See, e.g., Adam Houldsworth, The key covid-19 compulsory licensing developments so far, IAM, April 7, 2020, reporting on Israel, Canada, Germany, France, Chile, Ecuador and Australia, https://www.iam-media.com/article/the-key-covid-19-compulsory-licensing-developments-so-far.

[18] See, e.g., Adam Houldsworth, The key covid-19 compulsory licensing developments so far, IAM, April 7, 2020, reporting on Israel, Canada, Germany, France, Chile, Ecuador and Australia, https://www.iam-media.com/article/the-key-covid-19-compulsory-licensing-developments-so-far.

South African law in its Patents Act, by way of example, makes provision for the grant of compulsory licenses it does not include provisions specifically authorizing government use under any type of facilitated procedure, except with respect to the military for armaments. Companies and Intellectual Property Commission, Exceptions and Limitations: Submission by South Africa, WIPO Standing Committee on Patents (2017), https://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/south_africa.pdf. In preparing the recently adopted IP Policy, DTI took note of this gap in South African law and proposed to introduce facilitated procedures for government use licensing.

As the South African Patents Act currently stands, the provisions on compulsory licensing require application from an interested person to the Commissioner of Patents. Substantial discretion is placed in the hands of the Commissioner to make determinations concerning whether a license should be granted, including the terms and conditions of that license. A third party such as the patentee may oppose the application, and rules are established governing the relevant administrative processes. Whatever may be the merits of such a system for general private law purposes, it is not suitable to addressing situations of urgent public health needs, or other circumstances where the government may find it important to take advantage of patented inventions.

Another aspect of South African patent law that was highlighted in the IP Policy is the absence of substantive examination of patent applications. To the extent foreign patent applicants are able to more easily obtain patent protection in South Africa than in other jurisdictions, there is a greater likelihood that local companies seeking to develop and implement new vaccine technologies will confront blocking patents, or a so-called "patent thicket". This author has not undertaken to study whether there is a proliferation of vaccine-related patents in South Africa that is not reflective of the general worldwide trend, but it is worthwhile to be mindful of this possibility.

D. Research and Regulatory Review Exemption

Patent law has long recognized the possibility for third parties to make use of patented technology without the authorization of the patent owner under a "research exemption". The underlying concept is that the principal rights of the patent owner are designed to give it the ability to prevent third parties from commercializing a patented product during the term of the patent. The research exemption does not give a third party the right to commercialize a product covered by a patent. It authorizes the third party to make a limited use of the patented technology to conduct experiments for various reasons, including to verify whether the patented technology does what it is claimed to do, and potentially to develop new or different products based on some aspect of the patented technology.

The patent law of the United States and the patent laws of the European Union and its member states generally recognize the research exemption, for the United States particularly in the pharmaceutical sector. The US Supreme Court in Merck KGaA v. Integra Lifesciences (545 U.S. 193 (2005)) held that the US Patent Act authorizes a third party to use patented technology for R&D in the pharmaceutical sector as long as the research is reasonably related to the development of a pharmaceutical product that may eventually be submitted to the FDA for approval, whether or not such approval is ever sought or secured. This includes preclinical research. The pharmaceutical research exemption is substantially broader than the "common law" research exemption in the United States which is generally restricted to experimentation intended to demonstrate that a patented technology works.[19] The research exemption in the pharmaceutical sector is based on specific provisions in the Hatch-Waxman Act. The US research exemption does not authorize a third party to commercialize a product using a patent without the consent of the patent owner. Therefore, a third party that develops a new product that makes use of technology in a pre-existing patent must secure a license to make and sell the new product from the owner of the pre-existing patent. If the developer of the new product secures a patent on its new product (e.g., an improvement), the original patent owner may not make and sell the improved product without the consent of the new (e.g., improvement) patent owner.

In the EU there is no Union-wide research exemption, but individual member states maintain such exemptions which in some cases are similar to those of the United States in the pharmaceutical sector.[20] For example, Section 11(2) of the German Patent Act has been interpreted broadly by the German Supreme Court to allow research in the pharmaceutical sector (including clinical trials) up to the point of commercialization. Other member states while maintaining research exemptions have interpreted it more narrowly, such as to permit research only on the patented technology itself, but not to develop new technology.[21]

The patent research exemption should be distinguished from a regulatory review exception, sometimes referred to as a "Bolar" exemption. That exemption, first adopted in the United States as part of the 1984 Hatch-Waxman Act, allows a generic producer of a patented pharmaceutical chemical product to use the technology of the originator for purposes of developing and submitting an application for approval of a generic drug to the

[19] See Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

[20] Marco Stief, The European Research and Bolar Exemptions — Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation, GRUR International, Volume 73, Issue 9, September 2024, Pages 824–837, https://doi.org/10.1093/grurint/ikae094

[21] Id.

drug regulatory authority.[22] In the United states this means submitting an abbreviated new drug application (ANDA) to the Food and Drug Administration (FDA). This permits the generic version of the originator drug to be placed on the market at the same time the patent expires, rather than waiting until the patent expires to begin developing the generic version. In the United States there is a separate mechanism for preparing and submitting biosimilar drug applications to the FDA prior to the expiration of the reference (originator) product market exclusivity and patent term.[23] The European Union has its own regulatory review exception that permits a generic producer to submit an application for regulatory approval before expiration of the patent and market exclusivity term. Member states have interpreted the scope of the directive providing for this exemption differently, and there is currently a proposal in the EU for a harmonized system for a regulatory review exception which would address both biologics and small molecule chemical drugs.[24]

In the context of attempting to build up R&D and manufacturing capacity for vaccines in the African region the ordinary research exemption is probably more useful than the regulatory review exception since the latter comes into play when patents and market exclusivity on vaccines are nearing their expiration. Developing vaccines based on newer patented technologies when the vaccines are needed an outbreak is more likely to involve at an earlier stage in the life-cycle of existing patents and market exclusivity.

E. Experience

As a practical matter most technology licensing in the United States or Europe takes place between private parties negotiating voluntary licenses. The National Institutes of Health (NIH) is a major source of funding for basic research in the US. The NIH provides more than $40 billion a year of funding which very predominantly goes to research institutions in the United States.[25] The recipients of the funding are entitled to patent the results of their research, and downstream licensing is most likely to be from the recipient of the funding which owns the resulting patents to some third-party enterprise.[26] The US government itself does not often act as licensor, though it takes back a non-exclusive right to use the patented technology for its own purposes under the Bayh-Dole scheme. In addition to this, the legislation requires that licensing for manufacturing be directed towards entities producing in the United States. However, in practice the NIH has not enforced the domestic manufacturing requirement due, presumably, to industry lobbying citing costs and the lack of domestic production capacity. The intention of the legislation was to bolster domestic production capacity, and the provision

[22] See Frederick M. Abbott, The Generics Pathway in the USA: The American Experience, a Model for the World?, in INDUSTRIA FARMACÉUTICA, DERECHO A LA SALUD Y PROPIEDAD INTELECTUAL: EL RETO DEL EQUILIBRIO, PP. 253-67, eds., Universidad Nacional Autónoma de México (UNAM) (2018), available at SSRN: https://ssrn.com/abstract=2570922

[23] The biosimilar pathway in the United States was created by the Biologics Price Competition and Innovation Act of 2009. Section 351 of the PHSA (42 USC §262. Regulation of biological products) gives the Food and Drug Administration (FDA) the authority to regulate biological products and ensure their safety, purity, and potency. This includes licensing requirements, manufacturing standards, and post-market surveillance.

