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STATE DEPARTMENT FOR FOREIGN AFFAIRS

Ref. No. MFA.AU 16/54 VOL. 24 (110) Date. 21st May, 2025

Clerk of the National Assembly
The National Assembly
NAIROBI.

GUIDELINES ON INTELLECTUAL PROPERTY STRATEGY IN JOINT RESEARCH AND COLLABORATION DURING OUTBREAKS

The Executive Secretariat of the African Union Scientific, Technical and Research Commission (AU-STRC) and the African Scientific Research and Innovation Council (AU – ASRIC) has written vide Note Verbale Ref AU-STRC/ASRIC/11.04.25/ASRIC-CON dated 11th April, 2025 forwarding Guidelines on Intellectual Property Strategy in Joint Research and Collaboration During Outbreaks.

The objective of these guidelines is to support the domestication of these guidelines within national policies, with the ultimate aim of establishing a harmonized, continent-wide standard across Africa.

Submitted for your information and necessary action.

Amb. Katana Angore
FOR: PRINCIPAL SECRETARY

Encls.

AFRICAN UNION

SCIENTIFIC, TECHNICAL AND RESEARCH COMMISSION

UNION AFRICAINE

COMMISSION SCIENTIFIQUE, TECHNIQUE ET DE LA RECHERCHE

Ref: AU-STRC/ASRIC/11.04.25/ASRIC-CON

The Executive Secretariat of the African Union Scientific, Technical and Research Commission (AU-STRC) and the African Scientific Research and Innovation Council (AU-ASRIC) presents its compliments to the African Union Embassies/ High Commissions and has the honor to inform the Embassies/High Commissions to disseminate the following documents:

S/N	Document	Recipient
1	White paper on Eradicating Stunting in Africa	a. Ministry of Health b. National Health Commission
2	Africa Free of Hepatitis Report and Framework	
3	Guidelines on Intellectual Property Strategy in Joint Research Collaboration During Outbreak developed	a. Parliament: Justice Committee b. Ministry of Justice

In this regard, the AU-ASRIC Secretariat kindly requests your esteemed assistance in disseminating the attached documents to the aforementioned recipients. The objective is to support the domestication of these guidelines within your national policies, with the ultimate aim of establishing a harmonized, continent-wide standard across Africa. The documents can also be found in the ASRIC Website: https://asric.africa/

The Executive Secretariat of the AU-STRC and AU-ASRIC avails itself of this opportunity to renew to the African Union Embassies and High Commissions, the assurance of its highest consideration. NK

The High Commission of the Republic of Kenya

AFRICAN UNION COMMISSION
Scientific, Technical & Research Commission
ABUJA

Abuja, 11th April, 2025

African Scientific Research and Innovation Council

GUIDELINE ON INTELLECTUAL PROPERTY STRATEGY IN JOINT RESEARCH AND COLLABORATION DURING OUTBREAKS

2023

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2023

Preface

The emergence of pandemics, from H1N1 and Ebola to the unprecedented COVID-19 crisis, has highlighted both the strengths and vulnerabilities in global health infrastructure and intellectual property (IP) frameworks. While countries with robust IP strategies and access to advanced healthcare technologies rapidly mobilized resources, many developing nations, particularly in Africa, faced significant challenges in accessing essential medical supplies, vaccines, and technologies. This disparity underlines the need for a comprehensive, collaborative approach to intellectual property management during outbreaks, one that balances innovation incentives with equitable access.

The "Guideline on Intellectual Property Strategy in Joint Research and Collaboration During Outbreaks" is an essential framework for fostering cooperation and creating a fair IP landscape across African nations. Developed by the African Scientific Research and Innovation Council (ASRIC), this guideline serves as a crucial tool for AU Member States, research institutions, policymakers, and industry stakeholders, aiming to improve IP literacy, foster effective research collaboration, and address the legal and operational complexities of IP rights in the context of public health emergencies. It provides best practices for managing IP rights through all stages of research collaboration—from initial idea development to commercialization and equitable benefit-sharing—while respecting Indigenous knowledge systems and ensuring that local communities are included in the innovation ecosystem.

This guideline is particularly timely, as it not only addresses current needs but also builds a foundation for resilience against future outbreaks. By outlining a structured approach to IP management that is sensitive to both regional needs and global standards, the document seeks to enhance Africa's capacity for self-sustained innovation, creating a more resilient and self-sufficient public health infrastructure. This collaborative framework encourages a network of African researchers and innovators to develop and share knowledge, ensuring that African countries are better equipped to respond swiftly and effectively to the next public health crisis.

Forward

The COVID-19 pandemic was a stark reminder of the critical role that intellectual property rights play in the development and distribution of life-saving technologies. For Africa, the pandemic underscored the urgent need for an IP framework that supports both local innovation and international collaboration. IP rights, often viewed as legal instruments to incentivize individual creativity, must also be adapted to address collective needs during global health emergencies. In such times, intellectual property management becomes not only a legal necessity but also a moral imperative, requiring a balance between protecting innovators and ensuring public access to essential technologies.

This guideline, "Guideline on Intellectual Property Strategy in Joint Research and Collaboration During Outbreaks," is a pioneering initiative by ASRIC that aims to create a cohesive and adaptable IP strategy for Africa. The document is meticulously structured to guide researchers, policymakers, and industry leaders through each phase of joint research, from resource sharing and knowledge generation to commercialization and equitable benefit-sharing. By clarifying ownership, licensing, and benefit-sharing terms, the guideline provides a transparent framework that protects the rights of all stakeholders involved while promoting an ecosystem of trust and collaboration.

Special attention is given to the unique context of African nations, where access to resources and IP infrastructure varies greatly. The guideline emphasizes the need to protect Indigenous knowledge and offers strategies to incorporate traditional knowledge systems into modern research without compromising the rights of local communities. Furthermore, it addresses the critical role of government interventions, such as compulsory licensing, in ensuring equitable access to technologies during emergencies.

In establishing this guideline, ASRIC has not only filled a critical gap but has also provided a roadmap for a future where Africa can be an equal partner in global health innovation. This document is more than a set of rules; it is a call to action for African nations to join forces, leverage their unique strengths, and contribute meaningfully to the global fight against pandemics. This guideline sets the stage for a resilient, self-reliant Africa that is prepared to meet future health challenges with confidence and unity.

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Abbreviations and Acronyms

ABS	The Nagoya Protocol on Access and Benefit-sharing
ASRIC	African Scientific Research and Innovation Council
ARIPO	Africa Regional Intellectual Property Organization
ARV	antiretroviral
CBD	Convention on Biological Diversity
COVID-19	severe acute respiratory syndrome coronavirus 2
FAO	Food and Agriculture Organization
HIV/AIDS	Human immunodeficiency virus, acquired immunodeficiency syndrome
ITPGRFA	International Treaty on Plant and Genetic Resources for Food and Agriculture
LDCs	Least Developed Countries
MTA	Material Transfer Agreement
MERS	Middle East Respiratory Syndrome
OAPI	Africa Intellectual Property Organization
RSCB PDB	Research Collaboratory for Structural Bioinformatics Protein Data Bank in the United States
SADC	Southern African Development Community
SERS	Severe Acute Respiratory Syndrome
TCE	Traditional Cultural Expression
TK	Traditional Knowledge
UPOV	International Union for the Protection of New Varieties of Plants
UNESCO	United Nations Educational, Scientific and Cultural Organisation
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. INTRODUCTION

The COVID-19 pandemic has brought many intellectual property (IP) access issues to the forefront of international debate. While wealthier countries were able to deliver vaccines to their residents, treat their patients and recover economically, developing countries struggle to access the knowledge and technologies to do the same. Pandemics usually pose global public health problems leading governments, health technology and pharmaceutical companies to increase efforts to develop ventilators, diagnostic tests, pharmaceutical drugs, disinfection technologies, vaccinations, personal protective equipment, and other medical technologies to combat infectious disease outbreaks.[1]

The global race for vaccines and medical equipment during outbreaks is not a novel phenomenon. From H1N1[2] (2009) and Ebola[3] (2014) to the more recent COVID-19 outbreak, infectious disease epidemics have posed an ongoing risk to global health, security, and economic prospects in Africa. Past epidemics have illustrated the importance of immediate collaborative efforts to respond to transnational public health crisis.[4]

The unprecedented pandemic of the coronavirus disease 2019 (COVID-19) triggered the need for a sustainable framework for research and innovation collaborations among research institutions within and outside Africa. A single research institution in Africa may not have sufficient resources or incentives to respond to global outbreaks affecting the whole continent. The lack of robust and coordinated research and development efforts in Africa reduces the ability of African nations to manage both current and future outbreaks.

From diagnostics tools, ventilators, protective equipment, and disinfection technologies to vaccines necessary to help build immunity, intellectual property (IP) rights are at the forefront

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[1] Ana Santos Rutschman, 'The Intellectual Property of COVID-19' (2020) Saint Louis U Legal Studies Research Paper No 2020-28 <https://ssrn.com/abstract=3691239> accessed 26 June 2021.

[2] Centres for Disease Control and Prevention, "2009 H1N1 Pandemic" (last modified 11 June 2019), online: *CDC* <https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html>. The H1N1 flu is a subtype of Influenza A virus, commonly known as swine flu. In the spring of 2009, a novel influenza A (H1N1) virus was detected first in the United States and spread quickly across the world. It contained a unique combination of influenza genes not previously identified in animals or people.

[3] See World Health Organization, "Ebola virus disease" (23 February 2021), online: *WHO* <https://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease>. (Ebola virus disease (EVD), formerly known as Ebola haemorrhagic fever is a rare, severe, and often fatal illness with numerous outbreaks since 1976)

[4] World Health Organization, "An R&D Blueprint for Action to Prevent Epidemics" (May 2016) at 5, online (pdf): *WHO* < https://www.who.int/publications/m/item/an-r-d-blueprint-for-action-to-prevent-epidemics >.

of innovation activities. They play a significant role in the development, dissemination, and exploitation of technology required in Africa to mitigate the negative effects of outbreaks.

Intellectual property rights are legal rights which result from intellectual activity in the industrial, scientific, literary, and artistic fields. They protect the intangibles of creativity and innovation, rather than the physical property in which that creativity and innovation is expressed, embodied, or manifested. Intellectual property rights are exclusive rights established under national law, granted to creators and innovators over the use of their creation for a certain period of time.

Joint research and collaboration during outbreaks require a comprehensive IP strategy to identify the rights of use and ownership of potential intangible assets. An IP strategy to determine the rules of intangible assets management and commercialization, and to establish mechanisms for sharing and distributing the economic benefits that arise from such collaborations.

The current document is an effort by the African Scientific Research and Innovation Council (ASRIC) to develop guidelines to manage IP rights in collaborative research during outbreaks and beyond.

1.1 Objective of the guideline

The objective of this guideline is to improve IP literacy and raise awareness regarding the role of IP rights within the African Union (AU) Member States to ensure effective operational cooperation among African researchers.

The guideline emphasises best practice modalities for the management of IP rights in collaborative research during outbreaks and beyond.

The guideline aims to:

- Improve AU Member States knowledge on the role of intellectual property rights to ensure an effective operational cooperation among African researchers.
- Create a prosperous ecosystem for innovation and creativity among universities, research institutions, and policy makers in Africa by elevating the technical knowledge required to develop an IP strategy.
- Facilitate collaborative research among African countries and industries by sharing best practice rules and regulations.

- Leverage local research capacities by establishing a network of African IP Scholars to support African researchers and research institutes.

1.2 Scope of the guideline

This guideline outlines the significant role that intellectual property rights play in the various stages of a joint research venture. It assesses the IP challenges that may arise at each stage of the collaboration and offers strategies for addressing issues during the negotiation and planning stages of the collaboration.

The first part of the guideline examines the interrelationship between IP rights and innovation that arises in the context of joint research undertaken during pandemics. It describes the different types of intellectual property rights involved in the development and commercialization of vaccines and related medical treatments. It also delineates the frameworks of domestic and regional IP laws and regulations as well as defining the minimum standards in multilateral IP treaties.

The second part focus on the research phase of collaborative innovation and explores the IP challenges related to the research inputs. It describes the different types of intellectual property rights that can emerge during the joint basic and applied research. This includes patentable inventions, copyrightable works, and trade secrets. Next, it examines the various forms of cooperation during the drug and/or vaccine development and testing; this includes licensing, cross-licensing, material transfer agreements and the use of open-source materials. The exceptions and limitations related to scientific research and experimental use of materials are then examined as well as the use of materials in the public domain. Additionally, the guideline recognises the importance of African Indigenous knowledge and provides an analysis of how traditional knowledge of African communities should be protected and used during the research phase. Ultimately it concludes with a discussion of the ownership of IP rights jointly generated by the different contributors (authorship and inventorship) and the different IP policies adopted by certain research institutions in Africa.

The third part examines the research outcomes phase and describes the legal framework to protect, disseminate, and exploit the research outputs. It discusses the potential mechanisms for IP rights exploitation and commercialization including licensing, cross-licensing, and joint ventures collaboration. Additionally, it addresses types of exploitation including non-profit use

of protected works and inventions, royalty free access on humanitarian grounds, and requirements of prior informed consent and benefit sharing mechanisms with local communities. The guideline also examines the government intervention in the case of national emergency or market abuse to grant compulsory licenses aiming to facilitate access to medicines and related technology, as well as the concept of exhaustion of IP rights and the parallel importation of goods or services from one country to another.

2. INTELLECTUAL PROPERTY RIGHTS AND RESEARCH COLLABORATION

Collaborative research is rapidly gaining traction in modern times. This is attributable to factors such as availability of modern technology; improved means of communication; increased specialisation; intra-disciplinary and multidisciplinary approach to research; and the desire to maximize resources by sharing risks and expenses associated with research.[5] Research collaboration and partnerships take place within and across different groups including academic and research institutions, private sector corporations and industries, government agencies and other public sector bodies, international groups, as well as non-governmental organisations. These collaborations span disciplines and industries, and take place within and across national, regional, and international boundaries. In the context of Africa, collaboration may also involve partnerships between scientific bodies and traditional and local communities, their indigenous resources, knowledge, and practices.

Collaborative research facilitates the pooling of resources and expertise, minimization of duplication, as well as robust outlooks resulting from the inputs of unique perspectives. However, it also comes with several concerns, including those resulting from the cultural orientation of specific sectors and other dynamics associated with varying agendas, perspectives, and approaches to research and development. Avoiding these challenges requires proactively establishing rules to regulate research interaction, whether it be for a one-off collaboration for a specific purpose or a continuing relationship for an indefinite duration. Failure to do this may result in delays, disputes, fractured relations, and other complexities which hinder the attainment of the desired outcome. Given that IP rights lie at the heart of research and development, it is important to address complex IP rights issues that will likely arise in research collaborations.

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[5] Rochelle C. Dreyfuss, "Collaborative Research: Conflicts on Authorship, Ownership, and Accountability" (2000) 53:4 *Vand L Rev* 1161 at 1162-1163.

Creating a common understanding at the onset is particularly important to ensure that researchers from diverse backgrounds can reach a common understanding regarding expectations, priorities, duties, and benefits. For example, researchers who work in academia tend to operate from a "publish or perish" perspective. Promoting the diffusion of information and the publication of research through journal articles and presentations at conferences are their ultimate goals.

Conversely, industry participants are often business-oriented and profit-driven, targeting commercialization, the securing of proprietary rights and the associated exclusivity that it assures for research outcomes. Additionally, they tend to be wary about disclosing business related information, often deploying means to protect and track the use of the equipment, data and other resources related to the project. This is all for the purpose of securing an advantageous position over competitors.

Research and development collaborations funded by the public sector or government agencies are generally public-oriented providing free or affordable access to medicines, vaccines, diagnostics, and resources needed to respond effectively and expediently to pandemics. In an environment where poverty rates are overwhelmingly high, governments are likely to be more interested in innovation-oriented collaborations that are readily affordable and accessible to the public. Other possible partners in collaborative research ventures such as NGOs, international and regional bodies also tend to be publicly spirited.

The lack of uniformity in the IP laws of African Union Member States, particularly those outside of the framework of the two regional IP bodies in Africa,[6] creates an additional layer of complexity for collaborators from different countries. The diversity of IP laws within the continent highlights the need for a uniform policy. Such a policy will aid in the development of a homogeneous understanding of IP rights, effectively balance private rights with the public interest, and provide guidance regarding the IP issues that are likely to arise during the process of collaborative research.

2.1 Context of Intellectual Property Rights in Test Data, Diagnostics and Medical Equipment

It is expected that collaborative research during epidemics and pandemics will result in the invention of new drugs, vaccines, diagnostics and other resources needed to provide an

[6] The African Regional Intellectual Property Organization (ARIPO) established by the Lusaka Agreement in 1976, and the Organisation Africaine de la Propriété Intellectuelle (OAPI) created by the Bangui Agreement in 1977.

effective regime to address the disease. However, before these products are approved by regulatory agencies and put in the market for public use, they must first undergo clinical and other trials. The approval process typically entails the submission of test data which helps to ascertain safety, efficacy and general fitness of the product. Thus, data is important in research which targets the development of these products required to respond to new pandemics, such as Ebola and COVID-19. The collection, and use of data involve investments of time, labour, and money. Without proper protection, this compiled data is vulnerable to exploitation by competitors who can simply gain access to the information and use it for their own purposes. Since the lack of protection of IP rights can result in the loss of competitive advantage, the question remains: how can IP rights be effectively deployed to protect the private rights in these important research investments?

It is therefore important to address IP issues related to test data. In most jurisdictions, raw, factual data is not ordinarily within the scope of subject matter protected by IP rights; rather, it is in the public domain. However, where the data has been selected, arranged, organised, or built into a database or further populated or enhanced through some value addition, it is important to address IP issues associated with the ownership, use, and management of the aggregated data. Such IP rights may include copyright, which protects original expressions. Although test data, as factual information, is not ordinarily protected by copyright, copyright may become relevant where there is some value-added to the data. This may include as a result of original elements inherent in the selection, arrangements, or organisation of such data. In that case, what is protected by copyright is the selection or arrangement, rather than the content itself.

Beyond copyright, test data may also be protected as confidential information or trade secrets at common law or where available, under a statutory regime. In order to obtain protection, information is deemed to be confidential where it has the necessary attributes of secrecy or confidence, steps are taken to maintain its secrecy, and it does not comprise data that is in the public domain. Where divulged to third parties, as may inevitably occur during the course of collaborative research, it must be shared in circumstances that import an obligation of confidence. An important way of achieving this is through the signing of a non-disclosure agreement or a confidentiality clause as part of a larger agreement between the researchers. The clause should also extend the obligation to others who may be informed strictly on a need-to-know basis, including employees and others involved in the research or development of the product or process.

The Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement) specifically provides for the protection of test data as undisclosed information under Article 39 (3) as follows:

> *"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use".*

This is an important measure for safeguarding researcher investment in data creation from competitors and thus helps to preserve competitive advantages. However, the enjoyment of this obligation of confidentiality is dependent on secrecy; thus, parties in collaborative research need to take steps to preserve confidentiality.

Beyond securing a competitive advantage, confidentiality and strict adherence to ethical guidelines is particularly important where the research uses health-related test data derived from medical (clinical) information. Examples of such data include health status, treatment information, diagnostic-related information like laboratory results from blood tests and culture results, imagery outputs from x-rays and MRIs.[7] For these types of data, access and use are strictly circumscribed by privacy laws and medical ethical standards. Thus, it is important to take steps to prevent unauthorized use and disclosure.

In this regard, advances in technological protection measures (TPM) have also played a role in safeguarding confidentiality and competitive advantage by making possible the deployment of data masking technologies for the protection of test data.[8] This is useful where the information needs to be shared and there are concerns about dissemination. The law backs TPMs and thus,

[7] Patient/disease registries, which collect and track clinical information of specified patient populations; health surveys, and clinical trial data from treatment experiments associated with clinical research.

[8] Examples of data masking techniques include substitution of data with random characters or figures, scrambling or translation of information into other languages, and alteration of numbers by the addition or subtraction of a specific percentage in order to disguise the data.

any attempt to circumvent or otherwise interfere with these measures renders the violator liable.[9]

On the other hand, it has become commonplace for researchers to waive copyright or database rights and put their information in the public domain. This may be either without limitations or subject to limitations, provided in the terms of use. Examples include the Creative Commons (CC) and the Open Data Commons (ODC) groups. The terms vary from free, unrestricted, and unregulated use of the database and its contents; free use, subject to appropriate acknowledgement of or attribution to the source and a third, stricter category which provides for attribution as well as a requirement that outputs from the use of the data are to be made publicly available and distributed on similar terms as those involving the ODC or CC as the case may be.[10] Collaborators, especially those contributing valuable information, need to make informed decisions about whether their information is to be private and proprietary, or public, via ODC or CC. The selected approach may, beyond IP considerations, likely be influenced by the background and culture of the owner or the custodian of the data (public or private sector). Ultimately, a decision should be reached through considering all relevant facts, including the varied interests of the collaborators, requirements for innovation and commercialization, and other legal considerations, such as privacy rights.

