〔論　説〕

Traditional Knowledge and Biodiversity in South Africa: CSIR case

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Summary

The focus of this paper is traditional knowledge (TK) and indigenous biological resources protection in South Africa, through the analysis of the existing policies and legislations, in order to provide a useful insight for a developed country such as Japan which has recently adopted the guidelines for the protection of TK and biological resources and promotion of access and benefit sharing (ABS). South Africa is the 3rd most diverse country in terms of natural resources, culture and traditions, languages and geology and its comprehensive legislative framework system shows the country's seriousness to safeguard TK and conserve biological resources for future generations.

The paper uses the South Africa's government owned research and technology development institution, Council for Scientific and Industrial Research (CSIR), as an example to demonstrate the application of the TK protection and biodiversity conservation (including access and benefit sharing) laws, through case studies approach for lessons learned for other African countries, contemplating creation of their own TK protection and environmental conservation. Due to the repositioning of CSIR within the local and global research and develop, the organisation has adopted Industrialisation Strategy, and TK will play a significant role in technology development and new business models in rural agroprocessing and production to enhance inclusive development (through benefit sharing) and support economic growth.

The paper concludes that TK and indigenous biological resources protection through the relevant government laws, as well as value addition to TK and biodiversity through research and development supported by government funding, is necessary for socioeconomic attainment, especially for local and indigenous communities and rural agroprocessing businesses as part of

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benefit sharing.

1. Introduction

The advancement in scientific knowledge and technological changes over centuries has brought profound societal changes. Through new international regimes, knowledge has become a commodity to be bought and sold. At the same time, traditional knowledge has also continued to develop, though at a different pace, especially in the developing countries.

South Africa is one of the most diverse countries in the world, in terms of the natural resources, geology, culture, people and languages. There are 11 official languages in South Africa: English, Afrikaans, IsiZulu, IsiXhosa, IsiNdebele, SiSwati, Sepedi or Sesotho, Tshivenda, Xitsonga, Sesotho sa Borwa and Setswana recognised and protected by the constitution of the country. According to the official reports, South Africa's total land surface area is more than 1.2 Million km^2, which represents 2% of the world's land surface area. It houses 10% of the world's plants, 7% of the world's reptiles, birds and mammals, 15% of known coastal marine species, and one entire floral kingdom[1)]. As of 2009, there were 23,000 plant species and 65% of these are endemic to South Africa[2)]. The most biodiversity hotspot areas in South Africa are found in the Maputaland-Pondoland-Albany, the Cape Floristic Region and the Succulent Karoo. In terms of the number of endemic species of mammals, birds, reptiles and amphibians, South Africa ranks the fifth richest country in Africa and the 24th in the world.

South Africa also has a long tradition of medicinal use of indigenous plant species. There is an estimated 500,000 Traditional Health Practitioners (THPs) in South Africa, found in the provinces of South Africa. The THPs play an important role in the health care delivery for the majority of the people of South Africa[3)4)]. The South African Traditional Health Practitioners Act of 2007, recognizes the THPs as part of the health care system. The Act defines a THP is someone who is registered under this Act at the South African Department of Health, to perform functions, activities, processes or services based on a traditional philosophy, which includes the utilisation of traditional medicine or traditional practice, as well as the physical or mental preparation of an

1) See: https://www.cbd.int/reports/search/?country=za

2) ibid.

3) Zuma, T., Wight, D., Rochat, T. and Moshabela, M (2016). "The role of traditional health practitioners in Rural KwaZulu-Natal, South Africa: generic or mode specific?", Complementary and Alternative Medicine, Volume 16, pp.304-317

4) Sorsdahl K, Stein DJ, Grimsrud A, et al. (2009) "Traditional healers in the treatment of common mental disorders in South Africa", Journal of Nervous System and Mental Diseases, Volume 197, pp.434

individual for puberty, adulthood, pregnancy, childbirth, and death[5]. The Act includes herbalists (*izinyanga* or *amaxhwele*), diviners (*izangoma* or *amagqirha*), traditional surgeons (*iingcibi*) who mainly do circumcisions, and traditional birth attendants (*ababelethisi* or *abazalisi*) under the THP category. The THPs are, however, not institutionalised in South Africa into mainstream primary health care systems, due to lack of regulations for their practices including the traditional medicine formulations they administer to their patients, often the health claims are not supported by the scientific evidence.

Despite, about 80% of South Africans consult a THP for health care including cultural purposes. This mainly due to the fact that the THPs are integral members of the society and therefore easily accessible for consultations which are affordable compared to western form of consultations, and also THPs are part of traditional and cultural practices. About 3 000 plant species are used in traditional medicines by the THPs to treat human diseases. About 25% of prescription medicines and drugs worldwide have been developed from plant species that have TK[6].

The United Nations Conference on Environment and Development (UNCED) was introduced with the following three primary objectives[7]: 1) conservation of biological diversity, 2) sustainable use of the components of biological diversity (such as plant genetic resources) and 3) the fair and equitable sharing of benefits arising from the utilisation of genetic resources recently. Because of the value of TK to drug development, for instance, the CBD translates its guiding objectives of conservation, sustainable use and equitable sharing of benefits into binding commitments in its articles to implement. There are currently 191 parties to the CBD including South Africa.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits[8] was adopted by the Conference of the Parties to the Convention on Biological Diversity on 29 October 2010 in Nagoya, to advance the third objective of the CBD and has been in enforcement since 12 October 2014, as two thirds majority countries have ratified the Protocol. South Africa ratified the Nagoya Protocol on 12 October 2014.

The realization that TK and associated biodiversity can stimulate R&D and innovation to commercialise valuable drugs, cosmetics and functional food products. On the other hand,

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5) South African Traditional Health Practitioner Act, 2008

6) Yuan, H., Ma, Q., 1, Ye, L. & Guangchun Piao, G. (2016)" The Traditional Medicine and Modern Medicine from Natural Products", Molecules, Volume 21, pp.1-18, see: www.mdpi.com/journal/molecules

7) Conservation on Biological Diversity, see https://www.cbd.int/convention/text/

8) Nagoya Protocol on Access and Benefit Sharing, 2010, see https://www.cbd.int/abs/

accessing TK for R&D and commercialisation purposes of indigenous and local communities without their consent has led to concerns in recent years that protection of some kind is required to prevent abuse. The realization that TK and associated biodiversity can stimulate R&D and innovation to commercialise valuable drugs, cosmetics and functional food products. On the other hand, accessing TK for R&D and commercialisation purposes of indigenous and local communities without their consent has led to concerns in recent years that protection of some kind is required to prevent abuse.

South Africa has amended several of its intellectual property right laws, to align to the provisions of the CBD and the Nagoya Protocol on Access and Benefit Sharing, to prevent unauthorised access to TK and unsustainable use of indigenous biological resources, to the legislative protection and commercialization of TK.

In order to provide an understanding of the protection and commercialization of TK and indigenous biological resources from the South African context, this paper begins by describing the South African intellectual property rights (IPRs) systems, amendment to and introduction of certain laws to strengthen the protection of TK, and linkages of these laws with the access and benefit sharing (ABS) legislations. The paper then demonstrates the application of these laws in practice, through the Council for Scientific and Industrial Research (CSIR) case studies. This paper concludes that South Africa has a comprehensive legal framework for the protection of TK, to prevent the illegal access of TK and indigenous biological resource for research and development (R&D) and commercial purposes. CSIR has been the leading institution on the African continent in managing to translate TK and R&D into technologies and products of commercial potential and recognising the TK holders in benefit sharing agreements and conserving biological diversity through the agroprocessing community businesses, as part of poverty alleviation and job creation. The CSIR experiences are shared with Japan, in order to begin conversations to develop ties between the two countries on natural products for mutual benefit. Japan ratified the Nagoya Protocol on 22 May 2017, and the Guidelines on ABS went into effect on 20 August 2017, to ensure ABS practice by business and universities in accordance with the Nagoya Protocol on ABS principles. This in turn increases a body of knowledge that is made available for research.