[24] See European Commission, 'Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC' COM(2023) 192 final, 2023/0132(COD), 26 April 2023.

[25] https://www.nih.gov/about-nih/what-we-do/budget: "The NIH invests most of its nearly $48 billion budget1 in medical research for the American people.

[26]Pursuant to the Bayh-Dohl Act and related legislation, the recipients of this funding are authorized to secure patents in their own names, and to own those patents, subject to the possibility of government March-In rights

of an escape clause appears contrary to this intention. Post the COVID-19 pandemic the US federal government may become more serious about requiring local production based on federally funded research.[27]

Similarly in the EU, technology transfer licensing predominantly takes place between private sector owners of patents and related trade secret technology. There are very few instances either in the United States or Europe in which compulsory or government use licensing has played a significant role in vaccine development and/or approval.

[27] There have been various proposals and initiatives aimed at amending the Bayh-Dole Act to strengthen the requirement for domestic production of inventions developed with federal funding. Here are some notable examples:

1. Executive Order 14005:
- Issued in 2021, it directs federal agencies to strengthen implementation of the Bayh-Dole Act's provisions regarding U.S. manufacturing.
- It specifically urges agencies to consider requiring domestic manufacturing for products embodying subject inventions, even for non-exclusive licensees and products sold outside the U.S.

2. Proposed Legislation:
- Several bills have been introduced in Congress to amend the Bayh-Dole Act to explicitly require domestic manufacturing for all inventions resulting from federal funding.
- These proposals often emphasize the importance of domestic manufacturing for national security, economic competitiveness, and job creation.

3. Policy Advocacy:
- Various organizations and think tanks have advocated for amending the Bayh-Dole Act to prioritize domestic production.
- They argue that the current law's flexibility in granting waivers for domestic manufacturing requirements undermines its intended purpose of promoting U.S. innovation and economic growth.
- The Bayh-Dole Act already requires exclusive licensees to manufacture substantially in the U.S. any products embodying a subject invention intended for use or sale in the U.S.
- Proposals to amend the law aim to extend this requirement to non-exclusive licensees and products sold abroad, or to eliminate the possibility of waivers altogether.
- Proponents of these changes emphasize the benefits for domestic manufacturing, job creation, and national security.
- Opponents argue that such restrictions could hinder innovation and discourage international collaboration.

The Bayh-Dole Act has not yet been formally amended to explicitly require domestic production in all cases. The debate surrounding this issue highlights the complex balance between promoting innovation, economic growth, and national interests in the context of federally funded research and development. Google Gemini Advanced, Sept. 28, 2024.

2. Pandemic and Post-pandemic Vaccine Technology Licensing

During the course of the COVID-19 pandemic a great deal of technology licensing took place.[28] The development, production and distribution of vaccines involves a complex "web" of technology-related relationships. These go from the entities that undertake basic research and often are responsible for the initial patenting of technologies, to more substantial pharmaceutical/vaccine enterprises that have the capacity to move products into more usable states, to pursue clinical testing and regulatory approvals, to develop and implement production process technologies, and to engage in distribution. Even among the major integrated industry actors, technology was developed and transferred through various steps performed by different individuals and entities, and as evidenced by license agreements.

The types of business arrangements and the licensing terms and conditions regarding COVID-19 varied widely. In HICs, and particularly in the United States, vaccine development agreements were concluded between federal government agencies and pharmaceutical/vaccine developers, mainly (though not exclusively) with larger well-established enterprises with a track record of successful product development. This included Moderna, Johnson & Johnson (Janssen), Sanofi and Novavax. Pfizer did not rely on government financing to develop its vaccine, but entered into a collaboration agreement with BioNTech that gave Pfizer control over product sales in most of the world.[29]

The agreements involving the federal government did not require the companies to assign intellectual property rights to the government. Consistent with the Bayh-Dole Act the agreements allowed the private enterprises to file for and retain patent rights, but generally gave the government rights to "March In" and use patents in defined circumstances.[30]

A. Product Development Arrangements

The technology used in the various vaccine candidates to protect against SARS-CoV-2 was different, and the product development agreements necessarily reflected those differences. In general, however, the terms and conditions of product development licenses

[28] See generally Frederick M. Abbott, Intellectual Property and Technology Transfer for COVID-19 Vaccines: Assessment of the Record, 2023 (WIPO), https://www.wipo.int/publications/en/details.jsp?id=4684; attached as Appendix 1.

[29] By keeping its arrangement with BioNTech privately funded, Pfizer/BioNTech would not be subject to U.S. Federal government march-in rights with respect to its patents, but it would be subject to "government use" licensing pursuant to 28 USC §1498 as described above.

[30] US Federal Government, "Federal Acquisition Regulation 52.227-11 Patent Rights-Ownership by the Contractor." https://www.acquisition.gov/node/32149/printable/pdf.

"(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©, 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."

See also Government, "Title 37 Chapter IV Part 401 § 401.6 Exercise of march-in rights.."; March-in Rights; Patents - Precedence of chapter, 35 USC 210©.

tend to follow along common lines. A detailed description and analysis of these agreements, and downstream agreements discussed subsequently are set out in an analysis this author prepared for the World Intellectual Property Organization regarding intellectual property and technology transfer to address COVID-19, which is attached here to as Appendix .[31] The principal topic headings would include:

1. The contribution of technology, e.g., patents, know-how, biological materials, that each party will be making to the endeavor
2. Funding for the development
3. Allocation of responsibilities throughout the project, including, e.g., responsibility for conducting any necessary clinical trials and securing regulatory approval
4. Benchmarks against which funding is provide
5. Reporting and rights to monitor progress
6. Ownership of resulting technology, e.g., patents and know-how
7. Fees and royalties if applicable
8. Rights to sublicense or subcontract
9. Accounting and auditing for expenses
10. Tax treatment
11. Confidentiality
12. Warranties and allocation of liability
13. Breach, termination and residual obligations
14. Dispute settlement, applicable law and forum

A product development agreement might be independent from any type of follow-on production and supply agreement. For example, a product development agreement between a university or teaching hospital and a vaccine producer would probably not obligate the university or teaching hospital to go beyond basic research and potentially the formulation of a vaccine candidate. Such agreements might well involve the licensing of patents that already had been secured by the university or teaching hospital but not yet been translated into vaccine products. It may remain for the better-funded, integrated vaccine producer\supplier would then take the product through clinical trials, registration, production and distribution.

One policy issue that confronts research institutions worldwide, and their home governments, is that the integrated enterprises with the resources to translate basic research into marketable vaccine products are predominantly based in high income countries, and these integrated enterprises deploy their resources to seek out the most promising research wherever it might be developed. In this regard, an African research institution might well develop a promising vaccine technology and find that the "highest bidder" for licensing that technology is located in Europe or North America. It is important to recognize that there are many promising technologies that ultimately do not successfully transition into marketable products. An integrated major pharmaceutical or vaccine manufacturer might well afford to license 20 technologies in expectation that one will prove to be commercially valuable. Vaccine manufacturers in LMICs are much less likely to be able to afford a trial-and-error approach. What is the consequence of this differentiation? The higher end of the value chain where profits are made is in the manufacture and sale of vaccines. This means that ultimately the integrated major vaccine manufacturer will capture the higher end of the value chain. That said, as evidenced by the commercial relationship between Pfizer and BioNTech, technology developers (in this case BioNTech) may be successful in sharing profits at the higher end of the value chain.