Equipment and diagnostics are very important in carrying out research related to new and emerging diseases. However, the poor capacity for local testing due to inadequate diagnostics, state of the art laboratories, and equipment poses a major problem for development. Collaboration is a mechanism to address this problem; whereby research partners from the developed countries contribute their practical knowledge, diagnostics, and equipment. Efforts should be made to include terms in research contracts which permit local deployment of proprietary processes for effective testing; this should be done as much as it is practicable. Furthermore, priority should be given to transfer of technology to facilitate local production of test kits, diagnostics, and equipment, particularly by public entities, NGOs, and SMEs.

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[9] The WIPO Internet treaties provide international standards pertaining to the safeguarding of technological protection measures.

[10] *See Open Data Commons* online: <http://opendatacommons.org>, and *Creative Commons* online: <http://creativecommons.org>, accessed August 3, 2020.

2.2 Identification of potential types of intellectual property rights in joint research and collaboration

Research and collaboration during outbreaks might entail various types of intellectual property rights both in the research and commercialization phases. The types of IP rights are vast, varying from inventions that can be protected by patents, utility models (petty patents or innovation patents) or undisclosed information (trade secrets), to literary works protected by copyright such as publications of different types (papers, reports, and technical ….), software, and databases. Trademarks may also be obtained for the brand-name of a particular product or process.

It is important to properly define the IP rights developed prior to or outside the scope of the research collaboration; particularly, where such rights might be required to exploit the results of the research.

The following briefly describes the content of common types of IP rights and the legal requirements for protection.

2.2.1 Patents

A patent is an exclusive right over the exploitation of inventions in all fields of technology, for a set period (20 years from the date of filing an application). The inventor discloses the invention to the public in exchange for a temporary, state-enforced monopoly to make, construct, use, and sell the invention. Patent rights encourage investment in innovation, while contributing to public knowledge by providing access to the invention. To be patentable, an invention must be novel, involves an inventive step (not obvious), and be capable of industrial application (useful).

Certain inventions may be excluded from patentability according to the TRIPS Agreement: (a) inventions, the prevention within a certain territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; (b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (c) plants and animals other than micro-organisms, and biological processes for the production of plants or animals other than non-biological and microbiological (article 27.2 and 3).

Subject to several limitations and exceptions, a patent confers its owner the right to prevent third parties from (a) making, using, offering for sale, selling or importing for those purposes a product; (b) using a process; and (c) using, offering for sale, selling, or importing for these purposes a product obtained directly by a patented process. Unlike copyright protection, patent rights are granted based on a patent application and registration process. Patent owners have the right to assign or transfer by succession, the patent, and to conclude licensing contracts.

2.2.2 Utility Models

Utility models, also known as petty patents or innovation patents, protect new technical inventions by granting a limited exclusive right to prevent others from commercially exploiting the protected inventions without consents of the right holders.[11] The common features of utility models include short term protection, waiving the requirement of non-obviousness and inventive step and simpler application procedure compared to patents. The requirements for acquiring utility models are less stringent than patents. While the novelty of the invention is always to be met, the requirement of inventive step may be lower or absent in certain legislations. The term of protection for utility models is shorter than for patents and varies between 7 to 10 years. Compared with patents, a utility model is cheaper to obtain and maintain. The utility model can be used to respond to the needs of local innovators, by offering a short period of protection and easier and cheaper procedures to obtain and maintain protection.

2.2.3 Undisclosed Information

While ensuring effective protection against unfair competition, any confidential business information that provides a business with a competitive edge shall be protected. The right holders shall prevent information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices.

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[11] Utility models are defined in *section 3ter* of the *Harare Protocol on Patents and Industrial Designs*, Zimbabwe (2020),as "any form, configuration or disposition of elements of some appliance, working tools and implements as articles of everyday use, electrical and electronic circuitry, instrument, handicraft, mechanism or other object or any part thereof in so far as they are capable of contributing some benefit or new effect or saving in time, energy and labour or allowing a better or different functioning, use, processing or manufacture of the subject matter or that gives utility advantages, environmental benefit, and includes micro-organism or other self-replicable material, products of genetic resources, herbal as well as nutritional formulations which give new effects".

Undisclosed information may encompass manufacturing, industrial, or commercial secrets. Trade secrets may include business methods, advertising strategies, lists of suppliers and clients, and manufacturing processes. Undisclosed information can be protected for an unlimited period of time as long as the person lawfully in control of the information has taken reasonable steps in the circumstances to keep the information secret.

While there are no procedural requirements for the protection of undisclosed information, in practice, they are often protected through confidentiality or non-disclosure agreements.

As a condition of obtaining a marketing authorization of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the undisclosed test or other data required to be submitted, shall be protected against unfair commercial use. In addition, such data shall be protected against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

2.2.4 Trademarks

A trademark is any sign or combination of signs that is used by a person to distinguish their goods or services from those of others. A sign can take the form of a word, design, letter, numeral, drawing, color or any combination of these forms. A trademark helps consumers identify and purchase a product or service because its nature and quality, indicated by its unique trademark, meets their needs. Trademarks also protect the investment of trademark owners in the goodwill associated with their marks.

The owner of a registered trademark has the exclusive right to prevent others from using without his/her consent in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion.

A trademark registration is usually valid for 10 years from the date of application and can be renewed every 10 years indefinitely upon payment of annual fees.

2.2.5 Copyright

Copyright protects the various original means and formats by which ideas or opinions are expressed by a creator. Copyright does not protect the underlying idea, facts, procedures, methods of operation, or mathematical concepts themselves; rather, it protects these ideas as manifested in a tangible format. According to the Berne convention, copyright lasts for the life of the authors and 50 years after their death. The kinds of works in relation to collaborative

research that may be covered by copyright include among others software in any expressed form (source code), computer programs, graphical user interfaces (GUI), databases, technical manuals, reports, articles, specifications, and drawings. As with other IP rights, a copyright provides its owner the right to prevent others from copying, publishing, distributing to the public, or broadcasting the protected work without the author/rightsholder consent. Copyright also provides a set of moral rights which preserves the author's integrity of the work and the intent behind the work (rights of attribution and association and rights of integrity).

Unlike patents, copyright does not depend on a formal procedure for registration. Copyright exists from the moment of creation of the literary and artistic work. Generally, the author of the work is considered the first owner of copyright in the work. However, if the work was made in the course of an employment contract, then the employer owns the copyright.

2.3 Intellectual Property laws and regulations: domestic, regional (ARIPO/ OAPI), and international (TRIPS)

Intellectual property laws are territorial meaning that each jurisdiction regulates the IP rights available in its territory through national legislation. National legislation is informed by various international agreements, the most fundamental being the Agreement on Trade-related aspects of Intellectual Property Rights, known as TRIPS. The World Intellectual Property Organisation (WIPO) administers 26 intellectual property agreements. These agreements establish minimum standards that must be met by the national laws of states that are party to them and are bound by these agreements.

2.3.1 Domestic IP laws

National IP frameworks typically consist of IP policies and strategies as well as a suite of legislation dealing with the various IP rights such as a Patents Act, a Copyright Act, and an Industrial Designs Act. For the World Intellectual Property Organization (WIPO) member states, these resources are available on the WIPO Lex Database.[12] A review of national IP legislation shows that it sets out the subject matter eligible for IP protection, the scope of protection offered, and the application procedures, if any, to secure the protection for IP rights. The legislation also sets out the national administrative structures for the issuing of intellectual property rights. For example, a patent office that receives applications and issues patents in that

[12] See "WIPO Lex Database", online: *WIPO* <https://wipolex.wipo.int/en/main/legislation>.

country. Finally, remedies available for IP rights infringement are also provided in the legislation. In some countries, there are IP policies specific to certain Industries such as an IP policy for universities. Further, there may be other policies that are relevant to, and mention, IP such as National Innovation Policies and National Development Plans. A detailed overview of the contents of IP policies and legislation of AU member states is beyond the scope of these guidelines.

2.3.2 Regional IP frameworks

Looking at the African continent as a region, two approaches are evident. The first approach focuses on regional IP organisations, namely the African Regional IP organisation (ARIPO)[13] and the Organisation Africaine de la Propriété Intellecturelle (OAPI).[14] The second approach is to canvass the Regional Economic Communities (RECs) to see what extent they are involved in IP regulatory frameworks and how the African Continental Free Trade Area (AfCFTA) will integrate the RECs approaches, since they will form the building blocks of the AfCFTA.[15] The IP protocol under the AfCFTA has yet to be finalised and will not be discussed here; therefore, the following two subsections of the guideline will consider the regional IP organisations and the RECs. In addition, the establishment of an Africa-wide IP structure that would sharpen the visibility of IP issues as they relate to economic development. As it adds impetus to the African Union Assembly's political will and commitment to inventiveness and innovation, thus emphasizing the significance of political leadership in such a strategic field of development. The Assembly decision taken in this regard was in January 2013 to create a Pan African Intellectual Property Organization (PAIPO).

[13] As of June 2022, the ARIPO Current Member States are Botswana, Eswatini, the Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Seychelles, Sierra Leone, Somalia, Sudan, Tanzania, Uganda, Zambia and Zimbabwe.

[14] The OAPI Member States are Benin, Burkina Faso, Cameroon, the Central African Republic, Chad, Comoros, the Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal, and Togo.

[15] The African Continental Free Trade Area (AfCFTA) was signed in March 2018 and came into force in January 2021. The AfCFTA brings together fifty-four African countries and creates a single market for goods, services to deepen the economic integration of the African continent. The AfCFTA aims to build a liberalised market for goods and services and to contribute to the movement of capital and natural persons, creating new business dynamics that offer investors access to a population of 1.7 billion people and a combined gross domestic product of more than US $3.4 trillion. The agreement establishing the AfCFTA is available at https://au.int/sites/default/files/treaties/36437-treaty-consolidated_text_on_cfta_-_en.pdf.

2.3.2.1 The Regional African IP organizations - ARIPO and OAPI

Africa has two well-established regional organizations for intellectual property administration. The African Regional Intellectual Property Organization (ARIPO) generally caters to anglophone and lusophone African countries by providing a harmonization of IP standards through its various binding instruments, which member states voluntarily subscribe to. In addition to the centralised service established by the Harare Protocol, ARIPO's member states also have their own national IP laws and administrative structures which coexist with the legislation adopted by the regional office. Meanwhile, the Organisation Africaine de la Propriété Intellectuelle (OAP) mostly covers French-speaking African countries.[16] OAPI's contracting member states could only obtain a regional patent since they do not have national IP laws. A right granted by the central office in Yaoundé, Cameroon, subsists in all member states. The table below lists the IP right instruments for each organisation.

ARIPO[17]	OAPI[18]
Harare Protocol The Harare Protocol on Patents and Industrial Designs Administrative Instructions under the Regulations for Implementing the Protocol on Patents and Industrial Designs within the Framework of ARIPO **Banjul Protocol** Banjul Protocol on Marks Administrative Instructions for Implementing the Banjul Protocol on Marks **Swakopmund Protocol** Swakopmund Protocol on the Protection of	**Bangui Agreement** Relating to the Creation of an African Intellectual Property Organization, constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property (Bangui (Central African Republic), March 2, 1977) The **Bangui Agreement** deals with patents, utility models, trademarks and service marks, industrial designs, trade names, geographical indications, literary and artistic property, unfair competition,

[16] "African Intellectual Property Organization (OAPI) – OA", online (pdf): *WIPO* <https://www.wipo.int/export/sites/www/patent_register_portal/en/docs/oapi.pdf>.

[17] "Protocols, African Regional IP organisation", online: *ARIPO* <https://www.aripo.org/protocols/>.

[18] *Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property*, 2 March 1977, OAPI, Bangui, Central African Republic (entered into force February 7, 1982) online: <https://wipolex.wipo.int/en/treaties/details/227>, as revised. Last revision made in 2015 and came into force in November 2020.

Traditional Knowledge and Expressions of Folklore Administrative Instructions under the Regulations for Implementing the Swakopmund Protocol Policy Framework on Access and Benefit Sharing Arising from the Use of Genetic Resources in the ARIPO Member States **Arusha Protocol** Arusha Protocol for the protection of new varieties of plants **Kampala Protocol** Kampala Protocol on Voluntary Registration of Copyright and Related Rights	topographies of integrated circuits, and plant varieties.
When filing an ARIPO application, desired states can be designated, and application fees are payable only for those designated states.	When filing an OAPI application, all the member countries are automatically included, and designation of only certain countries is not possible.

The two organizations have entered into co-operation agreements to work towards the harmonization of their systems and to exchange documentation and technical information.[19]

2.3.2.2 RECs: a summary of the relevant IP instruments and provisions

Common Market for Eastern and Southern Africa (COMESA)[20]: IP regulatory framework consists of the following provisions:

[19] "OAPI and ARIPO Sign New Cooperation Agreement" (9 February 2017), online: *ARIPO* <https://www.aripo.org/oapi-and-aripo-sign-new-cooperation-agreement/>. ; *Memorandum of Understanding between the World Intellectual Property Organization (WIPO), the African Regional Intellectual Property Organization (ARIPO), and Organisation africaine de la propriété intellectuelle (OAPI)* (July 23 2018) online: <https://inventa.com/uploads/5bb4edae02557_WIPO,%20AOPI%20and%20ARIPO%20Agreement.pdf>.

[20] COMESA Member States are Burundi, Comoros, the Democratic Republic of Congo, Djibouti, Egypt, Eswatini, Eritrea, Ethiopia, Kenya, Libya, Madagascar, Malawi, Mauritius, Rwanda, Seychelles, Somalia, Sudan, Tunisia, Uganda, Zambia and Zimbabwe.

Article 104(1) (d) of the COMESA Treaty provides for information sharing on 'legislation on patents, trademarks and designs'. Further Article 128(e) provides that:

> In order to promote co-operation in science and technology development, the member States agree to jointly develop and implement suitable patent laws and industrial licensing systems for the protection of industrial property rights and encourage the effective use of technological information contained in patents.

COMESA has several protocols, policies, and strategies. Amongst these, is the COMESA Regional Policy on Intellectual Property rights and Cultural Industries (COMESA IP Policy).

East African Community (EAC):[21] The EAC Treaty provides for IP in articles 75, 103 (1)(i) and 112.2 (n) which provide as follows:

> Article103(1)(i): Recognising the fundamental importance of science and technology in economic development, the Partner States undertake to promote co-operation in the development of science and technology within the Community through: the harmonisation of policies on commercialization of technologies and promotion and protection of intellectual property rights.
>
> Article 112(2)(n): For purposes of paragraph 1 of this Article, the Partner States undertake to adopt common policies for conservation of biodiversity and common regulations for access to management and equitable utilisation of genetic resources.

In addition, the EAC has the following protocols, policies, and strategies, which are relevant to IP rights:

1. East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016)
2. Poverty Impact Assessment of the East African Community Regional Pharmaceutical Plan of Action
3. EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation

[21] EAC Member States are Burundi, Kenya, Rwanda, Tanzania and Uganda.

Economic Community of West African States (ECOWAS):[22] Article 27(10) c of the ECOWAS Treaty provides:

> In their cooperation in this field member states shall harmonize their National development plans by placing special emphasis on indigenous and adapted Technologies as well as their regulations on industrial property and transfer of technology.

ECOWAS States have adopted a TRIPS policy and guidelines, as well as a regional Pharmaceutical Plan.[23]

Southern African Development Community (SADC):[24] Article 24 of the SADC Protocol on Trade provides that member States shall 'adopt policies and implement measures within the Community for the protection of Intellectual Property Rights, in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)'. SADC also adopted an IP rights Framework in 2018.

COMESA-EAC-SADC Tripartite IP Agenda: COMESA, EAC and SADC reached agreement on the establishment of tripartite FTA in October 2008.[25] Art 27 of the tripartite agreement provides:

1. Tripartite member States shall protect intellectual property rights in a balanced manner that promotes the social economic welfare of society through ensuring that the people of the region meaningfully benefit from and participate in advancements in the arts and science and technology in accordance with Annex 9 on Intellectual Property Rights.[26]

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[22] ECOWAS Member States are Benin, Burkina Faso, Cape Verde, Cote d'Ivoire, the Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, the Niger, Nigeria, Senegal, Sierra Leone, and Togo.

[23] *Guidelines For Implementation of TRIPs Flexibilities in National Legislation To Improve Access to Medicines in the West African Region*, West African Health Organization, Bobo-Dioulasso, Burkina Faso (2012) online: <https://www.healthresearchweb.org/?action=download&file=ECOWAS_TRIPsGuidelines_English.pdf>; *ECOWAS Regional Pharmaceutical Plan (ERPP)*, West African Health Organization, Bobo-Dioulasso, Burkina Faso (April 2014) online: < https://www.unido.org/sites/default/files/2016-01/ECOWAS_Regional_Pharmaceutical_Plan_0.pdf>.

[24] The SADC Member States are Angola, Botswana, Comoros, Democratic Republic of Congo, Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Tanzania, Zambia and Zimbabwe.

[25] *The Study on the Establishment of Inter-RECs' Free Trade Areas in Africa: Drawing on Lessons from the COMESA-SADC-EAC FTA Experience: Final Report*, United Nations Economic Commission for Africa (UNECA) (2011) online: < http://www1.uneca.org/Portals/ctrci/7th/Tripartite%20_COMESA_EAC_SADC_FTA%20Study%20FINAL%20REPORT.pdf>.

[26] *TFTA Annex 9: Intellectual Property Rights*, 2010. https://www.eac.int/index.php?option=com_documentmananger&task=download.document&file=bWFpbl9k

2. Tripartite member States shall adopt policies on intellectual property rights including the protection and promotion of cultural industries in accordance with international agreements.

3. Tripartite member States shall cooperate and develop capacity to implement and utilise the flexibilities in all relevant international agreements on intellectual property rights.

2.3.2.3 The Pan African Intellectual Property Organization (PAIPO)

The Pan African Intellectual Property Organization (PAIPO) is established as a continental body to manage IP affairs that will cater for all AU Member States. The formation of this umbrella body does not imply the dismemberment of the two existing regional organization on IP. As stipulated in the decision adopted by the African Union Assembly in 2016[27], the PAIPO structure recognizes the autonomy of ARIPO and OAPI and the efforts to modernize IP legislation within their Member States. The goal of the PAIPO is to provide a broad-based platform for AU Member States to benefit from a coordinated stock of specialized intellectual property knowledge and services with a view to promote innovation, techno-industrial competitiveness, and economic growth in Africa. The objectives of the PAIPO can be summarized as follow:

- set continental IP standards that reflect the needs of AU Member States;
- facilitate the realization and harmonization of national legislation and regional treaties with the continental IP standards;
- set benchmarks for best practices on intellectual property;
- promote the growth of knowledge-based economies in Africa;
- collect, process and disseminate relevant information on intellectual property to Member States;
- facilitate the utilization of relevant IP information by Member States;
- strengthen/facilitate the establishment of collective management organizations in Member States;
- promote the protection and exploitation of IP rights within Member States including conclusion of bilateral and multilateral agreements;

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b2N1bWVudHNfcGRmX1hMc1FkTE5QbW92c3NURmZ2ZnNaVkRNVEZUQSBBbm5leCAwOSBJUFIgUmV2aXNlZCBEZWMgMjAxMA==&counter=187 , https://www.eac.int/documents/category/comesa-eac-sadc-tripartite

[27] Assembly/AU/Dec.589 (XXVI)

- assist Member States in training and capacity building to maximize benefits of the IP system; and
- support to the African negotiations to ensure attainment of African common positions by providing a forum for policy discussions and formulation (especially relating to genetic resources, traditional knowledge, geographic indications matters pertaining and arising from the Convention on Biological Diversity) and emerging topics on IP.

2.3.3 International framework

The substantive standards in national legislation are informed by international agreements. The agreements African Union member states are party to are listed below, together with the international organizations responsible for administering them.

