UNIVERSITY OF CAPE TOWN

FACULTY OF LAW

SCHOOL FOR ADVANCED LEGAL STUDIES

PATENTS OF TRADITIONAL MEDICINE INVENTIONS AND THEIR RELATIONSHIP WITH TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES IN NAMIBIA: PROPOSALS FOR LEGAL REFORM

A DISSERTATION SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE MASTER OF LAWS

(INTELLECTUAL PROPERTY LAW)

BY

CISLÉ STELLA JACOBS (JCBCIS001)

JCBCIS001@myuct.ac.za

SUPERVISOR: DR LEE-ANN TONG

Date: MARCH 2017

Word Count: 23 415

Research dissertation presented for the approval of Senate in fulfilment of part of the requirements for the degree Master of Laws (Intellectual Property Law) in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of degree Master of Laws (Intellectual Property Law), including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation/research paper confirms to those regulations.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ARIPO	Africa Regional Intellectual Property Organisation
CBD	Convention on Biological Diversity
DST	Department of Science and Technology (South Africa)
GR	Genetic Resources
IBR	Indigenous Biological Resources
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IK	Indigenous Knowledge
ILC	Indigenous and Local Communities
IP	Intellectual Property
IPR	Intellectual Property Rights
NEMBA	National Environmental Management Biodiversity Act 10 of 2004 (South Africa)
R&D	Research and Development
TK	Traditional Knowledge
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
WHO	World Health Organization
WIPO	World Intellectual Property Organization

CHAPTER 1: INTRODUCTION

1.1 Background of the Study

Traditional medicine was formerly suppressed, subjected to ridicule and believed to be witchcraft during the period of colonialism and apartheid.[1] Today, it is one of the leading sources for the development of pharmaceutical products by companies from the global North.[2] Millions of people around the world depend on traditional medicines, traditional treatments, and traditional practitioners as a source of health care, and in some places it is the only source of care.[3] According to the World Health Organization (WHO) about 70 to 80 per cent of the population in developing countries depend on traditional medicine for their basic health care needs.[4]

Frequently referred to as medical knowledge[5] held by indigenous and local communities (ILCs), traditional medicine is but one of the vast facets of traditional knowledge (TK). Some TK is closely associated to genetic resources (GRs)[6] and most GRs are sources of traditional medicine. The terms "TK associated with GRs"[7] and "traditional medicine" will be used interchangeably in this study because the product of the association between TK and GRs is traditional medicine on which patents of inventions may be based or derived from.[8]

Drug discovery and development strategies based on or derived from natural products and traditional medicines are re-emerging as attractive options for big pharmaceutical companies and research institutions.[9] To patent an invention based on or derived from traditional medicine the applicant must overcome a few obstacles.

---

[1] Witchcraft Suppression Proclamation 27 of 1933. The Witchcraft Suppression Act 3 of 1957 which applied to Namibia then South West Africa as a proclamation by virtue of being a mandate territory administered by South Africa see J Dugard *The South West Africa/Namibia Dispute: Documents and Scholarly Writings on the Controversy Between South Africa and the United Nations (*1973) 73.

[2] G M Cragg & D J Newman 'Natural Products: A Continuing Source of Novel Drug Leads' *Biochim Biophys Acta* (2013) 2-10.

[3] WHO *Traditional Medicine Strategy: 2014-2023* (2013) 16.

[4] WHO *Fact Sheet No.134: Traditional Medicine* (2008).

[5] World Intellectual Property Organization (WIPO) *Documenting Traditional Medical Knowledge* (2014) 3. (WIPO *Documenting TMK*).

[6] The definition for GRs is provided under chapter 2 of the study.

[7] The term 'TK associated with GRs', 'GRs and associated TK' and 'TK and associated GRs' have the same meaning in this study.

[8] The terms TK associated with GRs and traditional medicine will be explained in further detail under chapter 2.

[9] B Patwardhan & R A Mashelka 'Traditional medicine-inspired approaches to drug discovery: can Ayurveda show the way forward?'(2009) 14 (15/16) *Drug Discovery Today* at 805.

First, the novelty and occasionally the inventiveness requirement would normally impede the patentability of such invention.[10] However, the patent system may confer rights over GRs and associated TK that have been altered and such alteration has led to the development of a novel and sufficiently inventive product in the sense that the new invention constitutes an improvement of the traditional medicine.[11]

Second, the defensive legislative approach towards excluding all GRs even when isolated or purified including genome or germplasm may lead to exclusion of products based on GRs.[12] The Namibian government has responded to the challenge of protecting TK and GRs by passing the Industrial Property Act 1 of 2012. Both TK and GRs enjoy defensive protection in terms of the Industrial Property Act.[13] When applied to TK and GRs defensive protection essentially prevents third parties from asserting or acquiring the IPRs over TK or GRs.[14] Thus, traditional medicine or its derivatives cannot be patented as oppose to positive protection whereby TK holders are essentially given rights and legal tools to authorise or prevent use of their TK.[15]

Consequently, defensive protection of this kind may cause the patent law to fall below the international minimum requirements under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 1994 because it excludes certain innovations from being protected by patents.[16] The TRIPS Agreement provides flexibility for governments, particular those from developing and least-developed nations, to adjust the protection granted in order to meet socio-economic goals of the country.[17] It provides for exemptions from patentability,[18] which excludes a subject-matter from protection and result in a non-grant of a patent.[19] However, the TRIPS Agreement does not exclude GRs in isolated or purified form including its genome or germplasm. Therefore, by excluding all forms of

---

[10] C du Champ d'Anier *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (2000) Geneva: the South Centre.
[11] P Ebermann *Patents as Protection of Traditional Medical Knowledge?* (2012) 132.
[12] S 17(1)(i) of the Industrial Property Act.
[13] S 12(1)(c) of the Industrial Property Act.
[14] WIPO IGC *Practical Mechanisms for the Defensive Protection of TK and GRs within the Patent System,* WIPO/GRTKF/IC/5/6.
[15] G Dutfield *Protecting Traditional Knowledge and Folklore* (2003) 27.
[16] Art 27(3) of the TRIPS Agreement.
[17] World Trade Organization (WTO) *Fact Sheet September 2006: TRIPS and Pharmaceutical Patents* at 2.
[18] Art 27(3) of the TRIPS Agreement.
[19] S F Musungu & S Oh 'The Use of Flexibilities in Trips by Developing Countries: Can They Promote Access to Medicines?' (2006) *South Centre in collaboration with the World Health Organization* at 33.

GRs may lead to questions about whether Namibia is meeting the TRIPS minimum standards.

Third, the patent system can be used to facilitate biopiracy of TK and associated GRs as will be seen in the *Hoodia* case. It is, therefore, no revelation that the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) found that a momentous number of patent applications are of inventions that involve TK in some way.[20] However, cases of misappropriation can be overcome by incorporating disclosure requirements in patent laws.[21] The international community, including the IGC, has recognised such requirement as preferable to prevent granting 'erroneous patents'.[22] Disclosure of the place of origin and the source of TK associated with GRs in patent applications for products based on or derived from traditional medicine assist in preventing misappropriation and provide support to a compensatory benefit-sharing regime.[23]

Finally, the ownership of TK associated with GRs is a general issue. Normally, the question is which ILCs constitutes 'knowledge holders' for the purpose of benefit sharing arrangements, where the use of the TK is widespread and cuts across many ILCs may be an issue.[24] Nonetheless, as illustrated in the case studies discussed below ILCs are willing to share benefits with other knowledge holder communities.

Moreover, using the patent system for inventions based on or derived from traditional medicine can contribute to economic development of a country. TK associated with GRs is a highly valuable intangible asset of developing countries.[25] The economic value of this asset could be improved by the use of IPRs particularly patents through commercialising inventions based on or derived from traditional medicine the manifestation of TK associated with GRs.[26] Commercialisation can also enable ILCs to actively exploit their TK associated with GRs for their benefit and the

[20] WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) *Recognition Of Traditional Knowledge Within The Patent System* (2008) at para 1.
[21] Ebermann op cit note 11 at 175.
[22] Art 1 & art 3 of the IGC Document.
[23] Ebermann op cit note 11 at 175.
[24] E P Amechi, 'Using Patents to Protect Traditional Knowledge on the Medicinal Uses of Plants in South Africa' (2015) 11 *Law, Environment and Development Journal* 51 at 68.
[25] Amechi op cit note 24 at 64.
[26] Ibid.

benefit of the Namibian economy.[27] Thus, it is crucial for developing countries to examine the experiences of other developing countries to learn from their policies and experience in the field of traditional medicine innovations.[28]

Socio-economic development for a country such as Namibia endowed with unique GR base is possible particularly since international interest in bio trade with and bioprospecting in Namibia has grown in the last two decades.[29] This can provide a platform where the relationship between TK and the patent system can be used for research and development of products based on or derived from TK associated with GRs by local and international users.

However, this relationship between TK and the patent system has rarely been to the advantage and benefit of ILCs which have generated and nurtured such TK systems in most biodiversity rich developing countries like Namibia.[30] In fact, there have been recorded instances where bioprospectors have used the patent system to facilitate the misappropriation of TK associated with GRs.[31] Pharmaceutical corporations are heavily criticised for drawing on TK and biological resources and filing patent applications for their findings without permission from, or acknowledging the ILCs.[32] In contrast to the commercial pharmaceutical enterprises' interest in TK, for ILCs, TK is an integral part of the ILCs identity.[33] TK is a valuable asset for their livelihoods and the ILCs play a crucial role in the sustainable management of GRs specifically and biodiversity generally.[34] ILCs undoubtedly facilitate the process of discovery, development and conservation of medicinal GRs that are used and traded globally.[35]

The two players, pharma and ILCs operate under national government. The interest of a government in TK and associated GRs usually emanates in the form of

---

[27] C M Correa *Protection and Promotion of Traditional Medicine - Implications for Public Health in Developing Countries* (2002) Geneva: the South Centre at 47.
[28] J Erstling 'Using Patents to Protect Traditional Knowledge' (2009) 15 *Texas Wesleyan Law Review* 295.
[29] H Krugmann *Namibia's Thematic Report on the Benefit-Sharing Mechanisms for the Use of Biological Resources* (2001) 5.
[30] Amechi op cit note 24 at 58.
[31] T Beharie & T Shabangu 'Traditional knowledge, traditional cultural expressions and folklore' in Owen Dean & Alison Dyer (eds) *Introduction to Intellectual Property Law* (2014) 335.
[32] D F Robinson *Confronting Biopiracy: Challenges, Cases and International Debates* (2010) 14.
[33] C Oguamanam *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (2006) at 4.
[34] K T Kate & S A Laird *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing* (1999) 6.
[35] Ebermann op cit note 11 at 23.

rights and obligations arising out of various international, multilateral or regional instruments– as well as national imperatives and needs. Consequently, Namibia has obligations under the Convention on Biological Diversity, (CBD) 1993, the TRIPS Agreement and the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore (Swakopmund Protocol or Protocol) as well.[36]

Consequently, the main concern for ILCs, states and the international community is to protect TK and associated GRs from misappropriation by third parties aided by the intellectual property (IP) system particularly patent law.[37] Discussions taking place at the IGC has considered a new disclosure requirement for all patent application which includes utilization of or is based on or derived from TK associated with GRs.[38] This disclosure requirement, if implemented correctly, may be a means to prevent misappropriation of TK and GRs.

Hence, the study intends to investigate the relationship between patentable traditional medicine inventions and TK associated with GRs. This study argues that patentable traditional medicine inventions will not hinder the protection accorded to TK associated with GRs in Namibia. In making this determination the study will investigate the extent of the protection accorded to TK and GRs in specific international and regional instruments and the Namibian Industrial Properties Act 1 of 2012 and Access to Genetic Resources and Associated Traditional Knowledge Draft Bill, 2014.

The study further argues that patents of inventions using traditional medicine can assist in preventing the misappropriation of TK associated with GRs and thereby, improve interaction of TK and GRs with patents in order to coexist in beneficial manner. To this end, the study will discuss the relevant provisions of patent law in aforementioned international, regional and national instruments including the system under South African National Environmental Management Biodiversity Act 10 of 2004, the Patents Act 57 of 1978 (as amended by the Patents

---

[36] S 1.1 of the Swakopmund Protocol 2010.

[37] WIPO *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions,* available at http://www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_93.pdf; last accessed on 10 December 2016.

[38] Art 3 of the WIPO IGC, *Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources* (2016) (IGC Document).

Amendment Act 20 of 2005), and the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill, 2016.

1.2 Focal research questions

1. Is patenting of traditional medicine inventions possible through the implementation of a disclosure requirement for all patent applications based on or derived from TK associated with GRs?
2. In doing so, will patents of traditional medicine hinder the protection accorded to TK associated with GRs?

1.3 Methodology

Qualitative rather than quantitative type of methodology was used. Literature-based relevant publications, legislation, draft bills, books, internet sources, cases, journals and WIPO documents were used as guiding tools. Overall a desktop-based methodology was used in this study.

1.4 Thesis Structure

Chapter 1

This chapter outlined the background to the study, focal research questions, methodology, and the thesis structure.

Chapter 2

Chapter two consists of the conceptual framework of key concepts namely; traditional medicine, traditional knowledge associated with genetic resources, bioprospecting, biopiracy, access and benefit-sharing, patents, and disclosure requirement. This will provide a comprehensive understanding of the main concepts in order to understand the manner in which they are used in this study. The chapter will further discuss previous instances under which patents were granted for TK associated to GRs i.e. the *Hoodia* plant and *Sceletium tortuosum*.

Chapter 3

This chapter is divided into three parts, namely the international instruments; regional instrument; and the IGC text-based negotiations. It serves as the international legal basis for the protection of patents, traditional knowledge and genetic resources, and is limited to the key instruments which affect Namibia.

The first part provides an overview of relevant international treaties to which Namibia is a signatory. This part of the chapter examines the CBD, the Nagoya Protocol and the TRIPS Agreement as the key international instruments that regulate the relationship between traditional knowledge associated with genetic resources and Intellectual Property generally, and patent law specifically. In addition due to the important role indigenous people play in the processing and development of traditional medicine it follows that United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) will be discussed.

Part two of this chapter examines the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization (ARIPO) to which Namibia is a member state.

Part three looks at the international initiatives lead by the WIPO IGC aimed at developing an international agreement for the protection of genetic resources, traditional knowledge and traditional cultural expressions.

Chapter 4

The chapter compares approaches taken for patents of traditional medicine inventions and the protection of TK and associated GRs by Namibia in the Industrial Property Act 1 of 2012; and the Access to Genetic Resources and Associated Traditional Knowledge Draft Bill, 2014, against the approach taken by South Africa in the National Environmental Management Biodiversity Act 10 of 2004, the Patents Amendment Act 20 of 2005, and the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill, 2016. The aim of this chapter is to determine a suitable system Namibia can adopt.

Chapter 5

Chapter five comprises of a conclusion of the study and explores possible legal reforms that will lead to sound recommendations for the consideration by the Namibian legislature and the Law Reform and Development Commission (LRDC) of Namibia.

CHAPTER 2: Conceptual Framework

2.1 Introduction

The focus of the study is the relationship between patents of traditional medicine inventions and TK associated with GRs. A topic of this nature is generally difficult as it involves different interrelated concepts. The use of terms in this study is very specific in terms of how they are defined, thus this chapter provides a comprehensive conceptual framework by defining the key terms and concepts important for understanding and following the argument of this study. The key concepts are specifically traditional medicine, traditional knowledge associated with genetic resources, bioprospecting, biopiracy, misappropriation, access and benefit-sharing, patents, and disclosure requirement. This chapter draws definitions from sources such as the CBD, the IGC Document and the Namibian AGR Draft Bill but the sources are discussed in chapter three and four in more detail.

2.2 Defining traditional knowledge and 'traditional knowledge associated with genetic resources'

Traditional knowledge forms the cultural heritage and intellectual property of ILCs.[39] Despite being the subject matter of many international discussions there is no universally accepted definition of traditional knowledge.[40] As author Gibson eloquently stated '[d]efinitional certainty where necessary…must be derived on a case by case (or community) basis; indeed, "traditionally"'.[41] This is the opposite of a universally accepted definition of TK that is potentially constraining to the knowledge different ILCs possess the world over.[42] Conversely, perhaps the reason why these international discussions have been so unsuccessful can be attributed to the lack of

[39] T Greiber et al (eds) 'An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing' *IUCN Environmental Policy and Law Paper No. 83* (2012) at 54.
[40] Examples of this discussions happened under the rubric of WIPO, ARIPO and International Workshop on Traditional Knowledge held by the United Nations.
[41] J Gibson *Community Resources: Intellectual Property, International Trade and Protection of Traditional Knowledge* (2005) 28.
[42] Ibid.

one working definition which in turn makes it difficult to advance talks on how to protect TK.[43] Nonetheless, the WIPO has defined TK as follows:

> Refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.[44]

The Namibian AGR Draft Bill provisional definition of TK is much shorter:

> Knowledge, practices, innovations or technologies created or developed over generations by local communities on the conservation and utilization of genetic resources.[45]

It is clear from both definitions that TK encompass GRs but only after the adoption of the CBD in 1993[46] were the terms TK and GRs formerly interrelated.[47] The CBD as the international framework for the conservation and sustainable use of biological diversity recognised that ILCs are central to the protection and promotion of *in situ* conservation of biodiversity and its sustainable development.[48] TK is not defined under the CBD but GRs are defined to mean 'genetic material of actual or potential value'.[49] The Namibian AGR Draft Bill takes a step further and defines GRs as:

> any material of plant, animal, microbial or other origin containing or derived from functional units of heredity and which has actual or potential value within or outside Namibia; all biological resources are genetic resources.[50]

---

[43] C B Graber & M A Girsberger 'Traditional Knowledge at the International Level: Current Approaches and Proposals for a Bigger Picture That Includes Cultural Diversity' in J.Schmid & Hansjörg Seiler (eds) *Recht des ländlichen Raums* (2006) 23.

[44] WIPO IGC*, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*, (2011) (WIPO IGC, *Glossary*).

[45] S 1 of AGR Draft Bill of 2014.

[46] CBD 'History of the Convention' available at *https://www.cbd.int/history/* last accessed 21 September 2016. CBD is discussed in more detail under chapter 3 part 1.

