GENERATION, PROTECTION AND COMMERCIALIZATION OF INTELLECTUAL PROPERTY ASSETS BASED ON TRADITIONAL KNOWLEDGE AND ASSOCIATED GENETIC RESOURCES, INCLUDING BIOTECHNOLOGY, IN SELECTED PUBLIC INSTITUTIONS IN KENYA

BY

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Dedication

This research is dedicated to my wife Rita, my three sons Carl Andabwa, Eugene Nabuteya, Yusuf Mbinji Atsali, and my two daughters, Loise Ayuma and Mariam Ayako.
ABSTRACT

This study sought to determine how selected public institutions in Kenya are generating, protecting and commercialising intellectual property (IP) assets that utilise traditional knowledge associated with genetic resources, including Agricultural, environmental and pharmaceutical biotechnology. Kenya is rich in biodiversity and associated traditional knowledge. It also has an elaborate network of public institutions, and an aggressive small and medium size (SME) enterprise, popularly known as “juakali”, that can provide opportunities for commercialisation of protected (IP) assets.

It has been observed that many companies in developed countries are utilising traditional knowledge associated with genetic resources to generate, protect and commercialise (IP) assets. This is evident in fields like agricultural, pharmaceutical and environmental biotechnology. These IP assets have successfully been commercialized, indicating that public institutions in Kenya have potential to do the same.

The study covered seven public universities and five research and development institutions. It found out that, public institutions must have institutional (IP) policies for successful and sustainable generation, protection and commercialization of IP assets based on traditional knowledge associated with genetic resources, including biotechnology. Other factors considered in the study were implications of the international debate on the relationship between the Convention on Biological Diversity (CBD), that influences access to genetic resources and resultant technologies, and the agreement on trade related aspects of intellectual property rights (TRIPS Agreement), that influences protection and commercialization of generated (IP) assets. It recommends adoption of the proposed TRIPS 29 bis to create mutual support of CBD and TRIPS Agreement.

It finally recommends for a review of national (IP) laws, to address emerging issues in relation to genetic resources, traditional knowledge and intellectual property rights. It is anticipated that, such amendments, together with NEMA’s legal notice number 160 of December 2006, will fill identified gaps in the management of genetic resources, traditional and intellectual property rights, and hence, create an enabling environment for generation, protection and commercialization of (IP) assets based on traditional knowledge associated with genetic resources, including biotechnology.
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CHAPTER 1

1.0: INTRODUCTION

1.1. Background to the study

It has been observed in the west that public universities and research and development institutions are increasingly generating, protecting and commercialising their inventions and creations ranging from software products to genetic resource based technologies. The rise in protection of creations and inventions from public universities and research institutions has helped in attracting additional funding for research and start up enterprises. The increase in public universities Intellectual Property(IP) protection, particularly by use of patents, has occurred against a broader policy framework aimed at fostering a greater interaction between public institutions and private sector, particularly industry, in order to foster socio-economic development.

Kenya has seven public universities and several research and development institutions. The country has a very rich heritage in form of traditional knowledge associated with genetic resources that can be utilised by public universities and research institutions to generate, protect and commercialize the resultant intellectual property assets through a network of small and medium size enterprises, commonly known as “jua kali”.

This research project investigated intellectual property assets based on lead traditional knowledge and associated genetic resources, and the possibility of collaborative research between traditional knowledge holders, public universities and research institutions, in promoting start up companies and Small and Medium size Enterprises (SMEs) for commercialisation. The research also investigated why public universities and research institutions are not taking advantage of lead knowledge provided by traditional knowledge holders and ready infrastructure of SMEs network to generate and commercialise resultant protected intellectual property assets.
It has been observed over the past decade that application of agricultural, environmental and pharmaceutical biotechnology have increased. Interest is mainly in natural products as sources of new biochemical compounds for drugs, chemical and agro-product development. This has brought about the resurgence of interest in traditional knowledge related to medicine. This interest has been stimulated by the importance of traditional knowledge as a lead in advancing the frontiers of science and technology.

Traditional knowledge has been extensively used to gain useful understanding of how ecological systems generally work and interrelate. United Nations Commission on Trade and Development (UNCTAD) and General Agreement in Trade and Tariffs (GATT) estimated in 2002 that natural products accounted for trade volume of approximately 60-80 billions globally. According to the African Regional Intellectual Property Office (ARIPO), it is estimated that of the 119\(^1\) drugs developed from higher plants, 74% were discovered from a pool of traditional herbal medicine.

In spite of the important role traditional knowledge plays in sustainable development, it continues to be lost and disregarded in development planning. It only plays a marginal role in biodiversity management and its contribution to society in general is neglected. The accessed traditional knowledge and associated genetic resources has never been acknowledged, making knowledge holders to be reluctant to disclose this knowledge to researchers for value addition.

It has been observed in Kenya that knowledge holders are dying with this knowledge undisclosed, since youths who are supposed to pass it on have been made to view it as primitive. Youths who are traditional “knowledge patents”, and therefore obliged to pass on the knowledge to the next generation, have been made to believe that traditional knowledge is backwards, and are no longer willing to learn the skills and practices.

A significant part of the global economy is based on the appropriation and use of traditional knowledge and associated genetic resources, particularly in agricultural, environmental and pharmaceutical biotechnology. This has contributed to the

\(^1\) ARIPO TK Text
development of innovative products and played a significant role in Research and Development programs of many industries. This knowledge and resources have been, and continues to play a substantive role in the generation, protection and commercialization of resultant products. This undue exploitation needs to be paid for in some form. Concerns over the growing interest in traditional knowledge and its economic importance has generated a wide range of public policy issues, including issues related to genetic resources and intellectual property protection.

ARIPO acknowledges that, in order to understand the role that traditional knowledge and indigenous technologies play in socio-economic development of societies, it is important to understand the concepts of traditional and indigenous knowledge system. The concepts of indigenous traditional knowledge are widely used yet the meanings are rarely provided. There have been various efforts to define these concepts but there are so far no universally adopted definitions.

Ikechi Mgbeoji in patents, plants and indigenous knowledge, defines traditional knowledge and use of plants as encompassing a diverse range of traditional based innovations and creations arising from intellectual activity in the industrial, literary, or artistic fields of indigenous and traditional people. However, ARIPO defines traditional knowledge as a cumulative body of knowledge and beliefs handed down through generations by cultural transmission, about the relationship of the living beings with one another, and with their environment. It includes an attribute of societies with historical continuity in resource use practices. Traditional knowledge and practices, whether used explicitly or implicitly in the management of socio-economic and ecological facets of life, is established on past experiences and observation.

In 2006, Prof. Tom Ogada conducted a national intellectual property audit in Kenya, which revealed that between 1990 and 2001, Small and Medium Size Enterprises (SMEs), also known as (Jua Kali), was the most innovative sector, with a total of 116 patent applications at Kenya Industrial Property Institute (KIPI). They were followed by Industry with 45 patent applications. Research and Development Institutions had 14 applications; individuals from universities had 2 applications, while secondary schools had one application. Public universities were conspicuously absent.

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2 Global bio-piracy Patents, Plants and Indigenous Knowledge.
The substantive issue that drove me to carry out this research was that, if traditional knowledge associated with genetic resources provides leads in advancing development of technologies in agricultural, environmental and pharmaceutical biotechnology in the west, why is it that public universities and research and development institutions in Kenya are not utilising this knowledge and the abundant biodiversity, to generate, protect and commercialise intellectual property assets based on traditional knowledge and associated genetic resources, including biotechnology?

In conducting this research, the subject public universities were the University of Nairobi (UoN), Moi University, Kenyatta University, Jomo Kenyatta University of Agriculture and Technology (JKUAT), Egerton University, Maseno University and Masinde Muliro University of Science and Technology (MMUST). The selected subject research institutions were the Kenya Industrial Research and Development Institute (KIRDI), the Kenya Agricultural Research Institute (KARI), Kenya Medical Research Institute (KEMRI), Kenya Forestry Research Institute (KEFRI) and Kenya Marine and Fisheries Research Institute (KEMFRI).

1.2: Purpose of Study

The purpose of the study was to determine how selected public universities and research institutions in Kenya are generating, protecting and commercialising intellectual property (IP) assets, and investigate obstacles faced by public institutions in generating, protecting and commercialising IP assets that are based on traditional knowledge and associated genetic resources, including biotechnology.

1.3: Statement of the problem

Public universities and research institutions in Kenya are not utilizing traditional knowledge and associated genetic resources to generate, protect and commercialize intellectual property assets, including biotechnology.
1.4: Sub-Problems and Research Questions

The questions that the research addressed were:
1. How public institutions are generating IP assets based on traditional knowledge and associated genetic resources, including biotechnology
2. How the generated IP assets are protected
3. What are the obstacles in protecting the generated IP assets
4. How is collaborative research with industry and traditional knowledge holders managed and
5. Have the generated and protected IP assets, including biotechnology been commercialised

1.5: Justification of the Study

According to the African Regional Intellectual Property Office (ARIPO), it is estimated that of the 119\(^4\) drugs developed from higher plants, 74% were discovered from a pool of traditional herbal medicine. It is also believed that approximately 90% of all medical drugs in the world are obtained from plants that come from biodiversity rich counties like Kenya. All these drugs are developed, protected and commercialised in developed countries, and end up being sold to developing and least developed countries at very exorbitant prices.

It is believed that, if our public universities and research institutions collaborate with traditional knowledge holders, they are able to utilise traditional knowledge associated with genetic resources to generate, protect and commercialise intellectual property assets, including biotechnology, for sustainable development.

Kenya is an agricultural country and needs to generate new technologies in both crops and animal husbandry, using domestic and traditional resources. This is relevant for ethno botany including ethno-veterinary natural products because of the need for technological advances in the field of agriculture and animal husbandry.

A perceptible change has to be promoted in the farming community to enable it drift from low crop and livestock production to high potential crop and livestock farming systems based on the traditional crops and breeds that are well adapted to the local

\(^{4}\) ARIPO TK Text
conditions. This needs collaborative efforts in generating, protecting and commercialisation of traditional crops and livestock breeds. Intellectual property rights (IPRs), particularly patents, is the most relevant in the management of this partnerships through implementation of the third objective of the Convention on Biological Diversity, which deals with fair and equitable sharing of benefits.

Article 16 (3) of CBD requires each contracting party to take legislative, administrative or policy measures, with an aim that contracting parties, in particular those that are developing countries that are providers of genetic resources, are provided access to and transfer of technology that makes use of those resources, on mutually agreed terms, including technology protected by patents\(^5\) and other intellectual property rights.

However, the issuance of bad patents and other proprietary rights have compromised the ability of local communities and individuals who are providers of traditional knowledge and genetic resources to derive maximum benefits from their traditional knowledge associated with genetic resources. Is there need for a national, regional and international mechanism to address this problem of miss-appropriation and bad patents?

**1.6: Assumption of the study**

The study assumed that all public institutions have institutional intellectual property policies and are enforcing them together with the NEMA legal notice no.160 on access to genetic resources and associated intangibles. It also assumed that the institutional IP policies are known to all staff members, and that the policies guide and inform all collaborative research arrangements in relation to generation, protection and commercialization of resultant intellectual property assets. And lastly, traditional knowledge is assumed to have the same meaning as indigenous knowledge.

**1.7: Delimitations of the study**

The study focuses on generation, patent and utility model protection and commercialization of IP assets that are based on traditional knowledge and associated genetic resources, including agricultural, environmental and pharmaceutical

\(^5\) CBD and Patent protected technologies
biotechnology. Collective community marks are also discussed. Other intellectual property regimes are only mentioned for clarity.

The study is limited to selected subject public institutions that have launched at least one patent application at KIPI. Masinde Muliro University for Science and Technology (MMUST) and Kenya Marine and Fisheries Research Institute (KEMFRI) are used as control subject institution.

1.8: Limitations of the study

The study is limited to generation, patent and utility model protection, and commercialization of Intellectual Property (IP) assets, particularly agricultural, environmental and pharmaceutical, that are based on traditional knowledge and associated genetic resources, including biotechnology. Not all universities and research institutions are covered due to financial limitations and time constraint. Hence, it is limited to selected public funded universities and research institutions. In particular, the subjects are public institutions that have made at least one patent or utility model application at Kenya Industrial Property Institute (KIPI).

1.9: Definition of important terms

“Access”- means obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use:

“Access permit”- means a permit that allows a person to access genetic resources issued under regulation 4 (see annex ii);

“Benefit sharing”- means the sharing of benefits that accrue from the utilization of genetic resources;

“Genetic material”- means any genetic material of plant, animal, microbial or other origin containing functional units of heredity;

“Habitat” -means the place or type of site where an organism or population naturally occurs and includes areas colonized by introduced organisms;
“holotypes-” means the single specimen chosen for designation of a new species

“Intangible components or traditional knowledge”- means any information held by persons that is associated with or regarding genetic resources within the jurisdiction of Kenya;

“Intellectual property assets”-include patents, utility models, industrial designs, marks, geographical indications, copyrights and related rights, breeders rights and aspects of traditional knowledge and associated genetic resources, and expressions of folklore;

“Inventory”- means a detailed list, report or record of resources, or the process of making such a list, report or record;

“Material Transfer Agreement”- means an agreement negotiated between the holder of an access permit and a relevant lead agency or community on access to genetic resources and benefit sharing;

“Misappropriation” –means acquiring and continued use, either intentionally or negligently, of traditional knowledge and associated genetic resources, in violation of applicable domestic legislation of a party that requires prior informed consent (PIC) and mutually agreed terms (MAT) for access to traditional knowledge and associated genetic resources.

“Natural environment system”- means relatively intact ecosystems of unique value, such as perennial and seasonal wetlands, highly diverse aquatic ecosystems, or ecosystems promoting a high concentration of rare and unusual species;

“Prior Informed Consent”- means an international operation procedure for exchanging, receiving and handling notification and information by a competent authority

1.10: Conclusion

Kenya has a Science, Technology and Innovation (STI) policy which acknowledges that in the current knowledge based economy, it is globally recognized that for any nation to achieve competitive socio-economic growth, it must utilize Science, Technology and Innovation (STI) in its entire economic and social sectors. The country has recognized the importance of Science, Technology and Innovation (STI) and its utilisation in transforming the socio-economic status of her people.
In this regard, the STI Policy and Strategy is of importance and focuses on among other policies, governance framework, STI infrastructure and human resource capacity, linkages and collaboration, indigenous resources and traditional knowledge, technology development, transfer and diffusion and generation and management of Intellectual Property Rights (IPR)\textsuperscript{6}. This policy is very instrumental in this respect, since it addresses issues concerning genetic resources, indigenous or traditional knowledge and intellectual property rights.

It is believed that with an appropriate public–private sector partnership, and an appropriate policy and support mechanism for maintaining the relationship between traditional knowledge holders and public universities and research institutions, Kenya can generate, protect and commercialise intellectual property assets in agricultural, environmental and pharmaceutical biotechnology, including other technologies based on traditional knowledge associated with genetic resources.

As a developing country, Kenya shall benefit economically and in technological terms, and have greater opportunities to benefit from traditional knowledge associated with genetic resources through intellectual property regime, if public universities and research institutions are able to partner with traditional knowledge holders and other collaborators in generating, protecting and commercialising intellectual property assets.

\textsuperscript{6} Science, technology and innovation policy
CHAPTER II

2.0: LITERATURE REVIEW

2.1. INTRODUCTION

The main focus of this research is the generation; protection and commercialization of intellectual property assets based on traditional knowledge and associated genetic resources, including biotechnology. Although these tree concepts are different, it is generally agreed that they play a very important role in development of intellectual property assets by public institutions.

Kenya is nearly divided into two by the equator, and occupies an area of approximately 182,646m. Ecological data shows that a large part of the country is arid and semi arid, constituting approximately 80% of the entire country. Approximately 2% of the country is aquatic ecosystem, while 2% is under forest cover. The annual rainfall is bimodal and ranges from less than 100mm to 1500mm annually. The country has varied topography made up of mountains, plateaus and lowlands. These factors have created diversity in plants, animals and micro-organisms.

In a country study carried out in 1992, it was found that the country has approximately 35,000 known species of plants, animals and micro-organisms, and that the 42 communities in Kenya hold traditional knowledge associated with this bio-diversity. Biodiversity is defined as the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. (CBD- Secretariat, 2005).

A review of international treaties shows that Kenya is a signatory to among other treaties, the Convention on Biological Diversity(CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRF/A) and the Agreement on Trade Related Aspects of Intellectual Property rights(TRIPS). These treaties and their objectives are very relevant to the substantive issues addressed in this research.
The convention on biological diversity (CBD), one of the outcomes of the United Nations Conference on environment and development (UNCED) that was held in Rio in June 1992, urges parties, Kenya included, to develop appropriate legal, policy and institutional regimes to regulate access to genetic resources and ensure fair and equitable sharing of accrued benefits. This is a fundamental factor in research and generation of technologies that utilise genetic resources and subsequent protection of the resultant intellectual property assets. The global program of action on sustainable development, also known as Agenda 21, in chapter 15, links this development to poverty alleviation, equity and social justice, and emphasizes the need to ensure fair and equitable benefit sharing from the sustainable use of genetic resources.

The objectives of the Convention on Biological Diversity (CBD), pursued in accordance with its relevant provisions, are the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

The objectives of the TRIPS agreement is that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Kenya is party to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRF/A), having ratified it in 2003. Consequently, as a party to the treaty, the country must strive to meet its obligations. In order to fast track and expedite the process of treaty implementation, Food and Agricultural Organisation (FAO), Treaty Secretariat and Bioversity International have jointly been providing technical assistance and capacity building for implementation of the Multilateral System of access and benefits sharing. Kenya Agricultural Research Institute (KARI) is the national focal point for the treaty.

The objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRF/A) are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity (CBD),
for sustainable agriculture and food security. The treaty has 69 crops⁷ listed under the multilateral system. These crops are available to researchers and provide opportunities for access for generation of intellectual property assets.

The treaty states that its objectives will be achieved by closely linking the treaty to the Food and Agriculture Organization of the United Nations and to the Convention on Biological Diversity. Article 9 of the treaty recognises the enormous contribution that the local and indigenous communities and farmers have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production. It states that the responsibility of realising farmer’s rights rests with national governments.

The Convention on Biological Diversion (CBD) calls for the regulation on access to genetic resources and resultant technologies, including biotechnology, and the fair and equitable sharing of benefits arising from the commercialization and sustainable utilization of the resources. While recognizing the sovereign rights of the states over their genetic resources, the CBD in article 15, urges parties to facilitate access to genetic resource for environmentally sound use, but emphasizes that such access should be granted based on mutually agreed terms (MAT), and should be subject to prior informed consent (PIC) of the provider of the knowledge and genetic resources. This is a fundamental issue in relation to access to genetic resources for generation, protection of the resultant technologies, and eventual commercialization of the resultant intellectual property assets.

The 42 Kenyan communities have a very rich cultural heritage⁸. These include, but is not limited to traditional literature, traditional arts and crafts, music, visual arts, ceremonies, traditional beliefs, traditional architecture associated with particular sites, as well as forms of traditional knowledge related to traditional-medicines and traditional-practices in medicine, agriculture, forest management and conservation and sustainable use of biodiversity. This knowledge is transmitted from one generation to the next in many ways including songs and dances, repeated practice, apprenticeship with elders and specialists. It can be harnessed and applied in many fields of industry, through collaborative research between traditional knowledge holders and public funded institutions.

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⁷ Annex 1 of the ITPGRF/A-List of crops covered under the multilateral system.
⁸ Draft National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2010
This knowledge is holistic, inherently dynamic and constantly evolving through experimentation and innovation. A great deal of traditional knowledge and traditional cultural expressions has cultural or spiritual value that cannot be quantified in monetary sense. It embraces information about location, movements and other factors explaining spatial patterns and timing in the ecosystem.

The African Model law in chapter three recognizes that 80% of the south’s medical needs are met by community healers using local medicine systems. (RAFI, 1977). It states in section 3.6 that access to any biological resources and knowledge or technologies of local communities in any part of the country shall be subject to an application for the necessary prior informed consent. It acknowledges the principle of fair and equitable sharing of benefits accrued from the use of knowledge and resources, and that traditional knowledge has contributed significantly to the present body of knowledge possessed by scientists, such as ethno botanists, ethno pharmacologists, and by agriculturists, foresters, and food technologists. The fact that traditional knowledge is being widely disseminated and commercially exploited, with only a small proportion of the benefits flowing back to provider people and communities, raises the question of fairness, justice and intellectual property ownership.

The biggest challenge is that traditional knowledge, innovations and practices derived from traditional knowledge and associated genetic resources cannot be credited to a single inventor. In other cases, genetic resources, especially not directly associated with traditional knowledge, have been utilized in bio-prospecting and neither acknowledgment of the knowledge nor resource providers. Active bio-prospecting is on microbes, extremophiles, animals, plants, marine biodiversity and other genetic material. This genetic material can be utilized by our public institutions to generate intellectual property assets that can be protected and commercialized, as is the case with Universities in the west, particularly in the United States of America after the enactment of the Bayh-Dole Act.

The Bayh-Dole Act allows the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization. The contracting universities and businesses are then permitted to exclusively license the inventions to other parties. The federal government, however, retains rights to license the invention to a third party,

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9 See case studies 1-4
without consent of the patent holder or original licensee, where it determines that the invention is not being made available to the public on a reasonable basis. This is also known as compulsory licensing.

Bench marking this scenario with the Kenyan situation reveals that, the existing policy and legal framework is not harmonized. This creates a challenge in addressing issues of generation, protection and commercialization of intellectual property assets based on accessed traditional knowledge and associated genetic resources, and subsequent sharing of accrued benefits.

There is a national policy development initiative that aims at addressing these issues. The initiative is informed by Kenya’s Vision 2030 that takes cognizance of the Millennium Development goals (MDGs) and the economic Recovery Strategy for Wealth Creation (ERS). The aim of Vision 2030 is to create a globally competitive and prosperous country with a high quality of life by 2030.

