PATENT PROTECTION OF TRADITIONAL KNOWLEDGE RELATING TO BIOLOGICAL RESOURCES IN SOUTH AFRICA

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1 Introduction

The search for new and better drugs by pharmaceutical companies is an ongoing and intensive one, in order to meet the growing demands of the population.[1] These companies have increasingly realised that useful and valuable compounds lie in the natural resources that indigenous and local communities around the world have been utilising for centuries.[2] Indigenous people have developed these natural resources into remarkable remedies that are now part of their traditional knowledge.[3] The exploitation of indigenous communities by multinational companies wanting to benefit from such knowledge, spurred on by vast financial incentives, is devastating the communities' ability to economically benefit from the knowledge that they have developed.[4] The race for scientific and commercial progress is thus argued to be bypassing the rights of indigenous communities.

Even though the significance of biological resources to global health and human livelihood is duly recognised both locally and internationally, it is obvious that countries such as South Africa that are rich in traditional knowledge need to take every possible measure to protect their resources and prevent them being exploited by technology-rich nations. The countless debates on the controversial issues surrounding the legal ownership, control and derived benefits from the traditional knowledge relating to such resources are ongoing in South Africa and more generally in a global context, in that effective and equitable protection for indigenous communities are simply not being

[1] A Andrzejewski "Traditional Knowledge and Patent Protection: Conflicting Views on International Patent Standards" (2010) 13 *PELJ* 94 95.
[2] 95.
[3] 95.
[4] 95.

implemented to widespread satisfaction.[5] A key reason is that the current international system for protecting intellectual property was developed during the age of industrialisation in Western countries, and therefore fashioned exclusively to the needs of technologically advanced societies.[6] The patent system in particular is argued to be founded solely in the Western concepts of ownership and invention, which is wholly inadequate to justly recognize, protect and compensate indigenous peoples for their unique form of intellectual property, namely traditional knowledge.[7]

Firstly, this research paper aims to set out the relevant factual background surrounding the patent protection of traditional knowledge relating to biological resources in South Africa, including key conceptual definitions. An analysis of the relevant applicable law in South Africa will follow, subsequent to a selection of the problems that have surfaced when the legislation is implemented in the specific context of traditional knowledge. The *Hoodia* and *Rooibos* cases are used as examples of instances where traditional knowledge played a crucial role. India is then discussed as a comparative jurisdiction, with the Indian Traditional Knowledge Digital Library considered as an aid for more effective protection of traditional knowledge. An ambitious plan is currently underway in South Africa to replicate this system in the form of a National Recordal System. An analysis of the ambitious objectives of this system will conclude the paper.

2 A background perspective and relevant definitions

There is no universal definition of traditional knowledge, and it therefore has become a diverse entity with no legally and scientifically acceptable definition.[8] Article 8(j) of the Convention on Biological Diversity[9] ("the CBD") makes reference to the "knowledge, innovations and practices of indigenous and local communities embodying a traditional lifestyle". However, a formal definition of traditional knowledge is not present in the

[5] JR Kloppenburg *First the Seed: The Political Economy of Plant Biotechnology* (2005) 3.
[6] WIPO "Background Brief: Intellectual Property and Traditional Knowledge" *WIPO* <http://www.wipo.int/pressroom/en/briefs/tk_ip.html> (accessed 10-10-2013).
[7] WIPO "Background Brief: Intellectual Property and Traditional Knowledge" *WIPO.*
[8] C Finetti "Traditional Knowledge and the Patent System: Two Worlds Apart?" (2011) 33 *World Patent Information* 58 58.
[9] Convention on Biological Diversity, 1992.

CBD.[10] The World Intellectual Property Organisation (WIPO) refers to traditional knowledge as being:

> "the tradition-based literary, artistic or scientific works; inventions; scientific discoveries; design; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations, resulting from intellectual activity in the industrial, scientific, literary or artistic fields".[11]

One can clearly see the broadness of the concept in this definition. Traditional knowledge is very significant for the world economy, with the world market for herbal medicines derived from traditional knowledge alone estimated to be over 60 billion US dollars.[12]

South Africa, along with sixteen other countries including India, is considered one of the seventeen megadiverse countries that collectively account for 70% of global diversity.[13] The country holds over 19 500 indigenous plant species in about 350 plant families, making it the holder of the richest temperate flora in the world.[14] Biological materials are a very important source of medicine and also constitute the basis of many pharmaceutical products.[15] In the past, a lack of bioprospecting legislation and regulations has permitted almost unconstrained access to South African bioresources.[16] While it is true that biodiversity prospecting does not always involve the use of traditional knowledge, it is clear that valuable chemical compounds derived from plants are more easily identified and of greatest commercial value when collected with indigenous knowledge and/or found in territories traditionally inhabited by indigenous people.[17]