[47] Art 8(j) of the CBD.

[48] T Bubela & E R Gold 'Introduction' in T Bubela & E R Gold (eds) *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interest* (2012) 8.

[49] Art 2 of the CBD.

[50] S 1 of AGR Draft Bill.

It is seemingly because of the GRs value that art 15 requires member states to the CBD to provide access to GRs whilst respecting and preserving TK in terms of art 8(j).[51]

The text of the Nagoya Protocol is of particular importance to this discussion because it expressly recognised the interrelationship between TK and GRs and applies to TK associated with GRs and GRs as covered by the CBD.[52] It is also the first time the phrase 'TK associated with GRs' was incorporated into an international instrument. The Nagoya protocol unfortunately failed to take advantage of the opportunity to define and thereby clarify any uncertainties around what TK associated with GRs actually encapsulates. However, the WIPO IGC has increased text-based negotiations on TK associated with GRs[53] and according to the Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources released on 3 June 2016 (the Document)[54] there are two options of a possible definition for TK associated with GRs. They are the following:

Option 1: "Traditional knowledge associated with genetic resources" means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, [that subsist in] [that are associated with] genetic resources.]
Option 2: "Traditional knowledge associated with genetic resources" means substantive knowledge of the properties and uses of genetic resources [and their derivatives] held by [rightful holders, including] indigenous [people[s]] and local communities [and which directly leads to a claimed [invention] [intellectual property]] [and where, but for the traditional knowledge, the invention would not have been made].]

Figure 1 WIPO IGC definitions of TK

[51] Art 8(j) of the CBD is discussed under chapter 3.
[52] Nagoya Protocol.
[53] WIPO General Assembly, *Twenty-Sixth WIPO General Assembly: Report,* WO/GA/26/10 (2000) 71 [WIPO, '26 GA report'].
[54] IGC Document op cit note 37.

It is apparent from these two options that there are different views on the subject matter. Option 1 is broader in scope regarding the nature of the knowledge, how it is developed, what forms of activity it may include, and it is open-ended because of the use of 'including but is not limited to'. On the other hand, it seems that option 2 is narrower and more specific. It is particular about the type of knowledge, who the right holders of such knowledge are by referring specifically to ILCs and finally draws a direct link between such knowledge and any intellectual property that may arise from such knowledge. This definition says that the TK associated with GRs is an indispensable condition to an invention, the *causa sine qua non*.

Option 1 carries the spirit of TK in that it recognises fundamental characteristics of TK namely; (i) dynamic, varied and ever changing nature of TK; (ii) aspects of how it is developed and preserved; (iii) passing it on from one generation to the next. However, it is not clear on who creates this knowledge, which is arguably the most important characteristic of TK. Conversely, option 2 isolates protection of TK associated with GRs to instances where it leads to intellectual property. This could have an undermining effect on the objectives of the CBD and the Nagoya Protocol to protect genetic resources regardless of its association to TK.[55] It could also be contrary to the boundaries placed by the IGC's on any developments arising out of its text-based negotiations which must be 'without prejudice to the work pursued in other fora'.[56]

The challenge for the IGC to define and have a meaningful international consensus about the protection of TK associated with GRs can be traced back to diplomatic side-steps made during the negotiations of the Nagoya protocol.[57] The Nagoya protocol left a few unresolved questions: '(i) [W]hat is the subject matter for TK protection associated with GRs? (ii) how is the protection to be afforded? and (iii) how will protection be enforced (particularly in patent applications)?'[58] These questions will be considered under chapter 3 part 3 of this thesis. To sum up, there is a real challenge to define TK and there is no set definition, however, for purposes of this discussion option 2 of the IGC Document is appropriate as it defines TK associated with GRs in relation to IPRs which is essential for the study.

[55] The preamble provisions of the CBD and the Nagoya Protocol.
[56] WIPO, *Thirty-Eighth WIPO Assembly: Report*, WO/GA/38/20 (Geneva: 2009) 217 [WIPO, '38 GA report'].
[57] Bubela op cit note 48 at 59.
[58] Ibid.

2.3 Traditional medicine

As noted above traditional medicine is a product developed over many generations by the ILCs with a long history.[59] Worth noting is that the term 'traditional medicine' not only refers to products of GRs but also include traditional medical practices.[60] These practices are interpretations of how ILCs perceive diseases, illnesses and health in general.[61] Traditional medicine is thus an umbrella term for various things. The WIPO is silent on defining traditional medicine but it have quoted the definition provided by the WHO directly in the past.[62] The WHO defined traditional medicine as a:

> Sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.[63]

"Traditional" in this context does not mean old or untechnical. It is simply an expression of ILCs cultures and the way such communities have developed, preserved and transmitted the knowledge.[64] In industrialised countries adaptations of traditional medicine are called complementary or alternative medicine (CAM). The terms are interchangeable and are defined as follows:

> The terms "complementary medicine" or "alternative medicine" refer to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.[65]

A common example of CAM is acupuncture, a known traditional Chinese medicinal treatment.[66] CAM systems are characterized by a holistic and highly individualized approach to patient care, an emphasis on maximizing the body's inherent healing ability, involving patients as active participants in their own care, addressing physical,

---

[59] WIPO *Documenting TMK* op cit note 5 at 3.
[60] L A D Williams 'Ethnomedicine' (2006) 55 *West Indian Medical Journal* 4 at 215.
[61] Ibid.
[62] WIPO *Documenting TMK* op cit note 5 at 3.
[63] WHO *Traditional Medicine Strategy* op cit note 3 at 2.
[64] Hansen & Van Fleet *Traditional Knowledge and Intellectual Property* (2003) 3.
[65] WHO *Traditional Medicine Strategy* op cit note 3 at 15.
[66] WIPO *Intellectual Property and Traditional Medical Knowledge: Background Brief No. 6* (2016) 1.

mental and spiritual attributes of a disease, and placing a strong emphasis on preventative medicine.[67] In contrast, traditional medicine varies between geographical regions and the practices are more diverse.[68] Traditional medicine practices are governed by ILCs and as such cultural association is stronger. Traditional medicine inspires trust about its safety and efficacy when it is used in clinical settings.[69] Nonetheless both traditional medicine and CAM have been recognised by the WHO to '[have] many positive features, and that traditional medicine and its practitioners play an important role in treating chronic illnesses, and improving the quality of life of those suffering from minor illness or from certain incurable diseases'.[70]

The use of traditional medicine in this study refers to knowledge that led to the development of medicine from GRs by ILCs, which they use to treat, diagnose or prevent illnesses.

2.4 Bioprospecting, biopiracy and misappropriation

Bioprospecting is a form of access to genetic resources. According Beharie and Shabangu the term bioprospecting is 'the process of searching for new potentially valuable products when such products are based on biological resources and traditional knowledge, and then of commercialising such new products. This includes research on, or developments or applications of, indigenous biological resources for commercialisation or industrial exploitation'.[71] Bioprospectors of TK associated with GRs usually include research institutes, universities, *ex-situ* collections, and pharmaceutical, biotechnology and botanical private companies.[72]

The Namibia AGR Draft Bill makes a distinction between bioprospecting and the commercial phase of bioprospecting project. Bioprospecting is defined to mean 'an exploratory activity that aims to identify genetic resource components and information

[67] R B Abbott et al 'Medical Student Attitudes toward Complementary, Alternative, and Integrative Medicine' (2011) 2011 *Evidence Based Complementary and Alternative Medicine*, Article ID 985243 at 1.
[68] WIPO *Documenting TMK* op cit note 5 at 4.
[69] Ibid.
[70] WHO, *Fifty-Sixth World Health Assembly*, *Agenda item 14.10,* Traditional Medicine, WHA56.31 (2003) 1.
[71] Beharie op cit note 31 at 334.
[72] Greiber op cit note 39 at 4.

on associated traditional knowledge'.[73] Whereas, "commercialisation phase" of bioprospecting project means 'any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is sufficiently established to begin the process of commercialization'.[74]

Advocates of ILCs as users of GRs have challenged the legitimacy of bioprospecting projects which have in many instances involved participation of ILCs who share their TK but end up not receiving compensation for their contribution or at least, acknowledgement.[75] This type of activity is known as biopiracy.[76] Biopiracy has been described as the 'situation where traditional knowledge originating from indigenous people is used by others for profit, without permission from, and with little or no recognition of, the indigenous people'.[77] Southern African ILCs are familiar with episodes of biopiracy where bioprospectors have used TK associated with GRs and then patent their findings without recognising or sharing benefits with ILCs.[78]

Additionally, misappropriation is an act of acquiring and appropriating TK and GRs by unfair means[79] i.e. in violation of domestic ABS legislation requiring PIC and MAT.[80] Biopiracy is a form of misappropriation.[81] The IGC Document provides two possible definitions for misappropriation.[82] They are the following:

Option 1: "Misappropriation" is the [acquisition] [utilization] of genetic resources, [their derivatives] [and] [or] [traditional knowledge associated with genetic resources] without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [in accordance with

[73] S 1 of AGR Draft Bill.
[74] S 1 of AGR Draft Bill.
[75] B Ong 'Harnessing the Biological Bounty of Nature: Mapping the Wilderness of Legal, Socio-Cultural, Geo-Political and Environmental Issues' in Burton Ong (ed) *Intellectual Property and Biological Resources* (2004) 7.
[76] Ibid.
[77] Beharie op cit note 31 at 335.
[78] The patents claimed over the Hoodia plant, Rooibos and the Devils claw are examples of biopiracy.
[79] P Cullet et al 'Intellectual property rights, plant genetic resources and traditional knowledge' in S Biber-Klemm et al (eds) *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives* (2006) 211.
[80] Greiber op cit note 39 at 12
[81] B B Mathew 'Traditional knowledge Misappropriation and Biopiracy in India: A study on the legal measures to protect traditional knowledge' (2013) 2(12) *International Journal of Marketing, Financial services & Management Research* 202 at 207.
[82] IGC Document *List of Terms*.

national legislation] [of the country of origin or providing country].]

Option 2: “Misappropriation” is the use of genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources] of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

Figure 2 WIPO IGC definitions of Misappropriation

The definition of misappropriation provided under option 1 is simpler. It further provides specific requirements for the use of TK associated with GRs to be lawful, namely: obtain prior informed consent (PIC) from right holders and/or competent authority and disclose source and country of origin, which must be met for the use. However, option 2 is broader in scope and refers specifically to what an act of misappropriation would be, namely: breach of contract and violation of national law. What is mean by ‘improper means’ is not clear from the definition but one can deduce that it can be any act that is in violation of any statute or regulation in place to protect TK associated with GRs from misappropriation. Option 2 laudably includes what lawful use or acquisition of TK associated with GRs and its derivatives are and provides a list of lawful means to acquire TK associated with GRs. This, however, creates a positive obligation on right holders to provide ‘reasonable protection measures’. This provision may introduce practical challenges for ILCs.

It is my view that a combination of option 1 and the first portion of option 2 where misappropriation is defined can result in a sound final definition. Furthermore, the use of the term misappropriation in this study means the use of TK associated with GRs or its derivatives without PIC, disclosing of the country of origin or providing country or an access and benefit-sharing agreement.

2.5 Access and benefit-sharing

In response to increasing interest in the actual and potential wealth of *in situ* GRs, access to GRs and the fair and equitable sharing of the benefits arising out of their utilisation was introduced as the third objective of the CBD.[83] ABS is a complex concept and in order to provide adequate understanding of the concept one has to divide it into two parts, (i) access and (ii) benefits.

i. Access

There is no definition of access to GRs in the CBD nor the Nagoya Protocol but Namibia has provided a definition for access to GRs in the AGR Draft Bill. It is worthy to note that the AGR Draft Bill makes a distinction between access to GRs and access to TK. Access to GRs to means:

> [T]he acquisition of samples of genetic resource components for the purpose of scientific research, technological development, or bioprospecting, with a view to their industrial or other applications, including through the application of biotechnology.[84]

Whereas access to traditional knowledge means:

> [T]he acquisition of traditional knowledge for the utilization thereof in research or development of genetic resources.[85]

Article 15(1) of the CBD recognises that governments have the authority to regulate physical access to GRs within their jurisdictions.[86] It is important, however, to note that the CBD does not vest ownership over those GRs in the State.[87] Ownership over GRs is left to be decided by national laws which include both common law and customary law.[88] Article 15(2) of the CBD further requires Member States to provide favourable conditions in the endeavour of providing access to GRs:[89]

---

[83] Art 1 of the CBD. See also Greiber op cit note 39 at 4.
[84] S 1 of the AGR Draft bill.
[85] Ibid.
[86] Art 15 of the CBD. Greiber op cit note 39 at 8.
[87] L Glowka et al *A Guide to the Convention on Biological Diversity* (1994) 76.
[88] Greiber op cit note 39 at 8.
[89] Art 15(2) of the CBD.

> [T]o facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.[90]

This sub-article grants discretionary powers to States to decide what 'environmentally sound uses' are but it is safe to assume that States are required to provide the support necessary for potential users to access GRs.[91] It is understood that the 'logic behind art 15(2) of the CBD is that fair and equitable sharing of benefits can only be realized after access to genetic resources has actually been granted'. [92]Access is not allowed to all GRs in terms of art 15(3) of the CBD which states that:

> For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are *countries of origin* of such resources or by the Parties that have *acquired the genetic resources in accordance* with this Convention'.

Two categories of GRs emerge from this article, GRs from 'countries of origin' and GRs 'acquired the genetic resources in accordance' with the CBD, which will entitle a provider (the State) of GRs to benefit under the CBD.[93] Access to either GRs can only be granted subject to the PIC[94] of a State providing the GRs, unless otherwise determined by that State under art 15(5) of the CBD. This access will only be granted on 'mutually agreed terms' (MAT)[95] between the provider and the potential users.[96] The use of MAT by the CBD suggests that negotiations take place between the provider and the potential user. The MAT are to be negotiated on a case-by-case basis.[97]

According to *An Explanatory Guide to the Nagoya Protocol* PIC and MAT are means of enabling States to 'authorize access to genetic resources; control their subsequent use; and establish the fair and equitable sharing of benefits from their subsequent use'.[98] PIC simply means potential users should inform those (State or

[90] Art 15(2) of the CBD.
[91] Greiber op cit note 39 at 8.
[92] Ibid.
[93] Greiber op cit note 39 at 8.
[94] Hereinafter referred to as PIC.
[95] Hereinafter referred to as MAT.
[96] Art 15(4) of the CBD.
[97] Greiber op cit note 39 at 10.
[98] Greiber op cit note 39 at 9.

ILCs) that will be affected and those authorised to make decisions prior to accessing GRs in order for them to make an informed decision.[99] The *Guide* further explains the concept of PIC within the context of ABS which entails the following:

i. '[T]he provider who makes the genetic resources available gives his/her consent through an affirmative act;
ii. this decision (affirmative act/consent) is based on information provided by the potential user of the genetic resources; and
iii. the information is provided prior to the actual decision (affirmative act/consent) that grants access'.[100]

However, it remains the prerogative of the State to decide whether or not to have a PIC system in place because art 15(5) of the CBD states 'unless otherwise determined by that [S]tate'.[101] This provision reiterates the sovereign rights of States over GRs as recognised under art 15(1) of the CBD. This does not mean States are exempted from the obligation to allow access to GRs.[102]

The use of the term "access" to TK associated with GRs is essentially a marriage between PIC and MAT which must be ordained by the State and ILCs the result of which must lead to benefits. A bioprospector who requires access to GRs and TK must meet the aforementioned requirements to obtain such access. Access contrary to PIC and MAT is illegal and could lead to misappropriation.

ii. Benefit

The Namibian AGR Draft Bill defines benefits as 'arising from the economic use of the product or process developed from genetic resources or from associated traditional knowledge'.[103] The CBD does not define benefits but it is clear from the wording of art 15 (7) that there are easily identifiable benefits that Member States can regulate through legislature, administrative or policy measures. The object of such measures is to share in a fair and equitable manner the benefits arising from access to GRs.[104]

[99] Ibid.
[100] Greiber op cit note 39 at 9.
[101] Art 15(5) of the CBD.
[102] Glowka op cit note 87 at 81.
[103] S 1 of the AGR Draft bill.
[104] Art 15(7) of the CBD.

There are numerous forms of benefits. Benefits such as R&D results;[105] commercial or other benefits derived from utilising the GRs provided;[106] access to and transfer of technology using the GRs;[107] participation in all types of scientific research based on the GRs;[108] participation in biotechnological research activities based on the GRS;[109] priority access to the results and benefits arising from biotechnological use of the GRs.[110] These benefits must all be part of MATs.[111] The inclusion of benefits in MATs bounds the user to compensate the provider for allowing access to GRs and associated TK.

2.6 Patentable traditional medicine inventions

The law of patents is a statutory regulated system which provides protection for inventions as opposed to discoveries.[112] These inventions must further meet the requirements of novelty (new); involve an inventive step (non-obvious) and be industrially applicable.[113] The patentee is granted a monopoly right to prevent others from exploiting his or her invention for a fixed period of time.[114] In return the patentee is required to fully disclose the invention to enable third parties to exploit the invention once the protection period has lapse. A patent is territorial in nature in that patent protection will only apply in the country where the patent was applied for and granted.[115] This means a patentee needs protection in other territories; he or she will need to file patent applications in the chosen territories.[116]

Due to its inherent characteristics traditional medicine may encounter problems meeting the patent requirements, mainly because the threshold for the requirements of novelty and non-obviousness are not easily met.[117] The concept of novelty simply

[105] Ibid
[106] Ibid.
[107] Art 16(3) of the CBD.
[108] Art 15(6).
[109] Art 19(1).
[110] Art 19(2).
[111] Art 15(7).
[112] Ebermann op cit note 11 at 117.
[113] Art 27(1) of the TRIPS Agreement.
[114] T Grant 'Patents' in Owen Dean & Alison Dyer (eds) *Introduction to Intellectual Property Law* (2014) 239.
[115] Grant op cit note 114 at 239.
[116] Ibid. See also The Patent Cooperation Treaty (1990), which is a system in place to facilitate applicants seeking patent protection internationally for their inventions.
[117] Ebermann op cit note 11 at 117.

determines that the state of the art invalidates a patent in that all subject matter made available in public forms part of the state of the art and therefore, it prevents patents to be granted for inventions that already exist.[118] On the other hand, the requirement of non-obviousness examines whether the invention is obvious to a person skilled in the art, if the answer is in the affirmative the invention is not patentable.[119] The last requirement of industrial applicability is straightforward in that the invention must be able to be used or applied in trade or industry.[120]

The test for novelty and non-obviousness is discussed in depth in the chapters three and four below and how these patent requirements are applied to traditional medicine is also discussed below.