In its goals and objectives, Vision 2030 seeks to identify and implement flagship projects that will trigger development in key sectors in the economic, political and social arena. No society can achieve its development goals if it ignores its cultural heritage that is imbedded in traditional knowledge associated with genetic resources that forms the basis for generation of intellectual propriety assets.

This draft policy provides a national framework for recognition, preservation, protection and promotion of sustainable use of traditional knowledge and associated genetic resources. It aims at mainstreaming such knowledge systems into national development planning and decision making processes at all levels, including research and development. Traditional knowledge and associated genetic resources play a very important role in enhancing Kenya’s national cohesion and development. However, there are several challenges that impede their integration in the national development planning and decision making processes at all levels.

The main challenges that the draft policy notes include; Lack of recognition and mainstreaming of traditional knowledge and genetic resources into national policies and decision making processes, where it is generally acknowledged that traditional knowledge is not recognized in many of the national policy and legal frameworks. The majority of the rural communities rely heavily on the traditional knowledge, innovations and practices for their day to day activities, in particular agriculture and medicines. It is
therefore imperative to have the traditional knowledge and associated genetic resources integrated into the national policies and decision making processes. It is aimed at protecting interests of the communities; Lack of a comprehensive traditional knowledge and associated genetic resources database where it recognizes that traditional knowledge systems are scattered in different community institutions and in different formats. This makes its access cumbersome. To improve its integration and application, the draft policy notes that it is important to establish a framework that will facilitate the establishment of comprehensive national traditional knowledge and associated genetic resources database(s) and inter-database linkages with intellectual property institutions; High cost of collation and documentation of traditional knowledge and associated genetic resources where it notes that the cost of collation and documentation of traditional knowledge systems is high.

Communities lack the requisite financial resources to undertake such tasks. Consequently, there are inadequate resources to support a comprehensive framework for collation and documentation of traditional knowledge and associated genetic resources. This results in low use of traditional knowledge and the associated genetic resources; Weak community institutional linkages where it has been observed that communities have a lot of traditional knowledge, innovations and practices that is neither documented nor packaged in a manner to be accessed. Yet, there is no community institutional framework for exchange of information. This problem is compounded by lack of a national legal mechanism to facilitate such exchange and sharing of information to protect against misappropriation, while ensuring equitable sharing of benefits; Inadequate capacities have been noted in that whereas communities hold a lot of traditional knowledge, innovations and practices, much of this information is transmitted orally. Consequently, most communities have inadequate capacities to collate and document the traditional knowledge and associated genetic resources; Protection of Intellectual property rights poses a challenge of how to protect the communal rights of the holders of traditional knowledge and associated genetic resources, innovations and practices.
2.2: Review of Legislations Affecting Access to Genetic Resources

2.2.1: Draft constitution of Kenya

2.2.1.1: Environment

Chapter eight of the draft constitution of Kenya proposes that the state shall: respect the integrity of natural processes and ecological communities and promote the conservation of habitats and species; ensure sustainable exploitation, utilization, management and conservation of the environment and natural resources and the equitable sharing of the accruing benefits; ensure that social and cultural values traditionally applied by communities of Kenya for the sustainable management of the environment and natural resources are observed; domesticate international and bilateral agreements and treaties relating to protection of the environment to which Kenya is party; ensure that planning and utilization of the environment takes account of disadvantaged areas and their inhabitants; promote energy saving and the use of renewable energy sources; prevent pollution and ecological degradation; allocate adequate resources to reclaim and rehabilitate degraded areas and areas prone to disasters to make them habitable and productive; work to achieve and maintain a tree cover of at least ten per cent of the land area of Kenya; protect and enhance the intellectual property in, and indigenous knowledge of, biodiversity and genetic resources of the communities; and encourage public participation in the management, protection and conservation of the environment.

It states that every person has a duty to cooperate with State organs and other persons to; ensure ecologically sustainable development and use of natural resources; respect, protect and safeguard the environment; prevent or discontinue any act which is harmful to the environment; take measures to prevent or discontinue any act or omission which is harmful to the environment; and maintain a clean, safe and healthy environment.

On Conservation of the environment, it states that, in the utilization and management of the environment, the State shall; protect genetic resources and biological diversity; establish systems of environmental impact assessment, environmental audit and monitoring of the environment; encourage public participation; protect and enhance the intellectual property in, and Indigenous Knowledge of, biodiversity and genetic resources of communities; and ensure that the environmental standards enforced in the Republic are the accepted international standards.

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10 Harmonized Draft Constitution of Kenya
It further states that the State shall ensure the protection, management, promotion and sustainable development of natural resources and shall undertake research to ensure their enhancement; eliminate unfair trade practices in their production, processing, distribution and marketing; regulate their exportation and importation; regulate their origin, quality, methods of production, harvesting and processing; eliminate processes and activities that are likely to endanger or curtail their existence; and utilize them for the benefit of all the people of Kenya.

2.2.1.2: Culture

Chapter five of the draft constitution recognizes culture as the foundation of the nation and the cumulative civilization of the Kenyan people and communities and, in particular affirms the values and principles of the communities of Kenya, their traditions, present struggles and future aspirations; recognizes and protects the fundamental values and goals of culture and appreciates culture as the basis for nurturing national pride and identity; and reflects and affirms the sovereign uniqueness and distinctiveness of the Kenyan people and communities contributing to, and sharing in, the global culture.

It provides that the State shall; promote understanding, tolerance and appreciation of diversity; respect, preserve, protect and promote the heritage of Kenya, and in particular, its cultural, historical, religious, sacred, archaeological and other significant sites and artifacts; promote research and an education policy that enhances culture and cultural values and enables the people to develop strong moral, ethical and spiritual foundations; all forms of national and cultural expression through literature, the arts, traditional celebrations, science, communication, information, mass media, publications and libraries and other cultural heritage; and research into and documentation of the cultures of Kenya, including national history and customary law.

The state shall recognize, support and promote the appropriate application of modern and traditional medical practices; recognize the role of science and indigenous technologies in the development of the nation; support, promote and protect indigenous knowledge and the intellectual property rights of the people of Kenya.
The draft constitution also states that, through legislation, the state shall ensure that communities receive compensation or royalties for the use of their cultures and cultural heritage; promote, where applicable, the use of traditional farming systems, and traditional foods and drinks; and through legislation, recognize and protect the ownership of indigenous seeds and plant varieties, their genetic and diverse characteristics and their use by communities of Kenya.

2.2.1.3: Observation

This draft constitution, if adopted by Kenyans, shall form a very important entry point for enhanced protection of intellectual property rights for technologies and practices based on traditional knowledge and associated genetic resources, including traditional cultural expressions. The NEMA legal notice number 160\(^{11}\) of Dec 2006 provides a framework, measures and a mechanism for regulating access to genetic resources and the equitable sharing of accrued benefits. However the existing national legislative and policy framework shows an absence of a mechanism of accessing traditional knowledge.

2.2.2.0: Other Legislations on Management of Genetic Resources

Other than the draft constitution, there are other laws in place that address sector based genetic resources management, and are discussed below\(^ {12}\).

2.2.2.1: Wildlife (conservation and management) Act, 1985

The wildlife (conservation and management) Act provides that it is an offence for any person, without authorization, to cut, injure or set fire to any vegetation, clear, cultivate or be in possession of any animal or trophy within or outside national Parks. The Act also empowers the responsible minister, by notice in the Gazette, to declare any area and to prohibit, restrict or regulate particular acts in such an area for ensuring the security of the animals or vegetation in the area, or for conservation.


\(^{12}\) (See table 1).
2.2.2.2: Forest Act, 1992 (Cap 385)

The forest Act provides for the control and regulation of forest area on alienated land. It empowers the minister responsible to declare any forest area to be a nature reserve for purposes of conserving the natural flora and fauna therein. In a nature reserve, no cutting, grazing, removal of forest product or disturbance of the flora is allowed, without permission of the Director of Forestry (section 6(2)). Permission is given only with the object of conserving the natural flora and amenities of the reserve and takes the form of a licensing system that defines the product to be harvested, the season during which the activity is permitted or may be carried on, and the prescribed fee or royalties to be paid for the licenses (section 7 and 8).

Identified gaps

The Wildlife (conservation and management) Act, 1985 and Forest Act, 1992 (Cap 385) do not cover or regulate access to forest resources outside the forest reserves or protected areas. The result is that, access to genetic resources outside protected areas has taken place in a very unsustainable manner, with little or no benefits to the Kenyan communities. The Acts do not provide for benefit sharing arrangement. Although many institutions are involved in bio-diversity related activities, there is lack of coordination as far as conservation and sustainable utilization of biological resources are concerned. Each institution seems to follow its own mandate, resulting in duplication of work and unsustainable management and use of the scarce resources.

2.2.2.3: Fisheries Act, 1989 (Cap 378)

Access to aquatic genetic resources in Kenya is currently regulated by the fisheries Act. The Act prohibits certain fishing methods and protects certain species and sizes of fish. The director of fisheries is empowered to impose certain regulatory measures, including limitation on the amount and composition of species that may be caught and traded (section 5). The Director is empowered to issue and review fishing licenses, or grants preferential licensing of certain fisheries and imposes certain limitation on the person or vessels in a particular fishery. Foreign nationals and vessels are not allowed to fish, attempt to fish or participate in fishing operations in Kenya’s territorial waters without a valid license (section 11,12 and 13).
Gaps: The Act has no mechanism for sharing of accrued benefits generated as a result of sustainable utilisation of aquatic genetic resources in Kenya.

2.2.2.4: Seeds and plant varieties Act, 1979 (Cap 326)

The seed and plant varieties Act protects the rights of plant breeders. These rights are exclusive and enforceable in national courts in case of infringement. Under provisions of section 19, exclusive rights are granted to a breeder of a new plant variety for a maximum period of twenty-five years and a minimum of fifteen years depending on the plant variety. The holder of such rights enjoys the exclusive rights to authorize use of the variety on specified conditions such as the production of the propagating material of the variety for commercial purposes, commercialization of the variety, and offering it for sale, export, or stocking.

Identified gap: There is no act that protects the rights of animal breeders. It is important to note that whereas Kenya is rich in traditional knowledge associated with both plant and animal genetic resources, that can be used to generate intellectual property assets, there is the seed and plant varieties Act, 1979 (Cap 326), and nothing on the protection of traditional animal breeds.

2.2.2.5: Agricultural produce (Export) ACT, 1970 (Cap 319)

Section 4 of the Act prohibits the export of any agricultural produce or products of any animal for human consumption, if such produce is unsound, that is, infected with any diseases rendering it unfit for human consumption (section 4). The articles declared to be agricultural produce for purposes of this rules include potatoes, beans, coffee, and vegetables such as asparagus, Brussels sprouts, cauliflower, onions, and fruits such as bananas, plums, strawberries, and mangoes.
2.2.2.6: Agricultural Produce and Marketing Act, 1983 (Cap 320)

The Agricultural Produce and Marketing Act provides for the control and regulation of the marketing of agricultural produce, that is, anything live or dead, produced in the course of agriculture (section 2).

2.2.2.7: Crop production and livestock Act, 1977 (Cap 321)

The crop production and livestock Act makes provision for the control and improvement of crop production and livestock and the marketing and processing thereof, and empowers the minister responsible for agriculture to make rules for improving the cultural conditions of any crop or the method of its production and the prevention of its destruction or waste (section 4 (1)(b)), improving the quality of any agricultural produce (section 4 (1) (c)), specifying any kind of crop, tree or plant, or variety thereof as the kind which may or may not be grown, or which may not be destroyed (section 4 (1) (d)).

Gaps

The three Acts, (Agricultural produce (Export) ACT, 1970 (Cap 319); the agricultural Produce and Marketing Act, 1983 (Cap 320); and the crop production and livestock Act, 1977 (Cap 321) have provisions for the control, improvement of crop and livestock marketing and processing. However, the Acts have no mechanism on benefits sharing of accessed and improved animal genetic resources.

2.2.2.8: Industrial Property Act, (IPA-2001)

The definition of utility models and sections 26 and 29 of Industrial Property Act 2001 (IPA-2001), together with its implementation regulations 11, have provisions for utility model and patent protection that can help in management of partnerships in generation, protection and commercialisation of technologies that are based on traditional knowledge and associated genetic resources, including biotechnology. Industrial property Act has provisions for protecting traditional knowledge and genetic resources based technologies by either patents or utility models.
Gaps

On disclosure requirement, it can be stated that currently, the national IP laws do not require applicants to disclose the source of origin, provide Prior-informed Consent (PIC) and include benefit sharing arrangement in Intellectual Property applications. However, section 19 of the NEMA legal notice no.160 of December 2006 that regulates access to genetic resources and its intangibles, states that matters related to Intellectual Property shall be addressed by the existing intellectual property laws. Neither Kenya Copyrights Board (KCB), Kenya Plant Health Inspectorate Service (KEPHIS) nor Kenya Industrial Property Institute (KIPI) address issues on disclosure of source of origin of genetic resources and its intangibles in intellectual property applications, to enable enforcement of section 19 of NEMA legal notice no 160 of December 2006, as is the case with India’s amended patent Act of 2005.

On biotechnology, the Industrial property Act 2001 has provisions for deposit of micro-organisms as a condition for complete disclosure in patent applications. It however lucks provision for the "Budapest Treaty" on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent application. KIPI is also mentioned as a regulator in the second schedule of the Biosafety act 2009, but the Biosafety act has no implementing regulations. This means that technologies based on genetically modified organisms can not be commercialised.

It is recommended that, to promote biotechnology development in all sectors, there is need to see if the Industrial Property Act and its implementing regulations adequately cover micro-organism deposits for Marine science research (MSR). The patent law should recognise and embrace the practise of the 1977 Budapest treaty on the international Recognition of the deposit of Micro-organisms, for the purposes of Patent procedure. Implementing regulations of the Biosafety Act-2009 should also be developed to enable commercialization of products of genetically modified organisms, including other biotechnologies. The scope of the Biotechnology Act of 2009 should go beyond genetically modified organisms, and regulate all biotechnologies.

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13 Industrial Property Act (Section 29 and Regulations).
14 The Gazette of India Extraordinary
Table 1: National Legislations relating to Genetic resources and Traditional Knowledge in Kenya

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>IMPLEMENTING INSTITUTION</th>
<th>LEGISLATION</th>
<th>CATEGORY</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>National Environment Management Authority</td>
<td>Environmental &amp; Coordination Act, 1999</td>
<td>ABS Regulations under Legal Notice No. 160 of 2006.</td>
<td>Genetic resources and associated Intangible knowledge</td>
</tr>
<tr>
<td>3.</td>
<td>Kenya Plant Health Inspectorate Service</td>
<td>Seed and Plant Varieties Act, Cap 326</td>
<td>Farmers’ Privileges</td>
<td>In part</td>
</tr>
<tr>
<td>5.</td>
<td>Department of Culture</td>
<td>Witchcraft Act</td>
<td>Traditional Health Practitioners (THPS)</td>
<td>The Act criminalizes traditional knowledge</td>
</tr>
<tr>
<td>7.</td>
<td>Forest Department</td>
<td>The Forest Act, 1992 (Cap 385):</td>
<td>In-situ conservation</td>
<td>Resource manager</td>
</tr>
<tr>
<td>8.</td>
<td>Fisheries Department</td>
<td>The Fisheries Act, 1989 (Cap 378):</td>
<td>In-situ conservation and sustainable utilization</td>
<td>Resource manager</td>
</tr>
<tr>
<td>10.</td>
<td>Ministry Of Agriculture</td>
<td>The crop production and livestock Act, 1977 (Cap 321):</td>
<td>Crops and animals production</td>
<td>Technology consumers</td>
</tr>
</tbody>
</table>

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15 Witchcraft Act was originally meant to ban Witch Doctors and cultural beliefs in Kenya. The Act criminalises traditional knowledge and practices

16 Appointed pursuant to section 32(1) (a) (i) of the Constitution of Kenya Review Act, 2008.
2.3: Institutional Framework

There are two national draft policies addressing protection of traditional knowledge and associated genetic resources, which are important in generation, protection and commercialization of technologies based on traditional knowledge and associated genetic resources, including biotechnology. These are the draft National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expression of 2010, that covers Traditional Knowledge (TK), genetic resources (GR) and intellectual property ((IP). The policy proposes to protect traditional knowledge through a *sui -generis* system, and ensure **mandatory disclosure** of origin of genetic resources and traditional knowledge in intellectual property applications. The drafted Traditional Medicine and Medicinal Plants Policy (TMMP)-2010), addresses traditional pharmaceutical technologies and other issues like intellectual property rights of traditional knowledge holders, safety and efficacy of traditional medicine, its domestication and cultivation for sustainable utilization.

Lack of guidelines concerning the implementation of the disclosure requirement on accessed resources in intellectual property applications, and benefits sharing arrangement, is the biggest challenge to national intellectual property institutes. There are no provisions in the national intellectual property laws to facilitate synergies between accessed genetic resources and related traditional knowledge and benefit-sharing arrangement , as is required by section 19 and 20 of the NEMA legal notice number 160 of December 2006.(see annex ii)

Whereas legislative and policy frameworks may be crucial to the regulation of access to Kenya’s genetic resources and related traditional knowledge, institutional arrangement is fundamental for effective implementation of an access regime. This is substantive in determining generation, protection and commercialization of (IP) assets that utilise traditional knowledge and associated genetic resources, including biotechnology. Each of these institutions has their own administrative agenda, and retains legal control of all matters of natural resources management within its scope.

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17 See table 2
2.3.1: National Environment Management Authority

NEMA LN no 160 is Kenya’s regulations on access to genetic resources and benefits sharing arrangement. It works in collaboration with lead agencies. The National Environment Management Authority was created in the 1970’s with the mandate to coordinate all environmental matters in the country and to advice the government on the same. It is the focal point for coordinating the implementation of the regulations, in collaboration with lead agencies.

There are numerous government ministries and departments whose mandates impact on access to genetic resources. The key institutions include the National Environment Management Authority (NEMA), Kenya Wildlife Service (KWS), the Forest Department, the National Museum of Kenya (NMK), the National Council for Science and Technology (NCST) and the President’s office for research clearance, Kenya Agricultural Research Institute (KARI) particularly the National Gene Bank, the Kenya forestry Research Institute and the Kenya Marine and Fisheries Research Institute.

Gaps: NEMA legal notice no 160 of December 2006 is silent on the 69 crops listed under the multilateral system of the ITPGRF/A. These crops are available to researchers in both public and private institutions.

2.3.2: Kenya Wildlife Service, (KWS)

The Kenya wildlife service is a corporate body that was created in 1989 by an act of parliament through an amendment to the wildlife (conservation and management) Act. The main function of KWS is the formulation of policies regarding the conservation, management and utilization of all types of wild fauna and flora.

KWS has no specific policy and administrative mechanism on regulating access to genetic resources. However, there are in-house procedures that are used for this purpose. For example, any person interested in undertaking research in national parks or game reserves is required to submit a detailed research proposal to the biodiversity department for evaluation regarding the viability and feasibility of the research. The proposal must be in accordance with the services conservation objectives.
If the proposal meets the requirements, the applicant is allowed to carry out the research. This research approval procedure could be modified to include access to genetic resources and the associated traditional knowledge and the sharing of accrued benefits.

2.3.3: Forest department

The forest department is currently responsible for ensuring efficient management, conservation and sustainable use of forest resources within forest reserves. Like KWS, the forest department has no specific measures yet to regulate access to genetic resources in the forest reserves. The existing licensing system with respect to exotic species only, requires the applicant for a harvesting license to state the species and the amount to be extracted and the location from where to extract. With respect to medicinal plants, the position is that there is no requirement of a permit for subsistence use. A license is only required in case of commercial exploitation. The applicant must specify the species and the number to be extracted. There is a requirement that the licensee replants as per collection in order to avoid the eventuality of lack of propagating material.

Gaps: Large quantities of our exotic species are leaving the country through this harvesting license. When value is added to these materials, protected and commercialized, Kenya has no control over the granted patents and other IP rights and the sharing of benefits generated from its use.

2.3.4: Kenya Agricultural Research Institute (KARI)

The Kenya agricultural research institute (KARI) is one of the research institution established under the provisions of the science and technology Act. It is mainly involved in research aimed at increased agricultural production through the use of improved plant and animal varieties, and covers a wide range of commodities. It carries out research through a network of national agricultural research centres located in various ecological zones of the country.

Within KARI, there is the National Gene Bank of Kenya (NGBK) that is engaged in ex-situ plant germplasm conservation. The NGBK stores germplasm under three main
categories, namely working collections, medium term accessions, and long-term accessions. The working collections are annually supplied to plant breeders in national agricultural research stations and public universities. Duplicates of the accessions stored at the Gene bank are deposited with local research stations and with Gene banks under the international board for plant genetic resources.

**Gaps:** The NGBK does, however, face a number of limitations as far as conservation of germplasm and access to genetic resources are concerned. The first is lack of a legal framework within which to operate. In the absence of an articulate legal framework, the NGBK has no clearly defined mandate and direction regarding the nature and measures to be taken to regulate access to its collections and the equitable sharing of any benefits accrued from its sustainable utilisation.

### 2.3.5: National Museums of Kenya

The mandate of National Museums of Kenya (NMK) include; preservation of culture and history of the peoples of Kenya, collection, study and conservation of Kenya’s biodiversity and seeking solutions for sustainable utilization of Kenya’s biotic wealth. Several departments of NMK, particularly the National Herbarium, the botanic gardens, plant conservation and propagation unit, Institute of Primate Research (IPR) and the centre for biodiversity are involved in research involving access to genetic resources. The application procedure for research permit is similar to that of the National Council for Science and Technology and the office of President.

**Gap:** Large quantities of material collected from the wild leaves the country by use of false permits or lack of information by relevant authorities. The institution (NMK) has no control over the sharing of benefits generated from the plant data it provides.

