LL.M.
INTELLECTUAL PROPERTY LAW

Patent System and its Role in the Conservation of South African Biodiversity

NAEEMA SADAF
(SDFNAE001)

Thesis Presented for the Degree of
MASTER OF LAWS
In the Department of Commercial law, Faculty of Law
UNIVERSITY OF CAPE TOWN

March, 2017

Supervisor: Prof. Tobias Schonwetter
(University of Cape Town)

Declaration

1. I know that plagiarism is wrong. Plagiarism is to use another's work and pretend that it is one's own.
2. I have used the footnoting convention for citation and referencing. Each contribution to, and quotation in, this opinion from the work(s) of other people has been attributed, and has been cited and referenced.
3. This opinion is my own work.
4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

ACKNOWLEDGMENT

After several months of reviewing IP and Biodiversity laws, I think it's time to put all this aside and acknowledge all those personalities who have been instrumental in successful completion of this project.

Firstly, my sincere gratitude to the Dean, Prof. Penelope Andrews for her warm welcome, cooperation and support during my time at the University of Cape Town.

Never enough thanks to Prof. Schonwetter (Research Supervisor), who indeed deserves high praise for his professionalism in all respects of this thesis-completion. I highly appreciate his industrious contribution, invaluable comments and perceptive criticism; and feel no hesitation in saying that this piece-of-writing could not have taken the present shape without his support and guidance. It was a pleasant experience to work with him as a student.

My special thanks to Dr. Tong and Dr. Ncube; discussions with them on various IP topics turned out of great value as they helped me in developing better understanding of patent and biodiversity related issues.

Endless encouragement of my family and nice companionship of my dear friends Jillian, Catherine, Shumi, Kula, Cisle and Tatenda who made my stay at UCT really unforgettable.

Naeema Sadaf

TABLE OF CONTENTS

LIST OF ACRONYMS

ABS	Access and Benefit Sharing
BoA	Board of Appeal
BSAs	Benefit Sharing Agreements
CBD	Convention on Biological Diversity
CSIR	Council for Scientific and Industrial Research
DEAT	Department of the Environmental Affairs and Trade
DNA	DeoxyriboNucleic Acid
DST	Department of Science and Technology
EDVs	Essentially Derived Varieties
EPC	European Patent Convention
EPO	European Patent Office
ESG	Environmental Support Group
FAO	Food and Agriculture Organization
GI	Geographical Indication
IBRs	Indigenous Biological Resources
ICBG	International Co-operative Biodiversity Group
IFOAM	International Federation of Organic Agriculture Movement
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MATs	Mutually Agreed Terms
MTAs	Material Transfer Agreements
NDUS	New, Distinct, Uniform, Stable
NEMA	National Environmental Management Act
NEMBA	National Environment Management: Biodiversity Act

NGOs	Non-Governmental Organizations
NIH	National Institute of Health
NSF	National Science Foundation
PBR	Plant Breeders' Rights
PCT	Patent Corporation Treaty
PIC	Prior Informed Consent
PVP	Plant Variety Protection
R&D	Research and Development
TBA	Technical Board of Appeal
TK	Traditional Knowledge
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNEP	United Nations Environmental Program
UPOV	International Union for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
USPTO	United States Patent and Trade Mark Office
WTO	World Trade Organization

ABSTRACT

South Africa is a biologically diverse but technologically less advanced economy. Like many other developing countries in the world, its biodiversity is exposed to danger due to certain human activities. Among these, patents are charged as the easiest routing for misappropriation of indigenous biological resources and traditional knowledge associated therewith. Being member of the United Nations Convention on Biodiversity, South Africa is under obligation to ensure that its patent system supports the Convention's objectives including biodiversity conservation and sustainable use rather than its destruction and decline. The purpose of this dissertation is not only to dilute this misconception about South African patent system but to prove that with an access and benefit sharing mechanism it is an effective tool for biodiversity conservation, capacity-building and industrial development in the country. To make the system more protective of the rights of the indigenous communities, various modifications have also been proposed in the existing stature of the Act.

A. RATIONALE BEHIND THE STUDY

The real consideration behind granting patent is to protect and promote technological innovations. Though innovation may find its own way through granting exclusivity over a fixed period of time in exchange for a complete disclosure of the invention to the public, the patent system incentivizes entrepreneurs and researchers to invest into new ideas and technological innovations. For high-tech industries such as biotechnology and cell biology, where creation of the next generation of drugs requires years-long and unpredictably costly research and development (R&D), the need for an effective patenting system is enormous for the value of a company and its ability to raise finance. In parallel, innovations and patenting in pharmaceutical and biotechnology industries particularly demand greater genetic diversity.[1] This among others requires maintenance of diverse traditional plant varieties, in the farmer's field (*in-situ*).[2]

Notwithstanding the fact that patents provide exclusive rights to researchers and innovators in exchange for disclosure of their inventions, the general public's presumption is that it is destructive of the biological resources of the indigenous community.[3] On the other hand, the practical experience reflects that, during the last two decades, growing of a relatively small number of high-yielding genetically uniform crop varieties for uniform food production[4] has unknowingly exposed the traditional crop varieties and other genetic resources to greater risks of extinction.[5] This loss in diversity has greatly affected the availability of new drugs and treatments in the market.[6] Added to the issue is the economic marginalization of the farmers or growers of diverse traditional plant varieties; consequent exodus of farmers to non-farm employment; unfair acquisition of genetic resources and traditional knowledge related thereto; inequitable sharing of benefit flowing from the utilization of

---

[1] Louise Sperling '*Using diversity: enhancing and maintaining genetic resources on-farm*' (1995), International Development Research Centre, CRDI, p130.
[2] Ibid.
[3] Carl-Gustaf Thornström '*Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials'* (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1461-67.
[4] 'Biodiversity: Plants – Food and Agriculture Organization of the United Nations' available at *http://www.fao.org/biodiversity/components/plants/en/* accessed on 4 January, 2017.
[5] H. F. Van Emden '*Biodiversity and habitat modification in pest management'* (2011), International Journal of Tropical Insect Science, Vol. 15, Issue 6, p605-20.
[6] Christian Wolfe et al. 'Human Genetic Diversity and the Threat to the Survivability of Human Populations*'* available at *https://www.ohio.edu/ethics/2003-conferences/human-genetic-diversity-and-the-threat-to-the-survivability-of-human-populations*/ accessed on 23 January, 2017.

biological resources; and the competitive disadvantage of the traditional crops compared to the modern genetically uniform varieties.[7]

This thesis endeavors to explore the role of patents in conserving biodiversity especially the genetic resources and sustainable use of its components. While recognizing fair and equitable compensation for their stewards under the international conventions and agreements on biodiversity to which the South Africa is a member, this thesis probes factors contributing to the extinction of biodiversity, and suggests amendments to the existing South African Patents Act that may ensure greater protection to the South African biodiversity, traditional knowledge; and rights of the indigenous communities.

[7] Stephen B. Brush '*The Lighthouse and the Potato: Internalizing the Value of Crop Genetic Diversity'* (2002), Political Economy Research Institute (PERI), Working paper No. 37, University of Massachusetts.

CHAPTER ONE: INTRODUCTION

This chapter aims to provide a conceptual understanding of the issue of biodiversity extinction and contributing factors from both the national and international perspectives. As far as the international perspective the concerned, the focus is on the key provisions of the most relevant international conventions and agreements. An important question is whether these provisions are indeed supportive of the instruments' overarching objectives, or whether there are inconsistencies in some respects. Further, this chapter examines the impact of international agreements and conventions on national legislations and the role of national governments in biodiversity conservation.

1.1 WHAT IS BIODIVERSITY AND WHY DO WE NEED TO CONSERVE IT?

The Convention on Biodiversity (CBD)[8] defines 'biodiversity' to mean- 'the variability among living organisms from all species, including inter alia, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems'. This definition reflects that living things make up the biodiversity of the earth. It includes not only the naturally occurring species (the biological resources) 'as such' but also their functional unit of heredity (the genetic resources) and a dynamic complex of plants, animals, microbial or other origins containing functional unit of heredity.[9]

It is well-accepted that biodiversity is critical for development and to maintain life-sustaining systems of biosphere, human well-being, the livelihood and cultural integrity of people[10]. A stable ecosystem is dependent on greater biodiversity.[11] Greater biodiversity increases the chances of discovering new compounds of increasing medicinal value[12], diagnostic tools (new genes/DNA[13] sequences), and methods of treatment. In the past, various species of plants and animals have proven to be useful for the treatment of various diseases. Examples include: Digitalin,

---

[8] The United Nations Convention on Biodiversity, 1992.
[9] 'Genetic resources and intellectual property' World Intellectual Property Organization available at *http://www.wipo.int/tk/en/genetic/* accessed on 12 April 2016.
[10] '*Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*' (2002), Secretariat of the Convention on Biological Diversity, p III.
[11] Edward Wilson 'The Diversity of Life' available at *http://www.hup.harvard.edu/catalog.php?isbn=9780674058170* accessed on 19 August, 2016.
[12]David G.I. Kingston '*Modern natural products drug discovery and its relevance to biodiversity conservation'* (2011) Journal of Natural Products Mar 25; 74(3): 496-511.
[13] DeoxyriboNucleic Acid.

isolated from the plant *digitalis purpurea*[14] which was found to be useful for various cardiac conditions particularly for patients in atrial fibrillation; Vincristine isolated from *rosy periwinkle*[15] of Madagascar which helps in treating childhood leukemia; *Aloe ferox* has long been known and used by South Africans as a purgative[16]; *Aspalathuslinearis* (commonly: Rooibos), growing in South Africa's Fynbos, which has successfully been used in iron-deficiency anemia.[17]

1.2 FACTORS CONTRIBUTING TO BIODIVERSITY EXTINCTION

In the preamble of the CBD, the contracting parties affirmed that 'conservation of biological diversity is a common concern of mankind'. Natural selection, as opposed to directed or designed selection, is the common process of evolution and variability within species to adapt to the environment. Loss in variability is directly equivalent to the extinction of species[18]. This has happened countless times in the earth's history but with the increasing instances of human intervention in the natural selection process for enhanced productivity, the rate of extinction of species and variability has now increased to an alarming extent.[19] More so, lack of information and knowledge about the significance of biodiversity and consequently the need for its conservation by developing countries that are rich in biological diversity[20] has already destroyed many of the world's strongest varieties of farm animals. Moreover, lack of resources to develop scientific, technical, and institutional capacities in developing countries has resulted in failure to assess future threats to biodiversity, and to plan and put into practice a course of action to conserve biodiversity.[21] This situation[22] has made it vital for the States[23] to foresee, prevent,

---

[14] (commonly: the foxgloves or 'finger-like' - native to western and southwestern Europe, western and central Asia, Australasia and Northwestern Africa).
[15] Raymond Cooper 'Africa's gift to the world' available at *http://www.rsc.org/eic/2015/12/rosy-periwinkle-cancer-vinblastine* accessed on 3 May 2016.
[16] Weiyang Chen '*Cape aloes—A review of the phytochemistry, pharmacology and commercialisation of Aloe ferox*' (2012) El Sevier, Phytochemistry Letters 5 (2012) 1–12.
[17] Cecilia van Niekerk '*Indigenous South African Medicinal Plants Part 11: Aspalathus linearis ('Rooibos')*' (2008) SA Pharmaceutical Journal – November/December.
[18] Anup Shah 'Loss of Biodiversity and Extinctions' available at *http://www.globalissues.org/article/171/loss-of-biodiversity-and-extinctions* accessed on 28 April 2016.
[19] Graham Bell '*Adaptation, extinction and global change'* (2008) Evolutionary Applications, 1: 3–16. doi:10.1111/j.1752-4571.2007.00011.x.
[20] (such as Africa, Asia and South America).
[21] '*Study on understanding the causes of biodiversity loss and the policy assessment framework*' European Commission Directorate-General for Environment, Report (2009), Framework Contract No. DG ENV/G.1/FRA/2006/0073 Specific Contract No. DG.ENV.G.1/FRA/2006/0073.
[22] i.e. Loss of variability, extinction of species, lack of awareness about loss of biodiversity, etc.
[23] i.e., signatories to the CBD and other conventions

and attach the causes of significant decrease or loss of biological resources at source.[24]

Developing countries are the center of diversity and abundance of biological resources.[25] This is why issues relating to the conservation of biodiversity, unfair acquisition, and inequitable sharing of benefits are more of concerns for the developing countries;[26] and within them, for farmers and the stewards of these resources.

1.3 BIODIVERSITY CONSERVATION: THE INTERNATIONAL AGREEMENTS

1.3.1 The CBD, 1992

Based on the Charter of United Nations and the principles of international law, the CBD - adopted in 1992 in Rio de Janeiro, Brazil - is the first instrument which provides a comprehensive framework to staunch the loss of biodiversity.[27] Recognizing the seriousness of threats to biodiversity, the CBD makes it incumbent upon the parties to the convention, to co-operate directly or through competent international organizations to meet the CBD's objectives.[28] For developed nations, this requires supporting biodiversity-rich but research and development lagging, economically poor countries in their efforts to conserve biodiversity[29] and advance sustainable use.[30] Within the meaning of the CBD, promoting biodiversity conservation, its sustainable-use, and fair and equitable sharing of benefits arising out of the use of genetic resources is thus a legally and morally binding obligation for the contracting states.[31] Though not directly concerned with the patent standards, the CBD projects a new approach to deal with the issues relating to the conservation of

---

[24] United Nations Convention on Biological Diversity, 1992, p 1.
[25] Klaus Ammann, '*Reconciling Traditional Knowledge with Modern Agriculture: A Guide for Building Bridges'* (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1552.
[26] Dennis S. Karjala '*Biotechnology Patents and Indigenous Peoples'* (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1442.
[27] J. Spangenberg 'Biodiversity Pressure and the Driving Forces Behind' *(2006) available at http://www.academia.edu/339491/Biodiversity_Pressure_and_the_Driving_Forces_Behind accessed on 23 January, 2017.*
[28] Art. 5 of the CBD, 1992.
[29] Ademola A. Adenle et al. 'Stakeholder Visions for Biodiversity Conservation in Developing Countries' (2015) available at *www.mdpi.com/2071-1050/7/1/271/pdf* accessed on 20 January, 2017.
[30] 'Ecosystems and Human Well-being: Biodiversity Synthesis' available at *www.unep.org/maweb/documents/document.354.aspx.pdf* accessed on 18 January, 2017.
[31] Bonn Guidelines op cit note 10.

biological resources.[32] It provided developing nations with an opportunity to record their protest concerning the unlawful exploitation of their indigenous resources and traditional knowledge. The CBD recognizes the states' sovereignty over biological resources, and empowers them to regulate access to genetic resources.[33] It further authorizes states to stipulate the terms and conditions of the Access and Benefit Sharing (ABS) mechanism including the sharing of the results of research and development fairly and equitably.[34] The CBD provides that ownership over bio-resources rests with the country of origin, regardless of whether the resources or knowledge related thereto merits protection under intellectual property laws.[35] Through recognizing national sovereignty over genetic resources, the CBD presaged a property system over them. The CBD thus represents a step towards a negotiated settlement between parties who manage genetic resources and are interested in their conservation. The CBD facilitates access to genetic resources on mutually agreed terms (MATs), subject to prior informed consent.[36] Its key objectives have significantly impacted upon the way biological resources were exploited in the past. Bioprospecting contracts between pharmaceutical companies[37] and indigenous communities in exchange for short- or long-term financial returns are a practical manifestation of the success of the CBD's objectives, especially the ABS mechanism.[38]

1.3.2 The Bonn Guidelines, 2002

Through recognition of national governments' autonomy over biological resources and helping access to them on MATs, the CBD has provided a general guideline for concluding bioprospecting contracts between the parties. However, it was only when the Conference of the Parties to the Convention at its 6th meeting, held in Hague in

---

[32] Chapter 2 of the CBD, 1992.
[33] Art. 15.1 of the Convention on Biological Diversity, 1992.
[34] Art. 15.7 of the Convention on Biological Diversity, 1992.
[35] Achim Seiler et al. '*Regulating Access and Benefit Sharing: Basic issues, legal instruments, policy proposals'* (2001), German Federal Agency for Nature Conservation, BfN –Skripten 46, p93-100;
Hanns Ullrich '*Traditional knowledge, biodiversity, benefit-sharing and the patent system: Romantics v. Economics?'* (2005), EUI Working paper law No. 2005/07, p13;
Carl-Gustaf Thornström 'Science, Genetic Resources and Regulation' (2014) available at *http://www.slu.se/globalassets/.gamla_strukturen/externwebben/centrumbildningar-projekt/grip/grip-12-13-science-genetic-resources-and-regulation-final-report-to-sida-.pdf* accessed on 14 January, 2017.
[36] Art. 15.4 & Art. 15.5 of the CBD, 1992.
[37] (either research-based or generics).
[38] Robert J. Lewis '*Case studies on access and benefit-sharing'* (2006), The International Plant Genetic Resources Institute (IPGRI).

April, 2002 adopted the voluntary Bonn Guidelines, that the access and benefit-sharing objective of the CBD could be operationalized. The Bonn Guidelines principally aimed at helping parties to develop an overall access and benefit-sharing policy, which may become part of their national biodiversity and action plan.[39] And to advance this objective, it provides preliminary information about the rules on access to genetic resources and a concrete procedure to be followed by researchers, scientists, and pharmaceutical companies interested in bioprospecting.[40]

Apart from the principal commonality with the CBD, the Bonn Guidelines have the following objectives: i) promotion of awareness on implementation of relevant provisions of the CBD; ii) provision of a transparent framework to make it easier the access to genetic resources and ensure fair-and-equitable sharing of benefits; iii) promotion of adequate and effective transfer of 'appropriate' technology to providing parties, and iv) capacity building to guarantee the effective negotiation and implementation of ABS arrangements.[41] The Bonn Guidelines state legal certainty and minimization of transaction costs as pre-requisites for the development of MATs.[42] The Guidelines also provide the following list of subjects[43] to be agreed upon for the success of contractual agreements: i) type and quantity of genetic resources; ii) limitation on the use of material; iii) recognition of national sovereignty over genetic resources; iv) capacity-building; v) whether terms of agreement can be negotiated in certain circumstances; vi) whether genetic resources can be transferred to third parties and if so, under what conditions; vii) whether practices, knowledge, and innovations of indigenous communities are preserved, maintained and respected; viii) whether conventional use of biological resources is protected; ix) treatment of confidential information; and x) sharing of benefits (types, distribution, timing, and mechanism of benefits to be shared).