2.7 Disclosure requirement

At the core of the patent system is the disclosure requirement because the grant of a patent and the effective use of such rights are anchored on the principle of sufficient disclosure.[121] Moreover, the disclosure requirement is an integral aspect of any relationship that may exist between patents and TK associated with GRs. The disclosure requirement is a possible means to prevent misappropriation of TK associated with GRs. This is so because it could be used to impose a condition that a patent may not be granted involving a traditional medicine invention without also disclosing the source of the TK and GRs and the country of origin.[122] This is so since misappropriation has been defined for purposes of this study to mean the use of TK associated with GRs or its derivatives without, *inter alia*, "disclosing of the country of origin or providing country". Although, the definition of misappropriation does not sufficiently include all factors that must be disclosed it still recognises that some form of disclosure is necessary to prevent misappropriation.

Also, it can be a tool to improve ABS agreements, thereby creating a positive relationship between patent legislation and legislation regulating access to GRs and

[118] W M Landes *The Economic Structure of Intellectual Property Law* (2009) 303.
[119] Ebermann op cit note 11 at 119.
[120] Grant op cit note 114 at 251.
[121] WIPO IGC, *Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge,* Study No. 3 (2004) 65 (WIPO *Technical Study*).
[122] Ibid, 30.

associated TK.[123] The nature of the disclosure requirement may shape policy considerations that may clarify and strengthen this interaction between patents and TK associated with GRs. Consequently, it is necessary to define and analyse what triggers a disclosure requirement.

Disclosure requirement is a term used to describe:

> [R]eforms made to patent law at national, regional or international level, which would specifically require patent applicants to disclose several categories of information concerning TK and/or GRs when these are used in developing the invention claimed in the patent application.[124]

The IGC identified three broad functions that must be considered for disclosure methods relating to TK associated with GRs, specifically:

i. [T]o disclose any GRs/TK actually used in the course of developing the invention (a descriptive or transparency function, pertaining to the GR/TK itself and its relationship with the invention);
ii. to disclose the actual source of the GR/TK (a disclosure of origin function, relating to where the GR/TK was obtained) – this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that GRs can be accessed, so as to ensure the invention can be duplicated or reproduced);
iii. to provide an undertaking or evidence of PIC (a compliance function, relating to the legitimacy of the acts of access to GR/TK source material) – this may entail showing that GR/TK used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording the PIC; or showing that the act applying for a patent was in itself undertaken in accordance with PIC.

These methods form the basic building blocks to formulate a disclosure requirement provision, although it is not intended to be exhaustive nor comprehensive.[125] These disclosure methods, nonetheless, are intended to set the development and

[123] WIPO *Technical Study* op cit note 121 at 30.
[124] WIPO IGC*, Glossary* op cit note 44.
[125] WIPO *Technical Study* op cit note 121 at 65.

application of the disclosure requirement in a practical and operational manner.[126] All three disclosure methods are integrated in the IGC Document which provides for a mandatory disclosure requirement provision. Article 3 of the Document reads as follows:

> Where the [subject matter] [claimed invention] within a [IP Rights] [patent] application [includes utilization of] [is directly based on] [is directly based on the utilization of] genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] each Party shall/should require applicants to:
>
> a) Disclose the [providing country that is the country of origin] [country of origin [and]] [or [if unknown],] source of the genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources.]
> b) [Provide relevant information, as required by national law, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]
> c) [If the source and/or [providing country that is the country of origin] [country of origin] is not known, a declaration to that effect].

It is the opinion of some developed countries that this mandatory disclosure requirement would introduce uncertainty into the patent system and would make the implementation of benefit-sharing complicated.[127] Whereas, most developing countries maintain that the disclosure requirement must be mandatory not only for patent but also for other IP rights.[128] These opposing views were evident when the European Union suggested that the obligation to disclose must only be triggered if an applicant had actual physical access to the GRs and associated TK that they have used subsequently.[129] A delegate from Namibia opposed this view and emphasised that due to rapid evolution of genetic manipulation and sequencing of genomes

[126] WIPO *Technical Study* op cit note 121 at 65.
[127] C Saez 'WIPO Members Debate Disclosure of Origin for GRs in Patents' *IP Watch* 17 Feb 2016, available at http://www.ip-watch.org/2016/02/17/wipo, last accessed 16 December 2016.
[128] Ibid.
[129] Ibid.

physical access to GRs would become unnecessary, thus disclosure must be mandatory.[130]

Further discussions around the triggers of the disclosure requirement are explored further in chapter three under part three of this thesis. Needless to say, the current international discussions of the disclosure requirement relating to TK associated with GRs are dynamic and fairly complex. Formulating a comprehensive legal provision that appreciates the complex nature of the disclosure requirement plays a central role in how patents would interact with TK associated with GRs.

2.8 Case studies of patents granted for traditional medicine inventions in Southern Africa

Hypothetical scenario

Cisko Ltd is a pharmaceutical company from the United Kingdom carrying out a research project to confirm whether the traditional knowledge that Kanna (*Sceletium tortuosum*) extracts work to treat depression and anxiety. This TK is derived from the San community from Southern Africa who have used this plant for decades as a mood enhancer giving them a sense of happiness and calmness. It is also used to lessen cravings and drug use related withdrawal symptoms. After further studies Cisko Ltd develops a new formula that isolates the Kanna extracts and successfully applies for a patent for the use of the Kanna extracts and the new formula for treating depression and anxiety.

Figure 3 Hypothetical scenario

The hypothetical scenario illustrates how bioprospectors acquire TK relating to GRs from traditional communities, and how they employ the traditional uses of the GRs in their drug R&D. The result of the R&D is patented without any PIC, ABS agreement in place or acknowledgement of the relevant ILC. The purpose of this hypothetical is to shed light on how patents relating to TK and associated GRs take place in practice because this scenario is based on true events.

[130] Ibid.

In addition, the scenario is used in this study to argue that traditional medicines need not be subject to patent applications that are a result of biopiracy. Bioprospectors can adhere to national legislative requirements to obtain PIC from the relevant ILC and the state, agree on an ABS scheme based on MAT. This will ensure that successful leads to biochemical screening for drug discovery carried out by pharmaceutical companies and profits made from it can flow back to the ILCs. In doing so, the patenting of traditional medicine inventions does not have to stop the protection TK associated with GRs enjoys. It also does it inhibit interaction and coexistence of TK associated with GRs with patent laws. Below are two case studies under which TK associated with GRs has been used in patent inventions.

2.8.1 Hoodia gordonii

Hoodia gordonii commonly known by the colloquial term '*!Khoba'* or '*Ghaap*' is a cactus-like plant that grows in Southern Africa including Namibia, South Africa and Botswana.[131] For centuries the San community used the flesh of the hoodia plant to suppress hunger and thirst.[132] For medicinal purposes it was consumed to treat abdominal pain associated with peptic ulceration.[133] The knowledge of the traditional uses of the hoodia plant was first published by colonial botanists.[134]

A South African-based Council for Scientific and Industrial Research (CSIR) discovered that specific extracts of the hoodia plant were active in suppressing appetite.[135] In 1997, after isolation, synthetisation and development, the CSIR patented the use of the plant's active constituents responsible for suppressing appetite.[136] This was done without the authorisation and PIC from the San community the original holders of the TK associated to the hoodia plant.[137]

[78131] R Wynberg 'Rhetoric, Realism and Benefit-Sharing' (2005) *Journal of World Intellectual Property* at 1.

[132] Ibid.

[133] I Vermaak & A Viljoen 'Indigenous South African Medicinal Plants Part 9: Hoodia Gordonii' (2008) *SA Pharmaceutical Journal* at 37.

[134] R Wynberg 'Bioprospecting, Access and Benefit-Sharing in South Africa: Towards a Strategic Assessment' (2004) *National Botanical Institute* at 31.

[135] S Holt & T V Taylor 'Hoodia Gordonii: An Overview of Biological and Botanical Characteristics: Part I' (2006) *Townsend Letter for Doctors and Patients* at 107.

[136] R Wynberg & J Silveston et al 'Value adding in the Southern African Natural Products Sector: How much do Patents Matter?' in WIPO *The Economics of Intellectual Property in South Africa* (2009) at 42.

[137] Wynberg op cit note 134 at 31

In 1998, the CSIR entered into an exclusive licensing agreement with an English biopharmaceutical company Phytopharm.[138] As exclusive licence holders Phytopharm could manufacture and market products derived from the hoodia plant and exploit other aspects of the CSIR's intellectual property rights (IPRs) relating to the hoodia plant.[139] Phytopharm entered into a further licence and royalty agreement with Pfizer, the pharmaceutical giant.[140] Pfizer discontinued development of the hoodia plant and Phytopharm to enter into an agreement with Unilever.[141] In 2008, Unilever also pulled out from the agreement and discontinued development of 'P57'.[142]

From 2001 to 2002, CSIR received heavy criticism for exploiting the San's TK. After which the South African San Council - representing the San communities from Namibia, South Africa and Botswana - was mandated by the Working Group of Indigenous Minorities in Southern Africa (WIMSA) to enter into negotiations with CSIR.[143] The negotiation led to one of the first benefit-sharing agreements that would give ILCs a 6 per cent share of royalties from successful commercialisation of the hoodia plant.[144] Consequently, the San Hoodia Benefit Sharing Trust was established.[145]

By 2006 illegal trade had escalated to high levels 'from just 25 tons in 2004 to more than 60 tons of wet, harvested material per year, sold as ground powder for incorporation into non-patented dietary supplements'.[146] Vigilant regulation of illegal products on the part of the American Herbal Products Association and permit systems introduced in South Africa, Namibia and Botswana for harvesting of the hoodia plant led to the rapid decrease of the illegal exporting of hoodia products. As, a result those involved in growing commercial hoodia on high quantities negotiated

[138] R Wynberg 'Green Diamonds of the South: An Overview of the San- Hoodia Case Equitable' in R Chennells (ed) *Access to Human Biological Resources in Developing Countries: Benefit Sharing Without Undue Inducement* (2015) at 95.
[139] Ibid.
[140] Ibid.
[141] Wynberg op cit note 138 at 96.
[142] Wynberg op cite note 138 at 97.
[78143] Ibid at 102.
[144] R Wynberg 'Bioprospecting delivers limited benefits in South Africa' (2004) *EIPR* 239 at 6.
[145] Beharie op cit note 31 at 340.
[146] Wynberg op cit note 138 at 112.

another benefit-sharing agreement with the San, based on a levy on processed Hoodia.[147]

2.8.2 Sceletium tortuosum

Sceletium tortuosum is the subject matter of the hypothetical scenario discussed above. The bioprospecting of the *sceletium tortuosum* plant by foreign pharmaceutical companies is not hypothetical. Accordingly, the *sceletium tortuosum* known by the San community as '*Kanna*' grows in South Africa.[148] The San community originally held the TK associated with GR but overtime the TK of its mood enhancing properties spread to other ILCs such as the Nama community.[149] *Sceletium tortuosum* has been described as reducing anxiety, causing relaxation and mellowness with no cognitive impairment.[150] It is also said to be good for stomach ailments, relief for jaw pains including pain in general, and treatment for substance dependency.[151] The Namaqua people from lower parts of Namibia are also known to use Kanna in tea to alleviate hunger and for minor pains.[152]

A South African-born medical doctor named Nigel Gericke used the TK associated with GR with the assistance of Nama-speaking traditional healers from Nourivier and Paulshoek villages in the Northern Cape.[153] Dr Gericke established HGH Pharmaceuticals in Johannesburg.[154] Ever since then, HGH Pharmaceuticals acquired seven patents, including a patent in the United States of America, and registered two trademarks, namely Zembrim and Eletium, while using the San logo on their products.[155] HGH Pharmaceuticals is currently the only legal permit holder issued in terms of NEMBA and Bio-Prospecting, Access and Benefit Sharing

[147] Ibid.
[148] R Chennells 'Traditional Knowledge and Benefit Sharing After The Nagoya Protocol: Three Cases From South Africa' (2013) 9/2 *LEAD Journal* at 170.
[149] Ibid.
[150] A Lubbe & A Khatib et al 'Cannabinoid CB1 receptor binding and acetylcholinesterase inhibitory activity of Sceletium tortuosum L' (2010) 17 *International Food Research Journal* at 349.
[151] Ibid.
[152] M T Smith & N. Gericke et al 'Psychoactive Constituents of the Genus Sceletium N.E. Br. and Other Mesembryanthemaceae: A Review' (1996) 50 *Journal of Ethnopharmacology* 119–130.
[153] Chennells op cit note 148 at 170.
[154] S Carey 'A South African herb that may rival Prozac' *Zembrin* available at http://www.zembrin.com/2013/02/11/a-south-african-herb-that-may-rival-prozac/ last accessed on 20 November 2016.
[155] L Tshitwamulomoni 'South African Case Study on Sceletium Tortuosum' *Expert Meeting on ABS and Intellectual Property Rights Addis Ababa,* Ethiopia 5-9 September 2011 at 6.

regulations to research, export and commercialise the proprietary *sceletium tortuosum* extract Zembrin.[156] The patent for Zembrin extract of the *sceletium tortuosum* is 'for the treatment of depression, anxiety, alcohol and drug dependence, bulimia nervosa and obsessive-compulsive disorder'.[157]

The use of Zembrin is the same or similar to the traditional uses of *sceletium tortuosum,* thus HGH Pharmaceuticals acknowledged the San community as 'the "primary knowledge holders" of the TK', and resulting in an ABS agreement between the HGH Pharmaceuticals and the South African San Council.[158] The San community further acknowledged the Paulshoek and Nourivier Community as second beneficiaries.[159] Subsequently the Council also entered into an ABS agreement with the Paulshoek and Nourivier Community.[160] The benefits will be a fixed value for three years, which consist of 6 per cent of net proceeds including a percentage for the use of the San logo as a trademark by HGH Pharmaceuticals.[161] Thus, 50 per cent of the royalties received by the San community will be paid to the Paulshoek and Nourivier Community.[162] In 2008, an advance has been paid out annually in lieu of royalties.[163] Zembrin was released in the formal market in 2013 and won the Most Sustainable Ingredient Award an international award in the same year.[164]

2.9 Conclusion

This chapter has revealed the complexity of concepts and issues that relate to patents of traditional medicine inventions and TK associated with GRs. It also illustrates the dependency and interrelation of all the concepts discussed above. Of particular importance is the role ILCs play in the formation of TK and because of their close connection to biodiversity they hold actual and potential knowledge about GRs.

---

[156] Expert Meeting on *ABS and Intellectual Property Rights Addis Ababa, Ethiopia* 'Details of the Workshop' 5-9 September (2011) (Expert Meeting).
[157] Lubbe op cit note 150 at 349.
[158] Chennells op cit note 148 at 170.
[159] Expert Meeting op cit note 156 at 5.
[160] Expert Meeting op cit note 156 at 5.
[161] Ibid.
[162] Ibid.
[163] Chennells op cit note 148 at 170
[164] D Totten 'Local Product Wins International Award' (2013) *The South African Journal of Natural Medicine* 102.

Although the definitions of TK associated with GRs are still heavily bracketed from the IGC Document and could be changed what remains undeniable is that traditional medicine is the product of the connection between ILCs and GRs. The interest of bioprospectors in GRs and associated TK is responsible for the creation of concepts such as the PIC, MAT and ABS agreements which are measures implemented to confront misappropriation of TK and GRs. Misappropriation i.e. biopiracy, of TK associated with GRs leading to the patenting of pharmaceutical products derived from or based TK associated with GRs is a common occurrence.

However, as illustrated by the *hoodia* and *sceletium tortuosum* case studies patenting of drugs or other products derived from these two plants does not necessarily lead to negative outcomes. If regulated properly and based on PIC, MAT, ABS and the disclosure requirement, patents of traditional medicine inventions can lead to real benefits for ILCs and the local economy. The disclosure requirement proves important for the elimination of misappropriation. It is also true that traditional medicine patent applications may experience some problems with the patentability requirements, particularly the novelty and inventive step requirements. However, if, for example a pharmaceutical product influenced by traditional medicine is new and non-obvious, it can still be patented.

CHAPTER 3: INTERNATIONAL AND REGIONAL FRAMEWORK

3.1 Introduction

This chapter aims to introduce the international and regional framework, which regulates the protection of TK associated with GRs in general and Namibia's efforts in particular, in the context of the patenting of traditional medicine inventions. It provides the framework for the more detailed analysis of the Namibian system, which follows in Chapter 4. To this end, it discusses international standards of patent law, TK and GRs, which are relevant to the definitions of key concepts discussed in Chapter 2. This chapter further breaks down contentious international discussions underway at the IGC surrounding TK and associated GRs and their interaction with intellectual property rights, particularly patent rights, in the context of medicinal uses of GRs and associated TK and what that means for Namibia. This chapter is divided into three parts, namely the international instruments, regional instrument and the IGC text-based negotiations.

3.2 Part 1: The current international framework

3.2.1 The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

The Declaration on the Rights of Indigenous Peoples of 2007[165] is wide-ranging but contains some articles relevant to TK and its protection. The Declaration recognises the right of indigenous peoples 'to maintain, control, protect and develop', *inter alia*, TK 'as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora…'.[166] This is a property-based approach of TK.[167] The Declaration further articulates the duty of States to 'consult and cooperate in good faith with the indigenous peoples concerned through their own representative

[165] *The Declaration on the Rights of Indigenous Peoples*, UNGAOR, 61st Session, UN Doc A/61/L.67 (2007).
[166] Art 31 of the UNDRIP
[167] Bubela op cit note 48 at 7.

institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures' that may affect indigenous peoples.[168] The States must take positive steps to recognise and protect such rights.[169] The purpose of this study is to recommend legal reform as far as TK and GRs is concerned, thus it is imperative for the Namibian government to take account its duty to recognise ILCs rights to TK and actively include them should the government decide to change or make any law regarding TK.