Table 1: International IP treaties

Treaty (year)	IP regime	Source
Beijing Treaty on Audiovisual Performances (2012)	Copyright	WIPO
Berne Convention for the Protection for Literary and Artistic Works (1886)	Copyright	WIPO
Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974)	Neighbouring Rights	WIPO
Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)	Patents	WIPO
International Treaty on Plant Genetic Resources for Food and Agriculture (2001)	Plant Genetic Resources	FAO
Hague Agreement Concerning the International Registration of Industrial Designs (1925)	Industrial Designs	WIPO

Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1958)	Geographic Indications	WIPO
Locarno Agreement Establishing an International Classification for Industrial Designs (1968)	Industrial Designs	WIPO
Madrid Agreement for the Repression of False or Deceptive Indications of Sources of Goods (1891)	Trademarks	WIPO
Madrid Agreement Concerning International Registration of Marks (1891)	Trademarks	WIPO
Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989)	Trademarks	WIPO
Marrakesh Visually Impaired Persons Treaty (2013)	Copyright	WIPO
Nagoya Protocol on Access and Benefit Sharing (2010)	Access and Benefit Sharing	CBD Secretariat
Nairobi Treaty on the Protection of the Olympic Symbol (1981)	Trademarks	WIPO
Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks (1957)	Trademarks	WIPO
Paris Convention for the Protection of Industrial Property (1883)	Patents and Trademarks	WIPO
Patent Cooperation Treaty (PCT) (1970)	Patents	WIPO
Convention for the Protection of Producers of Phonograms against Unauthorised Duplication of Their Phonograms (1971)	Neighbouring Rights	WIPO
Patent Law Treaty (2000)	Patents	WIPO

Rome Convention for the Protection of Performers, Producers of Phonographs, and Broadcasting Organisations (1961)	Copyright	WIPO
Singapore Treaty on the Law of Trademarks (2000)	Trademarks	WIPO
Strasbourg Agreement Concerning the International Patent Classification (1971)	Patents	WIPO
Trademark Law Treaty (1994)	Trademarks	WIPO
Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1995)	Comprehensive	WIPO
Universal Copyright Convention (UCC) (1952)	Copyright	UNESCO
Universal Copyright Convention (UCC) (1971)	Copyright	UNESCO
International Convention for the Protection of New Varieties of Plants (UPOV Convention) (1961)	Plant Varieties	UPOV
International Convention for the Protection of New Varieties of Plants (UPOV Convention) (1978)	Plant Varieties	UPOV
International Convention for the Protection of New Varieties of Plants (UPOV Convention) (1991)	Plant Varieties	UPOV
Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks (1973)	Trademarks	WIPO
Washington Treaty on Intellectual Property in Respect of Integrated Circuits (1989)	Computer Chips	WIPO
WIPO Copyright Treaty (WCT) (1996)	Copyright	WIPO
UN Convention on WIPO (1967)	Copyright	WIPO

WIPO Performances and Phonograms Treaty (WPPT) (1996)	Neighbouring Rights	WIPO

source: de Beer, Baarbe & Ncube, 2018, at p.58

The majority of African states are bound by these treaties as recorded in the WIPO Lex entry for each Member State. In addition, several studies have been conducted on the rate of ratification of these treaties by African states which indicate a high rate of ratification.[28]

3. IP RIGHTS AND RESEARCH INPUTS (THE RESEARCH PHASE)

The development of new drugs and vaccines is a lengthy and multi-phasic process that requires significant public and/or private investments of time and money.[29] To fund these research ventures, virtually all successful pharmaceutical innovations are protected as IP rights and commercialized through either product sales or licensing agreements. The result is a research and development (R&D) landscape that is densely populated by property rights, and there is a high likelihood of derivative research activities treading upon existing third-party rights. To mitigate the risk of investing in infringing projects, an analysis of competitor-held IP is often conducted prior to beginning the R&D process. If no overlapping IP is identified, or alternatively, if the rights to any adverse property are obtained, the researching party is said to have "freedom to operate" (FTO) and may conduct commercial activities without committing infringement.[30]

The pharmaceutical industry has endeavoured to increase its efficiency by implementing strategic methods of R&D, which tailor potential therapeutics towards optimal interaction with

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[28] See Jeremy De Beer, Jeremiah Baarbé & Caroline Ncube, "Evolution of Africa's Intellectual Property Treaty Ratification Landscape" (2018) 22 African J Information and Communication 53 at 66-67.

[29] For example, the estimated cost of developing one vaccine candidate for each of the 11 epidemic infectious diseases identified by WHO following the West African Ebola epidemic is US$2.8 to 3.7 billion. See Dimitrios Gouglas et al, "Estimating the Cost of Vaccine Development Against Epidemic Infectious Diseases: A Cost Minimisation Study" (2018) 6:12 The Lancet Global Health e1386 at e1386, DOI: <10.1016/S2214-109X(18)30346-2>; "An R&D Blueprint for Action to Prevent Epidemics: Plan of Action" (15 May 2016, last visited 14 June 2022), online (pdf): *World Health Organization* <cdn.who.int/media/docs/default-source/blue-print/an-randd-blueprint-for-action-to-prevent-epidemics.pdf > [perma.cc/XH8Q-DXJ6]. Moderna, a leading pharmaceutical company, received over $2 billion in research aid from the United States government during COVID-19 Pandemic to develop their COVID vaccines. See < https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s>.

[30] The term "freedom to operate" (FTO) describes a situation where commercial activity can be undertaken without infringing on intellectual property rights held by other parties. Dan Ciuriak, "Generalized Freedom to Operate" (2016) MegaReg Forum Paper 2016/3, Institute for International Law and Justice | NYU School of Law.

disease-causing molecules known as "targets".[31] Researchers seeking to identify new drugs and vaccines may apply their knowledge of disease at the microscopic level to design promising treatments at the early stages of preclinical development. The rise of target-focused drug and vaccine development has been made possible by discoveries in molecular biology, genomics, and related fields, which provide insight into target characteristics and the mechanisms through which they cause disease. Accordingly, modern pharmaceutical research is an interdisciplinary effort and frequently draws upon multi-party knowledge and innovation to address the advanced problems that remain to be solved by the industry.

New drugs and vaccines can be developed from publicly available materials, licensed or pledged IP, and the sacred knowledge of Indigenous communities. The research phase can take the form of voluntary collaboration between various partners to develop the new drug. Bringing together collaborative partners, each with their own expertise, resources, and assets, is frequently more efficient than a single innovator working to bring a drug candidate from design to distribution.[32] Cooperative research efforts were vital to the development of COVID-19 vaccines, and more than half of the 190 candidates registered with the World Health Organization (WHO) were developed through joint research ventures.[33]

This section first explores the different ways to facilitate access to knowledge necessary to develop medical treatments in times of crises, followed by an analysis of the ownership of the IP research results.

3.1 Ways to facilitate access to information necessary in the research phase

Cumulative innovation is dependent on the flow of information from originators to downstream collaborators. The products of basic research (e.g., data, protocols, algorithms or know-how) can be reinvested as inputs to drive further scientific exploration.[34] Publicly available materials that are non-proprietary may be disseminated to other researchers through public platforms

[31] Glenn E Croston, "The Utility of Target-based Discovery" (2017) 12:5 Expert Opinion on Drug Discovery 427.
[32] Frederick M Abbott, "Public Private Partnerships as Models for New Drug Research and Development: The Future as Now" in Margaret Chon, Pedro Roffe & Ahmed Abdel-Latif, eds, *The Cambridge Handbook of Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development*, (Online: Cambridge University Press, 2018) 29 at 29; *Report of the UN Secretary General's High Level Panel on Access to Medicines*, (2016) at 14–15 [*Report of UN SGAM*], online (pdf): <www.unsgaccessmeds.org/final-report> [perma.cc/4HD8-22EP].
[33] Louise C Druedahl, Timo Minssen & W Nicholson Price, "Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships" (2021) 39 Vaccine 6291 at 6292 (ScienceDirect).
[34] Stephen Hilgartner & Sherry I Brandt-Rauf, "Data Access, Ownership, and Control: Toward Empirical Studies of Access Practices" (1994) 15:4 Science Communication 355 at 359 (Sage Journals).

such as academic journals or curated databases. When research inputs are protected by intellectual property rights, the terms and conditions of their use must be negotiated with the rights holder (e.g., licensing agreements) or waived before their utilization in the research phase (e.g., shared information). As such, the licensing or pledging of IP rights is a frequent precondition to cooperative innovation. Patents are the dominant form of IP rights used in pharmaceutical research; however, copyrightable works and trade secrets may also arise.

3.1.1 Publicly available materials

The "public domain" describes a collection of available materials that are not protected by IP rights and that are accordingly available to the public for use without authorization or restriction.

> Knowledge and information that are available for unlimited use can be divided into three major categories:
>
> (1) information that is not subject to protection under IP regimes;
>
> (2) information available for the public use at the end of their term of protection (50 years after the author's death for copyrighted works; 20 years from the patent application); and
>
> (3) information which can be used under one of the exceptions and limitations on IP rights for scientific research or experimental use.

Research inputs that exist in the public domain include abstract ideas, scientific laws and theorems, which can be used for further study without authorization from their originator. The scientific data and other results contained in scholarly communications are generally ineligible for copyright protection, as they are owned by society in common.[35] Publicly available information might also arise from patents that have been abandoned or cancelled, either at the application stage or after being granted, or from the expiration of rights in patented or copyrighted works.[36] The non-proprietary nature of these materials has been exploited by various archival initiatives seeking to digitally catalogue research outputs. Online databases serve as convenient repositories of otherwise decentralised information and allow for rapid and discerning searches across wide swaths of knowledge. One such example is the US Research Collaboratory for Structural Bioinformatics Protein Data Bank (RSCB PDB), which contained

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[35] Robert K Merton, "The Normative Structure of Science" in Norman W Storer, ed, *The Sociology of Science: Theoretical and Empirical Investigations* (Chicago and London: The University of Chicago Press, 1973) 267 at 273.
[36] See James G Conley et al (2013) "Study on Patents and Public Domain (II)" (CDIP/12/INF/2 REV).

seven protein structures when it was founded in 1971.[37] Today, it contains more than 190 000 structures of proteins and other large biological molecules that serve as key inputs for pharmaceutical research.[38] The information in the RSCB PDB is available to scientists, students and any other member of the public without cost or usage limitations.[39]

Another category of publicly available information may arise from the use of the exceptions and limitations for scientific research and/or experimental use conferred in the TRIPS Agreement. In accordance with the TRIPS Agreement, patents provide the exclusive right to make, use, offer for sale, sell, or import a protected product. However, these rights are subject to exceptions stated in Article 30 of the agreement which states: "*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*" The objective of such flexibilities is to promote scientific research and to encourage technological development in general. In most African countries, the rights conferred by a patent, for example, do not extend to activities for experimental or research purposes. The Bangui Agreement creating the African intellectual property organization (OAPI) provides that a patent holder's rights are not infringed by third-party experimentation in derivative scientific or technical research.[40] The Agreement does not stipulate that experimentation must be non-commercial and therefore creates a broad third party right of use.[41]

In addition to the research exception, manufacturers of generic drugs under the "Bolar exception" are allowed to use actively patented inventions to obtain marketing approval without the patent owner's permission. This allows generic producers to develop less expensive equivalents of the same medicines while the original drug remains patented, thereby positioning them to market their product as soon as the name-brand patent expires. The Bolar exception was first introduced by the US Drug Price Competition and Patent Term Restoration

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[37] US Research Collaboratory for Structural Bioinformatics, "PDB History" (last visited 5 June 2022), online: *RCSB PDB* <www.rcsb.org/pages/about-us/history> [perma.cc/K5SG-MJCP].
[38] US Research Collaboratory for Structural Bioinformatics, "Welcome" (last visited 5 June 2022), online: *RCSB PDB* <www.rcsb.org> [perma.cc/D7N9-HRU4].
[39] *Ibid.*
[40] Evans Misati & Kiyoshi Adachi, "The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda" (March 2010, last visited 14 June 2022) at 2, online (pdf): *UNCTAD-ICTSD Project on IPRs and Sustainable Development* <unctad.org/system/files/official-document/iprs_in20102_en.pdf> [perma.cc/6NW7-DT5Z].
[41] *Ibid.*

Act of 1984 to strike a compromise between innovators and generic pharmaceutical producers.[42] By implementing this exception to infringement, the inventors of expired patents are prevented from enjoying a de facto additional period of monopoly power while competitors develop a generic version of the product and obtain regulatory approval.[43] The consistency of the Bolar exception with Article 30 of the TRIPS Agreement was approved in a World Trade Organization (WTO) dispute settlement in 1998 between the European Communities and Canada, which had introduced a Bolar exception in its domestic legislation.[44] The WTO panel concluded that Canada was not in violation of the TRIPS Agreement in terms of its practice of allowing the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent holder.

Moreover, Least Developed Countries (LDCs) in Africa can also benefit from an extended transition period for the application of TRIPS Agreement provisions, granted in recognition of their special requirements, their economic, financial and administrative constraints, and their need for flexibility in order to create a viable technological base.[45] The transition period for LDC members to protect intellectual property rights under Article 66.1 of the TRIPS Agreement had been extended twice before (in 2005 and 2013) and was recently extended until 1 July 2034.[46]

3.1.2 Voluntary mechanisms of collaboration

The second strategy to facilitate African countries' access to medical research inputs is voluntary mechanisms of cooperation and collaboration, which include licensing agreements, public private partnerships, and patent pool models. For decades, IP rights were mainly used by scientists defensively as a shield against imitation and to increase their inventiveness. However, the defensive function has been tempered by the need to work collaboratively if the required demand for new medical treatments is to be met. Scientists are in constant need of

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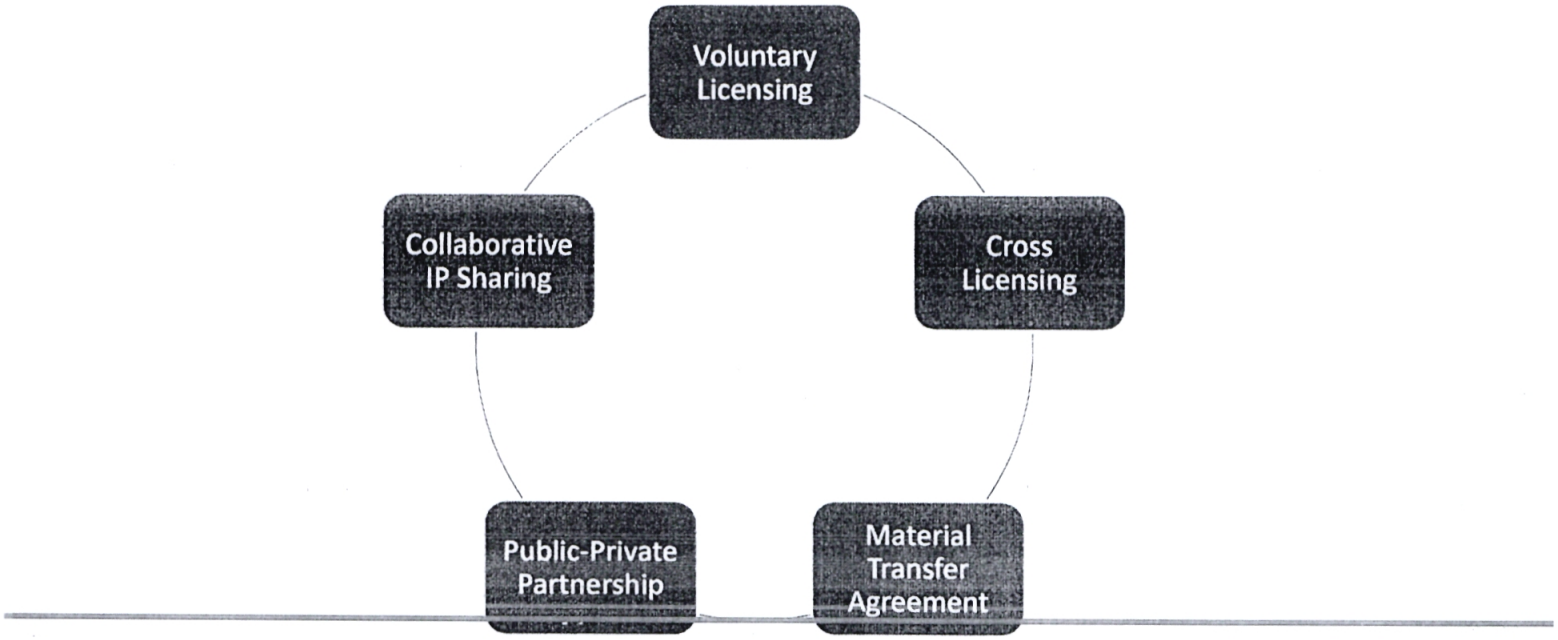
[42] US, HR 3605, *Drug Price Competition and Patent Term Restoration Act of 1984*, 98th Cong, 1984.
[43] Carlos M Correa, "The Bolar exception: Legislative models and drafting options" (2016) South Centre Research Paper 66.
[44] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/13, adopted 7 April 2000, DS114, online: <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm>.
[45] Of the 54 countries that comprise Africa, 33 are currently classified as LDCs. However, Angola and São Tomé and Príncipe are expected to graduate from this category in 2024. See United Nations Development Programme, Regional Bureau for Africa, *Graduation of Least Developed Countries (LDCs): Emerging Issues in a New Development Landscape*, (1 April 2021) at 14, online: <www.undp.org/africa/publications/graduation-african-least-developed-countries-ldcs-emerging-issues-new-development-landscape> [perma.cc/GNP2-M4ZS].
[46] WTO, "WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034" (29 June 2021), online: *World Trade Organization* <www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm> [perma.cc/BB7C-GZY9].

more tangible materials for their research, such as biological samples and data which can be shared between researchers and laboratories.



Voluntary licensing refers to the practice of IP owners (licensors) voluntarily granting a third-party (licensee) permission to use their IP rights while the owner continues to retain the ownership of that right. The licensing of IP rights is the main mode of information exchange in the pharmaceutical sector. A license authorizes the user to perform activities that would otherwise be considered an infringement of the owner's rights. The license usually sets quality requirements and defines markets where the licensee can sell the product(s).[47]

Cross-licensing is a voluntary agreement between two parties who wish to exchange their IP rights with each other. This is a common practice for collaborations within the same industry, as partners may innovate by employing each other's patented technology to their respective knowledge bases. The mutual benefit received from cross-licensing agreements supports

[47] See Bassem Awad, "If Not Now, When? Access to COVID-19 Treatment and Patent Law" (2020) 11:1 WIPO-WTO Colloquium Papers (WTO Publications, 2022), 86; K D Raju, "Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries" (2017) 22 J Intellect Prop Rights 23.

lower-cost information sharing, and the exchange of equal valuation IP rights may take place without any monetary consideration.[48]

Patent rights may also be granted as a component of a larger **material transfer agreement (MTA)** that governs the movement of tangible research materials and tools between two organizations (e.g., universities, public or private research centres and government entities), when the recipient intends to use it for their own research purposes.[49]

Historically, these exchanges were based on trust and goodwill where the provider required only an acknowledgement at the end of the recipient's research, or in some cases, restricted further material transfer to third parties.[50] Nevertheless, the modern fusion and use of diverse sources of data, knowledge and technologies and more sophisticated legal models facilitates the advancement the global scientific knowledge.

MTAs frequently form the basis of academic-industry partnerships where the former specializes in novel exploration but lacks the resources to carry out clinical testing and manufacturing. For example, AstraZeneca's COVID-19 vaccine was developed using academic research products transferred from the University of Oxford.[51] MTAs ensure that the provider of transferred material is properly acknowledged in others' research. They also represent an effective mechanism to promptly acquire the research material and permit its circulation among laboratories.[52] Establishing the terms and conditions of these large and complex transfers requires expensive and time-consuming negotiations, and as a result, standard form MTAs have been developed by public institutions to help expedite this process. These agreements may also be used to ensure the ethical treatment of sensitive research inputs. For example, South African law requires that the transfer of human biological material be

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[48] Carl Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting" (2000) 1 Innovation Policy and the Economy 119 at 127 (The University of Chicago Press Journals).

[49] See Thomas Margoni, "The Roles of Material Transfer Agreements in Genetics Databases and Bio-Banks" in Giovanni Pascuzzi, Umberto Izzo & Matteo Macilotti, eds, *Comparative Issues in the Governance of Research Biobanks* (New York: Springer Heidelberg, 2013) at 236; Organisation for Economic Co-operation and Development, *Guidelines for the Licensing of Genetic Inventions* (2006), online (pdf): *OECD* <www.oecd-ilibrary.org/fr/science-and-technology/oecd-guidelines-for-the-licensing-of-genetic-inventions_9789264018273-en-fr?mlang=en> [perma.cc/BVB5-F6U2].

[50] See David C Mowery & Arvids A Ziedonis, "Academic Patents and Materials Transfer Agreements: Substitutes or Complements?" (2007) 32:3 J of Technology Transfer 157 at 161; Jane Kaye et al, "Data Sharing in Genomics-Re-shaping Scientific Practice" (2009) 10:5 Nature Reviews Genetics 331 at 332.

[51] Druedahl, *supra* note 5 at 6292.

[52] See Katharine Ku & James Henderson, "The MTA – Rip it Up and Start Again?" (2007) 25:7 Nature Biotechnology 721 at 721.

accompanied by an MTA, such as the standard form of South African MTA provided by the Minister of Health.[53]

A variety of information-sharing partnerships can exist between public and/or private entities who wish to exchange IP assets. Hybrid **public-private partnerships** (**PPPs**) are an increasingly popular model of collaboration being used to address global health challenges.[54] The public partners in these agreements are government-funded organizations such as universities, and private partners may be corporations, Non-governmental Organizations (NGOs), or philanthropic foundations.[55] The legal structures and style of information-sharing adopted by these PPPs are dependent on the parties' goals and values.[56] For example, a step-wise model of collaboration can be used that involves a single infusion of research products generated by Partner A into the second phase of innovation, by Partner B. Alternatively, a PPP may implement a fluid model of information exchange which occurs continuously between parallel research programs.[57]

The use of patent pools and other collaborative mechanisms of innovation provides an alternative to strict licensing strategies and promotes information sharing between different partners. A **patent pool** is created when multiple parties agree to grant usage rights to each other and to third parties in a fair and non-discriminatory manner.[58] The licenses obtained from the pooling process are more permissive than traditional patent licenses, with the goal of eliminating lengthy and expensive negotiations to expedite innovation. Patent pools can enhance innovation and competition by promoting the voluntary sharing of IP assets, improving the efficiency of developing goods and services, reducing transaction costs and

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[53] Donrich W Thaldar, Marietjie Botes & Annelize Nienaber, "South Africa's New Standard Material Transfer Agreement: Proposals for Improvement and Pointers for Implementation" (2020) 21:85 BMC Medical Ethics at 2, DOI: <10.1186/s12910-020-00526-x>.