There are policy measures that an African government could adopt to prevent or ameliorate the movement of domestically developed technology offshore. For example, governments could include in their legislation

[31] Frederick M. Abbott, Intellectual Property and Technology Transfer for COVID-19 Vaccines: Assessment of the Record, 2023 (WIPO), https://www.wipo.int/publications/en/details.jsp?id=4684

that recipients of research funding may not license their technology to enterprises abroad. This could be combined with conditions. For example, if adequate efforts to pursue local licensing have been undertaken and there are no reasonable local licensing alternatives, then licensing to offshore enterprises could be undertaken. But even in such cases, the legislation could include a requirement that the offshore licensee provide a license to a local vaccine manufacturer if and when a product is introduced.

B. Product Manufacturing Arrangements

A product development agreement may be part of a broader arrangement for the production and supply of vaccines. This does not necessarily mean that the developer of the vaccine would be producing it in its own production facilities. Manufacturing is frequently contracted to third parties within the home country of the developer and to other countries. The terms and conditions of a manufacturing and supply agreement are different than the terms of a development agreement. The manufacturer will be receiving the "product" technology from the developer. The manufacturer may (or may not) be responsible for developing necessary production process technology, or this may already be part of its internal know-how and IP. The manufacturer may be relying on process technology coming from the product developer or from a third party. Either the developer or the manufacturer may have information regarding potential suppliers of input materials, and any equipment that would not already be part of the manufacturer's organization. Information regarding these elements would be part of the arrangement. Quality control is fundamental to manufacturing of vaccines, and an agreement will address good manufacturing practice, including the relevant standards. In addition, the manufacturer will be under an obligation to test its products for quality, with the relevant tests dependent on the type of vaccine that is being manufactured.

Agreements for the development and manufacture of vaccines are in large part similar to agreements entered into by enterprises and other actors in different fields of endeavor. Legal agreements serve to set out the expectations of the parties regarding contributions and behaviors, and how the results of the endeavor will be allocated. This means that the parties must be properly identified, their expected contributions specified, who is paying whom (with what and when), how the project output will be distributed among them, how the project will be governed, who bears liability for problems, how disputes will be settled, and so forth. These elements are common among business ventures, and while vaccines serve a crucial public interest the suppliers of vaccines are nonetheless involved in a business with commercial considerations, even if the suppliers are in some cases operated by governments.

Development of vaccine manufacturing processes, the construction of facilities, the securing of sources of inputs, hiring and training of personnel, and so forth, are costly. As a consequence, agreements for collaboration among different parties along the value chain often include financial components beyond the payment of fees for services. These can include arrangements for contributions of capital, purchase of equity interests, loan guarantees and other matters. There are cases in which the parties seeking to initiate production will outright purchase the owner of the technology effectively moving the entire technology supply chain "in house".

Technology licensing is generally subject to competition law that seeks to prevent abuses of dominant position and anticompetitive agreements between undertakings.[32]

A number of African countries have well-developed systems of competition law, including competition regulators and judicial frameworks. The parties negotiating technology transfer agreements in whatever form must be mindful of terms and conditions that may unduly restrain the market or cause harm to consumers. There are substantial resources and materials addressing competition law aspects of licensing and joint venture arrangements, including with respect to the pharmaceutical sector.[33]

The principal topic headings of a manufacturing agreement would include:

1. Identification of the parties and contact information
2. Intention of the parties in entering into the agreement
3. Contribution of party seeking manufacturing assistance
    a. Product information and relevant underlying technology (including materials, e.g., biologics, where relevant)
    b. Regulatory approvals where applicable
    c. Potential identification of input supply sources
    d. Technology transfer services (e.g., know-how support)
4. Contribution of contract manufacturer
    a. Potential development of process technologies specific to product
    b. Manufacturing facilities (including location) including personnel and processes
        i. Responsibilities for provision of equipment and materials, including allocation of materials costs
    c. Compliance with relevant regulatory standards, e.g., cGMP, testing
        i. Regulatory approvals and inspections
5. Quantities to be manufactured, location and schedule
6. Price and delivery
7. Rights of parties to manage or monitor elements of production (e.g., joint production council)
8. Rights with respect to technological improvements (product and/or process), including patents and know-how
9. Potential for sublicensing or subcontracting
10. Procedures for changing terms (e.g., quantities, product characteristics, schedule of deliveries)
11. Tax responsibilities
12. Record-keeping and audit
13. Confidentiality obligations
14. Warranties, liability and indemnification
15. Breach, termination and residual obligations
16. Dispute settlement, applicable law and forum

C. IP in Technology Transfer

The technology that is subject to the technology transfer license is typically protected by some form of intellectual property right (IPR). The types of IPR and their relevance to technology transfer licensing is described below:

Patents: A patent is a set of legal rights granted to the inventor of a new product or process that allows the patent owner to preclude others from making or using the invention. As a practical matter, most of the information needed about patents in a

[32] See discussion in Section I.B, supra.

[33] See, e.g., UNDP, Using Competition Law to Promote Access to Health Technologies: A Supplement to the Guidebook for Low- and Middle-Income Countries, UNDP (2022), available at SSRN: https://ssrn.com/abstract=4076955, and; UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries, United Nations Development Program (ed. F. M. Abbott) (2014), Available at SSRN: https://ssrn.com/abstract=2439416.

technology transfer license involves identifying the jurisdiction where the patent was granted, and confirming the registration number of the patent, and the dates on which the patent was granted and is expected to expire. Patents are granted for each country or region where the patent owner wishes to assert rights. A single invention may be the subject of more than 100 patents in different jurisdictions, each with its own local identifying number (with some qualification) and expiration dates that may differ among the jurisdictions. Added to the fact that there may be 100 patents on the pharmaceutical product in different jurisdictions, many such products are the product of multiple "inventions" that involve different patent subject matter.

In terms of preparing a technology transfer license, it is generally the responsibility of the licensor to properly identify the patents that are needed by the licensee to make and sell the product, and in the license agreement the technology transferor/licensor will warrant its ownership of the relevant patents as well as confirm the patents needed to produce and use the product are included in the license.[34]

"Process": A technology transfer license frequently addresses the "process" by which the "product" is made. Processes may be protected by "process patents". Process patents are largely the same as product patents except that they protect not only against a third-party using the process, but also the sale of a resulting product made without authority using that patented process. In many cases processes are maintained in secrecy by the technology owner, i.e., as "trade secrets". The owner of the trade secret may license and transfer its technology to a third-party provided that the licensee agrees to maintain the secrecy, using it only for its own purposes. This will typically require the licensee to assure that it maintains nondisclosure agreements with its own employees, and otherwise takes reasonable measures to protect against disclosure of the trade secret.

Whether a process is the central focus of a license or needed to produce the main product subject matter, it is nevertheless important to identify the process being transferred, including whether it is a patent-protected process or a process that is part of the know-how (including trade secrets) of the licensor. If the process is protected by patent, the relevant patent or patents should be identified in the patent annex to the license agreement. Otherwise, the process may be included within the definition of the technical know-how being transferred under the license.