3.2.2 *The Convention on Biological Diversity, the Bonn Guidelines and the Nagoya Protocol*

More specific international framework for the conservation and sustainable use of biological resources is the CBD,[170] a legally binding international treaty.[171] It is founded on three objectives: the conservation of biological diversity, sustainable use of its components, and the fair and equitable sharing of the benefits arising out of using GRs, which should include appropriate access to GRs and appropriate transfer of technologies having regard to all rights over those resources, technologies and by appropriate funding.[172] Namibia became a party to the CBD by ratification in 14 August 1997 and as such, it is obliged to uphold the three objectives of the CBD.[173]

Article 15 of the CBD reaffirms a long-standing international legal principle of State sovereignty over biological resources within its territorial boundaries. This right rests on the State, which has the duty to develop national legislation to ensure access to GRs results in fair and equitable sharing of benefits arising from the commercial and other uses of GRs with their ILCs.[174] However, PIC and MAT act as prerequisites for access to GRs.[175] The CBD presumes that access to GRs is

---

[168] Art 19 of the UNDRIP.
[169] Art 31(2).
[170] Convention on Biological Diversity, Rio de Janeiro on 5 June 1992 and entered into force on 29 December 1993.
[171] CBD 'History of the Convention' available at *https://www.cbd.int/history/* last accessed 21 September 2016. Many aspects of the CBD were discussed when the definitions where set out in Chapter 2.
[172] Art 1 of the CBD.
[173] CBD 'Namibia: Country Profile' available at *https://www.cbd.int/countries/default.shtml?country=na* last accessed on 21 September 2016.
[174] Art 15(7) of the CBD.
[175] Art 15(4) & (5).

granted in exchange for transfer of technologies, rights over resources and appropriate funding.[176]

Most importantly, the CBD recognises how central ILCs are in the promotion of *in situ* conservation and sustainable development of biodiversity and obliges States, as far as possible, to 'protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements'.[177]

Further, art 8(j) requires States to - subject to national legislation- 'respect, preserve and maintain knowledge, innovations and practices of ILCs embodying traditional lifestyles' which are 'relevant for the conservation and sustainable use of biological diversity'. This is intended to 'promote their wider application' subject to the 'approval and involvement' of ILCs.[178] The result of these measures is to 'encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices'.[179]

While the CBD entered into force in 1993, earnest operation of these provisions above only materialised in 1999.[180] The result is the Bonn Guidelines. The purpose of the Bonn Guidelines is to assist States in the ABS process,[181] with particular emphasis on the obligation of potential users to acquire PIC of providers.[182] The Guidelines identify the basic requirements for MAT, define the main role and responsibilities of users and providers, and stress the importance of the involvement of all stakeholders.[183]

Although, the Bonn Guidelines are a step in the right direction, they are not legally binding[184] and were not accepted as a final and sufficient guidance.[185] This led to the Nagoya Protocol, which was adopted in 2010 after years of discussions

[176] Art 1 of the CBD.
[177] Art 10 (c).
[178] Art 8(j).
[179] Art 8(j).
[180] Secretariat of the Convention on Biological Diversity *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (2002) at III.
[181] Ibid p IV, see also art 11(1) Bonn Guidelines.
[182] Ibid art 13 A.
[183] Ibid p IV.
[184] Ibid.
[185] Greiber op cit note 39 at 19.

and negotiations.[186] The Nagoya Protocol received all deposits of ratification and accession required and entered into force on 12 October 2014.[187] Namibia ratified the Nagoya Protocol in 15 May 2014.[188]

Moreover, art 5 of the Nagoya Protocol echoes the sentiments of article 15 of the CBD discussed above. Article 6 of the Nagoya Protocol provides access to GRs, however, for purposes of this study art 7 is of particular importance. Article 7 calls on States to take measures in accordance with domestic law aimed at 'ensuring that TK associated with GRs…held by ILCs is accessed with the PIC or approval and involvement of these ILCs, and that MAT have been established'.[189]

The Nagoya Protocol reiterates the relationship between TK and GRs and the essential role of ILCs in this relationship. States are also required in terms of art 12 to take into consideration the customary laws, community protocols and procedures' of ILCs with respect to TK associated to GRS when translating the obligations of the Protocol into domestic laws. Some care must be taken by States 'not to restrict the customary usage and exchange of GRs and associated TK within and amongst ILCs in accordance with the objectives of the CBD'.[190]

More importantly, the Nagoya Protocol further addresses enforcements mechanisms in art 12*bis* which relates to TK and associated GRs, including 'situations of non-compliance' and 'cooperate in cases of alleged violation of domestic ABS legislation or regulatory requirements'.[191] The Nagoya Protocol has provided significant advances for the protection of TK and associated GRs, albeit the subject of TK protection remains unresolved on the international level.

Like the UNDRIP, the CBD and the Nagoya Protocol reiterate the importance of involving ILCs when it comes to access to GRs and associated TK. The CBD and more specifically the Nagoya Protocol introduced principles such as PIC, MAT and ABS, defined in Chapter 2, as essential factors in protecting TK and GRs, on the one

---

[186] Bubela op cit note 48 at 9.
[187] CBD 'The Nagoya Protocol on Access and Benefit-sharing' available at *https://www.cbd.int/abs/* last accessed 21 September 2016.
[188] CBD 'Parties to the Nagoya Protocol' available at *http://www.cbd.int/abs/nagoya-protocol/signatories/* last accessed 21 September 2016.
[189] Art 7 of the Nagoya Protocol.
[190] Art 12 (4) of the Nagoya Protocol.
[191] Art 12*bis* (2) & (3) Conference of the Parties to the CBD, *Report of the Seventh Meeting of the Conference of the Parties to the CBD*, UNEP/CBD/COP/7/21 (Montreal: CBD Secretariat, 2004) Annex I (Decision X/1).

hand and regulating access to them, on the other hand. However, whilst recognising the relationship between TK and GRs and access thereto, the Nagoya Protocol failed to clarify the instance under which the GRs and associated TK – i.e. traditional medicine – is used in an invention subject to a patent application.

Nonetheless, Namibia's obligations under the CBD and the Nagoya Protocol are reflected in the AGR Draft Bill. It is important to note here that both the CBD and the Nagoya Protocol requires that Namibia take legislative measures to protect and preserve GRs and TK. However, they also require that such measures must be taken to ensure access to GRs and associated TK.[192] This shows that protection for TK and GRs is not absolute, and that such protection is subject to access based on PIC, MAT and the involvement of ILCs.[193] This creates a balance between protection and access, which is a fundamental aspect of this study's argument that access and use of TK associated with GRs does not stop the protection they enjoy.

3.2.3 The TRIPs Agreement

The TRIPS Agreement is built on the principles of most-favoured-nation treatment and national treatment.[194] It further establishes a broad set of minimum international standards which is binding on all members of the World Trade Organization (WTO).[195] TRIPS sets these standards by requiring that the substantive obligations under the main conventions of the WIPO such as the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions must be complied with.[196] The Paris Convention regulates a number of IPRs, namely; patents, trademarks, unfair competition, industrial designs, utility models, geographical indications, trade names, to trade secrets within the context of

[192] [189]Art 7 of the Nagoya Protocol.
[193] Ibid.
[194] Art 3 & 4 of the TRIPS Agreement.
[195] J H Reichman 'The Know – How Gap in the TRIPS Agreement: Why Software has Fared Badly, and what are the Solutions' (1995) 17 *Hastings Communication and Entertainment Law Journals* 7 at 765. See also Art 9 – 40 of the TRIPS Agreement.
[196] Art 2.1 of the TRIPS Agreement.

unfair competition, but not copyright.[197] Thus, the Paris Convention is relevant to this discussion; however, referring to it specifically is unnecessary as provisions specific to patents in the Paris Convention were carried over to TRIPS.

Proponents of TRIPS argued that developing countries who signed on would enjoy two kinds of gains. First, there would be incentive for research and development and invention from local companies leading to the strengthening of potential investment.[198] Second, companies and patent holders from developed industrialised countries would be more likely to invest in developing countries and/or facilitate technological transfer provided they implement stronger IPRs.[199] Opponents of TRIPS argued that for many sectors IP did not matter much and that TRIPS would have no effect.[200]

Nonetheless, the TRIPS Agreement mattered significantly for the pharmaceutical industry as lobbyists of big pharma from the United States of America and Europe played a powerful role in the establishment of TRIPS.[201] Since the ratification of TRIPS, developing countries have frequently sought amendments. In order for patent applications based on or derived from biological resources and TK to provide disclosure of the source and country of origin of the biological resources and TK, evidence of PIC through appropriate authorities and evidence of fair and equitable benefit sharing.[202] These are measures aimed at preventing misappropriation of TK and represent legally binding defensive protection against 'bad patents'.[203] The WTO has generally refused such amendments.[204] The TRIPS Agreement has been described, elsewhere, as having a narrow understanding of TK

[197] S M Reiss *Commentary on the Paris Convention for the Protection of Industrial Property,* 2010 available at *http://www.lex-ip.com/Paris.pdf;* last accessed on 21 September 2016.
[198] S Mani & R R Nelson (eds) *TRIPS Compliance, National Patent Regimes and Innovation* (2013) 1.
[199] Ibid.
[200] Mani op cit note 198 at 3.
[201] Ibid at 4.
[202] WTO 'TRIPS Review Article 27(3) and Related Issues: Background and Current Situation' available at *http://www.wto.org/english/tratop_e/trips_e/art27_3_background_e.htm*; last accessed 14 February 2017. See also S Twarog 'Protecting And Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions' in Twarog S & Kapoor P (eds) *UNCTAD Summary Publication Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions* (2004) 62.
[203] Twarog op cit note 202 at 62.
[204] Bubela op cit note 48 at 72.

as it tends to favour the economic interests of developed countries and has little to no recognition for the value of preserving TK.[205] In direct contrast to the CBD.

Therefore, it comes as no surprise that there have been divergent views between developed and developing countries regarding patent protection.[206] Concerns of the fundamental difference between the developed and developing countries led to incorporating a number of flexibilities within the TRIPS Agreement.[207] These include (i) the transition period;[208] (ii) compulsory licencing;[209] (iii) public and non-commercial use of a patent;[210] (iv) parallel importation;[211] (v) exception to patents rights;[212] and (vi) exemptions from patentability.[213] The TRIPS flexibilities are described as essential tools to economic development for developing countries.[214] The exemption from patentability flexibility is of particular importance to this discussion and will be expanded on below.

Exemptions from patentability simply mean that a subject matter is excluded from protection which results in an unsuccessful patent application.[215] In terms of article 27 (1) of TRIPS patent protection must be extended to all inventions without discrimination to any field of technology. This article also sets out the criteria of novelty, inventive step, and industrial applicability for an invention to be granted patent protection. The terms 'novelty', 'inventive step', and 'industrial applicability' are not defined under TRIPS and therefore, members of the WTO have the flexibility to determine the scope of patentability for inventions.[216]

Article 27(3) of the TRIPS Agreement allows countries to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'; plants, and animals other than micro-organisms, and essentially

---

[205] Bubela op cit note 48 at 72
[206] Ibid.
[207] Mani op cit note 198 at 4.
[208] Art 65 of the TRIPS Agreement.
[209] Art 31.
[210] Art 31(b).
[211] Art 31.
[212] Art 30
[213] 27.2 & 27.3
[214] Tejan-Cole 'A Flexibilities in The Trips Agreement and Its Impact on National Intellectual Property Policy' available at *http://www.belipo.bz/wp-content/uploads/2011/12/TRIPS-FLEXIBILITIES.pdf*; last accessed on 30 September 2016.
[215] Musungu op cit note 19 at 58.
[216] Cole op cit note 214 at 59.

biological processes for their production.[217] From the definition of biological resources in chapter 2, one can deduce that patents of inventions that are based on or derived from traditional medicine can be granted provided that they are not 'essentially biological processes'. The TRIPS Agreement does not exclude from patentability GRs, which is isolated or in a purified form neither does it exclude GRs genome or germplasm.

The TRIPS Agreement identifies enforcement mechanisms in Part III, which obliges Members to adopt effective action against any infringement of IPRs covered under TRIPS including speedy remedies.[218] This enforcement includes civil[219], administrative[220] and criminal procedures and remedies.[221] Nonetheless, Members can decide on their own legal system.

3.3 Part 2: The current regional instrument

3.3.1 The Swakopmund Protocol

The Swakopmund Protocol is an IP instrument tailor made in such a way that legal protection fits 'the specific characteristics' of TK and TCE. The Swakopmund Protocol[222] was adopted August 2010, at a Diplomatic Conference in Swakopmund, Namibia under the auspices of the African Regional Intellectual Property Organisation (ARIPO). The Protocol was signed by nine African states,[223] including Namibia, and expected to come into force three months after six states have deposited their instruments of ratification or accession.[224] The main purpose as the Protocol expresses is to provide protection for TK holders and custodians against infringement and acts of 'misappropriation, misuse and unlawful exploitation beyond their traditional context'.[225] The Protocol appreciates the 'dynamic and evolving

[217] Art 27(3)(b) of the TRIPS Agreement.
[218] Art 41(1) of the TRIPS Agreement.
[219] Art 42-48.
[220] Art 49.
[221] Art 61.
[222] The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, 2010.
[223] The Swakopmund Protocol 'List of Contracting Countries' (Status as at February 2016): Botswana, Ghana, Kenya, Lesotho, Liberia, Mozambique, Zambia and Zimbabwe.
[224] Sec 27.3 of the Swakopmund Protocol.
[225] Sec 1.1.

nature of TK and the characteristic of TK systems as frameworks of ongoing innovation'.[226] Laudably the Protocol grants high importance to customary law.[227] This is so especially since TK belongs to the ILCs and as custodians of TK it is fitting their laws regulate the system.[228] Section 3 of the Protocol provides for the establishment of a National Competent Authority directed to implement the provisions of the Protocol. Education, advice, regulation and the settlement of disputes are amongst the duties of the National Competent Authority – as well as the ARIPO office.[229]

The Protocol is divided into two sections, namely, Part II on traditional knowledge and Part III on expressions of folklore, which are both prefaced by "Protection criteria".[230] Automatic protection is granted to TK that meets the following criteria in terms of section 4, it must be:

i. generated, preserved and transmitted in a traditional and intergenerational context;
ii. distinctively associated with a local or traditional community; and
iii. integral to the cultural identity of a local or traditional community that is recognized as holding the knowledge through a form of custodianship, guardianship or collective and cultural ownership or responsibility. Customary practices, laws or protocols may establish such a relationship formally or informally.

The protection of TK is not subject to any formalities.[231]The duration for protection is for as long as these criteria are met and 25 years if the TK belongs to an individual.[232]

In terms of the obligations of Namibia under the Swakopmund Protocol the beneficiaries of TK are the holders of that knowledge, i.e. the ILCs and individuals within the communities who are involved in the creation, preservation and

[226] Sec 1.3 of the Swakopmund Protocol.
[227] L Y Ngombe 'The Protection of Folklore in the Swakopmund Protocol Adopted by the ARIPO' 2011 *The Journal of World Intellectual Property* 403-411.
[228] Saima Nghihalwa *An Analysis of The Registration of Traditional Product Names, Terms, Symbols and Other Cultural Expressions as Trademarks in Namibia* (unpublished LLM thesis, University of Cape Town, 2014) 54.
[229] S 14 of the Swakopmund Protocol.
[230] O'Hinz M 'The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore' (2011) 3 *Namibia Law Journal* 1 at 108.
[231] S 5 of the Swakopmund Protocol.
[232] S 13.

transmission of TK.[233] According to s 7, the Protocol grants exclusive rights to ILCs to authorise the exploitation of their TK and to prevent exploitation without their PIC. The fair and equitable sharing of benefits (including non-monetary benefits) generated by the commercial or industrial use of TK will be determined by a mutual agreement between parties and in the absence of such mutual agreement, the National Competent Authority must act as mediator for the parties to reach an agreement.[234] Acknowledgement of the right holders is also required for use of TK 'beyond its traditional context'.[235]

Insofar as GRs is concerned, s 15 explains that authorised access to TK associated with GRs does not mean the user has the right to access such GRs.[236] The Protocol thereby recognises the relationship between TK and GRs. However, it also means that under the Protocol, bioprospectors may have access to TK that is associated with GRs but it does not mean that such bioprospectors can have access to the said GRs. Consequently, the Protocol creates no link between it and the CBD. This is a major oversight by the regional instrument, which had an opportunity to clarify the African position on TK associated with GRs and, how it should relate to IPRs. The Protocol does not address IP issues that may arise out of the use of TK associated with GRs, which may create practical challenges for a person seeking an IPR. This means that Namibia must decide in terms of domestic legislation how TK associated with GRs will interact with IP laws.

3.4 Part 3: International discussions and legal alternatives

3.4.1 The Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore

The Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) was established in 2000 by the WIPO.[237]

---

[233] S 6.
[234] S 9 of the Swakopmund Protocol.
[235] S 10.
[236] S 15, see also O'Hinz op cit note 229 at 110.
[237] WIPO, IGC, available at *http://www.wipo.int/tk/en/igc/*, last accessed on 19 October 2016. See also Dutfield, G 'Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation' *ICTSD Intellectual Property Rights No. 4* (2003) at 1.

The main purpose of the IGC is to undertake text-based negotiations in order to reach an agreement for an international treaty to ensure the balanced and effective protection of, *inter alia*, GRs and TK.[238] The Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources (the Document) is the latest draft document from the 30th session released 3 June 2016.[239] The main objective is to prevent misappropriation of GRs and associated TK in the context of IPRs particularly the patents systems.[240] The revised document was passed on to the 34th session of the IGC for discussion, after which it will be deferred to the WIPO General Assembly in 2017 in accordance with the committee's mandate.[241]

The Document remains heavily bracketed reflecting the international dissensus about the protection of TK associated with GRs. The objectives are the most contested provision in the Document. The Document is divided into two main proposals. The first proposal of the Document contains three formulations for possible objectives in terms of art 1 as a result of disagreement amongst member states on whether to include prevention of misappropriation and permitting erroneous patents.[242] Another cause of objection was the use of 'erroneous patents', where it was argued that it is not a legal term and should be replaced by reference to the patent not meeting the patentability requirements.[243]

The subject matter of this Document is clearly GRs, TK and TK associated with GRs.[244] The alternative subject matter is whether specific inclusion of patent applications for inventions directly based on GRs and associated TK should be made.[245] In my view the specific inclusion of patent application derived from or based on TK associated to GRs as part of the subject matter links it to the objective of the Document which is to prevent misappropriation through the granting of 'erroneous patents' and as such should form part of the subject matter.