2. The South African intellectual property right laws

2.1 The South African IP and TK protection laws

The South African Constitution is the supreme law of South Africa, which provides the legal foundation for the protection of intellectual property rights (IPR) from arbitrary deprivation and in

recent decades, South Africa has made significant strides in the just protection, administration, management, and deployment of intellectual property[9]. The National Development Plan of South Africa calls for a greater emphasis on innovation, improved productivity, an intensive pursuit of a knowledge economy and the better exploitation of comparative and competitive advantages[10]. Intellectual Property is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), creative expression, consumer protection, industrial development and more broadly, economic growth, to address national issues of poverty, unemployment and inequality. There is an empirical evidence to confirm that intellectual property rights has a positive impact on developing countries innovations and competiveness and subsequently socioeconomic development.[11]

South Africa has a comprehensive laws for the protection of IP and TK, to protect people's rights to own their creative products and such protection extends from an idea, a name or an invention (Table 1). The legal definition of intellectual property is broad and inclusive of creations of the mind, inventions; literary and artistic works; and symbols, names and images used in commerce. An intangible right protecting the products of human intelligence and creation, such as copyrightable works, trademarks and trade secrets.

Table 1: The South African IP and TK protection laws and the associated government Departments

Laws (legislation/policy)	Responsible government
• Intellectual Property Laws Amendment Act 2013 (Act No. 28 of 2013)	Department of Trade and Industry
• Intellectual Property Rights from Publicly Financed Research and Development Act 2008 (Act No. 51 of 2008)	Department of Science and Technology
• Traditional Health Practitioners Act 2008 (Act No 30660 of 2008)	
• Patents Amendment Act 2005 (Act No. 20 of 2005)	Department of Trade and Industry
• Patents Act 1978 (Act No. 57 of 1978, as amended up to Patents Amendment Act 2002)	Department of Trade and Industry
• Merchandise Marks Act 1941 (Act No. 17 of 1941, as amended up to Merchandise Marks Amendment Act 2002)	Department of Trade and Industry
• Performers' Protection Amendment Act 2002	Department of Trade and Industry

9) The Constitution of the Republic of South Africa (as adopted on 8 May 1996 and emended amended on 11 October 1996 by the Constitutional Assembly), The Government of South Africa, Pretoria

10) "The National Development Plan: Vision 2030", Government of South Africa, Pretoria, South Africa

11) Yongmin Chen and Thitima Puttitanum (2005)," Intellectual property rights and innovation in developing countries", Journal of Development Economics Volume 78, pp. 474-493

• Copyright Act, 1978 (Act No. 98 of 1978, as amended up to Copyright Amendment Act 2002)	Department of Trade and Industry
• Intellectual Property Laws Amendment Act 1997 (Act No. 38 of 1997)	Department of Trade and Industry
• Designs Act 1993 (Act No. 195 of 1993, as amended by Intellectual Property Laws Amendment Act 1997)	Department of Trade and Industry
• Plant Breeders' Rights Amendment Act 1996 (Act No. 673 of 1996)	Department of Trade and Industry
• Plant Breeders' Rights Act 1976 (Act No. 15 of 1976, as last amended by Plant Breeders' Rights Amendment Act 1996)	Department of Trade and Industry
• Indigenous Knowledge Systems Policy, 2004	Department of Science and Technology
• Trade Marks Act 1993 (Act No. 194 of 1993)	Department of Trade and Industry
• Indigenous Knowledge Systems Bill, 2016	Department of Science and Technology

The DTI (Department of Trade and Industry) is the custodian of intellectual property rights South Africa. It provides an enabling legislation and services required for the registration, examination (in the case of trademarks), and adjudication of intellectual property. However, the related legislations to intellectual property can originate or involve participation from a number of government departments and statutory bodies, such as the Departments' of Arts and Culture, Science and Technology, Health, Communications, Environmental Affairs, Agriculture: and Education, as well as statutory bodies such as the National Advisory Council on Innovation and the Council for Scientific and Industrial Research(CSIR)[12]. New legislation regarding genetically modified foods, for instance, requires an assessment of the agricultural, health, environmental and industrial policy aspects, thus requiring careful policy coordination, balancing potentially conflicting policy goals.

The South African intellectual property laws are in line with provisions of the various international agreements and conventions, including the World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Patent Cooperation Treaty (PCT). Therefore, South Africa is obliged to comply with the minimum standards set by these agreements for the protection of intellectual property. The standards define the scope of the inventor's exclusive rights, the limitations set the boundaries of those rights (e.g. by allowing compulsory licensing) and the administrative and judicial enforcement determine the effectiveness of the intellectual property rights regime. All three elements vary widely across countries, even among developed countries. South Africa is not party to ARIPO (African Regional Intellectual Property Organisation) and has developed a comprehensive intellectual property right protection laws that are in line with

12) Ethèl Teljeur (2003), "Intellectual Property Rights in South Africa", The Edge Institute, South Africa

the provisions of the WTO TRIPS.

The South African intellectual property laws have certain limitations when applied to traditional knowledge. For instance, the South African Patent Act of 1978 makes it difficult to protect traditional knowledge, due to the nature of the knowledge, which is in the public domain and also is community owned. Therefore, there is a need for a suitable law to protect traditional knowledge to strengthen socioeconomic benefit.

2.2 Patent Act, 1978

South Africa adopted the Patent legislation, hereto referred to as Patent Act, 1978, to "provide for the registration and granting of patents for inventions and for matters connected therewith"[13]. The legislation states that a patent may be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture. Therefore, a patent is a negative right, awarding inventors the exclusive right "to prevent others from making, selling, distributing, importing or using their invention, without licence or authorisation, for a fixed period of time". Technological innovations are protected through a patent, even those informed by traditional knowledge and associated by biodiversity.

A patent generally consists of a document issued by the government that describes an invention (product or process) and creates exclusive rights for a limited period in which the patented invention can only be exploited with the authorisation of the patent holder and in exchange for licensing or royalty payments. The minimum requirement for the protection of the intellectual property according to the legislation is 20 years, from the date of application[14]. This is in line with the WTO TRIPS Agreement, which stipulates a 20 years minimum protection from filing date. The legislation provides an annual renewal obligation of a patent with costs. No extension is possible. Patents are awarded to the first applicant; this so-called 'first-to-file' rule is nearly universal, with the main exception being the US, which uses the 'first-to-invent' rule.

2.3 Intellectual Property Rights from Publicly Financed Research and Development Act, 2008

The South African government promulgated the Intellectual Property Rights from Publicly Financed Research and Development Act on 22 December 2008 and the objective of the law is "to provide for more effective utilisation of intellectual property emanating from publicly financed

13) South African Patent Act, No. 57, 1978

14) South African Patent Act, 1978, Section 46(1)

research and development"[15]. This means that the law has been adopted with the intention to enhance the production of patents from research and technological activities undertaken by the South African research institutions including universities through public funds and ensuring that such intellectual property benefits the socioeconomic development of South Africa, including capacity development, technology transfer, job creation, enterprise development, social upliftment and products, or processes or services that embody or use the intellectual property[16]. Therefore, the law seeks to address the situation where the intellectual property developed by the research institutions benefits the research institution, the government or South African people[17].

The Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 defines intellectual property as "*any creation of the mind that is capable of being protected by law... any rights in such creation... but excludes copyrighted works... in the ordinary course of business, is associated with conventional academic work*". In this case, intellectual property will includes inventions, designs, etc. and excludes copyrighted works such as thesis, articles, handbooks or any other publications[18]. However, if there is an invention which is the subject of the thesis or an article, such invention will be subject to the law. A trademark associated with commercialization of a particular invention is also the subject of the law. Publicly financed research and development, in terms of the law, refers to research and development undertaken using any funds allocated by a funding agency (i.e. state, a state agency or an organ of state) but excludes funds allocated for scholarships to be publicly financed research and development and the provisions of the law shall not have any impact thereto. Therefore, the parties can negotiate with regard to ownership of such intellectual property. For example, the private entity can then negotiate that it retains ownership of such intellectual property.

Under certain conditions, the law make provides the ownership of the intellectual property by a privately owned company or institution or may become a co-owner of the intellectual property emanating from publicly financed R&D undertaken at an institution. There conditions are:

- there has been a contribution of resources, which may include relevant background intellectual property, or other resources by the private entity or organisation; and

15) The Intellectual Property Rights from Publicly Financed Research and Development Act, 2008

16) Regulations in terms of section 17 of the Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 (Act No. 51 of 2008)

17) Bansi, R, & Reddy, K. (2015), "Intellectual property from publicly financed research and intellectual property registration by universities: A case study of a university in South Africa", Procedia - Social and Behavioural Sciences Volume 181, pp. 185-196

18) Adams & Adams: patent, trademark, copyright, commercial, property and litigation attorneys (2013)

- there is joint intellectual property creatorship; and
- appropriate arrangements are made for benefit sharing for intellectual property creators at the institution;
- the institution and the private entity or organisation conclude an agreement for the commercialisation of the intellectual property.

However, the law does not apply when the private company or institution has funded the research and development by the university on a full cost basis. "Full cost" means the full cost of undertaking the R&D as determined in accordance with international financial reporting standards, and includes all applicable direct and indirect costs as may be prescribed. The indirect costs can include operational costs, costs relating to raw material, the use of laboratory, the use of electricity and water in the laboratory, and the costs associated with the time that each member of a research team of the institution spends conducting the research and development. Therefore, both the private company and the university can negotiate with regard to ownership of such intellectual property. For example, the private entity can then negotiate that it retains ownership of such intellectual property.

The Intellectual Property Rights from Publicly Financed Research and Development Act established the National Intellectual Property Management Office, as well as the Intellectual Property and Technology Transfer Offices at South African universities. There are more than 14 Technology Transfer Offices established at publicly funded research institutions including universities, with well-defined organisational structures, technology transfer systems and practices[19]. The law, administered by the Department of Science and Technology, including provision of funding for implementation including capacity building through the National Intellectual Property Management Office.

3 South African legislation and policy: TK and biodiversity protection

3.1 Indigenous Knowledge Systems Policy, 2004

The IKS Policy was approved by the South African government in November 2004, to create a platform to recognize, affirm, develop, promote and protect IKS which includes TK in South Africa; and to interface IKS with other knowledge systems, such as scientific and technological knowledge especially in the modern biotechnology and pharmaceutical sectors to increase the rate

19) Alessandrini, M., Klose, K. and Pepper, M (2016) "University Entrepreneurship in South Africa: Developments in Technology Transfer Practices", Institute for Cellular and Molecular Medicine, University of Pretoria, South Africa, University of Pretoria, South Africa.

of innovation, through active participation of the local communities in the research and innovation processes[20]. The Department of Science and Technology is the custodian of the Policy, which provides management and administrative leadership including funding for the implementation of the Policy, through the National Indigenous Knowledge Systems Office (NIKSO) within the Departments. NIKSO has three Directorates: Advocacy and Policy Development, Knowledge Development and Knowledge Management.

The IKS Policy was adopted after extensive consultations with the academic institutions and a wide range of stakeholders in business, NGOs and Traditional Health Practitioners Associations who reflected, debated and participated to reflect the aspirations of the country in socioeconomic development. One of the areas of action identified by the Policy is the protection of TK, and the recognition of the TK Holders in benefit sharing agreements and other knowledge production outputs, such as publications. According to the Policy, protection of TK includes ensuring TK Holders receive a fair and sustained recognition and, where appropriate, financial remuneration for the use of this knowledge.

The main drivers of the IKS Policy in developing the innovation capacity in the South African system of innovation include, among others: towards the recognition and protection of IK Holders include: 1) Affirmation of African cultural values in the face of globalisation imperative given the need to promote a positive African identity; 2) Practical measures for the development of services provided by the TK Holders including the THPs, with a particular focus on traditional medicine, but also including areas such as agriculture, indigenous languages and folklore; 3) Underpinning the contribution of indigenous knowledge to the economy – the role of TK in job and wealth creation and poverty alleviation; and 4) interfaces with other knowledge systems, for example indigenous knowledge is used together with modern biotechnology in the pharmaceutical and other sectors to increase the rate of innovation.

The main implementation drivers of the IKS Policy, through the functions, institutions and legislative provisions are:

- An Advisory Committee on indigenous knowledge systems, reporting to the Minister of Science and Technology;
- A development function; including, academic and applied research, development and innovation in respect of IKS;
- National Recordal System for indigenous knowledge and indigenous knowledge holders;

20) Indigenous Knowledge Systems Policy, 2004

where appropriate, to pro-actively secure their legal rights;

- The promotion of networking structures among practitioners, to be located in the Department of Science and Technology; and
- Legislation to protect intellectual property associated with indigenous knowledge, to be administered by the Department of Trade and Industry

This policy document became the key document for IKS in South Africa and has been funded by the Department of Science and Technology National Indigenous Knowledge Systems Office. The key achievements of the policy are outlined in Table 2.

Table 2: The achievements of the IKS Policy, 2004 to date

- Education and training: IKS Bachelor degree programme established at the University of KwaZulu Natal, South Africa and University of North West-Mahikeng Campus, funded by the Department of Science and Technology National Indigenous Knowledge Systems Office
- IKS Research Chairs, to interface IKS with other knowledge systems with a special emphasis on scientific and technological knowledge. The IKS Research Chairs are managed by the National Research Foundation on behalf of the Department of Science and Technology. Two Research chairs on IKS have been established: 1) University of KwaZulu Natal (four projects - HIV and AIDS, Tuberculosis, Diabetes and Cancer); and 2) Walter Sisulu University (two projects – IKS Systematisation and Vegetable & medicinal plants)
- IKS Calls for funding proposals, aimed at enforcing collaborations between the local communities and research institutions on R&D projects. The Call is management by the National Research Foundation on behalf of the Department of Science and Technology NIKSO. IKS Ring fenced funding for IKS research is annually transferred to the National Research Foundation. Following the IKS Fund review, IKS Programme piloted and implemented the New Research Management System as an IKS Policy imperative. About eight Calls have been published by the National Research Foundation since 2012.
- Documentation of IKS (e.g. National Recordal System), to provide both positive and defensive protection of TK. The system constitute a semantic web digital system, comprising of TK networks, documentation centres and confidential local registers and records unrecorded TK in various multimedia and aims to collect grassroots community TK and experiences in local languages. The National Recordal System is a documented data on TK and associated biological resources linked to a person, community, geographical area and biological resource. About 56 communities participated in the establishment of the National Recordal System.
- IKS expo's in South Africa and internationally, aimed to disseminate information targeted at audiences to enhance public understanding of the South African IKS. About 5 National IKS Expo's held, IKS part of National Science Week, 5 SADC Biennial Workshops International Conference: Value of IKS in 21st Century
- Digital database (pharmacopoeia) was developed to give access to 1536 open access journals, 269 South African theses, 32 digitised books, 185 updated monographs including conference papers.