### 2.3.6: National Council for Science and Technology (NCST) and Research Clearance at the office of the President (OP)

The Office of the President (Research Clearance Unit), with technical guidance from the National Council for Science and Technology (NCST), is responsible for granting permission to carry out any kind of research in Kenya by both nationals and foreign researchers. It is a requirement that an application must be made to the President’s Office for an authority to be granted to conduct research in Kenya. The application must be accompanied by a comprehensive project proposal that includes details of the objectives, hypothesis, methodology, literature review and
envisaged application of the research results. If permission is granted, the applicant must undertake to deposit a minimum of two copies of the research findings including notes and methodology with the ministry of Education, Science and Technology on completion of the research. The final research reports must be submitted within a year from the completion of the research. Of importance is that specimens, information or documents obtained in the course of the research work must not be used or disposed in a manner prejudicial to the interests of Kenya, and the Government reserves the right of access to the generated data and research premises of the project. The national council of Science and Technology requires that researchers may take out of Kenya raw materials or specimens only with the endorsement of the affiliating institution, but because the council does not oversee the research, it cannot enforce this requirement. If the material taken out of Kenya is developed into a commercial product, Kenya has no control over the intellectual property assets generated nor benefits accrued from commercialization of the material. Although many institutions are involved in bio-prospecting activities, there is lack of coordination in conservation and sustainable utilization of biological resources.

There is lack of awareness of the utility value of the genetic resources collected. There’s little understanding of the contribution made by genetic resources to the social and economic development of the country and the need to strengthen mechanisms for sustainable conservation and utilization of genetic resources.

2.3.7: Collection Missions

There are other ways in which genetic resources can be accessed without going through the research procedures. Collection missions for accession of genetic resources have no requirement for a research permit. Some of the collection mission in Kenya started as early as 1964 when coffee accessions were collected. Since then, several plants, animals and micro-organisms have been collected in collaboration with international and local institutions. By 1985, it was reported that there were over 18,739 plant accessions collected from Kenya, comprising coffee, tea, wheat, sorghum, barley, maize, pulses, roots, tuber crops, oil crops, forest species, fruits, and vegetables, among others. These accessions were collected and are conserved in international gene banks. The challenge is that, even where research involves utilization of genetic resources, there is a problem of capacity to police and ascertain its commercialization outside the country.

In any case, it is difficult to monitor genetic resources that may have been taken out of the country as micro-organisms or cells and tissue cultures. This is why Kenya is
advocating for an international instrument to address disclosure of source of genetic resources and associated knowledge in intellectual property applications. This factor is very important, since it forms a basis for generation of intellectual property assets.

### Table 2: A summary of Institutional Mandates and National Laws Related to CBD in Kenya

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>PARENT MINISTRY</th>
<th>LEGISLATION</th>
<th>INSTITUTION</th>
<th>ACCESS PERMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Ministry of Forests &amp; Wildlife</td>
<td>Forest Act, 2006</td>
<td>Kenya Forest Service</td>
<td>Logging Permit</td>
</tr>
<tr>
<td>3</td>
<td>Ministry of Environment &amp; Mineral Resources</td>
<td>Environmental &amp; Coordination Act, 1999</td>
<td>National Environment Management Authority</td>
<td>Access and Benefit Sharing Permit</td>
</tr>
<tr>
<td>5</td>
<td>Ministry of Agriculture</td>
<td>Seeds &amp; Plant Varieties Act, Cap 326</td>
<td>Kenya Plant Health Inspectorate Services</td>
<td>Phytosanitary Licence/Permit</td>
</tr>
<tr>
<td>6</td>
<td>Ministry of Fisheries Development</td>
<td>Fisheries Protection Act, 1977 Cap 379</td>
<td>Fisheries Department</td>
<td>Fishing Permit</td>
</tr>
<tr>
<td>7</td>
<td>Ministry of Livestock Development</td>
<td>Crop Production and Livestock Act, 1979 Cap 321</td>
<td>Livestock Department</td>
<td>Livestock Movement Permit</td>
</tr>
<tr>
<td>8</td>
<td>Ministry of Livestock Development</td>
<td>Crop Production and Livestock Act, 1979 Cap 321</td>
<td>Veterinary Department</td>
<td>Meat Sample Inspection/Export Permit</td>
</tr>
<tr>
<td>10</td>
<td>Ministry of Industrialization</td>
<td>Industrial Property Act, 2001</td>
<td>Kenya Industrial Property Institute</td>
<td>Patented Microbe Release Permit</td>
</tr>
</tbody>
</table>

*Source: Government Printers, 2010*
2.4: Observations

2.4.1: Generation of inventions

While several factors affect generation of traditional knowledge based intellectual property assets associated with genetic resources, including biotechnology, access to traditional knowledge and genetic resources is very instrumental. Article 15 of CBD is clear on sovereign rights of States over their genetic resources and conditions for Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) but is not clear on access to traditional knowledge.

This calls for development of a practical and efficient regime on access to traditional knowledge and designate a national focal point that should advice and inform interested users and applicants for access to traditional knowledge and associated genetic resources, including procedures for prior informed consent, mutually agreed terms and benefit-sharing.

A look at the Kenyan situation shows that traditional knowledge holders or herbalists are registered as associations\(^\text{18}\) of herbal health practitioners or individuals by the department of Culture. The only legislation available is the Witchcraft Act\(^\text{19}\). This act smacks of oppression of African traditions and colonial mentality that everything African is primitive. It criminalises traditional practices including brews, and has no provisions or mechanism on accessing traditional knowledge. This creates a gap on access to traditional knowledge by public institutions.

An institute of combination therapy and traditional medicine established in Mali, since 1973, has since become the National Institute for Research on Pharmacopoeia and Traditional Medicine (INRPMT). The National Institute for Research on Pharmacopoeia and Traditional Medicine is directly attached to the Office of the Minister of Public Health. The final text of legislation of the practice of traditional medicine of Mali establishes the operating procedures of INRPMT. The Institute's mission is to study medicinal plants and any other products or process\(^\text{20}\) used in traditional medicine.

\(^{18}\) National draft policy on Traditional Medicine and Medicinal Plants Policy (TMMP)

\(^{19}\) Witchcraft Act was originally meant to ban Witch Doctors and cultural beliefs in Kenya.

\(^{20}\) Products, processes and uses are substantive patent examination matters in Kenya.
It is important to note that products and process are fundamental elements for patents and utility models protection in Kenya. The institute (INRPMT) also carries out phytosanitary control of medicinal plants and their operation, and organizes the traditional herbalists for a rational development of the **pharmacopoeia** for traditional medicine. This is a good case to compare with the Kenyan situation, and see how the relationship between public universities and research institutions can help in generating, protecting and commercializing pharmaceutical products and processes that are based on traditional knowledge. In this relationship, a mechanism for access to traditional knowledge should be developed. It could help in development of a national pharmacopoeia research on traditional medicine.

As literature reviewed shows, the critical national law that controls access to genetic resources and associated intangibles is the legal notice NO.160 of 1st December, 2006(Legislative Supplement No. 47)\(^{21}\).

Case studies can help in bringing out real issues. A review of the following case\(^{22}\) on genes, jeans and detergents, by Peter Munyi\(^{23}\) of the International Centre for Insect Physiology and Ecology (ICIPE), demonstrates the challenge that institutions and genetic resource managers are facing in relation to access to genetic resources and subsequent commercialization of resultant intellectual property assets.

Sections 15 (c) and 18\(^{24}\) of the environment management and co-ordination, conservation of biological diversity and resources, access to genetic resources and benefits sharing regulations of 2006, stipulates that, reasonable access to all genetic resources collected shall be guaranteed to all Kenyan citizens, whether such genetic resources and intangible components are held locally or abroad, and that notwithstanding any provisions in the regulations, no person shall transfer any genetic resources outside Kenya, unless such a person has executed a material transfer agreement. It is important to find out how public universities and research institutions are implementing this provision that is crucial in accessing and transferring genetic material for generating intellectual property assets for protection and commercialization.

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21 See annex ii  
22 See case study 3  
23 Genes, Jeans and Detergents, 09.2009, the enzyme case from Kenya- Peter Munyi, ICIPE.  
24 See annex ii
Kenya has various legislations on genetic resources, most of which are pre- CBD. Other than the National Environment Management Authority’s legal notice number 160 of December 2006 (see annex ii), all the other legislations do not address issues of access to genetic resources and its intangibles, and equitable sharing of accrued benefits. The Environment Management and Co-ordination Act (1999)\(^\text{25}\) is Kenya’s framework legislation coordinating all environmental management activities in the country. As such, it constitutes the primary implementing legislation for the Convention on Biological Diversity, including biotechnology.

A number of the provisions of the Act have either direct or indirect potential impact on the issue of access to genetic resources and its intangibles for commercialization which is principle in generation of intellectual property assets. The most obvious of these is section 53, on access to genetic resources of Kenya.

Section 53 mandates the National Environment Management Authority (NEMA) to issue guidelines and prescribe measures for the sustainable management and utilization of genetic resources of Kenya, for the benefit of the people of Kenya. Accordingly, the provisions of any guidelines issued or measures prescribed, shall include appropriate arrangements for access to genetic resources of Kenya including the issue of licenses and fees to be paid for that access; Measures for regulating the import or export of germplasm; The sharing of benefits derived from genetic resources of Kenya and any other matter that the Authority considers necessary for the better management of genetic resources of Kenya.

Pursuant to these provisions, NEMA has issued the relevant regulations, namely the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006 issued under Legal Notice No. 160. All bio-prospectors in Kenya are required to obtain a research clearance certificate, prior informed consent (PIC) from the community and/or property owners, and sign a material transfer agreement (MTA) that includes the sharing of monetary and non-monetary benefits.

This implies that although genetic resources may be privately owned by virtue of common law principles or constitutional rights, all access to genetic resources as defined, must be granted only with the permission of the relevant lead agencies\(^\text{26}\). Sub-

\(^{25}\) Environment Management and Coordination Act no 8 of 1999.

\(^{26}\) Kent Nnadozie, Legal Status of Genetic Resources in National Law. UNEP/CBD/WG-ABS/5/5, 2007
section 50(f) of the Environment Management and Co-ordination Act provides that any measure for the conservation of biological diversity “shall protect indigenous property rights of local communities in respect of biological diversity.” As per provisions of the NEMA legal notice no.160 of December 2006, access to Kenya's genetic resources shall be on mutually agreed terms, and with prior-informed consent (PIC). Any matter related to IP shall be subject to the provisions of national intellectual property laws.

The reviewed literature shows that Kenya has an Access and Benefit Sharing (ABS) regulatory framework that is anchored in the Environment Management and Co-ordination Act (No 8 of 1999) and its regulations on Conservation of biological Diversity and resources, Access to Genetic resources and Benefits Sharing. The current ABS framework does not make any mention of the International Treaty on Plant Genetic Resources for Food and Agriculture, and is not clear on access to traditional knowledge. The current ABS regulatory framework has been found by lead agencies to have weaknesses that act as impediment to its successful implementation.

Traditionally, National Gene Bank of Kenya (NGBK) has had the mandate to exchange germplasm without seeking authority from any other institution. With the new regulations, it is not clear whether accessed germplasm from NGBK is subject to the permit of NEMA. Similarly, while KWS serves as the focal point for ABS in national parks and protected areas, these responsibilities and their relationship to those of NEMA have been unclear since the NEMA legal notice came into force in December 2006.

The definite conclusion is that NEMA legal notice no.160 of December 2006 is a national law regulating access to genetic resources that collaborators with public universities and research institutions can use to access genetic resources for generation of intellectual property assets. However, a clear mechanism for accessing traditional knowledge is lacking. It is heavily influenced by national obligations under the Convention on Biological Diversity (CBD).

There is need to build confidence in germplasm exchange through development of clear national and institutional policies on as well as reviewing the current ABS regulatory framework.

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27 See annex ii
2.4.2: Protection of the generated IP assets

Intellectual property assets are looked at as a legal collection of intellectual property rights by public universities and research institutions. Though intellectual property protection includes among others protection by patents, utility models, industrial designs, marks, geographical indications, trade secrets and protection of undisclosed confidential information, copyright and related rights and plant variety protection, this study concentrates on protection by patents, utility models and marks. Literature reviewed shows that, the best options for protecting generated inventions that are based on traditional knowledge and associated genetic resources in Kenya are by use of utility models (UM), trade secrets and marks.

The main institute of relevance in relation to industrial property protection of traditional knowledge based technologies and associated genetic resources, including biotechnology, is the Kenya Industrial Property Institute (KIPI). The Institute was established on 2nd May 2002 upon coming into force of the Industrial Property Act 2001. Previously the Institute existed as Kenya Industrial Property Office (KIPO), that was established in February 1990, after enactment of the Industrial Property Act, CAP 509 of the Laws of Kenya.

A utility model\textsuperscript{28} is defined by the Industrial Property Act (2001), as any form, configuration or deposition of elements of some appliance, utensil, tool, electrical and electronic circuitry, instrument, handicraft mechanism or other object or any part of the same, allowing a better or different functioning, use, or manufacture of the subject matter that gives some utility, advantage, environmental benefit, saving or technical effect not available in Kenya before, and includes micro-organisms or other self replicable material, products of genetic resources, herbal as well as nutritional formulations that give new effects.

The functions of the Institute are to administer industrial property rights; provide technological information to the public; Promote inventiveness and innovativeness in Kenya; and provide training on Industrial property. The Industrial Property Act protects patents, utility models, industrial designs and technovations. The Act also provides for registration of technology transfer agreements and licenses. The Institute is also mandated to implement the Trademarks Act Cap 506 that deals with registration of marks.

\textsuperscript{28} Definition of a Utility Model- Industrial Property Act (2001)
The rights are protected in order for the inventors to acquire exclusive rights over the commercial exploitation of the inventions or creations. This enables inventors to recoup the cost of creating and developing the technology. As a result, international legal framework for the management of biological resources, such as CBD, has had to increasingly take into account not only the needs for biodiversity conservation but also access to genetic resources for research and development and concerns about its economic importance and potential in contribution to the process of wealth creation and general economic development. CBD Article 16.3 is particular about access to genetic resources and resultant technologies particularly those that are protected by patents.

The Doha Ministerial declaration called for the harmonization of the Convention on Biological Diversity, and the agreement on trade related aspects of intellectual property rights (TRIPS). Patents, utility models and marks that are substantive subject matter of TRIPS agreement, can be used to protect generated IP assets based on traditional knowledge and associated genetic resources, hence the need for harmony of with the CBD. There is need to evaluate the implications of the proposed amendment to TRIPS Article 29, "TRIPS 29 bis," to ascertain its role in promoting generation, protection and commercialization of intellectual property assets that utilize traditional knowledge associated with genetic resources, including biotechnology, by public institutions.

The proposal stipulates that, where the subject matter of a patent application concerns, is derived from or developed with biological resources and or associated traditional knowledge, members shall require applicants to disclose the country providing the resource and associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Member states are also to require that applicants provide information including evidence of compliance with the applicable legal requirement in the providing country for prior informed consent (PIC) for access and equitable sharing of accrued benefits (ABS) arising from the commercial or other utilization of such resources and associated traditional knowledge.

Regulations on access to genetic resources and its intangibles in Kenya require that applications be accompanied by evidence of prior informed consent. The NEMA legal
notice number 160 addresses these issues in part II, on conservation of biological diversity, part III on access to genetic resources and part IV, on benefit sharing arrangements. In section 19, the regulations are explicit that intellectual property issues related to access to genetic resources and its intangibles shall be by the national intellectual property institutes.

In the proposed TRIPS 29 bis, member states, including Kenya, are required to put in place effective enforcement procedures so as to ensure compliance with the proposed obligations. In particular they have to ensure that administrative and judicial authorities have the authority to prevent processing of patent applications or their grant, subject to Article 32 of the TRIPS agreement, on revocation and forfeiture, or render the granted patent unenforceable, if fraudulently acquired.

It calls for a review of national intellectual property laws to enable them embrace the spirit in the amendment proposal. The proposed TRIPS 29 bis is in harmony with the NEMA Conservation of biological diversity and resources, access to genetic resources and benefits sharing regulations of December 2006. Kenya Industrial Property Institute and Kenya Plant Health Inspectorate Service will be instrumental in implementing part III and Articles 19 and 20 of part IV of the regulations, on issues related to access to genetic resources and the associated intangibles. Institutional intellectual property policies in public institutions are a necessary tool that can compliment activities and functions of KIPI and KEPHIS in the management of mutual agreements on access to knowledge and resources, and the management of the resultant institutional intellectual property assets.

In relation to biotechnological inventions, KIPI and KEPHIS play a very instrumental role in terms of Plant Varieties Protection, patents and trade marks. Industrial property act section 29 and regulation 11 requires that if an invention concerns a micro-biological process or product thereof, and involve the use of a micro-organism which is not available to the public, and which can not be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed if a culture of the micro-organism has been deposited with a depository institution not latter than the date of filling of the application. These regulations provide that Kenya Agricultural Research Institute (KARI) and Kenya Medical Research Institute (KEMRI) are the designated depository institutions for biotechnology patent purposes.

32 See Annex ii
Where as Kenya is one of the world’s mega-biodiversity countries, and is among others, party to the Paris Convention for the protection of industrial property rights, WTO’s TRIPS agreement and the Convention on Biological Diversity (CBD) that came into force on 29 December 1993, literature reviewed shows that there are no synergies and specific programmes or institutional arrangements to implement the provisions of the international agreements related to intellectual property rights and traditional knowledge and associated genetic resources. However, Kenya supports ARIPPO’s regional initiative on the protection of Genetic resources and traditional knowledge.

Protection by patents, utility models, trade secrets and marks is the most viable option for industrial property protection of generated inventions utilizing traditional knowledge associated with genetic resources, including biotechnology. Patents, utility models, trade secrets and marks are very important assets for commercialising and eventual equitable sharing of accrued benefits through sustainable utilisation of the generated and protected inventions based on traditional knowledge and associated genetic resources, including biotechnology.

It is important to note that the African model law stipulates that there should be no patents on life forms. It believes that the privatization of life forms through any intellectual property rights violates the basic right to life and goes counter to African sense of respect for life. Kenya is in conflict with this position, because it has in place an Industrial Property Act of 2001 that provides for patent protection of life forms.

It can be argued that, if the infringement of patents, copyrights and trademarks constitutes intellectual piracy, so does the failure to recognize and compensate indigenous and traditional communities for the inventions arising from utilisation of their knowledge and the associated genetic resources.

The management of biological resources has been an increasingly contentious subject at national and international levels. This is linked to the progressive recognition of new economic opportunities arising from the use of biodiversity, primarily the possibilities opened up by genetic engineering, in particular genetic modification. Part IV of NEMA legal notice number 160 of December 2006, states that benefit sharing shall apply subject to the laws in force relating to intellectual property rights, and that, without prejudice to the generality of the foregoing, the holder of an access permit shall facilitate an active involvement of Kenyan citizens and institutions in the execution of the activities under the permit. The facilitation by the holder of an access permit shall
include enjoyment of both monetary and non-monetary benefits arising from the right of access granted, and the use of genetic resources.

It is recommended that KIPI (for patents) and KEPHIS (for plant varieties) review their acts to accommodate the disclosure requirement of genetic resources and associated knowledge in patent and plant varieties applications.

2.4.3: Commercialization of Protected IP Assets, Including Biotechnology

Commercialization is defined as the final step in new product development when the product developer makes a major marketing commitment to the product. At this stage the product developer implements a total marketing plan and works towards production capacity. Commercialization procedures involve deciding the timeliness of the product introduction, the locations where the product should be introduced, the market to be targeted, and the budget and promotional strategies for the product introduction. All this aspects could be based on patents, utility models and marks among other intellectual property assets.

The commercialization of intellectual property assets based on traditional knowledge and associated genetic resources, including biotechnology, is subject to the relevant agencies that regulate trade of the final product. If the product is Pharmaceutical, Agricultural or Environmental, it has to conform to the process of the drugs and poisons, seeds quality department of agriculture or other environmental regulations respectively. However, if the technology involves a genetically modified organism, it has to be approved by the National Bio-safety Committee or the National Bio-safety Authority, as per the Bio-safety Act of 2009.

In Kenya, the generated and protected inventions based on traditional knowledge associated with genetic resources can be commercialised, subject to other regulatory requirement for commercialization of the product. Seeds are regulated by Kenya Plant Health Inspectorate Service after meeting the standards as per the National Performance Trials (NPTs), while pharmaceuticals are regulated by the drugs and poisons board.
In case the technologies to be commercialised are agricultural, environmental or pharmaceutical biotechnologies, they can only be commercialised after meeting the requirements of the National Biosafety Committee\(^{33}\), that exercises general supervision and control over the transfer, handling and use of genetically modified organisms, with a view to ensuring safety of human and animal health and provision of an adequate level of protection of the environment. The Biosafety Act 2009 is in place. However, its implementing regulations are lacking. It can be concluded that biotechnological inventions can not be commercialised in Kenya, until the implementing regulations are in place.

### 2.5: Conclusion on literature reviewed

Access and benefit sharing as per the legal notice no 160 of December 2006 includes among other benefits, joint ownership of relevant intellectual property rights and transfer to Kenya of genetic resources, knowledge and technology under fair and most favoured terms, including knowledge and technology that makes use of the resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity.

Literature reviewed shows that Kenya has a position on some of the issues discussed in this chapter. Its position aims at promoting research and development in biotechnology to eradicate poverty and achieve sustainable development; build capacity to develop and safely apply biotechnology in agriculture, mining, industry and bio-fuels and ensure development of policies that are science-based and promotes food security and economic growth.

Kenya believes that a harmonised international regime would assist in achieving the above objectives by facilitating access to genetic resources to foster research and development; respecting the rights of both national governments and local communities; and establishing a formalized system of sharing benefits, monetary or not, to ensure the flow of benefits accrued from utilisation of genetic resources and its associated traditional knowledge. Capacity building and technology transfer are generally considered as non-monetary benefits and it can be expected that such issues will be addressed as part of the Access and Benefits Sharing (ABS) regime.

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\(^{33}\) National Biosafety Authority –Biosafety Act 2009
Kenya seeks to see such provisions included in the ABS regime to enable the country to develop its capacity on ABS matters as well as those of the region (Africa) to utilise its genetic resources and associated traditional knowledge. Kenya believes that an international system of regulated access and sharing of benefits would foster agricultural research and general economic development in Africa and enhance its capacity to achieve food security and economic growth.