---

[238] The WIPO IGC *Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,* IGC Mandate 2016/2017/ 17 (2015) (WIPO *IGC Mandate*).
[239] WIPO IGC *Mandate* op cite note 237 at 2.
[240] Alternative 2 of Article 1 of the IGC Document.
[241] WIPO *IGC Mandate* op cit note 237 at 3.
[242] International Centre for Trade and Sustainable Development (ICTSD) 'WIPO Committee Advances Working Document on Genetic Resources, Though Divisions Remain' *Bridges* (2016) available at *http://www.ictsd.org/bridges-news/bridges/news/wipo-committee-advances-working-document-on-genetic-resources-though*; last accessed on 20 October 2016. (ICTSD *Bridges*)
[243] Ibid.
[244] Art 2 of the IGC Document.
[245] Ibid.

Furthermore, most of the discussion was around the 'triggers' of the proposed mandatory disclosure requirement for patent applications.[246] Developing countries supported disclosure if a claimed invention includes utilisation of GRs and TK associated with GRs, which they contended 'to be a clearer and more objective standard'.[247] Whereas, developed countries found 'a direct link' approach between the claimed invention and the TK associated with GRs more suitable.[248] According to this approach the claimed invention must be directly based on GRs and associated TK to trigger the disclosure requirement.[249] Nonetheless, it is must be noted that even though there are differing views on the 'triggers' of the disclosure agreement, there is at least a sense that the disclosure requirement is important in the relationship between patents and TK associated with GRs. As mentioned in chapter 2, the disclosure requirement is instrumental in preventing improper patents and preventing misappropriation of TK associated with GRs.

In addition, article 4 of the Document provides two alternatives for an exception and limitation clause. Alternative 1 requires the adoption of 'exceptions and limitations necessary to protect the public interest' without unduly prejudicing the implementation of this instrument.[250] In contrast, alternative 2 provides for instances under which disclosure is not necessary such as TK in the public domain, commodities, human GRs, and GRs beyond territorial boundaries of a country.[251] Furthermore, the disclosure requirement should not be imposed on patent applications filed before the entry into force of this instrument.[252] More importantly, the Document requires States to provide 'effective and proportionate legal and administrative measures to address non-compliance'.[253]The provision on sanctions and remedies will apply for both 'pre-grant' and 'post-grant' for a patent invention based on or derived from GRs associated with TK.[254]

---

[246] C Saez 'WIPO Update: Improved Text on Genetic Resources; Disclosure Still Undecided' *IP Watch* 08 Feb 2013, available at *http://www.ip-watch.org/2013/02/08/wipo-update-improved-text-on-genetic-resources-disclosure-still-undecided/,* last accessed on 20 October 2016.
[247] ICTSD *Bridges* at note 241.
[248] Ibid.
[249] Ibid.
[250] Art 4 of the IGC Document.
[251] Art 4.1.
[252] Art 4.2.
[253] Art 5
[254] Ibid Art 5(a) & (b).

Interestingly, the second proposal of the Document proposes to completely do away with the first proposal, in that no new disclosure requirement must be imposed on patent applications provided it meets the patentability criteria.[255] The premise of this study will be nullified if the IGC decides to incorporate this proposal in the final instrument.

Defensive measures such as databases are also under consideration in terms art 6 of the Document. The purpose of such a database would be to assist a patent office in examining a patent application for patentability requirements particularly the novelty and inventive step requirements, to prevent misappropriation of TK associated with GRs.[256]The Indian Traditional Knowledge Digital Library (TKDL) is a model registry for many other countries aiming to adopt such a system.[257]

Although, no consensus was reached on major issues discussed above, however the IGC has made significant progress in identifying what those issues are and provided options for addressing them. Consequently, there is no international instrument, which deals specifically with TK associated with GRs and how it relates to IPRs and more specifically patent rights. There are currently no international obligations for Namibia to deny patents of traditional medicine inventions.

3.5 Conclusion

At an international level, the debates and issues concerning TK and associated GRs are fundamentally challenging as it involves many different stakeholders and many international agreements. At the centre of each agreement or negotiation is the issue of TK and associated GRs misappropriation aided by the formal IP system, particularly the patent system. The CBD provides a broad international legal framework regulating access to GRs and benefits arising out of its use but the Nagoya Protocol provides specific requirements i.e. PIC, fair and equitable sharing of benefits arising from their utilisation based on MAT, for a regulatory framework. On the other hand, the TRIPS Agreement is silent on TK. However, patents of

[255] Art 6 of the IGC Document.
[256] Art 6 of the IGC Document, see also Bubela op cit note 48 at 16.
[257] The Indian Traditional Knowledge Digital Library (TKDL) available at *http://www.tkdl.res.in/tkdl/langdefault/common/home.asp?GL=Eng*, last accessed on 2 4 October 2016.

traditional medicine inventions may be granted, insofar as it concerns TK associated with GRs provided the normal patentability requirements are met. Furthermore, it should is not be an excluded subject matter such as ‘essentially biological process’.

At the regional level, the Swakopmund Protocol conceptualises the *sui generis* protection for TK. It is similar to the Nagoya Protocol in many respects but differs in respect of TK associated with GRs because the Swakopmund Protocol does not provide an extensive provision, which caters for instances under which such TK associated with GRs may become subject to an IP right such as patents.

Finally, the IGC has explored, *inter alia*, the misappropriation of TK associated with GRs through the granting of improper patents without disclosing whether the claimed invention is based on or derived from TK and associated GRs. The discussions at the IGC are highly contentious because of opposing views on how to protect TK from misappropriation. This chapter also revealed that the international community understands that the disclosure requirement is a practical measure through which misappropriation of TK and GRs can be prevented. This is so regardless of the shape such disclosure requirement would take, which is one of the main issues debated before the IGC. Most importantly, no international instrument discussed above prohibits the patenting of traditional medicine inventions. It also means that Namibia is under no obligation to prohibit inventions based on or derived from TK associated with GRs.

This chapter provided foundation for the domestic legislation subject to the chapter 4 discussion, from which many provisions were adopted in national laws.

CHAPTER 4: A COMPARATIVE STUDY OF THE NAMIBIAN AND SOUTH AFRICAN PATENT AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES LEGAL SYSTEMS

4.1 Introduction

The aim of the study is to investigate whether patenting traditional medicine inventions are possible without hindering the protection accorded to TK associated with GRs. The instruments discussed under chapter 3 provided the international and regional obligations that Namibia must implement through legislation regarding TK associated with GRs and patents. This chapter identifies how these obligations have been adopted in Namibia and compares the approach taken in the Namibian legal system in providing for patents and the protection of TK and associated GRs against the approach taken in the South African legal system.

This is done by providing a brief background into the Namibian and South African legal history, which will show why a comparison between two countries is appropriate. The chapter is then divided into two sections, each dealing with the respective jurisdictions. Section 4.3 deals with Namibia and the separate legislation that deals with TK associated with GRs and patents. Whereas section 4.4 deals with South Africa and its parallel legislation.

4.2 Background

The Republic of Namibia previously known as South West Africa (SWA) was declared a German Protectorate in 1884.[258] However, from 1920 SWA became a Mandated Territory of South Africa in terms of the Peace Treaty of Versailles.[259] As a result, the Namibian judicial and legislative systems were an extension of the South African legal system.[260] Namibia attained independence in 1990 followed by the

[258] S K Amoo 'The rule of law in Namibia' in N Horn & A Bösl (eds) *Human Rights and the Rule of Law in Namibia* (2009) 17.
[259] Treaty of Peace with Germany (The Treaty of Versailles) Paris 10 January 1920 and entered into force 10 January 1920.
[260] S K Amoo 'The structure of the Namibian judicial system and its relevance for an independent judiciary' in S K Amoo *Introduction to law: Materials and cases* (2008) 69.

promulgation of the Constitution of the Republic of Namibia in the same year.[261] The Constitution is the supreme law of Namibia and all laws derive legitimacy from the Constitution.[262] Subsequently, in terms of article 66 (1) of the Constitution all common law in force on the date of independence will remain valid to the extent it does not conflict with this Constitution or any other statutory law. The parliament is vested with the power to repeal or modify any part of the common law, which is inconsistent with the Constitution, or any other statutory law.[263] Therefore, some statutes and regulations that were in force during South Africa's administration in SWA, still remain valid and enforceable in Namibia.

People from both Namibia and South Africa suffered during Apartheid, a political and legal system.[264] The effects of apartheid were also evident in the context of traditional medicine and traditional healers. Traditional healers and the use of traditional medicines have since endured a negative image in Namibia and South Africa.[265] One of the main contributing factors to this negative association with traditional medicine is the role colonial powers played through enactment of legislation such as the Witchcraft Suppression Act 3 of 1957 and the Witchcraft Suppression Amendment Act, 1970 implemented in South Africa.[266] Fortunately, the South African Law Reform Commission determined the Witchcraft Suppression Act as unconstitutional insofar as harmful witchcraft practices are concerned.[267]

As far as Namibia is concerned, the Witchcraft Suppression Proclamation 27 of 1933 was repealed and the use of traditional medicine was legalised.[268] An estimate of 2400 traditional medical practitioners in Namibia are registered with the National Eagle Traditional Healers Association (NETHA), however, the actual number of

---

[261] Amoo op cit note 259 at 69.
[262] Art 1(6) of the Constitution of the Republic of Namibia 1990.
[263] Art 66(2) of the Constitution of the Republic of Namibia 1990.
[264] Amoo op cit note 257 at 17.
[265] M Richter 'Traditional medicine and traditional healer's in South Africa' available at http://www.tac.org.za/Documents/ResearchPapers/Traditional_Medicine_briefing.pdf; last accessed on 14 November 2016.
[266] Ibid at 4-5.
[267] T P Ward 'South Africa's Witchcraft Suppression Act ruled unconstitutional' *The Wild Hunt* 27 January 2016 , available at http://wildhunt.org/2016/01/south-africas-witchcraft-suppression-act-ruled-unconstitutional.html; last accessed on 14 November 2016.
[268] WHO *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review* (2001) at 27.

practicing traditional healers could be higher.[269] More recently, traditional healers have been approached by international bioprospectors, local research institutions and governments for their traditional medicine.[270] This has triggered the formulation of national legislation such as the Access to Genetic Resources and Associated Traditional Knowledge Draft Bill, 2014 (AGR Draft Bill). This Draft Bill takes on a *sui generis* approach which is intended to align national laws with the obligations of Namibia under the Nagoya Protocol.[271] The AGR Draft Bill regulates access to GRs and associated TK based on principles of PIC, ABS, and MAT.[272] The AGR Draft Bill makes no express mention of IPRs that may arise from access and use of the GRs and associated TK in the sense where it links with the Industrial Property Act. However, the Industrial Property Act provides protection for both TK and GRs.[273]

Similarly, the South African National Environmental Management Biodiversity Act 10 of 2004 (NEMBA) is aimed at, *inter alia*, redressing the inequalities and injustices of the past which excluded rural communities from using natural resources.[274] This was a result of an exclusionary paradigm developed by the colonial government.[275] Furthermore, as a signatory of the CBD, South Africa has given effect article 8 of the CBD through the enactment of NEMBA.[276] To ensure full compliance with the CBD on access to GRs, and fair and equitable sharing of benefits arising from their use, the Patents Act 57 of 1978 (as amended by the Patents Amendment Act 20 of 2005)[277] is linked to NEMBA for instances where a patent is sought for inventions based or derived from TK and associated GRs in South Africa.[278]

In 2004, the South African Cabinet further approved a National Indigenous Knowledge Systems Policy and in 2013 the Department of Science and Technology

---

[269] A Cheikhyoussef et al 'Ethnobotanical study of indigenous knowledge on medicinal plant use by traditional healers in Oshikoto region, Namibia' (2011) 7 *Journal of Ethnobiology and Ethnomedicine* 10.

[270] M Meincke 'Negotiating traditional medicine in Namibia: the politics of health and development' *Nordiska Afrikainstitutet* available at http://www.nai.uu.se/research/finalized_projects/negotiating-traditional-m/ last accessed on 22 November 2016.

[271] S Watanabe & K N Farrell *Challenges of Namibian administrative structure to implement the Access to genetic resources and Benefit Sharing legislation* (2015) 2.

[272] Preamble of the AGR Draft Bill.

[273] S 17(1)(i) & S 12(1)(c) of the Industrial Property Act.

[274] H A Strydom and N D King (eds) *Environmental Management in South Africa* 2nd ed (2009) 107.

[275] Ibid.

[276] Strydom op cit note 273 at 107.

[277] Hereinafter referred to as the Patent Act.

[278] Beharie op cit note 31 at 336.

(DST) developed a draft Bill for the protection, promotion, development and management of Indigenous Knowledge Systems (IKS Bill), which is based on the Indigenous Knowledge Systems Policy.[279] The DST published a latest draft of the IKS Bill on 8 April 2016.[280] The IKS Bill like the AGR Draft Bill proposes a *sui generis* system[281] for TK including knowledge of GRs.[282]

Caution must be taken concerning the Namibian AGR Draft Bill and the South African IKS Bill as both are still in the drafting phase and could change in the future. This study exclusively deals with the provisions of the latest Bills from Namibia and South Africa. Furthermore, it would be appropriate to draw inspiration from the South African case law as the Namibian Courts have yet to interpret IP laws, generally and patent laws specifically.

4.3 The Namibian legal system

4.3.1 The Industrial Property Act 1 of 2012

In terms of s 13 of the Industrial Property Act, patents are available for any invention, including products or process, in all fields of technology, provided the invention is new, involves an inventive step and is industrially applicable. The term of a Namibian patent is 20 years after the filing date of the application for the patent.[283] A patent granted in Namibia only provides monopoly within Namibia and its territorial waters.

There are certain matter excluded from patentability and they are listed in the statute. The exclusions are listed in s 17 of the Industrial Property Act but for purposes of this discussion only one needs mention. In terms of s 17(1)(i) of the Industrial Property Act all natural living beings and biological materials even when isolated or purified including genome or germplasm are excluded from patentability.[284] It follows that regardless of whether it is associated with TK, any

[279] Memorandum on the objects of the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill B 6 of 2016.
[280] S Karjiker 'The Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill, 2016: Has the DST lost its resolve?' *The Anton Mostert Chair of Intellectual Property* (2016).
[281] L Daniels 'A Cautious Welcome for South Africa's Traditional Knowledge Legislation' *Intellectual Property Watch*29 April 2015, available at http://www.ip-watch.org/2015/04/29/a-cautious-welcome-for-south-africas-traditional-knowledge-legislation/; last accessed on 14 November 2016.
[282] S 1 of the IKS Bill.
[283] S 45 of the Industrial Property Act.
[284] Industrial Property Act.

invention involving GRs cannot be patented. This is a defensive protection of GRs from misappropriation.[285] The exclusions under s 17 of the Industrial Property Act are more expansive then the exemptions provided under art 27(3)(b) of the TRIPS Agreement.

Furthermore, the main argument against patenting traditional medicine is that it lacks novelty and in some instances inventiveness as the alleged invention forms part of the state of art – otherwise known as prior art.[286] In terms of s 14(1) an invention is new if it is not anticipated by prior art. Section 12 further defines 'anticipated' to mean forming part of or disclosed by prior art. This includes:

> [K]nowledge developed by or in possession of a local or indigenous community and which originated at a date prior to the priority date of the relevant invention.[287]

Thus, TK forms part of prior art.[288] This is known as defensive protection whereby TK is protected from misappropriation of it by potential patent applicants.[289] Consequently, during the examination procedure the patent officer will assess whether the claims of the invention in the patent application meet the novelty and inventive step requirements for patentability by comparing it to the state of the art.[290] A brief explanation of how novelty and inventive step is examined in light of the prior art is important to understand how they relate to each other.

i. Novelty and prior art

It is a basic concept of Namibian patent law that an invention is new if it is not anticipated by prior art immediately prior to the filing date or priority date of a patent application.[291] Prior art is generally understood to comprise of everything made available to the public by means of written or oral description, by use, or in any other form on or after the priority date[292] but does not include confidential information.[293] The description of "state of the art" in the South African Patent Act is similar to the

[285] This provision has not been subject to previous commentary or interpretation.
[286] Amechi op cit note 24 at 59.
[287] S 12(1)(c) of the Industrial Property Act.
[288] S 12(1) (c).
[289] J Curci *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* (2010) 131.
[290] Curci op cit note 288 at 210.
[291] S 12(1) & 14(1) of the Industrial Property Act.
[292] S 12(1)(a).
[293] *McCauley Corporation Ltd v Brickor Precast (Pty) Ltd* 1989 BP 314 (CP) at 335E.