The IKS Policy is relevant to other government policies and legislations and has been an advocate for the amendment of the IPRs laws to protect IKS promote access and benefit sharing.

3.2 Biodiversity Act, 2004 and its BABS Regulations, 2008

The South African government, through the Department of Environmental Affairs, adopted the National Environmental Management: Biodiversity Act, 2004 and the Bioprospecting, Access and Benefit Sharing Amendment Regulations of 2015. The objectives of the Act include, among others measures, conservation of South Africa's biodiversity within the framework of the National Environmental Management Act, 1998, the sustainable use of indigenous biological resources and the fair and equitable sharing of benefits arising from bioprospecting involving indigenous biological resources[21]. Indigenous biological resources, in terms of the Act, include: any animals, plants or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology; any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms; any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms[22]. The Act excludes (i) genetic material of human origin, (ii) any exotic animals, plants or other organisms, other than exotic animals, (iii) indigenous biological resources listed in terms of the International Treaty, (iii) Plant Genetic Resources for Food and Agriculture.

The Act also seeks to give effect to the ratified international agreements relating to biodiversity which are binding on the Republic, such as the Convention on Biological Diversity, 1993 and its two protocols, i.e., the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit Sharing. The Biodiversity Act regulates bioprospecting involving indigenous biological resources and the export from the Republic of indigenous biological resources for the purpose of bioprospecting or any other kind of research. The Act also provides for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The Nagoya Protocol on Access and Benefit Sharing provides a legal framework for the effective implementation of one of the three objectives of the Convention on Biological Diversity, namely, the fair and equitable sharing of benefits arising out of the utilization of genetic resources and traditional knowledge associated with genetic resources. Furthermore, the Nagoya Protocol on Access and Benefit Sharing represents an important tool for greater legal certainty and transparency for both providers and users of genetic resources, and for strengthening the ability

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21) National Environmental: Biodiversity Act, 2004, Government of South Africa, Pretoria,

22) Chapter 6 (Section 8(2): Bioprospecting, Access and Benefit Sharing), Biodiversity Act, 2004

of indigenous and local communities to benefit from the use of their traditional knowledge, innovations, and practices associated with genetic resources. The Nagoya Protocol on Access and Benefit Sharing came into force on 12 October 2014 and South Africa ratified the Protocol in October 2014.

The South African Biodiversity Act, 2004 establishes the National Bioprospecting Trust Fund (Section 85(1)), to administer all the milestones and royalty payments received from the bioprospecting permit holders in terms of the benefit sharing agreements and material transfer agreements and disburse to the funds to the rightful owners of the traditional knowledge that informed the bioprospecting project. The Director General of the Department of Environmental Affairs manages the Fund and accountable for the money in the Fund in terms of the Act[23], in terms of the Public Finance Management Act[24]

3.3 Patent Amendment Act, 2005

The South African Patent Act of 1978 was amended in 2005, to give to Patent Amendment Act, 2005. The Patent Amendment Act requires an applicant for a patent to furnish information relating to any role played by an indigenous biological resource, a genetic resource or traditional knowledge"[25]. This is to ensure that indigenous communities are adequately compensated when an invention which is sought to be patented in South Africa is derived from indigenous biological resource and associated traditional knowledge from South Africa.

Consequently, the Patents Amendment Act, 2005 requires that every applicant who lodges an application for a patent must state whether or not the claimed invention is:

- based on or derived from an indigenous biological resource or an indigenous genetic resource; and/or
- based on or derived from traditional knowledge or use from South Africa.

Every applicant is required to lodge a statement of this type, irrespective of the nature of the invention sought to be protected, and it will not be possible to obtain a patent if the required statement is not lodged at the patent office. In addition, the Patents Amendment Act also provides a ground of revocation of a patent in cases where the required statement lodged by the applicant is false.

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23) Biodiversity Act, 2004 (Section 85 (3 a&b))

24) Public Finance Management Act, 1999 (chapter 5, Section 39)

25) Patent Amendment Act, 2007

It should be noted that the required statement relates to indigenous (i.e. South African) resources and knowledge only. In other words, the required statement does not refer to biological or genetic resources or traditional knowledge from countries other than South Africa. It should also be noted that although still indigenous, the genetic resources to which the amendments to the Patents Act relate are broader than the indigenous biological resources defined in the Biodiversity Act, and in particular the amendments to the Patents Act do not have the exceptions that are included in the Biodiversity Act.

If an applicant acknowledges that the invention is based on or derived from an indigenous biological or genetic resource, or traditional knowledge, they will also have to submit proof of their title or authority to make use of the resource or traditional knowledge. In most instances, it is likely that this title or authority would need to be a permit issued in terms of Chapters 6 and 7 of the Biodiversity Act. Where, however, the resource is human genetic material or one of the other excluded sources defined in the Biodiversity Act, then it will obviously not be possible to obtain a permit in terms of the Biodiversity Act and alternative proof of title or authority will be required.

3.4 Intellectual Property Laws Amendment Act, 2013

The Intellectual Property Laws Amendment Act, 2013 deals with the amendment and "grafting" of TK to IPR Acts Laws (refer to Table 1) using an IP-based approach to the protection of IKS, to-

- consider the development dynamics of South Africa and improve how IP supports small institutions and vulnerable individuals in society, including in the domain of public health
- nurture and promote a culture of innovation, by enabling creators and inventors to reach their full potential and contribute towards improving the competitiveness of our industries
- promote South African arts and culture
- solidify South Africa's various international obligations, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Protocol on ABS), in the service of our genetic resources and traditional knowledge associated with genetic resources

The strategy employed in developing the Intellectual Property Amendment Act, 2013 included:

- advancing a balanced and coordinated approach to IP that regulates IPRs in line with the South African Constitution
- introducing key policy reforms that account for the development dynamics of South Africa
- promoting innovation and a knowledge economy
- leveraging competitive and comparative advantages to advance the transformation of the

South African economy

The Act has amended four IPRs Acts namely the Performers' Protection Act, the Copyright Act, the Designs Act, and the Trade Marks Act. In so doing, it provides for recognition and protection for, and creates, new IP forms (-so-called "Indigenous/Traditional IP") from respectively indigenous performances, indigenous copyright works, indigenous designs, and indigenous trademarks. In addition, the Intellectual Property Amendment Act, 2013 creates new derivative IP forms, which are IP forms adapted from the original indigenous forms. The Act defines an indigenous term or expression throughout the Act as including indigenous cultural expressions or knowledge[26]. This inclusion of TK with what in essence are indigenous cultural terms or expressions in Acts that do not in principle protect technology.

The Intellectual Property Amendment Act, 2013 provides that the Minister of Trade and Industry to establish a National Council for Indigenous Knowledge, among others, to advise the Minister and the Registrars of Patents, Copyright etc on the above and other relevant matters. Lastly the Act provides for the commercialization and licensing of TK in an attempt to provide income to indigenous communities from the marketing of their TK and indigenous cultural expressions.