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[10] Convention on Biological Diversity, 1992.
[11] WIPO "Intellectual Property Needs and Expectations of Traditional Knowledge Holders" (2001) *WIPO* 25 <http://www.wipo.int/export/sites/www/freepublications/en/tk/768/wipo_pub_768.pdf> (accessed 30-10-2013).
[12] WIPO "Intellectual Property Needs and Expectations of Traditional Knowledge Holders" *WIPO.*
[13] N Crouch, E Douwes, MM Wolfson, GF Smith & TJ Edwards "South Africa's Bioprospecting, Access and Benefit-sharing Legislation: Current Realities, Future Complications, and a Proposed Alternative" (2008) 104 *South African Journal of Science* 355 355.
[14] 355.
[15] KT Ten & SA Laird *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing* (1999) 3.
[16] 3.
[17] 3.

Biopiracy may be defined as the "misappropriation of traditional knowledge for the purpose of seeking exclusive patent ownership over that knowledge".[18] In essence, biopiracy involves making commercial profit from freely available natural products by copying traditional knowledge techniques used daily by local people in order to feed or take care of themselves, without any compensatory benefit to the stakeholders of such knowledge. This is typically performed by corporations in developing countries, where a slight modification, development or laboratory extraction can transform this natural common good into a private good.[19] A patent over the private good is awarded to the firm or person who "invented" it, thus making them the exclusive owners and proprietors of the good.[20] This is evidently inherently unfair to the communities who have developed the traditional knowledge.

In recent years, indigenous peoples, local communities and governments, especially in developing countries, have called for two types of intellectual property protection for traditional knowledge; namely, defensive protection and positive protection.[21] When applied in the context of patents, defensive protection aims to stop people from outside of the traditional community acquiring unjustifiable patents over their traditional knowledge.[22] This concept has both legal and practical intentions. These intentions concern firstly whether the traditional knowledge can be recognized as relevant prior art under the patent law of the nation concerned and thus cannot be patented, and secondly entailing that such information is actually available and accessible to search authorities and patent examiners.[23] In securing effective defensive protection, India has developed a searchable database of traditional medicine that can be used by patent examiners when assessing patent applications.[24] The concept of positive protection, on

[18] Commission on Intellectual Property Rights "Integrating Intellectual Property Rights and Development Policy'' (September 2002) *Biopirateria* 74 <http://www.biopirateria.org/libros/02-1%20Integrating%20Intellectual%20Property.pdf> (accessed 10-10-2013).
[19] M Mayet, F Meienberg, M Ruiz, MS Hassane, V Shiva, A Tiouka & A Valladolid "Understanding, Resisting and Acting against Biopiracy: A Guide on How to Act in the Face of Illegal Appropriation of Life and Traditional Knowledge" (2012) *Biopiracy Collective* <http://www.biopiraterie.org/sites/default/files/etudes/Livret_Uk_010612.pdf> (accessed 10-10-2013).
[20] Andrzejewski (2010) *PELJ* 113.
[21] WIPO "Recognition of Traditional Knowledge within the Patent System" (2008) *WIPO* 5 <www.wipo.int/edocs/mdocs/tk/en/wipo...ic.../wipo_grtkf_ic_9_8.do> (accessed 30-10-2013).
[22] WIPO "Background Brief: Intellectual Property and Traditional Knowledge" *WIPO*.
[23] WIPO "Recognition of Traditional Knowledge within the Patent System" *WIPO*.
[24] M Hirwade "Traditional Knowledge Protection: An Indian Perspective" (2012) 32 *Journal of Library & Information Technology* 240 240.

the other hand, is the granting of rights that empower communities to promote their traditional knowledge, control its uses and benefit from its commercial exploitation.[25]

It is crucial for a nation as remarkably rich in traditional knowledge as South Africa to ensure that their intellectual property law is an effective and equitable means of positively and defensively protecting traditional knowledge. This will prevent it from being exploited by technology-rich countries and enable local communities to be able to protect, control and benefit collectively from their knowledge.