'anticipated art' description in the Industrial Property Act.[294] However, s 25(6)-(8) of the Patent Act, describes state of the art by creating three categories which mostly involve disclosure under namely; (i) 'all matter made available to the public', (ii) matter forming part of patent applications, and (iii) 'an invention used secretly and on a commercial scale'. State of the art can either be in documentary or oral form, if it is documentary, it must be so clear to enable a person skilled in the art to perform the invention without extra effort.[295]

No Namibian Court has had the opportunity to adjudicate on a patent case and in this regard interpretations of patent requirements done by South African Courts can be a useful guide. The test for novelty was set out in the *Gentiruco A.G. v Firestone South Africa (Pty) Ltd case*[296] related to the claims of the invention. In order to establish whether TK has been made available to the public and therefore, destroys novelty of an invention (pharmaceutical product) as claimed in the claims, the court will apply a three-step test summarised as follows:

1) the claims of the patent have to be construed;
2) the piece of prior art (TK) has to be construed; and
3) the construed claims have to be compared to the piece of prior art.[297]

The courts have further clarified the invalidating nature of prior art in *Veasey v Denver Rock Drill and Machinery Co Ltd*[298] through the following statement:

> Anticipation destroys the claim to novelty, but the prior publication (or public) relied upon as an anticipation must be of the identical – or substantially identical – invention claimed…But novelty is not destroyed by prior publication or an invention closely resembling that of the patent challenged if the difference between the two, however small, is a real difference'.[299]

One can therefore argue that patents of pharmaceutical products consisting of extracts of traditional medicine that are derived in one way or another from TK associated with GRs can be novel provided that there is a difference between them, however small. This is more likely because pharmaceutical drugs which consist of

---

[294] S 25(6)-(8) of the Patent Act.
[295] *Gentiruco A.G. v Firestone South Africa (Pty) Ltd* 1971 SA 1972 (1) SA 589 (A) at 650.
[296] 1971 BP 58 (A) at 149.
[297] Grant op cit note 114 at 247.
[298] 1930 AD 243 at 282.
[299] *Veasey v Denver Rock Drill and Machinery Co Ltd* 1930 AD 243 at 282.

active ingredients that do not exist in their pure form in nature are patentable.[300] It follows that the defensive mechanism for TK and GRs in this instance is not as effective because inventions that closely resemble traditional medicine may still be patented if there is a real difference. It also means that if the traditional medicine invention is patentable, the applicant would have to disclose such TK rendering the misappropriation thereof resolved.

ii. Inventive step and prior art

In terms of this requirement an invention must be sufficiently different from all other previous inventions in such a way that it is not obvious to persons skilled in the art.[301] First, one has to determine the art relating to the patent, second, the person skilled in the art, and third, the prior art at the relevant date.[302] This includes using the four-step established in the South African *Ensign-Brickford (SA) (Pty) Ltd and Others v AECI Explosives & Chemicals Ltd:*[303]

1. What is the inventive step said to be involved in the patent?[304]

   In *Ausplow (Pty) Ltd v Northpark Trading* 3 *(Pty) Ltd*[305] the court with reference to the *Ensign* case held that the claims must be considered to determine the inventive step.[306] This means the content of the specification are not to be considered when determining inventiveness.[307]

2. What was the state of the art, at the priority date of the patent, relevant to the step?[308]

   For this step the state of the art excludes prior co-pending patent applications in South Africa and the any secret use on a commercial scale[309] In other words, all material made available to the public except those mentioned above.

3. How does the step go beyond, or differ from, that state of the art?[310]

---

[300] Ebermann op cit note 24 at 102.
[301] S 15 of the Industrial Property Act. In *Speedmark Holdings (Pty) Ltd v Roman Roller CC* (502/93) [1995] ZASCA 78; 1996 (1) SA 405 (SCA) the notional person was said to be wholly unimaginative but have the ability to absorb new information and knowledge. This simply means that the notional person must have the cognitive abilities to distinguish between new inventions and those that are ordinary.
[302] *Ensign-Bickford (SA) (Pty) Ltd and others v AECI Explosives and Chemicals Ltd* 1998 BIP 271 (SCA) 280.
[303] 1998 BIP 271 (SCA).
[304] *Ensign-Brickford (SA) (Pty) Ltd and Others v AECI Explosives & Chemicals Ltd* 1998 BIP 271 (SCA).
[305] 2011 BIP 12 (SCA) at 33.
[306] Ibid.
[307] Grant op cit note 114 at 250.
[308] *Ensign-Brickford (SA) (Pty) Ltd and Others v AECI Explosives & Chemicals Ltd* 1998 BIP 271 (SCA).
[309] Grant op cit note 114 at 250.

The inventive step is not necessarily a step forward or a big change in the existing technology; a small but significant improvement can be considered to be inventive.[311]

4. Having regard to the further development or difference, would taking the step be obvious to the skilled man?[312]

The court will require explanation of the aforementioned three steps as primary evidence from properly qualified expert witnesses bearing in mind that the court has been known to note that expert witnesses views should not supersede the judge's decision-making.[313]

There are secondary considerations that are used where the meanings of inventive and obvious are unclear.[314] Nonetheless, as long as the specific TK and associated GRs has not been made available in public and the traditional medicine invention is a small yet significant improvement the TK will pass the inventiveness step test. This must, however, be the further step in development which is not obvious to the person skilled in the art which will be based on evidence given by 'properly qualified witnesses'.

iii. *Capable of industrial application*

The invention must be industrially applicable. The invention must be capable of being used or applied in industry, trade or agriculture.[315] This is a question of fact and seemingly apparent from the invention itself.[316] The argument here is that traditional

---

[310] *Ensign-Brickford (SA) (Pty) Ltd and Others v AECI Explosives & Chemicals Ltd* 1998 BIP 271 (SCA).
[311] Grant op cit note 114 at 250.
[312] *Ensign-Brickford (SA) (Pty) Ltd and Others v AECI Explosives & Chemicals Ltd* 1998 BIP 271 (SCA).
[313] *Bromine Compounds Ltd v Buckman Laboratories (Pty) Ltd* 2006 BIP 25 (CP).
[314] Klopper, Pistorius & Rutherford et al *Law of Intellectual Property in South Africa* (2011) at 287. *Veasey v Denver Rock Drill & Machinery Co Ltd* 1930 AD 243 at 289-290 summarised the second considerations as follows:
a) Solving a technical problem that awaited a solution for a very long time;
b) the efforts of the inventor;
c) interminable and active yet unsuccessful efforts by others skilled in the art to solve the technical problem;
d) positive acknowledgement by persons skilled in the art that an invention represents an important step forward can be indicative of inventiveness;
e) the progress of the industry in a different direction;
f) commercial success of the invention with a combination of other indicators relating to technical value; and
g) the admissibility of expert witness evidence.
In the end the court decide whether or not the invention involves an inventive step.
[315] Grant op cit note 114 at 251.
[316] Ibid.

medicine invention is capable of industrial application particularly in the pharmaceutical and healthcare industries.

4.3.2 The Access to Genetic Resources and Associated Traditional Knowledge Draft Bill, 2014 (AGR Draft Bill)

The AGR Draft Bill is proposed to regulate access to GRs and associated TK and all matters incidental thereto. All rights relating to GRs are vested in the State in terms s 3(1). This provision is consistent with art 100 of the Namibian Constitution.[317] Whereas, all rights relating to TK associated with GRs is vested in the particular ILC.[318] First, the AGR Draft Bill[319]objectives include: the conservation and sustainable use of GRs and associated TK for a sustainable life support systems; the recognition and protection of the *inalienable rights* of ILCs to TK; and the facilitation of access to GR and associated TK based on PIC, ABS and MAT including effective participation of ILCs particularly focused on integrating women in decision-making and benefit-sharing.[320]

Second, the Draft Bill incorporates notable definitions. 'Commercialisation' includes filing, obtaining or transferring IPRs in Namibia or abroad.[321] 'Community intellectual property rights' which recognises community rights over TK and associated GRs whether registered or not; and 'community protocols' that incorporate ILCs' customary law into the framework as procedural norms.[322]

Third, in terms of s 4(1) a national authority[323] known as the Genetic Resources Unit is established falling under the Ministry of the Environment and Tourism. The Unit will be led by a Director appointed by the Minister. The Minister through the Director is empowered with a wide range of governance powers and duties to

[317] Art 100 of the Constitution of the Republic of Namibia 1990 states that 'Land, water and natural resources below and above the surface of the land and in the continental shelf and within the territorial waters and the exclusive economic zone of Namibia shall belong to the State if they are not otherwise lawfully owned'.
[318] S 3(2) of the AGR Draft Bill
[319] Preamble of the AGR Draft Bill .
[320] ibid
[321] S 1 of the AGR Draft Bill.
[322] S 1 of the AGR Draft Bill. See also F K Phillips Intellectual Property Rights in Traditional Knowledge: Enabler of Sustainable Development (2016) 32(83) *Utrecht Journal of International and European Law* at 10.
[323] The national authority is equivalent to the National Competent Authority contemplated in s 9 of the Swakopmund Protocol.

regulate access to GRs and associated TK which includes establishing procedures for recognition and protection of community IPRs relating to TK and ensuring that community IPRs of ILCs are protected.[324]

Fourth, ILCs are endowed with the following community rights in terms of s 9(1) of the AGR Draft Bill:

a) the right to collectively benefit from the utilization of genetic resources;
b) the right to protect their traditional knowledge and technologies associated with genetic resources as the traditional custodians and users thereof, and in terms of customary law; and
c) the right to use their traditional knowledge and technologies in the conservation and sustainable use of biological diversity;
d) the right to refuse any access to traditional knowledge or technologies associated with a genetic resources where such access would be detrimental to the integrity of their natural or cultural heritage, subject to the Minister's right to override this right in the public interest within the framework of the Constitution of Namibia.

Fifth, any person who requires access to GRs and associated TK must apply to the Director of the Unit for an access permit.[325] This permit can either take the form of an academic research permit, a commercial research permit, or a commercial exploitation permit.[326] Furthermore, exporting of GRs will only be allowed for persons who possess an export permit.[327] However, a permit will only be granted based upon PIC from both the State and the specific ILC involved[328] and an access agreement has been concluded between the applicant, the State and the ILC.[329]

Lastly, benefits shared from access to GRs and TK may take many forms including:

i. money from permit fees;
ii. royalties; research funding;
iii. joint ownership of intellectual property;
iv. employment opportunities;

[324] Ibid, s 4(3).
[325] S 6(1) of the AGR Draft Bill.
[326] S 6(3).
[327] S 6(2).
[328] S 7(1)
[329] S 8(1).

v. contracts to supply the raw GRs;
vi. access to products and technologies developed from GRs and associate TK; institutional and ILC training; and
vii. providing of equipment, infrastructure and technology support; and any other appropriate benefit.[330]

Any monies received from access to GRs and associated TK are paid into the National Bioprospecting Account in the Environment Investment Fund managed by the Unit.[331] The funds must be used in the interest of ILCs and for the conservation of biological diversity.[332] Any person who commits an offence under this Act will be liable and punished accordingly.[333] It is however, not clear whether the punishment is criminal or civil in nature.

The AGR Draft Bill proposes the right system insofar as the following is concerned: first, it recognises the inalienable right of ILCs to TK through bestowing upon them community IPRs. Secondly, it highlights the importance of GRs conservation and sustainable use by ensuring that access to GRs must be based on PIC, MAT, ABS and the effective involvement of ILCs. All of the above are consistent with obligations contained in the CBD and the Nagoya Protocol. Thirdly, it notes that access to GRs and associated TK can result in its 'commercialisation' -including obtaining/filing of IPRs - which is important for the advancement of this study's argument in using patents. Fourthly, it establishes an administrative structure – Genetic Resource Unit – necessary to regulate access to GRs and all procedures incidental thereto, and it also establishes a financial body responsible for receiving and sharing monies from access to GRs and associated TK. Lastly, it includes sanctions and remedies for non-compliance.

However, the AGR Draft Bill has failed to address two material aspects resulting from access to GRs and associated TK. First, it failed to address how GRs and associated TK subject to 'commercialisation' (obtaining/filing of IPRs) will relate to the existing Industrial Property Act because this Act clearly excludes GRs from patentability and includes TK in prior art. Thus, in practice a person who has fulfilled all requirements under the AGR Draft Bill who wishes to file a patent application in

[330] S 11(1) of the AGR Draft Bill.
[331] S 5.
[332] S 5(4).
[333] S 18 of the AGR Draft Bill.

Namibia involving an invention based on or derived from GRs and associated TK will not be able do so. Second, since the AGR Draft recognises that filing for an IPR might follow from access, it, however, failed to include a disclosure requirement, which is important to prevent misappropriation.

4.4 The South African legal system

4.3.1 The National Environmental Management Biodiversity Act 10 of 2004 (NEMBA)

The main legislation for bioprospecting of TK associated with GRs in South Africa is NEMBA[334] and the Amendments to the Regulations on Bio-Prospecting, Access and Benefit sharing, 2015(Amendment Regulations)[335]. The NEMBA is based on three main objectives, namely:

i. the management and conservation of South Africa's biodiversity;
ii. sustainable use of indigenous biological resources (IBRs); and
iii. the fair and equitable sharing of benefits arising from bioprospecting involving IBRs.[336]

These objectives are acutely similar to the objectives of the CBD discussed above. It is important from the onset to state that NEMBA includes provisions which regulate cases under which patents are sought for inventions based on or derived from TK associated to GRs, otherwise referred to as indigenous biological resources (IBRs).[337] The regulations apply to commercial or industrial sectors that use TK associated to IBRs 'for biotrade or for research, application or development of drugs and complementary medicines', amongst others.[338] The use of TK means 'traditional

[334] Chapter 6 of NEMBA.
[335] Reg 43 of the Amendments to the Regulations on Bio-Prospecting, Access and Benefit-sharing GN 447 *GG* 38809 of 19 May 2015 repealed the Regulations on Bio-Prospecting, Access and Benefit-Sharing in GN 138 GG 30739 of 8 February 2008.
[336] Preamble of NEMBA.
[337] S 1 of NEMBA defines 'indigenous biological resources as (a) when used in relation to bioprospecting, means any indigenous biological resource as defined in section 80(2); or (b) when used in relation to any other matter, means any resource consisting Of-(i) any living or dead animal, plant or other organism of an indigenous (ii) any derivative of such animal, plant or other organism; or (iii) any genetic material of such animal, plant or other organism'.
[338] Reg 3(1)(b) of the Amendment Regulations.

use or knowledge'. In terms of reg 1 traditional use or knowledge is defined to include:

> customary utilisation or knowledge of indigenous genetic and biological resources by an indigenous community or specific individual, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, and include discoveries about the relevant indigenous genetic and biological resources by that community or individual.

This definition encapsulates the nature of TK because it understands that TK is closely connected with GRs, it can be held by a whole community or by one individual and it is not always written.

Moreover, provisions contained in chapters 6 and 7 of NEMBA are most notable as they regulate bioprospecting projects involving IBRs and by extension TK associated with GRs. The export of IBRs for purposes of bioprospecting or any other kind of research, and provide for a fair and equitable sharing by stakeholders benefits arising from bioprospecting involving IBRs.[339]

Similar to s 6(2) of the Namibian AGR Draft Bill, s 81(1) of NEMBA prohibits bioprospecting involving IBRs carried out by any person without a permit. When applying for a permit the applicant must disclose to the issuing authority all information pertaining to the proposed bioprospecting activities and the IBRs that will be used in such bioprospecting project.[340] The permit will only be issued subject to certain requirements, particularly;[341] the interest of stakeholders including any person (organ of state) or community providing access to the IBRs, which should be protected by the issuing authority.[342] In addition to any ILCs whose traditional use or knowledge of the IBRs to which the application relates have initiated or will contribute to the proposed bioprospecting.[343] Thus, the issuing of the permit will only be successful if:

i. the applicant discloses 'all material information relating to the relevant bioprospecting to the stakeholder and on the basis of that disclosure has

[339] S 80 of NEMBA.
[340] S81(1).
[341] S 82
[342] S 82(1)(a).
[343] S 82(1)(b)(i) & (ii).

obtained the prior consent of the stakeholder for the provision of or access to such resources';[344]

ii. the applicant and stakeholders have entered 'into a material transfer agreement regulates the provision of or access to such resources';[345] and

iii. a benefit-sharing agreement that provides for sharing by the stakeholder in any future benefits that may be derived from the relevant bioprospecting.[346]

The benefit-sharing agreement the applicant enters into with the stakeholders must set out the manner in which, and the extent to which, the IBRs will be used or exploited in the bioprospecting project.[347] This includes the manner in which and the extent to which ILCs will share in the benefits that accrue from the bioprospecting.[348] The benefit-sharing agreement must further specify the following:

i. the IBRs to which the bioprospecting relates,

ii. the area or sources from which the IBRs will be collected including the quantity of the IBRs to be collected,

iii. the current traditional uses of the IBRs by the ILCs and any current potential uses of the IBRs.[349]

This ABS agreement provided by NEMBA includes specific requirements that must be fulfilled compared to the ABS agreement provided in terms of the Namibian AGR Draft Bill, which only states that there must be an access agreement and provides a list of benefits that may accrue from such access.[350]

NEMBA goes beyond similar provisions set out in the AGR Draft Bill by providing a material transfer agreement. This agreement must prescribe the particulars of the supplier, and the exporter or recipient of the IBRs.[351] Like the benefit-sharing agreement, the material transfer agreement must specify the type of IBRs, the area or source from which the IBRs is to be collected, the quantity of the IBRs to be collected and the purpose for which such IBRs is exported.[352] The

[344] S 82(2)(a).
[345] S 82(2)(b)(i).
[346] S 82(2)(b)(ii).
[347] S 83(1)(d)
[348] Ibid.
[349] S 83(1)(b) of NEMBA.
[350] [325]S 6(1) of the AGR Draft Bill.
[351] S 84(1)(b)(i).
[352] S 84(1)(b).

Minister must approve both the benefit-sharing agreement and material transfer agreement.[353]

Moreover, the NEMBA makes a distinction between the discovery phase of a bioprospecting project and the commercialisation phase.[354] The former phase is about using IBRs for commercial research.[355] Whereas, the latter phase includes biotrade; bioprospecting and integrated biotrade.[356] 'Biotrade' is a new term introduced by the Amendment Regulations that involves 'buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic and biological resources for further commercial exploitation'.[357] As mentioned above, permits are required for all forms of bioprospecting, which should include proof of PIC, signed material transfer agreement, a signed benefit-sharing agreement and a non-refundable fee.[358]

Lastly, a 'Bioprospecting Trust Fund' managed by a Director-general must be established into which moneys flowing from benefit-sharing agreements and material transfer agreements must be paid.[359] Furthermore, all money due to the stakeholders (including ILCs) must be paid.[360] This financial body is similar to the one in the Environment Investment Fund (National Bioprospecting Account) established by the AGR Draft Bill.[361]

It follows, that NEMBA has ensured that all bioprospecting projects must be subject to certain procedures and checks to safeguard TK and IBRs from misappropriation. A successful bioprospecting permits depends on full disclosure of material information and on agreements that are aimed at benefiting stakeholders i.e. ILCs, for authorising access to their TK and associated GRs.

---

[353] S 82(2)(c).
[354] Beharie op cit note 31 at 338.
[355] Chapter 3, Part 2 of the Amendment Regulations.
[356] Chapter 3, Part 3 of the Amendment Regulations.
[357] Reg 1 of the Amendment Regulations.
[358] Regs 14(3), 15(4), 17(4) & 18(4) of the Amendment Regulations.
[359] S 85 of NEMBA.
[360] Ibid.
[361] [331]S 5 of the AGR Draft Bill.