The Act will come into operation on a date to be determined by the President by proclamation in the Gazette after the regulations have been approved for to the Act. The Department of Trade and Industry is the custodian of the Act, providing administrative leadership to the relevant government departments involved, such as Department of Science and Technology.

3.5 Indigenous Knowledge Systems Bill, 2016

The South African government, through the Department of Science and Technology, has developed the Indigenous Knowledge Systems (IKS) Bill, 2016. The Bill has been subjected under extensive public consultation to gather inputs and comments from other government departments, research institutions including the universities, private sector companies involved in bioprospecting research and commercial activities based on TK and associated indigenous biological resource and local and indigenous communities. The Bill is currently in government process to be approved into a law.

The IKS Bill follows the Intellectual Property Laws Amendment Act, 2013 that was signed into law in South Africa on 10 December 2013. Once, the Bill has been approved into a law, it will provide

26) South African Intellectual Property Amendment Act, 2013

"sui generis" protection, promotion, development and management of TK including the registration of TK, the establishment of the National Indigenous Knowledge Systems Office ("NIKSO"), and an Advisory Panel to advise NIKSO[27]. The Bill defines indigenous knowledge as "tangible and intangible aspects of the whole body of knowledge that has been held, used, refined and transmitted by the indigenous communities collectively or as individual custodians of such knowledge as part of expressing their cultural identity and includes but is not limited to –

a. knowledge of and management of biological resources and ecosystems;
b. literary, performing and artistic works (arts and culture);
c. all items of moveable cultural property;
d. all items of immoveable cultural property;
e. indigenous institutions, philosophies, governance matters and languages;
f. scientific, technical and spiritual knowledge;
g. indigenous environmental resources; and
h. indigenous communities' heritage;

The IKS Bill provides for the Act to protect indigenous knowledge (IK), whether it is functional or cultural, or both, including medical, agricultural or scientific practices, as long as it complies with the eligibility criteria set out below. Such IK is regarded as being property as defined in section 25 of the Constitution.

The eligibility criteria for protection applies to IK which – has been passed on from generation to generation within an indigenous community; has been developed within an indigenous community; and is associated with the cultural make-up and social identity of that indigenous community. The term of protection granted in respect of IK by this Act will last as long as the IK satisfies the above eligibility criteria for protection in terms of the new Act.

The exclusive rights conferred upon the holders of IK registrations are to: the benefits arising from its commercial use; be acknowledged as its source; and restrain any unauthorized use of the IK.

The functions and duties of NIKSO (which will be a non-juristic entity) include keeping a Register of IK, establishing a Registration Office, and the accreditation and certification of IK practitioners who may be recorded in the Register of Designations kept by NIKSO. NIKSO will also attend to

27) South African Indigenous Knowledge Systems Bill, 2016

registration of IK on behalf of an IK holder. A person seeking to obtain a copy of documents from the Register of IK must first enter into a non-disclosure agreement with NIKSO, as prescribed. In performing its functions, NIKSO must develop and implement an effective regulatory framework for the protection, promotion, development, management and education in respect of IK systems. NIKSO may, at the request of an indigenous community, provide assistance or facilitate the commercialization and use of its IK.

If the holder of IK cannot be identified and designated, NIKSO must act as custodian of that IK. A person wishing to acquire the right to use IK shall apply to NIKSO for a licence and shall enter into a benefit-sharing agreement with NIKSO. Any person who uses IK without authorization, or otherwise contravenes certain important provisions of this Act, shall be guilty of an offence and liable on conviction to imprisonment for a period not exceeding three years or to a fine of R30 000, or both.

IK originating in a foreign jurisdiction must be given the same protection given to IK originating in South Africa, provided that the laws of that foreign jurisdiction provide reciprocal protection to IK originating in South Africa. A sharing of ownership of IK is possible where IK originates in one or more foreign jurisdictions and in South Africa.

An IK holder wishing to register IK which existed prior to the commencement of the new Act, must register such IK within 12 months from the date of commencement of this Act.

4. Traditional knowledge and Biodiversity: CSIR case studies

This section describes the CSIR proprietary case studies based on the South African indigenous plant species and the related traditional knowledge, to support the value of traditional knowledge to scientific research, and demonstrate the beneficiation of local communities' traditional knowledge and sustainable use and conservation of biodiversity.

A Consortium of eight Traditional Health Practitioners from South Africa approached CSIR during the early nineties in connection with a panel of the South African indigenous plant species, to investigate for their traditional uses. The Consortium represents the Traditional Health Practitioners constituencies in the different provinces of South Africa, except the Western Cape. CSIR entered into a benefit sharing agreement with the Consortium whereby royalties on sales of the products developed from the use of their traditional knowledge and associated biological diversity are paid. Several agreements were entered into to protect the traditional knowledge of the

Consortium, as Memorandum of Understanding and Heads of Agreement. Four of the South African indigenous plant species from the Consortium were subjected to scientific investigation for their traditional uses using public funds, namely *Lippia javanica*, *Monsonia angustifolia*, *Siphonochilus aethiopicus* and *Elephantorrhiza elephantina*. Another South African indigenous plant species, *Schlerochiton ilicifolium* is discussed - which is not part of the panel of the plant species brought to CSIR by the Traditional Health Practitioners' Consortium.

4.1 CSIR (host of SANBio Network) Context

The CSIR is one of the several science councils in South Africa which are responsible for scientific and technology research, development and implementation. South Africa's CSIR was established in 1945 as a science council by an Act of Parliament. It is a parastatal that is required to contribute to R&D in South Africa by undertaking integrated, multidisciplinary research across diverse areas of science.

The detailed mandate of the CSIR is set out in the Scientific Research Council Act, (Act 46 of 1988, as amended by Act 71 of 1990), section 3 as follows:

> *"The objects of the CSIR are, through directed and particularly multidisciplinary research and technological innovation, to foster, in the national interest and in the fields which in its opinion should receive preference, industrial and scientific development, either by itself or in co-operation with principals from private or public sectors, and thereby to contribute to the improvement of the quality of life of the people of the Republic, and to perform any other functions that may be assigned to the CSIR by or under this act."*

The CSIR works closely, either as a partner or a client, with tertiary educational institutions, other science councils, research institutions and a range of private sector organizations' locally and abroad. According to internal corporate documents, the CSIR places a focus on quality science and skills development for socio-economic impacts.

The CSIR owns and/or manages a number of specialist facilities of national importance. These include centers for laser technology, satellite applications, nano-structured materials, high-performance computing, notational analysis of sports performance, coastal engineering and other modelling facilities, as well as testing facilities for wind resistance, mine hoist equipment, environmental samples and more. CSIR receives an annual grant from the Parliament through the Department of Science and Technology (DST), which accounts for some 40% of its total income. This is invested in knowledge generation, scientific infrastructure and enhancing skills. The CSIR's

total operating income is more than R1 billion per annum. Income generated from contract research for public and private sector clients, locally and abroad, as well as from royalties, licenses and dividends from intellectual property management and commercial companies created by the CSIR is added to the income directly from government. CSIR earns in excess of R30 million in royalties per annum and also earns fees from consulting and analytical services that range from project management and fieldwork, and specialist testing.

CSIR has a dedicated unit for enterprise creation to facilitate the implementation of community-owned, technology-based businesses that generate innovative products and employment opportunities. CSIR has a staff complement of around 2,300, of which close to two thirds are science, engineering and technology (SET) specialists; of these 50% are qualified at Master's level and higher. CSIR invests in human capital development through under and postgraduate bursaries, internships and a range of training interventions to foster young talent and further develop expertise.