Kenya supports the adoption of a legally binding instrument as it is one of the key avenues for addressing issues of access and use of unauthorized knowledge and genetic resources and misappropriation in the international arena. Considering that Kenya is one of the like minded mega diverse countries that is home to biodiversity of great potential value, it has to ensure that a strong regime to address international misappropriation is developed. It proposes a binding instrument or an appropriate combination of binding and non-binding elements.

Kenya has adopted a position that supports mandatory requirement for disclosure of origin of knowledge and genetic resources, Mutually Agreed Terms (MAT), Prior informed Consent (PIC) and benefit sharing in patent applications, where the subject matter incorporates genetic resources and associated traditional knowledge.

KIPI, in consultation with other relevant institutions, should ensure that institutional intellectual property policies capture issues of bio prospecting, particularly issues related to access to knowledge and resources, technology transfer, and equitable sharing of benefits, as per the requirements of NEMA legal notice no 160 of December 2006.

There is need to harmonise existing legislations on genetic resources and intellectual property rights and develop a bio prospecting strategy and policy for the country. This will enable traditional knowledge holders to disclose their knowledge to public institutions for generation of research products that can be protected and commercialized.

Utility models and patent application and granting system should be reviewed to include certificate of origin of source of knowledge and genetic resources. That can be fundamental in benefits sharing arrangement as per the protected industrial property rights. The government should establish a critical mass in bio prospecting and undertake model projects to evaluate existing bio prospecting arrangements.
CHAPTER III

3.0: METHODOLOGY

3.1: Research Methodologies

This research sought to investigate the level of interaction between selected public institutions and the private small and medium scale industries and traditional knowledge holder within the republic of Kenya. In this research, interviews, questionnaires (see appendix 1), desktop survey at KIPI using the Industrial Property Administration System (IPAS-WIPO), and case study research methodology was used. Desk top survey at KIPI, using the IPAS, helped in identifying the subject institutions.

Masinde Muliro University for Science and Technology (MMUST) and Kenya Marine and Fisheries Institute (KEMFRI) were used as control institutions. Questionnaires were distributed to the selected institution, and were instrumental in probing general information about the subject institutions. This was followed up by focused interviews to get clarification on several issues that were not clear. Case studies were used to pick out practical issues on generation, protection and commercialization of intellectual property assets, including biotechnology.

The advantage of questionnaires was that they helped in capturing the actual situations in each subject institution. The only disadvantage is that important information is classified as confidential, particularly contracts related to intellectual property rights and commercialization. That was the main reason why interviews were used to clarify some issues that were not clear. The four case studies were very helpful in identifying the practical challenges for generation, protection and commercialization of intellectual property assets based on traditional knowledge and associated genetic resources, including bio-technology.
3.2: Research Instruments

The research instruments were focused interviews, administration of questionnaires, desktop survey at KIPI using the Industrial Property Administration System (IPAS), and four case studies. Questionnaires were distributed to the twelve selected public institutions. The questionnaire dwelt on generation, protection and commercialization of Intellectual Property Assets by selected Public Universities and Research Institutions in Kenya, based on Traditional Knowledge and Associated Genetic Resources, including Biotechnology.

It has been observed from literature reviewed that public Universities and research institutions in Kenya are not utilizing traditional knowledge and the associated biological resources to generate, protect and commercialize intellectual property assets. The objectives of this research was to find out how selected public universities and research institutions generate, protect and commercialize intellectual property assets including biotechnology, and the management of collaborative research partnerships with traditional knowledge holders and industry.

The objectives of the research were to establish how selected public universities and research institutions in Kenya are accessing traditional knowledge and associated genetic resources to generate intellectual property assets including biotechnology. It also sought to find out how the generated traditional knowledge based intellectual property assets, including biotechnology, are protected with the assistance of institutional Technology Transfer Offices (TTOs) and assess how the selected public universities and research institutions are commercializing the generated and protected intellectual property assets.

The research also aimed at finding out how the selected public universities and research institutions collaborate with traditional knowledge holders, and the mechanism for collaborative research with industry and associations of traditional knowledge holders and establish the obstacles and challenges facing the selected public universities and research institutions in generating, protecting and commercializing the protected intellectual property assets, including biotechnology.
It probed how collaborative bio prospecting programmes with industry or international organizations is managed, and the role of the NEMA ABS Regulations under Legal Notice No. 160 of December 2006. On protection of intellectual property assets, it sought to find out how the generated traditional knowledge based intellectual property assets, including biotechnology, are protected with the assistance of institutional Technology Transfer Offices (TTOs). It tried to establish if the institutions have an IP Policies and how the policy has helped in management of IP asset, access to traditional knowledge and genetic resources, arrangements for benefits sharing and transfer of technology. The questionnaire sought to establish how many patents, trademarks, utility models, and industrial designs are protected by the subject institutions.

In conclusion, it sought the opinion of the subject institutions on what should be done to promote generation of technologies that utilise traditional knowledge and associated genetic resources, protection of the generated technologies and commercialization of institutional intellectual property assets.

### 3.3: Data Collection Plan

In November 2009, the project proposal was prepared and presented. Literature was reviewed in December 2009 and collection of data and conducting interviews was done in January 2010. Questionnaires distributed to selected public institutions were collected, and data collated. Interviews were conducted in February 2010.

Data was derived from the questionnaires submitted by subject institutions, and confirmation searches in the Industrial Property Administration System (IPAS) at KIPI. IPAS administers processing of industrial property applications. Some data was derived from the United Nations International Development Organisation (UNIDO) Indstat 4 that has International Standards Industrial Classification (ISIC) ver.2 and 3. ISIC ver.2 and 3 provides data coded according to International Standards Industrial Classification version 2 and 3 respectively. The data on reductions in Biotechnological and Pharmaceutical research and development stock for European nations was by OECD standard database.

Compiled data was analysed in early March 2010. Analysis of compiled data and documented interviews to draw conclusions and recommendations was done in March 2010. The research findings are discussed in the next chapter.
CHAPTER IV

4.0: PRESENTATION AND ANALYSIS OF RESEARCH FINDINGS

4.1: Introduction

In 2006, Prof. Tom Ogada\textsuperscript{34} conducted a national intellectual property audit in Kenya, which revealed that between 1990 and 2001, Small and Medium Size Enterprises (SMEs), also known as (Jua Kali), was the most innovative sector with a total of 116 patent applications at KIPI. They were followed by Industry with 45 patent applications. Research and Development Institutions had 14 applications; individuals from universities had 2 applications, while secondary schools had one application. Public universities were conspicuously absent. This audit raised questions on why Public funded institutions are not generating and protecting their inventions.

It is on the basis of this audit that this research sought to find out why Public Universities and Research institutions in Kenya are not utilising traditional knowledge associated genetic resources, to generate, protect and commercialise intellectual property assets, including biotechnology. Questionnaires were distributed to the selected public institutions (seven public Universities and four research institutions) and findings are discussed below.

Follow up interviews were carried out to clarify issues raised in the completed questionnaires by the selected public universities and research institutions, including associations of traditional healers. This was mainly in relation to generation, protection and commercialization of intellectual property assets, including biotechnology, and the management of collaborative research partnerships with traditional knowledge holders and industry in general.

The seven selected public universities are the University of Nairobi (UoN), Moi University, Kenyatta University, Jomo-Kenyatta University of Agriculture and Technology (JKUAT), Egerton University, Maseno University and Masinde Muliro University of Science and Technology (MMUST).Masinde Muliro University of Science and Technology

\textsuperscript{34} National Intellectual Property Audit- 2006.
was selected by virtue of the fact that it is the latest public university situated in the vicinity to Kakamega forest, the only remaining tropical rain forest with a lot of biodiversity, including medicinal plants.

The selected public research institutions as study subjects were Kenya Agricultural Research Institute (KARI), Kenya Medical Research Institute (KEMRI), Kenya Forestry Research Institute (KEFRI), Kenya Marine and Fisheries Research Institute (KEMFRI) and Kenya Industrial Development Institute (KIRDI).

4.2: Findings

A search in KIPI’s Industrial Property Administration System (IPAS) revealed that some public universities and research institutions have made patent or utility model applications. Table 3\textsuperscript{35} and figure 2 bellow shows patents and utility model applications at Kenya Industrial Property Institute (KIPI) by the selected subject Public Universities. The table also indicates the availability of institutional IP policies, and Technology Transfer Offices (TTOs), in the respective Universities, in response to the distributed questionnaires.

All selected universities, except Maseno University and Masinde Muliro University of Science and Technology (MMUST), have institutional intellectual property policies. Answered questionnaires and follow up interviews revealed that all Universities with an institutional IP policy had at least one patent or utility model application at KIPI, while those without institutional IP policies had neither patent nor utility model applications, as was demonstrate by Masinde Muliro University of Science and Technology (MMUST) for public universities, and Kenya Marine and Fisheries Research Institute, for research and development institutions.

However, it clearly emerged that all institutional technology transfer offices are not sure if their protected intellectual property assets have been commercialized. Findings are that there is a very strong link between existence of institutional intellectual property policies, and the possibility for a University or research institution to generate, protect and commercialize protected intellectual property assets.

\textsuperscript{35}Public Universities
Table 3: Public Universities

<table>
<thead>
<tr>
<th>SN</th>
<th>NAME OF PUBLIC UNIVERSITY</th>
<th>PATENT APPLICATIONS</th>
<th>Utility Model Applications</th>
<th>Institutional IP policy and TTOs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Moi University</td>
<td>6</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>2</td>
<td>University of Nairobi (UoN)</td>
<td>2</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>3</td>
<td>Kenyatta University (KU)</td>
<td>2</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>4</td>
<td>Jomo Kenyatta University of Agriculture and Technology (JKUAT)</td>
<td>2</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>5</td>
<td>Egerton University</td>
<td>1</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>6</td>
<td>Maseno University</td>
<td>1</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>7</td>
<td>Masinde Muliro University of Science and Technology (MMUST)</td>
<td>0</td>
<td>0</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

*SOURCE: Industrial Property Automated System (IPAS) and questionnaires- Atsali-2010*

A chat representing public universities:

![A chat representing public universities and patent applications](image)

*Fig 1: A chat representing public universities and patent applications*
Findings from this research were that Moi University was the fastest public University to develop an Institutional Intellectual Property policy, and Masinde Muliro University of Science and Technology (MMUST), has no institutional IP policy, possibly due to the fact that it is the latest public university in Kenya. It can be concluded that, Moi University is the most inventive public University, followed by the University of Nairobi. Masinde Muliro University of Science and Technology has no Institutional IP policy, and consequently, neither patent nor utility model application.

Commercialization of the generated intellectual property assets is generally poor in all subject universities. Follow up interviews revealed that, other than Kenyatta University that has a school of alternative medicine, none of the other subject Universities is actively collaborating with traditional knowledge holders in generating and protecting innovative natural products. Interviews by representatives of Traditional Health Practitioners (THPs) revealed that, they are not willing to disclose their knowledge and associated genetic resources under the current intellectual property regime. They would rather use trade secrets and marks to market their products. The danger with this is that, most of the THPs end up dying before disclosing their knowledge. This scenario is creating the danger of totally losing this wealth of traditional knowledge held by elderly knowledge holders. The situation is made worse by the findings that youths, who could be equated to traditional knowledge patents, are not willing to learn and acquire this knowledge, believing that it is primitive.

Table 4 and figure 3 bellow shows that, the selected public Research and Development institutions, other Kenya Marine and Fisheries Research Institute (KEMFRI), have institutional Intellectual Property policies. All research and development institutions with IP policies have at least a patent and utility model application at KIPI. Kenya Marine and Fisheries Research Institute (KEMFRI), has no institutional IP policy and neither patent nor utility model application.

Kenya Industrial Research and Development Institute (KIRDI), and Kenya Medical Research Institute (KEMRI), are the most innovative public Research and Development institutions. However KEMRI has no single application from collaborative research with traditional knowledge holders, in spite of being a medical research institute with a designated department dealing with development of traditional medicine. No single application from KEMRI is in collaboration with traditional knowledge holders, indicating lack of co-operation or unwillingness of disclosure by traditional knowledge holders.

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36 Public Research Institutions
Findings on Public Research Institutions;

Table 4: Public Research Institutions

<table>
<thead>
<tr>
<th>S.N</th>
<th>Name of institution</th>
<th>Patent applications</th>
<th>Utility Model Applications</th>
<th>Institutional IP policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kenya Industrial Research and Development Institute (KIRDI)</td>
<td>10</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>2</td>
<td>Kenya Medical Research Institute (KEMRI)</td>
<td>7</td>
<td>8</td>
<td>Available</td>
</tr>
<tr>
<td>3</td>
<td>Kenya Agricultural Research Institute (KARI)</td>
<td>6</td>
<td>6</td>
<td>Available</td>
</tr>
<tr>
<td>4</td>
<td>Kenya Forestry Research Institute (KEFRI)</td>
<td>1</td>
<td>0</td>
<td>Available</td>
</tr>
<tr>
<td>5</td>
<td>Kenya Marine and Fisheries Research Institute (KEMFRI)</td>
<td>0</td>
<td>0</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

*Source: Industrial Property Automated System (IPAS) and questionnaires - Atsali - 2010*

A chat representing public research institutions

![A chat representing public research institutions and patent applications](image)

*Fig 2: A chat representing public research institutions and patent applications*
As was the case with public universities, commercialization of the generated intellectual property assets by the selected research and development institutions is generally poor. It also becomes very clear that Kenya Marine and Fisheries Research Institute, with no institutional IP policy, consequently, has no single patent or utility model application at KIPI. This confirms the hypothesis that without an institutional IP policy, it is not possible for public institutions to generate, protect and commercialize intellectual property assets.

4.3: Discussion of the findings

It can be observed that, since the National audit of intellectual property assets in 2006 by Prof. Tom Ogada, six public universities and several public Research and Development institutions have managed to make applications for patents and utility models at KIPI. This could be attributed to increased awareness on the importance of intellectual property protection by public institutions, and the acknowledgement that research and development is vital for economic development and wealth creation.

From these findings, it can be concluded that, in order to strengthen the national intellectual property regime, there is need to focus on measures that provide an enabling environment for public institutions to collaborate with traditional knowledge holders to generate, protect and commercialize technologies based on traditional knowledge and associated genetic resources, including biotechnology. One such measure is the use of institutional intellectual property policies to manage access to traditional knowledge and associated genetic resources.

4.3.1: Generation

Research findings were that, the selected public institutions in Kenya have provisions in their Institutional intellectual property Policies, on accessing traditional knowledge and associated genetic resources, for generation, protection and commercialization of intellectual property assets, including biotechnology. They all have collaborative bio-prospecting programmes with industry and international organizations, which are managed and implemented with the guidance of their institutional Intellectual Property policies.

All institutions with institutional IP policies are reviewing them to address requirements of the NEMA regulations on Access and Benefits sharing as per the Legal Notice No. 160
of December 2006 (see annex ii). However, Kenya Marine and Fisheries Research Institute (KEMFRI), and Masinde Muliro University of Science and Technology, have no institutional intellectual property policies, but are in the process of developing it with the help of Kenya Industrial Property Institute (KIPI), Kenya Plant Health Inspectorate Service (KEPHIS) and Kenya Copyrights Board (KCB).

NEMA’s Legal Notice No. 160 of December 2006, CBD and the International Treaty on Plant genetic resources for Food and Agriculture (ITPGRF/A), are most important documents on access to traditional knowledge, associated genetic resources and benefits sharing. The International Treaty on Plant genetic resources for Food and Agriculture has 69 crops listed under the multilateral system. These crops are available to researchers. However, none of the institutions is aware of its availability, hence missing out on opportunities to access the genetic resources for generation of intellectual property assets.

4.3.2: Protection

All interviewed public institutions have institutional intellectual property policies, except Masinde Muliro University of Science and Technology and Kenya Marine and Fisheries Research Institute. Public institutions with institutional intellectual property policies in place acknowledged that, IP policies, and the NEMA legal notice number 160 of December 2006, have helped them address issues on access to knowledge, genetic resources and benefits sharing arrangement. It has helped them appreciate the importance of prior informed consent (PIC) while dealing with local communities and other resource holders in development of Material Transfer Agreements (MTAs) for access and benefits sharing arrangements.

Interviewed personnel in the Technology Transfer Offices (TTOs, advocate for the Patent based- ABS disclosure requirement, and they feel that, it should be internationally recognise. They argue that, it shall help in reducing bio piracy and promote access to traditional knowledge and associated genetic resources, and provide a sustainable mechanism for equitable sharing of benefits, since miss-appropriation of traditional knowledge and associated genetic resources is normally done outside Kenya, and by use of intellectual property system.

TTOs felt that, the international recognition of the disclosure requirement will create an enabling environment for disclosure, and encourage traditional knowledge holders to
collaborate with public research and development to add value to their natural products. This will in turn, promote technology transfer, foreign direct investments (FDI) and regulated bio-prospecting programmes in public institutions in Kenya. Interviewed institutions felt that, documentation of genetic resource and traditional knowledge can reduce bio-piracy and promote access and benefits sharing. Kenyatta University (KU), one of the subject institutions, has an institute of complimentary and alternative medicine, which is involved in collaborative with Traditional Health Practitioners (THPs), on traditional knowledge and associated genetic resources.

It was however found that, none of the research products have been protected, either by patents or utility models. The challenge that the school faces in terms of generation, and protection and commercialization of IP assets, is the general reluctance by traditional healers to disclose all their knowledge. Traditional healers claim that patents are expensive and limited in time. Their fear is that, patents will make them disclose their knowledge that has been passed on for generations, and end up with a twenty years limited period of protection. This, they claim will eventually put all their traditional knowledge in to public domain.

The institutions are not aware of the provisions of the multilateral system on access to genetic resources of the International Treaty on Plant Genetic Resources for Food and Agriculture. The treaty provides that access to genetic material under the standard Material Transfer Agreement (sMTA), shall include a requirement that, a recipient, who commercialises a product that is a plant genetic resource for food and agriculture, and that incorporates material accessed from the multilateral system, shall pay an equitable share of the benefits arising from the commercialization of that product, unless such a product is available without protection by intellectual property rights.

The institutions felt that the Seed and Plant Varieties Act, Cap 326, and the Industrial Property Act of 2001, should be reviewed, to enable mandatory disclosure of the source of knowledge and associated genetic resources, and compliment the requirements of sections 19 and 20, of NEMA legal notice number160, of December 2006. It can well be concluded that, all selected public institutions engage in collaborative research, and have provisions for joint ownership of the generated intellectual property rights. This was particularly common in biotechnology related research activities in Kenya Agricultural Research Institute (KARI). It was however, not possible to have a look at the technology transfer documents, since all the IP clauses are treated as confidential information not to be disclosed.
4.3.3: Commercialization

All the institutions with an IP policy have at least one application at KIPI for Patents or marks. None of them have applications for Utility models or Industrial designs. It was observed that currently, none of the institutions have traditional knowledge holders or local communities mentioned as joint inventors in patent applications. It was notable that traditional knowledge holders are not acknowledged in the applications for patents or other industrial property rights.

The biggest challenge that KARI, and other research institutions working on biotechnological inventions are facing, is that, whereas the Bio-safety Act of 2009 is in place, and regulates generation and commercialization of biotechnology, it is apparent that, commercialization of biotechnological inventions is not possible. The Biosafety Act of 2009 can only be made operational, after development of its implementing regulations. In the absence of Bio-safety regulations, commercialization of biotechnology, particularly in relation to genetically modified products, can not be possible. It can be concluded that, there is no enabling legislative environment for commercialization of biotechnological invention, a factor that could be hampering generation, protection and commercialization of biotechnology in Kenya.

4.3.4: Interpretation of Data from public institutions

In Kenya, products of traditional knowledge and associated genetic resources can be protected by industrial property rights as utility models or patents. However, whereas utility model protection is available, and is defined as any form, configuration or deposition of elements of some appliance, utensil, tool, electrical and electronic circuitry, instrument, handicraft mechanism or other object, or any part of the same, allowing a better or different functioning, use, or manufacture of the subject matter that gives some utility, advantage, environmental benefit, saving or technical effect not available in Kenya before, and includes micro-organisms or other self replicable material, products of genetic resources, herbal as well as nutritional formulations that give new effects, the selected public institutions have not taken advantage of the provision to acquire utility model protection.

Table 3 (on public universities), indicates that, the selected public universities have a combined total of 14 patent applications at KIPI. Moi University is the most innovative with a total of six patent applications, and Masinde Muliro University of Science and Technology has none. Public research institutions have 14 utility model applications, while none of the public universities have utility model applications. Table 3 and 4
clearly reveals that, public institutions are not utilizing the utility model provision, and yet it is very clear on protection of traditional knowledge and the associated genetic resources.

Interviewed traditional knowledge holders revealed that, they are not willing to disclose their traditional knowledge associated with genetic resources because the current intellectual property regime does not recognize their contribution in the development of natural products and conservation of knowledge and associated genetic resources. This was the most substantive observation that needs national, regional and international solutions, to enable traditional knowledge holders to disclose their knowledge to public institutions for value addition and generation of intellectual property assets utilizing traditional knowledge and its associated genetic resources. India went through a similar situation, and can provide a clear case for comparative purposes. It is an established fact that traditional Knowledge includes codified knowledge (documented) as well as non-codified information (not documented but may be orally transmitted). Traditional knowledge and associated genetic resources has always been an easily accessible treasure, and thus, has been susceptible to misappropriation.

Traditional knowledge, particularly, related to the treatment of various diseases, has provided leads for development of biologically active molecules, by the technology rich western countries. In other words, traditional knowledge is being exploited for bio-prospecting. Traditional knowledge is often misappropriated because it is conveniently assumed that, since it is in public domain, communities have given up all claims over it. Patent examiners in patent offices, while examining the patentability of any claimed subject matter, use available resources for searching the appropriate non-patent literature sources. Patent literature is usually wholly contained in several distinctive databases, and can be more easily searched and retrieved, whereas non-patent literature prior art is often buried somewhere in many diverse sources. Therefore, a need was felt to create more easily accessible non-patent literature databases, on traditional knowledge of India.