[54] Anatole Krattiger, Thomas Bombelles & Ania Jedrusik, "Driving Innovation for Global Health through Multi-stakeholder Partnerships" in Margaret Chon, Pedro Roffe & Ahmed Abdel-Latif, eds, *The Cambridge Handbook of Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development*, (Online: Cambridge University Press, 2018) 47 at 47; *Report of UN SGAM*, *supra* note 4 at 14–15 (note that "public-private partnership" and "product development partnership" may be used interchangeably, Abbott, *supra* note 4 at 30–31).

[55] Tania Bubela, Garret A FitzGerald & E Richard Gold, "Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations" (2012) 4:122 Science Translational Medicine 338 at 338.

[56] Veronica Vecchi & Niccolò Cusumano, "Choosing the Right PPP Model" in Vecchi & Hellowell, eds, *Public Private Partnerships in Health: Improving Infrastructure and Technology* (Cham, Switzerland: Springer International Publishing, 2018) 15 at 15.

[57] Druedahl, *supra* note 5 at 6291.

[58] Esteban Burrone, "Patent Pooling in Public Health" in Margaret Chon, Pedro Roffe & Ahmed Abdel-Latif, eds, *The Cambridge Handbook of Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development*, (Online: Cambridge University Press, 2018) 93 at 94; Jorge L Contreras et al, "Pledging intellectual property for COVID-19" (2020) 38 Nat Biotechnol 1146.

reducing the need to seek alternatives to existing patents.[59] A patent pool may take the form of a PPP when an aggregation of private industry patents is created for the benefit of a public partner. This is the model employed by the UN-backed Medicines Patent Pool (MPP), which manages a collection of industrial patent licenses for the purpose of improving access to medicines in middle- and low-income countries.[60] The MPP provides publicly available sub-licenses for their pooled patents, which can be used by manufacturers in these regions to produce generic or new formulations in exchange for reasonable royalties.[61]

Open-Source platforms have proven to be effective tools for facilitating public access to IP in times of crisis. In response to the COVID-19 pandemic, a pool of IP rights was created by the Open Covid Pledge, founded by the Program on Information Justice and Intellectual Property at American University Washington College of Law.[62] The Pledge allows rights-holders to make their patents, copyrights and other IPRs available for unrestricted public use to support the fight against COVID-19.[63] IP can be added to the pool under royalty-free licenses that agree to grant all the rights necessary to make, have made, use, sell, import, reproduce, adapt, translate, distribute, perform, display, modify, create derivative works of and otherwise exploit all patent, copyright and other intellectual and industrial property rights until one year after the WHO declares an end to the pandemic, or until at least January 1, 2023.[64]

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[59] In May 2020, the WHO and other partner organizations launched the COVID-19 Technology Access Pool (C-TAP) to facilitate access to COVID-19 health products. This voluntary patent pool, signed on to by 40+ countries, aims to leverage collective research and incentivize international cooperation by reducing license-related transaction costs. Implementing partners of C-TAP include the Medicines Patent Pool (MPP), the Open COVID Pledge and the Tech Access Partnership (TAP). See WHO, "How WHO C-TAP Works? Commitments to share knowledge, intellectual property and data" (27 October 2020), online: *WHO* <www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap>.

[60] "About Us" (last visited 5 June 2022), online: *Medicines Patent Pool* <medicinespatentpool.org> [perma.cc/4UV2-BR7M].

[61] Burrone, *supra* note 30 at 97.

[62] "About Us" (last visited 10 June 2022), online: *Open Covid Pledge* <opencovidpledge.org/about/> [perma.cc/9SWL-EHRE].

[63] "About the Licenses" (last visited 10 June 2022), online: *Open Covid Pledge* <opencovidpledge.org/licenses/> [perma.cc/FVG7-AA83].

[64] Jorge Contreras, "The open COVID pledge: design, implementation and preliminary assessment of an intellectual property commons" (2021) 416 Utah Law Review, University of Utah College of Law Research Paper < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3780850>.

3.1.3 Intellectual property rights and the use of Indigenous knowledge of African communities during the research phase

Concepts of Indigenous knowledge such as traditional medicinal knowledge, folk songs or genetic resources that are closely associated with specific traditional communities in Africa, have been with us for time immemorial. It is difficult, if not impossible, to determine their specific origins of ownership, save for the fact that custodial communities are known. Indigenous or traditional knowledge, as well as traditional cultural expressions, are perceived as IP rights that has long ceased to have an attribution of ownership. It is, as such, knowledge in the public domain and free for all to use. However, to the custodial communities in which such knowledge springs from, the element of cultural heritage in such works is equally as important, if not more important, than the utilitarian aspects.

This section provides a breakdown of these key aspects, including defining the key terms; tracing the relationship between traditional knowledge (TK), traditional cultural expressions (TCEs), genetic resources (GRs) and IP rights; reviewing the relevance of customary law in the protection of TK, TCEs and GRs; examining the utilization of TK, TCEs and GRs through Access and Benefit Sharing (ABS) mechanisms; and, considering the documentation of TK, TCEs and GRs.

3.1.3.1 Defining key terms

There is no single universal or formal definition for the key terms used in this guideline. Nonetheless, the definitions provided hereunder can suffice to give a general understanding.

Traditional Knowledge (TK) or **Indigenous Knowledge** is a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. This can be, for example, agricultural, environmental or medicinal knowledge, or knowledge associated with genetic resources.[65] TK is knowledge that an Indigenous (local) community accumulates over generations of living in a particular environment.[66]

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[65] WIPO, "Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions" (2020) at 13–14, online (pdf): *WIPO* <www.wipo.int/edocs/pubdocs/en/wipo_pub_933_2020.pdf> [perma.cc/TFU5-SE5R] [WIPO, "Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions"].

[66] Graham Dutfield, "Protecting Traditional Knowledge and Folklore – A review of progress in diplomacy and policy formulation" (June 2003) at 22, online (pdf): *UNCTAD-ICTSD Project on IPRS and Sustainable Development* <unctad.org/en/PublicationsLibrary/ictsd2003ipd1_en.pdf> [perma.cc/W2TY-E2HG].

Traditional Cultural Expressions (TCEs) are also referred to as "folklore" and some nations prefer using the term "folklore" in their national laws. TCEs are the forms in which traditional culture is expressed. TCEs can be either tangible, intangible or a combination of both, and can include dances, songs, handicraft, designs, ceremonies, tales and other artistic or cultural expressions.[67]

Genetic Resources (GRs) associated with Traditional Knowledge refers to TK that provides guidance and insights as to the properties and potential applications of GRs and their preservation, maintenance and use.[68] Genetic resources are genetic material of actual or potential value. They involve material from any biological source, with the exception of humans, which contains genes or defined biochemical compounds that may be of use.[69] GRs associated with TK are those which manifest into traditional knowledge in instances where a technical input or know-how is employed prior to the use of the GR.[70]

Access and benefit-sharing (ABS) refers to the way in which GRs may be accessed and used, and how the benefits arising from utilization are shared between the people or countries using the resources and those that provide them.[71] Additionally, negotiations for ABS mechanisms in the exploitation of TK, GRs and TCEs should, and normally, include negotiations over Prior Informed Consent (PIC).[72]

3.1.3.2 Tracing the growing relationship of TK, GRs and IP rights

Indigenous and local communities have been demanding recognition and protection for their traditional forms of creativity and innovation. Under the conventional IP system, such creativity and innovation are considered to be in the public domain and thus free for anyone to use.[73] This is because it has been around since time immemorial and has no individual recognized owner. However, the custodial (Indigenous and local) communities are against the

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[67] WIPO, "Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions", *supra* note 37 at 15.
[68] WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 19.
[69] Examples include medicinal plants, agricultural crops and animal breeds. WIPO, "A Guide to Intellectual Property Issues in Access and Benefit-Sharing Agreements" (2018) at 17, online (pdf): *WIPO* <www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf> [perma.cc/XC7S-PAWT] [WIPO, "Issues in Access and Benefit-Sharing Agreements"].
[70] *Ibid*.
[71] *Ibid* at 17.
[72] "Prior Informed Consent" refers to explicit authorization that may be required before access to GRs and/or associated TK is granted, *ibid* at 20.
[73] See Ruth L. Okediji, "Traditional knowledge and the public domain" (2018) CIGI Papers No. 176, online < https://www.cigionline.org/publications/traditional-knowledge-and-public-domain/>; William Fisher, "Toward Global Protection for Traditional Knowledge" (2018) CIGI Papers No 198, online < https://www.cigionline.org/publications/toward-global-protection-traditional-knowledge/>.

categorization of their TK as 'public domain' because it only encourages unwanted misappropriation and devaluation of what they consider as their cultural heritage.[74] For example, a traditional remedy could be appropriated by a pharmaceutical company with the resulting invention being patented by that company.[75] Furthermore, third parties could come up with patents for inventions derived from GRs, which underlies the relationship between the patent system and the conservation and sustainable use of biodiversity as well as the equitable sharing of benefits. These scenarios are easily possible especially where the custodial community does not have the means or capacity to oppose the grant of patents or where, during patent prosecution, the patent examiner has no way of knowing that there is existing prior art through the TK/GRs that is related to the patent application.

Considering that elements of TK and GRs can be protected under the IP system, custodial communities need to begin evaluating strategies which will allow them to capitalize on IP protection for their indigenous cultural heritage.

3.1.3.3 Customary law and traditional knowledge

Customary laws are at the core of Indigenous and local communities as they make up the very identity of such communities. They define the rights, obligations and responsibilities of community members relating to major aspects of their lives. Customary law can be defined as a set of customs, practices and beliefs that are recognized and shared collectively by Indigenous peoples and local communities as obligatory rules of conduct.[76] Customary law normally contrasts with written law, which emanates from given authority such as the State and does not necessarily speak for the people.[77]

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[74] *Ibid.*

[75] *Ibid.*

[76] WIPO, "Customary Law and Traditional Knowledge: Background Brief No 7" (2016), online (pdf): *WIPO* <www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_7.pdf> [perma.cc/FF56-WX3U].

[77] Several factors of customary law must be considered in the use of customary law to enforce the rights of custodial communities regarding their TK and GRs:

(i) Customary law is a legal basis for a community's legal rights over TK and GRs.
(ii) It is an element in establishing the relationship between the TK and GRs and the community that is central to the concept of TK.
(iii) It is the means through which a community's 'prior informed consent' can be established through procedure.
(iv) It is the basis for specific user rights or exceptions through defensive or positive protection measures.
(v) It is a guide for assessment of cultural or spiritual offence or damage caused by inappropriate usage of TK.

In appreciating customary law, the guideline is prompting individuals to consider the issue of whether or not intellectual property regulation, which is part of written law, requires Indigenous cultural tradition to yield, in some respects, to the modern creative spirit. Thus, the use of the guideline must draw out situations or mechanisms under which customary law can be relied upon by an Indigenous or local community in order to assert its control rights over intangibles such as traditional medicinal methods that are of a sacred nature. Such mechanisms include free and prior informed consent and access and benefit-sharing mechanisms. Users of the guide must determine, with respect to customary law, what determines 'prior informed consent', as well as agree on contractual terms that devise the access and benefit-sharing mechanisms.

However, the use of customary law to protect local indigenous knowledge have both negative and positive attributes.[78] The negative attributes can be summarized as follow:

(i) Customary law is orally transmitted, while IP law is based on document-intensive, codified and governmentally administered structures and procedures.
(ii) TK in customary law has an element of secrecy, while patent applications in the case of IP require full disclosure of the invention.
(iii) IP protection is limited in time, while safeguards in customary law require transmission of knowledge through generations over time.
(iv) Customary law for Indigenous cultural property is difficult to define in the modern day and age.
(v) Stewardship is another challenge to identify who could speak for the Community when negotiating prior informed consent or access and benefit-sharing measures.

Furthermore, customary law can play an active role in protecting local indigenous knowledge. The positive attributes are summarized below:

(i) Customary laws on rituals or inheritance can help determine legal identity of a community as a TK rights holder.
(ii) Customary laws imposing an obligation of confidentiality may be effective in preventing disclosure beyond the traditional circle.

(vi) It is a means of determining appropriate remedies, sanctions or restitution following breach of rights over TK usage.
(vii) It can be an avenue for resolving disputes over ownership or other forms of custodianship over TK.
(viii) It is a guide for transmission of rights over TK from generation to generation.

[78] WIPO, "Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions", *supra* note 37.

(iii) Customary laws governing use of a sacred symbol or cultural expression may be drawn upon to prevent a third party from registering the symbol as a trademark.

(iv) Customary law can govern dispute resolutions between IP holders and TK custodians, reconciliation of competing claim and application of compensation and remedies.

A decisive factor in determining if certain customs have status as laws, and as such, if they are able to influence access to and utilization of TK and GRs by third parties, is whether such customs have been viewed by Indigenous peoples and local communities as having a binding effect, or whether they simply describe actual practices.

Deciding whether to acquire IP rights mainly depends on whether the benefits of IP protection will outweigh the cost of obtaining it. A helpful checklist to this effect is as follows[79]:

(i) What benefits might the acquisition and use of IP rights give to the holders of the genetic resources? For example, the San of South Africa were able to secure monetary and non-monetary benefits such as research, collaboration, and training from the South African Council for Scientific Industrial Research as part of an ABS over the use of the Hoodia Succulent Plant.[80]

(ii) What kind of output (e.g., products or processes) arising from the utilization of GRs have sufficient potential commercial value to justify the expense of seeking IP protection? For example, the extract of Pacific yew trees in the United States lead to the development of Taxol, the most well-known natural source cancer drug in the United States with annual sales in 2000 of $1.6 billion.[81]

(iii) Are these outputs prone to rapid change and development? For example, synthetic biology, new genome engineering and next generation sequencing are providing new insights on the potential use of GRs which could quickly make prior discoveries obsolete or commercially non-viable.

(iv) Should there be any exclusions from the use of IP rights in the initial phase? For example, some material transfer agreements oblige the user not to seek IP rights on the

[79] WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 22–25.
[80] *Intellectual Property Rights on Genetic Resources and the Fight Against Poverty*, Report, by Katriona McGlade et al, www.ecologic.eu, Report (European Parliament, Committee on Development, 2011) at 40.
[81] "Success Story: Taxol", online: <https://dtp.cancer.gov/timeline/flash/success_stories/s2_taxol.htm>.

transferred material or require further negotiation and agreement at the stage when basic research begins to deliver commercial results.

When negotiating, parties should consider results that could arise from the utilization of GRs and associated TK. Any probable IP implications in the context of the mutually agreed terms should also be considered, including the point of conclusion of the agreement, the granting of access to the GRs and the carrying out of R&D. Other possible aspects to be considered in this respect are as follows[82]:

(i) What conditions or restrictions should apply to those seeking and obtaining IP rights?
(ii) Who will be responsible (including financially) for filing/registering the IP right and its prosecution?
(iii) How should IP rights be owned, exercised, maintained and licensed?
(iv) What approach to obtaining, holding and exercising rights best promotes a mutually beneficial outcome and the equitable sharing of benefits from the permitted access and utilization?
(v) Who will be responsible for enforcing IP rights once they have been obtained?
(vi) In which countries should IP protection be sought?
(vii) What IP legislation is in place in those countries?
(viii) How early or late in the process should IP protection be applied for?
(ix) What measures should be taken to not disclose the invention before seeking patent protection?

R&D from utilization of GRs can result in several different IP rights. These include patents, trademarks, copyright and trade secrets. Each of these IP rights is protected differently, and therefore would require a unique set of considerations if parties decide to pursue that type of IP protection. These considerations are explored through the checklists below.

Patent-related issues to consider in ABS negotiations[83]:
(i) Patentability of R&D results • Can the results of the utilization of GRs and related information be subject to patent protection?

[82] *Ibid* at 25–26. WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 25–26.
[83] WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 32–33.

(ii) Jurisdictions for patent protection

- In view of key markets, strategic manufacturing locations or other considerations, in which countries might it make sense to obtain patents?

(iii) Ownership of patents

- Who will be the owner(s) of the resulting patent(s)?
- Will ownership depend on the value of the contribution of GRs and TK, the level of scientific contribution, or other factors?
- Will the patent be jointly owned by the provider and user, regardless of their contribution to the invention, or will the access provider retain ownership? (Consideration may need to be given to the demands of a sponsoring private organization or government body regarding the ownership and use of any patents arising out of the collaboration).
- In cases of joint ownership, how will responsibilities flowing from the co-ownership be apportioned? Who will be responsible for filing, maintaining and enforcing the patent, and where will the resources come from to carry out these activities?

(iv) Exploitation of patents

- What is the most appropriate model for the exploitation of the patent and for the use and dissemination of the new technology developed – for instance, a license, assignment or joint venture?
- Who will negotiate and agree to the terms of any subsequent arrangement to exploit the patent? For example, the parties themselves could negotiate licenses to commercialize the research outcomes, or a separate commercial or industrial partner could be brought in once the research outcomes are proven and/or the is patent granted.

(v) Sharing of benefits

- How, when and between whom will any monetary or non-monetary benefits arising from the commercial exploitation of the patent be apportioned?

(vi) Confidentiality

- What elements should be kept confidential to ensure that disclosure does not jeopardize the chances of obtaining patent protection?

Trademark-related issues to consider in ABS negotiations[84]:

(i) Authorization

- Does permission need to be sought to use a word or symbol and, if so, from whom and on what mutually agreed terms?
- What limitations, if any, should be imposed on the use of the trademark, for instance to reflect cultural concerns?

(ii) Ownership

- Who would own such a trademark?
- Who would be responsible for the cost of development, registration and upkeep of a trademark, including payment of renewal fees and enforcement?

(iii) Exploitation model

- Could the trademark be licensed or assigned?

(iv) Benefit-sharing

- How would any benefits arising from the use and licensing of the trademark be apportioned?

Copyright-related issues to consider in ABS negotiations[85]:

(i) Ownership

- Who owns the copyright in works that contain TK associated with GRs and other information about GRs?

(ii) Joint authorship

- In cases of joint authorship, how will responsibilities flowing from co-ownership of copyright be apportioned?
- Can copyright material produced from the collaboration be assigned or otherwise licensed to third parties? If so, on what terms?

(iii) Benefit-sharing

- How will any monetary and non-monetary benefits arising out of the publication of copyright works be shared?

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[84] WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 36.
[85] WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 40.

It is worth noting that many of the traditional health practitioners are facing challenges in protection of their practices e.g. the Hwlenganton Medical Clinic in Porto Novo, Benin uses a combination of traditional and modern medicinal approaches. Although the State recognizes traditional health practitioners, there is currently no formal means of protecting such TK. As such, the current practice is for the recipes used in the traditional medicinal knowledge to be *protected as family-owned trade secrets*.[86]

3.1.3.4 Exploiting and managing IP rights under ABS mechanisms

The acquisition of IP rights is not an end in itself. Individuals must think about appropriate mechanisms that can be exploited out of the acquired IP rights to ensure that the desired outcome is achieved for all parties concerned. The practical issues to be considered in this respect are as follows[87]:

(a) Non-commercial ABS agreements

If such agreements are for non-commercial purposes (e.g., academic purposes), the use of IP rights over GRs is excluded. A clause should be provided for in the agreement, on mutually agreed terms, to the effect that no IP rights may be sought without obtaining prior informed consent from the provider or custodial community. Such resources should be specifically described in the agreement to enable a court or arbitrator to identify what falls within the obligation.

(b) Commercial ABS agreements

Where the focus of access and utilization of GRs is ultimately for commercial gain, then the IP issues need to be addressed in detail with clear terms on the commercial utilization of the IP rights.

(c) Change of intent and/or transfer to third parties

There should be consideration for previously unplanned ideas, products or processes that may arise out of utilization of GRs for basic research. In such situations, a second agreement can be executed which addresses a change of intent involving product development and commercialization. This should factor into issues such as obtaining prior informed consent and the negotiation of new mutually agreed terms, inclusive of negotiating new terms over the IP rights. It is also important to consider future transfers

[86] *Ibid* at 43.

[87] WIPO, "Issues in Access and Benefit-Sharing Agreements", *supra* note 40 at 46–55.

of GRs to third parties, including ensuring that any third-party beneficiary is to be bound to the same IP obligations as the first user.