In 2005, the CSIR was selected by the New Partnership for Africa's Development to host the SANBio Network for Biosciences. SANBio operates with a multi-country; regional approach and it consists of a regional hub (SANBio Hub at the CSIR) and a number of national nodes. A Hub is an institution that is involved in cutting edge research, has state-of-the art research facilities and human resources that is actively involved in research and development while Nodes are institutions that are also actively involved in research and have expertise that provide unique skills and research facilities to complement the capacity of the Hub[28]. The SANBio Hub which has been designed to support the SANBio Network, aims to create the CSIR footprint in the SADC region and Africa as a whole, by providing, among others, access to work-class research and translational infrastructure and expertise in multidisciplinary and diverse scientific fields and capacity building.

Through the SANBio Hub, the Southern African region can leverage the extensive experience and world-class facilities at the CSIR to accelerate technology development coupled to human capital development. Furthermore, the Hub can facilitate access to other competencies within the CSIR (such as ICT, logistics, materials manufacture, resource monitoring and build environment planning) to facilitate the implementation of innovation programs to realize maximum societal impact in reasonable time frames.

28) Africa's Science and Technology Consolidated Plan of Action (2005), "New Partnership for Africa's Development", NEPAD Agency, Johannesburg, South Africa

4.2 CSIR case studies on TK and ABS

4.2.1 Lippia javanica

The South African local communities based in rural areas have traditionally utilised *Lippia javanica*, commonly known as musukudi in Sepedi, as a mosquito repellent. The community cut branches of this plant species to wipe on the skin and around the entrances to dwellings at night or the branches are thrown on an open fire at night. The Traditional Healers' Committee approached the CSIR regarding the traditional use of the plant. The traditional knowledge stimulated scientific research by the CSIR. The scientific research included identification of the chemotype of the *Lippia javanica* species with superior mosquito repellency properties, extraction of the essential oil from the plant using CSIR customized processes and chemical profiling and characterization of the essential oil using GC-MS (gas chromatography mass spectrometry).

The CSIR entered into a benefit sharing agreement with the Traditional Healer's Committee in 2003, with 6% royalty negotiated, for the role played of their traditional knowledge in scientific research, technology development and commercialisation. The CSIR filed a South African patent (PCT1/20141021/COB/CSIR/77) on the use of extracts and chemical compound identified in the plant as mosquito repellents and CSIR became the owner of the invention. According to the South African Patent Act of 1978, any person or institution who or that have discovered something and made a invention on it is the owner of the intellectual property, hence CSIR has the rights on the ownership of the intellectual property derived from the *Lippia javanica* plant. In August 2013, CSIR obtained the bioprospecting permit (BP 0006) to develop and commercialise products, as well as to cultivate the *Lippia javanica* for commercial purposes.

The CSIR licensed the intellectual property to a local entrepreneur to manufacture, market and distribute the mosquito repellent candles (Figure 1). The candle is being marketed under the "Fever-Tree" brand by the local entrepreneur[29].

29) http://www.fever-tree.co.za/products.php

Figure 1: Mosquito repellent candles containing the Lippia javanica especial oil based on the CSIR technology

Source: Author [1]

In 2005, CSIR, through funding from the Department of Science and Technology' Socioeconomic Innovation Partnerships Programme, transferred the *Lippia javanica* technology to a local community in Giyani, Limpopo province for the establishment of a community owned business, called Hi-Hanyile, to cultivate, distil and extract the oil from commercial production of mosquito repellent candles (Figure 2).

Figure 2: Commercial cultivation of Lippia javanica *in Giyani, Limpopo through funding from the Department of Science and Technology,*

Source: CSIR

The Hi-Hanyile community-owned business has been managed by the CSIR' Enterprise Creation and Development Unit since 2005, to provide administrative support (i.e. financial, human resources and legal management).

Between 2015 and 2017, the business has produced a total of 166.33 kg essential oil of *Lippia javanica* for the manufacture of the mosquito repellent candles, resulting in the creation of total 61 jobs (both full time and part time) from the community of Giyani in Limpopo province. The employees are responsible for plant cultivation and harvesting and oil distillation. An experienced commercial farmer, through the facilitation of the CSIR, provided training to the community workers to implement the activities of agricultural and processing relating to *Lippia javanica* business, such as crop propagation from seed, crops establishment and planting, crop maintenance practices (such as irrigation, fertiliser application and weed-control), harvesting practices and processing through distillation for Lippia javanica oil production. About 46 576 candles have been sold on the South African market by the commercial partner under "Fever Tree" brand between 2015 and 2017. The Hi-Hanyile community owned business is

In terms of the requirements of the Biodiversity Act, 2004 and the Benefit Sharing Agreement of 6% between the CSIR and the Traditional Healers Committee, three monitory benefits were made to the Traditional Healers Committee via the National Bioprospecting Trust Fund, generated from the commercialisation of the Fever Tree mosquito repellent candles, have been made thus far.

In summary, the case study demonstrated the intrinsic value of traditional knowledge shared by the Traditional Healer's Committee with CSIR to the CSIR to scientific research which led to the identification of the chemotype of the *Lippia javanica* species with superior mosquito repellency properties through government funding from the Department of Science and Technology, and to innovation (R&D linked to business and traditional knowledge holders collaboration with researchers and business) based on biodiversity, by applying the Patent Act, 1978, Patent Amendment Act, 2003 and Biodiversity Act, 2004 and its Chapter 6 of the Amended Bioprospecting, Access and Benefit Sharing Regulations, 2008 to intellectual property protection and management. The intellectual property relating to the chemical compound identified in the essential oil of *Lippia javanica* is owned by the CSIR. The CSIR is holding the bioprospecting permit on *Lippia javanica* to develop and commercialise products.

The community owned business in Giyani business based on *Lippia javanica* is a positive contribution to the efforts to ensure management of traditional knowledge and biodiversity conservation and a contribution to business, and to economic development of South Africa.

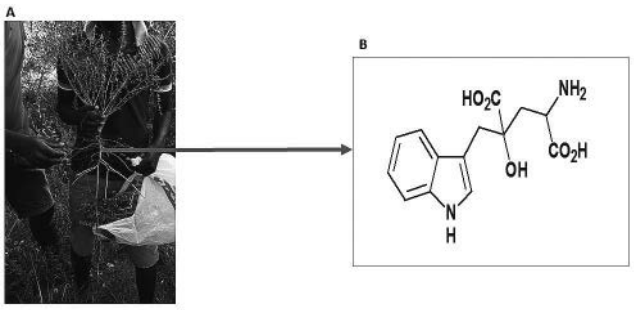
4.2.2 Schlerochiton ilicifolius

During the 1970s, CSIR went out of its way to search for plant species to develop into food technologies across South Africa and subsequently came across *Sclerochiton ilicifolius*, commonly

known as “molomo monate” in Limpopo province. According to the local communities of Limpopo province, it is believed that when eating the bark of the roots of “molomo monate” would make one words sweet. Figure 3A shows the local community member from Limpopo holding “molomo monate”, showing the roots of the plant species. The sweetness of the bark of the roots promoted the CSIR research and development, to investigate the properties of this indigenous plant species by extracting and characterizing a non-carbohydrate chemical compound sweetener, called Monatin (Figure 3B). CSIR discovered that Monatin was more than 1 400 times sweeter than the normal sugar although it is a non-nutritive sweetener.