---

[39] Bonn Guidelines op cit note 10.
[40] Klaus Liebig et al. '*Access to Genetic Resources and Approaches to Obtaining Benefits from their Use: the Case of the Philippines*' (2002), German Development Institute, Reports and Working Papers 5/2002, p50-51;
'ABS-Management Tool Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities' (2007), available at *https://www.iisd.org/pdf/2007/abs_mt.pdf* accessed on 4 January, 2017.
[41] Art. 11 of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, 2002.
[42] Art. 42 of the Bonn Guidelines, 2002.
[43] Art. 44-48 of the Bonn Guidelines, 2002.

1.3.3 TRIPS, 1994

In order to further advance the CBD's objectives, and to structure the terms and conditions in bioprospecting arrangements, in 1994, the United Nations member states concluded the WTO's[44] Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS provides minimum protection standards for IP. However, member states are at liberty to set higher standards for IPRs protection if they consider it appropriate.

In literal terms, the CBD and TRIPS stand in conflict in that Art. 27(3)(b) of TRIPS on one hand permits its members states to exclude from patentability - '*plants and animals other than micro-organisms and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes*'; while on the other, it does mandate the plant varieties' protection either by patents, or by an effective *sui generis* system, or a combination thereof. In contrast, the CBD does not favour patent protection to product when found in its natural environment.[45]

The apparent conflict between TRIPS and the CBD is more of a nuisance than a real problem in that most of the concerns are imaginary. TRIPS clearly allows states to exclude naturally occurring plants (wild-type or landraces), including all varieties that are the results of natural selection process (crossing and selection), from patentability.[46] It further authorizes member states to set an even higher standard of patentability resulting in exclusion of trivial inventions. Art. 27(2) of TRIPS permits member states 'to exclude from patentability inventions the commercial exploitation of which is necessary to protect *ordre public* or morality including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'.[47] *Ordre public* and morality have different meanings in different societies and cultures. Art. 27(1) of TRIPS allows protection to inventions that are new; are capable of industrial applications; and involve an inventive step. This means that traditionally developed or existing knowledge in the possession of local or indigenous community may not be the subject of patent protection.

---

[44] The World Trade Organization, 1995.
[45] Paul Gepts '*Who Owns Biodiversity, and How Should the Owners Be Compensated*?' (2004), Plant physiology, 134(4), p1295-1307.
[46] Art. 27(3)(b) of the TRIPS, 1994.
[47] Dan Leskien '*Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*' (1997), The International Plant Genetic Resources Institute (IPGRI), p 15.

1.3.4 The International Treaty on Plant Genetic Resources for Food and Agriculture, 2001

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), adopted in Rome in 2001, is another international agreement governing agricultural biodiversity. The treaty states as its objectives, in harmony with the CBD, 'the conservation and sustainable use of all plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, for sustainable agriculture and food security'.[48] It clarifies that these objectives will be achieved by closely linking the treaty to the Food and Agriculture Organization (FAO) of the United Nations and to the CBD.[49] The treaty advocates promotion of an integrated approach towards exploration, collection, conservation, characterization, regeneration and evaluation, and documentation of plant genetic resources for food and agriculture, however, in cooperation with other contracting parties and subject to national legislation.[50] It also emphasizes further co-operation to promote development of an efficient and sustainable system of *ex-situ* (off-farm) conservation and development, and transfer of appropriate technologies for the purpose.[51]

Art. 9 of the treaty is exclusively devoted to farmers' rights: Art. 9.1 recognizes 'the enormous contribution of the local and indigenous communities and farmers of all regions of the world particularly those in the centers of origin and crop diversity'. In terms of Art. 9.2, responsibilities for realizing the farmer's rights, as they relate to plant genetic resources for agriculture and food, rest with the national governments and this is made subject to national legislation. In particular, 'the contracting parties are urged to take measures to protect and promote farmers' rights, including: i) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; ii) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and iii) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture'. Art. 9.3 expressly states that: 'nothing in this Article [Art. 9] shall be interpreted to limit any rights that farmers have'.

---

[48] Art. 1.1 of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.
[49] Art. 1.2 of the ITPGRFA, 2001.
[50] Art. 5 of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.
[51] Art. 5.1(e) of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.

The treaty provides a multilateral system of access and benefit-sharing.[52] It requires benefit-sharing[53] through: 'a) exchange of information; b) access to technology transfer; c) capacity building; and d) the sharing of monetary and other benefits of commercialization'.[54] Subject to national legislation, the legally binding treaty recognizes the fundamental rights of farmers to save, use, sell, and/or exchange farm-saved seeds and other propagating materials.[55]

Hence, the very aims and objectives of the treaty in unification with the CBD suggest that most of the concerns by NGOs and other non-profit organizations about exploitation of farmers' rights need to be addressed by their respective governments. It is a failure on their own part when the national governments show connivance in making timely and appropriate legislation to protect their public rights and/or address their concerns.

TRIPS, the CBD and the ITPGRFA are all legally binding instruments; so if they are in conflict with each other in any way, it is the responsibility of United Nations' Office of the Secretariat to take measures to resolve any such controversies in cooperation with the contracting parties.[56] Until their resolution, contracting parties must not be concerned about any outside threats. What the farmers, local and indigenous communities of the developing countries need to do is, not to let their respective governments make any conflicting provisions to be the part of their national legislation. Additionally they must focus on building capacity and infrastructure so that crop genetic resources and diversity may be protected and promoted.

1.3.5 The Cartagena Protocol on biosafety to the Convention on Biological Diversity, 2000

The Cartagena Protocol[57] is another instrument of great significance to meet the aims and objectives of the CBD.[58] It provides rules on the biosafety and trans-boundary

[52] Art. 10 of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.
[53] Art. 13 of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.
[54] Christine Frison '*Plant Genetic Resources and Food Security: stakeholder perspectives on the international treat y on plant genetic resources for food and agriculture*' (2011), FAO, Bioversity International and Earthscan, p 263.
[55] Regine Andersen '*Realising Farmers' Rights to Crop Genetic Resources: Success Stories and Best Practices*' (2013), Routledge, p15.
[56] Art. 24 of the CBD, 1992.
[57] An international agreement on biosafety as a supplement to the Convention on Biological Diversity effective since 2003.

movements of genetically modified living organisms. Art. 2 of the Protocol requires its parties 'to ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account the risks to human health'.

The Protocol explicitly states that it shall not have any affect or bearing on the sovereignty of the states over their biological resources.[59] It further provides that - 'nothing in the protocol shall be interpreted as restricting the right of a party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the protocol'.[60] Thus developing countries are at liberty to take legislative, administrative, and any other measures that are appropriate for the protection of their biological resources. In meeting the conservation and sustainable use objectives, developing countries can do more than the protocol called for. So once again, the concerns voiced by developing countries about exploitation of their rights are indicative of some ignorance concerning these provisions. Farmers, local and indigenous communities with the assistance of their scientists, researchers, and economist must urge their respective governments to take measures that are not only protective of the world biodiversity but also their own indigenous biological resources.[61]

1.3.6 The Nagoya Protocol, 2010

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 ("Nagoya Protocol") entered into force in 2014. It is another landmark treaty that significantly advances the CBD's third objective (access and benefit sharing) by providing a strong base for transparency (for both providers and users of genetic resources) and greater legal certainty.[62]

---

[58] (i.e., conservation of biodiversity, sustainable-use of its components, and fair and equitable sharing of benefits arising out of the utilization of biological resources).
[59] Art. 2.3 of the Cartagena Protocol, 2000.
[60] Art. 2.4 of the Cartagena Protocol, 2000.
[61] Francesco Mauro '*Traditional knowledge of indigenous and local communities: International debate and policy initiatives*' (1999), Ecological Applications: Vol. 10, No. 5, pp. 1263–1269.
[62] María Julia Oliva '*Sharing the Benefits of Biodiversity: A New International Protocol and its Implications for Research and Development'* (2011), Thieme Planta Medica, 77(11), p1221-27.

Among the various objectives, Nagoya protocol aims to promote the use of genetic resources and associated traditional knowledge. It also strengthens the opportunities for fair and equitable sharing of benefits. Stating differently, the Nagoya Protocol aims 'to provide incentives to conserve biodiversity leading to sustainable development and human well-being'. The Protocol specifies means by which the CBD can be implemented. In order to address issues relating to fair-and-equitable sharing of benefits derived in trans-boundary situations and where the possibility to grant or obtain prior informed consent is not an option, Nagoya Protocol provides a global working mechanism.[63]

The Protocol defines its relationship with other international agreements and instruments.[64] It provides that- 'this Protocol shall not affect the rights and obligations of any party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity'.[65] It further allows states to join any other relevant international agreements.[66] This suggests parties may refuse to implement conflicting provision in other international agreements that are in conflict with the CBD's and the Nagoya Protocol's objectives.[67] And if this rule is to prevail then any provision of TRIPS working against the CBD's objectives may be held responsible.

1.3.7 UPOV, 1991

The International Union for the Protection of New Varieties of Plants Convention[68] (UPOV) provides legal protection for plant varieties fulfilling the new, distinct, uniform, and stable (NDUS) criteria. One of the key objectives of the UPOV is to ensure that 'the members of the UPOV acknowledge the achievement of breeders of new varieties of plants, by granting them an intellectual property right, on the basis of a set of clearly defined principles'.[69]

---

[63] Art. 10 of the Nagoya Protocol, 2010.
[64] Art. 4 of the Nagoya Protocol, 2010.
[65] Art. 4.1 of the Nagoya Protocol, 2010.
[66] Art. 4.2 of the Nagoya Protocol, 2010.
[67] '*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'* (2011), Secretariat of the Convention on Biological Diversity Montreal.
[68] The International Union for the Protection of New Varieties of Plants Convention, 1991.
[69] UPOV Press Release No. 43, (2000) - International Union for the Protection of New Varieties of Plants, 1991.

The UPOV Convention contains exceptions[70] to infringements so that the breeders of a variety cannot prevent others from the following activities: 'i) acts done privately for non-commercial purposes; ii) acts done for experimental purposes; iii) acts done for the purpose of breeding other varieties'. Moreover, farmers are free to use the farm-saved seeds for re-propagation on their own land.[71] Another salient feature of the 1991 revision of the UPOV Convention is that protection to NDUS varieties now extends to 'essentially derived varieties' (EDVs).[72]

There is general presumption that by requiring parties to protect plant varieties through patent or by a *sui generis* system, TRIPS threatens crop biodiversity; undermines the CBD's objectives; and usurps the rights of the plants growers and/or their stewards.[73] Ironically these are the issues connected with the nations' status. Until the developing nations attain the status of developed, these issues shall keep on sprouting in one way or the other. The TRIPS provides states with this flexibility; national governments face an array of options in choosing the intellectual property regime applicable to plant varieties.[74] An act of national PVP legislation, complying with the UPOV Convention is one of them. Understanding of the reality and implications of the UPOV regulations for farmers in developing countries could inform decision-making and contribute to designing national PVP laws that take the particular situation of these countries into account.

This chapter concludes that irrespective of apparent conflictions in some international conventions and agreements, these unanimously urge the need of conserving biological diversity for evolution; and direct states to use their biological resources in a sustainable manner. Based on these findings, the next chapter focuses on how to protect the biological diversity from piracy and the role of intellectual property laws in achieving this objective.

---

[70] Art. 15 of the International Union for the Protection of New Varieties of Plants, 1991.
[71] Anja Christinck et al. '*The UPOV Convention, Farmers' Rights and Human Rights'* (2015), Federal Ministry for Economic Cooperation and Development (BMZ), Germany; p15.
[72] Art. 14 of the UPOV, 1991.
[73] GRAIN 'TRIPS versus biodiversity: What to do with the 1999 review of Article 27.3(b)' available at *https://www.grain.org/article/entries/11-trips-versus-biodiversity-what-to-do-with-the-1999-review-of-article-27-3-b* accessed on 23 June, 2016.
[74] Laurence R. Helfer '*Intellectual property rights in plant varieties International legal regimes and policy options for national governments'* (2004) Food and Agriculture Organization of the United Nations, Rome.

CHAPTER TWO: BIOPIRACY AND IP

Whatever the nature of factors fueling the issue of biopiracy, its impact on the national economy and biodiversity conservation strategies is devastating.[75] In the first part of this chapter, beyond defining the concept of biopiracy and its implication on biodiversity, a significant number of landmark cases concerning biopiracy are discussed. In the second part, different IP mechanisms available to companies to protect the results of their investments in bioprospecting are examined. With specific reference to patents, this chapter endeavors to critically examine existing conceptions about the scope of protection provided to the innovations based on IBRs.

2.1 WHAT IS BIOPIRACY?

Protecting TK and IBRs such as plants, microbes, and genetic materials (commonly: the biodiversity) from unlawful misappropriation is one of the challenges faced by developing countries, and South Africa is no exception.[76] Conservation of biodiversity is critical to thwart unlawful exploitation of indigenous people's rights, and to ensure that patent rights are not granted for products and treatments lying in the public domain. In parallel, it is another reality that exponential growth of intellectual assets requires that the pharmaceutical and biotechnology companies are allowed access to biological resources of the developing countries for the development of new pharmaceutical and agricultural products.

Unfair exploitation of indigenous people's knowledge with regards to the medicinal qualities of plants and other biological resources by research-based companies, without prior permission from, and with little or no compensation or recognition to the indigenous people, is a practice commonly termed as 'biopiracy'.[77] Stated differently, biopiracy is a depressing consequence of a practice called 'bioprospecting' involving: i) use of indigenous people's knowledge to identify the local plants, previously known for their curative value, which are then synthetically

---

[75] Hanspeter Rejhling '*Bioprospecting the African Renaissance: The new value of muthi in South Africa*' (2008), Journal of Ethnobiology and Ethnomedicine, http://doi.org/10.1186/1746-4269-4-9; Deborah Andrews 'Traditional Agriculture, Biopiracy and Indigenous Rights' (2012) available at *https://sciforum.net/conference/wsf2/paper/928/download/pdf* accessed on 11 January, 2017.

[76] Charles McManis '*Trends and scenarios in the legal protection of traditional knowledge'* (2011), Public Interest Intellectual Property Advisors, ch. 4.

[77] James Otieno Odek '*The Kenya Patent Law: Promoting Local Inventiveness or Protecting Foreign Patentees?*' (1994) Journal of African Law 38.

reproduced; ii) the use of TK or IBRs as a precursor for producing valuable products such as biopharmaceuticals; iii) the discovery and isolation of previously unknown compounds from the IBRs for the development of new drugs and other valuable products and/or iv) the use of traditional medicines as an escort to screen plants and other biological resources for the discovery of medicinally active new compounds.[78]

2.1.1 Examples of biopiracy

Turmeric (commonly: 'Haldi') is the most hotly debated case of biopiracy. Since olden times, turmeric has been used in India and Pakistan for wound healing. In 1995, two Indian scientists Suman K. Das and Hari Har P. Cohly obtained a use-bound US patent[79] specifically covering use of turmeric for external wound treatment. The patent was challenged by the Indian Government on account of anticipation and consequently the United States Patent and Trade Mark Office (USPTO), upon receipt of a compelling case for novelty destroying prior art, revoked the patent.[80]

Neem tree (*Azadirachta Indica*) is a traditional plant of Pakistan, India and Nepal renowned for its medicinal and insecticidal activities. In early 1990s, the U.S. Department of Agriculture and W.R. Grace Chemical Company in the U.S. obtained a patent[81] with a principal claim for a 'method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil'. The company, jointly with P.J. Margo Pvt. Ltd. of India, set up a plant in India for processing Neem seeds. In 2000, the patent was successfully opposed by several groups from the EU and India including the European Union Green Party, Vandana Shiva, and the International Federation of Organic Agriculture Movement (IFOAM), on the basis that the fungicidal activity of Neem-extract had long been known in Indian traditional medicine.[82] The appeal was lost in 2005.[83]

Basmati cultivated in Pakistan, Bangladesh, and India is a variety of rice unique in taste, aroma and grain's length. Ricetec Inc. of USA developed a new plant

---

[78] Naeema Sadaf '*Bio-prospecting: Pakistan patent law treats contribution of indigenous knowledge as 'non-inventive*'' (2011), CIPA Journal, Vol. 40 (10), 633-635.
[79] US Patent No. 5,401,504.
[80] JM Finger '*Poor People's Knowledge : Helping Poor People to Earn from Their Knowledge'* (2004), World Bank Policy Research Working Paper 3205.
[81] EP0426257.
[82]Cormac Sheridan '*EPO Neem patent revocation revives biopiracy debate'* (2005), Nature Biotechnology 23(5):511-12.
[83] '*India wins landmark patent battle*' (2005) BBC News, 9 March.

variety by crossing American long grain rice and Basmati rice, and obtained a patent[84] for it in the U.S. The Government of India challenged the patent and all specific 'per se' claim to genetic lines of basmati were ultimately withdrawn.[85]