3 The current South African legislative position

3 1 International legislation

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)[26] sets the global minimums for patentability across the member states of the World Trade Organisation. Article 27(1) of TRIPS sets out three requirements for patents, namely that they are novel, involve an inventive step and are capable of industrial application. No universal definitions for these terms are provided, which means that the World Trade Organisation member states can apply different interpretations of the provisions depending on what they consider to be an invention that is "new" or that involves an "inventive step" for the purpose of granting patent protection.[27]

3 2 National legislation

The Patent Act 57 of 1978 regulates patenting in South Africa in terms of the TRIPS provisions. The Companies and Intellectual Property Registry Office (CIPRO) is the custodian of all patent applications that are filed within the Republic. According to s25 the South African Patent Act,[28] "a patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture requirements before it can be registered and enjoy protection". An invention will be new if it did not form part of the state of the art at the time of the application.[29] The "state of the art" is defined as

[25] WIPO "Background Brief: Intellectual Property and Traditional Knowledge" *WIPO*.
[26] The Agreement on Trade-Related Aspects of Intellectual Property, 1994.
[27] Andrzejewski (2010) *PELJ* 102.
[28] 57 of 1978.
[29] S 25(5).

comprising all matter that has been made available to the public by way of written or oral description, or by use or any other ways.[30] It will involve an inventive step if it is not obvious to those skilled in that field. [31] The Act provides that the duration of a patent shall, unless otherwise provided, be 20 years from the date of application. A patent is therefore in essence the grant of a property right to the inventor of an invention by the government, acting through CIPRO.

South Africa is a signatory to the International Convention on Biological Diversity (the "CBD"),[32] which applies to patents along with TRIPs. In order to comply with its international obligations under this Convention, South Africa promulgated the National Environmental Management Biodiversity Act (the "Biodiversity Act").[33] Importantly, the official definition of bioprospecting in the Biodiversity Act is 'any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, including the utilization for purposes of research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities'.

The Biodiversity Act's main objectives are to manage and conserve the biological diversity in South Africa and to ensure that indigenous biological resources are used in a sustainable manner.[34] It also seeks to combat biopiracy and provides for the fair and equitable sharing of benefits arising from the bioprospecting of genetic material derived from indigenous biological resources. In terms of Chapter 7 of the Biodiversity Act, before a party may legally bio-prospect in South Africa, the party must obtain a permit from the South Africa government. The Act also states in Chapter 6 that where a patent is based on, or derived from, traditional knowledge or an indigenous biological or genetic resource, compensation must be paid to the owner of the traditional knowledge, or the person or community giving access to the indigenous biological or genetic resource. However, the problem here lies in the fact that rural communities are usually uninvolved in the decision-making process through which the research or plant

[30] S 25(6).
[31] S 25(10).
[32] International Convention on Biological Diversity, 1992.
[33] National Environment Management: The Biodiversity Act 10 of 2004.
[34] National Environment Management: The Biodiversity Act 10 of 2004.

collection permits are issued or refused to prospective applicants.[35] They are thus not legally empowered to control access and to minimise the misappropriation of their natural resources.

The legal process did not end with the Biodiversity Act, as further legislative protection was required in order to assure full compliance with the CBD. To this end, the South African Patents Act was subsequently amended to link it to the provisions of the South African Biodiversity Act. Persons carrying out research on indigenous biological resources and bioprospecting projects within the borders of South Africa accordingly need to consider the effects of both the Biodiversity Act and the relevant amendments. According to the Patent Amendment Act,[36] every applicant for a South African patent must now, within 6 months of filing a patent application, also lodge a declaration stating whether or not the invention is based on, or derived from, any traditional knowledge or any indigenous (South African) biological or genetic resource.[37] "Indigenous biological or genetic resource" is defined as a South African biological or genetic resource. Similarly, "traditional knowledge or use" means the knowledge or way in which an indigenous community has used the indigenous biological or genetic resource.[38] If it is derived from such a resource, the applicant must submit proof of title or authority to make use of that knowledge or resource.[39] In the case of traditional knowledge, the applicant must also state whether the patent is co-owned by the owner of the traditional knowledge.[40] If the declaration contains a false statement or representation which is material and which the applicant knew, or ought reasonably to have known, to be false at the time which the statement or representation was made, the patent can be revoked.[41] In this type of case, it is likely that it will not be possible to take any corrective action.