Monatin is a naturally occurring, novel non-nutritive, high intensity sweetener originally isolated from the barks of the roots of the plant species *Sclerochiton ilicifolius* (Figure 3) .The CSIR first patent (1988 US Patent 4,975,298) was granted in 1988 and the various related patents (1991 US Patent 5,128,164, 2009 European Patent 2 090 173 A1) followed. CSIR obtained the bioprospecting permit (BAP0003) in 2012, which was one of the first such permits to be granted in South Africa, in terms of the Biodiversity Act, 2004.

Figure 3: Root of the Sclerochiton ilicifolius *(“molomo monate”) (A) and the Monatin compound isolated from the root of the plant species (B)*



Source: Council for Scientific and Industrial Research

In May 2004, the CSIR, through its fully owned subsidiary, Technifin signed a “Monatin license agreement” with Cargill, a multinational company, based in the United States of America. Monatin is currently being developed as a non-nutritive sweetener and a rigorous program of safety studies is currently underway. The safety data on the monatin chemical compound has been produced and is being analysed and evaluated, to determine whether any additional studies may be required. The safety studies have been completed and submitted to the FDA for a review as part of the GRAS process. Monatin will not be extracted from the plant species *Sclerochiton ilicifolius* but will be produced through a novel enzymatic process.

CSIR was supported by the National Departments' of Environmental Affairs and Science and Technology and Limpopo Provincial Department of Tourism and Environment, to identify the communities associated with "molomo monate" and negotiate the benefit sharing agreements. The respective communities identified are Seleka and Shongoane communities and CSIR has respective benefit sharing agreements with the communities, which were approved by the South African Minister of Environmental Affairs in terms of the Biodiversity, Act, 2004. A total of R 2.6 Million as milestone payment was paid to these communities via the National Bioprospecting Trust Fund, in terms of the Biodiversity Act, 2004, used towards community upliftment projects.

In summary, this project is one of the promising benefit sharing agreement to make the biggest payment to the communities for their contribution with traditional knowledge to the CSIR research and development. The milestone payment is the biggest in the history of the South African ABS.

4.2.3 Monsonia angustofolia

Monsonia angustifolia is a member of the Geraniaceae family. It is perennial herb which bears pink flowers and whose geographic distribution is in open grassland throughout South Africa.

Figure 4: Monsonia angustifolia

South African National Biodiversity Institute

Monsonia is traditionally used for various diseases such as increasing male and female libido, diarrhoea, ophthalmia, haemorrhoids, stomach ulcer, indigestion and liver disorder. An aqueous and different organic extracts were prepared from the leaves and stems of the plant and chemically profiled. Four lignan compounds were isolated from the dichloromethane/methanol extract of the plant and biologically evaluated for their activity in Alzheimer's disease assays. Both the plant extract and one of the lignan-type compounds isolated from the extract were found to actively inhibit the production of Aβ42 and Aβ40 in vitro.

In 2014, CSIR applied two patents (US20140087008A1 and US20140088186A1) for “Composition for preventing or treating dementia comprising extracts of Monsonia species” and “Composition containing arylnaphthalene lignan derivative for preventing and/or treating dementia” respectively. CSIR signed the benefit sharing agreement with the Traditional Healers Committee in 2003 and the bioprospecting permit (BABS 000711P) issued by the Department of Environmental Affairs in terms of the Biodiversity Act, 2004, to develop and market products.

No products have been produced and commercialised. The CSIR is exploring potential commercial partners whom to license the technology from the plant species. No licensing agreement has been signed and no royalties collected.

4.2.4 Siphonochilus aethiopicus

The CSIR (through Biosciences Unit) interactions with the Traditional Healers Committee led to the identification of *Siphonochilus aethiopicus*, commonly known as African Ginger (Figure 5). It is one of the most widely used medicinal plants in South Africa, used traditionally for managing allergic diseases such as asthma, colds, influenza and sinus problems. Scientific research conducted, demonstrated the beneficial properties of the plant extract. The CSIR was granted a PCT patent for use of the extract and compound (PCT/IB2007/050649) and there is no private sector company involvement in terms of licensing agreement.

Figure 5: African Ginger

Source: South African National Biodiversity Institute

The CSIR is planning to undertake clinical studies on humans to investigate the anti-asthmatic and allergy properties of African Ginger through the Department of Environmental Affairs and UNDP GEF (United Nations Development Plan Global Environment Fund) and the proposal requesting funding for clinical studies has been submitted. There were no monetary (financial) benefits that

were paid to the Traditional Healers Committee in terms of Benefit Sharing Agreement of 2003. However, the Traditional Healers Committee was trained on agroprocessing, i.e. from extract preparation to making formulations (such as capsules, tea back and creams).

Based on the preclinical data and anecdotal use of the plant, process optimisation resulted in the development of a proprietary extraction method for African ginger. The most effective extraction method has been used by industrial partner Afriplex (a botanical manufacturing company) to conduct trial pilot-scale extractions leading to eventual commercial scale production. Afriplex's key technology is the specialized extraction process that will result in a specific, active pharmaceutical ingredient (API) linked to specific therapeutic claims that will not be easily copied by a competitor. The API can be formulated into a range of products including cough mixtures, capsules, lozenges, decongestant rubs and hot tonics.

Highest levels of analytical quality control such as HPLC MS/MS have been used to show batch to batch reproducibility. The medicinal use of African Ginger is well known to the South African population and there is a high demand from the public for products based on this plant. Current products are mainly traded on the internet and are based on dried ground plant material.

A propagation programme for the plants from tissue-cultured material has been established by CSIR to prevent depletion of the plants in the wild and to ensure a reliable and sustainable supply of plant material for commercialization purposes (Figure 6).

Figure 6: Propagation Programme of African Ginger in KwaZulu Natal by CSIR

Source: CSIR

Community driven cultivation programmes have been established in collaboration with CSIR's

Enterprise Creation for Development and the Agricultural Research Council and will have to be expanded to meet commercial demands for the raw material.

4.2.5 Elephantorrhiza elephantina

The CSIR received traditional knowledge information through its collaboration with the Traditional Health Practitioners Consortium on the use of *Elephantorrhiza elephantina*, to help relieve urinary pains, reduce the enlargement of the prostate and incontinence. This type of condition is called benign prostatic hyperplasia. *Elephantorrhiza elephantina* belongs to the Fabaceae family. Its common names are eland's bean, elandswortel, elandsboontjie and intolwane[30].

Elephantorrhiza elephantina is one meter in height, growing from an enormous underground rhizome as a native weed (Figure 7). It is very invasive and a non-climbing, perennial shrub, which is not a threatened species. The branched root system often forms extensive colonies of visible plants. Seeds can be used to propagate this plant species[31]. According to a farmer from the Limpopo province in South Africa, the plant species is traditionally used to treat diarrhoea, dysentery, stomach disorders, sexually transmitted diseases, haemorrhoids and perforated peptic ulcers. It is also used traditionally for promoting blood circulation, as an immune booster, treatment of urinary problems, and topically for treatment of skin problems and acne. The plants species is reported to be used for earaches, for treating diarrhoea in children, dysentery and sexual transmitted diseases[32]. In Botswana, roots are used to clean wombs after an abortion and in Zimbabwe, roots are used for abdominal pain, infertility in women and as aphrodisiacs[33]. This plant has also been proven scientifically to possess antimicrobial and antibacterial activity at the University of Botswana[3]. Traditionally, the rhizomes of this plant are prepared and drunk as a tea.