Hoodia, a succulent South African plant, found in Kalahari Desert, was long known to the San people as an appetite suppressant. The South African Council for Scientific and Industrial Research (CSIR), in 1996, began working with pharmaceutical companies to develop a dietary supplement based on Hoodia.[86] Initially, the San people were not included to reap the benefits of use and commercialization of their traditional knowledge, but in 2003 the South African San Council came to an agreement with the CSIR under which they would receive between 6 and 8% of the revenue from the sale of Hoodia products.[87] Interestingly, in 2008, after having invested more than 20 million euro in R&D to know if Hoodia can be a potential ingredient in dietary supplement for weight loss, Unilever[88] terminated the project as the results of their clinical trials did not favor Hoodia as a safe and effective marketable product.[89]

A continuing reflection of biopiracy may be seen in the ongoing *Bt* Brinjal[90] case between U.S. company Monsanto and the Environmental Support Group (ESG), India; and Monsanto's patent[91] covering, *inter alia*, conventionally bred plants such as Indian-melons.[92]

2.2 IMPLICATIONS OF BIOPIRACY:

Adverse implications of biopiracy may be seen when pharmaceutical companies attempt to monopolize, through patenting, traditional medicines and practices by

---

[84] US patent 5663,484.
[85] 'A study of the basmati case (India-US basmati rice dispute): geographical indication perspective' available at *http://csbweb01.uncw.edu/people/eversp/classes/BLA361/Intl%20Law/Cases/Study%20of%20Basmati%20Rice%20Intl%20Case.ssrn.pdf* accessed on 10 February, 2017.
[86] Maharaj VJ 'Hoodia, a case study at CSIR' available at *http://researchspace.csir.co.za/dspace/handle/10204/2539* accessed on 13 June, 2016.
[87] Foster Laura A 'Inventing Hoodia: Vulnerabilities and Epistemic Citizenship in South Africa' available at *http://escholarship.org/uc/item/5qd3z4hr#page-2* accessed on 23 June, 2016.
[88] Unilever is a British-Dutch multinational consumer goods company
[89] 'Sustainable Development 2008: An Overview' available at *https://www.unilever.com/Images/unilever_sustainable_development_overview2008_v3_tcm13-387377_tcm244-409843_en.pdf* accessed on 5 September, 2016.
[90] Insect-resistant Bacillus thuringiensis (Bt) variety of brinjal.
[91] (e.g. EP 1962 578, EP 1714545, EP 1896567, EP 1371284, EP 1890709, EP 1765060)
[92] Lucas Laursen '*Monsanto to face biopiracy charges in India'* (2012) Nature Biotechnology Vol. 30, No. 1.

reproducing them synthetically. When enforcing such patents, indigenous people may be deprived of their right to practice traditional knowledge or to use IBRs in traditional ways.[93] Critics claim that these practices of pharmaceutical companies contribute to the economic disparity between developing countries rich in biodiversity, and developed countries hosting companies that engage in 'biopiracy'.[94] This criticism poses two basic questions: i) Whether it is justified to give access to the genetic resources and TK associated with them to the companies from the developed world (and if so, to what extent); and ii) what are the circumstances under which it is fair and equitable to share the benefits arising from utilizing these resources between the pharmaceutical company and the IBRs holder.

In order to find answers to these questions, the following should be considered:

From an economic perspective, information or knowledge, which is already in the public domain, is less attractive in that it has low momentum to accelerate the existing market. On the other hand, patents on naturally occurring substances, even in isolated or purified form, are not available for want of non-obviousness.[95] Thus, what is left to the innovator companies is either to modify the activity of the original resource product (for instance, by using some new processes or schemes or intermediary agents) or discover new resources for isolation of new active ingredients having potential for medicinal or non-medicinal activities to secure some form of patent protection. While considering bioprospecting options, research-based companies are generally aware of the fact that the scope of patent protection to any invention involving the use of IBRs cannot extend to the original resource product.[96] So the critics' allegation of economic disparity between the developed and developing nations over use of IBRs as part of bioprospecting is imaginary.[97] Patents as such do not allow bioprospectors to exploit the indigenous communities. A parallel reality is

---

[93] Robert K. Paterson '*Looking Beyond Intellectual Property in Resolving Protection of the Intangible Cultural Heritage of Indigenous Peoples'* (2003), 11 Cardozo Journal of International & Comparative Law 633.
[94] 'Agriculture and food' - Green Peace Australia Pacific, available at *http://www.greenpeace.org/australia/en/what-we-do/Food/* accessed on 22 June, 2016.
[95] Art. 27(1) of the Trade Related Aspects of Intellectual Property Rights, 1994.
[96] Graham Dutfield 'Indigenous Peoples, Bioprospecting and the TRIPs Agreement: Threats and Opportunities' available at *http://www.iatp.org/files/Indigenous_Peoples_Bioprospecting_and_the_TRIP.htm* accessed on 12 February, 2017.
[97] Ibid.

that the patent law has no provision to regulate any such attempts. The foregoing supports the view that giving access over IBRs to research-based companies for developing improved products or searching new bio-actives is also in the interest of indigenous communities both from an economic and a health perspective. However, for economically poor territories, an associated adverse impact of patents on economic activity in the form of increase in the price of access shall continue to exist.

When considering the circumstances justifying the sharing of benefits arising from the utilization of IBRs, the deciding factor is the contribution made by the indigenous community. For instance, if the contribution is to merely give access to the resources, or supply information or knowledge relating to the medicinal properties or therapeutic values of the local plants/herbs, or identification of starting material, such contribution does usually not justify creating joint-ownership rights for the indigenous community over any patentable innovation that is made using IBRs. In other words, it depends on the nature of the indigenous community's contribution (i.e., inventive or non-inventive contributions) whether and to what extent it is fair to share the benefits arising from the utilization of IBRs with the holders of the IBRs or TK.

Another implication of biopiracy is the depletion of physical resources (e.g., plants, animals, soils nutrients) of the source country.[98] This allegation is, however, not considered a problem associated with intellectual property. If an active ingredient is isolated from a medicinally active plant and synthetically manufactured, there is no further contribution to depletion in the source country. On the other hand, if the source country grants a patent on the isolated compound, the patentee can prevent others from using the plant for the purpose of isolating the active component and thus may add something to control depletion.

Seen in the above light, having access to genetic resources for the sake of commercialization or for conserving biodiversity and promoting its sustainable use are two different issues and must be assessed differently.

---

[98] Whitt LA. '*Indigenous Peoples, Intellectual Property & the New Imperial Science'* (1998) Okla. City. U. L. Rev. 23:211, 213-14, 220.

2.3 PROTECTING BIODIVERSITY: THE ROLE OF INTELLECTUAL PROPERTY

IBRs and the TK associated therewith are considered as subjects of 'collective' ownership. Passed down from generation to generation and developed through specific culture, tradition, need, and lifestyle in communities, these resources and knowledge- especially the knowledge related to the specific uses of plants for medicinal purposes – require adequate protection from exploitation particularly by the developed economies.[99] In the early 20th century, a shift to non-traditional sources for medicine had substantially declined the significance of ethnobotany in drug-discovery programs[100] but the discovery of anticancer and antiviral agents from plants (such as turmeric and Neem), have revived the pharmaceutical and agricultural industries' interest towards screening of IBRs and traditional practices, and in parallel increased the need for their protection under the appropriate IP laws.

From another perspective, non-availability of funds and lack of efficient means of States to incentivize and mandate farmers to grow traditional plant varieties has tilted the balance of strategies for reducing the externality of genetic erosion towards privatization and bioprospecting.[101] Under this approach, farmers and local communities can negotiate with their users (the seed and pharmaceutical companies) as a logical and practical solution for conservation of biodiversity and sustainable-use of its components. Such contracts may be in exchange for monetary benefits (such as access fee for collecting samples; payment of royalties in case the use of biological sample or TK has resulted into a novel or improved patentable technology; and joint-ownership of relevant IPRs) or long-term non-monetary benefits (such as sharing of R&D results; collaboration in scientific research and development programs particularly biotechnological activities; access to *ex-situ* facilities of databases and genetic resources).[102] An effective IP protection system is, therefore, the 'must'

---

[99] Priya Shetty 'Integrating modern and traditional medicine: Facts and figures' available at *http://www.scidev.net/global/author.priya-shetty.html* accessed on 4 July, 2016.
[100] Will C. McClatchey '*Ethnobotany as a Pharmacological Research Tool and Recent Developments in CNS-active Natural Products from Ethnobotanical Sources'* (2009), Pharmacol Ther. 2009 Aug; 123(2): 239–254.
[101] Stephen B. Brush '*The Lighthouse and the Potato: Internalizing the Value of Crop Genetic Diversity'* (2002), Political Economy Research Institute (PERI), Working paper No. 37, University of Massachusetts, p11.
[102] Michael Jeffery et al '*Biodiversity Conservation, Law and Livelihoods: Bridging the North-South Divide: IUCN Academy of Environmental Law Research Studies'* (2008), Cambridge University Press, p544.

requirement of the companies thinking of investing in bioprospecting contracts to protect the results of their investments as well as to conserve biodiversity.[103] In contrast to the pre-TRIPS situation, a number of different IP mechanisms is now available to protect new and/or improved medicinal products and plant varieties in the forms of, e.g., patents; plant variety protection (PVP) / plant breeders' rights (PBR); utility patents; trade secrets; and geographical indications. These are discussed below.

2.3.1 Patents:

A patent concerns with an invention that is novel, industrially useful, non-obvious, and expressed in a way that can be followed by others.[104] A patent establishes exclusive rights to certain dealings (such as use, production, and sale) with the invention. One of the pre-requisites for patentability is novelty. This means that an invention that is already known to the public at the patent filing date cannot be patented because it is not 'new'. This principle is now contained in Art. 27(1) of the TRIPS agreement which states that: '--- patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.'

As a result of the rule of worldwide novelty, it is less likely that biodiversity rich countries shall grant intellectual property rights over knowledge that is widely spread amongst communities.[105] And companies/researchers cannot hold product patents on naturally occurring substances of known utility even if they isolate or purify and transform them into commercially viable products,[106] such as-

i) quinine, isolated from Neem (*Azadirachta Indica*) for treating fever or for use as insecticide;

ii) Foeniculoside I isolated from Saunf (*Foeniculum Vulgare)* for the regulation of menstruation, as carminative, insect repellant etc.;

iii) Aspirin derived from a traditional Arab plant for treating fever and headache;

iv) Artimisinin isolated from Qing Hao (China) for treating malaria;

---

[103] Paul J. Ferraro '*Direct Payments to Conserve Biodiversity'* (2002), Vol. 298, Science's Compass.
[104] Thomas Pogge et al. '*Incentives for Global Public Health: Patent Law and Access to Essential Medicines*' (2010), Cambridge University Press, p297
[105] Stephen B. Brush op cit note 7, p11.
[106] Demaine LJ and Fellmeth '*Reinventing the Double Helix: A novel and non-obvious reconceptualization of the Biotechnology patent'* (2002), Stan. L. Rev. 55:303, 366-84.

v) *solanum indicum* ('Mulli') for treating asthma, dry cough; and chronic febrile affection;

vi) *Nigella sativa* (Kalonji) for use as an antioxidant and antimicrobial agent;

vii) Lipoxygenase I (LOX-I) protein isolated from Barley plant for use in the manufacture of a beverage.

However, ever since the US Supreme Court's landmark ruling in the *Chakrabarty* case,[107] isolated cells, and genes/ DNA sequences, resulting in the creation of the new and/or improved medicinal products, and plant varieties have been the subject of patent grants. Nonetheless, the scope of this protection did not extend to the original native or resource product. The pre-patent product continued to be available, for instance, to the local community for use in their own traditional way. It is against this background that it is argued here that the general public's presumption that patents work against or contribute to the destruction of biodiversity[108] is unfounded. Patents provide incentives for investment into new ideas or technological innovations and, at least in the pharmaceutical and agriculture sectors, this is not possible unless there is greater genetic diversity.[109] Conservation and sustainable-use of biodiversity is, therefore, in the interest of pharmaceutical and seed companies from the developed world. Thus contrary to the general presumption, patents are critical for conserving genetic resources and the real challenge appears to be the safeguarding of fair and equitable sharing of benefits in the form of royalty sharing. Bioprospecting contracts provide a simple and direct way of implementing the CBD objectives with resulting patents contributing to the calculation of price-of-access.[110]

By now, many biodiversity-rich countries[111] are bound by the Paris Convention,[112] WTO's TRIPS agreement, the PCT[113], and/or the UPOV. Consequently, most developing countries now provide patent protection to all technologies including biotechnology.

---

[107] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
[108] Dennis Karjala '*Biotechnology Patents and Indigenous Peoples'* (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1447.
[109] Robert E. Evenson '*International Trade and Policies for Genetically Modified Products'* (2006), CABI p126.
[110] Michel Trommetter '*Biodiversity and international stakes: A question of access*' (2005), Ecological Economics p573 – 583.
[111] (e.g., South Africa, Nepal, India, Pakistan, Mexico, Argentina, and Ecuador).
[112] The Convention for the Protection of Industrial Property, signed in Paris, France, on 20 March 1883.
[113] Patent Corporation Treaty, 1970.

2.3.2 Plant Variety Protection / Plant Breeders' Rights:

Many countries, including South Africa, have adopted plant variety protection (PVP) mechanisms for two reasons: i) to fulfill their obligation under Art. 27(3)[114] of the TRIPS agreement, and ii) to protect the rights of breeders of sexually reproducing plant varieties.[115] The very objective behind granting PVP certificates is to provide economic incentives for breeders to continue breeding new plant varieties. This may be substantiated from the fact that TRIPS has allowed member states to exclude from patentability animals, plants and essentially biological processes for the production of plants and animals. Only microbiological and non-biological processes can be the subjects of patent grants.[116]

Therefore, contrary to the presumptions by local or indigenous communities, backed by some NGOs and other non-profit organizations, naturally occurring animals, plants, and essentially biological processes (such as crossing and selection) for their production are freely available to the public for traditional use or practices even if an agricultural or pharmaceutical company has secured patent rights over the gene or DNA sequence isolated from the naturally occurring plant for use in some innovative process or technology.[117]

Across all countries that offer PVP certificate, the protection standard is uniform. The variety must meet NDUS criteria i.e. newness; distinctness from existing commonly known varieties; uniformity, and stability. Principally and logically the protection criteria set out under the UPOV is supportive to meet the objectives of the CBD. Search for novel, distinct, uniform and stable varieties is the key to conservation and sustainability of biodiversity.

---

[114] Article 27(3)- 'Members may also exclude from patentability: (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement'.

[115] Kenneth Sibley, '*The law and strategy of biotechnology patents: Biotechnology Series'* (1994), Butterworth-Heinemann, ch-11.

[116] Lionel Bently, Brad Sherman '*Intellectual Property Law'* (2014), Oxford University Press, p499.

[117] Adam Andrzejewski '*Traditional knowledge and patent protection: conflicting views on international patent standards*' (2010), PER: Potchefstroomse Elektroniese Regsblad, 13(4), 94-125.

2.3.3 Utility Patents:

Utility models/patents provide protection similar to patents but with a relatively low threshold of inventiveness[118] and a shorter protection term, usually between seven and ten years.[119] Novelty still remains to be a 'must' requirement.[120] So far TRIPS has not recognized utility patents as a minimum standard for IP protection[121] but being an appropriate channel for TK protection, this is getting increased significance in many WTO member states. Because of the low thresholds of novelty and inventiveness, utility patents appear to be more suitable to protect indigenous claims to traditional herbal medicines as one can see in the Kenyan legislation.[122] In the USA, a new plant variety whether produced sexually or asexually may be claimed in a utility patent by simply reciting the variety's designation. Plants products such as plant genes, gene transfer vector, and processes for producing transgenic plants may also be protected under utility patents.[123]

2.3.4 Trade Secrets:

A trade secret is a type of intellectual property.[124] It is defined as 'any formula, pattern, device, or compilation of information that is used in someone's business and gives him/her an opportunity to obtain an advantage over competitors who do not know or use it'.[125] Under this mechanism, a wide range of products (such as cell lines, plasmids, vectors, isolated purified protein and biological materials), patentable subject matter, and non-patentable 'know-how' can be protected.[126] Traditional knowledge relating to the medicinal value of a plant or other genetic resources, which

---

[118] Kadidal S. '*Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy'* (1997), IDEA: The Journal of Law and Technology. p371–403.
[119] WIPO 'Protecting Innovations by Utility Models' available at *http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm* accessed on 11 July, 2016.
[120] WIPO 'Protecting Innovations by Utility Models' available at *http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm* accessed on 12 July, 2016.
[121] 'Advice on Flexibilities under the TRIPS Agreement' World Intellectual Property Organization available at *http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html* accessed on 21 August, 2016.
[122] Stephen A. Hansen et al '*Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property*' (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1525.
[123] Kenneth Sibley, '*The law and strategy of biotechnology patents: Biotechnology* Series' (1994), Butterworth-Heinemann, p178-179.
[124] 'Trade Secret Policy' USPTO, available at *https://www.uspto.gov/patents-getting-started/international-protection/trade-secret-policy* accessed on 13 February, 2017.
[125] Restatement of Torts Section 757, Comment b, available at *https://www.law.cornell.edu/cfr/text/40/part-350/subpart-A/appendix-A* accessed on 11 August, 2016.
[126] Kenneth Sibley, '*The law and strategy of biotechnology patents: Biotechnology Series'* (1994), Butterworth-Heinemann, p53.

is of commercial significance and is maintained within a group of people or community can be considered a trade secret and be protected as such.[127] However, once the information or material has lost confidentiality, it no longer is a trade secret.[128] Generally, indigenous people or communities have the culture of exchanging information and biological resources freely and as such for them to maintain secrecy is often difficult.[129] This is why despite its enormous significance in terms of value, unlimited duration, and capability of protection worldwide with little expense, trade secrets have proved to be less effective in protecting traditional knowledge;[130] except where the disclosure is the result of breach of confidence and other acts contrary to honest business practices, trade secrets have no legal protection. Conditions for protection of trade secrets vary from country to country, but Art. 39 of TRIPS has introduced some general standards for consideration. According to Article 39.2- '*Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:*

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) *has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret*'.