Where as India has a Traditional Knowledge Digital Library (TKDL), it is apparent that Kenya lacks such a facility (data base). TKDL of India is being documented by sifting and collating the information on traditional knowledge from existing literature in local languages such as Sanskrit, Urdu, Arabic, Persian and Tamil, in digitized format,

37 Bio-piracy of Traditional Knowledge in India.
which will be available in English, German, Spanish, French and Japanese. Traditional Knowledge Resource Classification (TKRC), an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval, was evolved for about 5,000 sub-groups, against few subgroups available in International Patent Classification (IPC), related to medicinal plants. This information is being structured under sections, classes, subclasses, groups and subgroups, as per the International Patent Classification (IPC) system, for the convenience of its use by patent examiners. It is recommended that Kenya develops such a data base, which is searchable, to be used by patent examiners at Kenya Industrial Property Institute.

On the other hand, bench marking the Kenyan situation with the United States of America (USA), it can be concluded that, public institutions in Kenya are experiencing the situation that existed in the USA before enactment of the Bayh-Dole Act of 1980. A comparison of tables 3 (on public universities), table 4 (on public research and development institutions, with table 5 below, (of top ten universities in the USA), shows that public institutions in Kenya are not generating and protecting intellectual property assets like their counterparts in the United States of America.

The Department of Commerce in the United States Patent and Trademark Office (USPTO) announced the top “Ten U.S. Universities” receiving the most patents during the calendar year 2002. (See table 5). Michigan State University\(^{38}\) is ranked tenth, and has more patent applications than all selected public Universities in Kenya. In 2001, Michigan State University had 39 patent applications as compared to patent applications by all selected public Universities in Kenya that currently have a combined total of 14 patent applications as at 31\(^{st}\) March 2010.

It can there for be concluded that, public institutions in Kenya are not taking advantage of existing traditional knowledge associated with genetic resources, and the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture, to generate, protect and commercialize intellectual property assets. It can also be concluded that institutional IP policies are very important if any institution is to manage access to knowledge and genetic resources for generation, protection and commercialization of its IP assets. Prior to the Bayh-Dole\(^{39}\) Act of 1980, fewer than 250 patents were issued to universities in the US per year. In 2000, over 330 U.S. and Canadian institutions and universities engaged in technology transfer. The generated technology was transferred to industry

\(^{38}\) United States Patent and Trademark Office

\(^{39}\) PL 96-517, Patent and Trademark Act Amendments of 1980
and helped to spawn new businesses, create industries and open new markets. Core technologies, likely to spark new industries, often result from university patents. Public universities and industry collaborations helped to move new discoveries from laboratories to the market. This enabled faster and more efficient way of ensuring that products and services based on public funded research reached the public.

Table 5: TEN TOP UNIVERSITIES RECEIVING MOST PATENTS IN 2002

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>431</td>
<td>University of California</td>
<td>(1)</td>
<td>(402)</td>
</tr>
<tr>
<td>2</td>
<td>135</td>
<td>Massachusetts Institute of Technology</td>
<td>(2)</td>
<td>(125)</td>
</tr>
<tr>
<td>3</td>
<td>109</td>
<td>California Institute of Technology</td>
<td>(3)</td>
<td>(124)</td>
</tr>
<tr>
<td>4</td>
<td>104</td>
<td>Stanford University</td>
<td>(5)</td>
<td>(84)</td>
</tr>
<tr>
<td>5</td>
<td>93</td>
<td>University of Texas</td>
<td>(4)</td>
<td>(89)</td>
</tr>
<tr>
<td>6</td>
<td>81</td>
<td>Johns Hopkins University</td>
<td>(6)</td>
<td>(80)</td>
</tr>
<tr>
<td>7</td>
<td>81</td>
<td>University of Wisconsin</td>
<td>(7)</td>
<td>(73)</td>
</tr>
<tr>
<td>8</td>
<td>55</td>
<td>State University of New York</td>
<td>(17)</td>
<td>(41)</td>
</tr>
<tr>
<td>9</td>
<td>50</td>
<td>Pennsylvania State University</td>
<td>(11)</td>
<td>(52)</td>
</tr>
<tr>
<td>10</td>
<td>49</td>
<td>Michigan State University</td>
<td>(18)</td>
<td>(39)</td>
</tr>
</tbody>
</table>

Source-USPTO

4.5: Analysis of Case Studies

4.5.1: Introduction

According to a report by the African Centre for Biosafety, seven new suspected cases of bio piracy in Africa take the form of applications for or grant of patents in the United States and Europe. These seven cases add to the 36 cases found in the Centre's 2006 study. The seven new cases are based on a preliminary study of patent applications in the US and European Union. This merits African states to investigate and conclusively
determine whether biopiracy has occurred and appropriate action to be taken. It is very interesting when Timothy A. Wolfe and Benjamin Zycher, argue in their study that, by the year 2025, if the patent based -ABS regime is accepted internationally, it shall reduce biotechnological and pharmaceutical research and development investment capital stock by about US $ 144 billion, that is almost 27% for the 27 European nations.

They argue that, by the year 2025, biotechnological and pharmaceutical research and development capital stock would get a loss of about US$ 144 billion, translating into a loss of 150-200 new drugs, and warn nations to consider the loss before they adopt the patent based ABS system. This fact is faulted by the following case studies, of which four are discussed latter in details. It can in fact be argued that, the patent based ABS-system that can be achieved by adoption of the proposed TRIPS 29 biss, will reward the providers of traditional knowledge and associated genetic resources in developing countries.

Cases that are subject for discussion involve universities, government departments as well as small and large companies. The claims I patents relate to a wide range of natural products, anti- aging drugs, skin care natural products, sex enhancing drugs, vaccines, insect repellants and cancer treatment drugs. The scientific community, industry and government agencies in the west generally do not disclose the existence of prior art in their patent applications. Furthermore, patent examiners rarely consider traditional knowledge held by local and indigenous people and published in journals, databases and periodicals.

It is charged that, the patent system in Europe and USA is being used to promote misappropriation of traditional knowledge and biological resources from the South. The cases examined involve patents pending or granted by United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO). Some include stated potential applications in South Africa and the regional patent offices of the African states that are parties to ARIPO or OAPI.

40 Pacific Research Institute.-May 2005
41 See annex iii
In one case, German based Bayer Consumer Care is seeking patents on the Madagascan Vernonia extracts for skin treatment. Their claims are on the use of extracts from any plant of the Vernonia genus in Madagascar, for improving skin status. In addition, Bayer makes specific claims to eight Vernonia species. The plant extracts are sold by Bayer to industries and companies, which use it as an ingredient in up market natural products. Creams with a small amount of the extract sell for approximately $49-79 for a 14-28 grams container. It is observed that, with Madagascar’s per capita gross domestic product of $377 (2007), it implies that an average Malagasy could exhaust his or her entire annual income on seven jars of the cream containing about 2 grams of the active ingredient known as ambiaty.

On the alleged novelty of Bayer’s patent claims, the report discloses documented traditional use of the ingredient in herbal steam baths, and its use in dyes. Bayer’s patent application makes no reference to these and other traditional uses of ambiaty. The report also criticizes the scope of the patent application as being broad; pointing out that Vernonia is used in medicines across Africa. Bayer’s patent claims appear to be a case of misappropriation and biopiracy of African traditional knowledge and associated genetic resources by use of international patent system. The company claims that its business is ethical and beneficial for Africa. Its Malagasy corporate collaborators claim that the plants are sustainably harvested and that a premium market price is paid for the raw plant material. A premium is paid in the form of new classrooms and school supplies for children in Malagasy.

The report notes that Serdex\textsuperscript{42} is a member of the Swiss-based Union for Ethical BioTrade. This Union is a private outgrowth of the BioTrade Initiative of the United Nations Conference on Trade and Development (UNCTAD), and is supposed to be promoting sourcing of natural products with respect. It is recommended that, Bayer be asked to back its fair trade claims with real numbers, including prices paid per kilogram to plant collectors, the yield in plant extracts, and how much income the company and its corporate customers derive from sales of the extracts.

A patent application by a Swedish based company called Dicotyledon AG, utilizes extracts from Neobeguea mahafalensis, a tree commonly known as ‘handy’, whose extracts it’s claimed, have sex enhancing effects, and can be used for treatment of

\textsuperscript{42} Bayer’s French subsidiary that produces ambiaty
sexual dysfunction. Dicotyledon may want to claim handy as its own invention, but it has long been used as an aphrodisiac in traditional Malagasy medicine. There is no indication in Dicotyledon's patent application that it has any intention of sharing its benefits on equitable terms by the providers of traditional knowledge and associated genetic resources. However, the application makes concession that *N. mahafalensis* is already used as an aphrodisiac in Malagasy by traditional health practitioners, and lists 11 citations of its traditional use as an aphrodisiac. Dicotyledon advances its novelty argument by insulting the holders of traditional knowledge on the uses of the plant. It states that Malagasy traditional practitioners use so many plants as aphrodisiacs and that not all of them are true claims. The company further claims that Malagasy traditional healers provide inaccurate information to researchers, and that they lack scientific skills in identification and characterization of active ingredients of the plants.

Universities of Basel, Bern and the Swiss Tropical Institute have a patent application whose claims are on drugs from *Cussonia zimmermannii*, a tree found in Kenya, Tanzania, Uganda, Mozambique and other countries in East and Southern Africa. Extracts from this plant are active on the human central nervous system, and may be of use in treating a variety of diseases such as epilepsy, mental disorders and anxiety. The Swiss inventors concede that, Kenyan researchers noted in 1986 that the plant is traditionally used to treat mental illness, and that, in 1964; an article on ethno botany noted its traditional use in treating epilepsy. It has been observed that Swiss institutions use western modern and advanced technology to confirm African traditional knowledge about plants, rather than inventing.

In spite of all these cases, *Timothy A. Wolfe* and *Benjamin Zycher* of Pacific Research Institute (PRI) claim in their study conducted in May 2005 that a patent based- ABS system would have significant implications for the future of biotechnological and pharmaceutical research and development. The report equates patent based ABS system to a long-run tax on biotechnological and pharmaceutical research and development investment.

In the study by *Pacific Research Institute* (PRI) in May 2005, it was argued that, if a proposed patent based international regime governing access and benefits sharing of traditional knowledge and associated genetic resources is adopted as proposed by the

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43 Biotechnological and pharmaceutical research and development investment under a patent based access and benefit-sharing regime-(May 2005)
Like Minded Mega-Diverse Countries (LMMCs), it will have a very significant economic impact on countries in the developed world.

Using a careful methodology that transforms biotechnological and pharmaceutical research and development into capital stocks, the detailed study claims that adoption of the proposed **TRIPS 29 biss** will create a cumulative loss of approximately $79 billion by 2025 to the fifteen countries of the European Union. In my opinion, this loss as claimed by Timothy and his Pacific Research Institute (PRI) is the benefit that shall have been transferred to developing countries through a Paten Based –Access and Benefits Sharing (ABS) system, with the help of Mutually Agreed Terms (MAT), Prior Informed Consent ((PIC) and disclosure in patent applications.

Timothy A. Wolfe and Benjamin Zycher are possibly not aware of the fact that some countries in Europe like **Norway**\(^\text{44}\), have acknowledged the fact that disclosure of source of origin in patent applications is necessary, and have amended their national patent law to support compliance with the CBD and Prior Informed Consent (PIC) of the country of origin of traditional knowledge and associated genetic resources.

The amendment applies to patent applications submitted from 1\(^{\text{st}}\) February 2004 when the law came into force. It is recommended that Europe borrow a leaf from Norway and amend their national patent laws to require disclosure of source of knowledge and associated genetic resources in patent applications. These cases bring to the fore an issue that developing-country governments have repeatedly raised at the World Trade Organisation, WIPO and the Convention on Biological Diversity (CBD) in discussions on traditional knowledge and patent applications.

\(^{44}\) Birthe Ivars; Ministry of Environment: Norway: [www.canmexworkshop.com](http://www.canmexworkshop.com); 2004 (page 305-308)
Table 6: Research and Development Capital Stocks with Patent-Based ABS, Year 2025

<table>
<thead>
<tr>
<th>Country</th>
<th>Biotechnological</th>
<th>Pharmaceutical</th>
<th>Total</th>
<th>Decline</th>
<th>Percent Decline</th>
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</thead>
<tbody>
<tr>
<td>Australia</td>
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<td>2323</td>
<td>3367</td>
<td>1393</td>
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<td>Austria</td>
<td>1290</td>
<td>7073</td>
<td>8363</td>
<td>2038</td>
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<tr>
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<td>2223</td>
<td>9295</td>
<td>11518</td>
<td>3729</td>
<td>28.6</td>
</tr>
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<td>Brazil</td>
<td>178</td>
<td>708</td>
<td>878</td>
<td>245</td>
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<tr>
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<td>2189</td>
<td>10042</td>
<td>12231</td>
<td>3930</td>
<td>28.1</td>
</tr>
<tr>
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<td>1744</td>
<td>8608</td>
<td>10352</td>
<td>3440</td>
<td>28.6</td>
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<tr>
<td>Colombia</td>
<td>73</td>
<td>355</td>
<td>428</td>
<td>131</td>
<td>27.1</td>
</tr>
<tr>
<td>Denmark</td>
<td>2042</td>
<td>9938</td>
<td>11980</td>
<td>3782</td>
<td>27.6</td>
</tr>
<tr>
<td>Finland</td>
<td>178</td>
<td>865</td>
<td>1043</td>
<td>318</td>
<td>26.9</td>
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<tr>
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<td>8398</td>
<td>10975</td>
<td>3094</td>
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<tr>
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<td>33675</td>
<td>39616</td>
<td>11878</td>
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<td>1938</td>
<td>611</td>
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<td>13255</td>
<td>15983</td>
<td>5008</td>
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<tr>
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<td>8522</td>
<td>10276</td>
<td>3205</td>
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<td>63776</td>
<td>20836</td>
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<td>52531</td>
<td>61345</td>
<td>17833</td>
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<td>701</td>
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<td>13094</td>
<td>15787</td>
<td>4994</td>
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<tr>
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<td>408</td>
<td>383</td>
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<tr>
<td>Peru</td>
<td>31</td>
<td>153</td>
<td>464</td>
<td>50</td>
<td>24.9</td>
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<tr>
<td>Portugal</td>
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<td>2159</td>
<td>678</td>
<td>27.5</td>
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<tr>
<td>Singapore</td>
<td>641</td>
<td>3122</td>
<td>3763</td>
<td>1198</td>
<td>27.7</td>
</tr>
<tr>
<td>Spain</td>
<td>1591</td>
<td>6424</td>
<td>8015</td>
<td>2591</td>
<td>28.7</td>
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<tr>
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<td>6046</td>
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<td>44906</td>
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<tr>
<td>United Kingdom</td>
<td>6599</td>
<td>33738</td>
<td>40337</td>
<td>12143</td>
<td>26.5</td>
</tr>
<tr>
<td>United States</td>
<td>13160</td>
<td>62921</td>
<td>76081</td>
<td>21630</td>
<td>25.6</td>
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<tr>
<td>TOTAL</td>
<td>79113</td>
<td>393613</td>
<td>472726</td>
<td>144061</td>
<td>26.8</td>
</tr>
</tbody>
</table>

(Source: Timothy A. Wolfe and Benjamin Zycher)
Table 7: Reductions in Biotechnological and Pharmaceutical R&D Capital Stock

This table shows reductions in Biotechnological and Pharmaceutical R&D Capital Stock for 27 Nations under a Patent-Based ABS Regime (Millions of year 2004 dollars)

<table>
<thead>
<tr>
<th>Year</th>
<th>Biotechnological</th>
<th>Percent Decline</th>
<th>Pharmaceutical</th>
<th>Percent Decline</th>
<th>Total</th>
<th>Percent Decline</th>
</tr>
</thead>
<tbody>
<tr>
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<td>3405</td>
<td>7.1</td>
<td>3434</td>
<td>2.4</td>
<td>6839</td>
<td>3.6</td>
</tr>
<tr>
<td>2010</td>
<td>19368</td>
<td>29.4</td>
<td>19611</td>
<td>10.9</td>
<td>38979</td>
<td>15.8</td>
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<td>2015</td>
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<td>15.3</td>
<td>70133</td>
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</tr>
<tr>
<td>2020</td>
<td>51537</td>
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<td>52463</td>
<td>17.6</td>
<td>104000</td>
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<tr>
<td>2025</td>
<td>71327</td>
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<td>18.8</td>
<td>144061</td>
<td>26.8</td>
</tr>
</tbody>
</table>

Source- Timothy A. Wolfe and Benjamin Zycher

The situation discussed above is also rampant in Kenya, and is hereby discussed in details. The four cases are used to bring out real issues in Kenya that are related to access to traditional knowledge and associated genetic resources in generation, protection and commercialization of resultant intellectual property assets. Case one on *Mondia whytei* highlights the partnerships and challenges in adding value to traditional knowledge based technologies and how communities are sharing in the benefits.

Case two on Seeds 45 for Life Project is highlighting issues on genetic resources and need for disclosure on access. Case study three is highlighting international bio-piracy and misappropriation of genetic resources through intellectual property system, particularly patents and marks, and strengthens the need for disclosure requirement of the source of genetic resources and associated traditional knowledge in intellectual property applications and registrations. Finally, case study four highlights the fast ever community collective mark and utility model protection of traditional knowledge based Turkana technologies based on *Aloe turkanensis*.

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45 “Seeds for life” project biannual monitoring reports (1-8) 2000-2010.
4.5.2: Case Study 1;

Access to traditional knowledge and associated genetic resources: A case of *Mondia whytei* bio-prospecting around Kakamega Forest.

Bio-prospecting is viewed as a useful tool in generation, protection and commercialization of traditional knowledge based technologies that can help in improvement of livelihoods and biodiversity conservation. It has been recommended that bio-prospecting in developing countries should be operated on a commercial scale if it is to add value to biodiversity and sustainable utilisation of traditional knowledge and associated genetic resources (Weiss et al 1998).

Findings of the project funded by the African Academy of Science (AAS) on *Mondia Whytei* raised awareness on the value of the plant species and its potential for commercialization. This has led to aggressive cultivation, processing and marketing of *Mondia whytei* through established bio-enterprises around Kakamega forest in Western Kenya.

![Fig 3: Left: Roots of Mondia being sold in Kakamega town. Right: M. whytei plant in -situ.](image)

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46 Mukonyi K. W
Case Study Areas⁴⁷:

Fig 4: Map of the study area around Kakamega Forest

⁴⁷ Kakamega forest communities involved in the cultivation of *Mondia whytei*. 
Community based *Mondia whytei* processing has been established around Kakamega forest, serving various farmers around the area. In 2000, ten groups, with about five hundred farmers, had been engaged. In 2003, sixty seven youth groups, ninety eight women groups, sixty one church groups and sixteen school clubs had been recruited.

Issues of access to genetic resources associated traditional knowledge and equitable sharing of benefits has raised a major debate internationally. Sustainable utilization of biodiversity, ownership of protected intellectual property assets and transfer of derived components in an acceptable manner, appears to direct the future of world trade (Michael A. Gollins 1993). Various scholars have proposed that the best way to promote sustainable utilization of biodiversity and equitably enjoy benefits of derived components is through bio prospecting (Weiss et al 1998, Baker et al 1995).

It has been proposed that biodiversity conservation should be treated as a business that is operated through partnerships between governments, private institutions and communities (knowledge holders and owners of resources). This review explores achievements of bio- prospecting activities on *Mondia whytei*, a medicinal plant that is highly utilized by communities in western Kenya. Documentation of traditional knowledge associated with the plant genetic resources was undertaken and value addition through research and development established. Products developed are now being commercialized through a centralized system in partnership with communities living adjacent to Kakamega forest.

### 4.5.2.1: Nutritional bioactive components of *Mondia whytei*

Various research initiatives to evaluate the nutritional and bioactive photochemistry of *Mondia whytei* have been undertaken. Initial studies were by African Academy of Sciences (Mukonyi et al 1998, 2001, 2002), explored its traditional knowledge and uses of *M. whytei*. Kenya Forestry Research Institute (KEFRI), validated the potential of the species as nutritional food supplement for humans and livestock feed.

Many researchers have undertaken studies to validate traditional knowledge claims on the uses of the plant and its value to the community. Some attributes of the plant are that leaves and roots have potential as fodder for enhanced milk production in livestock. It has been revealed that the leaves have high crude protein averaging between 20-25% and ash content of 16.98% as compared to standard dairy meal that showed crude protein of 16.76% and ash content of 7.83%. These values were higher than other fodder material sources such as Rhodes grass, maize and lucerne.

Mineral content determination showed variation that is specific to particular habitats. In general, plant roots had high levels of potassium that ranges from 11.34mg/g to 32.05mg/g as compared to roots which ranged between 3.08 and 8.25 mg/g. Trace elements like Zinc, Copper, Iron, and Manganese were low but in significant amount. The toxic elements like Cadmium and lead were within the safety requirements of the World Health Organisation (WHO) (Niihau 2005, Mukonyi et al 2004). Evaluation of fodder properties of Mondia roots and leaves showed the later had a high percentage of crude protein content ranging from 18.71 to 20.25 ether extract 12.44 and ash 15.23 to 16.98 and the former crude protein content 4.39 to 10.04, Ether 2.94 to 9.51 ashes 7.97 to 10.50. Comparison of basal diets showed Mondia leaves had highest crude protein and ash content of 20.25 and 16.98 as compared to dairy meal of crude protein content of 16.76 to 7.83 respectively. This showed the leaves to have potential as livestock feed. Studies showed Mondia had superior nutritional value compared to other feed supplements such as Rhodes grass, maize germ and lucerne.

Studies have shown that Mondia roots have several vitamins that vary depending on the habitats. For example, vitamin β carotene from leaves varied from 21.812 µg/g to 4.35µg/g; Thiamine from 3.69 mg/g to 0.77 mg/g; Riboflavin from 2.45 mg/g to 0.65mg/g; and niacin from 8.15 mg/g to 0.53µg/g. These shows that Mondia could be used food supplement. The plant samples show varied levels of sugars such as fructose, xylose, glucose and sucrose. Young plants have the highest concentration as compared to older ones. Photochemical value of the roots has been done by various researchers. The main flavouring principle has been linked to a compound identified as compound (I) [–2-hydroxy-4-methoxy benzaldehyde], (Mukonyi et al 1998, 2001, 2002, Koorbanally et al 2000, Kubo et al 1999).