(d) Ownership and licensing of IP rights

Issues concerning ownership and licensing of IP rights, as well as responsibility for maintaining and exercising IP rights, should be carefully considered in ABS agreements.

Exploitation of IP rights drawn out of GRs can be expensive and commercially risky. As such, many users of GRs opt to license out such rights instead of using them themselves. A typical licensing agreement for the use of GRs can cover the following aspects:

- What is being licensed? This can be a process (e.g. a unique method of extracting a valuable ingredient from an indigenous plant) or a product (e.g. a unique seed variety).
- What type of license can be granted (e.g., exclusive, sole or non-exclusive)?
- What rights are granted and what restrictions are imposed or applicable (e.g. the right to produce a product arising from a GR, but not to use a trademark associated with the GR)? These may be research-related or for commercial purposes.
- What fees and payment agreements apply (e.g., lump-sum payments, royalties)?

3.1.3.5 Documentation of TK and GRs associated with TK[88]:

Documentation of TK and GRs is a useful tool as part of the mechanisms in the protection of TK. The objectives vary depending on the specific context, the interests at stake, and the needs and expectations of Indigenous and local communities as well as other stakeholders involved in the process.

The benefits in documentation of TK include the following:

- Monetary or in-kind benefits
- TK being organized and systematized (preserved) for future generations
- Collaboration and partnerships among a broad range of actors

[88] WIPO, "Documenting Traditional Knowledge – A Tool Kit" (2017) at 9, online (pdf): *WIPO* <www.wipo.int/edocs/pubdocs/en/wipo_pub_1049.pdf> [perma.cc/E24A-E3P8] [WIPO, "Documenting Traditional Knowledge"].

- Identification and broader social recognition of Indigenous peoples and local communities in relation to specific TK
- Capacity building and educational uses of databases or registers
- Defensive IP protection, i.e., scope to prevent the unjustifiable acquisition of IP rights over TK
- Positive IP protection for TK or products related to it.

Poor or complete disregard for documentation can lead to several risks, including:

- No monetary or in-kind benefits
- TK systematized in ways that are culturally foreign to Indigenous peoples and local communities, and disenfranchise them
- An informal process that does not consider prior informed consent and other relevant principles
- Indigenous peoples and local communities losing some control over their TK, especially undisclosed or secret TK
- Uses of TK that are difficult to monitor and may lead to misuse and misappropriation.

Contextual and situational TK documentation

TK documentation can take various forms depending on circumstances. Some examples that have been utilized in some communities include[89]:

- Writing down of medical preparations by the Shipibo communities in Peru, the Māori in New Zealand or the Maasai in Kenya and Tanzania
- Taking notes about herding traditions of the Tuareg peoples in the Sahel, North Africa
- Digitizing ancient manuscripts such as the Ayurvedic medical texts in India
- Photographing land and agro-forestry management activities of the Campas peoples of Brazil or medicinal practices of the Shuar in Ecuador
- Videotaping traditional agricultural practices and technologies of the Aymara people of Bolivia, or the Nahua in Mexico.

Other considerations in the documentation process:

(i) The legal framework

[89] WIPO, Documenting Traditional Knowledge, *supra* note 61.

The documentation process should consider the laws of the land. Not all States acknowledge or recognize the existence of particular Indigenous or local communities, and this can affect legal rights and utilization of GRs and TK drawn from such communities. Some African countries such as Kenya, Zambia, and South Africa have *sui generis* laws in place that provide for utilization of TK and GRs. Such laws may have stipulations on the documentation of TK and GRs that must be adhered to.

(ii) Customary laws and practices

Consideration must be given towards customary laws and practices and the determinations these have over documentation of their practices. This includes determination of whether and how TK can be obtained and shared avoiding abuse of sacred values, how it must be presented, in what form and by whom.

3.2 Ownership of intellectual property rights in the research results

The question of who owns IP rights in respect to the output of joint research is a vital issue that needs to be clearly agreed on and documented in the research contract at the inception of the collaboration. This is necessary to effectively manage collaborators' expectations and responsibilities as ownership has many associated rights and obligations.

First, the owner is vested with certain rights of exclusivity in respect of the protected output, which affords the opportunity for exclusive exploitation and windows to assign, license, or otherwise commercialize the research output. It should be noted, however, that ownership does not extend to background IP that is brought in by the collaborators individually or by the sponsor or funder, as this continues to be vested in the owners. Ownership only extends to foreground IP arising from the collaborative research. In the event that there is serendipitous IP, it shall be owned by the sponsor subject to any remuneration to other collaborators as specified by the terms of the research contract.

The benefit accruing to owners comes with the corresponding obligation that it is the prospective owner of foreground IP who, unless otherwise provided in the research contract, bears the responsibility of ensuring that the right, if registrable, is properly registered in a timely manner. Failure to do so may result in the right being forfeited, as the law of most jurisdictions encourage promptness in filing due to the "first to file" approach to the determination of the statutory inventor. Costs for registering, protecting and maintaining the IP are also borne by

the owner, and if the IP is co-owned, the costs may be equally shared, or shared proportionally, according to quantum of IP ownership. This is also a matter for the research contract.[90]

Several factors contribute to the determination of ownership. These include the status of the collaborating parties (e.g., whether they are employees and whether the research output is deemed to be made in the course of employment), the sponsor or funder of the research, the existence of an IP policy, employment contract or other agreement, express or implied, to assign or transfer ownership. Due diligence is vital in drawing up the contract to address potential areas of conflict. In drafting research agreements for collaborators, it may be necessary to provide for instances where members of the consortium who do not qualify as owners are nevertheless granted a license to use the work, on a non-exclusive basis.

Research outputs include publications and other literary or copyrightable works, as well as products and processes, which are protected by patents.

3.2.1 Ownership of works and publication

Publications are literary works and are protected by copyright. It should be noted that copyright in a work protects the particular expression of an idea, rather than the idea itself, provided the expression is original to the creator and has been fixed in a definite medium of expression from which it can be perceived, reproduced or otherwise communicated either directly or with the aid of any machine or device. Beyond publications, the categories of eligible works include creative works falling within the scope of literary, artistic and musical works, as well as entrepreneurial rights in sound recordings, cinematograph films and broadcasts. Copyright in these works confers exclusive rights to carry out certain activities, including the reproduction, publication, performance, translation, adaptation and other forms of use or exploitation of the protected work during the currency of the right. Qualified works automatically enjoy copyright protection the moment they are written down or otherwise fixed in a definite medium of expression. Thus, there is no need to register the right, although some copyright systems provide for some sort of notification or deposit scheme.

Publications include textbooks, reports, scientific articles, conference presentations, guidelines, and other literary expressions of the idea underlying the research activity. Also eligible for copyright protection are artistic or pictorial representations of the work through

[90] See generally WIPO, "WIPO Intellectual Property Policy Template for Universities and Research Institutions" (2019) at 14–15, online: *WIPO* <www.wipo.int/about-ip/en/universities_research/documents/ip_toolkit/policy_template.docx> (see Article 7.7).

maps, drawings and other artistic expressions, sound recordings, videos, films as well as broadcasts. The challenge lies in ensuring that the sharing of knowledge arising from research outcomes do not precede the filing of patent applications for inventions arising from the research in order to safeguard newness. Additionally, care must be exercised to ensure the publication does not violate any confidentiality obligations.

Typically, ownership of copyright may be acquired in different ways, notably through authorship, transfer or transmission of some or all of the different rights which make up copyright in a work. In certain limited circumstances, copyright may also vest in the employer of the author of a work, or in the case of a commissioned work, in the person who commissioned the work. Copyright in works made by or under the direction or control of the Government, a state authority or a prescribed international body shall vest in such government or body.

However, due to disparate legal approaches in different jurisdictions, it is important to agree on provisions to determine ownership of copyright in collaborative works involving researchers from different countries. For example, in Nigeria, the general rule under Section 10(1) of the Act is that copyright vests initially in the author, and this rule applies even where such author has been paid by someone else to create the work by way of commission or pursuant to a contract of employment.[91] Thus, according to Section 10(2) of the Act, where a work has been commissioned by a person who is not the author's employer under a contract of service or apprenticeship, or not having been so commissioned, is made in the course of the author's employment, copyright shall belong in the first instance to the author.[92] This provision conferring ownership rights in employee works on the employee rather than the employer constitutes a radical departure from the position in other jurisdictions where commissioned works and employee works (works for hire) vest in the employer or the person who commissioned the work, subject to any agreement between the parties.

It is important to ascertain the provisions of employment contracts, institutional policies and other relevant documents pertaining to the status of participants to ensure that there are no conflicts. Another option is to include a warranty to that effect in the research collaboration agreement, which all parties sign, alongside an obligation of indemnity. Parties may also sign a waiver or a release Agreement, by virtue of which all rights in the copyright work created

[91] Copyright Act (Cap 28, Laws of the Federation of Nigeria) 2004.
[92] *Ibid.*

pursuant to a commission are released, relinquished and/or deemed to be vested in the person designated in the release (usually the commissioner of the work).

Authorship is central to the ownership of copyright and it is therefore important to ascertain who the author of a given work is. Determination of authorship is also important because the qualification for copyright protection may hinge on the status of the author as a citizen or otherwise under the law, although provisions in international agreements regarding reciprocal treatment have minimized the effects of these provisions. Furthermore, the duration of copyright protection is sometimes determined by reference to the date of the author's death, while certain moral, perpetual and inalienable rights are vested exclusively in the author of a work.

The question of who an author is, to a large extent, linked with the intellectual effort, labour and skill involved in creating a work. Regarding publications as literary works, the term 'author' refers to the creator of a work. 'Creator' in the context contemplates input into the original expression which gives rise to the work. Thus, the author of a literary work is the person who expends effort, in terms of input of labour, judgment and skill in creating the particular expression that constitutes a work, rather than a mere contributor of ideas. Expression here encompasses the language and choice of words as well as their sequence or construction. Furthermore, a person does not qualify as an author or creator if the contribution or input of such person is purely of a mechanical character, such as that of an amanuensis or shorthand typist who, though may be responsible for fixation of the work, is not the originator of the form of expression of the work. The agreement may however stipulate additional bases for authorship and hence ownership of copyright, including employment, financial input or responsibility.

In collaborative research where a work is created by more than one author, such a work may qualify as a work of "joint authorship". These are works produced by the collaboration of two or more authors, in which the contribution of each author is inseparable from the contribution of the other author or authors and written in furtherance of a joint or common design. Also, the parties must be 'authors' in the sense that each is a creator who has contributed effort, skill or labour to the particular expression or form which makes up the work. The contribution of ideas, directions or information do not ordinarily suffice, although this depends on the circumstances. There is no requirement that the contributions of each author must be equal in quantity or

quality. It suffices that the contribution be significant, original and contributed to the creation or outcome of the publication.

Additionally, joint authorship where collaborators share a joint interest in the whole or any part of a copyright, is distinguishable from co-authorship, where the authors have interests in the various copyrights in a composite or collective production consisting of two or more works (e.g., distinct chapters or sections of a book). Typically, collaborators are co-owners, and an assignment or license granted by one copyright owner shall have effect as if granted by his co-owner also, although this is subject to any contrary agreement, as is the position regarding sharing of royalties or other remuneration. Here again, the default rule is that the contributors take in equal shares.

3.2.2 Inventorship and ownership of patents

Patents protect inventions, that is, products or processes which are sufficiently new, inventive and industrially applicable. An invention comprising a new drug, vaccine, diagnostic, equipment or other product or process which results from research collaboration may be patented where it satisfies the tripartite requirements and provided it does not otherwise fall within the scope of subject matter excluded from patentability.

Where the output from inventive activity is sought to be patented, the right to the patent is vested in the statutory inventor, that is, the first person to file or to validly claim foreign priority for a patent application in respect of the invention. The inventor is entitled to be named as such in the patent, whether or not he is also the statutory inventor filing for the patent. Thus, even where there is an agreement by an inventor under which he assigns or otherwise transfers the right to patent to another, such inventor still retains a right to be named in the application. The statutory inventor, that is, the person in whose name the patent is filed, automatically becomes the first owner of patent rights.

The law provides for the possibility of joint ownership of patent rights, in which case each named inventor is presumed to hold an interest in the patent, and in the absence of a contrary agreement, the rights will be deemed to be held in equal proportions. Thus, research collaborators, to the extent that they are involved in contributing inventive activity towards the making of an invention, may apply jointly for patent rights. The right to be named as an inventor does not, however, extend to persons who have merely assisted in doing mechanical, administrative or other work connected with the development of an invention without having contributed any inventive activity. Owners are vested with rights of exploitation, including the

right to separately transfer or assign their shares, manufacture directly or through joint ventures and other modes. A license, however, must be jointly granted.

A further consideration is that which relates to employee inventors and commissioned research. In this situation, patent ownership vests in the employer or the entity that commissioned the research. In the context of joint research, the sponsoring organization will therefore be the owner of the patent, and if sponsorship is by more than one entity, they may apply as joint owners, subject to any contrary agreement. The agreed terms regarding ownership need to be considered by all collaborators vis-à-vis employment terms, institutional IP policies and other obligations affecting the status of collaborators to ensure that any possibility of conflict is clarified. However, this arrangement pertaining to vesting of patent ownership rights in sponsors does not preclude the extension of pecuniary and other benefits to other collaborators in line with the profit-sharing arrangement, nor does it preclude the naming of the inventors.

3.2.3 IP policies in research institutions – the interrelationship between intellectual property law, IP strategies and IP policies in research institutions

It is integral for research institutions to have IP strategies and IP policies in place that guide the utilization and commercialization of IP generated from such institutions. The strategies and policies are guided by the existing IP legal frameworks within the country where the research institution is based because IP is territorial in nature and in order to receive protection there must be IP legislation in place that offers such protection. Therefore, as a research institution draws up its policy, it must ensure that such policy is in line with and customized to fit within the existing IP legislation.

The IP strategy of the research institution follows the mission of the institution, while the IP policy should be used to reinforce the strategy being pursued.[93] Thus, an IP policy is an element of an IP strategy. An IP policy encompasses the basic IP rules that the institution follows in handling its IP and is meant to ensure consistency and effectiveness in the process of recording, evaluating and protecting the institutional IP.[94]

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[93] Anatole Krattiger & Stanley P Kowalski, "Unit 5 – IP Policy and Strategy: Context and Implementation" online < https://storage.ning.com/topology/rest/1.0/file/get/8417462870?profile=original>.

[94] WIPO, *IP Asset Management Course DL450E Module VII: Strategy for Intellectual Property Management*, Distance Learning Program (WIPO, 2022) at 11, online: <welc.wipo.int/acc/index.jsf?page=courseCatalog.xhtml&lang=en&cc=DL450E#plus_DL450E> [perma.cc/3PNF-G289].

Structure of an institutional IP policy

An institutional IP policy should be able to define IP ownership and explain the rules applicable to independent contractors. The reporting of newly created IP rights by employees should also be provided for as well as procedures for IP filings and maintenance and institutional handling of confidential information for the protection of trade secrets. The IP policy serves the purpose of setting out the commercialization principles of the institution, requiring the policy to explain how income generated from the IP will be distributed in a benefit-sharing clause. It must also outline how to handle the rights and obligations of inventors vis-à-vis the institution, as well as any rights retained by the institution (e.g., a royalty-free perpetual license for research and humanitarian purposes). The policy must also provide for enforcement of IP rights and employee responsibilities in such regard.

A generic breakdown of an IP policy structure for a research institution should generally include the following[95]:

1. **Preface**

This should reflect the research institution's mission, vision and values and explain how the objective of commercializing the IP fits within these institutional principles. The preface should also give a brief description as to the genesis of the desire for an IP policy by the institution and the goal of the policy.

2. **Definitions**

Defining key terms is meant to enable the IP policy to be correctly interpreted and applied by stakeholders. They should be brief, clear and precise. They should be reflective of giving an understanding of the most commonly used terms in the implementation of the IP policy.

3. **Scope**

The scope of the policy addresses the various stakeholders that are to be affected by the policy, including staff members, students and visitors. It also covers the type of IP within the institution's jurisdiction, ensuring it is legally binding and in conformity with the IP law.

[95] See WIPO, "Guidelines for Customization of the WIPO Intellectual Property Policy Template for Universities and Research Institutions" (29 January 2019), online: *WIPO* <www.wipo.int/about-ip/en/universities_research/documents/ip_toolkit/guidelines_template.docx>.

4. Governance and operation

An important consideration to follow is incorporating a two-tiered structural approach in governing and implementing the IP policy. First, an IP Governance or IP Committee which is responsible for policy creation and overarching strategic guidance. Second, an IP Operations or IP Management Office whose domain is the day-to-day management and transactions involving the institutional IP. Both offices, although operating semi-independently, should fall under a higher-ranked designated officer of the institution.

5. Ownership of IP and rights of use

This segment of the IP policy should be guided by a number of factors in determining the ownership of IP generated within the research institution:

a) National IP legislation – the policy should comply with national legislation on institutional ownership of IP.

b) Established or best practices – the policy can give consideration to established practices of the institution, standards and traditions amongst similar institutions locally, and international best practices.

c) Outline of circumstances under which the IP should be owned by the research institution – the objective is to guarantee access to the institution's IP and research and maximize the economic and societal benefits that may result. Such circumstances should address how the institution is allowed to maximize benefits where the IP has been created by its staff members, students or visitors. Other matters that should be considered are moral rights as well as release of the IP into the public domain.

6. Publication, non-disclosure and trade secrets

This segment should address the researchers' ability to publish their research findings while at the same time balancing this right with the concerns of the sponsors on matters of confidentiality or loss of IP rights due to exposure of information to the public. The policy should address premature disclosure of research findings to third parties and outline factors that can help determine whether to take the direction of owning the institutional IP as a trade secret or as a patent.

7. Research Contracts

The IP policy should be specific as to who signs contracts on behalf of the research institution. It should include that any person who signs a contract without the designated authority renders the contract null and void and therefore deemed not to have been executed.

8. Determinations by the IP Management Office

The IP policy must provide for proper documentation of all research results. This helps the IP Management Office in decision making and assists the office in the drafting of all necessary IP applications for grant of patent rights, trademarks and acquisition of other IPRs. The documentation is also necessary for IP auditing of the institution, entering commercial transactions such as licensing or assignment of IPRs, and following up on claims of infringement or disputes as to IP ownership, either internally or externally.

9. Commercialization of IP

The IP policy should generate strategies for commercialization of the institution's IP. Such strategies can include licensing, establishing joint venture companies with third parties, establishing faculty-led or student-led start-ups or spin-off companies, or assignment of IP.

10. Incentives and distribution of revenues

The IP policy must provide for a rewards system that can effectively guarantee a continuous turn-around of knowledge transfer. Such incentives can be guided by a legislative framework, if any such provisions are legally catered for. This should include incentives such as revenue sharing and benefit-sharing, entrepreneurship support, moral prestige and recognition, access to equity or shares in a spin-off company, as well as career development-related benefits.

11. IP portfolio maintenance

The IP policy should include provisions for ways in which the research institute can keep monitoring the utilization of the institution's IP to ensure that it serves the institution's interests and strategies. The methodologies for checking up on the institutional IP in this regard are covered through recording, monitoring and evaluation.

12. Traditional knowledge (TK) and genetic resources (GRs)

Applicable IP laws or *sui generis* laws with specific provisions for access and benefit-sharing related to TK and GRs should be of assistance in structuring how the IP policy can address this topic. Where legislation is absent, contractual undertakings can be of guidance, but must be streamlined in such a way that they reflect an agreement on preservation of cultural rights of Indigenous communities, guarantee prior and informed consent, as well as benefit-sharing with custodial Indigenous communities before the institution can conduct IP-generating research involving TK and GRs.

13. Conflicts of interest and conflicts of commitment

Staff members of research institutes are likely to engage in more research collaborations or interactions with industry or corporate entities due to the nature of their work, which can give rise to potential conflicts of interest. The IP policy must therefore have guidelines in place to assist parties in navigating around potential conflicts of interest when operating in overlapping engagements with other parties.

14. Dispute resolution

Overly aggressive enforcement of institutional IP should be discouraged as it could turn away staff members and other stakeholders in the IP generation processes. The policy should therefore provide clear and consistent provisions on resolution of disputes related to the creation and management of its IP through alternative dispute resolution mechanisms that enable the parties to resolve their differences and continue working together.

15. Amendment

No policy is marked in stone, but each stakeholder that is to be affected by it needs to consent to any alterations to be made to the policy in a transparent manner. The policy needs to contain provisions on amendment of clauses to provide comfort to the signatories that they are able to amend any clause they consider worth amending.

4. INTELLECTUAL PROPERTY RIGHTS AND RESEARCH OUTCOMES

Intellectual property (IP) rights play a crucial role in the transfer and the commercialisation of knowledge. There are many ways in which owners of IP rights can commercialize and allow for exploitation of their IP rights at the end of the research phase.