"Regulatory data": Pharmaceutical products intended for human use ordinarily require approval from a drug regulatory authority (DRA) before they may be marketed and sold. In order to secure that approval, the product developer/owner must submit data to the regulatory authority. The characteristics of that data depend upon the type of product, and whether the approval sought is for a "new" pharmaceutical product or one that has been previously approved. Typically pharmaceutical components or compounds that are not yet ready for marketing and sale do not need regulatory approval. In this regard, the treatment of regulatory data under a transfer of technology license will depend upon the type of product and the stage of development.

A technology transfer licensee that Intends to manufacture and sell a pharmaceutical product will benefit from having access to the "regulatory dossier" of the licensor/owner. Because the information in such a dossier is often confidential and may not be used without the permission of the developer/licensor, the licensee will want the license to identify the relevant information and provide access to it in

[34] The licensor of a pharmaceutical product technology may hold interests in patents not yet granted. The licensee wants to make sure that it not only has the rights to use the patents in force when the license is executed, but also patents that may be granted to the licensor during the term of the license.

cases where it intends to market the product. It should specifically include an obligation on the part of the licensor to provide permission for use of the regulatory data by the licensee with the relevant DRAs.

"Trade Secrets": "Trade secrets" are a specifically defined concept in IP law. A trade secret is commercially valuable information not generally known in the form held by the trade secret owner and that such trade secret owner has taken reasonable steps to protect. A trade secret can involve virtually any type of information, including production processes, testing protocols, recipes, customer and supplier lists, component lists, and other information of use in the business. Of importance from the standpoint of technology transfer licensing, while ordinarily a trade secret may not be disclosed to a third-party without giving up trade secret protection, a trade secret may be the subject of a license to a third-party provided that the recipient is under an obligation to keep the information secret. When information is a trade secret, the misappropriation of that information violates the legal rights of the trade secret owner, and the party wrongfully taking the trade secret is subject to civil liability, injunction, and potentially criminal liability.

Material that is not "trade secret" in the sense of satisfying the legal definition may nevertheless be considered "confidential" by the parties to a technology transfer license. "Confidential" simply means that the parties have agreed between themselves that they will not disclose certain information, which may include the fact of a license agreement itself. In other words, the parties may agree that their business arrangement is a secret. There are limits to keeping agreements confidential, particularly those that may have a "material" impact on publicly traded companies. Such companies may be under disclosure obligations to securities regulatory authorities. Much of the information in the public domain regarding the terms and conditions of important technology transfer licenses is available precisely because of securities-related disclosure obligations.

The developer of valuable know-how may wish to keep it secret because it is valuable know-how which gives the developer a commercial advantage over potential rivals. Advocates for providing greater access to technology among a wide group of stakeholders advocate for relaxations of trade secret protection, particularly when access to trade secret information may assist in rapidly introducing urgently needed products onto a market.[35]

"Know-how": Know-how refers to the knowledge a business accumulates regarding the way in which its products are produced and function, including the expertise developed by its scientific staff and other employees in the course of operating the business. Although a patent document, for example, may allow scientists and engineers to understand the chemical composition or biological structure of a particular product, the patent document is not in the nature of an "instruction manual" that serves as a guide regarding how to produce the product. As a process is implemented in a manufacturing facility, those who are working with the product may need to deal with a very substantial number of issues such as the optimal mix of chemical components to induce particular reactions, adjustments in the temperature range at which reactions take place, how best to test the product dose as it moves through its various production stages, and so forth. Because different facilities use different equipment and operate in different environments, at least a part of a production process may involve

[35] Recent debates concerning access to trade secret information in the context of the COVID-19 pandemic are similar to those involving patents at the outset of the HIV epidemic. Justifications for broader confidentiality may be less compelling. They go to the rights of the public to know of developments. Nonetheless, pharmaceutical companies argue that information about matters such as the price of their products may give competitors a commercial advantage, for example, because competitors would learn how to undercut their pricing.

"trial and error" to reach the best result. The knowledge that is gathered becomes part of the knowhow of the manufacturer. While often the same result may be achieved by different scientists and engineers working in different facilities, the process of developing knowledge takes time and may not be successful. There is a benefit to learning from the experience of others.

A technology transfer license in the pharmaceutical sector typically makes provision for the transfer of know-how from the licensor to the licensee, and often the license clause defining the relevant know-how is quite detailed. The scientists and engineers working for the licensee are likely to run into issues that they have difficulty resolving, and will want to consult with the scientist and engineers at the licensor to address particular problems. A process that was working at the licensor facility may not be working at the licensee facility, and the licensee may want to engage the on-site presence of scientists and engineers from the licensor for a "hands-on" look and assistance with setting things right. This type of on-site work can be built-in to the initial technology transfer license in terms of a number of days or a milestone for technical support, but a technology transfer license may also define a fee structure and expenses (e.g., travel) that will be paid as a separate fee. A wide range of Issues may be resolved through remote visits, using video\conferencing equipment, but not all.

Trademarks: Trademarks are identifiers used by commercial enterprises to identify their goods and services in commerce. When the pharmaceutical originator company introduces a new pharmaceutical product onto the market, it typically will identify that product with a "brand name" or trademark that distinguishes the originator product from the generic or INN classification given to the product. There are detailed rules regarding the types of trademarks that may be used on pharmaceutical products. A technology transfer license may include a right granted by the licensor to the licensee to use its brand-name on the product manufactured by the licensee. This is largely a commercial question and does not affect the characteristics of the underlying product. A licensee may wish to establish its own brand-name identity in connection with a product, and it may not be interested in using the licensor's trademark. Conversely, the licensee may view use of the licensor's trademark as an important commercial advantage if users identify the particular pharmaceutical with that brand name. Because the licensor will be concerned about its reputation as a supplier of pharmaceutical products, if it allows the licensee to use its trademark it will naturally want to assure that the licensee maintains strict controls on production and distribution. Trademarks are in large measure a reputational device – they embody the goodwill of the trademark owner.[36]

"Design rights": Designs can be protected by various forms of intellectual property, including design patents, registered design rights, copyright and trade dress (a form of trademark). In order to enjoy intellectual property rights protection, designs must be at least predominantly non-functional. Designs are embodied in the shape, color and texture

[36] Trademarks may be "registered" or "unregistered". A pharmaceutical brand owner will typically register its trademark. As with patents, trademark registrations are granted on a country by country (or regional) basis. There is an international registration system operated by the World Intellectual Property Organization (WIPO), the Madrid System, but this still entails individual national (or regional) registrations as part of the process. Technology transfer licenses that include a trademark license may include a listing of the relevant trademark registrations in an annex, but such a listing is substantially less important from the standpoint of the licensee than patent listings, and it may be adequate that the licensor grants the right to use its trademark in the relevant territory. Recent improvements in databases internationally and nationally have made it comparatively easy to identify trademark registrations. It is significantly more difficult to identify relevant patent registrations since patent documents very often do not include the common name of the pharmaceutical product, and there may be many patents with similar chemical or biological compositions, making it difficult to ascertain which patent covers what product.

of products. Design rights will not ordinarily be a significant element in a technology transfer license but, as with copyright, designs and corresponding design rights may be relevant to some aspects.[37]

"Copyrights" are typically of limited relevance in technology transfer licenses in the pharmaceutical sector. The main forms of IP interest and protection will be patent and trade secret. But there are likely to be some copyrighted materials or products that are of concern to the parties, including copyrights in computer software, as well as copyrights in materials that accompany the promotion and sale of products, such as advertising brochures and product information leaflets. For this reason, it is important that the parties acknowledge the right of the licensee to use copyrighted material for purposes of carrying out functions foreseen by the license.[38]

"Confidential information" is a matter for self-designation by the parties. It is information and materials that the parties have agreed to keep between themselves and not to share publicly, or with third parties, unless the parties have consented. Confidential information differs from intellectual property referred to as "trade secret". A trade secret is protected by intellectual property law on grounds that the owner has committed resources to putting together information in a way that is not generally known in the industry and is commercially valuable. Confidential information is information that the parties do not wish to be disclosed, whether or not it is commercially valuable or required some effort to compile. The fact that parties have entered into a license agreement may be something they wish to keep in confidence. By establishing an obligation between the parties to keep the terms and conditions of a license confidential they may avoid disagreement among themselves about whether certain information is a trade secret based on its legal character. They have agreed on a broader obligation not to disclose information.