This compound has been shown to posses taste modifying properties, (Mukonyi et al 2001). It has also been shown to exhibit insect repellent properties, (Kubo et al 1999). Compounds (2) and 3, indicating isovanillin, 2-hydroxy-4-methoxy benzaldehyde-2-0-β gluco-pyranosy 1-6-0-β xylopranoside, have been isolated (Msonthi et al 1991, Mukonyi...
et al 2001, 2002). A tri-sacharide, (glucose-xylose-xylose), was isolated for the very fast time from *Mondia whytei* (Mukonyi et al 2004).

Other compounds that have been isolated from *M. whytei* include, sitosterol (compound 5) and compounds (6) (7) and (8). Bioassays have shown that the root extracts have antibacterial effects against *Escherichia coli, Salmonella typhii, Pseudomonas aeruginosa, Bacillus subtilis, Staphylococcus aureus* and *Shigella dysenteriae*. Extracts from the roots and leaves have exhibited anti-fungal properties on *Candida albicans* and *Aspergillus niger*.

![Chemical structures with labels [1] to [6].]
Studies revealed that root extracts of *M. whytei* has strong inhibition activities on *Neisseria gonorrhoea* in comparison to Norfloxaccine (Normax) and Minoglycine. Neat root extracts showed inhibition zone of 22 mm ± 0.2, Minoglycine 14 mm ± 0.3 and Norfloxaccine 35 mm ± 0.01. This showed that extracts from Mondia roots, mainly Minoglycine, can be used as a drug in management of *Neisseria gonorrhoea*, a sexually transmitted disease. Pierre et al (2004) showed toxicity level of LD of 11.9g/kg for aqueous extracts in mice, which showed root extracts have minimal toxicity levels.

Androgenic studies revealed that administration of *M. whytei* root extract caused an increase in serum and intra-testicular testosterone (9) levels, suggesting hormonal effect (Pierra et al 2004). The same group was also observed to induce an increased sperm density in caudal epidermis of treated rats, suggesting potential use as an aphrodisiac. Studies by Mwangale et al (2000) revealed that the root extracts had effects similar to ferusamide drug used in kidney disease management.

Studies by Githinji (2005) revealed that the root extracts causes contraction of smooth muscles and reduction in high blood pressure. Githinji et al (2004) revealed that the root extracts exhibit seroternigic properties for –5-HT-agonistic effect. This indicates that the root extracts may have effect on brain and muscular functioning, and enhances
sleeping properties. Lack of seroternic effect causes brain and muscular disarrangements. Serotonin (10) has been shown to control appetite, sleep memory, sexual behaviours and depression. The market value for serotonin drugs is believed to be worth billions of US $ worldwide.

**Table 8: Community Based Organisations reached in 2000**

<table>
<thead>
<tr>
<th>Community groups</th>
<th>Northern Kakamega forest site</th>
<th>Southern Kakamega forest site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kakamega environmental education group (KEEP)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Muliro farmers conservation group (MFCG)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Malava community based distributors women group</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Shamakhubu community based distributors women group</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Shikusa community based distributors women group</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Kakamega forest community based distributors women group</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Kambiri community based distributors women group</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Ileho community based distributors women groups</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Sabatia community based distributors women groups</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Shiru community based distributors women groups</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Mang’uliro community group</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Virhembe youth development group</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Ikuywa community based group</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

In 2000, Marcurthur funded ICIPE to collaborate with various community based\(^{48}\) groups adjacent to Kakamega forest and its outliers on sustainable utilisation of Mondia whytei. Community members from Malava, Bunyala and Kisero blocks were trained on the importance of *Mondia whytei*, its cultivation, harvesting and management. About 500 individuals were reached. Table (1) showing groups reached in 2000.

\(^{48}\) See table 8 and 9.
The initial program targeted specific self-help groups (Table 1), but current survey shows that various groups are now interested in Mondia domestication. Kakamega Environmental Education group (KEEP), took an active role in education and awareness creation. In addition to education and awareness, community nurseries and demonstration farms were established.

By 2002, about 40,000 seedlings had been planted. For sustainable utilization of *Mondia whytei*, it was felt that the CBOs should be transformed into co-operatives societries in order to procure and market *Mondia whytei* products. From 2001 to 2003, various groups were reached in addition to the earlier identified. Table (10) indicates categories of groups that were reached, between 2001 and 2003.

**Table 9: Number of individuals and groups reached from 2001-2003**

<table>
<thead>
<tr>
<th>Categories of groups</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community youth groups</td>
<td>28</td>
<td>62</td>
<td>67</td>
</tr>
<tr>
<td>Women groups</td>
<td>68</td>
<td>93</td>
<td>98</td>
</tr>
<tr>
<td>Church groups</td>
<td>21</td>
<td>42</td>
<td>61</td>
</tr>
<tr>
<td>School clubs</td>
<td>-</td>
<td>-</td>
<td>16</td>
</tr>
</tbody>
</table>

A system was put in place to promote the established co-operative societies to procure and supply *Mondia whytei* material to ICIPE and KEFRI for processing and marketing of developed and processed products. The first on farm harvesting began in December 2003 and a total of 193 Kilograms of Mondia root bark were harvested by farmers through the established co-operatives. An assessment was undertaken by Laurine in 2003 to establish the impact of planting on members farms and harvesting from the wild. The study revealed that most of the dealers were still harvesting their Mondia from the wild. The rate of on-farm cultivation was picking slowly.

Fresh root bark were being purchased at the price of Ksh 100/kg. This appeared to have discouraged farmers for it was realized Mondia root harvesting was labour intensive, which involved digging, washing and immediate peeling to avoid quality deterioration. Farmers also indicated on-farm management of *M. whytei* was costly since they required either poles or wires for support. It was also realized that few of the dealers and herbalists had established *Mondia whytei* plantations.
On evaluation, it was realized that most of the groups domesticated *Mondia whytei* as a source of income. Therefore any boost to income would increase domestication leading to conservation of the species. Success of the project depended on its ability to bring income to the community.

Lack of institutional support was identified as a major factor affecting domestication of medicinal plants. Cunningham (1997) reported that in spite of cultivation programmes in South Africa being in place for over 50 years, they have not succeeded due to lack of institutional support for production and dissemination of key species for cultivation and low prices paid for traditional medicinal plants by herbal traders and urban herbalists. Challenges faced were on establishing appropriate operational community and institutional framework for exploitation of *M. Whytei*. The assessment results showed that most farmers had acquired knowledge on sourcing of seeds/propagation materials, establish and management of nurseries, on-farm cultivation and sustainable harvesting.

4.5.2.2: Establishment of *M. whytei* community based processing unit in Kakamega

In 2005, ICIPE and KEFRI through funding from Ford Foundation acquired processing premises for KEEP, one of CBO around Kakamega forest. This group was identified based on its wider coverage around the forest. A was put in place, through KEEP, to link up farmers, promote cultivation, procurement and processing of *M. whytei* in collaboration with ICIPE and KEFRI. KEEP has been registered as a CBO, and a co-operative society.

Main actors in *Mondia whytei* products include the producers (farmers), industry (products), entrepreneurs and the consumers. The farmers were taught how to source quality Mondia seeds, best agricultural practices, including suitable harvesting and post-harvest handling techniques. During processing, conditions are checked for high quality production. After packaging the main challenge was marketing the new product. Free tins were given to community members in western Kenya, showing them the new product. Samples were distributed in selected shops and feedback and evaluation through questionnaires and personal interviews on product preference and packaging undertaken.
A request was made to market the product through leading supermarket chains like Uchumi and Nakumatt. The old customers were introduced to Uchumi. These customers intern introduced new ones. Community members and the public was excitement to see Mondia root packaged and being sold in supermarkets, creating an increase in the demand of the product. One thousand two hundred tins have been sold through supermarkets.

4.5.2.3: Access to traditional knowledge and associated genetic resources, Intellectual property ownership and benefit sharing of *Mondia whytei*

The project demonstrates how traditional knowledge helped in guiding research foe value addition of *Mondia whytei* products. The results of the research are being transferred to the community through the established KEEP CBO. Given that funding for research is expensive and communities can not afford it, researchers, through KEFRI and other partners, sourced for funds that were used in value addition. It was realized that some uses of Mondia as claimed are in public domain. The use of the plant as an aphrodisiac is common knowledge in most parts of Africa. Therefore a patented on Mondia based on this local use could not be granted. Part of the research findings was published in journals and presented in conferences.

A patent application on the processing technology for extraction of the flavouring component in Mondia *whytei* has been submitted by KEFRI to KIPI. Currently Mondia tonic has been developed based on KEFRI’s research findings. The application for Mondia tonic trademark has been forwarded to Kenya Industrial property rights (KIPI), under joint ownership between KEFRI, ICIPE, KWS, KARI, KEEP and other communities around Kakamega forest.

There are discussions on equitable sharing of derived benefit that will support livelihoods, conservation and research from sale proceeds of developed Mondia products. Communities are already benefiting from the sale of Mondia raw material and products, such as seeds and roots harvested from their farms. Farmers have recognized about three varieties of Mondia *whytei*, whose quality is still being researched.

Commercial Mondia roots are obtained from two sources, namely the wild and on individual farms. Those in the wild are owned by Kenya Wildlife Services and Forest Department. Communities have to get licences to harvest the roots in the forest from the resource managers. Programmes are being put in place for clean planting material.
Clean planting material for *Mondia whytei* in Kenya comes from a single plant on a private farm in Naitiri, in Bungoma North District of Western province.

### 4.5.2.4: Technology Management

Technology Licensing agreement for generation, protection and commercialization of Mondia tonic® between the communities and public institutions (ICIPE, KEFRI, UoN and KWS). Technology transfer terms were on research and development of commercial products. It was based on institutional IP policies. The agreement involved a review of existing intellectual property policies at the institutions and the role of national IP institutes. Intellectual property assets were identified and conditions set for transfer to third parties.

Most agreements are on confidentiality, material transfer, collaboration, technology license agreement and distribution. KEFRI’s IP policy covers all aspects of technology transfers including patents and utility models, know how, copy rights and trade marks in section 3, while section 4 addresses ownership of intellectual property asset, Access and Benefit Sharing. However, the agreement has been negotiated by institutions but it has not been signed by the communities. The proposed technology licensing defines what is being transferred and the use of Mondia tonic® trademark. It is however recommended that for fair trade, real numbers, including prices paid per kilogram to farmers and collectors, the yield in plant extract, and how much income the partners and customers derive from sales.

### 4.5.3: Case Study 2: Seeds for Life Project

The “seeds for life” project is a collaborative venture involving the major national institutions that are charged with the responsibility of Plant Genetic Resources (PGR) conservation in Kenya. These institutions are the Forest Department (FD), Kenya Agricultural Research Institute (KARI), Kenya Wildlife Service (KWS), and the National Museums of Kenya (NMK). The institutions are working in partnership with the Millennium Seed Bank (MSB) Project of the Royal Botanic Gardens Kew (RBG, Kew).

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49 Naitiri is a Division in Bungoma North District, of Western Province.
50 Seeds for life” project biannual monitoring reports. (1-8) 2000-2010
Each institution has a role and responsibility within the project that ensures synergy in delivery of the project outputs.

The Project was a joint conservation venture working to conserve the traditional **plant seeds** in Arid and Semi Arid Lands (ASALs) of Kenya. Experience in Kenya shows that conservation and cultivation of indigenous plants has been greatly undermined by undesirable depletion of forest cover, soil erosion, constant droughts, famine and rapid rates of desertification, leading to the weakening of the ecosystem. The project was aware of the communities’ efforts to reverse this trend through collecting, preserving and storing of plant seeds through various home grown methods. The aim of this project is to conserve plant from the ASALs of Kenya, promote better management and sustainability of the environment by increasing knowledge and capacity of the communities on the needs to conserve the plant genetic resource (PGR).

The research team was interested in knowing how indigenous plants seeds are collected, processed, and stored. It also sought to collaborate with communities in adding value and improving traditional methodologies. In order to achieve the above objectives, the project worked with communities to collect and document information on the following local seeds collection methods, ways of Seed processing and seed Storage methods.

The information obtained during this research work was documented and the information was shared with communities. It included records on existing harvesting, handling, processing and storage methodologies. With community’s permission, the information obtained was used in efforts to identify the most appropriate seed handling methodologies and where possible, improve on existing handling methods. Prior-informed Consent (PIC) was sought for seed collection, processing and storage methods and for the project to document the collected information and use the collected information for possible improvement on seed handling methods. This project is part of the Millennium Seed Bank that aims at conserving 10% of the world’s flowering plant species through long-term ex-situ conservation and provide for collaboration between Royal Botanic Gardens (RBG-Kew) and partner countries like Kenya.

The government of Kenya, through the lead institutions, (FD, KARI, KEFRI, KWS and NMK), signed material transfer agreements (MTA 1 and 2) with RBG-Kew in September 2000. The fast phase came to an end in 2003 while phase two ends in March 2010. This project was among the first projects in Kenya, to apply good practice in accessing genetic resources. The MTA has a clause on intellectual property rights and benefits sharing mechanism. It was ten-year project undertaken in phases upon approval.
The project has been addressing the guiding principles of the 1999 environmental management and coordination act and the National Biodiversity Strategy and Action Plan (NBSAP) of 2000 in relation to the need to prescribe measures for the conservation of biological resources.

The project addressed the National Biodiversity Strategy and Action Plan through the enhancement of ex-situ and in-situ conservation and unsustainable utilization of plant genetic resources indigenous to Kenya and enhancement of technical and scientific cooperation nationally and internationally, including exchange of information in support of biodiversity conservation.

The project aimed at conservation of traditional and indigenous plants from the Arid and Semi Arid Lands (ASALS) through *inter alia*; conducting of joint expeditions to collect seeds and corresponding herbarium material in ASAL by partners in ecologically sustainable manner; Storage and taxonomic verification of seed collections and voucher herbarium specimens in Kenya. The seeds and associated herbarium specimens are duplicated and transferred to the United Kingdom for storage in the Millennium Seed Bank and accession to RBG –Kew for long-term conservation and safe keeping; Conducting of seed studies upon the seed collections and of the herbarium studies upon the voucher specimens to determine their viability and to enable long-term conservation; and the establishment of community seed centres and indigenous species demonstration planting in three focal districts.

The projects outputs were an enhanced national capacity to conserve plant genetic resources and germplasm of priority plant species using appropriate and improved methods; appropriate scientific information was generated and disseminated to aid conservation of Kenyan biological diversity. Access and benefit sharing measures as stated in the CBD were addressed in MTA 1 and MTA 2 agreements of phase one and phase two respectively. Articles 5.1 and 5.2 of the MTAs prescribe access requirements. The MTAs state that, access will be based on permits or prior informed consent, and licences, in connection with subsequent use of the plant genetic material. The germplasm should not be transferred to third parties without the PIC of the government of Kenya.
Article 6.0 that deals with benefit sharing arrangement, states that, benefits shall be shared equitably. Some of the projects benefits include technical and academic training; granting of RBG Kew international diploma in plant conservation techniques; technical and research attachments at RBG Kew; participation in Millennium Seed Bank Project; post graduate studies; focused in country workshops on conservation and sustainable utilisation of genetic resources and local training of the lower cadre staff. Community benefits are short courses on seeds handling at KEFRI/NMK, compensation to local communities from protected areas and casual employment on field excursions for seed collection, where possible.

Article 9.0, 10.0 and 11.0 addresses issues of research and commercialization. Royal Botanical Gardens- Kew is not to commercialize or obtain any patents or any form of intellectual property rights on the 1818 collected and transferred material. It shall not supply the plant material or its progeny to any third party without obtaining prior written permission from the Government of Kenya. However, copyrights to publications are to be jointly owned.

This MTA has safeguards to any abuse that may arise from the misappropriation of Kenya’s genetic material. However, the contractual form on access to the associated traditional knowledge is not clear. Some of the achievements of the project a PhD student trained from KARI, and one with a Masters in Science. One student were trained at the NMK, three attained International diplomas, seven from Maseno University, two from KEFRI and an NMK staff attained diplomas in conservation and utilization of plant genetic resources.

Two technical diplomas in database and information handling were attained, and five researchers were on attachments at RBG Kew. Equipment and vehicles to Kenyan partners were provided. The ex-situ conservation of approximately 2000 plant accession covering 700 different species was realised, with duplicated storage of same seed material and herbarium specimen at RBG Kew.

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51 KIPI and National Gene Bank of Kenya accession records
52 KIPI-/TK/GR/NGBK/0000/09 (1818-accessions)- Secretariat-PEEC-SFLP-Phases 1 and 2.
4.5.3.1: Challenges

The challenge is that the MTAs for phase 1 and 2 states that, access will be based on permits or prior informed consent (PIC) and licences, in connection with subsequent use of the plant genetic material. The germplasm should not be transferred to third parties without PIC of the government of Kenya.

Challenges related to generation, protection and commercialization of intellectual property assets are on implementation of the above issues outside Kenya. It has a bearing on access to genetic resources under collaborative research agreements. Section 15 of legal notice no.160 (see annex ii) states terms and conditions of an access permit. They apply on conditions that duplicates and holotypes of all genetic resources collected shall be deposited with the relevant lead agency (National Gene Bank of Kenya) and records of all intangible components of plant genetic material collected shall be deposited with the relevant Authority, and that reasonable access to all genetic resources collected shall be guaranteed to all Kenyan citizens, whether such genetic resources and intangible components are held locally or abroad.

Section 19 on benefit sharing requires that all this shall apply subject to the laws in force relating to intellectual property rights, mandated to Kenya Industrial Property Institute, Kenya Copyrights Board and Kenya Plant Health Inspectorate Service. The absence of an international regime to ensure the implementation of this obligation is the genesis of supporting the review of the TRIPS Agreement to be supportive of national obligations under the Convention on Biological Diversity (CBD)\(^53\).

4.5.4: Case Study 3: Kenya Wildlife Service vs. Proctor and Gamble

Between 1974 and 1979, the Endorois, a semi-nomadic Kalenjin community of about 60,000 persons, were forcefully evicted from their ancestral land by the Kenyan government, to pave way for the creation of the world famous Lake Bogoria Game reserve. The Endorois community first launched their campaign in Kenya’s domestic courts in1997, challenging ownership of the reserve by Baringo and Koibatek County Council, who were the joint trustees of Lake Bogoria.

The Endorois community questioned allocation of revenue collected from the game reserve that left them out of the benefits sharing structure, consequently leaving them

\(^53\) See annex 2
poorer and destitute. Left without any other remedy, the Endorois petitioned the Commission on Human rights of the African Union. The African Charter on Human and Peoples rights was negotiated and opened for ratification in Nairobi in 1981. By ratifying the treaty on February 21, 1992, the Kenyan state agreed to put in place legislative and other measures to give effect to the charter.

Six years later, on February 4th 2010, the African Commission on Human and Peoples Rights (ACHPR) rescinded eviction of the Endorois from Lake Bogoria game reserve, and recommended that the Kenyan government restores the community back to its ancestral land, including Lake Bogoria. While the court cases were going on, from as far back as 1974, in 1988, a Kenyan student collected some soil samples from the Lake. The samples collected were for use in her PhD studies at a University in the United Kingdom (UK).

Soon after the collection, and armed with her admission to the UK university, the student left Kenya and headed to the (UK) with her soil samples. At the UK University, she found herself working in a very advanced laboratory. In the same laboratory, and coincidentally on a similar research, was a gentleman from a company based in Netherlands. This company happened to be engaged in collaborative research activities with the same University. Naturally, and as expected of scientists in an institution such as the one she was in, they got to know each other and of each others’ research.

As the Kenyan student undertook her studies, and as the collaborative researcher went on with his research, it soon emerged that, the soil samples that had been collected from Kenya, contained some **micro-organisms** that exhibited very interesting activities. These micro-organisms, letter identified as **extremophiles**, had the ability to thrive in very high alkaline conditions. With this knowledge, it was decided between the university, the student and the Dutch researcher, that another expedition was necessary. Therefore in 1991, the student, the researcher and others travelling as tourists, came back to Kenya and took away more soil samples from the same lake ((Bogoria). Meanwhile, the student researcher successfully completed her studies, and was awarded a PhD in biochemistry, and soon returned to Kenya, where she took up employment with a public university. In the meantime, the Dutch researcher continued carrying out more research on the micro-organisms collected from Kenya. He also became a prolific author of academic articles based on the same material.
It is not clear at what point inventions generated based on the micro-organisms from Kenya were protected. However, a series of events occurred that led to the filling and granting of several patents based on the micro-organism by a USA based conglomerate. The USA based conglomerate acquired the Dutch company, whose researcher was collaborating with the UK University. At some point, the research results were transferred to industry and commercialised.

Some time in 1993, and in the spirit of collaborative researcher, the Dutch researcher approached the former student, by then a lecturer, seeking to conduct further expeditions to Lake Bogoria. The student sought and obtained research permits from the National Council for Science and Technology, the national research regulator. The permits granted did not authorise shipment of the material out of Kenya. In any event, the permits granted did not grant the researchers permission to enter protected areas that fall under the authority of Kenya Wildlife Service. Entry into the protected area was not difficult since it is a tourist attraction and destination that is easily accessed after paying park entry fees. The researchers entered and collected more samples.

In 1996, another expedition was arranged, just like the 1993 one, where more soil samples were collected, researched on, and results patented by the US based conglomerate. It is well known that, patenting an invention is not enough. Based on the patents granted utilising the (1992) pre-CBD collections, the US based company and its subsidiaries, including the Dutch based company, intensified research on their findings. By 2004, two industrial products, namely Puradax™, that is an additive to ordinary detergents, and Indiga™, that is used to bleach jeans, had been developed and protected by patents and marks. These two products were commercialised and generated billions of US dollars.