2.3.5 Geographical Indications:

When a given quality, reputation, or characteristic of a good is associated with a specific geographical origin, territory, or locality,[131] geographical indications (GI)

---

[127] 'Intellectual Property and Traditional medical knowledge' WIPO Publication available at *http://www.wipo.int/export/sites/www/tk/en/documents/pdf/background_briefs-e-n6-web.pdf* accessed on 19 July, 2016.

[128] Gene Quinn 'Protecting a Trade Secret: Taking Precautions to Preserve Secrecy' available at *http://www.ipwatchdog.com/2016/04/16/trade-secret-preserve-secrecy/id=68168/* accessed on 10 May, 2016.

[129] Molly Torsen et al. '*Intellectual Property and the Safeguarding of Traditional Cultures'* (2010), WIPO, p21.

[130] Silke von Lewinski '*Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge, and Folklore*' (2004), Kluwer Law International, p135.

[131] Art. 22 of the Trade Related Aspects of Intellectual Property Rights, 1994.

protection comes into play. Examples include: Rooibos (South Africa); Roque fort Cheese (France), Swiss watches (Switzerland), Basmati rice (Pakistan, India, Bangladesh), Darjeeling tea (India), Maca (Andean), and Jasmine tea (Pakistan). Art. 22 of the TRIPS provide that to avoid misleading the public and to prevent unfair competition, geographical indications must be protected. Article 23 provides additional protection for wines and spirits. By using GI protection, indigenous people may promote their specific quality products with a distinguishing name, word, shape, or device. While the scope and approaches to protection of GIs varies from state to state, the principal objective behind this form of protection is to serve the purposes of an identifier of the source or origin of the product; an indicator of the product; a promoter of the product with a distinctive name; and a provider of the statutory rights of defense against infringement and unfair competition for using a location as a name for similar products, GIs protect the quality and character associated with the origin of that product. Through creating digital databases or other publicly accessible libraries or registries, preemptive protection of GIs can be generated.[132]

Protection through certification trademarks is another option available to indigenous people to protect their IBRs and TK associated therewith.[133] For instance, *Aspalathus linearis* (commonly: Rooibos) native to the high Fynbos of South Africa is known globally for its medicinal characteristics, quality and taste. A certification mark may officially be registered for South African Rooibos. Any other body or concern outside South Africa, using the same name for the product they grow in the plain fields of their country, shall be considered as violation of the rights conferred by GI or the trade mark laws of the South Africa.[134]

Concluding Remarks:

This chapter concludes that where IP recognizes the intellect of the researchers and scientists working in complex sciences (biotechnology, molecular and cell biology) through grant of exclusivity for a certain period of time, it simultaneously takes care of the interests and creations of the local or indigenous communities, including farmers, holding the TK and practices. Stating it differently, the key discussion in this area is whether the laws take sufficient care of these interests or not. What is desirable

---

[132] Ibid.
[133] '*Fact Sheets - Geographical Indications'* (2015), International Trade Association.
[134] Sec. 42 of the South African Trade Marks Act, 1993 (Act No. 194 of 1993).

is to create awareness amongst the indigenous communities about their rights and obligations towards society in reducing the existing threats to biodiversity and its sustainability.

CHAPTER THREE: SOUTH AFRICA'S BIOPROSPECTING AND BIODIVERSITY ACCESS AND BENEFIT SHARING MECHANISMS

This chapter focuses on the need for bio-prospecting collaborations and their significance in the conservation of South Africa's biodiversity. It discusses the role of international agreements (such as the CBD, the Bonn Guideline, and the Nagoya Protocol) to which South Africa is a party, in shaping the specific terms and conditions of the agreements on access, material collection and transfer on mutually agreed terms, and benefit-sharing where South African bioresources are involved. It further considers whether the South African biodiversity laws and regulations are in harmony with the various international legal frameworks. It also addresses issues relating to ownership over the resulting IP and distribution of funds generated from the utilization of IBRs and associated TK fairly and equitably.

3.1 WHAT IS BIOPROSPECTING?

Sec. 2 of the NEMBA defines the term 'bioprospecting' in relation to the IBRs to mean-

> 'any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes-
>
> (a) the systematic search, collection or gathering of such resources or making extraction from such resources for purposes of such research, development or application ;
>
> (b) the utilization for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or
>
> (c) research on, or the application, development or modification of, any such uses, for commercial or industrial exploitation'.

According to this definition, bioprospecting activities include:

i) Use of indigenous people's knowledge to identify the local plants, previously known for their curative value, and to isolate the active compounds which are then synthetically reproduced;

ii) Use of IBRs or TK as a precursor for producing valuable products such as biopharmaceuticals;

iii) Use of traditional medicines as an escort to screen plants and other biological resources for the discovery of medicinally active new compounds;[135]

iv) Discovery and isolation of previously unknown compounds from the IBRs (plants, animals, microbes, and other genetic materials) for the development of new drugs and other valuable products;[136] and/or

v) Use of IBRs and TK to bring development and/or modification in the already existing products, processes, and practices.[137]

3.2 BIOPROSPECTING COLLABORATIONS

Misappropriation of IBRs and TK is one of the biggest challenges faced by the science and technology lagging economies.[138] On the one hand, industrial development and exponential growth of intellectual assets in developing countries demands allowing access to bioresources and associated knowledge to the pharmaceutical and biotechnology companies; while on the other, conservation of biodiversity to thwart piracy of bioresources and assurance that patents shall not be granted for products and treatments already lying in the public domain,[139] is critical for sustainable development.

Harboring a majority of the earth's species, South Africa falls among the group of megadiverse countries.[140] Owing to the enormous potential for drugs discovery from genetic resources, South Africa is a country of significant interest to bioprospectors. In 2008, in discharge of its obligations under CBD, South Africa regulated bioprospecting ABS mechanisms, which are now principally in line with the Nagoya protocol on access to genetic resources and equitable sharing of benefits

---

[135] S Sasidharan '*Extraction, Isolation and Characterization of Bioactive Compounds from Plants'* Extracts' (2011), Afr J Tradit Complement Altern Med. 8(1):1-10.
[136] Gordon M. Cragg '*Natural Products: A Continuing Source Of Novel Drug Leads*' (2013), Biochimica et biophysica acta 1830.6: p3670–3695.
[137] Ibid.
[138] '*Traditional Knowledge & Biopiracy: The Peruvian Maca Root'* (2011), Public Interest Intellectual Property Advisors, Inc., Peru.
[139]Paul Gepts '*Who Owns Biodiversity, and How Should the Owners Be Compensated*?' (2004), Plant Physiology, *134*(4), 1295–1307. http://doi.org/10.1104/pp.103.038885.
[140] Neil R. Crouch 'S*outh Africa's bioprospecting, access and benefit-sharing legislation: current realities, future complications, and a proposed alternative'* (2008), South African Journal of Science, No. 104, p355-365.

arising from their utilization to the CBD.[141] Bioprospecting collaborations between pharmaceutical or seed companies and the local or indigenous communities for the discovery and development of new plant varieties, drugs and treatments may be assessed as one of the various mechanisms envisaged to conserve South African biodiversity; promote technological innovations; and to ensure sharing of economic benefits through formalized means.[142] Notwithstanding the fact that States must be responsible to take measures incentivizing farmers and farming communities[143] to continue planting traditional plant varieties and carrying traditional breeding practices, States generally have no such incentives and means to mandate farmers to do so.[144] Moreover, South Africa's agricultural development policies requiring replacement of genetically modified or improved varieties with the local plant varieties to increase food production, farm income, and food availability seem unsuited to reduce the negative externality of genetic erosion.[145] This is for the reason that genetically modified varieties produce uniform food products but in parallel reduce genetic-diversity and decrease shelf-life. Under these circumstances, bioprospecting contracts between the producers[146] and users[147] of IBRs, genetic resources and TK relating thereto seem to offer a logical solution of the issues involving access to these resources, and fair-and-equitable sharing of benefits derived from such access.[148]

In line with the laws and practices prevalent in other CBD member states, South Africa's Biodiversity Act and BABS regulations made thereunder provide an opportunity for indigenous communities to give access to their genetic resources and associated knowledge to research-based companies for screening and discovering a

---

[141] Freedom-Kai Phillips 'sustainable bio-based supply chains in light of the Nagoya Protocol' available at *https://www.academia.edu/31086435/Sustainable_bio-based_supply_chains_in_light_of_the_Nagoya_Protocol* accessed on 24 February, 2017.
[142] 'Biodiversity & Human Well-being' GreenFacts available at *http://www.greenfacts.org/en/biodiversity/l-3/6-conserve-biodiversity.htm* accessed on 23 August, 2016.
[143] Nick Hanley '*How should we incentivize private landowners to 'produce' more biodiversity*?' (2012), Oxf Rev Econ Policy, 28 (1):93-113.doi: 10.1093/oxrep/grs002.
[144] Stephen B. Brush '*The Lighthouse and the Potato: Internalizing the Value of Crop Genetic Diversity'* (2002), Political Economy Research Institute (PERI), Working paper No. 37, University of Massachusetts.
[145] Stephen B. Brush op cit note 7.
[146] (farmers, landowners, stewards, and local or indigenous communities).
[147] (pharmaceutical or seed companies).
[148] 'Report of the World Commission on Environment and Development: Our Common Future' UN Documents: Gathering a Body of Global Agreements available at *http://www.un-documents.net/wced-ocf.htm* accessed on 29 July, 2016.

potentially marketable bioactive.[149] Depending on their contribution in the screening and drug discovery program, rights to any ensuing patents may be determined for the assessment of benefit-sharing and allocation of funds for the conservation of biodiversity. The bioprospecting contracts signed between Shaman Pharmaceuticals and indigenous communities in Amazon;[150] Merck & Co., Inc. and a Costa Rican Biodiversity Research Organization-INBIO[151] are best reflective of this approach; and provide a guideline for the South African research centers and universities engaging in research and development activities. Such contracts provide short- and long- terms benefits to persons and communities that allow access and collection of the IBR or the genetic resource and share traditional knowledge about their properties.

In summary, by allowing access to bio-resources and associated TK or use to pharmaceutical or biotechnology companies for R&D of new medicinal products and treatments, indigenous communities[152] may not only increase the value of their bio-resources[153] but reduce genetic erosion through increasing potential for modern crops and so enhancing long-term food security; and conservation of biodiversity. This may conserve biodiversity, promote sustainability, and have increasing chances of reciprocity with companies benefitted from such arrangements.[154] However, two conditions must hold if the bioprospecting contracts are to be effective in reducing the genetic erosion and to promote conservation of biodiversity- i) established rights or well-defined ownership over the bio-resources or the TK to grant access; and ii) the minimum transaction costs, in particular, the costs of genetic resource must not be high for the research-based companies.[155]

It has been observed that in many instances of bioprospecting both conditions have been found difficult to satisfy by the holders of the bioresources because ownership over bioresources and TK associated therewith passes from generation to generation and there is no track record or written document available to establish

[149] Sec. 84 of the NEMBA, 2004.
[150] Stephen B. Brush, op cit note 7.
[151] Coughlin Jr., M. D '*Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity*' (1994), Columbia Journal of Transnational Law 31 (2): 337-75.
[152] (including farmers, landowners and stewards).
[153] Santiago Carrizosa '*Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*' (2004), IUCN, p132.
[154] Carmen Richerzhagen '*Protecting Biological Diversity: The Effectiveness of Access and Benefit*' (2013), Routledge, p71.
[155] Stephen B. Brush op cit note 7.

rights. This has resulted in poor advancement in the bioprospecting collaborations[156] in South Africa.[157]

In parallel, there is a perception that many cases of biopiracy are the consequence of poor legislation governing the use of bio-resources and TK; a costly and time consuming permit system, and identification of the stakeholders.[158] For instance some companies interested in bioprospecting do not meet the basic requirement or submit incomplete documents and then allege that the procedure is costly, and time consuming. However, the principal point of consideration is whether there are any internationally recognized standards for-

i) the identification of stakeholders and the establishment of ownership when TK passed down from generation to generation and has never been written down or made available in any authenticated document or record;

ii) assessing the private value of the bio-resources or TK;[159]

iii) securing returns from the IPRs resulting from the use of IBRs and associated TK to ensure equitable sharing of benefits.

It is well recognized that indigenous groups who contribute knowledge concerning medicinal or other properties of the bio-resource which is then successfully used for the development of further new innovations (products, drugs or treatments) should benefit from the resulting patent rights.**[160]** In South Africa, the owner of the land is deemed to be the owner of the bio-resource and the genetic resource present in his property and should benefit if the said resource is the base for

---

[156] Soejarto DD et al. '*Bioprospecting Arrangements: Cooperation Between the North and the South'* (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, p1516.

[157] Two bioprospecting arrangements through public-private partnerships - one between Rhodes University (Eastern Cape) and GlaxoSmithKline (USA) and the other between the Department of Chemistry of Rhodes University and SCRIPPS Institute of Oceanography, California-SanDiego for the use of South Africa's marine resources in anti-cancer drug development, however, remained successful. In the former case, GlaxoSmithKline, apart from delivering up-front benefits including building of infrastructure for research and development, agreed to pay royalties to the Rhodes if any patent rights are secured based on the use of marine resources. In the latter case, the rights to file, prosecute and maintain any intellectual property on inventions involving use of the South African marine resources were retained by the SCRIPPS.

[158] Neil R. Crouch, op cit note 140.

[159] Srividhya Ragavan '*Patent and Trade Disparities in Developing Countries*' (2012), Oxford University Press, p 362.

[160] Neil R. Crouch op cit note 140.

the development of a patented product or the process.[161] Recognizing the well-settled principles of patent law, providing mere access to the bio-resources or sharing information about their medicinal properties is a 'non-inventive' contribution, while a contribution to the conception of the invention is 'inventive'[162] and thus entitles the resource provider to a fair share in the form of royalty payments. An attempt to assess the price of access may be made following the guidelines under the Nagoya Protocol. Such guideline amongst others may include factors such as the scientific capacity of the access provider; valuation of the genetic resource and the efforts (such as processing, manufacturing, or marketing) involved in transforming the genetic diversity into a commercial product, and uniqueness[163] of the biodiversity.

3.3 TERMS AND CONDITIONS IN BIOPROSPECTING CONTRACTS

Starting from access to biodiversity to the marketing of the product developed, the parties have to firstly address some of the very basic issues that are common to standard contracts. In particular, the parties must take into account the below issues that are specific for bioprospecting contracts:

(i) Clearly defined property rights and authority to grant access;

(ii) Mechanism for calculating the transaction costs (valuation of the genetic resource and contribution of each party);

(iii) Mechanism for financial and non-financial benefit-sharing.

The principal legislation regulating the terms and conditions for the bioprospecting permit system in South Africa is the 'Bioprospecting, Access and Benefit Sharing Regulations, 2008' as amended by the 'BABS Amendment Regulations, 2015' (hereinafter the BABS Regulations). The BABS Regulations for ABS are devised under the NEMBA, 2004 responding to South Africa's obligation as a contracting party to the CBD. ABS rules[164] require the securing of bioprospecting permits for research and any other activities including export for research involving use of the IBR. According to Sec. 81 of the NEMBA and Art. 11(a)-(e) of the BABS

---

[161] South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework, 2008: Guidelines for Providers, Users and Regulators.

[162] Lionel Bently, Brad Sherman '*Intellectual Property Law'* (2014), Oxford University Press, p554-573.

[163] Costanza et al '*Deal making in bioprospecting'* (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1495-1510.

[164] Sec. 81 of the NEMBA, 2004; Art. 4 of the Bioprospecting, Access and Benefit Sharing Regulations, 2008.

Regulations, permit issuance has been made subject to the disclosure of all material information relating to the proposed bioprospecting[165] to the issuing authority (the Minister). Furthermore, any such permit is issued subject to the conditions that: all money due to the stakeholders shall be paid into the Bioprospecting Trust Fund; the permit-holder shall submit status report of the bioprospecting project on an annual basis;[166] the permit-holder shall be liable for the costs if an element of externalization[167] is involved; the permit-holder cannot sell, donate, or transfer the IBR or the genetic resource without written consent of the Minister of the Department of the Environmental Affairs and Trade (DEAT).[168]

The BABS Regulations have prescribed a permit issuance procedure, which is a replica of the provision of Art. 6(3) of the Nagoya Protocol. It is simple, quick and cost-effective if the requisite information and evidence (BSA, MTA etc.) are supplied at the time of permit application. Failure on part of the applicant may, however, result in complications and delays. Complaints against delays on the part of authorities may be lodged at the appropriate forum.[169] Until 2013, 73 applications for bioprospecting permits were received by the DEAT.[170] These statistics are not encouraging to meet the objectives[171] set by the NEMBA in line with the CBD.

---

[165] (such as detailed project proposal; specific IBRs involved; quantity to be used; and the source or country of origin).
[166] Sec. 85 of the NEMBA, 2004; Art. 11(f) of the BABS Regulations, 2008.
[167] (such as impact on environment).
[168] Sec. 81(1) & Sec. 85(1) of the National Environmental Management: Biodiversity Act, 2004; Art. 11 of the Bioprospecting, Access and Benefit Sharing Regulations, 2008.
[169] Sec.88(3)(e) and Sec.94 of the NEMBA read with Article 6(3)(d)&(g) of the Nagoya Protocol.
[170] '*Access and benefit sharing - ABS: Understanding international and national laws'* (2014), Union for Ethical BioTrade, p4.
[171] (ie., conservation of biodiversity, sustainable use of its components and the fair and equitable sharing of benefits arising out of their utilization).