Currently, *sui generis* legislation that makes provision for the protection of traditional knowledge in South Africa has been approved by Parliament awaits the President's

[35] V Tellez "Recognising the Traditional Knowledge of the San people: The Hoodia Case of Benefit-sharing" (22-12-2006) *Queen Mary University of London.* <http://www.ipngos.org/NGO%20Briefings/Hoodia%20case%20of%20benefit%20sharing.pdf> (accessed 9-10-2013)**.**
[36] 20 of 2005.
[37] S 30(3).
[38] S 30(3).
[39] S 2.
[40] S 3.
[41] S 3.

signature.[42] Several other countries including Brazil, Costa Rica, India, Peru, Panama, Thailand and Portugal have all adapted sui generis laws that protect some aspect of traditional knowledge, aimed exclusively at addressing the characteristics of this specific subject matter.[43] This legislation does not, however, make any amendments to the Patents Act, although it does make provision for a database of 'traditional intellectual property', covering 'traditional innovations'.[44] The need in South Africa for such a database will be discussed in further detail at a later stage in this paper.

4 The problematic nature of the South African patent system

The current South African patent system is argued to be an unsuccessful means of effectively and equitably protecting traditional knowledge from exploitation.[45] This argument is based on several structural and implementation problems contained within the law.

These problems substantially stem from the fact that the statutory requirements in the Patents Act and the procedure for patent applications means that the South African Patents Office operates a deposit or non-examining system, which entails that the Registrar of CIPRO looks at every application for a patent and every complete specification accompanying such patent; and, merely provided all the formalities are complied with, the patent application is accepted for registration.[46] There is no examination of the substance of the product or process and therefore the Registrar cannot refuse the patent registration on the basis of merits such as insufficiency of the content of the description and claims, matter outside of the patentable scope, lack of novelty; lack of inventive step or industrial applicability.[47] Part of the examining process would usually include a search of previously issued patents and other literature, otherwise known as prior art, to determine whether the claimed invention is novel, and

[42] D Owen "Inside Views: A NEW South Africa Traditional Knowledge Bill – *Sui Generis* Protection for TK" (18 March 2012) *Intellectual Property Watch* <http://www.ip-watch.org/2012/03/18/a-new-south-africa-traditional-knowledge-bill-%E2%80%93-sui-generis-protection-for-tk/> (accessed 10-10-2013).
[43] WIPO "Background Brief: Intellectual Property and Traditional Knowledge" *WIPO*.
[44] R Forster "Patents and Traditional Knowledge" (09-2012) *Ensight* <http://www.ens.co.za/news/news_article.aspx?iID=806&iType=4?> (accessed 20-10-2013).
[45] A Pouris & A Pouris "Patents and Economic Development in South Africa: Managing Intellectual Property Rights" (2011) 107 *South African Journal of Science* 1 10.
[46] 9.
[47] 10.

not an obvious extension or variation of something.[48] There is also no scope for pre-grant objections by third parties, who are not permitted to partake in the application process at all. The responsibility for ensuring that the application is valid therefore resides solely with the applicant. Consequently, almost every patent application with the appropriate drafting succeeds. This non-examining approach makes South Africa's patenting regime one of the cheapest in the world, but also makes it subject to a number of criticisms.[49]

The use of the non-examining procedure means that that there is a consistent danger that some patented inventions are already part of the public domain, as patents which fall into excluded categories are granted. A patent can, however, be revoked after a grant by a third party on the basis that it was not new or inventive on the basis of the Patent Act provisions. This can only be done by instituting application proceedings before a High Court of South Africa. In most cases, the proceedings are converted to costly action proceedings. The public is thus burdened with the task of monitoring patent applications in order to pick up unlawful patents where the thing was already in the public domain.[50] The non-examining approach thus opens the system up to frivolous and useless patents which increase "uncertainty, search and monitoring costs by interested patentees and which make more difficult the dissemination of prior art by the useful or real inventions".[51] The proliferation of low-quality and invalid patents not only swell the number of patents and patent applications that must be reviewed by potential innovators and patent offices, but also create uncertainty about the general validity and enforcement of patents.[52] It is difficult to maintain high patent standards if there is no examination on the basis of substantive merits.

In the context of traditional knowledge, the difficulties related to the deposit system are even more problematic as it is virtually impossible for usually rural-based indigenous communities to monitor patent applications of others to keep track of whether infringements are occurring, not to mention the costs involved in such an undertaking. In the famous *Hoodia* patent infringement case, the San were completely oblivious of the patent proceedings and commercial deals relating to the traditional benefits of the

[48] 6.
[49] 6.
[50] 6.
[51] 6.
[52] 6.