Research findings have it that, many micro-organisms from Kenya’s Lake Bogoria have been accessed and used to generate intellectual property assets, and have been commercialized without any benefits to the Endorois. William Proctor and James Gamble established the world’s largest detergent and household products company in 1837. The company’s audit reports show that it has become a US $38 billion international giant, with more than 300 patent protected products.

An ICIPE scientist, who had been bio prospecting in Kenya, came across the issue of extremophiles in Kenya’s soda lakes that had been used as a basis for development of products that were commercialised by Proctor and Gamble in 2001. Genencor, that is
actively bio-prospecting on microbial biodiversity, particularly extremophiles, that are essential in the generation of innovative cleansing ingredients, have signed research partnership agreements with Proctor and Gamble, in the tune of approximately US$600 million, for a five-year supply of biotechnology based solutions, to Proctor and Gamble, for 18 years.

4.5.4.1: The case:

From press releases of 1998, Genencor’s annual report showed that the company commercialized an extremophiles enzyme, *puradex cellulase*, derived from a new bacillus species that was accessed from the rift valley soda lakes of Kenya. Genencor had also introduced *Indiage neutra*, an enzyme derived from a bacterium isolated from soda mud flats on the shores of Lake Nakuru. This is documented in publications by Dr. William E. Grant of Leicester University, UK, on microbial biodiversity in East African soda lakes.

Prof. Mwatha, of Kenyatta University, did extensive studies on Kenyan microbial biodiversity in soda lakes, while she was at Leicester University. Evidence has it that Dr. William E. Grant, of the Department of Microbiology and Immunology, at the University of Leicester in the UK, scooped extremophiles from Lake Bogoria (Grant et al., 1998) and availed it to Brian Jones of Genencor. Brian Jones of Genencor international, who discovered the enzymes, cloned them by genetic manipulation, and sold the technology to Proctor and Gamble, who now reproduce extremophiles that have essential cleansing ingredients in the company’s popular Tide brand range of products. Kenya Wildlife Service (KWS), a resource manager of the claimed soda lakes, is seeking compensation on behalf of the government of Kenya and Endorois and communities of Lake Bogoria, from Proctor and Gamble, through Public Interest Intellectual Property advisors (PIIPA) of the USA.

The issue involves Genencor International, a subsidiary of Genencor international Inc. a California and New York based biotechnology Research Company. It has annual revenues of more than US $ 380 m. Records show that Genencor has been conducting research expeditions in partnership with Leicester University in the UK and Kenyatta University in Kenya. Dr. Grant, a research scientist at Leicester, complied with Kenyan research approval and licensing regulations. Prof. Mwatha of Kenyatta University was part of the Leicester expedition team in the rift valley. The National Council for Science and Technology (NCST) vetted the application from the University of Leicester and granted a research permit and permission for exploration.
This case raises several concerns. How would the situation have been if the research was conducted in collaboration with public universities or research institutions and traditional knowledge holders, using associated genetic resources? Do the public universities and research institutions have intellectual property policies that stipulate procedures for such collaborative research? How are traditional knowledge holders organised, and how do they collaborate with public institutions? Can they collaborate with these public institutions to generate, protect and commercialise intellectual property assets, including biotechnology? Is the national law on access to traditional knowledge and genetic resources adequate? Are national, regional and international IP laws and policies adequate? Are the CBD (1993) and the TRIPS agreement (1995) mutually supportive of each other?

4.5.4.2: Discussion of the case:

This is a case of miss-appropriation of genetic resources by use of patents and other intellectual property instruments. NEMA, through lead agencies, is charged with enforcement of environmental regulations, including biodiversity conservation, access to resources and equitable sharing of accrued benefits. The principle law in Kenya on access to genetic resources is the legal notice no. 160 of December 2006. The challenge however, is how to address pre and post CBD accessions, and enforcement of NEMA legal notice no. 160 of December 2006. The Endorois, who are legal owners of Lake Bogoria, have the right to share in the benefits accrued from utilisation of resources from the lake.

In some countries like India\textsuperscript{54}, biodiversity and traditional knowledge issues are handled by one focal point that grants access and is recognised in the patent laws. Section 25 (1) of India’s amended act of 2005 states that, where an application for a patent has been published, but a patent has not been granted, any person may, in writing, represent by way of opposition to the controller, against the grant of a patent on grounds that, the complete specification does not disclose, or wrongly mentions the source or geographical origin of biological material used for the invention; and that the invention so far as is claimed in any claim of the complete specification is anticipated, having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

\textsuperscript{54} India-Patent (Amendment) Act 2005
This shows that, if proper bio-prospecting mechanisms are put in place, including amendment of the Industrial Property Act- 2001, to embrace the spirit of *TRIPS 29 biss*\(^{55}\), our patent law (IPA-2001) will help in creating an enabling environment for bio-prospecting, including utilisation of traditional knowledge associated with genetic resources and biotechnology.

4.5.5: Case Study 4: Echuchuka-Turkana Collective Mark and Utility Models

This is a case highlighting how communities can use collective marks and utility models, to protect traditional knowledge, innovations and practices. Following the Presidential directive on the marketing of Turkana\(^{56}\) artefacts and other traditional knowledge based products in 2006, the Ministry of Trade and Industry constituted an Inter-ministerial consultative committee, to address challenges facing marketing of Turkana artefacts and other technologies based on traditional knowledge and genetic resources. The objective of the survey was to verify the list of products produced in Turkana district; ascertain whether the products can be traded locally and internationally; ascertain the supply base and production capacity for the producer groups; Ascertain the formal status of the various producers groups; identify other existing producer groups and their linkages; obtain samples for test marketing; and establish delivery logistics to the market from production and collection centres.

The main challenges facing Turkana community in this respect were among others; poor production methods and tools; lack of knowledge on intellectual property (trade marks, utility models & certification and collective marks); low quality products for regional and export markets; unsustainable utilization of *Aloe turkanensis*; and poor public-private partnerships in product development and marketing.

It was recommended that; more involvement of cooperatives in value addition ventures was necessary for collective marketing of traditional knowledge based products; market opportunities be identified domestically and at the international levels; Awareness be carried out on the importance of Intellectual Property protection of traditional knowledge based.

\(^{55}\) See annex 2

\(^{56}\) Turkana is in of the north Rift valle. It borders Uganda, Southern Sudan and Ethiopia.
Data held at KIPI reveals that Turkana Bio-Aloe organization (TUBA) has the fast ever collective mark in Kenya (TM 59849) and three utility model applications, based on traditional knowledge and associated genetic resource known as *Aloe turkanensis*. The utility model applications are KE/UM/06/00081; KE/UM/06/00082; KE/UM/06/00083 for lotion, soap and shampoo respectively. However, these applications are not properly drafted. There is need to make a proper disclosure and draft proper claims. Echuchuka is the fast Kenyan collective mark protecting traditional knowledge and associated genetic of the Turkana community.

4.5.6: Conclusion of the case studies

From the discussed case studies, it can be concluded that, successful generation, protection and commercialization intellectual property assets, utilising traditional knowledge and associated genetic resources is possible. However, public institutions need institutional IP policies and substantial funding to avoid overlaying on donors. Bio-prospecting on *Mondia whytei* has shown that, communities, researchers and private entrepreneurs can collaborate in utilising traditional knowledge associated with genetic resources to generate, protect and commercialise intellectual property assets.

Case study two on seeds for life Project shows that bio prospecting is possible using existing regulations on access to intangible traditional knowledge and genetic resources. However, there is need for enabling legislation and an international framework for disclosure of source of origin of knowledge and genetic resources, to comply with the requirements of NEMA’s legal notice number 160, of December 2006. On the other hand, case study three of Kenya Wildlife Service vs. Proctor and Gamble confirms that luck of an international regime to regulate access to traditional knowledge and associated genetic resources has made it possible for the patent system to be used as a tool of misappropriate traditional knowledge and associated genetic resources.

Case study four on the Turkana collective mark “Echuchuka”\(^{57}\), and Utility Model applications on *Aloe turkanensis*, shows that communities can use existing intellectual property system, to protect its assets that utilize traditional knowledge associated with genetic resources. It can however be noted that the existing regime is not comprehensive. These cases show that, access to genetic resources can be regulated

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\(^{57}\) Trade Mark number 59849- Industrial property Automated System-KIPI
using NEMA regulations as provided for by the legal notice number 160 of December 2006. However, the process for accessing traditional knowledge, and a mechanism for sharing accrued benefits, is not clear.

It can be concluded that, African terrestrial and aquatic biodiversity continues to be claimed as exclusive intellectual property assets of international corporations in the west. Apart from adding to the exploitation and gross inequity, these African resources are often patented for use in expensive luxury goods or healthcare products that relatively few Africans can afford. The solution of misappropriation of African resources, particularly traditional knowledge associated with genetic resources, should be patent based. Disclosure of knowledge and genetic resources should be made mandatory in all patent applications.

Biopiracy in Africa, and particularly in Kenya, remains a huge problem and there is little to suggest that the true owners of these resources have consented to its use in the patent claims. In most cases, there is even less evidence that sharing of benefits is taking place. This is the main hindrance for traditional knowledge holders to disclose their knowledge to researchers in public institutions for generation, protection and commercialization of the resultant intellectual property assets.
CHAPTER V:

5.0: SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1: Summary

The national intellectual property assets audit conducted by Prof. Tom Ogada, between 2005 and 2006, was used as a benchmark, and its shortcomings formed the genesis of this research. Research products based on traditional knowledge associated with genetic resources, particularly pharmaceutical, environmental and agricultural, end up being sold to Africa and particularly Kenya, at exorbitant prices. The source of knowledge and associated genetic resources is never acknowledged. It’s on this basis that this research sought to investigate why public institutions in Kenya are not utilizing the available traditional knowledge and the abundant genetic resources, to generate, protect and commercialise the protected intellectual property assets.

Chapter one provides an introduction to the problem relating to collaboration between traditional knowledge holders and public institutions in generating, protecting and commercialising intellectual property assets. It is documented that public institutions in the west are utilising traditional knowledge associated with genetic resources to generate and protect intellectual property assets, including biotechnology, while institutions in Kenya are not doing the same.

Chapter two reviewed the relevant literature, particularly legislations affecting access to traditional knowledge and genetic resources. Table 1 summarises national legislations relating to access to genetic resources and its intangibles, while table 2 summarises the institutional mandates and national laws related to the Convention on Biological Diversity (CBD). It highlights the importance of the CBD, TRIPS agreement and the International Treaty on Plant Genetic Resources for Food and Agriculture, in accessing genetic resources and associated traditional knowledge for generating, protecting and commercialization of the resultant protected intellectual property assets, including biotechnology. It is worthy noting that the African Model law is in conflict with Kenya’s

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58 Paper presented to stakeholders round table on IP strategy in Addis Ababa-July 12-14, 2006

In chapter three, data collected and findings was analysed, interpreted and presented. Different ways including charts, graphs and other data presentation methods are used. Questionnaires and interviews were used to gather data and findings are discussed in chapter four. Chapter four presents findings from interviews, observations and interpretation of the collected data, while in this chapter, an informed conclusion is drawn and recommendations are made.

As provided for in the introductory remarks, this study aimed at finding out how public universities and research institutions in Kenya are generating, protecting and commercialising intellectual property assets based on traditional knowledge and associated genetic resources, including biotechnology. The research investigated collaboration between the selected public institutions and the private sector including small and medium size enterprises and traditional knowledge holders within Kenya.

It can be summarised that all selected institutions except Masinde Muliro University of Science and Technology (MMUST) and Kenya Marine and fisheries Research Institute (KEMFRI) have institutional Intellectual Property policies that harmonises activities related to generation of traditional knowledge based intellectual property assets, including biotechnology, and subsequent protection and commercialization of the generated and protected intellectual property assets. The biggest challenge facing generation of traditional knowledge based technologies is the absence of an enabling legal mechanism, while commercialization of biotechnology is hampered by the absence of implementing regulation to the Bio safety Act of 2009.

It was apparent from interviews conducted and answered questionnaires that very few or none of the protected technologies by public institutions have successfully been commercialised or used to create start up companies. The institutions have very many scientific publications, and no single product is commercialised. On collaborative research, it was found that financiers are only willing to fund research, but are reluctant to fund product commercialization.

Obstacles and challenges facing the selected public institutions in generating, protecting and commercializing intellectual property assets, including biotechnology, were found to
be lack of an enabling legal mechanism mainly because traditional knowledge holders are not willing to disclose their knowledge under the current intellectual protection regime. The main obstacle and challenge facing the selected public institutions in generating, protecting and commercializing biotechnological intellectual property assets is that the Bio safety Act 2009 which regulates biotechnology, only deals with genetically modified organisms, and is silent on other biotechnologies. It is recommended that a framework be developed for the other biotechnologies that are not covered by the Biosafety Act 2009.

It was found that the subject public institutions were not aware of successful commercialization of their generated and protected intellectual property assets. KARI has many biotechnology research products that could be commercialized. For example, the Insect Resistant Maize for Africa (IRMA) is ready for commercialization, but that can only happen if implementing regulations to the Biosafety Act 2009 are developed. This gap implies that biotechnological inventions in Kenya can not be commercialized currently. It is recommended that for public institutions to commercialize the generated and protected biotechnologies, the Bio safety regulations have to be put in place.

It can be summarised from interviews carried out that institutional IP policies and the NEMA legal notice no 160 of December 2006 have helped the selected public institutions to manage collaborative research agreements with traditional knowledge holders, industry and other research collaborators. It is important to note that, in spite of their location in the vicinity of habitats with abundant genetic resources, lack of a single patent application at KIPI by Masinde Muliro University of Science and Technology and the Kenya Marine and Fisheries Research Institute, could be attributed to lack of institutional intellectual property polices. From these findings, development of institutional intellectual property policy is recommended for all public research and development institutions.

According to the Global research report, Kenya’s research output has been ranked sixth in Africa after South Africa, Egypt, Nigeria, Tunisia and Algeria. Although Kenya was among the leaders in research, it only produced 6,500 papers compared to South Africa’s 47,000 between 1999 and 2008. In spite of all these publications, it is apparent that less that 1% gets developed into products. There are many printed publications, and little or no conversion into products. It is apparent that, to develop innovations into products, significant additional expenditure is required. The report also shows dominance of local studies by western researchers, particularly from the USA and

59 Thomson Reuters global research report 2010
Britain. Total involvement in South Africa’s research by foreigners is approximately 41%, 21% in Nigeria, 29 % in Egypt and **75% in Kenya**.

This indicates that, there is an over reliance on foreign donors for funding research in public institutions in Kenya. Although the study does not indicate who owns the study findings or funding sources, Kenya’s research institutions have for long complained of research agenda being set by the west. Providers of funds have been known to have a lot of influence on intellectual property assets of the generated and protected assets.

This is in complete contrast with the success story of public Universities in the USA after the enactment of the Bayh-Doe Act. The Act created an enabling environment for funding research and subsequent ownership of the resultant intellectual property assets. It was observed that a single university like Michigan State University that is ranked tenth in the USA has more patent applications than all public universities in Kenya. This leads to the conclusion that public Universities and research institutions in Kenya are not optimally utilizing traditional knowledge associated with genetic resources to generate, protect and commercialize intellectual property assets, including biotechnology. This can be attributed to poor research funding and lack of an international framework on intellectual property and genetic resources that has created an avenue for bio-piracy and misappropriation of Kenya’s traditional knowledge and associated genetic resources by use of intellectual property regimes.

The four focused case studies revealed that there is need for periodic investigation of changing international concepts and emerging issues in genetic resources and intellectual property management, and assessment of the ability of technology markets to disseminate patented inventions based on traditional knowledge and associated genetic resources, and identify effective policy measures for promoting traditional knowledge based natural products. It is documented in journals that many pharmaceuticals are derived from plant and animal materials, and from numerous forms of traditional knowledge developed over time by indigenous communities. These genetic material and knowledge have immense economic value as has been demonstrated in the four case studies discussed in the previous chapters.

This is contrary to the provisions of **Articles 15 and 16** of the Convention on Biological Diversity that recognises the property rights of states with respect to their biological resources and resultant technologies, including biotechnology. Implementation of the CBD is in progress in Kenya. As a result of this development, an effort is under way to
change international patent law so as to give states the right to litigate over patent rights for inventions utilising traditional knowledge and associated genetic resources in biotechnological and pharmaceutical fields⁶⁰.

5.2: Conclusion:

It has been observed that Bilateral and multilateral cooperation offers new and increasing prospects for Kenya’s scientific and technological development through research for generation, protection and commercialisation of Intellectual Property assets. International cooperation in Science, Technology and Innovations is increasing in intensity and complexity due to globalization and increasing recognition of the benefits of collaborative research. If our public institutions enforce their institutional Intellectual Property policies, it could provide the basis for mobilizing resources, improving infrastructure for research, development and commercialization of technologies based on traditional knowledge and associated genetic resources, including biotechnology.

Literature reviewed and interviews conducted by representatives of public universities and research institutions shows that the most important documents affecting generation, protection and commercialization of technologies based on traditional knowledge and associated genetic resources are the NEMA legal notice no. 160 of December 2006, the Biosafety Act 2009 and intellectual property laws administered by Kenya Industrial Property Institute (KIPI) and Kenya Plant Health Inspectorate Service (KEPHIS). However there is a gap in enforcement of Sections 15 (c), 19 and 20 of the NEMA legal notice no 160 of December 2006. The notice attempted to fill most gaps that were identified at the national level in the literature review, and requires that reasonable access to all genetic resources collected from Kenya shall be guaranteed to all Kenyan citizens, whether such genetic resources and intangible components are held locally or abroad. If the proposed amendment to TRIPS Article 29 (TRIPS 29 bis) is adopted, identified gaps at the international level shall have been field. All agreements entered into with respect to access to genetic resources shall be strictly for the purposes for which they were entered into.

In case study 2 on Seeds for life project, Kenya has 1818 accessions of genetic resources from Arid and Semi Arid Lands (ASALs) at the Royal Botanical Gardens (RBG-Kew). RBG-Kew is not to commercialize or obtain any patents or any other form of

⁶⁰ See annex 2 - TRIPS 29 bis
intellectual property rights on the 1818 accessions, and that it shall not supply the plant material or its progeny to any third party without obtaining prior written permission from the Government of Kenya.

Sections 19 and 20 stipulate that benefits sharing arrangement shall apply subject to the laws in force relating to intellectual property rights. Without prejudice to the generality of the foregoing, the holder of an access permit shall facilitate an active involvement of Kenyan citizens and institutions in the execution of the activities under the permit. It further states that the facilitation by the holder of an access permit shall include enjoyment of monetary and non-monetary benefits arising from the right of access granted and the use of genetic resources. It can be concluded that an international frame work to enforce this requirement that is vital for access to genetic resources for generation of intellectual property assets is absent and national intellectual property institutes are yet to amend their laws to accommodate this provision.

This is a substantial matter that WIPO's 61 Inter-Governmental Committee (IGC) on Genetic Resources and Traditional Knowledge is addressing in relation to intellectual property and genetic resources. This has raised three substantive technical issues. They are technical matters concerning defensive protection of genetic resources, disclosure requirements in patent applications for information related to genetic resources used in the claimed inventions and intellectual property issues in mutually agreed terms for the fair and equitable sharing of benefits arising from the use of genetic resources.

The technical measures that have been identified as possible means to address these concerns include improving the availability and searchability of publicly available information about disclosed genetic resources to patent examiners, improved search tools for prior art searches, in particular thesauri for genetic resource nomenclature in order to allow examiners to translate vernacular names of genetic resources that might be referred to in patent applications and prior art documentation on the other. 62 There is no data or documentation of Kenya’s genetic resources and associated traditional knowledge.

Discussions also covers questions surrounding specific disclosure requirement in patent applications for information relating to genetic resources which have been utilized in the claimed invention and alternative proposals for dealing with the relationship between

61 WIPO/GRTKF/IC/11/8 (a)
62 WIPO/GRTKF/IC/11/8 (a)
intellectual property and genetic resources. This has been highlighted mostly in relation to improved defensive protection of genetic resources and in relation to emerging linkages of intellectual property systems with national and international access and benefit-sharing regimes for genetic resources.

Other multilateral organizations have taken up the issue with regard to specific agreements administered by them, such as the WTO. With regard to the TRIPS Agreement, a specific proposal has been tabled to amend the TRIPS Agreement so as to introduce a mandatory disclosure requirement.

NEMA’s legal notice no. 160 of December 2006 created a mechanism that the subject institutions can use to access genetic resources and associated traditional knowledge to generate intellectual property assets in collaboration with international institutions. However, literature reviewed shows that a mechanism for accessing traditional knowledge is not clear, and commercialization of biotechnology is hampered by the absence of implementing regulations of the Biosafety Act 2009.

When the NEMA legal notice number 160 was gazetted in 2006, it was expected that public institutions will now be able to access genetic resources easily and in an orderly manner, for purposes of generation, protection and commercialization of the protected intellectual property assets. This has however not been the case. Whereas some Public institutions have intellectual property policies, the staffs of the institutions are not aware of its existence, making it hard to be enforced. This could be one of the reasons why public institutions in Kenya are not as innovative as public universities in the USA.

From a historical perspective, there was need for a reliable technology transfer mechanism and for a uniform set of federal rules to make the process work. In 1980, the federal government had approximately 30,000 patents of which only 5% led to new or improved products. Many patents were not being used as the government did not have the resources to develop and market the inventions. Thus, Bayh-Dole gave universities control of their inventions.

In 1980, the Bayh-Dole Act in the USA created a uniform patent policy among the many federal agencies that fund research. As a result of this law, universities retain

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63 See proposed TRIPS 29 bis
64 PL 96-517, Patent and Trademark Act Amendments of 1980
ownership to inventions made under federal funded research. In return, universities are expected to file for patent protection and to ensure commercialization upon licensing. The royalties from such ventures are shared with the inventors; a portion is provided to the University and department or college; and the remainder is used to support the technology transfer process.