3.3.1 Prior Informed Consent (PIC)

Literally, prior informed consent is seeking advance approval from the local or indigenous community for the use of their genetic resources and the associated TK.[172] *Prior* suggests that the 'approval must come before the access is allowed'.[173] *Informed* specifies that 'information is provided how the resource and the TK will be used'.[174] *Consent* indicates 'permission to use the resource or knowledge'.[175]

In order to give effect to the provision of Art. 8(j)[176] of the CBD and Art. 6(1)[177] & 6(3)(e)[178] of the Nagoya Protocol, access to genetic resources for bioprospecting activities has, in South Africa, been made subject to the prior informed consent of the access providers,[179] either of the country of origin of such resources or any other member country in the lawful possession of the resources.[180] Therefore, obtaining PIC of the stakeholders providing access to the IBR, genetic resource or the associated TK and requiring to submit it as evidence in support of the application for a bioprospecting permit is a pre-requisite, well within the scope of the CBD and the Nagoya Protocol. The PIC should specify the time for sample collection, geographical area or areas of collection, the sample species or genera of interest, and the conditions of transferring samples to third parties.[181]

---

[172] Art. 6 of the Nagoya Protocol, 2010.
[173] Stephen A. Hansen op cit note 122, p1531.
[174] Ibid.
[175] Ibid.
[176] Each Contracting Party shall, as far as possible and as appropriate: Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.
[177] In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.
[178] Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly; (f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources.
[179] (local or indigenous communities with established right to grant access to the IBR).
[180] Sec. 88 of the National Environmental Management: Biodiversity Act, 2004; Art. 8(1)(c) of the NEMBA Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2008.
[181] Sec. 84 of the NEMBA, 2004; Art. 11-13 of the BABS Regulations, 2008.

3.3.2 Benefit-Sharing Agreements (BSAs)

Another condition that needs to be satisfied for the issuance of bioprospecting permits in South Africa is the proof of benefit-sharing agreements.[182] Utilization of the bio-resources for research and development activities[183] generating benefits provides the basis for benefit sharing. The agreement must be fair and equitable[184] to all parties in terms of the benefits (monetary and non-monetary)[185] arising from the utilization and subsequent application and commercialization of the innovative technology based on the IBR or the TK associated therewith. For approval, it is critical that the agreement makes some provision for enhancing the scientific knowledge and technical capacity of the stakeholders to conserve, use, and develop IBRs or any other activity that promotes the conservation, sustainable use, and development of the relevant IBR.[186]

Under the Nagoya Protocol, the capacity-building/development and strengthening of human resources and institutional capacities to effectively implement the Protocol is central to all benefits.[187] This requires parties to identify their national capacity needs and priorities through national capacity self-assessment.[188] The key areas needing capacity-building identified by the Protocol include implementation of the protocol; negotiation of the MATs; development, implementation, enforcement of domestic legislation on ABS; and development of endogenous research capabilities to add value to their own genetic resources.[189]

For incentivizing collaboration, a successful benefit-sharing negotiation is described in Figure 1.

---

[182] Sec. 83 of the National Environmental Management: Biodiversity Act, 2004; Art. 17 of the NEMBA Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2008.
[183] (such as isolation, genetic modification; biosynthesis, crossing and selection, purification, characterization and evaluation, DNA sequencing).
[184] Sec. 82 of the NEMBA 2004; Art. 17 of the BABS Regulations, 2008.
[185] Annexure to the Nagoya Protocol, 2010.
[186] Art. 17(4) of the NEMBA Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2008
[187] Art. 22.1 of the Nagoya Protocol, 2010.
[188] Art. 22.3 of the Nagoya Protocol, 2010.
[189] Art. 22.4 of the Nagoya Protocol, 2010.

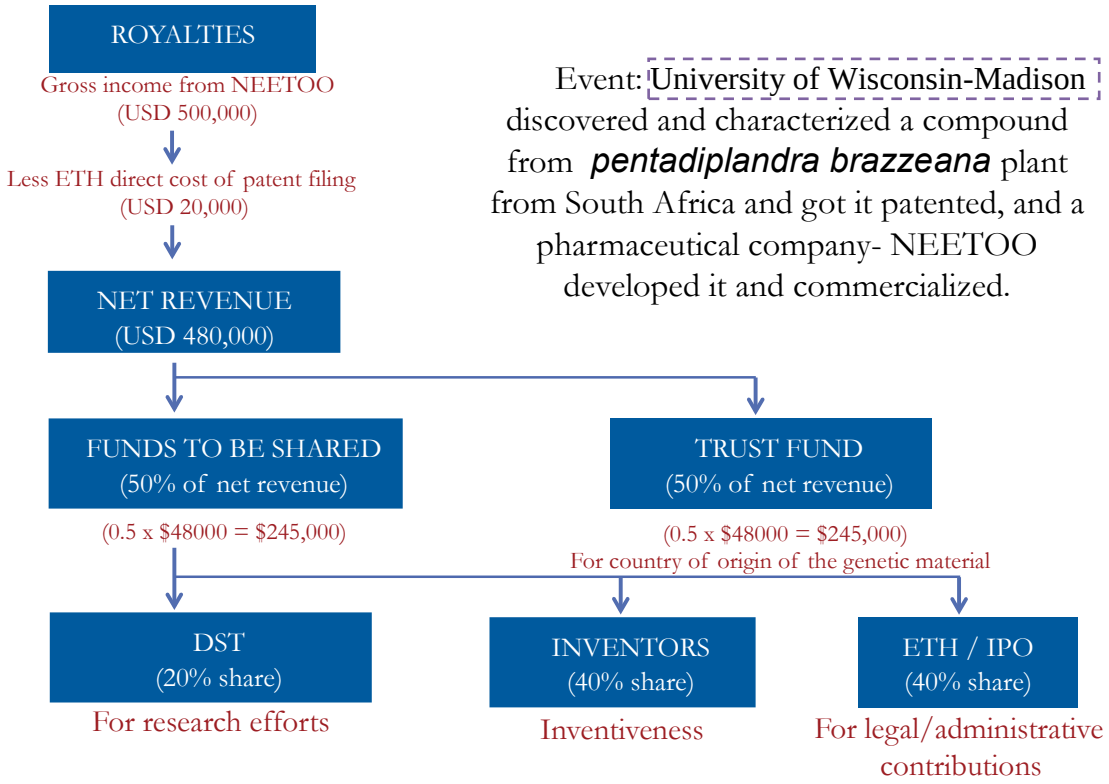

Fig. 1

This graphic summarizes a royalty sharing mechanism in a situation where the University of Wisconsin-Madison (UW)[190] discovered and characterized a compound from the *pentadiplandra brazzeana*[191] plant (South Africa) and successfully applied for patent protection[192] at the USPTO and EPO.[193] A pharmaceutical company- NEETOO - then developed and commercialized it. The net gross income received by the UW from NEETOO,[194] after deduction of out-of-pocket costs, is divided into two equal halves. The first half (the common fund) is to be distributed to the collaborating institution (the Department of Science and Technology (DST), South Africa), the inventors and the UW's administration, while the remaining half is to flow back to

[190] A public research university in Madison, Wisconsin, United States of America.
[191] It is the sole specie in the plant genus Pentadiplandra. Brazzein is 2000 times as sweet as sugar, and has low calorific value.
[192] '*Patents on life: the final assault on the commons'* (2000), GRAINS, p6.
[193] Ibid. (Researchers at the University of Wisconsin have been granted US patents 532658, 5346998, 5527555, and 5741537, as well as European patent 684995 for a protein isolated from the berry of Pentadiplandrabrazzeana).
[194] (the industrial partner or licensee).

local or indigenous communities in South Africa as the country of origin of the genetic material of the commercialized product, through the Bioprospecting Trust Fund.[195]

3.3.3 Material Transfer Agreements (MTAs):

An MTA needs to be signed by the provider and exporter/recipient,[196] if the user of the IBR desires to export it to a foreign territory for the purpose of undertaking bioprospecting activities. The MTA needs to specify the name of the providers and the exporter of the IBR; the type of the IBR involved; the area or source from where the IBR is to be collected; the quantity of the IBR to be collected and exported; the potential uses of the IBR; and the conditions under which the recipient may transfer the IBR or its progeny, to a third party.[197]

3.3.4 Mutually Agreed Terms (MATs)

In terms of Art. 15(7) of the CBD:

> 'Each Contracting Party shall take legislative, administrative, or policy measures, as appropriate, […] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.'

The development of MATs is critical to ensure fair and equitable sharing of benefits. In terms of Art. 6(3)(g)[198] of the Nagoya Protocol such a development requires establishment of clear rules and procedures by the party requiring PIC. According to the Bonn Guidelines, legal certainty and clarity as well as minimization of transaction costs may be considered as the basic requirement for the development of MATs.[199] In addition, the following may also be considered as guiding parameters in contractual agreements- 'i) regulating the use of bio-resources; ii) making provision

---

[195] SoeJarto DD op cit note 156.
[196] Sec. 84 of the NEMBA, 2004.
[197] Sec. 84 of the National Environmental Management: Biodiversity Act, 2004.
[198] Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia: (i) A dispute settlement clause; (ii) Terms on benefit-sharing, including in relation to intellectual property rights; (iii) Terms on subsequent third-party use, if any; and (iv) Terms on changes of intent, where applicable.
[199] Art. 42 of the Bonn Guidelines, 2002.

to ensure the continued customary use of the genetic resources and the related knowledge; iii) making provision for the use of IP rights including joint research, obligations to implement rights on the inventions obtained, and to provide licences by common consent; and iv) taking into account the possibility of joint-ownership of IPRs depending on the degree of contribution'.[200]

An analysis of the NEMBA, 2004 and the ABS Regulations, 2008, reveals that no guidelines have been provided for users and providers in developing mechanisms and arrangements for ABS based on their PIC and MTA. In order to give effect to the provision of Art. 6(3)(g) of the Nagoya Protocol, a clause in the NEMBA establishing clear rules and procedure for requiring and establishing MATs is required. Such terms may include amongst others: i) a dispute settlement clause; ii) terms on benefit-sharing, including in relation to IPRs; iii) subsequent third-party-use terms; and iv) terms on changes on intent.

3.3.5 Recommendations for successful bioprospecting activities

For bioprospecting activities, selecting a suitable partnering country is crucial to avoid substantial future conflicts. What is typically required in the partnering country is: the existence of distinctive and secluded biological systems, a concrete legal framework, adequate political will, non-discriminatory treatment of all access seekers, technical experts or institutions to partner with, the ability to assign and clearly define legal rights over the genetic resources, and accession to international conventions and treaties.[201]

In addition, the rights over genetic resources, rights to patent and commercialize, and the rights of transfer to third party must be clearly addressed to avoid future ownership claims against any commercial discoveries and disputes concerning distribution of benefits. Thirdly, drafting a proper confidentiality clause appears to be key for establishing a trusted and productive relationship. It must be strictly stated that technology transfer is exclusively for the benefit of the bio-resource providers or it can be shared between the parties under particular set of circumstances.

---

[200] Art. 43 of the Bonn Guidelines, 2002.

[201] Carl-Gustaf '*Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials* '(2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1461-66.

This may otherwise affect the collaborators in the context of their own capacity building.[202]

Another element meriting consideration is whether the agreement should contain an exclusivity requirement. Restricting collaborations may reduce opportunities for generating funds that could then be utilized for biodiversity conservation. Care must, therefore, be taken to avoid the presence of exclusivity clauses in these agreements.[203]

Based on the experiences of companies frequently engaged in bioprospecting collaborations, a successful collaboration also requires consideration of factors such as i) efficient and reasonable benefit-sharing negotiations; ii) a speedy bioprospecting permit system; and iii) capacity-building.[204]

South Africa is- a land with unique and protected habitats, great genetic diversity, and a strong legal system. However, as a science and technology lagging territory, it requires an efficient and cost-effective system of considering and approving bioprospecting permit applications.[205] More bioprospecting collaborations may lead to increasing viability and resources for South Africa to utilize in the conservation of its biodiversity, and enhancing capacity-building.[206] It is clear that delays in granting bioprospecting permits have resulted in a decrease in bioprospecting activities for novel drug screening, development and commercialization in the pharmaceutical and biotechnology areas, hampering technological developments (such as capacity-building to prepare plant extracts; training to use laboratory equipment, training in sample screening and preparation), in South Africa.[207]

---

[202] Ibid.
[203] Charles Costanza et al '*Deal Making in Bioprospecting* '(2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1495-1502.
[204] Charles Costanza op cit note 163.
[205] Neil R. Crouch op cit note 140.
[206] Charles Costanza op cit note 163, p1502.
[207] Bhatia P and Chugh A '*Role of marine bioprospecting contracts in developing access and benefit sharing mechanism for marine traditional knowledge holders in the pharmaceutical industry'* (2015), Global Ecology and Conservation, Vol. 3, p176-187.

CHAPTER FOUR: PATENTS AS A TOOL FOR ASSESSING ECONOMIC VALUE OF THE GENETIC RESOURCES AND CONSERVATION OF BIODIVERSITY

Where modern biotechnology tools[208] are increasingly helping the diagnosis of life threatening diseases such as cancer and AIDS;[209] crop protection, or production of industrial chemicals,[210] these have also proven to be useful in enhancing the value of the genetic resources.[211] This chapter sheds light on how patents contribute to the assessment of the economic value of genetic resources and, ultimately, in the conservation of biodiversity and promotion of sustainability. It supports the proposition that for pharmaceutical and biotechnology companies, investment in biodiversity conservation in South Africa is economically feasible.

4.1 THE ECONOMIC VALIDATION

The conception to conserve biodiversity seems to be absent in developed economies and the principal reason for this is economic: Companies hold that major benefits of conservation are benefitted by society and cannot sufficiently be recovered by them.[212] This imbalance between investment and returns has greatly impacted and resulted in failure of many bioprospecting contracts for access and collection, scientific research and analysis, and commercialization of the products built on genetic resources in South Africa[213].

This situation led pharmaceutical/biotechnology companies to instead approach gene banks, botanical gardens, or other collections to continue with their research activities. However, owning to the government agriculture policy[214] for increasing food production and nutritional security, indigenous communities,

---

[208] Patrick Heffer 'Biotechnology: a modern tool for food production improvement' available at *http://www.fao.org/docrep/005/y2722e/y2722e1f.htm* accessed on 16 August, 2016.
[209] Acquired Immune Deficiency Syndrome.
[210] 'Uses of genetic resources' UNEP, available at *https://www.cbd.int/abs/infokit/factsheet-uses-en.pdf* accessed on 26 August, 2016.
[211] Biotech tools such as genetic engineering including directed evolution techniques involving DNA shuffling, sequence saturation mutagenesis, etc have brought revolution in the diagnostic tools and the new plant varieties production. For instance, a new plant with improved genetic traits such as high resistance against pests and drought is more of an economic value than without such characteristic.
[212] Charles Lawson '*The role of patents in biodiversity conservation'* (2009), Nature Biotechnology Vol. 27, p994 – 995, doi:10.1038/nbt1109-994
[213] 'Public understanding of biotechnology' (2014), South African Agency for Science and Technology Advertisement available at *http://www.pub.ac.za/wp-content/uploads/2015/06/Factsheet-Pub-BioprospectingPRINT2.pdf* accessed on 5 September, 2016.
[214] The South African Agricultural Baseline: BUREAU FOR FOOD AND AGRICULTURAL POLICY, 2011.

especially the farmers in South Africa, generally do not have alternative options for compensation against the contributions they have made for maintaining the biodiversity; letting them to continue with their traditional farming practices.[215] Consequently, the cultivation of traditional plant varieties and the conservation of biodiversity are threatened, with negative effects for farmers and landowners. In the long run, however, the pharmaceutical/biotechnology companies are also affected when they require new genetic resources, not available under *ex-situ*[216] arrangements, to continue with new drug discovery and development process. *In-situ* conservation of genetic resources is therefore valued for maintaining genetic diversity, fostering innovations, and enhancing economic performance in South Africa.[217]

4.2 THE ROLE OF PATENTS

There is general perception that patents are the legal routes of bio-piracy and biodiversity destruction. In support, it is argued that biodiversity research-based pharmaceutical and biotechnology companies attempt to monopolize traditional medicines, treatments, or practices by reproducing them synthetically and developing them into commercial products.[218] Allegations are also made that such companies access the IBRs or the genetic resources without authorization, involvement, and prior consent[219] of the stakeholders.[220] Furthermore, it is alleged that physical resources (such as traditional plants and plant varieties) are exposed to threats or extinction when the scientists use them or export them without obtaining the concerned authorities' approval in the holder-country.[221] This debate poses a few essential questions: i) whether patents are really destructive to biodiversity or causative to genetic erosion; ii) whether and to what extent it is fair to have access to the bio-resources and knowledge of the other nations and develop them into patented and

---

[215] Stephen B. Brush '*Genes in the Field: On-farm Conservation of Crop Diversity'* (2000), International Plant Genetic Resources Institute, IDRC, p138

[216] Ex-situ means 'off-site conservation', i.e., protection arrangement for a specie outside its natural habitat.

[217] '*Patents and innovation: trends and policy challenges'* (2004), Organisation for Economic Co-operation and Development, OECD Publications.

[218] Dennis S. Karjala, '*Biotechnology Patents and Indigenous Peoples*' (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, p1439.

[219] David Vivas-Eugui '*Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC)*' (2012), ICTSD Programme on Innovation, Technology and Intellectual Property, Issue Paper No. 34.

[220] (i.e. the local or indigenous communities, landowners, farmers, stewards etc.)