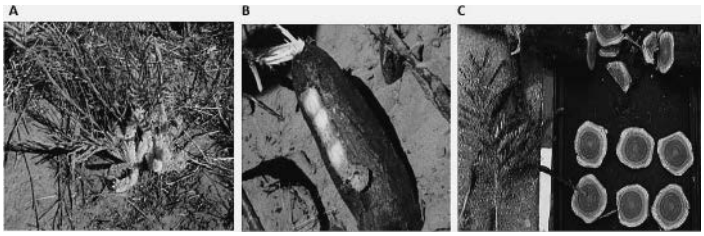
30) J.M. Watt, M.G. Breyer-Brandwijk, *The medicinal and poisonous plants of Southern Africa,* 2nd Edition, Edinburgh, 1962, pp. 596-597.

31) H.P. Van der Schijff, L. Snyman, *International Journal of Plant Sciences* 1970, 76, pp. 114-128

32) E. Aaku, M. Office, S.P. Dharani, R.R.T. Majinda, M.S. Motswaledi, *Fitoterapia*, 1998, 69, pp. 464-465.

33) A. Hutchins, A.H. Scott, G. Lewis, A.B. Cunningham, *Zulu Medicinal Plants. An inventory.* University of Natal Press, Pietermaritzburg, 1996, p. 126.

Figure 7: Elephantorrhiza Elephantina, *leaves (A), underground rhizome (B) and sliced rhizomes (C)*



Source: CSIR

Based on the assessment of a South African botanist, *Elephantorrhiza elephantina* is believed to be abundantly available in certain sites and this assessment was further supported by strong evidence published by scientists from the Department of Botany, University of Witwatersrand in Johannesburg, South Africa[34]. The plant species is widely distributed in southern African countries such as Mozambique, Lesotho, South Africa, Swaziland, Zimbabwe, Botswana and Namibia[35].

On receiving this plant, an urologist based in Pretoria, South Africa evaluated the crude spray-dried extract for benign prostatic hyperplasia and a verbal positive result was reported to CSIR. No published reports on the use of this plant as a treatment for benign prostatic hyperplasia were found.

A number of sites in different South African provinces were identified for the collection of this plant. The CSIR thus decided to attempt to investigate the medicinal properties of this plant, scientific research and development. The research included the identification of the correct plant species responsible for the reported activity and this was done in consultation with SANBI (South African National Biodiversity Institute). Literature searches were then conducted on the identified plant species, suitable extracts prepared and relevant *in vitro* and *in vivo* biological assays identified to investigate this claim.

A bioassay-guided fractionation was conducted to isolate and identify the biomarkers and active ingredient(s). Seven compounds were identified and investigated for *in vitro* inhibition of the steroid 5α-reductase enzyme. These compounds are being used as chemical markers to standardize the extract of *Elephantorrhiza elephantina* for quality control purposes to show batch to batch reproducibility. Limited biological published information of these compounds led to their

34) W.N. Ellery, B.H. Walker, *South African Journal of Botany.* 1986, 52, pp. 100-104.

35) I. Hedberg, F. Staugard, *Traditional medicine in Botswana. Traditional medicinal plants.* Ipelegeng publishers, Gabarone, 1989 pp. 119-120.

testing *in vitro* against other available biological targets. These compounds were therefore evaluated *in vitro* for different therapeutic applications such as anticancer, antimalarial, antioxidant and cytotoxicity.

Third party's involvement in the project from South Africa prepared suitable formulations from *Elaphantorrhiza elephantina* such as shampoos and scalp massage serums. A three month stability study was conducted on *Elephantorrhiza elephantina* and the formulations. The results showed good stability at room temperature, very low temperature (4°C) and higher temperatures (40°C and 50°C).

The formulations (scalp massage serum) were further tested for skin irritancy properties using patch testing on human test subjects. The formulation was shown to be non-irritants as they showed a decrease in irritancy potential relative to the negative control. The clinical safety assessment of *Elephantorrhiza elephantina* and other ingredients in the formulation was evaluated on a monolayer of rabbit cornea fibroblasts and was considered safe to use on humans.

Plans are underway to investigate the formulations developed from *Elephantorrhiza* elephantina for anti-hair loss properties on humans. Technology licensing agreement has been signed with a commercial partner for large scale manufacture of *Elephantorrhiza elephantine* extracts, marketing and selling. The CSIR has obtained the bioprospecting permit (BABS/000611P), to develop and market products.

Communities in the Northern Cape Province at Abbey and Avontuur have been identified to collect and supply *Elephantorrhiza elephantina* rhizomes. Field studies were conducted on methods of sustainable harvesting, propagation, management and commercialization of plant resources of *Elephantorrhiza elephantina*. The plant is very successful in its survival and proliferation. The community area has been fenced for land banking, and is a registered type locality for the specific chemo-type of *Elephantorrhiza elephantina*, which will act as a chemical reference standard. A community SMME is being established for harvesting and pre-processing of the plants.

The environmental impact assessment study was carried out by the CSIR Enterprise Creation for Development on *Elephantorrhiza elephantine* wild harvesting and found that the plant species has a high potential of *in situ* sustainable use. This high potential is largely due to the high abundance of the species and the fact that it has the potential to reproduce vegetatively. The CSIR obtained a harvesting permit from Northern Cape Provincial Department for harvesting 20 tonnes of the plant material per annum.

No non-monetary benefits have been transferred as the final products will be evaluated in clinical studies on humans for anti-hair loss properties. No products have been produced and commercialised.

5. Conclusion

There is no doubt that South Africa is committed to the protection of TK, as well as value addition of TK and the associated indigenous biological resources. This is evident to the comprehensive legal framework and system on intellectual property and access and benefit sharing. For instance the Patent Act, 1978 was amended, herein referred to as Patent Amendment Act, 2005, to allow the protection of TK through ABS contacts and ensuring that the TK Holders become part of the benefit sharing recipients and are part of the value chain for the development of the South African Bio-economy and sustainable use of indigenous biological resources. This complement the provisions provided for in the Biodiversity Act, 2004 legislation on access and benefit sharing.

The government of South Africa is working on making some improvement in these laws to make it necessary for research institutions like CSIR, private sector companies and local and indigenous communities in order to deal with some complex issues of TK protection measures during technology development and commercialisation. The South African Bio-economy Strategy of 2014[36] and the Bio-diversity economy Strategy[37] support the development of TK into technologies and products of market value. These strategies capitalises on the unique biodiversity and TK that is found in the country, to develop technologies, products and industries that will help the country strengthen its GDP growth. For instance, the Bio-economy Strategy put an emphases on agriculture, health and industry as pillars to develop the bio-economy sector, by promoting industry-science-local communities-government linkages to work closely to each other, to ensure that technologies and products are market relevant and find easier application in South Africa. The Bio-diversity economy Strategy has identified the bioprospecting and wildlife sectors, promote linkages between these industries, research institutions and local communities based on indigenous biological resources to develop products of economic benefit to the country.

The CSIR, one of the largest research and technology development for industrialisation institution government owned institutions in South Africa, supports these government Strategic intents and the National Development Plan: Vision 2030, and has been at the forefront of adding value to TK

36) The National Biodiversity Strategy of South Africa, 2014

37) The National Bio-diversity Economy Strategy, 2015

and associated indigenous biological resource through scientific innovation and community owned agroprocessing businesses, while ensuring that the TK Holders benefit in the process, as required by the South African Biodiversity Act, 2004. The case studies discussed for *Lippia javanica*, *Monsonia angustifolia*, *Siphonochilus aethiopicus*, *Elephantorrhiza elephantina* and *Schlerochiton ilicifolius* are clear examples that TK is also important for innovation to grow and development the Bio-economy sector.