Access-oriented NGOs have voiced concern about provisions in technology transfer license agreements that impose an obligation of confidentiality because this means that the relationship between the licensor and licensee is not "transparent" or open to public view. It is difficult to assess in advance which provisions of a technology transfer license may be of interest from a public knowledge standpoint. Typically, the type and amounts of payment would be of public interest because this data is relevant to ultimately establishing prices. Other terms such as the scope of the licensed territory and the grantback provisions may also be of interest.

Certain license agreements must be available to the public. For publicly traded companies there may be a requirement to disclose "material" agreements. Even with that type of disclosure obligation, there is room for the parties to redact terms such as royalty rates that the licensor or licensee consider to be confidential business information in the sense that their competitors may gain an advantage by having knowledge of those terms.

[37] For example, the shape of a glass beaker may be unique and visually pleasing, even if that shape does not serve any purpose beyond those of a common beaker. Or packaging may have a unique design that does not serve a function beyond that of ordinary packaging. It may be difficult to foresee what elements of a technology transfer may be covered by design rights protection, so a generally framed grant of rights to use the design rights owned by the licensor that are relevant to the license might be used. Technology transfer licenses are typically most concerned with "utility patents" that cover useful inventions, and these patents will be listed in the license. There may be cases where there is a "design patent" involved. If there is a design patent that is known to the parties, it should also be incorporated by reference in an annex.

[38] For subject matter such as computer software, the licensor may not be the copyright owner and may not have the right to sublicense the computer software to the licensee, in which case the licensee would need to separately negotiate with the software provider for its own license.

3. Acquiring Technology for Vaccine Manufacturing

An enterprise built around supplying vaccines has several potential avenues for acquiring the technology needed to do that.

1. **Internal development:** The enterprise may elect to develop the technology itself. There are significant costs and risk associated with internal development. The enterprise (small or large) may rely on government support for R&D, which is typical in the vaccine field.[39] This is dependent on the government having the resources to invest in this type of activity. Availability of funding may be less common in LMICs than in high-income countries.

2. **Developmental technology in-licensing:** The enterprise may choose to in-license technology that has been developed by university researchers, foundations, teaching hospitals, and smaller R&D centric firms. This is a traditional path to development of vaccines, though substantial investments remain to be made, and risks absorbed. Universities, for example, maybe adept at creating "vaccine candidates", but they are not usually responsible for taking those products through clinical trials and submitting for regulatory approval. In addition, universities and smaller actors typically do not get involved in the development of the production process technology necessary to commercialize a vaccine product.

3. **Product in-licensing:** An enterprise may seek to acquire the rights to produce a developed vaccine through acquiring a patent and know-how license. Obtaining rights to use a patented technology solves only one part of the technology equation. There is inevitably technical know-how used by vaccine manufacturers that is not readily available in the public domain such that a substantial learning curve may be required if licensing is limited to the right to use a patent.

   - For "older" types of vaccines, e.g., inactivated vaccines,[40] the enterprise may well have the technical know-how in house. Established vaccines may not be subject to patent protection, so no license is needed to overcome a potential blocking obstacle.

4. **Joint venturing:** An enterprise may seek to enter the vaccine manufacturing and distribution market through some type of collaboration arrangement or joint venture with another enterprise that is developing or has already developed the vaccine product, potentially including through clinical trials and securing regulatory approval in at least one jurisdiction. There are many types of collaboration possible.

   - An enterprise may seek to license a complete "technology package". For a vaccine this would include patents, technical know-how (including production processes and testing), complete lists of materials and suppliers, access to the

[39] Even for large integrated suppliers, vaccine technology is commonly acquired from developmentally-oriented external actors.

[40] US CDC, How Influenza (Flu) Vaccines Are Made, https://www.cdc.gov/flu/prevent/how-fluvaccine-made.htm; US NIH, Influenza Vaccine Production and Design, https://www.niaid.nih.gov/diseases-conditions/influenza-vaccine-production-and-design.

regulatory dossier, and so forth. A license agreement would typically require lump sum payments and royalties.

- A less comprehensive arrangement may involve in-licensing the right to undertake downstream elements of production, such as fill and finish, packaging and distribution, with whatever geographic distribution rights and limitations are agreed upon. This may include obligations for product registration at the national level. Although downstream agreements are more limited than full collaborations on development and manufacturing, they nevertheless entail detailed contracting of rights and obligations.

- Joint venture collaborations can be established along a wide range of parameters. This can be a partnership in which the parties are making different types of contributions, whether of capital, technology, facilities, personnel, marketing expertise or other aspects. The parties will share the risks and rewards. This will depend on the economic and social objectives of the participants. If the goal of the African enterprise, for example, is to become an autonomous self-standing vaccine manufacturer, then a partnership or joint venture is one step on that path.

- The question that must be addressed is "what is the local enterprise offering" that is sufficient to persuade the owner of vaccine technology which may have the potential to invest in its own local manufacturing facility to enter into a partnership/joint venture arrangement? One element may be better knowledge and connections within the local health system that can facilitate the sale of products. This may be an area where government policies should be adapted to encourage joint-venturing, such as by providing tax incentives that would not be available to foreign-based enterprises on a standalone basis.

5. **Internationally supported technology transfer:** An enterprise may seek to make use of internationally supported vaccine technology transfer initiatives, such as the Medicines Patent Pool (MPP),[41] the WHO mRNA Vaccine Technology Hub,[42] and/or through non-profit organizations such as they Coalition for Epidemic Preparedness Innovations (CEPI). Vaccine manufacturing enterprises have traditionally relied on government support of one type or another because most vaccines represent a difficult "business case" from the standpoint of generating sustainable revenue and profits. Pandemics in particular present a difficult business case because of their unpredictability. There is considerable uncertainty regarding whether and when pandemic outbreaks will occur, and what the characteristics of the pathogen will be.

6. There are some issues associated with licenses from the MPP or other non-profit organizations. First, these licenses typically limit the geographic markets in which products may be sold or distributed. Therefore, if the business case depends on selling some vaccine products in higher income markets while others are sold in lower income markets, a license from the MPP may not allow that. Second, up until now MPP licensing has only involved access to patents, and not to broader technology transfer packages. MPP licensing has primarily been useful for established manufacturers in countries such as India that may not need the associated know-how. With these caveats, MPP licensing typically involves a low royalty rate Intended to allow the supply of product at access-oriented prices.