[221] Dennis S. Karjala '*Biotechnology Patents and Indigenous Peoples*' (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, p1437-1442.

commercial products, process, or treatments; iii) whether and to what extent domestic patent laws and international agreements/conventions relating to patents and biodiversity conservation are supportive to the aforesaid activities of the researchers and scientists; iv) whether bio-prospecting contracts are effective as a conservation tools for bio-resources including genetic resources and the traditional knowledge associated therewith.[222]

4.2.1 Are patents really destructive to biodiversity?

When considering the issue of biopiracy and biodiversity destruction, it is vital to draw a line between resources that are tangible and dividable[223] and in some form may be the subject of exclusivity (patent rights); and resources that are intangible and multipliable (information/knowledge) and 'as such' cannot be patentable. A body of case law[224] suggests that sources, whether tangible (genetic materials) or intangible (traditional knowledge), which are publicly diffused, cannot be the subject of patent rights.[225] This can be deduced from the fact that the WTO's TRIPS agreement requires member states to grant patent rights over innovations that are novel, and non-obvious to the person skilled-in-the-art.[226]

This means that patent rights over products, processes, or uses, which constitute a part of the state-of-the-art, are not available under the national and international laws and regulations. Indeed, if the end product constitutes a mere isolated and purified form of the natural resource product, identical in its structure and composition to the original, it can be refused patent protection.[227] On the other hand, the CBD requires the parties to ensure the patents rights support the CBD's objectives

---

[222] Stephen B. Brush '*The Lighthouse and the Potato: Internalizing the Value of Crop Genetic Diversity'* (2002), Political Economy Research Institute (PERI), Working paper No. 37, University of Massachusetts.
[223] (such as plants, animals, and microorganisms)
[224] *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009);
Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989);
Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984);
Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1306 (Fed. Cir. 2006);
Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003).
[225] European Patent Office Opposition Division, 2010 -- Decision revoking the European patent and grounds for the decision (Annex) — opposition with respect to patent EP1429795 available at *register.epoline.org/espacenet/application?number=EP02777223&tab=doclist* accessed on 6 October, 2016.
[226] Art. 27(1) of the TRIPs; Sec. 25(1) of the South African Patent Act 57 of 1978.
[227] Demaine LJ and Fellmeth '*Reinventing the Double Helix: A novel and non-obvious reconceptualization of the Biotechnology patent'* (2002), Stan. L. Rev. 55:303, p303-462.

including biodiversity conservation and sustainable-use.[228] It further obliges that incentive measures (economic and social)[229] should be supportive rather than in conflict with the CBD's objectives. This suggests that patents, and access and benefit-sharing objectives of the CBD constitute a vital component of the biodiversity conservation.[230]

This can further be substantiated from the fact that the Bonn Guidelines and the Nagoya Protocol provide a transparent legal mechanism for effective implementation of the CBD's access and benefit sharing objectives. This assurance is a great incentive for enhancing contribution towards conservation of biodiversity and sustainable-use of its components in the form of private bioprospecting contracts. Such contracts set out the terms and conditions of access-and-benefit sharing with required legal certainty, clarity and transparency.

Patents aim to provide an incentive for investment into new innovations and dissemination of technology protected thereunder. But, in parallel, patents have long been considered as creating tension between innovations at one end and competition in the market and diffusion of technology at the other.[231] Though limiting access to basic techniques or tools (most recently in BRCA1 and BRCA2[232] gene patents)[233] and broader patent protection may hamper further innovations[234] and adversely impact competition in the market, this impact is more of a policy issue and particular conditions rather than patents.[235] A carefully designed patent system that is balanced in its founding pillars (i.e., the patentable subject matter, patentability criteria and patent breadth) may progress innovations, dissemination of technology and economic performance.[236] This requires actions to be regulated through appropriate legislation or rules of law.

---

[228] Art. 16(5) of the CBD, 1992.
[229] Art. 11 & Art. 16(5) of the Convention of Biological Diversity, 1992.
[230] Charles Lawson '*The role of patents in biodiversity conservation* 'Nature Biotechnology' (2009), Vol. 27, p994 – 95.
[231] '*Patents and innovation: trends and policy challenges'* (2004), Organisation for Economic Co-operation and Development, OECD Publications.
[232] A BRCA mutation is a mutation in either of the BRCA1 and BRCA2 genes, which are tumor suppressor genes.
[233] Bar-Shalom A '*Patents and innovation in cancer therapeutics: lessons from CellPro*' (2002), The Milbank Quarterly, Vol. 80(4), p637-76.
[234] '*The Ethics of Patenting DNA: A Discussion Paper'* (2002), Nuffield Council on Bioethics, p39-54.
[235] '*Genetic Inventions, IPRs and Licensing Practices: Evidence and Policies'* (2002), OECD, p17-25.
[236] David Encaoua et al '*The economics of patents: from natural rights to policy instruments*' (2003), Cahiers de la MSE, p6-27.

Recent evolutions in science and technology, encouraged by the public and private sectors in various economies including South Africa; changes in patent policies after WTO's TRIPs agreement, CBD and its attendant agreements including UPOV and ITPGRFA, an open industrial economy, driven by effective capital markets and vigorous competition;[237] disclosure of underlying technology in exchange for the patent monopoly, technology- which otherwise may remain secret, and above all, progress in the economic evaluation of patents (gauged by the size of the market for which a patent is issued) have diluted the negative impact of patents on innovations and economic performance to a significant extent. The increasing number of patents, particularly in biotechnology, pharmaceuticals, and chemical sectors, reflects the strengthening of patent system in Europe, Japan, China, Korea and USA[238] and recognition as a tool for enhancing technological innovations. However, the concerns shall still be remaining there for probing deeper into the factors resulting in poor economic development and transfer of technology in developing countries. Nevertheless contrasting the position in the past, recent advances in biotechnology, bioinformatics, and software engineering resulting in high level of innovations, are a prima facie evidence of the fact that patent system is incentivizing innovations and contributing to the conservation of biodiversity, industrial development and economic well-being of the people in the developing countries.

Seen in the above light, patents may thus, in principle, be supportive of the CBD's objective rather than its destruction and decline. In parallel, beyond encouraging innovations and fostering dissemination of knowledge, patents with a reasonable scope of protection, may generate resources and promote economic activities.[239]This may indirectly contribute to the conservation of biodiversity and sustainable-use in developing countries. The NGOs, independent analysts, biodiversity conservationists, and communities[240] might have noticed in the Neem,

---

[237] Stephen A. Merrill et al. '*A Patent System for the 21st Century'* (2004), National Academies Press, p18.
[238] Richard C. Levin et al. *'Appropriating the Returns from Industrial R&D'* (1987), Brookings Papers on Economic Activity, p783-820;
Wesley M. Cohen et al. '*Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*' (2000), National Bureau of Economic Research, USA, p3-28.
[239] '*Patents and innovation: trends and policy challenges'* (2004), Organisation for Economic Co-operation and Development, OECD Publications.
[240] [NGOs such as African Conservation Center (ACC), Africa; Wetlands International, Africa; GRAIN (Genetic Resources Action International), Spain; Nature Cameroon, UK; Wildlife for Sustainable Development, Ethiopia; Seychelles Plant Conservation Action Group; and Action for Green Life,

Turmeric, Basmati and Hoodia biopiracy instances that- attempts to monopolize IBRs and associated knowledge by the research-based companies ultimately had resulted in revocation of the patented rights.[241] From a legal perspective, the perception that pharmaceutical and biotechnology companies get patent rights over indigenous resources and traditional knowledge and exploit them to their own benefits is generally incorrect. From the practical side, for any instances of unlawful exploitation of IBRs and associated TK, common and substantive laws (such as intellectual property laws) protect the rights of the indigenous communities.

4.2.2 Are national and international laws on patents supportive to monopolize bio-resources of other nations?

National as well as international laws on patents and biodiversity support access and utilization of IBRs, genetic resources and the TK under a defined mechanism.[242] However, in reality, the communities in the developing countries are self-exploiters and bio-pirates. The poor economic conditions and infrastructure, food insecurities, unemployment, and other social needs force them to collect and sell their resources directly or indirectly to the research-based companies of the developed world at nominal costs. Within such communities, the individual scientists and researchers with better living status or employment opportunities take out the collectively-owned resources, modify them and export genes/DNA samples for further researches under collaborative research programs so to place them in the commercial market as their own property rights.

Patent laws place no restriction on the use of IBRs, genetic resources, or TK for the development of new or improved products, processes, or treatments.[243] However, the rights over new or improved innovations in no way extend to the use of the IBR, genetic resources, or TK by the local or indigenous community in their traditional way. Together with the national law on biodiversity,[244] the South African Patents Act, 1978 recognizes the rights of the local or indigenous communities over

---

Ghana. International conservation organizations such as WRI (World Resources Institute) and IUCN (International Union for Conservation of Nature), France].

[241] Sayan Bhattacharya '*Bioprospecting, biopiracy and food security in India: The emerging sides of neoliberalism*' (2014), International Letters of Social and Humanistic Sciences, Vol. 23, p49-56.

[242] Art. 15 & Art. 16 of the Convention on Biological Diversity, 1992; Sec. 80-93 of the National Environmental Management: Biodiversity Act, 2004.

[243] Sec. 101 of Title 35 of the Unites States Code.

[244] The National Environmental Management: Biodiversity Act, 2004 and Bioprospecting, Access and Benefit Sharing Regulations, 2008.

bio-resources.[245] This is done by requiring the patent applicant, who lodges a statement with the Registrar that his invention is based on or derived from the IBR, genetic resource, TK, or use, to furnish proof of his title or authority to use the resource.[246] Such proof may comprise the PIC and the existence of agreements on material transfer and benefit sharing. Patents built on IBRs or genetic resources require the collector of the resources to share the benefits[247] as has been mutually agreed with the providers of such resources. A portion of such benefits is to be deposited to the Trust Fund for use in the conservation of biodiversity.

Allegations, that patents result in destruction, or depletion of bio-resources, may have held true to some extent in the past. In the modern era of technological innovations, development of laboratory techniques and research tools has significantly curtailed the use of bio-resources especially the plants and laboratory animals. Once a compound is isolated or extracted from its natural environment, its use in the biological systems (such as bacteria or yeast) is tested for enhanced activity and yield. Such systems have significantly reduced the time span for pre-clinical trials. Nevertheless, for any adverse situations, the South African National Environmental Management Act, 1998 and the NEMBA, 2004 aim to conserve biodiversity and protect their habitats.

In the agriculture sector, cultivation of genetically uniform crop varieties as part of the national governments' policies for increased productivity, food securities and farm income might have resulted in loss of biodiversity, or genetic erosion. This genetic erosion has also affected the number of patents and ultimately the availability of new drugs or treatments in the market.[248] It is therefore the national governments' responsibility to revisit their agriculture policies and provide farmers with incentives in the form of subsidies such as reimbursement for seeds, fertilizers, equipments and labour, to continue growing the traditional plant varieties.

---

[245] Sec. 25(3A) & 25(3B) of the Patents Amendment Act, 2005.
[246] Rule 44A(2) of the Bioprospecting, Access and Benefit Sharing Regulations, 2008.
[247] Such as cash payments, royalties, technology transfer, capacity-building etc.
[248] Emilien G. et al. '*Impact of genomics on drug discovery and clinical medicine'* 2000), QJM, Vol. 93(7), p391-423.

4.2.3 To what extent is it fair to have access to bio-resources of other nations

In pharmaceutical and biotechnology sectors, access to bioresources of other nations must be made easy without much documentary compliances.[249] However, such access must be subject to fair and equitable sharing of benefits derived from such access.[250] Development in health sectors requires new drugs and treatments to be available in the market. Therefore, knowledge or information held by any community about medicinal value of specific indigenous plants or genetic resources must be shared or exploited in the relevant circle (researchers and scientists) to be tested for its prospects of being developed into a new drug or treatment that may improve the lives of many within and outside the source country.[251] For providers to be in a better bargaining position in a bioprospecting contract over the resulting patented commercial product, the costs of bargain must not exceed the value of the genetic resource.[252]

Contrary to the practices prevalent in the past, the source providers must care for the non-availability of germplasm of the resource to the 'free riders' in the farming community and make reasonable efforts for excluding other communities from concluding the similar, competitive contracts.[253] Access to genetic resources and associated knowledge of indigenous communities is also vital for the development of the agriculture sector and to address the issues relating to erosion of crop genetic resources.[254] Such access may provide an incentive for the discovery of new products (genes/DNAs) and their uses that may outweigh the disadvantages associated with such access. Patents on isolated new genes/DNAs with substantial utility (as diagnostic tools, for instance) may provide indigenous communities with increasing opportunities for concluding new bioprospecting contracts for benefit sharing, including covering price of access. Such contracts are thus effective tools for conserving biodiversity as well as genetic resources and knowledge associated

---

[249] Art. 10, 11 and 12 of the Nagoya Protocol by requiring the parties to support the development of minimum requirements for MAT to secure fair and equitable sharing of benefits arising from the utilization of IBRs and the TK.

[250] including transfer of technology and capacity-building if use of the information leads to a patentable commercial product.

[251] Gupta R. et al '*Nature's Medicines: Traditional Knowledge and Intellectual Property Management. Case Studies from the National Institutes of Health (NIH), USA'* (2005), Current drug discovery technologies. 2005;2(4):203-219.

[252] Stephen B. Brush op cit note 7.

[253] Ibid.

[254] Susette Biber-Klemm '*Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*' (2006), CABI, p338.

therewith.

The increasing number of patents in pharmaceutical and biotechnology sectors[255] is reflective of technological advancement[256] and economic activity in a country awarding patent rights.[257] Ultimately the patent is to expire and technology transfers to the public providing local manufacturers an opportunity to make use of it in the local industry. The U.S. Bayh-Dole Act, 1980 allowing public research organizations to own and license the IP, generated by the public research funds, as a more recognized and effective channel for technology transfer is an example for the developing countries to use the legislation as a model for increasing commercialization of inventions and generating greater benefits for their society in terms of technology transfer and industrial development.[258] To assist in achieving this goal, Art. 22 of the Nagoya Protocol requires developing countries to identify their national capacity needs and priorities through national capacity self-assessments. Technology transfer and infrastructure, and technical capacity to make such technology transfer sustainable is among several measures that parties-to-the-Protocol are directed to take for capacity-building, capacity development and strengthening of human resources and institutional capacities in the developing countries. Scientific knowledge, capacity building and infrastructure are therefore the real challenges for the developing countries including South Africa to meet, if conservation of biodiversity and sustainable use of its component is really a point of concern. South African patent policy makers need to devise a scheme for assessing the ability of the patent system for incentivizing innovations and progressing technology transfer as well as economic evaluation of patents built on IBRs. Until such developments occur, NGOs, human rights organizations and generic manufacturers will continue to allege that 'patents' are a tool for exploiting their resources, creating barriers to technology transfer, and were conceived for the benefits of developed nations only.

---

[255] Susette Biber-Klemm '*Rights to Animal Genetic Resources – basic facts and debates'* (2011), NCCR Trade Working Paper.
[256] Wesley M. Cohen et al. '*Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*' (2000), NATIONAL BUREAU OF ECONOMIC RESEARCH, USA, p3-28.
[257] Richard C. Levin et al. *'Appropriating the Returns from Industrial R&D'* (1987), Brookings Papers on Economic Activity, p783-820;
'*Patents and innovation: trends and policy challenges*' (2004), Organisation for Economic Co-operation and Development, OECD Publications.
[258] Ibid.

CHAPTER FIVE: BIOPIRACY AND SOUTH AFRICAN LAWS

Biopiracy is a problem which is specifically associated with the biodiversity-rich but technologically-poor developing and least developing economies.[259] The problem is further amplified by poor legislation and adopting strategies which suit the status and economic conditions of the developed nations.[260]

This chapter analyzes biopiracy issues with specific reference to South Africa and the applicable biodiversity and patent laws. The analysis shall progressively move towards pointing out the inadequacies in the government's efforts to curb biopiracy; and will conclude by suggesting amendments to the South African Patent law that may better protect the biodiversity and traditional knowledge of the communities.

5.1 DEFINITION

The term 'biopiracy' has not been defined in the South African laws on biodiversity; however, the term 'bioprospecting' in relation to indigenous biological resources has been defined to mean 'any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation.'[261] In light of this definition, the term 'biopiracy' may be broadly defined as 'misappropriation or unlawful exploitation of IBRs[262] such as animals, plants, microbes, or other organisms of indigenous species including any derivatives or any genetic materials of such animals, plants, microbes, or other organisms on commercial or industrial scale'.

5.2 NATIONAL ENVIRONMENTAL MANAGEMENT: BIODIVERSITY ACT, 2004

In discharge of South Africa's obligations under the CBD, its attendant agreements, and within the framework of the NEMA, the NEMBA was enacted to provide for –

i) the management and conservation of biodiversity and its components;

ii) the use of IBRs in a sustainable manner; and

---

[259] Carl-Gustaf Thornström '*Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials*' (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, p1461;
Paul Gepts '*Who Owns Biodiversity, and How Should the Owners Be Compensated?*' (2004), Plant Physiol, Vol. 134(4), p1295-1307.

[260] Steffen Bohm et al. '*Upsetting the offset: The political economy of carbon market'* (2009), MayFlyBooks, London, p299.

[261] Sec. 1(1) of the National Environmental Management: Biodiversity Act, 2004.

[262] '*The National Agricultural Directory* 2009' CIPRO, RainbowSA, p496.

iii) the fair and equitable sharing of benefits arising from bioprospecting involving IBRs.[263]

The NEMBA is based on the CBD negotiated within the United Nations Environmental Program (UNEP). In order to prevent biopiracy, Sec. 81(1) of the NEMBA makes it incumbent upon the access seekers to secure permit before any research involving use of IBRs or TK is conducted. This requisite extends to the export of any IBR for the purpose of bioprospecting or any other kind of research.[264]

Within the meaning of Sec. 81(2) and 82, before the issuing authority is in a position to consider any application for permit, the applicant must follow the following procedural steps:

i) Identify the relevant stakeholders, which may be a person, an organ of state or community, providing or giving access to the IBR or TK associated therewith;

ii) Disclose all material information concerning the proposed bioprospecting for obtaining the prior consent of the stakeholder for the provision of or access to the IBRs, or the knowledge associated therewith;[265]

iii) Subject to the prior informed consent of the stakeholder, enter into two contracts with the stakeholder, particularly- a) a Material Transfer Agreement, which regulates the provision or access to the IBRs; and b) a Benefit Sharing Agreement, which provides for the sharing of future benefits that may be derived from the relevant bioprospecting. In order to give effect to both agreements, approval by the Minister of Environmental Affairs and Tourism is critical.[266] Only if the Minister is satisfied that the interests of the stakeholders are duly protected in the contracts, a permit for proposed bioprospecting may be issued. Any such permit may or may not contain certain conditions imposed by the Minister, or the issuing authority.