Commercial rights to the arising intangible assets are negotiated by the parties and can vary depending on the nature of the collaboration and the contributions of the parties. Consequently, some of the key IP provisions in these agreements relate to the IP produced through the research, rather than the rights to existing inventions or innovations. These key provisions ensure that there is clarity when it comes to the ownership of new IP that arises from or is developed during joint collaborative efforts.

4.1 Mechanisms for IP rights exploitation and Commercialization

Commercialization is the process of utilizing the economic rights to secure the financial benefits from innovation or IP assets.[96] Commercialization may be done by an individual, an informal business enterprise, a corporation, an organization or a state agency alone or by collaborating with other parties.

This guideline provides at least five ways in which IP rights can be commercialized or exploited in joint and collaborative research.

4.1.1 Licensing of Intellectual Property Rights in Africa

Inventions and/or creations confer certain benefits to the inventor or creator, even in the context of a pandemic or epidemic. These benefits refer to the rights that the creator or the inventor holds. Through IP rights, the inventor or creator is granted an exclusive right over the invention, that is, no one else is allowed to use the IP rights without the permission of the inventor or creator. It is noteworthy that these rights can either occur automatically, as is the case for copyright or trade secrets, or upon registration of the invention or creation, as in the case of patents or utility models. Further, upon registration, the IP rights owner shall be granted a document to represent ownership, which is crucial in licensing.

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[96] Ben Sihanya, "Commercialization, Securitization, and Taxation of Intellectual Property in Kenya and Africa" in Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials*, (Nairobi: Sihanya Mentoring & Innovative Lawyering, forthcoming 2022) at ch 29 [Sihanya, "Commercialization, Securitization, and Taxation"].

Licensing is one of the core mechanisms through which IP assets can be utilized, exploited or commercialized by IP rights holders to third parties. Licensing, assignment, and franchising are included in the exclusive rights held by the rights holders. A license is permission to do something that would otherwise be unlawful. A license for IP is a contractual commitment to allow commercialization or other forms of exploitation. The licensor grants rights to the licensee to use the IP without transferring its ownership, in exchange for monetary compensation, services, equity in a company or other consideration. The license may also be oral or implied from the conduct of the parties to a transaction involving IP assets or innovation. Writing and registration of licenses is the best strategy to ensure certainty.

There are two broad forms of licensing: voluntary or consensual licensing, and involuntary or compulsory licensing and government use. In contractual licensing, the licensor and licensee agree to the terms of the license. Compulsory licensing or government use occurs when a government agency authorizes a third party to exploit the license.

Licensing can also be conceptualized or defined based on the level of exclusivity provided to the licensee to sole, exclusive, or non-exclusive license.

Sole licensing occurs where there is only one licensee. The sole license, like all other licenses, may be oral or evidenced in writing. In the case of a sole license, the licensor may or may not compete with the licensee. The licensee is not authorized to sub-license the IP rights granted. On the other hand, **exclusive licensing** occurs where no one else is permitted to compete with the licensee, not even the licensor. The licensor cannot grant additional licenses to other third parties or use the IP themselves. The third type is the **non-exclusive license** which allows the licensor to continue exploiting the IP and granting additional licenses to other parties. Licensees will have to compete amongst each other and with the licensor in the use of the licensed IP.

Compulsory licenses are very important in the health and pharmaceutical industries, especially in developing African countries, such as Kenya, South Africa, Nigeria, Ghana, Uganda, and

Tanzania, because major pharmaceutical companies have had the tendency to file good,[97] bad,[98] and poor[99] patent applications.

Most African states suffer from insufficient interest, government support, and necessary pharmaceutical manufacturing capacity for effective use of compulsory licensing. Apart from Egypt and South Africa, most African countries do not have the pharmaceutical manufacturing capacity to utilize active ingredients and related research.[100] This poses a major challenge to African states where a patent has been filed as it curtails or bars the development or manufacturing of generic drugs. This in turn contributes to the high cost of such drugs as the big pharmaceutical companies ("big pharma") have monopolistic or oligopolistic control over the production and distribution of the drugs, thus making them inaccessible to poor and needy people in African states who need the drugs most.[101]

An example of this dilemma is the HIV/AIDS epidemic or pandemic that has affected most African countries. People suffering from HIV/AIDS are dependent on antiretroviral drugs (ARVs) where 80% of the medicines necessary for treatment are imported from outside Africa."[102]

The COVID-19 pandemic has exposed the need for African governments to increase their involvement and offer the necessary support for R&D and IP to the pharmaceutical industry to increase the ability to develop a vaccine against the novel coronavirus which has led to many deaths in African countries.[103]

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[97] Good patents are those patents that are scientifically, technologically, and technically sound or viable.

[98] Bad patents or poor patents are patents that are poorly written so that it is impossible to understand what it protects... See Paul Morinville & Gene Quinn, "Is a 'bad patent' really that bad?" (30 January 2018, last visited 16 July 2020), online: *IP Watchdog* <www.ipwatchdog.com/2018/01/30/is-a-bad-patent-really-that-bad/id=92966/>.

[99] *Ibid*.

[100] Olasupo Ayodeji Owoeyea, "Compulsory patent licensing and local drug manufacturing capacity in Africa" (2014) *Bulletin of the World Health Organization* 92((3:at 214–219, DOI <10.2471/BLT.13.128413>.

[101] *Cf* Mercy King'ori, "Intellectual property rights in pandemics: The case of the novel corona virus in developing countries" (6 April 2020, last visited 16 July 2020), online: *Strathmore University Centre for Intellectual Property and Information Technology Law* <cipit.strathmore.edu/intellectual-property-rights-in-pandemics-the-case-of-the-novel-corona-virus-in-developing-countries/>.

[102] Owoeye, *supra* note 12.

[103] "Africa response to COVID-19: What roles for trade, manufacturing, and intellectual property?" (23 June 2020, last visited 5 August 2020), online: *Organisation for Economic Co-operation and Development* www.oecd.org/coronavirus/policy-responses/africa-s-response-to-covid-19-what-roles-for-trade-manufacturing-and-intellectual-property-73d0dfaf/; Reuters, "South Africa roll out continent's first trials for COVID-19 vaccine" (24 June 2020, last visited 16 July 2020), online: *The Standard* <www.standardmedia.co.ke/article/2001376389/south-africa-rolls-out-continent-s-first-trials-for-covid-19-vaccine>; Jonathan Kamoga, "Uganda registers 87pc Covid-19 recoveries, no deaths" (24 June 2020, last visited

Relatedly, some of the African legislation governing Traditional Knowledge (TK) and Traditional Cultural Expressions (TCE) expressly provide for the application of compulsory licensing in TK and TCE. This includes the problematic Section 12 of the Kenyan Protection of Traditional Knowledge and Cultural Expressions Act, No. 33 of 2016. This section provides for at least two instances where the relevant Cabinet Secretary can grant compulsory licensing for protected traditional knowledge. The first instance is where the TK is not sufficiently exploited, and the second instance is where the rights holder does not grant licenses for the exploitation of the TK. Generally, such compulsory licensing must be subject to prior informed consent with adequate compensation to the rights holders.

Compulsory licensing for the non-exploitation of traditional knowledge is also provided for in the Swakopmund Protocol of the African Regional Intellectual Property Organisation on the Protection of Traditional Knowledge and Expressions of Folklore. Section 12 of the Swakopmund Protocol states:

> "*Where protected traditional knowledge is not being sufficiently exploited by the rights holder, or where the holder of rights in traditional knowledge refuses to grant licenses subject to reasonable commercial terms and conditions, a Contracting State may, in the interests of public security or public health, grant a compulsory license in order to fulfil national needs.*"[104]

Section 8 of the Swakopmund Protocol allows owners of TK to license their rights and conclude licensing agreements.[105] Furthermore, rights holders may also grant access to IP rights in exchange for royalty payments, especially on humanitarian grounds as discussed in the next section.

4.1.2 Royalty free access of intellectual property rights on humanitarian grounds

The pledging of IP rights occurs where the owner of the IP assets grants his or her rights to a third party to use or misuse accordingly, as long as the intended purpose for the exploitation of

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16 July 2020), online: *EastAfrican* <www.the-eastafrican.co.ke/news/ea/Uganda-Covid-recoveries/4552908-5581812-68mul0/index.html>; Nation Team, "Kenya COVID-19 cases hit 11 252 as 51 leave hospital" (15 July 2020, last visited 16 July 2020), online: *Nation* <nation.africa/kenya/news/kenya-covid-19-cases-hit-11-252-as-51-leave-hospitals-1798470>.

[104] *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore*, ARIPO, 9 August 2010, s 12.1.

[105] *Ibid*, s 8.

these rights is non-commercial or non-profit.[106] Some biotech or pharmaceutical firms, such as Moderna, a US-based producer of mRNA vaccines, granted patent pledges restricted to use and access only during the COVID-19 period. Moderna would then renegotiate for fee payments for the licensing of its vaccine.[107]

As discussed above and below, the COVID-19 pandemic has created a race for diagnostics, therapies and vaccines. AbbVie, a US pharmaceutical company, has dropped its rights for its patented drug, "Kaletra antiviral drug", allowing third parties to use the drug to find a cure for the novel coronavirus.[108]

The owner of IP rights can grant these rights to a third party by way of a license, making the IP owner the licensor and the third party the licensee. Usually when the owner of the IP grants the third-party permission to use these rights in an agreed-upon manner, the third party compensates the IP owner by way of royalty or related payments. Royalties are a form of taxable income charged for the use of one's (intellectual) property. In their most common form, royalties represent a percentage of profits raised from the use of IP rights.

Boehringer Ingelheim, a German-based pharmaceutical company, reportedly granted a free-license of patents of an HIV drug to Aspen Pharmacare, a South African pharmaceutical manufacturing company.[109] This free-license allows Aspen Pharmacare to produce and distribute the HIV drug in South Africa as well as in 13 other countries of the South African Development Community (SADC) at an affordable price. For Boehringer Ingelheim, this voluntary free-license marks a step towards its commitment to fighting HIV.[110]

Boehringer Ingelheim and other pharmaceutical firms have realized the need to pool resources to provide medical treatment to the poorest regions of Africa and the world.[111] In 2009, GlaxoSmithKline reportedly granted free licenses to more than 800 patents on tropical diseases

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[106] Joe Tidd, *Exploiting Intellectual Property to Promote Innovation and Create Value* (London, UK: World Scientific Publishing, 2017) at 370.

[107] Jorge L Contreras, "Deconstructing Moderna's COVID-19 Patent Pledge" (21 October 2020, last visited 17 June 2022), online: *Harvard Law Bill of Health* <blog.petrieflom.law.harvard.edu/2020/10/21/moderna-covid19-patent-pledge/>.

[108] Kaletra is one of the drugs identified as a potential treatment for COVID-19. See Maija Palmer & Donato Mancini, "Coronavirus puts Big Pharma's IP regime to the test" (20 April 2020, last visited 17 July 2020), online: *Financial Times* <www.ft.com/content/5a364eb0-780c-11ea-bd25-7fd923850377>.

[109] William Fisher & Cyril Rigamonti, "The South Africa AIDS Controversy: A Case Study in Patent Law and Policy" (10 February 2005, last visited 17 July 2020), online (pdf): *Harvard Law School* <cyber.harvard.edu/people/tfisher/South%20Africa.pdf>.

[110] *Ibid.*

[111] Nicole Ziegler, Oliver Gassmann & Sascha Friesike, "Why do firms give away their patents for free?" (2014) 37 World Patent Information 19, DOI: <10.1016/j.wpi.2013.12.002>.

to patent firms to enable them to realize their social responsibility by promoting access and affordability of medical treatment, especially in developing countries.[112]

The section below discusses assignment as an alternative mechanism through which intellectual property rights can be commercialized in collaborative research.

4.1.3 Assignment of intellectual property rights in Africa

An assignment is an agreement whereby the assignee replaces the assignor for the relevant intents and purposes with respect to all or specified IP rights. Unlike a license, wherein a licensor retains an interest in the property licensed, an assignment involves the full transfer of ownership of IP rights from an assignor to an assignee. The assignment should specify at least three matters. First, the scope of the rights assigned (the conceptual market). Second, the specific geographical market. And third, a specific duration.[113] Some assignments are similar to some licenses. ARIPO's Swakopmund Protocol under Section 8 provides that "owners" of TK have the right to assign their rights and conclude licensing agreements.[114]

Most African countries have also included clauses and provisions on assignment in their national legislation and regulations. Section 30(4) of Kenya's Industrial Property Act, 2001 grants the owner of a patent the right to assign or transfer it to a third party.[115] Similarly, the South African Patent Act No. 57 of 1978 provides for assignment of patent rights under its Chapter IX. Section 59 of the Act provides for the assignment and devolution of patents by operation of law[116] while Section 60 provides for assignment, attachment and hypothecation of patents or application for a patent.[117] The Nigerian Patent and Designs Act 1970 provides for assignment of patent rights under Section 24.[118]

Assignments of IP rights can be done either via licensing, sale or transfer (i.e., with or without direct financial compensation).[119] The next section discusses joint ventures as a way of commercialization of intellectual property rights through joint or collaborative research.

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[112] Ziegler, *supra* note 111.
[113] Sihanya, "Commercialization, Securitization, and Taxation", *supra* note 96.
[114] *Supra* note 104, s 8.
[115] *Industrial Property Act 2001* (Kenya), revised 2020, s 30(4).
[116] *Patent Act* (S Afr), No 57 of 1978, s 59.
[117] *Ibid*, s 60. Hypothecation means granting security rights (includes a pledge or bond) over a patent as a collateral in order to obtain a debt under section 60(5) of the South African Patent Act, 1978.
[118] *Patents and Designs Act 1970* (Nigeria), s 24.
[119] United Nations Economic Commission for Europe, *Intellectual Property Commercialization: Policy Options and Practical Instruments* (Geneva: United Nations, 2011).

4.1.4 Joint venture, partnership, venture capital, and special purpose vehicle

A joint venture is an arrangement between two or more individuals, parties, businesses or organizations who pool their resources together with the aim of accomplishing a specific objective, which also applies to situations of IP assets, innovation and technology transfer.[120]

Novartis Pharma AG and Bayer Schering AG entered a joint venture agreement to collaborate in the development of of PTK/ZK, an oral angiogenesis inhibitor used to slow the spread and growth of tumours.[121] Furthermore, the Kenyan Ministry of Health partnered with Amref Health Africa and AstraZeneca to promote mobile vaccination against COVID-19. The project was aimed at enhancing vaccine access and uptake in Kenya.[122]

Venture capital is a private equity and financing mechanism where an investor provides funding to start-ups or small- and medium-sized enterprises (SMEs) and businesses with the potential for long-term growth. In exchange, the investor receives equity or an ownership stake in the business or organization.[123] For example, companies enter such ventures or alliances for purposes of protecting their investment or innovation from political or economic risk.[124] Governments may be interested in production or distribution or simply rent seeking or primitive accumulation.

A strategic alliance (SA) is collaboration between two or more parties, businesses or organizations who become interdependent by entering into a formal or informal agreement which is built on a platform of mutual objectives, strategy, risk, and reward.[125] Relatedly, a special purpose vehicle (SPV) is an entity established with its main responsibility being to issue

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[120] A good illustration is the joint venture between Kenya Airways, Royal Dutch Airlines and Martin air which established Ken-Cargo. Other examples include the 4G network venture between the government and mobile network operators and Mpesa, which is a joint venture between Safaricom and Vodafone. Other notable ones include those between African governments and relevant companies. See Jackie Taylor, "Drafting Intellectual Property Joint Venture Agreements with an Eye Toward Termination" (2004) 4 Pittsburgh Journal of Technology Law and Policy, DOI: <10.5195/tlp.2004.10>.

[121] "Novartis (NVS): Some Examples of Joint Ventures, Partnerships, and Alliances" (29 August 2007, last visited 1 July 2020), online: *Knowledge Ecology International* <www.keionline.org/book/novartis-nvs-some-examples-of-joint-ventures-partnerships-and-alliances>.

[122] Amref, "Amref and AstraZeneca launch mobile clinics to support last mile COVID-19 vaccination efforts in Kenya" (27 June 2022, last visited 5 August 2022) online: *Amref* <amref.org/news/amref-and-astrazeneca-launch-mobile-clinics-to-support-last-mile-covid-19-vaccination-efforts-in-kenya/>.

[123] Andrew Sherman, "How Venture Funds can work for you" (1990) 79:5 Management Review 44–48.

[124] Kenyan company law has dubious provisions on strategic allegiances, joint ventures and mergers, hence the debate that the Copyright Act be reviewed to capture IP and ToT issues. It was a revision of the Restrictive Trade Practices, Monopolies, Price Control Act, 1988 to be reviewed. Most companies enter strategic allegiances to circumvent the provision on mergers and acquisitions. *Cf Competition Act 2010* (Kenya).

[125] *Ibid*.

bonds and pay interest and principal to investors. They are usually created for the sole purpose of acquiring certain assets or derivative exposures and issuing liabilities that are thereby linked solely to those assets or exposures.[126] There is little difference between the type of arrangement in the health sector (i.e., whether it is a partnership, JV, SA, or SPV), and it is the terms of engagement that matter more than the label.

4.1.5 Access Benefit-Sharing Agreements in Africa

Access benefit-sharing (ABS) agreements are another mechanism for the exploitation and commercialization of IP rights. ABS agreements provide guidelines or structures on how genetic resources may be accessed and used, and how the benefits arising from such utilization are shared among the parties, organizations, states or subnational units using the resources (as "users") and the people or countries that provide them.

ABS agreements can be divided into two categories. The first category consists of commercial ABS agreements where a user seeks access to utilize genetic resources for applied research for commercial purposes. The second category consists of non-commercial ABS agreements where the user seeks utilization of genetic resources for non-commercial purposes which normally exclude the use of IP rights over genetic resources.

In 2019, the KhoiKhoi and San communities entered an ABS agreement with the South African rooibos industry.[127] This agreement recognized the KhoiKhoi and the San as the traditional knowledge right holders of rooibos, an indigenous plant species that is found in the Cederberg region of South Africa. This agreement means that the KhoiKhoi and the San will have access to benefits as a percentage contribution from the commercialization of rooibos by the South African rooibos industry.[128]

ABS agreements are supported by the Convention of Biological Diversity (CBD) 1992, the Nagoya Protocol, the International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA) 2001, and the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore in Africa.[129] Some African states have enacted

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[126] David Ruder, *Strategies for Investing in Intellectual Property: Intangible Valuations, Real Returns* (Washington, DC: Beard Books, 2008) at 111.

[127] Rachel Wynberg, "San and Khoi claim benefits from rooibos" (19 November 2019, last visited 17 July 2020), online: *University of Cape Town* <www.news.uct.ac.za/article/-2019-11-18-san-and-khoi-claim-benefits-from-rooibos>. Rooibos is a widely renowned variety of tea.

[128] *Ibid.*

[129] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity 2010. It was a protocol to the Convention on Biological Diversity, 1992.

relevant policies, legislation, rules, and regulations. Kenya, South Africa, Lesotho, Angola, Rwanda, Chad, Burkina Faso and Burundi have ratified the CBD, but countries like Nigeria, Egypt, Botswana, Libya and Gabon had not ratified the CBD as of May 1994.[130]

Article 15 of the CBD outlines a set of ABS principles. The first principle is that access to genetic resources must take place with the approval or "prior informed consent" of the country from which the resource is accessed.[131] The second principle is that conditions for access to or use of genetic resources, including how any resulting benefits would be shared, must be agreed upon. Access and benefit-sharing must be based on mutually agreed terms to be negotiated with the country providing the resources (also, in some countries, delegated to an agency or community).[132]

Article 8(j) of the CBD affirms the need for national governments to respect, preserve and maintain knowledge, innovations, and practices of indigenous and local communities.[133]

The Nagoya Protocol 2010 provides key obligations in relation to access to genetic resources and fair and equitable sharing of benefits that arise from their utilization and compliance. Article 2 of the Nagoya Protocol provides that:

> "'[U]tilization of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention of Biodiversity."[134]

The Nagoya Protocol came under scrutiny after the outbreak of the COVID-19 pandemic. The Protocol has been praised for aiming to give each country sovereignty over its biological resources, however, some have argued that this could hinder the global collaboration required

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[130] Jorge Medaglia, Frederic Perron-Welch & Freedom-Kai Phillips, "Overview of national and regional sharing measures on access and benefit sharing" (25 June 2014, last visited 17 July 2020), online (pdf): *Centre for International Sustainable Development Law* <www.absfocalpoint.nl/upload_mm/8/a/9/2b706ea7-499e-4c3c-bc36-f9327a79813f_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf>.

[131] *UN Convention of Biological Diversity*, 1992, 1760 UNTS 79, art 15(3) (entered into force 29 December 1993).

[132] *Ibid*, art 15(7).

[133] UN, *supra* note 52, art 8(j).

[134] *Nagoya Protocol on Access and Benefit-Sharing*, (29 October 2010), art 2 (entered into force 12 October 2014).

for the development of new vaccines.[135] Balance is required among sovereignty over national resources, prior informed consent, mutual agreement, access and benefit-sharing, and access to biotechnology and related products, including medicines.