[41] https://medicinespatentpool.org/

[42] https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub#:~:text=Announced%20on%2021%20June%202021,the%20mRNA%20vaccine%20technology%20hub).

[43] https://cepi.net/

7. In principle, the WHO mRNA Vaccine Technology Hub is at the cutting edge of vaccine technology, and the technology provided by the hub should not be restricted in terms of downstream (e.g., downstream geographic market) use, allowing the manufacturer to make its own decisions about where and at what price it will offer products. (See further discussion below)

8. In the general case of pharmaceuticals, it can be argued that a business should avoid overreliance on government support in its economic model because of the uncertainties typically associated with government budgeting and decision-making. In the case of vaccines, reliance on government budgets and decision-making is all but inevitable because vaccines are very often made available through government programs. Whether or not vaccines will be purchased is dependent on what types of protection against disease governments deem necessary or appropriate. This gets to the question of "sustainability" in terms of financial support, and how a vaccine manufacturer can be financially structured for longer term viability.

4. Strategy for Enhancing Bargaining

A. Bargaining position

African firms up until now have not negotiated "deep" licensing and technology transfer commitments from the major vaccine manufacturers based in HICs. African firms may lack sufficient bargaining power, or a strategy for successfully deploying that bargaining power, such as to leverage the African market and/or the African Union market. By way of counterexample, although the Chinese government decided to pursue a policy that did not include manufacturing and provision of mRNA vaccines developed in Germany and the United States, a Chinese company (Fosun) successfully concluded an agreement with BioNTech that would have involved substantial technology transfer and local manufacturing in China.

B. Training

Establishing a strong bargaining position generally entails offering an opportunity to the party from whom concessions are sought (such as an integrated major vaccine developer and supplier). Usually this involves facilitating access to a potentially profitable market, whether that be private or public. Establishing this type of opportunity may be a matter of persuading the national government to pursue purchasing programs requiring participation of local suppliers, including with advance purchase commitments. It may be a matter of persuading providers of international financial support for vaccine distribution to require local participation in development and supply.

If there is an opportunity to negotiate preferable licensing terms and conditions, such as in the context of a joint venture investment, it is also important that there is expertise within the local system to negotiate successfully. In this regard, it might be useful to envision some type of technology licensing institute in Africa that would work to provide practical training to lawyers working within the pharmaceutical and/or vaccine sector. Such practical training could be undertaken during university education but may be better suited to post-graduate programs addressing attorneys and business managers already working in the industry. Such a program might include courses addressing intellectual property as such (including patents, regulatory exclusivity, trademarks, etc.), contract law as it applies to technology licenses, competition law that may affect the terms and conditions of licenses, business considerations such as royalties, fees and tax considerations, distribution-related issues, insurance and liability, governance, dispute settlement and so forth. Such a program could be tailored to address specific requirements of African law, as well as elements that may be needed to address international issues.

5. Existing Vaccine Licensing Arrangements for Africa

A. During the COVID-19 PHEIC

Technology transfer licensing played a minor role in Africa toward addressing the COVID-19 pandemic. China's 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.[44] Johnson & Johnson entered into a fill and finish COVID-19 vaccine agreement with Aspen Pharmacare, based on the South Africa, but while Aspen was able to initiate production, vaccine demand was insufficient to maintain it largely because of questions that arose regarding the safety of the Johnson & Johnson vaccine.[45] Pfizer and BioNTech announced a fill and finish agreement with Biovac for the production of their mRNA vaccine in Cape Town, although it is not clear what the result of this agreement was in terms of production quantities.[46] Moderna initially announced plans to build an mRNA vaccine manufacturing facility in Kenya. However, in April 2024, Moderna suspended those plans.[47]

B. BioNTech-CEPI in Rwanda

Recently BioNTech, in collaboration with CEPI, announced substantially increased investment to establish a manufacturing facility for mRNA vaccines in Kigali, Rwanda. This project was first announced by BioNTech in 2021 (with support from the European Union),[48] and appears to have been given a major boost by

[44] Egypt receives raw materials to produce Sinovac COVID-19 vaccine, ChinaDaily.com.cn, May 24, 2021.

[45] See, e.g., Lynsey Chutel, Africa's First Covid-19 Vaccine Factory Hasn't Received a Single Order, NY Times, May 12, 2022. https://www.nytimes.com/2022/05/12/world/africa/south-africa-covid-vaccine-factory.html#:~:text=Johnson%20&%20Johnson%20said%20the%20licensing%20agreement%20between%20it%20and; Aspen Pharmacare, pursuing J&J vaccine license, aims to shore up local capacity and quash shot inequality in Africa, https://www.fiercepharma.com/manufacturing/j-j-covid-19-partner-aspen-pharmacare-eyes-looks-to-shore-up-local-capacity-and-quash; https://www.fiercepharma.com/manufacturing/aspen-closes-talks-to-license-j-j-s-covid-19-vaccine-africa; Kevin Dunleavy, "A $200M injection from the U.S. will allow Aspen to produce more Johnson & Johnson COVID-19 vaccines for Africa," Fierce Pharma, Jul 22, 2021, 2021, https://www.fiercepharma.com/pharma/a-200m-injection-from-u-s-will-allow-aspen-to-produce-more-johnson-johnson-covid-19-vaccines.

[46] Kevin Dunleavy, "With Biovac agreement, Pfizer and BioNTech extend their COVID-19 vaccine manufacturing network to Africa," Fierce Pharma, July 21, 2021, 2021, https://www.fiercepharma.com/pharma/agreement-biovac-pfizer-biontech-extend-their-covid-19-vaccine-manufacturing-network-to.

[47] Moderna Press Office, Statement on Kenya Manufacturing Facility, April 11, 2024. Moderna cited a decrease in demand for COVID-19 vaccines in Africa and the lack of any vaccine orders from the continent since 2022. This decision drew criticism from the Africa CDC, which argued that it highlighted the challenges in establishing a robust vaccine production sector in Africa.

[48] Directorate-General for International Partnerships, Global Gateway: EU increases support to vaccine production in Rwanda as first mRNA facility opens, Press Release, December 18, 2023, https://international-partnerships.ec.europa.eu/news-and-events/news/global-gateway-eu-increases-support-vaccine-production-rwanda-first-mrna-facility-opens-2023-12-18_en#:~:text=Marking%20the%20inauguration%20today%20of%20the%20first%20BioNTech%20Africa%20manufacturing

the decision of CEPI to support the "modular" facility.[49] The text of the agreement between BioNTech and CEPI is not yet publicly available. CEPI's press releases indicates that there are provisions in the arrangement supporting a priority for developing and supplying vaccines at affordable prices within Africa:

- BioNTech and CEPI are committed to enabling equitable access. Under the terms of the agreement BioNTech intends to provide affordable access to BioNTech's prophylactic vaccines manufactured at the Kigali facility, such as vaccines against malaria, mpox and tuberculosis, to low and middle-income countries, with priority supply to African countries, if successfully developed and authorized. BioNTech and CEPI intend to work jointly to rapidly respond to outbreaks on the African continent caused by known viral threats, or an as-yet-unknown pathogen with epidemic or pandemic potential.