An important aspect of the NEMBA is that under Sec. 83 and Sec. 84 respectively, it requires both the BSA and MTA to specify amongst others- i) the type

[263] Preamble of National Environmental Management: Biodiversity Act, 2004.
[264] Sec. 81(1)(b) of the National Environmental Management: Biodiversity Act, 2004.
[265] Sec. 82(2)(a) of the NEMBA, 2004.
[266] Sec. 82(2)(c) of the NEMBA, 2004.

of IBRs to be involved in bioprospecting; ii) the area or source of collection; iii) the quantity to be collected; iv) the traditional uses of the IBRs by an indigenous community; and v) the present potential uses of the IBRs. The purpose behind such disclosure is not only to protect the interests of the stakeholders but the IBR in question from the potential risks of endanger or extinction.

Under the provisions of Sec. 101 of the NEMBA and BABS Regulations, it is an offence to undertake any activity, or allow any other person to do, or omit to do anything otherwise than the permit was issued for. Most commentators are of the opinion that the NEMBA is a well-drafted piece of legislation. It is balanced and protects the interests of both the access seekers and the access providers. [267] The national biodiversity framework, biodiversity management plans,[268] co-ordination and alignment of plans, monitoring and research to protect and avoid further extinction of the South Africa's biodiversity are some pivotal developments created by the Act. However, it is more than a decade since this legislation came into force but the number of reported cases of biopiracy in South Africa is very low.[269] Whether low numbers are reflective of few instances of biopiracy or whether this suggests that local authorities are not interested in keeping a track record of biopiracy-cases to bring them to the knowledge of the international community needs clarification. This requires in-house assessment of the actual position if the government is serious in delivering the benefits of the ABS legislation to the indigenous community.

On the other hand, no report is available to confirm that known South African biodiversity and TK has fully been documented and is now available to major Patent Offices[270] for screening and/or searching for prior art to prevent monopolization of South African biodiversity by pharmaceutical and agricultural companies from the developed world. The use of the word 'may' in Sec. 56(1) of NEMBA suggests that Minister can decide whether or not to publish, in the Government Gazette, a list of critically endangered, vulnerable, and even protected species of high conservation value or of national importance; however, Sec. 56(2) stipulates statutory obligation to

---

[267] A.F. Myburgh '*Legal developments in the protection of plant-related traditional knowledge: An intellectual property lawyer's perspective of the international and South African legal framework*' (2011), South African Journal of Botany, Vol. 77, p 844–849.
[268] Sec. 41 of the National Environmental Management: Biodiversity Act, 2004.
[269] Sifelani Tsiko 'Biopiracy highlights in Africa' (2015), The Southern Times, available at *https://southernafrican.news/2015/12/06/biopiracy-highlights-in-africa/* accessed on 13 October, 2016.
[270] (like USPTO, UKIPO, EPO, JPO, KIPO, CIPO, INPO etc.).

review such lists after five years. The said listing was published[271] online but its periodic review is not carried out as dictated by the Act.

5.3 THE SOUTH AFRICAN PATENTS ACT (ACT 57 OF 1978)

Biodiversity and patents are interrelated in that a greater genetic diversity is the mainstay for patentable technological innovations in pharmaceutical and agricultural sectors. In order to reflect some of the aspects of the NEMBA, the Patents Act of 57 of 1978 was amended by the Patents Amendment Act, 2005 (Act 20 of 2005). Sec. 30(3A) & (3B) of the amended Patents Act now requires every applicant for a patent to declare on the prescribed Form P-26 whether or not his invention is based on or derived from an IBR, genetic resource, or TK. If it is, the applicant may further be required to furnish proof of his or her title or authority to make use thereof. Such proof may comprise proof of prior informed consent, and proof of agreements on material transfer and sharing of benefits. Non-submission of such statement may lead to non-acceptance of the patent while a false statement may open the patent liable to revocation.

The requirement under Sec. 30(3A)&30(3B) of the Act, 2005, on the one hand, aims to avoid unlawful misappropriation of the IBRs or TK by the research-based companies while, on the other, strives to promote technological innovations as well as secure benefits for the stakeholders from the biodiversity to be used in bioprospecting. Irrespective of whether this requirement has merit to achieve the said objectives, making filing of Form P-26 also compulsory for non-pharmaceutical and non-biotechnological innovations appear overzealous and effectively makes the Patent Office a storehouse of papers as under the prevalent practices before the South African Patent Office, official documents have rarely been the subject of publication.[272]

---

[271] Red List of South African Plants 2015 Online (*http://redlist.sanbi.org/*). This represents the status of the species within South Africa.

[272] Sec. 12 and Sec. 91 of the Patents Act 1978; See also WIPO Handbook on Industrial Property Information and Documentation available at *http://www.wipo.int/export/sites/www/standards/en/pdf/08-01-01.pdf* accessed on 1 1 October, 2016.

5.4 LEGAL LACUNAS IN GOVERNMENT'S EFFORTS TO CURB BIOPIRACY

Under the internationally accepted principles of patent laws, indigenous knowledge that already resides in the public domain cannot be protected by patents because it does not meet the requirement of 'novelty'.[273] The rule of common heritage also supports this conception by stating that 'genetic resources, whether the resources are found in the farmer's field or gene banks, fall in the public domain'.[274] Furthermore, based on the rule of worldwide novelty, and to give effect to the provisions of the TRIPS agreement, many biodiversity-rich countries have explicitly defined in their national patent legislation the 'state of the art' and enjoined that this shall comprise the 'traditionally developed or existing knowledge available or in possession of a local or indigenous community'.[275] The South African Patents Act 1978 has excluded certain inventions from the scope of patentable inventions but in contrast to the position with other developing-country TRIPS member states, in order to substantiate its efforts to curb biopiracy, it has not amended the Patents Act to include TK or practices common among the indigenous people or communities in the list of novelty destroying prior art.

While the CBD has no *direct* impact on patent standards, it has since its inception-effected patent laws and practices of its member states in a variety of ways.[276] The most notable being the requirement to disclose information about the place of origin and source of biological material and/or TK in a patent specification involving use of IBR, genetic resource, and TK associated therewith. Through the 2005 amendments in the Patents Act, South Africa has attempted to give effect to the provisions of the CBD but that attempt fails to effectively support previous efforts to

---

[273] *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009);
Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989);
Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984);
Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1306 (Fed. Cir. 2006);
Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

[274] Stephen B. Brush '*The Lighthouse and the Potato: Internalizing the Value of Crop Genetic Diversity'* (2002), Political Economy Research Institute (PERI), Working paper No. 37, University of Massachusetts.

[275] Report on the International Patent System: Revised Annex II of document SCP/12/3 Rev. 2, WIPO, available at *http://www.wipo.int/export/sites/www/scp/en/meetings/session_17/annex_ii/pakistan.pdf* accessed on 13 May, 2016.

[276] Lionel Bently op cit note 116, p402.

prevent and limit the loss of biodiversity.[277] This may be corroborated by the fact that any officially prescribed document (such as application Forms including Form P-26), reports by the examiners, and information about granted patents, entered into the Register of Patents are not published by the South African Patent Office. More so, in exceptional circumstances, the scope of information disclosure remains restricted to the concerned parties and relevant authorities (such as the IP tribunal and Courts).[278] Therefore, the requirement under section 30(3A)&(3) of the Patents Act may not be taken as information disclosure statement about the use of IBRs. This makes no difference in the current and past practices because on publication of the patent specification for opposition in the Gazette, a distinction whether an invention is based on or derived from an IBR or TK is not provided. It is only an indication of the source and/or country of origin of genetic resources and/or the TK in the specification as part of the running description that may serve as a constructive notice to the public of the applicant's invention and their freedom-to-operate. In parallel, where a genetic resource constitutes an essential component of the claimed invention, and an access to that component is critical to satisfy the enable requirement, it is again an indication of the source of the IBR or its deposit details[279] in the specification that may ensure to give access to the genetic resource. Therefore, in strict legal terms, South Africa so far has no legal requirement that the source and/or country of origin of the genetic resources and/or TK be indicated in the patent specification for inventions based on or derived from the IBR or TK. Such requirements are, however, provided in South Africa's Act on Biodiversity (the NEMBA). But again, with the possible imperfection of restricting such information among the parties to the agreements on mutual transfer and benefit sharing and the bioprospecting permit issuing authority; not for the information of general public or indigenous community at large.

While the Patents Amendment Act 2005 defines the concepts 'indigenous biological resource', 'genetic resource', 'traditional knowledge', and 'traditional use', the concept of 'source or country of origin of the genetic resource' has not been clarified. In terms of Art. 2 of the CBD, the term 'country of origin of the genetic

---

[277] Emeka Polycarp Amechi '*Using patents to protect traditional knowledge on the medicinal uses of plants in south africa*' (2015), LEAD Journal 11/1, p53-71.

[278] Alexis Apostolidis '*The International Comparative Legal Guide to: Patents 2017*' (2017), Global Legal Group Ltd, London, p125-131.

[279] such as the accession number, the date of deposit in the genbank etc.

resources' refers to the country, which possesses those genetic resources in *in-situ* conditions. This definition excludes the countries, which are maintaining the same IBR or genetic resource in *ex-situ* conditions.[280] Defining the country of origin of the IBR, therefore, seems critical for the purposes of biodiversity conservation.

Another impact of the CBD on the patent standards in South Africa is the requirement to submit proof of the applicant's title or authority (commonly: a permit) to make use of the IBR or TK. A permit may be issued subject to an application for permit and submission of agreements on material transfer and benefit sharing made between the parties (researchers and stakeholders). Technically, prior informed consent, including conclusion of agreements on material transfer and benefit sharing are issues, which no doubt are related to IBR or genetic resources research and development, but do not establish any link with the patent standards. The concept of linking the patent's validity to securing of a permit appears to be in conflict with the patent system's general purpose of granting exclusive rights against disclosure for technological innovations, without regard to issues related to another system or law (here the Biodiversity Act).

The patent system requires certain matters or information to be disclosed in the specification but these are all for the purposes of practicing the claimed invention. For instance, patents for inventions involving use of or concern biological material[281] and which cannot be described in the specification in a manner satisfying the sufficiency requirement, a deposit of the biological material in the Genbank (or any other appropriate repository) is necessary to establish sufficiency. Member states of the Budapest Treaty[282] have set it as a pre-condition to provide information in the as-filed patent specification regarding- i) date of deposit; ii) the name of depositary institution; and iii) accession number of the deposit to satisfy the sufficiency (or enablement) requirement - a statutory criterion for patentability and not as an attempt to resolve issues unrelated to the patent system.

Given the above, the requirement to secure a permit or PIC of the stakeholder; to submit proof of the agreements on material transfer and benefit sharing; and to ensure compliance with the rules on access, export, or use of that material before any

[280] such as the genbank, botanical gardens, and other repositories.
[281] For example, an isolated DNA, gene, or microbes.
[282] The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977.

search is conducted, should not be required for patent applications based on IBR or genetic resource. This must be treated and assessed under the laws and regulations governing access to genetic resources and benefit sharing for the users of genetic resources or TK associated therewith.

5.5 SUGGESTED MEASURES

In view of the existing gaps in the South African Patents Act 57 of 1978 read with the Patents Amendments Act of 2005, it is suggested here to take the following suggestions for amendments into consideration so that the country's patent system can play its role in the conservation of South African biodiversity and promote technological innovations:

5.5.1 Proposed amendment in Sec. 2 (Definition):

In addition to the definitions of 'indigenous biological resource', 'genetic resource', 'traditional knowledge' and 'traditional use' introduced in the Patents Act of 1978 by way of the Patents Amendment Act, 2005, the following definition for 'country of origin of genetic resources' as defined in Art. 2 of the CBD, should be included in the Patents Act and, in parallel, in the NEMBA:

'Country of origin of the genetic resources' means the country, which possesses those genetic resources in in-situ conditions.

Justification:

The justification for adding this definition is the proper recognition of the country, which is the source of the IBR and genetic diversity. Information about the country of origin from the patent specification may in certain situations become critical to provide. For instance, when the sample maintained in *ex-situ* conditions proves to be non-viable and access to *in-situ* resource becomes critical to satisfy the enablement requirement.

5.5.2 Proposed amendment in Sec. 25(4) (Patentable Inventions):

Insertion of new clause (c) after Sec. 25(4)(b):

(c) for naturally occurring substances (isolated or synthetically produced) of known utility

Justification:

Naturally occurring substances 'as such' or if isolated from their natural environment are not subject to patent protection for want of 'non-obviousness' in almost all developed countries of the world.[283] For instance, if the invention making use of IBR involves mere reproduction of a previously known and identified product, having a utility well-known to the indigenous people, by the process of biotechnology or chemical synthesis, is obvious/non-inventive and may hence not be patented.

Notwithstanding the said legal position, the actual controversy in all the famous instances of biopiracy[284] concerned the synthetic reproduction of the known compounds of known utility in a commercially viable form. The very justification advanced by the biopirates was that it was 'new' and 'inventive' to isolate the compound from its natural environment and to transform it into a commercial product. Such an argument held force when Louis Pasteur[285] got US Patent No. 141, 072 on yeast free from organic germs of disease; however, nowadays, when pharmaceutical and biotechnology techniques are routinely applied in laboratories, such or similar arguments have been rejected by the various authorities revoking the Neem, turmeric and other patents on IBR and genetic resources. Therefore, exclusion of the naturally occurring substances of known utility from the scope of patentable invention is required in explicit terms to ensure that patents are not available for products or materials in the possession of local or indigenous community.

5.5.3 Proposed amendment in Sec. 25(7) (Patentable Inventions):

Insertion of new clause (7A) after Sec. 25(7):

(7A) 'The state of the art shall further comprise 'traditionally developed or existing knowledge available or in possession of a local or indigenous community'.'

Justification:

Within the meaning of Sec. 25(6) of the Act of 1978, the general qualification for a prior disclosure to be anticipatory has been set to be '*made available to the public*' (whether in the republic or elsewhere) by written or oral description, by use or in any other way. In this respect, the observation of Lord Hoffmann in Merrell Dow v.

[283] For example, USA, UK, Japan, Korea, China, Germany etc.
[284] Neem, turmeric, basmati, brazzein, for example.
[285] A scientist from France who invented improvements in the manufacture and preservation of beer and in the treatment of yeast & wort.

Norton[286] is referred to that may have impact on the determination of question of TK '*made available to the public*':

This observation suggests that a novelty attack may fail if the prior art disclosure is inadequate (i.e., non-enabling), failing to teach or give clear and unmistakable direction to enable the person skilled in the art to reproduce/work the invention without undue burden or the necessity of making further experiments. If this interpretation is to be applied to TK, which has never written down or of which, previous disclosure is not proven, difficult questions of law and fact may render the TK or traditional practices falling outside the 'state of the art'. In order to address or cater for such situations, the suggested amendment in the Patents Act seems to be of enormous value.

5.5.4 Proposed amendment in Sec. 30 (Form of application for a patent):

Sec. 30(3A) & (3B) of the Patents Amendment Act 2005 may be amended as-

'(3A) ~~Every~~ *An* applicant who lodges an application for a patent accompanied by a complete specification ~~shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed~~ *which* is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use:

(a) which is not available to the public at the date of filing the application;

(b) which cannot be described in the specification in such a manner as to enable the invention performed by a person skilled in the art

shall no later than the date of filing of the application deposit in a depository institution prescribed by the Minister which is able to furnish a sample of the biological material. The specification accompanying the application shall provide information as to the name of the depository institution and the accession number of the deposit.

~~(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is~~

[286] *Marion Merrell Dow v. Baker Norton Pharmaceuticals*, 948 F. Supp. 1050 (S.D. Fla. 1996).

~~claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.'~~.

Justification:

The proposed amendment is based on two reasoning:

i) Patent deals with all the technological innovations including electrical, mechanical, business-related methods or techniques and many more. While the requirement to submit a proof of title or authority is strictly related to IBRs, genetic resources, or traditional knowledge or use related innovations. To extend the requirement to the applicants of non-pharmaceutical and non-biotechnological innovations is not convincing.

ii) Patent and the Biodiversity Acts have their own defined working boundaries. Thus to import the requirement to furnish proof of title or authority to make use of IBR from another system and to make it a criterion for patent grant is technically and logically unsound.

CHAPTER SIX: CONCLUSION

This thesis set out to define the role of the patent system in the conservation of biodiversity and to show how greater genetic diversity can contribute to the progress of technological innovations and the economic activity in developing countries, particularly with reference to South Africa. The thesis analyzed the key provisions of various international and national agreements, conventions or legislations concerning conservation of biodiversity and access and benefit sharing; and showed how policy makers[287] can prevent exploitation of indigenous communities' biodiversity. The thesis projects that South African biological resources are an abundant source of distinctive genetic systems, making them attractive targets for development and discovery of potential drug candidates for human healthcare systems; and new genes/DNA for increasing food and nutritional securities in agriculture. The paper proposed various changes to the existing patent laws to safeguard increasing opportunities for bioprospecting and, in return, conservation of biodiversity and sustainability despite the differences in power when negotiating bioprospecting contracts and benefit sharing over intellectual property built on the IBRs and the associated TK.