The reason that the Bayh-Dole act is so instrumental to university research and technology transfer is that it speeds up the commercialization process of federal funded university research and helps new industries to develop. University gross licensing revenues in the US exceeded $200M in 1991 and by 1992 that number had risen to $250M. In the year 2000, U.S. and Canadian institutions and universities Gross Licensing Income was reported in the AUTM survey at $1.26 Billion. Public funded institutions in Kenya can learn from this and develop policies that can create an enabling environment for collaborative partnership in generation, protection and commercialization of protected intellectual property assets.

The international community should adapt a patent based –ABS system to address Ikechi Mgbeoji’s views in his book titled “Global Bio-Piracy, patents, plants and indigenous knowledge”, that appropriation of plants should be treated separately from appropriation of traditional knowledge and use of plants. It can finally be concluded that, if TRIPS 29 bis is adopted internationally, a mutually supportive relationship between TRIPS agreement and the Convention on Biological Diversity shall have been established, making it possible for states to implement their obligations, objectives and principles of the TRIPS Agreement and the objectives of the Convention on Biological Diversity.

**TRIPS 29 bis** proposes that where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent (PIC) for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.

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65 Ikechi Mgbeoji, Global Bio piracy-pg12.
66 See aannex iii
Members shall require applicants or patentees to supplement and to correct the information including evidence provided under paragraph 2 of this Article in light of new information of which they become aware. Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.

Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information. If this proposal is adopted, it will create an enabling environment for public institutions in Kenya to participate effectively in collaborative research with international organizations on traditional knowledge and associated genetic resources, including biotechnology. It shall also make TRIPS Agreement to be mutually supportive of the Convention on Biological Diversity.

This proposal is compatible with NEMA’s legal notice no. 160 of December 2006 on access to genetic resources and its intangibles. It shall make it possible to implement section 15 (c), 19 and 20 of NEMA’s legal notice no 160 which requires that reasonable access to all genetic resources collected from Kenya shall be guaranteed to all Kenyan citizens, whether such genetic resources and its associated intangible components are held locally or abroad. If these recommendations are put in place, a patent based ABS regime shall have been created. Such a patent based –ABS regime shall create an enabling environment for traditional knowledge holders to disclose to researches their knowledge associated with genetic resources for generation of intellectual property assets.

A patent based ABS system will help in transferring substantial part of accrued benefits from commercialisation of protected biotechnological and pharmaceutical IP assets to traditional knowledge owners or holders, and indigenous communities. Owners in this

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67 See annex ii section 15 ( c)
case include governments that would receive in whole or in part, the rights to the investments. This transfer would be accomplished not through contractual mechanism, but instead through litigation process in which a lawsuit filled anywhere could result in the loss of a given biotechnological or pharmaceutical patent anywhere.

### 5.3: Recommendations

In light of the above conclusions, it is recommended that, in order for public institutions in Kenya to compete globally by utilizing traditional knowledge associated with genetic resources to generate, protect and commercialize intellectual property assets, including biotechnology, as is envisaged by Kenya’s Vision 2030, the proposed *Trips 29 bis* should be adopted internationally and create a Patent based-ABS system.

The study also recommends, that for an enabling environment to be created for collaborative research between public institutions, traditional knowledge holders and industry in utilization of traditional knowledge associated with genetic resources, including biotechnology, all public institutions involved in collaborative research with Traditional Health Practitioners (THPs) and other collaborators, should develop institutional intellectual property policies, and encourage commercialization of generated and protected intellectual property assets.

Other recommendations are that:

1. All public institutions should develop institutional intellectual property policies to guide institutions on issues of access to resources and knowledge and intellectual property protection of the generated assets.

2. An international framework for bio prospecting, modeled on Patent based-ABS system, should be developed.

3. A framework should be developed for regulation of other biotechnologies that are not covered by the Biosafety Act of 2009, since this Act only deals with genetically modified organisms.
4. Bio safety regulations should be developed to enable implementation of the Biosafety Act -2009, particularly commercialization of the generated and protected genetically modified biotechnologies.

5. Genetic resources and associated traditional knowledge should be documented, and a national pharmacopoeia developed, for pharmaceutical research and development, and use by examiners for novelty searches for patent granting purposes.

6. A national code of Practice should be developed to cater for the utilisation of traditional knowledge and associated genetic resources. This Code of Practice could provide a set of principles, and provide consistency and a starting point for negotiations on access and benefits sharing that partners shall adopt in establishing collaborative research agreements, including a flexible commercialization approach to the issues related to genetic resources and intellectual property ownership.

7. Legal, institutional and regulatory framework should be reviewed to facilitate a regulatory regime that will allow for positive and defensive protection, and beneficial exploitation of traditional knowledge, technologies and practices, for the benefit of Kenyan communities.

8. Public institutions should make use of the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRF/A), to generate, protect and commercialize intellectual property assets.

9. TRIPS agreement should be reviewed to enable adoption of the proposed TRIPS 29 bis, to enable traditional knowledge holders to disclose their knowledge to researchers, for generation of pharmaceutical and other biotechnological inventions.

10. Further research should be conducted to establish effects of the Patent and plant variety protection based –Access and Benefits Sharing, on the economies of developing countries. If the system is found to be beneficial to developing country economies, they should review their intellectual property laws to accommodate the spirit of disclosure of source of origin of genetic resources and associated traditional knowledge, as envisaged in the proposed TRIPS 29 bis.
Annex (i) - Questionnaire

Questionnaire on Generation, Protection and Commercialization of Intellectual Property Assets by selected Public Universities and Research Institutions in Kenya, based on Traditional Knowledge and Associated Genetic Resources, including Biotechnology

Introduction:

It has been observed that public Universities and research institutions are not utilizing traditional knowledge and the associated biological resources to generate, protect and commercialize intellectual property assets. The objectives of this research is to find out how selected public universities and research institutions are generating, protecting and commercializing intellectual property assets including biotechnology, and the management of collaborative research partnerships with traditional knowledge holders and industry in general.

The objectives of this research were to:

1. Establish how selected public universities and research institutions in Kenya are accessing traditional knowledge and associated genetic resources to generate intellectual property assets including biotechnology.
2. Find out how the generated traditional knowledge based intellectual property assets, including biotechnology, are protected with the assistance of institutional Technology Transfer Offices (TTOs).
3. Assess how the selected public universities and research institutions are commercializing the generated and protected intellectual property assets.
4. Find out how the selected public universities and research institutions collaborate with traditional knowledge holders and the mechanism for collaborative research with industry and associations of traditional knowledge holders.
5. Establish the obstacles and challenges facing the selected public universities and research institutions in generating, protecting and commercializing intellectual property assets.
The questions that the research sought to answer were:

1. How the selected public universities and research institutions are accessing traditional knowledge and associated genetic resources to generate intellectual property assets including biotechnology?
2. How the generated traditional knowledge based intellectual property assets, including biotechnology, are protected? (The role played by institutional Technology Transfer Offices (TTOs).
3. How the selected public universities and research institutions are commercializing the generated and protected intellectual property assets?
4. How the selected public universities and research institutions are collaborating with traditional knowledge holders and industry?
5. What are the obstacles and challenges facing the selected public universities and research institutions in generating, protecting and commercializing intellectual property assets?

Section A. General

a) Name of Organization.................................................................
b) Postal address............................................................................
c) Telephone........................Fax....................................................
d) Email............................................................................................
e) Name of contact person..............................................................
f) What is the mandate of your institution...?

Section B: Generation:

How are the selected public universities and research institutions in Kenya accessing traditional knowledge and associated genetic resources to generate intellectual property assets including biotechnology?

a) Does your institute have any bio prospecting programme in collaboration with industry or international organizations? .............................................
b) Does it apply the NEMA ABS Regulations under Legal Notice No. 160 of December 2006? ....................................................
   (i) If not why...
   (ii) If yes, how has it helped you address access and benefits sharing arrangement and prior informed consent (PIC) with local communities and resource holders and managers...?
(iii) Do researchers in your institute require research permits from the National Council for Science and Technology (NCST) before commencing research?

(iv) Does your institute use MTAs in access arrangements with other parties?

(v) What kind of benefit sharing measures do you include in your MTAs?

(i) Do you think the NEMA ABS Regulations of Dec, 2006 are adequate to regulate access to Kenya’s Genetic Resources and associated Traditional knowledge?

(ii) If yes, do you think it can:
- Reduce bio piracy
- Promote equitable benefits sharing
- Encourage access to traditional knowledge and Genetic Resources
- Promote TT, foreign direct investments (FDI) and regulated bio prospecting programme in Kenya?

Explain:

(c) Have you ever applied for an Access Permit from the National Environment Management Authority (NEMA)?

Section C: Protection:
How the generated traditional knowledge based intellectual property assets, including biotechnology, is protected with the assistance of institutional Technology Transfer Offices (TTOs).

a) Does Your Institution have an IP Policy?
   If yes, does it address the following?
   (iii) Management of IP assets
   (iv) Access to traditional knowledge
   (v) Access to genetic resources
   (vi) Access and Benefits Sharing
   (vii) Technology transfer (TT)

b) If yes, how does your Institution handle each of the above components?

c) Do you think documentation of GR and TK can reduce biopiracy and promote ABS?

d) Is your institute involved in any research utilizing Traditional knowledge and associated genetic resources in collaboration with traditional healers in Kenya?

e) Did it result into any application for a patent or PVP?

f) Was protection granted?

g) Has it been commercialized?

h) Are there any challenges you faced in protection and commercialization of the IP assets? Explain:

i) Do you think the Industrial Property Act, 2001 section 34 (5)(6) on disclosure needs amendments to request for disclosure of source of TK and GR?
j) Do you think the Seed and Plant Varieties Act, Cap 326 requires some amendments? If yes why? …………………………………………………………
k) Have you ever made any application to KIPI or KEPHIS? What challenges did you face...?

Section D: Collaboration:
How the selected public universities and research institutions collaborate with traditional knowledge holders
i) How are the institutional and professional relationships that can arise from access and benefit sharing agreements and subsequent collaborative activities managed.................................................................?
ii) Do you have provisions for joint ownership of relevant generated intellectual property rights?

Section E: Commercialization:
How the selected public universities and research institutions are commercializing the generated and protected intellectual property assets.

1. How many of the following IP assets are owned by your institute?
   i) Patents...
   ii) Trademarks...
   iii) Utility models.....
   iv) Industrial designs....... 
   v) Is any based on biotechnology or traditional knowledge...
   vi) If yes, are any related to biotechnology, genetic resources based (GR) and/or TK? ...................
   vii) Do you include TK holders or local communities as joint inventors/breeders in patent/PVP applications or as beneficiaries of the commercialized inventions? 
   viii) Are traditional knowledge holders acknowledged in the applications for Intellectual Property rights? .................................................................
   ix) Have you ever made any application to the National Bio-safety Committee (NBC) for any approval of biotechnology activity, including commercialization? 
   x) Did you face any challenges............?

F. Conclusion: In your opinion, what should be done to promote generation of technologies based on traditional knowledge and associated genetic resources, its protection and commercialization of intellectual property assets by our public institutions?
Annex (ii) – NEMA Legal Notice

Legal notice NO.160 of 1st December, 2006 (Legislative Supplement No. 47)

The Environmental Management and Co-Ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006

IN EXERCISE of the powers conferred by section 147 of the Environmental Management and Co-ordination Act, 1999, the Minister for Environment and Natural Resources, upon recommendation of the Authority, and upon Consultation with the relevant lead agencies makes the following Regulations –

Part I – Preliminary:

1. Citation: These Regulations may be cited as the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006.

2. In these Regulations, unless the context otherwise requires –
   “access” means obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use;
   “access permit” means a permit that allows a person to access genetic resources issued under regulation 4;
   “benefit sharing” means the sharing of benefits that accrue from the utilization of genetic resources;
   “endangered species” means any species which is in danger of extinction throughout all or a significant portion of its range (due to man-made or natural changes in the environment);
   “genetic material” means any genetic material of plant, animal, microbial or other origin containing functional units of heredity;
   “habitat” means the place or type of site where an organism or population naturally occurs and includes areas colonized by introduced organisms;
   “holotype” means the single specimen chosen for designation of a new species;
   “intangible components” means any information held by persons that is associated with or regarding genetic resources within the jurisdiction of Kenya;
   “inventory” means a detailed list, report or record of resources, or the process of making such a list, report or record;
“Material Transfer Agreement” means an agreement negotiated between the holder of an access permit and a relevant lead agency or community on access to genetic resources and benefit sharing; “natural environment system” means relatively intact ecosystems of unique value, such as perennial and seasonal wetlands, highly diverse aquatic ecosystems, or ecosystems promoting a high concentration of rare and unusual species; “Prior Informed Consent” means an international operation procedure for exchanging, receiving and handling notification and information by a competent authority; “threatened species” means any species of plant or animal which is likely to become an endangered species within the foreseeable future throughout all or significant portion of its range.

3. Application. These Regulations shall not apply to:
(a) The exchange of genetic resources, their derivative products, or the intangible components associated with them, carried out by members of any local Kenyan community amongst themselves and for their own consumption; Cap. 326
(b) Access to genetic resources derived from plant breeders in accordance with the Seeds and Plant Varieties Act;
(c) Human genetic resources; and
(d) Approved research activities intended for educational purposes within recognized Kenyan academic and research institutions, which are governed by relevant intellectual property laws.

Part II – Conservation of Biological Diversity:

4. Environmental Impact Assessment License:

(1) A person shall not engage in any activity that may-
(a) Have an adverse impact on any ecosystem;
(b) Lead to the introduction of any exotic species;
(c) Lead to unsustainable use of natural resources, without an Environmental Impact Assessment Licence issued by the Authority under the Act.

(2) In this regulation, “exotic species” means any species of plant or animal or microorganism (life form) whose natural range does not, or did not in the past, exist in a specific part of, or the whole of, Kenya and which out-competes all other life forms.
5. Conservation of threatened species:

(1) The Authority shall, in consultation with the relevant lead agencies, impose bans, restrictions or similar measures on the access and use of any threatened species in order to ensure its regeneration and maximum sustainable yield.

(2) Without prejudice to the generality of the foregoing, the Authority shall, in consultation with the relevant lead agencies-

(a) Issue licenses for the establishment and maintenance of facilities for the recovery and rehabilitation of threatened species.

(b) Determine full recovery and rehabilitation measures of threatened species to ensure its restoration into its natural habitat.

6. Inventory of biological diversity:

(1) Within twenty-four months from commencement of these Regulations, the Authority shall, in consultation with the relevant lead agencies, identity and prepares an inventory of biological diversity of Kenya.

(2) The inventory shall include threatened, endangered, or rare species.

(3) The inventory shall be maintained and updated every year thereafter by the Authority.

(4) The inventory shall be a public record of the Authority and shall be accessible, in a prescribed manner, to any person on application to the Authority, and upon payment of such fees as may be prescribed by the Authority.

7. Monitoring of status: The Authority shall, in consultation with the relevant lead agencies, monitor the status and the components of biological diversity in Kenya and take necessary measures to prevent and control their depletion.

8. Protection of environmentally significant areas: This Part shall apply to any area of land, sea, lake or river which the Minister has, by notice in the Gazette, declared to be a protected natural environment system for purposes of promoting and preserving biological diversity in accordance with section 54 of the Act.
Part III-Access to Genetic Resources

9. Access permit:

(1) Any person who intends to access genetic resources in Kenya shall apply to the Authority for an access permit in the form set out in the First Schedule, and such application shall be accompanied by the fees prescribed in the Second Schedule to these Regulations.

(2) The application shall be accompanied by evidence of Prior Informed Consent from interested persons and relevant lead agencies, and a research clearance certificate from the National Council for Science and Technology.

10. Notification of application: The Authority shall, upon receipt of the application, give notice thereof by publication in the Gazette and at least one newspaper with nationwide circulation, or in such other manner as the Authority may consider appropriate, specifying –
(a) The name and other particulars of the applicant;
(b) The activity to be undertaken for which the access permit is required; and
(c) The time within which representations or objections in respect of the proposed access permit may be made to the Authority.

11. Determination of application:

(1) The Authority shall, on receipt of representations or objections to the proposed access permit from the public, review the application and if satisfied that the activity to be carried out shall facilitate the sustainable management and utilization of genetic resources for the benefit of the people of Kenya, issue an access permit to the applicant.

(2) Where the Authority has reasonable grounds for refusing to issue an access permit, it shall inform the applicant of the reasons of such refusal in writing.

(3) A person aggrieved by refusal of the Authority to grant a license may appeal to the Tribunal in accordance with section 129 of the Act.

12. Form of access permit: The form set out in the Third Schedule is prescribed as the form of access permit.
13. Communication of decision: The Authority shall, within sixty days of receipt of an application for an access permit, determine the application and communicate its decision in writing to the applicant.

14. Validity and renewal of access permit:
(1) An access permit shall be valid for a period of one year from the date of issue and shall not be transferable.

(2) Upon expiry, an access permit may be renewed for a further period of one year upon payment of the fee prescribed in the Second Schedule and upon such terms and conditions as the Authority may deem necessary to impose.

15. Terms, conditions of an access permit, etc:

(1) An access permit shall contain such terms and conditions as the Authority may deem necessary to impose.

(2) In addition to such terms and conditions as may be contained in an access permit, the following conditions shall be implied in every access permit:
(a) Duplicates and holotypes of all genetic resources collected shall be deposited with the relevant lead agency.
(b) Records of all intangible components of plant genetic material collected shall be deposited with the Authority.
(c) Reasonable access to all genetic resources collected shall be guaranteed to all Kenyan citizens whether such genetic resources and intangible components are held locally or abroad.
(d) All agreements entered into with respect to access of genetic resources shall be strictly for the purposes for which they were entered into.
(e) The furnishing of quarterly reports to the Authority on the status of research, including all discoveries from research involving genetic resources and/or intangible components thereof.
(f) The holder of an access permit shall inform the Authority of all discoveries made during the exercise of the right of access granted under the access permit.
(g) The holder of an access permit shall provide the following reports –
   (i) A semi-annual status report on the environmental impacts of any ongoing collection of genetic resources or intangible components thereof;
   (ii) A final status report on the environmental impacts of collection of genetic resources or intangible components thereof, in the event that the collection is of duration of three months or less.
(h) The holder of an access permit shall abide by the laws of the country.
(3) The Authority may, on its own volition or on the application by an access permit holder, vary the conditions of an access permit.

16. Suspension, cancellation, etc, of access permit:

(1) The Authority may suspend, cancel or revoke any access permit issued under these Regulations where the holder thereof is in contravention of any of the conditions imposed on the access permit or those implied under these Regulations, or of the agreements concluded pursuant to its grant.

(2) The Authority shall, before suspending, canceling or revoking an access permit, give a written notice of its intention to suspend, cancel or revoke the permit to the holder thereof, and shall accordingly invite the holder to make representations within thirty days from the date of such notice.

(3) Where the Authority suspends, cancels or revokes a permit, it shall publish the order suspending, canceling or revoking the permit in the Gazette and in at least one newspaper with nationwide circulation.

(4) The provisions of regulation 11(3) shall apply mutatis mutandis to the suspension, cancellation or revocation of an access permit.

17. Register of access permits: The Authority shall keep, manage and update as appropriate a register of all access permits which it has granted, and the register shall be a public record of the Authority and shall be accessible, in a prescribed manner, to any person on application to the Authority, and upon payment of the fees prescribed in the Second Schedule.

18. Material Transfer Agreement: Notwithstanding any provisions contained in these Regulations, no person shall transfer any genetic resources outside Kenya unless such person has executed a Material Transfer Agreement.

Part IV-Benefit Sharing:

19. Application of Part: This Part shall apply subject to the laws in force relating to intellectual property rights.

20. Benefits sharing:

(1) Without prejudice to the generality of the foregoing, the holder of an access permit shall facilitate an active involvement of Kenyan citizens and institutions in the execution of the activities under the permit.
(2) The facilitation by the holder of an access permit shall include enjoyment of both monetary and non-monetary benefits arising from the right of access granted and the use of genetic resources.

(3) Monetary benefits include –

(a) Access fees or fee per sample collected or acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) License fees in case genetic resources are to be utilized for commercial purposes;
(f) Fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights;

(4) Non-monetary benefits include –
(a) Sharing of research and development results;
(b) Collaboration, co-operation and contribution in scientific research and development programmes, particularly biotechnological research activities;
(c) Participation in product development;
(d) Admission to ex situ facilities of genetic resources and to databases by participating institutions;
(e) Transfer to Kenya of genetic resources of knowledge and technology under fair and most favorable terms, including concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(f) Strengthening capacities for technology transfer to Kenya;
(g) Institutional capacity building;
(h) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(i) Training related to genetic resources with the full participation of Kenya and where possible, in Kenya;
(j) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(k) Institutional and professional relationships that can arise from access and benefit sharing agreements and subsequent collaborative activities;
(l) Joint ownership of relevant intellectual property rights.
**Part V-Miscellaneous:**

21. **Confidentiality:**

(1) On the request of an applicant of an access permit, the Authority may hold some information relating to access to genetic resources the subject of the application as confidential.

(2) Where an access permit is granted, information held as confidential under paragraph (1), with respect to the relevant applicant, shall not be accessible to a person inspecting the register of access permits in accordance with regulation 17.

22. **Transition:** A person carrying out any activities involving access to genetic resources immediately before the coming into force of these Regulations shall, within six months from the coming into force thereof, take all necessary measures to ensure full compliance with these Regulations.

23. **Offences:** A contravention or failure to comply with any of the matters provided in these Regulations shall constitute an offence.

24. **Penalties:** Any person convicted of an offence under these Regulations shall be liable to imprisonment for a term not exceeding eighteen months, or to a fine not exceeding three hundred and fifty thousand shillings, or both.
Annex (iii): *Trips Article 29bis*

**Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge**

1. For the purposes of establishing a mutually supportive relationship between this Agreement (TRIPS) and the Convention on Biological Diversity (CBD), in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.

2. Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.

3. Members shall require applicants or patentees to supplement and to correct the information including evidence provided under paragraph 2 of this Article in light of new information of which they become aware.

4. Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.

5. Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in paragraphs 2 and 3 of this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information.

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**Title:** Generation, protection and commercialization of **IP** assets based on **TK** and associated **GR**, including biotechnology, in selected public institutions in Kenya.

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