The publicly announced terms of the BioNTech-CEPI collaboration do not detail terms and conditions regarding ownership or licensing of technology used at the Kigali facilities. As BioNTech is one of the principal developers of mRNA technology, such as used in the Pfizer/BioNTech COVID-19 vaccine, it is a reasonable presumption that BioNTech owns and will supply patented and other technology to the venture. CEPI through its various research partners also has access to mRNA technology and presumably will contribute that as needed by the venture. The question of how technology developed during the implementation of the project in Rwanda will be divided or allocated among the partners requires access to the underlining documentation.

C. The WHO-MPP Technology Hub

The vaccine technology transfer activity in Africa that has received the most public attention involves the WHO-MPP mRNA Hub. The concept of the mRNA hub originated during the early part of the COVID-19 pandemic as low- and middle-income countries (LMICs) found difficulty in securing mRNA vaccines from Moderna and Pfizer/BioNTech.[50] Afrigen, Biovac and the South African Medical Research Council (SAMRC) are principal collaborators. Additional collaborators within Africa are Biogeneric Pharma (Egypt), Biovax Kenya Institute (Kenya) and L'Institut Pasteur de Tunis (Tunisia).

Afrigen Biologics, established with support from the South African government, is responsible for R&D and product development for the Hub. Afrigen will also train personnel from partners. Biovac, a vaccine manufacturing

[49] CEPI Press Office, BioNTech and CEPI expand partnership to strengthen Africa's mRNA vaccine ecosystem, May 28, 2024:

- BioNTech and CEPI aim to enhance local R&D, clinical and commercial-scale manufacturing capacities to develop potential mRNA vaccines in Africa, for Africa
- CEPI to fund up to $145 million to support BioNTech in broadening the scope of the manufacturing facility in Kigali, Rwanda, aimed at addressing needs of African countries and in compliance with global standards
- Partnership intends to contribute to building a sustainable and resilient end-to-end African vaccine ecosystem
- BioNTech and CEPI commit to contributing to enabling equitable access, including affordable pricing to select vaccines made at the facility for LMICs, with priority access to African countries, and committed capacity to manufacture emergency response vaccines

https://cepi.net/biontech-and-cepi-expand-partnership-strengthen-africas-mrna-vaccine-ecosystem#:~:text=CEPI%20is%20committing%20up%20to,scale%20manufacturing%20capabilities%20at%20the

[50] WHO's participation is based on the concept of a technology hub that was developed to transfer publicly available technology for influenza vaccines.

entity based in Cape Town, will serve as the mRNA vaccine manufacturing facility in South Africa.[51] Several universities and the Africa Centres for Disease Control and Prevention (Africa CDC) are supporting the project.[52]

Another participant in this arrangement is the Medicine Patent Pool (MPP) based in Geneva, which is acting as the conduit for licenses between the entities in South Africa and other partner organizations.[53] MPP has taken on an increasingly substantial role, including hiring a team of technologists to assist in the technology transfer process. There is resistance to the role of MPP among countries such as Brazil.[54]

Collaboration agreements between the WHO and MPP, and technology transfer program arrangements between MPP on one side, and Afrigen and Biovac on the other, are posted on MPP's website.[55] These agreements give substantial control over the mRNA hub operations to MPP which has secured the rights to sublicense technology developed by Afrigen and Biovac to LMICs (as defined by the World Bank). The African participants in the development of RNA technology in the framework of the WHO-MPP mRNA Technology Hub have turned control over their technology to MPP (see quoted terms following). It appears Afrigen and Biovac, as well as their university and government partners in South Africa, retain the right to sell products and to license their technology to the high-income countries. The cession of control over technology developed and used by Afrigen and Biovac has been the object of at least one critical analysis.[56]

Grant Agreement between Medicines Patent Pool and Afrigen Biologics (Pty) Ltd., Jan. 1, 2022

8.3 Grant to MPP. Afrigen hereby grants to MPP a non-exclusive, transferable, sublicensable, irrevocable, fully paid-up, royalty-free, worldwide, license to practice and have practiced the data and the Inventions for the purposes of fulfilling its mission to facilitate the development and equitable access of health technologies in low- and middle-income countries (as defined by the World Bank). In the event that MPP wishes to make such Inventions available for other purposes, MPP and Afrigen will enter into good-faith negotiations. Afrigen agrees to provide to MPP a licence in relation to its background rights, as referred to in Section 8.1. only to the extent necessary to enable the use and exercise of the Inventions made by Afrigen hereunder. MPP shall have the right to share the data generated under the Program with WHO for further sharing with any third parties for the purposes of fulfilling its mission to facilitate the development and equitable access of mRNA technologies in low- and middle-income countries.

[52] Although the mRNA hub appears to have gone through several iterations of structure, the current iteration appears to be that Afrigen will act as the technology hub that will transfer technology to R&D centers and manufacturers in various other LMICs, serving as the "hub" with the other technology recipients referred to as partners or spokes.

[53] https://medicinespatentpool.org/what-we-do/mrna-technology-transfer-programme#:~:text=The%20mRNA%20technology%20transfer%20programme%20is%20a%20global%20initiative%20that

[54] Herder M, Benavides X (2024) 'Ourproject, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. PLOS Glob Public Health 4(9): e0003173.https://doi.org/10.1371/journal.pgph.0003173. Brazil's Bio-Manguinhos was situated to be a partner of the mRNA hub, but it has not yet joined the effort apparently, out of concern regarding the extent to which the initial proposal to create several hubs, capable of supporting and to end manufacturing was replaced with a central focus on Afrigen.

[55] https://medicinespatentpool.org/what-we-do/mrna-technology-transfer-programme/agreements

[56] Herder, supra note 56.

Amendment and Restatement Agreement to the mRNA Vaccine Technology Transfer Agreement Between the Medicine's Patent Pool and the Biological and Vaccines Institute of Southern Africa

- 7 Grant of Licence and Intellectual Property

- 7.1 Subject to the terms and conditions of this Agreement MPP hereby grants to Biovac:

  a. a non-exclusive, royalty-free, non-sublicensable, non-transferable, irrevocable, fully paid-up, royalty-free licence under the Technology and the Afrigen Rights to make, or have made, use, offer for sale, sell, have sold, export or import Product(s) in the Territory [i.e., LMICs].

  b. as necessary, a non-exclusive, royalty-free, non-sublicensable, non-transferable, irrevocable, fully paid-up, royalty-free licence under any Inventions to which MPP has or will acquire sublicensable rights from other Programme Agreements to make, or have made, use, offer for sale, sell, have sold, export or import Product(s) in the Territory.

- 7.2 Biovac grants to MPP a non-exclusive, non-transferable but sublicensable, irrevocable, fully paid-up, royalty-free, licence to practice and have practiced the data and the Inventions for the purposes of fulfilling its mission to facilitate the development and equitable access of health technologies in the Territory. In the event that MPP wishes to make such Inventions available for other purposes, MPP and Biovac will enter into good-faith negotiations. Biovac agrees to provide to MPP a licence in relation to any of its background rights only to the extent necessary to enable the use and exercise of the Inventions made by Biovac hereunder.

7.3 In the event that Biovac is provided with access to Third Party IP for the purposes of research, development and/or commercialization of Product(s), Biovac undertakes to use reasonable efforts to negotiate a licence to MPP for such Third Party IP under the same or similar terms as provided for in Section 7.2 herein.