Enormously rich in curative value and increasing food production, genetic/bio-resources of South Africa and associated knowledge are the source of great economic activity. However, lack of necessary infrastructure, financial resources, research tools, and capacity to grasp the latest technology, it is difficult for the local researchers and pharmaceutical companies to undertake the process of transforming natural products into commercial items. Exploitation of IBRs and associated TK for the discovery and development of new medicinal products for the benefit of present and future generations is critical for the conservation and sustainable use of South African biodiversity, and within the objectives of the CBD and its attendant agreements, including the Nagoya Protocol.

Insufficiencies aside, South African biodiversity laws and consequent amendments in the Patents Act have introduced a number of measures for protecting biodiversity from destruction; however, the real challenge is to have access to the advanced scientific knowledge or techniques and capacity-building that may bring

[287] (by strengthening the national patent system and streamlining the bioprospecting permit system)

economic stability and prosperity in the country. Until this is attained, the South African government should, in the *health* sector, devise a fair and simplified mechanism that allows easy and quick access to bio-resources for pharmaceutical and biotechnology companies in order to not unnecessarily delay respective patent applications as a result of the current BSA approval and permit required for patent protection. This delay creates additional barriers to the exploitation of patented technology and, in turn, delays in the utilization of benefits in biodiversity conservation. Such access, however, must be limited to those companies that are willing to only engage in bioprospecting activities in return for the fair sharing of the benefits that are derived from the utilization of the IBRs with the indigenous community.

In the *agricultural* sector, the real incentive for *in-situ* conservation is the increase in the value of genetic resources that may motivate farmers to continue growing the traditional plant varieties for generating a new stream of genetic diversity. Making the patent system stronger, both in terms of protection and enforcement of patented rights, can help increasing the genetic resources value and conservation of biodiversity through generation of monetary and non-monetary benefits if use of the IBRs and the associated TK result in the discovery and development of some patentable drug targets for human therapeutics or novel gene/DNA for increase in plant resistance against pests and drought, for instance. This may be accomplished, partly, through introducing further amendments that are more protective of the rights of the indigenous communities (a few are suggested as an integral part of this thesis), and partly through granting exclusivity over the use of genetic resources. In return for granting access, royalty payments and non-monetary benefits, including transfer of technology for innovations that are based on or have utilized the indigenous genetic resources and the associated knowledge, could prove to increase economic activity and the industrial development in the long run.

Patents on a novel gene/DNA isolated from genetic resource may thus create an opportunity for the wide distribution of benefits and flow of revenue among the indigenous community, including farmers, and for utilizing part of this return for the conservation of biodiversity. For local generic companies, opportunities arise to, first, have access to the underlying patented technology through licensing and, after the patent is expired, to utilize the off-patent drug or technology for their own commercial

benefits. Local researchers and companies may extend application of this knowledge to the isolation of new drug candidates from the newly discovered genetic resources, and then use or commercialize this knowledge in more effective ways. If carefully strategized, this may open-up new markets or introduce new patented articles in the existing product line for those companies who step-in first in the active component extraction process. Denying patent rights to gene or gene products, especially those isolated from plant genetic resources having markedly different characteristic from those outside the particular territories of South Africa, may hinder economic activity and innovation development.

Setting high standards for inventiveness,[288] and local exploitation of patented technology,[289] as required by the Paris Convention, can ensure technology transfer and increase in the value of bio-resources. Moreover, TRIPS recognizes import as satisfying the local working requirement, but the Paris Convention urges on local working of the patented invention and, as such, South Africa can use this local working-lever for its industrial growth. In summary, means for providing effective patent rights to genetic resources *per se* are instrumental in preventing bio-piracy in bio-resources; however, creating and maintaining, in parallel, a balance between the rights and obligations of parties[290] is the ultimate way to enhance bioprospecting activities and conserve biodiversity in South Africa.

[288] (particularly obviousness for distinguishing between trivial and non-trivial innovations).
[289] Sec. 57 of the South African Patents Act, 1978.
[290] (who manage genetic resources and those who are interested in their conservation as regulated by the patent laws and conventions on biodiversity).

BIBLIOGRAPHY

Primary Sources

Legislation

South Africa

- Bioprospecting, Access and Benefit Sharing Regulations, 2008
- National Environmental Management: Biodiversity Act 10 of 2004.
- Patents Act No. 57 of 1978.
- Patents Amendment Act No. 20 of 2005.

International

- Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, 2002.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977.
- Cartagena Protocol on biosafety to the Convention on Biological Diversity, 2000.
- European Patent Convention, 1973.
- International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.
- International Union for the Protection of New Varieties of Plants Convention, 1991.
- Nagoya Protocol on Access and Benefit Sharing, 2010.
- Patent Corporation Treaty, 1970.
- Title 35 of the Unites States Code.
- Trade Related Aspects of Intellectual Property Rights, 1994.
- United Nations Convention on Biological Diversity, 1992

Cases

- *Amgen Inc. v. Hoechst Marion Roussel, Inc.,* 457 F.3d 1293, 1306 (Fed. Cir. 2006).
- *Diamond v. Chakrabarty,* 447 U.S. 303 (1980).
- *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).
- *In re Skvorecz,* 580 F.3d 1262, 1266 (Fed. Cir. 2009).
- *Marion Merrell Dow v. Baker Norton Pharmaceuticals,* 948 F. Supp. 1050 (S.D. Fla. 1996).
- *Richardson v. Suzuki Motor Co*., 868 F.2d 1226, 1236 (Fed. Cir. 1989).
- *Structural Rubber Prods. Co. v. Park Rubber Co*., 749 F.2d 707, 716 (Fed. Cir. 1984).

Secondary Sources

Books

- Camena Guneratne '*Genetic Resources, Equity and International Law*' (2012), Edward Elgar Publishing, UK
- Carmen Richerzhagen '*Protecting Biological Diversity: The Effectiveness of Access and Benefit*' (2013), Routledge, UK.
- Charles Costanza et al. '*Deal Making in Bioprospecting*' (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, Oxford, UK
- Christine Frison '*Plant Genetic Resources and Food Security: stakeholder perspectives on the international treat y on plant genetic resources for food and agriculture*' (2011), FAO, Bioversity International and Earthscan, USA.
- Dan Leskien '*Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*' (1997), The International Plant Genetic Resources Institute (IPGRI), Italy.

- Dennis S. Karjala, '*Biotechnology Patents and Indigenous Peoples*' (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, Oxford, UK
- H.J. Silvis '*Economic viewpoints on ecosystem services'* (2013), WOt Rapport, Dutch Ministry of Economic Affairs (EZ), LEI Wageningen, Netherland.
- James Boyce '*Natural Assets: Democratizing Ownership of Nature'* (2003), Island Press, Washington, USA.
- Laurence R. Helfer '*Intellectual property rights in plant varieties International legal regimes and policy options for national governments'* (2004) Food and Agriculture Organization of the United Nations, Rome, Italy.
- Lionel Bentley, Brad Sherman '*Intellectual Property Law'* (2014), Oxford University Press, Oxford, UK.
- Michel Trommetter '*Biodiversity and international stakes: A question of access*' (2005), GAEL, France.
- Mpazi Sinjela '*Human Rights and Intellectual Property Rights: Tensions and Convergences*' (2007), Martinus Nijhoff Publishers, Boston, USA
- Padmashree Gehl Sampath '*Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-sharing*', United Nations University Press, Tokyo, Japan.
- Paul van Mele '*African Seed Enterprises: Sowing the Seeds of Food Security'* (2011), CABI, London, UK.
- Regine Andersen '*Realising Farmers' Rights to Crop Genetic Resources: Success Stories and Best Practices*' (2013), Routledge, UK.
- Robert B. McKinstry '*Biodiversity Conservation Handbook: State, Local, and Private Protection of Biological Diversity*' [2006], Environmental Law Institute, Washington, USA.
- Robert E. Evenson '*International Trade and Policies for Genetically Modified Products'* (2006), CABI, London, UK.

- Robert J. Lewis '*Case studies on access and benefit-sharing'* (2006), The International Plant Genetic Resources Institute (IPGRI), Italy.
- Santiago Carrizosa '*Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*' (2004), IUCN, Switzerland.
- Soejarto DD et al. '*Bioprospecting Arrangements: Cooperation Between the North and the South'* (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, Oxford, UK.
- Srividhya Ragavan '*Patent and Trade Disparities in Developing Countries*' (2012), Oxford University Press, UK
- Stephen A. Hansen et al '*Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property*' (2007), Handbook on Intellectual Property Management in Health and Agricultural Innovation, Vol. 2, PIPRA, Oxford, UK.
- Stephen B. Brush '*Genes in the Field: On-farm Conservation of Crop Diversity'* (2000), International Plant Genetic Resources Institute, International Development Research Centre (Canada), IDRC, Ottawa, Canada.
- Stephen B. Brush '*The Lighthouse and the Potato: Internalizing the Value of Crop Genetic Diversity'* (2002), Political Economy Research Institute (PERI), University of Massachusetts, USA.
- Stevens AJ '*Valuation and Licensing in Global Health*' (2007), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, MIHR and PIPRA, Oxford, UK
- Susette Biber-Klemm '*Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*' (2006), CABI, London, UK.

Reports/Policies

- *'Contribution of the Convention on Biological Diversity and the Principle of Prior and Informed Consent'* (2005), United Nations Department of Economic and Social Affairs, New York, USA.
- '*Genetic Resources: Assessing Economic Value'* (1993), The National Academies Press, USA.
- '*Plant Breeders' Rights Policy'* (2011), Department of Agriculture, Forestry and Fisheries, South Africa.
- '*Study on understanding the causes of biodiversity loss and the policy assessment framework*' European Commission Directorate-General for Environment, Report (2009), Ecorys, Netherlands.
- '*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'* (2011), Secretariat of the Convention on Biological Diversity Montreal, Canada.
- '*The National Agricultural Directory* 2009' CIPRO, RainbowSA, South Africa.
- '*Traditional Knowledge & Biopiracy: The Peruvian Maca Root'* (2011), Public Interest Intellectual Property Advisors, Inc., Peru.

Journals

- Adam Andrzejewski 'Traditional knowledge and patent protection: conflicting views on international patent standards' (2010), *PER: Potchefstroomse Elektroniese Regsblad* 13(4).
- C. Haris Saslis-Lagoudakis 'Phylogenies reveal predictive power of traditional medicine in bioprospecting' (2012) *PNAS* 109(39).
- Cecilia van Niekerk 'Indigenous South African Medicinal Plants Part 11: Aspalathus linearis ('Rooibos')' (2008) *SA Pharmaceutical Journal* Nov./Dec.
- Charles Lawson 'The role of patents in biodiversity conservation' (2009), *Nature Biotechnology* 27.

- Corinnecluis ‘Bioprospecting: A New Western Blockbuster, After The Gold Rush, The Gene Rush’ (2006), *The Science Creative Quarterly* 8.
- Cormac Sheridan ‘EPO Neem patent revocation revives biopiracy debate’ (2005), *Nature Biotechnology* 23(5).
- Coughlin Jr., M. D ‘Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity’ (1994), *Columbia Journal of Transnational Law* 31 (2).
- David G.I. Kingston ‘Modern natural products drug discovery and its relevance to biodiversity conservation’ (2011) *Journal of Natural Products* 74(3).
- Demaine LJ ‘Reinventing the Double Helix: A novel and non-obvious reconceptualization of the Biotechnology patent’ (2002) *Stan. L. Rev.* 55.
- Francesco Mauro ‘Traditional knowledge of indigenous and local communities: International debate and policy initiatives’ (1999), *Ecological Applications* 10(5).
- Gordon M. Cragg ‘Natural Products: A Continuing Source of Novel Drug Leads’ (2013), *Biochimica et biophysica acta* 1830(6).
- Graham Bell ‘Adaptation, extinction and global change’ (2008), *Evolutionary Applications* 1(1).
- Grethel Aguilar ‘Access to genetic resources and protection of traditional knowledge in the territories of indigenous peoples’ (2001) *Environmental Science & Policy* 4.
- Grose JH ‘Understanding the enormous diversity of bacteriophages: the tailed phages that infect the bacterial family Enterobacteriaceae’ (2014) *Virology* Nov.
- Gupta R. et al ‘Nature's Medicines: Traditional Knowledge and Intellectual Property Management. Case Studies from the National Institutes of Health (NIH), USA’ (2005), *Current drug discovery technologies,* Dec.
- James Otieno Odek ‘The Kenya Patent Law: Promoting Local Inventiveness or Protecting Foreign Patentees?’ (1994), *Journal of African Law* 38.

- Kadidal S. 'Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy' (1997), *IDEA: The Journal of Law and Technology* 37.
- Lucas Laursen 'Monsanto to face biopiracy charges in India' (2012) *Nature Biotechnology* 30(1).
- Naeema Sadaf 'Bio-prospecting: Pakistan patent law treats contribution of indigenous knowledge as 'non-inventive'' (2011), *CIPA Journal* 40(10).
- Neil R. Crouch 'South Africa's bioprospecting, access and benefit-sharing legislation: current realities, future complications, and a proposed alternative' (2008), *South African Journal of Science* 104.
- Nick Hanley 'How should we incentivize private landowners to 'produce' more biodiversity?' (2012), *Oxf Rev Econ Policy* 28 (1).
- Paul Gepts 'Who Owns Biodiversity, and How Should the Owners Be Compensated?' (2004), *Plant Physiology* 134(4).
- Paul J. Ferraro 'Direct Payments to Conserve Biodiversity' (2002), *Science's Compass* 298.
- Paul Oldham 'Biological Diversity in the Patent System' (2013), *PLoS ONE* 8(11).
- Robert K. Paterson 'Looking Beyond Intellectual Property in Resolving Protection of the Intangible Cultural Heritage of Indigenous Peoples' (2003), *11 Cardozo Journal of International & Comparative* Law 633.
- S Sasidharan 'Extraction, Isolation and Characterization of Bioactive Compounds from Plants' Extracts' (2011), *Afr J Tradit Complement Altern Med.* 8(1).
- Surendra Kumar 'Biodiversity Management Open Avenues for Bioprospecting' International Journal of Agriculture and Food Science Technology, (2013) *IJAFST* 4(6).
- Timo Goeschl 'Incentivizing ecological destruction? The global joint regulation of the conservation and use of genetic resources' (2005), *Indiana Law Review* 38:619.

- Weiyang Chen 'Cape aloes—A review of the phytochemistry, pharmacology and commercialisation of Aloe ferox' (2012) *El Sevier, Phytochemistry Letters* 5.
- Whitt LA. 'Indigenous Peoples, Intellectual Property & the New Imperial Science' (1998) *Okla. City. U. L. Rev.* 23:211.
- Will C. McClatchey 'Ethnobotany as a Pharmacological Research Tool and Recent Developments in CNS-active Natural Products from Ethnobotanical Sources' (2009), *Pharmacol Ther*. 123(2).

Academic Sources

- 'Advice on Flexibilities under the TRIPs Agreement' World Intellectual Property Organization. Last accessed from *http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html* on 21 August, 2016.
- 'Agriculture and food' - Green Peace Australia Pacific. Last accessed from *http://www.greenpeace.org/australia/en/what-we-do/Food/* on 22 June, 2016.
- 'Biodiversity & Human Well-being' GreenFacts. Last accessed from *http://www.greenfacts.org/en/biodiversity/l-3/6-conserve-biodiversity.htm* on 23 August, 2016.
- 'Genetic resources and intellectual property' World Intellectual Property Organization. Last accessed from *http://www.wipo.int/tk/en/genetic/* on 12 April 2016.
- 'Intellectual Property and Traditional medical knowledge' WIPO Publication. Last accessed from *http://www.wipo.int/export/sites/www/tk/en/documents/pdf/background_briefs-e-n6-web.pdf* on 19 July, 2016.
- 'Report of the World Commission on Environment and Development: Our Common Future' UN Documents: Gathering a Body of Global Agreements. Last accessed from *http://www.un-documents.net/wced-ocf.htm* on 29 July, 2016.

- Anup Shah ‘Loss of Biodiversity and Extinctions’. Last accessed from *http://www.globalissues.org/article/171/loss-of-biodiversity-and-extinctions* on 28 April 2016.
- Bryan Caplan ‘The Concise Encyclopedia of Economics Externalities’. Last accessed from *http://www.econlib.org/library/Enc/Externalities.html* on 8 August, 2016.
- Foster Laura A ‘Inventing Hoodia: Vulnerabilities and Epistemic Citizenship in South Africa’. Last accessed from *http://escholarship.org/uc/item/5qd3z4hr#page-2* on 23 June, 2016.
- GRAIN ‘TRIPs versus biodiversity: What to do with the 1999 review of Article 27.3(b)’. Last accessed from *https://www.grain.org/article/entries/11-trips-versus-biodiversity-what-to-do-with-the-1999-review-of-article-27-3-b* on 23 June, 2016.
- Maharaj VJ ‘Hoodia, a case study at CSIR’. Last accessed from *http://researchspace.csir.co.za/dspace/handle/10204/2539* on 13 June, 2016.
- Priya Shetty ‘Integrating modern and traditional medicine: Facts and figures’. Last accessed from *http://www.scidev.net/global/author.priya-shetty.html* on 4 July, 2016.
- Raymond Cooper ‘Africa’s gift to the world’. Last accessed from *http://www.rsc.org/eic/2015/12/rosy-periwinkle-cancer-vinblastine* on 3 May 2016.
- Report on the International Patent System: Revised Annex II of document SCP/12/3 Rev. 2, WIPO. Last accessed from *http://www.wipo.int/export/sites/www/scp/en/meetings/session_17/annex_ii/pakistan.pdf* on 13 May, 2016.
- Vladimar Tr Hafstein ‘The Politics of Origins: Collective Creation Revisited’. Last accessed from *http://muse.jhu.edu/article/171087* on 6 June, 2016.