Significantly, the ITPGRFA 2001 addresses the specifics of plant genetic resources for food and agriculture. The Treaty establishes a multilateral system of access and benefit-sharing which aims to facilitate the exchange of seeds and other genetic material of several crops deemed significant for food security.[136]

Food and nutrition contribute a crucial concept of health and wellness, and the constitutions of some African states, such as Kenya and South Africa, provide for them.[137] Article 43 of the Kenyan Constitution 2010 provides the most relevant clause(s).[138]

In this regard, the ITPGRFA constitutes a specialized international instrument on ABS that is consistent with the objectives of the CBD and the Nagoya Protocol, as stated in Article 4(4) of the Nagoya Protocol.[139] The majority of African countries are members of the ITPGRFA, apart from Mozambique, Botswana, Comoros, Equatorial Guinea, Gambia, and South Africa.[140] Cape Verde and Nigeria have signed the agreement but are yet to ratify it.[141]

Section 9 of ARIPO's Swakopmund Protocol also provides for the equitable benefit-sharing of traditional knowledge holders. Section 9.3 states:

> "*The right to equitable remuneration might extend to non-monetary benefits, such as contributions to community development, depending on the material needs and cultural preferences expressed by the traditional or local communities themselves.*"

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[135] Thomas Cueni, "Novel coronavirus 2019-nCoV exposes a flaw in the Nagoya Protocol" (5 February 2020, last visited 17 July 2020), online: *STAT* <www.statnews.com/2020/02/05/novel-coronavirus-exposes-nagoya-protocol-flaw/>.

[136] *International Treaty on Plant Genetic Resources for Food and Agriculture*, 2001, arts 10 and 13 (entered into force 29 June 2004).

[137] See *Constitution of Kenya*, 2010, art 43; *Cf Constitution of the Republic of South Africa* 1996, s 27.

[138] See Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials*, Nairobi: *Constitutional Democracy and Regulatory and Administrative Law in Kenya and Africa*, Nairobi: Sihanya Mentoring & Innovative Lawyering, vols 1 and 2.

[139] The Nagoya Protocol on access and Benefit-sharing, online <www.cbd.int/abs/>.

[140] "FAO Membership" (last visited 17 July 2020), online: *Food and Agriculture Organization of the United Nations* <www.fao.org/plant-treaty/countries/membership/en/?page=3&ipp=20&no_cache=1&tx_dynalist_pi1[par]=YToxOntzOjE6IkwiO3M6MToiMCI7fQ==>.

[141] *Ibid.*

This provision refers to non-commercial ABS agreements and related incentives for the conservation and sustainable utilization of generic and other resources, including for health and wellness.

Hence, the incentives and revenue generated from IP are key components to sustainable access and utilization of genetic resources and benefit-sharing. Therefore, some of the incentives and IP related revenues in joint and collaborative research are conceptualized below.

4.2 Incentives and Distribution of IP-related Revenues in Collaborative Research in Africa

The COVID-19 pandemic has illustrated the importance and need for joint and collaborative research in Africa, and for the world to develop diagnostics, therapies and vaccines. The pandemic has also demonstrated how most African states are currently unprepared to deal with disasters, epidemics and pandemics. This is because they have not invested in joint and collaborative research, but rather have relied on self-sponsored individuals and organizations for solutions, not only in the health sector, but also in other sectors including food, education and security. [142]

The most contentious aspects of research and development (R&D) and commercialization agreements, especially in health or pharmaceutical joint and collaborative research, often are related to IP interests, ownership, and exploitation. This is because all parties enter into the agreement with their own unique knowledge and input. Knowledge is a very important economic asset while enhancing or competing in any industry, especially health, and is crucial due to the high sunk costs, time and investments put into developing new diagnostic kits, chemical compounds, therapies, or drugs and vaccines.[143]

One of the most important goals of collaborative research, particularly in the health industry, is to develop a new technology that can be commercialized. Commercial rights to the arising IP are negotiated and can vary depending on the nature of the collaboration and the contributions of the parties.

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[142] Ben Sihanya, "Intellectual Property, innovation, and technology transfer in Health in Kenya and Africa: A case of COVID-19 and malaria" in Ben Sihanya, *Intellectual Property and Innovation Law in Kenya and Africa: Cases and Materials*, (Nairobi: Sihanya Mentoring & Innovative Lawyering, forthcoming 2022) [Sihanya, "A case of COVID-19 and malaria"].

[143] Carsten Fink, "Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry" in Carsten Fink & Keith Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: The World Bank and Oxford University Press, 2005) at 227.

There are at least two ways in which owners of IP in collaborative and joint research can be remunerated or given incentives to commercialize their IP.

First, a common incentive and distribution of revenue in the commercialization of IP rights is remuneration through the payment of royalties. As previously discussed, royalties are a form of (taxable) income charged for the use of one's IP assets. In their most common form, royalties represent a percentage of profits raised from the use or exploitation of IP. In 2004, the Government of Kenya collaborated with Cosmos, a domestic pharmaceutical company in Kenya, to obtain two voluntary licenses with GlaxoSmithKline (GSK) pharmaceutical company and Boehringer Ingelheim pharmaceutical company. These licenses allowed Cosmos to produce and sell generic versions of ARV drugs produced by GSK and Boehringer Ingelheim and pay them by way of royalties from proceeds of the sale of these ARVs.[144]

There are four ways that the owners of IP can negotiate for royalties.[145] First, license initiation fees or upfront fees. Second, running royalties that are based on gross revenue received by the licensee through exploitation of the licensed invention or innovation. Third, minimum royalties, milestone payments, or other resource commitments by licensees to the commercialization of the invention or innovation.[146] And fourth, royalty-free licensing. An example of this is the Water Efficient Maize for Africa project, where the Monsanto Company licensed its technologies royalty-free to AATF and the International Maize and Wheat Improvement Centre (CIMMYT) for use in developing drought tolerant maize for African farmers.[147]

The second form of incentive for commercialization of IP rights is remuneration of assignment or licensing of IP rights through a lump sum payment.[148] Licensing or transfer of IP rights through a lump sum payment usually involves an outright sale of IP rights for a fixed amount of money. This method of remuneration is mostly common in assignment of patent, utility model and trade secret rights where it can be difficult to negotiate the terms of the sale or

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[144] Moni Wekesa & Ben Sihanya, eds, *Intellectual Property Rights in Kenya* (Nairobi: Konrad Adenauer Stiftung and SportsLink Limited, 2009).
[145] United Nations Economic Commission for Europe, *supra* note 38.
[146] *Ibid.*
[147] Wekesa & Sihanya, *supra* note 144.
[148] Roya Ghafele & Benjamin Gibert, "Promoting Intellectual Property Monetization in Developing Countries: A Review of Issues and Strategies to Support Knowledge-driven Growth" (2012) Economic Policy and Debt Department, The World Bank Poverty Reduction and Economic Management Network Working Paper 6143.

licensing. For instance, the Serum Institute of India (SII) had a licensing agreement with AstraZeneca in 2020 for the supply of 1 billion doses of the vaccine.[149]

African governments must offer more support for R&D in order to encourage joint and collaborative research not only in the health sector, but across other sectors like education, agriculture, industrialization, information and communication technology. This can be done by enhanced IP protection and promotion through law, regulations, and policies supporting traditional, local or indigenous African content.

The COVID-19 pandemic has shown that Africans have the capability to conduct R&D. For example, individual researchers in Kenyan universities and research institutes created or proposed important innovations and even prototypes regarding personal protection equipment (PPE) or kits to prevent COVID-19 infection.[150] Some Kenyans also innovated wooden hand washing machines to help curb the spread of the coronavirus.[151]

For African countries, health innovation presents two crucial opportunities.[152] The first is the opportunity to increase domestic capacity to solve health challenges. The second is the opportunity for international funders. Health innovation is an opportunity for African countries to move beyond foreign aid and dependency, with the shared goal of creating self-sustaining innovation that has both health and development impacts.[153]

With sufficient government support and funding, health innovation can be improved greatly through collaborative and joint research as well as through promoting distribution and incentivization of IP related revenue.

To conclude, IP rights have a role in COVID-19 strategies that relate to copying, recovery or revival, and restructuring and rejuvenation of the African IP regimes and the relevant institutional frameworks. There are three main strategies.

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[149] Divya Rajagopal, "AstraZeneca & Serum Institute of India sign licensing deal for 1 billion doses of Oxford vaccine" (4 June 2020, last visited 17 June 2022), online: *The Economic Times* <economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/astrazeneca-serum-institute-of-india-sign-licensing-deal-for-1-billion-doses-of-oxford-vaccine/articleshow/76202016.cms?>.

[150] Star Reporter, "KU develops Sh500,000 ventilator prototype in war on Covid-19" (11 April 2020, last visited 6 August 2020), online: *The Star* <www.the-star.co.ke/news/2020-04-11-ku-develops-sh500000-ventilator-prototype-in-war-on-covid-19/>; *Cf* Sihanya, "A case of COVID-19 and malaria", *supra* note 64.

[151] "Coronavirus: Kenyan boy who made hand-washing machine awarded" (2 June 2020, last visited 6 August 2020), online: *BBC News* <www.bbc.com/news/world-africa-52898797>; *Cf* Sihanya, "A case of COVID-19 and malaria", *supra* note 64.

[152] Calestous Juma, "African health innovation systems: preface" (2010) 10:S1 BMC International Health and Human Rights I1, DOI: <10.1186/1472-698X-10-S1-I1>.

[153] *Ibid.*

First, there is need for IP and innovation economic recovery, economic stimulus, and economic and business restructuring in Africa. IP, technology, innovation and invention regarding COVID-19 and health generally can be acquired and promoted through R&D, consensual licensing and manufacturing under license or government use, subsidy, and other IP related complements and incentives. Second, African states must practice and engage in progressive and responsive politics, governance and integration driven by innovation and IP. And third, there is need to improve the standards, quality, and relevant education, training, research, innovation and mentoring ("ETRIM") that is accessible, inclusive, and IP- and technology-enabled or supported. African countries need ETRIM that will impart appropriate skills, knowledge, attitude, values and innovation ("SKAVI") while addressing IP health in the COVID-19 context.

Considering the discussions in the foregoing sections, one of the key incentives for joint and collaborative research in Africa is compulsory licensing, which is discussed in the next section.

4.3 Compulsory licenses and government use

Article 31 of TRIPS provides for conditions that must be included in national laws for the use "of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government". This is the compulsory license and government use provision, the difference between the two being that "government use" is restricted to state's own exploitation of the patent, whilst compulsory licensing extends to the use by third parties. Compulsory licenses (including government use) are "granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder".

> Article 31 of TRIPS provides a series of conditions under which a compulsory license may be issued:
>
> (a) authorization of such use shall be considered on its individual merits;
>
> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of

national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities

shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

The above extract from the TRIPS Agreement lists 12 conditions. These include article 31(h)'s provision that satisfactory remuneration must be paid to the patent-holder paying consideration to the "economic value of the license". This means that such use is not free but is subject to payment adjudged to be satisfactory. One can anticipate that the setting of such remuneration would be contested by both sides. Another condition, worthy of some discussion, is article 31(f)'s requirement that the medicines manufactured under compulsory license shall be "predominantly for the supply of the domestic market". This limitation stops countries with the requisite generic manufacturing capacity from exporting a significant amount of those generics to countries without generic manufacturing capacity (usually developing countries or LDCs). This limitation has since been modified by the "paragraph 6 solution" of the 2003 Waiver Decision which has been adopted as an amendment to TRIPS, introducing article 31 bis for those countries who have accepted it.[154] The amendment remains open for acceptance until 31 December 2023.[155] This modification has removed the limits on exports under compulsory license to WTO member states with limited pharmaceutical products manufacturing capacity,

[154] Article 31bis was inserted by the 2005 amendment to the TRIPS Agreement and came into force after its acceptance by 2/3 of WTO members: "Amendment of the TRIPS Agreement" (last visited 7 June 2021), online: World Trade Organization: www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[155] WTO, General Council, *Amendment of the TRIPS Agreement – Eighth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, Decision of 22 November 2021, WTO Doc WT/L/1122, online: WTO < https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/1122.pdf&Open=True >.

provided that the relevant member states comply with stated conditions. It required that both the exporting and importing countries issue compulsory licenses and advise the TRIPS Council of the import and export. However, due to its complexity and cumbersome nature it has only been used once, by Rwanda and Canada. However, as of June 2022, only 27 African countries[156] have accepted the 2005 WTO Decision that culminated in the TRIPS Amendment which came into force in 2017.

Several African states have introduced compulsory license provisions into their domestic patent laws and implemented them. Examples of such states include Ghana, Mozambique, Zambia and Zimbabwe, who implemented them to provide HIV/AIDs medications.[157]

4.4 Exhaustion of Rights and Parallel Importation

The concept of exhaustion of rights entails that when an IP right protected good or service is first sold, the IP rightsholder's right in controlling the further distribution of that good or service ceases to exist.[158] It is exhausted and further distribution may take place without seeking the IP rightsholder's permission. TRIPS article 6 reads:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Further, paragraph 5(d) of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, reads as follows:

> The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime

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[156] Benin (2016), Botswana (2014), Burkina Faso (2017), Central African Republic (2014), the Congo (2017), Cote d'Ivoire (2018), Egypt (2008), Gabon (2017), Gambia (2020), Kenya (2015), Lesotho (2016), Madagascar (2017), Malawi (2017), Mali (2016), Mauritius (2008), Morocco (2008), Niger (2020), Nigeria (2017), Rwanda (2011), Senegal (2011), Seychelles (2016), Sierra Leone (2017), South Africa (2016), Tanzania (2016), Togo (2012), Uganda (2010) and Zambia (2009).

[157] Vawda, Y.A. (2022). Compulsory Licenses and Government Use: Challenges and Opportunities. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_3, pp 73 - 104 at p. 79.

[158] Frederick Abbott, "Parallel Importation: Economic and social welfare dimensions" (June 2007), online (pdf): *International Institute for Sustainable Development* <www.iisd.org/pdf/2007/parallel_importation.pdf>; Enrico Bonadio, "Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?" (2011) 33:3 European Intellectual Property Review 153.

for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.1

Consequently, each TRIPS member state can set its own exhaustion regime. This regime then facilitates parallel importation. Parallel importation is the purchase of a good or service in one territory then importing them into another. The IP rightsholder cannot stop such further distribution/importation after the exhaustion of rights.

In this regard, there are 3 types of exhaustions. First, IP rights are exhausted under the **National exhaustion** of rights with the first authorized disposition of the product within the country. A *foreign sale* does not exhaust IP rights in the domestic jurisdiction and IP rightsholders can use IP rights to control the first sale in each jurisdiction that follows a principle of national exhaustion.

Second, where the **regional exhaustion** principle is in place, IP rights are exhausted once the product is first sold in the region. For example, if a regional economic community applies this approach, the introduction of a product in any state in that region exhausts the IP rights. This would be particularly useful in the distribution of medicines for example. In Africa, OAPI has adopted the principle of regional exhaustion.[159]

Third, as for the **international exhaustion** of rights, IP rights are exhausted within the jurisdiction with the first authorized disposition of the product anywhere in the world, no matter where the first sale took place. IP rightsowners cannot exercise domestic IP rights to restrict the importation of those products. The doctrine of international exhaustion adopted by a number of countries such as India and recently the United States[160] gives greater weight to consumer rights to control resale of a protected product that was placed on the market in one jurisdiction by or with the authority of the IP rightsholder and imported into another jurisdiction through a distribution channel that was not authorized by the IP rightsholder.

[159] Irene Calboli, (2022). Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_2, pp 31 – 71 at p.36.

[160] *Impression Products v Lexmark International*, 581 US 1 (2017) (available at www.supremecourt.gov/opinions/16pdf/15-1189_ebfj.pdf).

Exhaustion regime	When rights are exhausted	Parallel importation
National exhaustion	When goods or services are first sold within the national territory.	Not permitted.
Regional exhaustion	When a good or service is put onto the market within any country of a defined region, e.g. the African Union or a Regional Economic Community.	Permitted, but only with respect to goods first placed on the market within the regional territory.
International exhaustion	When a good or service is put onto the market anywhere in the world.	Permitted with respect to goods or services lawfully first placed on the market anywhere in the world.

Source: adapted from Abbott, 2007, p5 [161]

This makes the twin concepts of exhaustion of rights and parallel importation a very useful public interest tool to deliver goods or services to territories. For instance, under regional and international exhaustion regimes, where certain life-saving medication or educational materials are not available at all or at an affordable price in country A, it would be possible to go and buy them from country B, and then import them into country A. In some cases where the law did not permit such action at the time it was taken, it served as a catalyst for policy and legislative change.[162]

A regional or international exhaustion regime would be highly beneficial for the African continent as it would enable the importation of needed goods.[163] For instance, during the

[161] Abbott, *supra* note 129 at 5.

[162] Treatment Action Campaign in South Africa and the introduction of *Medicines and Related Substances Act* (S Afr), No 101 of 1965, s 15C.

[163] Brook K Baker, "A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and A Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities" (2019), online (pdf): <kelinkenya.org/wp-content/uploads/2019/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf>; Ermias Tekeste Biadgleng, "TRIPS Post-Grant Flexibilities: Parallel Imports" (Workshop delivered at the United Nations Conference on Trade and Development, Cape Town, 7-9 December 2009), online: <tralac.org/images/docs/4755/biadgleng-parallel-imports-presentation.pdf>; Rajnish Kumar Rai & Srinath Jagannathan, "Parallel imports and unparallel laws: an examination of the exhaustion doctrine through the lens of pharmaceutical products" (2012) 21:1 Information & Communications Technology Law 53, DOI: <10.1080/13600834.2012.644692>.

COVID-19 pandemic it would facilitate the importation of medication and personal protective equipment by some African states for further internal distribution within the continent. The following African states have adopted the principle of international adoption.[164]

Botswana	Section 25(1) Industrial Property Act, 2010
Burundi	Art 57 Industrial Property Law, 2009
Egypt	Art 10 Law on the Protection of Intellectual property rights, 2002
Ghana	Section 11(4) Patents Act, 2003
Kenya	Section 58(2) Industrial Property Act, 2001
Liberia	Section 13.11(b) Intellectual Property Act, 2016
Namibia	Section 43(1) Industrial Property Act, 2012
Seychelles	Section 19 Patents and Industrial Design Act, 2012
Sierra Leone	Section 23(1)(a) Patents and Industrial Designs Act, 2012
Zambia	Section 76 Patents Act No. 40, 2016
Zanzibar	Section 11(4)(a)(i) Industrial Property Act No.4, 2008
Zimbabwe	Section 24A Patents Act [Chapter 26:03]

[164] Calboli supra note 159, pp 52 -53.

APPENDIX 1: List of African Treaties, Conventions and Agreements

- ARIPO (1976) *Agreement on the Creation of the African Regional Intellectual Property Organisation*, adopted by the Diplomatic Conference, at Lusaka, Zambia.

- ARIPO (1982) *Protocol on Patent and Industrial Designs within the Framework of the African Regional Industrial Property Organization*, adopted at Harare, Zimbabwe.

- ARIPO (1993) *Banjul Protocol on Marks within the Framework of the African Regional Industrial Property Organization*, adopted by the Administrative Council at Banjul, The Gambia.

- ARIPO (2010) *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization*, adopted by the Diplomatic Conference of ARIPO, Swakopmund, Namibia.

- OAPI (2000) *Agreement to Revise the Bangui Agreement on the Creation of an African Intellectual Property Organisation* of 2 March, 1997, Bangui, 24th February.

- OAU (2000) *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, Addis Ababa, Ethiopia.

- OAU (2000) *Conference on Security, Stability, Development and Co-operation*, AHG/Dec. 175 (XXXVIII).
- OAU (2002) *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, Addis Ababa, Ethiopia.

- OAU (2002) *African Union Declaration on the Principles Governing Democratic Elections in Africa*, AHG/Decl.1 (XXXVIII).

- SADC (2012) *Draft Protocol for the Protection of New Plant Varieties of Plants (Plant Breeders' Rights) in the Southern African Development Community*, Gaborone, Botswana.

APPENDIX 2: List of International Treaties, Conventions, and Agreements

- FAO of the United Nations (2004) *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA).

- UN (1992) *Convention on Biological Diversity*, Treaty Series, 1760 UNTS 79; 31 ILM 818.

- UN (2010) *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization adopted by the Conference of the Parties to the Convention on Biological Diversity*, UNP/CBD/COP/DEC/X/1.

- UN General Assembly (1984) *Charter of the Economic Rights and Duties of States*, A/RES/39/163.

- UN General Assembly (2000) *United Nations Millennium Declaration*, A/55/L.2.

- UNESCO (1952) *Universal Copyright Convention*, 25 UST 1341;TIAS 7868, 943 UNTS 178.

- WIPO (1883) *Paris Convention for the Protection of Industrial Property*, 21 UST 1583, 828 UNTS 305.