- 7.4 MPP shall have the right to share any data generated under the Project with WHO for further sharing with any Third Parties for the purposes of fulfilling its mission to facilitate the development and equitable access of mRNA technologies in the Territory.

The decision by Afrigen and Biovac to give up control over the licensing of their technology for LMICs was presumably a consequence of the need to secure funding that primarily came from the European Union. It is worth noting that Afrigen and Biovac did not receive proprietary mRNA technology from high-income country companies such as Moderna and Pfizer, having unsuccessfully approached Moderna.

6. Recommendations Regarding African Technology Transfer Policy

The development and deployment of a robust technology transfer policy for Africa that will permit it to develop, produce and distribute vaccines to address public health emergencies and more routine vaccination programs should rely on lessons learned from the past several decades of developmental experience.

1. Vaccine development, manufacture and distribution operates on a significantly different business model than that of therapeutic pharmaceutical products. Vaccines to address emergencies are needed in "spikes" where demand increases at a very rapid pace, but also may diminish at a comparable pace. Business models that depend on continuity of demand are not transposable to the vaccine sector. This means that there must be forms of financial support for vaccine manufacturers when there is little or no real-time "market demand".

Development of vaccines using advanced technologies to address recent outbreaks such as COVID-19 and Mpox has been done mainly with government funding in the United States, Europe and Japan. The US Department of Defense through its various agencies has been a key actor. It engages in long term planning and preparation to protect military forces in combat zones where pathogens may pose a substantial risk to combat readiness. Private sector companies have benefited from these investments in vaccine technologies, but they have not been the primary risk bearers.

2. Vaccines to address non-emergency situations face markets with different characteristics than those of emergency markets. They are not prone to the same intensity of uncertainty and risk as vaccines to address pandemic emergencies. Yet, with some exceptions, such as influenza vaccines, most vaccines are administered once or twice to provide lifelong or long-lasting immunity, while others require periodic boosters, depending on age and other factors.[57] Even though there are some vaccines, such as those for influenza, where there may be relatively stable demand, nonetheless government funding and purchasing, both direct and indirect, remains an important element of these markets. In this regard, participation by African governments in support of vaccine production and distribution is necessary to creating conditions of demand that can sustain local development and manufacturing of vaccines.

One obvious way to promote licensing of vaccine technologies to African vaccine

[57] Some vaccines provide lifelong or long-lasting immunity with just one or two doses. Examples include:
- MMR (measles, mumps, rubella)
- Varicella (chickenpox)
- HPV (human papillomavirus)

Booster shots: Many vaccines require booster shots to maintain immunity over time. These boosters may be needed:
- Every few years: Tdap (tetanus, diphtheria, pertussis) every 10 years
- Every year: Flu vaccine
- Later in life: Shingles vaccine for adults over 50

Childhood vaccines: Children receive a series of vaccinations on a recommended schedule to protect them from various diseases. This often involves multiple doses spaced out over several months or years.

Travel vaccines: Depending on your destination, you may need specific vaccines or boosters before traveling.

producers and developers is to condition procurement on local production. Recognizing that procurement of vaccines for certain purposes, such as childhood vaccination programs, may be undertaken by international organizations (such as Gavi, the Vaccine Alliance) it will be helpful if such internationally funded procurers establish local manufacturing requirements (that presumably will entail some flexible level of cost competitiveness). Gavi apparently does maintain a preference for locally produced vaccines and is encouraging local/regional production in Africa,[58] so the objective here may be to strengthen that commitment, including with increased financial and technological support.

As noted earlier, CEPI is playing a constructive role in financing the transfer of technology and local production in Africa. In Rwanda, this appears to be mainly through a collaboration with a European based vaccine developer and manufacturer, BioNTech, but the venture includes a significant training portion for local personnel that should inevitably bolster African local capacity.

4. Vaccine development and manufacturing programs are probably best undertaken cooperatively. Vaccine development involves substantial scientific risk and concomitantly financial risk. Individual African governments and private sector enterprises may not be in a strong position to absorb the type of risk that is involved in creating and deploying cutting edge vaccine technologies. Non-African sources of capital and technology are likely to be necessary, and different sources will present different advantages and disadvantages. The prospects for South-South cooperation have improved in recent years. China, India and Korea have been advancing substantially in the fields of research toward the development and deployment of vaccines. This does not mean that South-South sources of capital and technology are preferable to European or American sources. Rather, the potential field of sources has expanded.

5. The question was raised in the terms of reference whether there is a type of licensing scheme that may act as an incentive for introduction of new vaccines in Africa. The developers of new vaccine technologies are typically – though not always - motivated by profits just as much as developers of conventional therapeutic drug products. If African countries are committed to introducing new vaccines, and if these vaccines are typically developed outside of Africa, it may be sensible for African countries to pool resources and agree to in-license necessary vaccine technologies from their developers. For the major originator vaccine developers, sales into Africa do not constitute a significant portion of their income stream. The African Union, by way of illustration, could agree to in-license on commercial terms new vaccine technology for manufacturing within Africa, including the requisite technology transfer, and agree that vaccines manufactured under the license(s) would be subject to geographical limitation (e.g., for sale and use within Africa). The licenses would not influence pricing or demand in the markets where the originators earn their principal revenues. Commercially in-licensing vaccine technology might well be combined with creating African "champion" manufacturers that could make and distribute the in-licensed products sufficient for continent-wide supply.

Up until now, the idea of local manufacturing under license in Africa has mainly revolved

[58] See https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy:

The African Vaccine Manufacturing Accelerator (AVMA) is a new instrument to provide financial support to accelerate the expansion of commercially viable vaccine manufacturing in Africa. This strategic initiative is designed to make up to US$ 1.2 billion available over ten years to support sustainable vaccine manufacturing in Africa that contributes to healthy global vaccine markets and improves pandemic and outbreak vaccine supply resilience in Africa.

around proposals for compulsory licensing or very low royalty concessionary arrangements. This has not induced participation or cooperation by the originators. It may be that relative priority on the government budget scale needs to be reconsidered. While there has been substantial resistance among the originators to licensing on concessionary terms, it might be useful to explore whether there is an alternative that does not rely on concession. It might be helpful to undertake a cost benefit analysis comparing the negative economic impact of a major pathogen outbreak and the cost of commercially in-licensing vaccine technology. Or, another possibility might be acquiring outright several well-developed vaccine producers in Europe or elsewhere and using those producers as platforms to transfer technology into Africa. By pooling African resources, solutions to the problem of acquiring leading edge technology might be found on an interim basis as African internal capacity for vaccine development continues to improve.

One of the lessons of the COVID-19 pandemic is that countries and regions should be prepared to manufacture and supply vaccines from internal sources (i.e., local production) in pandemic emergency situations. But this does not mean that each country or region needs to "go it alone". Instead, it may point to the necessity of building robust networks that are in place before the advent of a pandemic and that are capable of rapidly sharing technology that enables quickly scaled-up local manufacturing and distribution.

About the AVPA Initaiative

The AVPA Centers of Excellence Initiative builds on a strong collaborative effort among different institutions throughout Africa that act as nodes of learning and interaction. Various research, training and policy engagement activities bring together the private, public, and academic community trains talent and increase returns on innovation investments in the vaccine sector in Africa.

Credits

AVPA Program Director: Prof Padmashree Gehl Sampath
AVPA Program Manager: Reuben Langevin