4.4.2 The Patents Act 57 of 1978 (as amended by the Patents Amendment Act 20 of 2005) (Patents Act)

It is possible to protect traditional medicine inventions through patents depending on the nature and scope of domestic laws.[362] The Patents Act requires applicants who have lodged a complete patent application in South Africa to state whether or not the invention claimed in the application is based on or derived from any IBRs, GRs, or from TK and/or traditional use.[363] This means an applicant has to lodge a declaration or statement on Form P26, which is filed in South Africa on or after 14 December 2007.[364] This statement on Form P26 *only* relates to South African IBRs, GRs, and TK.[365] If the invention is based on or derived from IBRs, GRs, or TK the applicant must submit to the registrar proof of his/her authority or title to the aforementioned resources and knowledge through lodging one of the following:

i. A copy of the permit issued in terms of NEMBA;
ii. proof of prior informed consent;
iii. proof of material transfer agreement;
iv. proof of a benefit-sharing agreement;
v. proof of co-ownership of the invention for which protection is claimed; or
vi. any other proof to the satisfaction of the registrar.[366]

The P26 form is a practical tool for keeping track of all patent applications that include claims of TK and associated GRs. The P26 form is more consistent with the first half of the IGC Document in that patent applications for inventions based on or derived from TK associated with GRs is subject to a disclosure requirement.[367] Essentially, the P26 form provides a disclosure system for patent applications involving TK associated with GRs. As such, the link between the Patents Act and NEMBA is solidified by the 'commercialisation phase' of bioprospecting in that a patent application may be filed during this time. This also demonstrates that patents of traditional medicine can interact and coexist with the rights ILCs over their TK associated with GRs.

---

[362] M L Eiland 'Patenting Traditional Medicine' 2007 *Journal of the Patent and Trademark Office Society* 1.
[363] S 30(3A) of the Patents Act. See also Beharie op cit note 12 at 338.
[364] Patent Regulations Amendment, in GG 8807 *GN* 1226 of 14 December 2007.
[365] Regulation 44A (2) of the Patent Regulations Amendment in GN 1226 *GG* 8807 of 14 December 2007.
[366] Regulation 44A (2).
[367] Art 3 of the IGC Document.

While P26 form is an important part of acquiring a patent for an invention based on or derived from TK associated with GRs, the application must still meet all the requirements of patentability. Section 25(1) of the Patents Act requires that an invention must be novel, involve an inventive step and be industrially applicable. Since the patentability requirements were discussed under section 4.3.1 of this chapter and all South African case law had been used to advance that discussion, here it would simply be a repetition.

4.4.3 Intellectual Property Laws Amendment Act 28 of 2013 (IPLAA) and the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill, 2016 (IKS Bill)

The Department of Trade and Industry (DTI) drafted the IPLAA. The IPLAA created traditional knowledge and traditional cultural expressions (TCE) as a new form of IP.[368]The IPLAA has been criticised as poorly drafted 'ill-considered attempt at protecting TCE',[369] it is, however, irrelevant to TK related to GRs and therefore, will not be discussed any further.

In contrast, many South African IP professionals have applauded the IKS Bill 'as a step forward in the right direction'.[370] The IKS Bill puts forward a *sui generis* system[371] for the protection and commercialisation of indigenous knowledge system.[372] The IKS Bill establishes National Indigenous Knowledge Systems Office (NIKSO)[373], and an Advisory Panel to advise NIKSO to carry out the objectives of the Bill.[374] The Bill further requires registration for protection for IK at a registrations office to be established by NIKSO[375] and registration of all existing IK must be within 12

[368] A Van Der Merwe "The old and the new: A concise overview of the Intellectual Property Laws Amendment Act" (2014) 545 *De Rebus* 28-32 at 28.
[369] Karjiker op cit note 279.
[370] Ibid.
[371] Daniels op cit note 280 at 10.
[372] A Van Der Merwe 'Comments on the Protection, Promotion, Development, and Management of Indigenous Knowledge Systems Bill, 2016' *GoLegal Industry News and Insight* 30 August 2016 , available at *http://www.golegal.co.za/iks-bill-indigenous-knowledge-systems/;* last accessed on 21 November 2016.
[373] S 4 of the IKS Bill.
[374] S 7(1).
[375] S 16 of the IKS Bill.

months of the Act coming into force.[376] This placed enormous time pressure to act on ILCs.[377]

Nonetheless, in terms of s 9(1) all IK, both cultural and functional in nature, including medical, agricultural and scientific practices are subject to protection provided they meet the eligibility criteria set out in s 11 below:

a) has been passed on from generation to generation within an indigenous community;
b) has been developed within an indigenous community; and
c) is associated with the cultural make-up and social identity of that indigenous community.

These requirements are too limiting as it works on the assumption that TK are in fixed forms which are historically identifiable or linked to one particular ILC rather than understanding that TK may change overtime and may take on different yet related forms.[378] Nevertheless, the protection for IK lasts as long as it meets the criteria of eligibility for protection in terms of section 11,[379] after which the IK will be part of the public domain.[380] The ownership of IK is held by the ILCs and a trustee of the ILC holds the IK in trust on behalf of the community. If the holder of the IK cannot be identified NIKSO acts as custodian of the IK.[381] As holders of the IK ILCs are vested with a bundle of exclusive rights under the IKS Bill which includes: a) benefits arising from its commercial use; (b) be acknowledged as its source; and (c) restrain any unauthorized use of the IK.[382]

Furthermore, if potential bioprospectors require access to IK they must apply for a licence. [383] The applicant must include, the identity and place of origin of the IK, evidence of PIC of the IK holder has been obtained and an ABS arrangement has been entered into with the IK holder.[384] In other words, this section contains the disclosure requirement as proposed in the IGC Document.[385] As far as dispute

[376] S 33.
[377] Van Der Merwe op cit note 368.
[378] Daniels op cit note 280 at 10.
[379] S 10(1) of the IKS Bill.
[380] S 10(2).
[381] S 12.
[382] S 13(1).
[383] S 13(2).
[384] S 13(3).
[385] Art 3.

resolution is concerned any person who uses without authorisation or under false pretence commits an offence and liable for imprisonment for up to three years or a fine of R30 000 or both.[386]

Despite being well drafted, the IKS does not provide a link between patents and TK associated with GRs. Section 3 set outs the objects of the Bill, however, the s 3(1)(h) stands out for purposes of this study. Section 3(1)(h) of the Bill reads as follows:

> [R]ecognise indigenous knowledge as *prior art* in the determination of, and eligibility for, protection of subject matter under *intellectual property laws*.

At present, there is no interpretation of this section. However, this section makes it clear that IK is recognised as prior art when it is part of subject matter seeking IP protection, thereby providing defensive protection for IK when it is subject to a IPR i.e. patent right.[387] By doing so, the IKS Bill prohibits patents of inventions based on or derived from TK associated with GRs. There is no further indication of a relationship between patents and TK associated with GRs in the IKS Bill. It is also not clear how the IKS Bill will interact with existing legislation such as the Patents Act.[388] However, it states in terms of s 32 of the Bill that any rights conferred in respect of IP by any statute or common law will trump the provisions of the Bill, in practice, and this includes the NEMBA.[389] On the one hand, this means that patents of traditional medicine inventions can still be granted in terms of the Patents Act and NEMBA. On the other hand, it means that although the IKS Bill has made significant progress to protect TK defensively, s 32 undermines the creditable work done by the DST.[390]

Nonetheless, it seems South Africa's intention is to provide a hybrid system for TK. There are two statutes and one bill that regulate protection of TK associated with GRs and matters incidental thereto, which means there are potential legislative overlaps and duplication of provisions. Whilst NEMBA requires permits to access

---

[386] S 28.
[387] Curci op cit note 288 at 131.
[388] The Patents Act is expressly excluded from the list of statutes provided under s 32(2) of the IKS Bill
[389] S 32(2) of the IKS Bill states: '….this Act does not amend or detract from the provisions of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004), the Designs Act, 1963 (Act No. 195 of 1963), the Copyright Act, 1978 (Act No. 98 of 1978), the Trade Marks Act, 1993 (Act No. 194 of 1993), 1963 and the Performers Protection Act, 1967 (Act No. 11 of 1967), as amended.'
[390] Karjiker op cit note 279.

GRs and associated TK, the IKS Bill proposes a licensing system. This means that the departments responsible for governing each legislation must identify and resolve the overlaps.[391]

4.7 Conclusion

Namibia has complied minimally with international obligations in that the existing legislation and the proposed draft bill have given effect to art 8 of the CBD which ensures access to GRs. The AGR Draft Bill proposes to provide PIC, MAT and benefit-sharing measures for access to and utilisation of TK and associated GRs as required under the Nagoya Protocol. Furthermore, access to TK and associated GRs will be based on a permit system. The chapter hereby shows that Namibia is on the right path in providing the necessary protection for TK associated to GRs from misappropriation.

However, the AGR Draft Bill lacks the disclosure requirement envisaged in the IGC Document and when compared to the South African Patents Act and NEMBA. Although, the AGR Draft Bill recognises and makes provision for instances under which bioprospectors may file for a patent right arising out of an invention based on or derived from TK associated with GRs, it does not clarify how this will be possible in relation to the Industrial Property Act. More so since both TK and GRs cannot form part of claimed invention and testing whether the invention meets the patentability requirements becomes superfluous. Consequently, no patents can be granted for inventions based on or derived from TK associated with GRs in Namibia.

The South African Patents Act and NEMBA demonstrated that it is possible to patent traditional medicine inventions. The two Acts collaborated to design a disclosure requirement in the form of P26 Form. Proving that a relationship does exist between patents and TK associated GRs which works so far.

[391] Science and Technology Committee Meeting 'Indigenous knowledge system bill [B6-2016]: Departments of environmental affairs & health on comparative legislation' 31 August 2016 *Parliamentary Monitoring Group* available at *http://pmg.org.za/committee-meeting/23174/*; last accessed on 17 February 2017.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The growing importance of TK associated with GRs and the increasing number of patents granted for pharmaceutical and biotechnological inventions based on or derived from traditional uses of GRs has sparked international debates concerning its protection. There have been significant international developments within the legal framework that regulates access to GRs and TK and those aimed at protecting TK associated with GRs from misappropriation by third parties. However, instruments that are in place have not provided sufficient solutions for TK associated with GRs which is subject to IPRs. To date work on providing an international regulatory framework for TK associated with GRs and IPRs that may be sought for access to and use of TK associated with GRs has progressed gradually under the ambit of the WIPO IGC.

The value of traditional medicine to numerous bioprospectors i.e. pharmaceutical companies, for R&D of new drugs and other products cannot be overstated. Hence, at the centre of the research was the question of whether patenting of traditional medicine inventions is possible without encroaching on the protection of TK and GRs.

To this end, the study defined important key concepts that relate to TK associated with GRs and patents provided in the relevant international and regional instruments. This was done to highlight the specific use of terms in the study. What is evident from the discussion of these key concepts was how interrelated they are to one another and how important integration of each concept is when patenting of inventions based on or derived from TK associated with GRs becomes an issue.

The illustration of the *hoodia* case study showed how the plant and its traditional uses were misappropriated from the San communities in Southern African countries. This means the *hoodia* plant was subject to R&D and subsequently, to numerous patent applications without the authorisation and PIC from the indigenous community. However, the *sceletium tortuosum* case study showed that access to the GRs and traditional uses of *sceletium* that were subject to seven patents was based

on PIC of the San community who were identified as the primary knowledge holders and an ABS agreement between HGH Pharmaceuticals and the San community. Through this the study revealed that patents of traditional medicine inventions need not be a result of misappropriation. It was also found that the ongoing discussions at the IGC are primarily aimed at addressing the issue of misappropriation of TK and GRs which occurs through the granting of improper patents.

The study concluded that any patent application ensuing from a bioprospecting activity must be subjected to a disclosure requirement. The applicant must disclose any GRs and associated TK used in the claimed invention; disclose the country of origin and the source of the GRs; and provide evidence of PIC and ABS agreement as Namibian laws may require. Thus, the disclosure requirement is of such an important nature that PIC and ABS agreements are prerequisites to any patent application which the claimed invention is based on or derived from TK associated with GRs. It augments transparency in the patent system. The disclosure requirement will either be triggered by mere use of TK associated with GRs in an invention or a direct link between TK associated with GRs and the invention. Consequently, the obstacle for patents of traditional medicine, namely misappropriation is prevented. It further means that TK associated with GRs continues to enjoy protection under the relevant legal framework.

Furthermore, to determine the parameters of the protection accorded to TK and GRs the study explored the international and regional legal framework to which Namibia is a member state. The CBD provides general protection for GRs but it balances this protection by requiring access to GRs. The study further showed that the Nagoya Protocol goes a step further by ensuring that access to TK and associated GRs must be based on PIC obtained from ILCs and an ABS agreements are reached based on MAT. In addition, the Swakopmund Protocol provides comprehensive protection for TK, it, however, failed to clarify what the position on TK associated with GRs and how it relates to IPRs. The study found that there is currently no international instrument that specifically regulates TK associated with GRs. Admittedly, this study attempts to solve an issue that the international community has yet to find an answer to.

There is currently no law in Namibia that deals specifically with TK associated with GRs.[392] There is, however, an AGR Draft Bill proposed to regulate access to GRs and associated TK in Namibia. The study revealed that the AGR Draft Bill provides positive protection to GRs and TK as it endows ILCs with rights to authorise or deny access and use of their TK associated with GRs by third parties. It also gives them the right to benefit from authorising such access and use of their TK. Nonetheless, the Industrial Property Act accords defensive protection to TK and GRs. Defensive protection is another obstacle for patenting inventions based on or derived from TK associated with GRs as such a patent would be invalid.

This study further identified patentability requirements as an additional obstacle. Patents of traditional medicine must not fall short of the patentability requirements as provided under the TRIPS Agreement. The claimed invention influenced by traditional medicine must be new, non-obvious and applicable in industry. The study in chapter two and four indicated practical challenges patents of traditional medicine may face in meeting the requirements of novelty and non – obviousness. Nonetheless, by illustration of the *hoodia* and *sceletium tortuosum* case studies, this dissertation concluded that traditional uses and healing properties of these two plants resulted in actual patents of pharmaceutical and other products which are based on the TK associated to such GRs. This means that traditional medicine derived inventions can in certain instances meet the patentability requirements.

Through a comparative analysis of the Namibian and South African legal systems, the chapter concluded that a clear relationship must exist between laws which regulate patents and TK associated with GRs. In this regard, the South African Patents Act and NEMBA are exemplary as the link is clearly represented by Form P26. If Namibia amends its patent law to provide positive protection for TK associated with GRs then, perhaps, a clear link may exist between the Industrial Property Act and the AGR Draft Bill. In which case, South African decisions on patent law could be referred to by Namibian courts when a dispute arises.

[392] G Mengistie, N Halm & R A Kaakunga 'Multi-Stakeholders Workshop: Validation of the National Intellectual Property Strategy for Namibia' 2016 *Intellectual Property Audit Report of Namibia* at 33.

5.2 Recommendations

In light of the conclusion reached in this study owing from an investigation into the relationship between patents of traditional medicine and TK associated with GRs, here are number recommendations for the attention of the Namibian legislature and the LRDC:

1. Although defensive protection is aimed at preventing misappropriation of TK and GRs, it has been shown in this study that misappropriation can be prevented by implementing the disclosure requirement. Thus, section 12(1)(c) of the Industrial Property Act, 2012 which defines prior art to include TK must be amended to exclude TK. In addition section 17(1)(i) of the Industrial Property Act, 2012 includes GRs, 'in whole or in part found in nature, even if isolated from it or purified, including the genome or germplasm', under subject-matter excluded from patentability. This sub-section must be amended by removing 'even if isolated from it or purified, including the genome or germplasm'.

3. The disclosure requirement is essential to preventing misappropriation and creating a link between patents and TK associated with GRs. As such a disclosure requirement must be inserted into the Industrial Property Act, 2012, which must include the requirements of source of the TK and associated GRs, country of origin and evidence of PIC and ABS scheme.

3. The Namibian Access to Genetic Resources and Associated Traditional Knowledge Draft Bill, 2014 is not enacted yet thus; it would be prudent to revise the Bill so as to create a link between it and the Industrial Property Act, 2012.

4. The Namibian government needs to create awareness for ILCs and sensitise them about their rights over TK and empower them to ensure that they exercise these rights both locally and internationally. This can be done through workshops and consultations with the indigenous people.

BIBLIOGRAPHY

Primary Sources

Statutes

Constitution of the Republic of Namibia Act 1 of 1990.

Witchcraft Suppression Act 3 of 1957 as amended in 1970 (South Africa).

Witchcraft Suppression Proclamation 27 of 1933 (Namibia).

Industrial Property Act 1 of 2012 (Namibia).

National Environmental Management Biodiversity Act 10 of 2004 (South Africa).

Patents Amendment Act 20 of 2005 (South Africa).

Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill B 6 of 2016 (South Africa).

Access to Genetic Resources and Associated Traditional Knowledge Draft Bill, 2014 (Namibia).

Patent Regulations Amendment, 2007 *GG* 8807 *GN* 1226 of 14 December 2007 (South Africa).

Regulations on Bio-Prospecting, Access and Benefit-Sharing GN 138 GG 30739 of 8 February 2008 (South Africa).

Amendments to the Regulations on Bio-Prospecting, Access and Benefit-sharing GN 447 *GG* 38809 of 19 May 2015 (South Africa).

International and Regional instruments

The United Nations Declaration on the Rights of Indigenous Peoples of 2007.

Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994.

Convention on Biological Diversity of 1993

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization of 2002

The Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on biological Diversity of 2010.

Paris Convention for the Protection of Industrial Property of 1883.

Namibia (2009) 17.

Treaty of Peace with Germany (The Treaty of Versailles) of 1920.

Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore of 2010.

Cases

Gentiruco A.G. v Firestone South Africa (Pty) Ltd 1971 SA 1972 (1) SA 589 (A).

Mckelvey and Others v Deton Engineering (Pty) Ltd and Another (1) SA 374 (SCA).

McCauley Corporation Ltd v Brickor Precast (Pty) Ltd 1989 BP 314 (CP).

Veasey v Denver Rock Drill & Machinery Co Ltd 1930 AD.