- WIPO (1886) *Berne Convention for the Protection of Literary and Artistic Works*, September 9, 1886, last revised July 24, 1971, 828 UNTS 221.

- WIPO (1891) *Madrid Agreement on the International Registration of Marks*, 828 UNTS 391.

- WIPO (1925) *Hague Agreement on the International Registration of Industrial Designs*, 74 LNTS 289.

- WIPO (1957) *Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks*, [1979] ATS 2/1154 UNTS 89/23 UST 1336.

- WIPO (1961) *International Convention for the Protection of New Varieties of Plants*, [2000] ATS 6/33 UST 2703/815 UNTS 89.

- WIPO (1970) *Patent Co-operation Treaty*, TIAS 8733; 28 UST 7645; 9 ILM 978.

- WIPO (1973) *Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks*, 1863 UNTS 317.

- WIPO (1994) *Trade Mark Law Treaty*, 01/01/2100.

- WIPO (1996) *Copyright Treaty*, S. Treaty Doc No 105-17 (1997); 36 ILM 65 (1997).

- WIPO (1996) *Performance and Phonograms Treaty*, CRNR/DC/95.
- WIPO (2006) *Singapore Treaty on the Law of Trademarks*, [2009] ATS 9.

- WIPO (2012) *Beijing Treaty on the Protection of Audio-visual Performances,* adopted by the Diplomatic Conference on the Protection of Audiovisual Performances in Beijing, on June 24, 2012.

- World Conservation Union (1973) *Convention on International Trade in Endangered Species (CITES)*, March 3, 1973, 993 UBTS 243, 27 UST 1087, TIAS No 8249, 12.

- WTO (1994) *Agreement on Trade Related Aspects of Intellectual Property Rights*, 1869 UNTS 299; 33 ILM 1197.

- WTO (2005) *Amendment to the TRIPs Agreement*, WT/L/641.

APPENDIX 3: Sample of a **non-disclosure agreement** to protect intellectual property rights in collaborative research. [165]

NON-DISCLOSURE AGREEMENT

THIS NON-DISCLOSURE AGREEMENT is made the ..... day of ..... Two Thousand and Twenty Two

BETWEEN:

....., [a company duly incorporated and validly existing under the laws of the Republic of .....] [a research and development institute established by a statutory instrument in the Republic of .....] and whose registered office/principal place of business is situated at ..... in the Republic of ..... (hereinafter called "the Company"/"the Institute" [which expression where the context admits shall include its assigns, successors in title), of the one part

AND

....., [a public limited liability company duly incorporated and validly existing under the laws of the Republic of .....][a research and development institute established by a statutory instrument in the Republic of .....] [and whose registered address/principal place of business is situated at ..... in the Republic of ..... (hereinafter referred to as "the Prospective Collaborator", which expression where the context so admits shall include its assigns and successors in title), of the other part

WHEREAS:

A. The Company [the Institute] is engaged in research, development manufacture, distribution and sale of pharmaceutical products in the Territory;

B. The Prospective Collaborator is also engaged in research, development manufacture, distribution and sale of pharmaceutical products in ..... (*name of country*);

C. The Company [the Institute] and the Prospective Collaborator are desirous of entering into an agreement that would provide for their collaboration in joint research and development of pharmaceutical products and the protection of their respective intellectual property rights owned by them or arising from such collaboration;

D. In order to allow the Parties to make an informed decision regarding the collaboration agreement, the Parties are prepared to disclose confidential information to each other so that the joint research and collaboration agreement in joint research can be successfully concluded ("the Permitted Purpose");

[165] The draft agreement was prepared by Mr. Muzondi Chirambo.

E. The Parties recognise that unauthorised disclosure or use of the Confidential Information could cause the Parties commercial harm and, therefore, they are willing to enter into a non-disclosure agreement in accordance with the provisions of this Agreement.

NOW IT IS AGREED as follows:

1. DEFINITIONS

In this Agreement, unless there is something in the subject or context inconsistent therewith, the following expressions shall have the following meanings:

1.1 "***Affiliate***" means, with respect to any entity, any other entity controlling, controlled by or under common control therewith, and, without any derogation from such a definition, with respect to with respect to each of the Parties, shall mean the companies listed in the Schedule to this Agreement;

1.2 "***Agreement***" means this document and any schedule hereto as amended from time to time in terms hereof;

1.3 "***Confidential Information***" means any information of a confidential nature, which has been, or may be obtained directly or indirectly by one Party hereto from the other Party hereto, whether in writing or in electronic format, or pursuant to discussions held between the Parties, or which can be obtained by examination, testing, visual inspection or analyses, including, without limitation a Party's Know-How, all materials, technologies, inventions, information relating to a Party's past, present and future research and development or to a Party's business activities, opportunities, products, services, clients, suppliers, or to a Party's technical knowledge, including, without limitation, all such Party's trade secrets, as well as the terms and conditions of this Agreement, any information identified as confidential, and any other material which contains or otherwise reflect, or are generated or derived from any such information as is specified in this definition;

1.4 "***Disclosing Party***" means the Party to this Agreement that discloses Confidential Information, directly or indirectly, to the Receiving Party under or in anticipation of this Agreement and the Collaboration Agreement in Joint Research;

1.5 "***Effective Date***" means the date specified as such on the cover sheet failing which it will be the Signature Date;

1.6 "***Improvement***" means any improvement, enhancement, alteration or modification to or of the Intellectual Property or Confidential Information of one Party wholly or partly developed by the other Party pursuant to or in the course of the Project;

1.7 "***Intellectual Property***" means any and all intellectual property rights of a Party, including without limitation, patents, utility models, plant breeders' rights, industrial design, trade marks (whether registered or otherwise), traditional medicinal knowledge and genetic resources, copyright and all similar and related rights in all jurisdictions that grant similar rights as the foregoing, and the right to apply for registration of any of the foregoing;

1.8 "***Information***" means but is not limited to information and data, whether concerning commercial, financial, technical or any matter whatsoever provided directly or indirectly by the Disclosing Party to the Receiving Party orally or in documentary form or by way of models, including biological or chemical materials, or other tangible form or by demonstrations and whether before, on or after the date of this Agreement;

1.9 "***Joint Research and Collaboration Agreement***" means the collaboration agreement for joint research anticipated by this Agreement;

1.10 "***Know-How***" means any and all concepts, ideas, methods, methodologies, procedures, processes, know-how, formulae, techniques, models (including, without limitation, function, process, system and data models), clinical test data, templates, business rules, product architecture, utilities and routines; and logic, coherence and methods of operation of systems that a Party has created, acquired or otherwise has rights in;

1.11 "***Loss***" means all losses, liabilities, damages and claims, and all related costs and expenses (including legal fees at an attorney and own client scale and disbursements and costs of investigation, settlement, interest and penalties);

1.12 "***Parties***" means the Company [the Institute] and the Prospective Collaborator;

1.13 "***Party***" means either one of the Parties;

1.14 "***Permitted Purpose***" has the meaning given in Recital D above;

1.15 "***Personnel***" means any director, employee, student, agent, consultant, contractor or other representative of an entity;

1.16 "***Receiving Party***" means the Party to this Agreement that receives Information, directly or indirectly, from the Disclosing Party;

1.17 "***Signature Date***" means the date of signature of this Agreement by the Party signing last; and

2. INTERPRETATION

2.1 Unless otherwise specified, words importing the singular include the plural, words importing any gender include every gender, and words importing persons includes bodies corporate and unincorporated and (in each case) *vice versa*;

2.2 References to Clauses and other provisions are references to Clauses and other provisions of this Agreement and any reference to a sub-provision is, unless otherwise stated, a reference to a sub-provision of the provision in which the reference appears.

2.3 The headings shall not affect the interpretation of this Agreement.

2.4 The expressions "***hereunder***", "***hereto***", "***herein***", "***hereof***" and similar expressions relate to this entire Agreement and not to any particular provision thereof.

2.5 Any undertaking by any of the parties hereto not to do any act or thing shall be deemed to include an undertaking not to permit or suffer the doing of that act or thing.

2.6 References to this Agreement or any document shall, where appropriate, be construed as references to this Agreement or such other document as varied, supplemented, novated and/or replaced in any manner from time to time.

3. TERM

This Agreement shall commence on the Effective Date and be for a period of **ONE (1) YEAR** or until it is superseded or replaced with the Joint Research and Collaboration Agreement or any formal agreement concluded between the Parties superseding this Agreement.

4. CONFIDENTIAL INFORMATION

4.1 Confidentiality obligation

The Receiving Party must treat and hold as confidential all Confidential Information which they may receive from the Disclosing Party or which becomes known to it during the term of this Agreement.

4.2 Use of Confidential Information

The Receiving Party may disclose the Disclosing Party's Confidential Information to its Personnel who are actively involved in the Project on a "***need to know basis***" only, and such Personnel may be permitted to use such Confidential Information to the extent reasonably necessary for the pursuit of the Project only.

4.3 Improvements

If a Party creates any Improvement, such Party shall promptly inform the other Party of such Improvement. No Party may register or apply for the registration of any Intellectual Property right with respect to any Improvement (including without limitation under patent, utility model or design) without the prior written consent of the other Party.

5. UNDERTAKINGS OF THE RECEIVING PARTY

During the Term of this Agreement, the Receiving Party undertakes to the Disclosing Party to:

5.1 hold the Disclosing Party's Confidential Information in the strictest confidence and shall not disclose such information to any third party;

5.2 not make use thereof other than for the performance of its obligations under the Agreement;

5.3 only release such Confidential Information on a "***need to know***" basis subject thereto that the persons to whom such Confidential Information is released shall undertake to be bound by the confidentiality obligations contained herein;

5.4 take all reasonably necessary precautions to ensure that such undertaking is enforced and is enforceable and take such action as to ensure that confidence (which it undertakes to enforce and for which it is legally responsible) to those of its Personnel as need to have access thereto wholly necessarily and exclusively for the purposes of the Project whose identity the Receiving Party shall provide to the Disclosing Party at their request;

5.5 ensure that patentability of any invention or innovation that may the subject matter of the Confidential Information is not destroyed through making information available to the public, such as by written or oral description;

5.6 use the Confidential Information only for the Permitted Purpose;

5.7 only disclose the Confidential Information under binding obligations, without the Disclosing Party's prior written consent, any commercial use of or make any commercial gain from the Confidential Information or seek to obtain any protection of the intellectual property contained in the Confidential Information;

5.8 promptly notify the Disclosing Party if it becomes aware that any of the Confidential Information falls within the provisions of Clause 7.

6. THE RECEIVING PARTY'S OBLIGATIONS

The Receiving Party agrees that in order to protect the commercial interests of the Disclosing Party in the Disclosing Party's Confidential Information, unless the Disclosing Party has expressly agreed otherwise in writing, the Receiving Party shall not and shall ensure that its Personnel does not, during the Term of this Agreement, use or disclose any Confidential Information of the Disclosing Party other than as allowed in terms hereof. Without limiting the aforesaid, the Receiving Party shall:

6.1 Notify the Disclosing Party to the extent possible of all persons to whom the Disclosing Party's Confidential Information is to be disclosed or who are to be granted access to the Disclosing Party's Confidential Information before those persons are permitted access to the Disclosing Party's Confidential Information;

6.2 Procure that, upon request by the Disclosing Party, any materials containing Confidential Information of the Disclosing Party will be returned or otherwise disposed of as the Disclosing Party may direct;

6.3 Initiate internal security procedures, if the same are not already in place, to prevent unauthorized disclosure and will take all reasonable steps to impress upon those

Personnel who need to be given access to Confidential Information, the secret and confidential nature thereof; and

6.4 Promptly notify the Disclosing Party if it becomes aware of any breach of confidence in respect of Confidential Information of the Disclosing Party by any person to whom it has disclosed such Confidential Information and to the extent possible, give the Disclosing Party all reasonable assistance in connection with any actions and proceedings which it may institute as a result.

7. EXCEPTIONS

The obligations of the Receiving Party hereunder shall not apply to any information which:

7.1 has been lawfully in the public domain at the time of disclosure or subsequently and lawfully becomes part of the public domain by publication or otherwise;

7.2 subsequently comes into the public domain other than as a result of a breach by either party of the terms of the agreement;

7.3 is provided to the Disclosing Party by a third party in circumstances where there is no reason to believe there are confidentiality obligations;

7.4 has been lawfully in the Receiving Party's possession prior to disclosure;

7.5 subsequently becomes available to the Receiving Party from a source other than the Disclosing Party, which source is lawfully entitled without any restriction on disclosure to disclose such information;

7.6 is independently developed by or on behalf of the Receiving Party; and

7.7 subsequently becomes available to the Receiving Party from a source other than the Disclosing Party, which source is lawfully entitled without any restriction on disclosure to disclose such information.

8. RETENTION OF RIGHTS

Unless otherwise agreed in writing, no right or license is granted to a Party or its Affiliates in respect of the Confidential Information or Intellectual Property of the other Party. Each Party acknowledges that the Party from which the Confidential Information and Intellectual Property originates shall, remain solely entitled to all right, title and interest in and to such Confidential Information and Intellectual Property and that it has no claim of any nature in and to such Confidential Information or Intellectual Property or in respect of any of the Know-How pertaining thereto. Each Party undertakes that it shall not take any action to impute any right, title or interest in and to the other Party's Confidential Information or Intellectual Property.

9. RETURN OF CONFIDENTIAL INFORMATION

9.1 Should any unauthorised disclosure take place, the Disclosing Party shall be entitled by written notice to the Receiving Party to terminate all obligations to provide Confidential Information to the Receiving Party with immediate effect.

9.2 This Agreement may not be terminated save by either of the following:
9.2.1 written agreement between the Parties to terminate this Agreement;
9.2.2 expiry of the term of this Agreement in accordance with Clause 3.0;
9.2.3 closure of the transaction to which this Agreement relates; or
9.2.4 replacement with the Joint Research and Collaboration Agreement anticipated by and superseding this Agreement or any formal agreement concluded between the Parties superseding this Agreement.

9.3 Upon termination of this Agreement, in the event that the Receiving Party is in breach of any of the conditions of this Agreement, and at any other time on the written request of the Disclosing Party, the Receiving Party will immediately return the Confidential Information and any copies of it made by or in the possession of or under the control of the Receiving Party pursuant to this Agreement, and make no further use or disclosure of any of the Confidential Information. If the Disclosing Party so dictates, the Confidential Information shall be destroyed under the above circumstances.

9.4 The Receiving Party may, however, keep one copy of the Disclosing Party's Confidential Information in its legal adviser's files solely for the purpose of enabling it to comply with the provisions of this Agreement.

10. LIMITATION OF TRANSFERRED RIGHTS

10.1 The Receiving Party acknowledges and agrees that the property, copyright or other intellectual property rights in Confidential Information disclosed to it by the Disclosing Party, including any documents, files and any other items containing any Confidential Information, belong to the Disclosing Party. It will not be removed from the Receiving Party's address nor be given to any other person or parties.

10.2 This Agreement shall neither prejudice nor limit the rights of the Disclosing Party in respect of any intellectual property rights in the Confidential Information.

10.3 Except as provided for in this Agreement the Receiving Party may not assign or transfer any rights or obligations under this Agreement without the prior written consent of the Disclosing Party.

10.4 This Agreement is not to be construed as granting the Receiving Party any licence or rights other than as expressly set out in this Agreement in respect of the Confidential Information.

11. WARRANTY AS TO ACCURANCY AND COMPLETENESS BY THE DISCLOSING PARTY

The Disclosing Party warrants to the Receiving Party that the Confidential Information disclosed by it under this Agreement is, to the best of its knowledge and belief, accurate and complete.

12. TERMINATION

12.1 This Agreement can be terminated by either Party by giving the other THREE (3) MONTHS' [SIX (6) MONTHS'] notice in writing.

12.2 Notwithstanding any such termination the Parties agree that each party shall observe its obligations under Clauses 4, 5 and 6 of this Agreement.

13. NOTICES

13.1 Every notice required or contemplated by this Agreement shall be given in writing and:

13.1.1 if delivered by hand, be effective when received with receipt confirmation, or

13.1.2 if sent by prepaid courier services, registered or certified mail, be effective on the day it is officially recorded as delivered by return receipt or equivalent, or

13.1.3 if sent by facsimile effective at 10.00 a.m. with receipt confirmation, be effective on the business day after the date of dispatch where business day means a day on which the banks are open in the location to which the notice is sent and the times are those in that location, or

13.1.4 if sent by electronic mail, be effective when acknowledged by the answer back of the addressee's electronic mail system.

13.2 A notice sent by facsimile or electronic mail shall be validated by letter sent by prepaid courier service, registered or certified mail and where documentary evidence exists that a confirmatory letter was dispatched non receipt of that letter does not invalidate the notice sent by facsimile, e-mail or telex. In each , intended at its last known address as stated herein, (which includes an electronic mail address, and/or facsimile number) or at such other address as the intended recipient shall have designated by written notice.

13.3 All notices shall be sent to the Parties herein at their following addresses:

12.3.1 For ..... (*insert name of the Company or Institute*):

Correspondence : ....., ...
E-mail : .....
Attention : .....

12.3.2 For ..... (*insert name of Prospective Collaborator*)

Correspondence : .....

Email : .....
Attention : .....

14. GOVERNING LAW

The validity, construction and performance of this Agreement shall be governed by laws of the Republic of .....

15. DISPUTE RESOLUTION

15.1 Any dispute arising out of or in connection with this Agreement will in the first instance be referred to the Parties' Representatives for discussion and resolution within twenty-one working (21) days of a party notifying the other of the dispute. If the dispute is not resolved at that level, the dispute will be referred to the level of Chief Executives of the Parties who must meet within fourteen [14] working days of the reference to attempt to resolve the dispute. Each party shall appoint a representative for this purpose.

15.2 Each party will use all reasonable endeavours to reach a negotiated resolution through the above dispute resolution procedure. The specific format for such resolution will be left to the reasonable discretion of the relevant management level but may include the preparation and submission of statements of fact or of position.

15.3 If the dispute is not resolved at the meeting of the level of Chief Executives, then either party may (at such meeting or within fourteen [14] days of its conclusion) request that the dispute be referred to arbitration by a single arbitrator to be agreed between the Parties or, failing agreement, within 14 days by an arbitrator to be appointed at the request of any party under the arbitration laws of the Republic of ..... having due regard to any representations made to him as to the appropriate qualifications of such arbitrator. The arbitration shall take place at ..... in the Republic of ..... and shall be in accordance with the arbitration laws of that country.

15.4 Any dispute not resolved in accordance with the preceding paragraphs of this Clause shall be subject to the exclusive jurisdiction of the courts of the Republic of ..... to which the Parties to this Agreement submit.

16. GENERAL

16.1 Entire Agreement

The Agreement constitutes the entire agreement between the Parties in respect of the subject matter thereof and no agreements, representations or warranties between the Parties other than those set out therein are binding on the Parties.

16.2 Variation

No amendment or modification to this Agreement shall be effective unless in writing and signed by authorized signatories of both Parties.

16.3 **Waiver**

No latitude, granting of time or forbearance of a Party hereto regarding the performance of the other Party shall constitute a waiver of any term or condition of this Agreement and no waiver of any breach shall be a waiver of any continuing or subsequent breach. No waiver shall be effective unless it is expressly stated in writing and signed by the Party giving it.

16.4 **Non-Circumvention**

Neither Party, without the prior written consent of the other Party, shall have any discussions, correspondence, or other contact with any employee, director, representative or agent, of the stakeholders introduced by the other Party. This Clause survives until 24 months after the termination of this Agreement.

16.5 **Third Parties**

Except as provided in clause (number), this Agreement does not create any right enforceable by any person who is not a party to it ("Third Party"), but this clause does not affect any right or remedy of a Third Party which exists or is available by virtue of any other written law of the Republic of .....

16.6 **Damages**

Each party agrees that money damages would not be a sufficient remedy for any breach of this Agreement and that each party will be entitles to seek equitable relief, including injunction and specific performance, in the event of any breach of the provisions of this Agreement, in addition to all other remedies available at law or in equity, but excluding any indirect, consequential or punitive damages.

IN WITNESS WHEREOF the Parties, through their duly authorized representatives (who hereby covenant with each other that each has due power and authority to so do), have hereunto set their hands and seals the day and year first above written.

THE SCHEDULE

PART ONE
LIST OF AFFILIATES OF THE COMPANY [THE INSTITUTE]

1. .....
2. .....

PART TWO
LIST OF AFFILIATES OF THE PROSPECTIVE COLLABORATOR

1. .....
2. .....

SIGNED, SEALED and delivered by)
.....,
being the duly authorized representative)
of the said .....(*insert name of Company/*)
the Institute), in the presence of:

Witness' signature : .....
Full Name : .....
Address : .....
.....
Occupation : .....

SIGNED, SEALED and delivered by)
....., being the duly)
authorized representative of the said)
.....(*insert the name of*)
Prospective Collaborator), in the)
presence of:

Witness' signature : .....
Full Name : .....
Address : .....
.....
Occupation : .....