G I Marketing CC v I Fraser-Johnson 1996 (1) SA 939 (A) 945.

Speedmark Holdings (Pty) Ltd v Roman Roller CC (502/93) [1995] ZASCA 78; 1996 (1) SA 405 (SCA).

Ensign-Brickford (SA) (Pty) Ltd and Others v AECI Explosives & Chemicals Ltd 1998 BIP 271 (SCA).

Ausplow (Pty) Ltd v Northpark Trading 3 *(Pty) Ltd* 2011 BIP 12 (SCA).

Bromine Compounds Ltd v Buckman Laboratories (Pty) Ltd 2006 BIP 25 (CP).

Secondary Sources

Books

T Bubela & E R Gold (eds) *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interest* (2012) Cheltenham: Edward Elgar Publishing Ltd.

C du Champ d'Anier *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (2000) Geneva: the South Centre.

C M Correa *Protection and Promotion of Traditional Medicine - Implications for Public Health in Developing Countries* (2002) Geneva: the South Centre.

J Curci *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* (2010) Geneva: International Centre for Trade and Sustainable Development.

J Dugard *The South West Africa/Namibia Dispute: Documents and Scholarly Writings on the Controversy Between South Africa and the United Nations (*1973) London: University of California Press Ltd.

G Dutfield *Protecting Traditional Knowledge and Folklore* (2003).

P Ebermann *Patents as Protection of Traditional Medical Knowledge?* (2012) Cambridge: Intersentia Publishing Ltd.

J Gibson *Community Resources: Intellectual Property, International Trade and Protection of Traditional Knowledge* (2005) Aldershot: Ashgate Publishing.

L Glowka et al *A Guide to the Convention on Biological Diversity* (1994) Cambridge: ICUN.

S A Hansen & J Van Fleet *Traditional Knowledge and Intellectual Property* (2003) Washington, DC: American Association for the Advancement of Science.

K T Kate & S A Laird *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing* (1999) London: Earthscan.

Klopper, Pistorius & Rutherford et al *Law of Intellectual Property in South Africa* (2011) Cape Town: LexisNexis.

H Krugmann *Namibia's Thematic Report on the Benefit-Sharing Mechanisms for the Use of Biological Resources* (2001) Windhoek: Namibian National Biodiversity Programme.

W M Landes and R A Posner *The Economic Structure of Intellectual Property Law* (2009) Boston: Harvard University Press.

T Ludivine *Protecting Community Rights over Traditional Knowledge: Implications of Customary laws and Practices* (2009) Geneva: International Institute for Environment and Development (IIED).

S Mani & R R Nelson eds *TRIPS Compliance, National Patent Regimes and Innovation* (2013) Cheltenham: Edward Elgar Publishing Ltd.

C Oguamanam *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (2006) Toronto: University of Toronto Press.

W P Phillips & C Onwuekwe *Accessing and Sharing the Benefits of the Genomics Revolution* (2007) Dordrecht: Springer.

D F Robinson *Confronting Biopiracy: Challenges, Cases and International Debates* (2010) London: Earthscan.

H A Strydom and N D King (eds) *Environmental Management in South Africa* 2nd ed (2009) Cape Town: Juta law.

L Tshitwamulomoni 'South African Case Study on Sceletium Tortuosum' *Expert Meeting on ABS and Intellectual Property Rights* (2011) Addis Ababa.

Chapters in books

S K Amoo & I Skeffers 'The rule of law in Namibia' in N Horn & A Bösl (eds) *Human Rights and the Rule of Law in Namibia* (2009) Windhoek: Macmillan Education Namibia.

S K Amoo 'The structure of the Namibian judicial system and its relevance for an independent judiciary' in S K Amoo *Introduction to law: Materials and cases* (2008) Windhoek: Macmillan Education Namibia.

T Beharie & T Shabangu 'Traditional knowledge, traditional cultural expressions and folklore' in Owen Dean & Alison Dyer (eds) *Introduction to Intellectual Property Law* (2014) Cape Town: Oxford University Press.

T Bubela & R Gold 'Introduction' in T Bubela & E R Gold (eds) *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interest* (2012) Cheltenham: Edward Elgar Publishing Ltd.

P Cullet et al 'Intellectual property rights, plant genetic resources and traditional knowledge' in S Biber-Klemm et al (eds) *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives* (2006) Oxfordshire: CABI International.

C B Graber & M A Girsberger 'Traditional Knowledge at the International Level: Current Approaches and Proposals for a Bigger Picture That Includes Cultural Diversity' in J.Schmid & Hansjörg Seiler (eds) *Recht des ländlichen Raums* (2006) Zürich: Geburtstag, Schulthes.

T Grant 'Patents' in Owen Dean & Alison Dyer (eds) *Introduction to Intellectual Property Law* (2014) Cape Town: Oxford University Press.

B Ong 'Harnessing the Biological Bounty of Nature: Mapping the Wilderness of Legal, Socio-Cultural, Geo-Political and Environmental Issues' in Burton Ong (ed) *Intellectual Property and Biological Resources* (2004) Singapore: Marshall Cavendish International.

M Ouma 'The policy context for a commons-based approach to traditional knowledge in Kenya' in Jeremy De Beer et al (eds) *Innovation & Intellectual Property Collaborative Dynamics in Africa* (2014) Cape Town: University of Cape Town Press.

R Wynberg &R Chennells 'Green Diamonds of the South: An Overview of the San-Hoodia Case Equitable' in R Chennells (ed) *Access to Human Biological*

Resources in Developing Countries: Benefit Sharing Without Undue Inducement (2015) Cape Town: Springer.

R Wynberg & J Silveston et al 'Value adding in the Southern African Natural Products Sector: How much do Patents Matter?' in WIPO *The Economics of Intellectual Property in South Africa* (2009) Geneva: WIPO Publications.

Journals

R B Abbott et al 'Medical Student Attitudes toward Complementary, Alternative, and Integrative Medicine' (2011) 2011 *Evidence Based Complementary and Alternative Medicine*, Article ID 985243.

E P Amechi, 'Using Patents to Protect Traditional Knowledge on the Medicinal Uses of Plants in South Africa' (2015) 11 *Law, Environment and Development Journal*.

A Cheikhyoussef et al 'Ethnobotanical study of indigenous knowledge on medicinal plant use by traditional healers in Oshikoto region, Namibia' (2011) 7 *Journal of Ethnobiology and Ethnomedicine*.

R Chennells 'Traditional Knowledge and Benefit Sharing After The Nagoya Protocol: Three Cases From South Africa' (2013) 9/2 *LEAD Journal.*

G M Cragg & D J Newman 'Natural Products: A Continuing Source of Novel Drug Leads' 2013 *Biochim Biophys Acta.*

M L Eiland 'Patenting Traditional Medicine' 2007 *Journal of the Patent and Trademark Office Society.*

T Greiber et al (eds) 'An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing'(2012) 83 *IUCN Environmental Policy and Law Paper.*

A Lubbe, A Khatib et al 'Cannabinoid CB1 receptor binding and acetylcholinesterase inhibitory activity of Sceletium tortuosum L' (2010) 17 *International Food Research Journal.*

S F Musungu & S Oh ‘The Use of Flexibilities in Trips by Developing Countries: Can They Promote Access to Medicines?’ 2006 *South Centre in collaboration with the World Health.*

M O’Hinz ‘The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore’ *(*2011) 3 *Namibia Law Journal* 1.

B B Mathew ‘Traditional knowledge Misappropriation and Biopiracy in India: A study on the legal measures to protect traditional knowledge’ (2013) 2 (12) *International Journal of Marketing, Financial services & Management Research*.

G Mengistie, N Halm & R A Kaakunga ‘Multi-Stakeholders Workshop: Validation of the National Intellectual Property Strategy for Namibia’ 2016 *Intellectual Property Audit Report of Namibia.*

L Y Ngombe ‘The Protection of Folklore in the Swakopmund Protocol Adopted by the ARIPO’ (2011) 14(5) *The Journal of World Intellectual Property*, 403.

B Patwardhan & R A Mashelka ‘Traditional medicine-inspired approaches to drug discovery: can Ayurveda show the way forward?’(2009) 14 (15/16) *Drug Discovery.*

F K Phillips Intellectual Property Rights in Traditional Knowledge: Enabler of Sustainable Development (2016) 32(83) *Utrecht Journal of International and European Law.*

J H Reichman ‘The Know – How Gap in the TRIPS Agreement: Why Software has Fared Badly, and what are the Solutions’ (1995) 17 *Hastings Communication and Entertainment Law Journals* 7.

N G Siew Kuan ‘The Trips Agreement and its Implementation in Relation to Singapore Intellectual Property Law’ (1997) 9 *Singapore Academy of Law Journal*.

R D Singh Pharmaceutical Biopiracy and Protection of Traditional Knowledge (2014) 3 *International Journal of Research and Development in Pharmacy and Life Sciences* 2.

M T Smith & N Gericke et al 'Psychoactive Constituents of the Genus Sceletium N.E. Br. and Other Mesembryanthemaceae: A Review' (1996) 50 *Journal of Ethnopharmacology*.

D Totten 'Local Product Wins International Award' (2013) 102 *The South African Journal of Natural Medicine.*

I Vermaak & A Viljoen 'Indigenous South African Medicinal Plants Part 9: Hoodia Gordonii' 2008 *SA Pharmaceutical Journal.*

L A D Williams 'Ethnomedicine' (2006) 55 *West Indian Medical Journal* 4.

R Wynberg 'Bioprospecting delivers limited benefits in South Africa' 2004 *EIPR* 239.

R Wynberg 'Rhetoric, Realism and Benefit-Sharing' 2005 *Journal of World Intellectual Property.*

R Wynberg 'Bioprospecting, Access and Benefit-Sharing in South Africa: Towards a Strategic Assessment' 2004 *National Botanical Institute.*

Thesis

Saima Nghihalwa *An Analysis of The Registration of Traditional Product Names, Terms, Symbols and Other Cultural Expressions as Trademarks in Namibia* (unpublished LLM thesis, University of Cape Town, 2014).

Aina Vilho *A Critical Analysis of the Protection of Traditional Knowledge within the Namibian Legal System* (unpublished LLM thesis, University of Cape Town, 2014).

Internet sources

African Regional Intellectual Property Organization (ARIPO) 'Traditional Knowledge' available at *http://www.aripo.org/services/traditional-knowledge*; last accessed on 11 August 2016.

CBD 'History of the Convention' available at *https://www.cbd.int/history/* last accessed 21 September 2016.

CBD 'Namibia: Country Profile' available at https://www.cbd.int/countries/default.shtml?country=na last accessed on 21 September 2016.

CBD 'the Nagoya Protocol on Access and Benefit-sharing' available at *https://www.cbd.int/abs/* last accessed 21 September 2016.

CBD 'Parties to the Nagoya Protocol' available at *http://www.cbd.int/abs/nagoya-protocol/signatories/* last accessed 21 September 2016.

CBD 'Access and Benefit sharing: Hoodia case' The Dutch-German ABS Capacity Development Initiative for Africa available at *https://www.cbd.int/financial/bensharing/southafrica-hoodiacase.doc;* last accessed on 23 November 2016.

S Carey 'A South African herb that may rival Prozac' *Zembrin* available at http://www.zembrin.com/2013/02/11/a-south-african-herb-that-may-rival-prozac/ last accessed on 20 November 2016.

L Daniels 'A Cautious Welcome for South Africa's Traditional Knowledge Legislation' *Intellectual Property Watch*29 April 2015, available at *http://www.ip-watch.org/2015/04/29/a-cautious-welcome-for-south-africas-traditional-knowledge-legislation/;* last accessed on 14 November 2016.

Expert Meeting on ABS and Intellectual Property Rights Addis Ababa, Ethiopia 'Details of the Workshop' 5-9 September 2011 available at *http://www.abs initiative.info/uploads/media/Expert_Meeting_on_ABS___IPRs_-_06092011_Report_Day_Two.pdf;* last accessed on 20 November 2016.

International Centre for Trade and Sustainable Development (ICTSD) 'WIPO Committee Advances Working Document on Genetic Resources, Though Divisions Remain' *Bridges* 9 June 2016, available at *http://www.ictsd.org/bridges-news/bridges/news/wipo-committee-advances-working-document-on-genetic-resources-though*; last accessed on 20 October 2016.

A Gupta *Getting Creative Individuals and Communities Their Due: Framework for Operationalizing Article 8(j) And 10(c)* Draft Paper prepared for the CBD Secretariat (1997), available at *http://www.sristi.org/papers/cbd.pdf;* last accessed on 23 November 2016.

S Karjiker 'The Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill, 2016: Has the DST lost its resolve?' *The Anton Mostert Chair of Intellectual Property* 18 April 2016 available at *http://blogs.sun.ac.za/iplaw/2016/04/18/the-protection-promotion-development-and-management-of-indigenous-knowledge-systems-bill-2016-has-the-dst-lost-its-resolve/;* last accessed 14 November 2016.

M Meincke 'Negotiating traditional medicine in Namibia: the politics of health and development' *Nordiska Afrikainstitutet* available at *http://www.nai.uu.se/research/finalized_projects/negotiating-traditional-m/* last accessed on 22 November 2016.

S M Reiss *Commentary on the Paris Convention for the Protection of Industrial Property,* 2010available at *http://www.lex-ip.com/Paris.pdf;* last accessed on 21 September 2016.

M Richter 'Traditional medicine and traditional healer's in South Africa' available at *http://www.tac.org.za/Documents/ResearchPapers/Traditional_Medicine_briefing.pdf*; last accessed on 14 November 2016.

C Saez 'WIPO Update: Improved Text On Genetic Resources; Disclosure Still Undecided' *IP Watch* 08 Feb 2013, available at *http://www.ip-watch.org/2013/02/08/wipo-update-improved-text-on-genetic-resources-disclosure-still-undecided/,* last accessed on 20 October 2016.

C Saez 'WIPO Members Debate Disclosure of Origin for GRs in Patents' *IP Watch* 17 Feb 2016, available at *http://www.ip-watch.org/2016/02/17/wipo*, last accessed 16 December 2016.

Science and Technology Committee Meeting 'Indigenous knowledge system bill [B6-2016]: Departments of environmental affairs & health on comparative legislation' 31 August 2016 *Parliamentary Monitoring Group* available at

http://pmg.org.za/committee-meeting/23174/; last accessed on 17 February 2017.

The Declaration on the Rights of Indigenous Peoples, UNGAOR, 61st Session, UN Doc A/61/L.67 (2007) available at http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf; last accessed on 21 September 2016.

Tejan-Cole 'A Flexibilities in The Trips Agreement and Its Impact on National Intellectual Property Policy' available at http://www.belipo.bz/wp-content/uploads/2011/12/TRIPS-FLEXIBILITIES.pdf; last accessed on 30 September 2016

S Twarog 'Protecting And Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions' in Twarog S & Kapoor P (eds) *UNCTAD Summary Publication Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions* (2004) 62, available at http://unctad.org/en/docs/ditcted10_en.pdf; last accessed on 30 September 2016.

WHO, *Fifty-Sixth World Health Assembly*, *Agenda item 14.10,* Traditional Medicine, WHA56.31 (2003) available at http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r31.pdf, accessed on 24 August 2016.

WIPO *Advice on Flexibilities under the TRIPS Agreement,* available at http://www.wipo.int/ipdevelopment/en/legislative_assistance/advice_trips.html; last accessed on 01 November 2016.

WIPO, Intergovernmental Committee (IGC), available at http://www.wipo.int/tk/en/igc/, last accessed on 19 October 2016.

WIPO IGC *Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,* IGC Mandate 2016/2017/ 17 (October 14, 2015), available at http://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_1617.pdf; last accessed on 19 October 2016.

WIPO *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions,* available at *http://www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_93.pdf*; last accessed on 10 December 2016.

World Trade Organization (WTO) *Fact Sheet September 2006: TRIPS and Pharmaceutical Patents* available at *http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm;* last accessed 14 February 2017.

T P Ward 'South Africa's Witchcraft Suppression Act ruled unconstitutional' *The Wild Hunt* 27 January 2016, available at *http://wildhunt.org/2016/01/south-africas-witchcraft-suppression-act-ruled-unconstitutional.html*; last accessed on 14 November 2016.

A Van Der Merwe 'Comments on the Protection, Promotion, Development, and Management of Indigenous Knowledge Systems Bill, 2016' *GoLegal Industry News and Insight* 30 August 2016 , available at *http://www.golegal.co.za/iks-bill-indigenous-knowledge-systems/;* last accessed on 21 November 2016.

S Watanabe & K N Farrell Challenges of Namibian administrative structure to implement the Access to genetic resources and Benefit Sharing legislation, available at *https://dlc.dlib.indiana.edu/dlc/bitstream/handle/10535/9866/Watanabe_Shigeo_Namibian_ABS_May15.pdf?sequence=1&isAllowed=y;* last accessed on 22 November 2016.

WIPO & WHO Publications

WHO *Traditional Medicine Strategy: 2014-2023* (2013)

WHO *Fact Sheet No.134: Traditional Medicine* (2008).

WHO *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review* (2001).

World Intellectual Property Organization (WIPO) *Documenting Traditional Medical Knowledge* (2014).

WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) *Recognition Of Traditional Knowledge Within The Patent System,* WIPO/GRTKF/IC/13/7, Annex, page, (September 8, 2008).

WIPO IGC *Practical Mechanisms for the Defensive Protection of TK and GRs within the Patent System,* WIPO/GRTKF/IC/5/6.

WIPO IGC*, Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*, WIPO/GRTKF/IC/20/INF/7, Annex, page, (January 10, 2011).

WIPO General Assembly, *Twenty-Sixth WIPO General Assembly: Report,* WO/GA/26/10 (Geneva: 2000).

WIPO IGC, *Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources,* WIPO/GRTKF/IC/30/ (Geneva: 2016).

WIPO IGC, *Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge,* Study No. 3 (Geneva: 2004)

WIPO, *Thirty-Eighth WIPO Assembly: Report*, WO/GA/38/20 (Geneva: 2009).

WIPO *Intellectual Property and Traditional Medical Knowledge: Background Brief No. 6* (2016).

WIPO IGC, 'Traditional Knowledge – Operational Terms and Definitions', WIPO/GRTKF/IC/3/9 May 20, 2002.

Figures