Hoodia plant for a period of six years.[53] Furthermore, the complexities and high costs involved in instituting possible infringement applications are outside that which many holders of traditional knowledge can manage and afford in South Africa and other developing countries.[54]

An additional issue is that in many situations critical moral dilemmas can result, for instance in the *Hoodia* patent case.[55] Communities like the San view the sharing of knowledge as a culture and basic to their way of life.[56] Accordingly, traditional knowledge of plants is viewed as a 'collective' and the idea of 'owning' a life form highly objectionable.[57] The San regard their traditional knowledge relating to *Hoodia* as being a collective San right that should not morally be able to be owned by any other individual or entity, and the patenting of active compounds of *Hoodia* ran counter to their cultural beliefs. It is therefore vitally important for a strong defensive form of protection to be in place.

In an international context, the publication of patent applications is a central mission of patent offices because such disclosure of information constitutes the 'payment' society receives in return for the exclusive rights of exploitation conferred by the patent.[58] India, for example, practices an 11 step local examination patent system including publication and examination.[59] In comparison, all searches in South Africa by CIPRO are carried out by hand or through a card based system.[60] The introduction of a thorough search and examination process is of paramount importance to the South

[53] R Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" (2004) *Biowatch South Africa* <http://www.biowatch.org.za/main.asp?include=pubs/wjip.html> (accessed 30-10-2013).
[54] Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" *Biowatch South Africa.*
[55] Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" *Biowatch South Africa.*
[56] Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" *Biowatch South Africa*.
[57] R Chennells *Ethics and Practice in Ethnobiology, and Prior Informed Consent with Indigenous Peoples Regarding Genetic Resource* (2003) unpublished paper presented at a conference on *Biodiversity, Biotechnology and the Protection of Traditional Knowledge* by Washington University in St. Louis, School of Law, 04-04-2003 (copy on file with author).
[58] S Dell "South Africa: Intellectual Property Rights Failing" (17 July 2011) *University World News* <http://www.universityworldnews.com/article.php?story=20110715165939648> (accessed 30-10-2013).
[59] Y Wen & T Matsaneng "Patents, Pharmaceuticals and Competition: Benefiting from an Effective Patent Examination System'' (2013) *Competition Commission of South Africa* 6 <http://www.compcom.co.za/assets/Uploads/events/Seventh-Annual-Conference-on-Competition-Law-Economics-Policy/Parallel-3B/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf> (accessed 30-10-2013).
[60] Pouris & Pouris (2011) *South African Journal of Science* 7.

African system.[61] This endeavour is so vital that applications should perhaps be sent overseas for novelty searches and examination in the meantime. A major related problem is that no extensive online search facilities have existed for South African patents in the past. The need to document and record indigenous knowledge has been recognised by the World Intellectual Property Organisation.[62] In the WIPO Traditional Knowledge Documentation Toolkit, it is emphasised that the manner of documentation depends on specific contexts and objectives pursued by indigenous peoples, local communities and actors involved in the process.[63] Differentiated needs will guide a traditional knowledge documentation process and these may vary considerably depending on the interests at stake, as efforts to systemise traditional knowledge could also have an undesired negative impact on communities and cultures, especially where oral tradition and more ancestral types of social practices and livelihoods prevail.[64]

This general lack of documentation relating to traditional knowledge, coupled with the generally unrefined consequences of the South African non-examining system, clearly justifies the concern surrounding the efficacy and quality of the South African patent law system in the context of protecting traditional knowledge against exploitation.[65] However, the Companies and Intellectual Property Commission (CIPC) is currently engaged in research to consider the viability of a development of the patent protection system in South Africa from a depositary patent system to a substantive examination system, which would change the law to essentially involve an examination of the quality of the invention, involving several pre-requisites.[66] These are namely, the subject matter of the invention that must be patentable; the utility aspect of the patent in that it must perform a designed function or achieve some minimum human purpose; the novelty aspect, in that an invention to be patented must be novel, and the non-obvious aspect of the invention, in that the knowledge in the technological field at the time of the

[61] 7.
[62] WIPO "Traditional Knowledge Documentation Toolkit" (2012) *WIPO* 15 <http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_toolkit_draft.pdf> (accessed 30-10-2013).
[63] 15.
[64] United Nations University, Institute of Advanced Studies (UNU-IAS) "The Role of Registers and Databases in the Protection of Traditional Knowledge – A Comparative Analysis" (2004) UNU-IAS <http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf> (accessed 30-10-2013).
[65] Committee on Development and Intellectual Property (CDIP) "Study on Patents and the Public Domain Summary" (2011) *WIPO* <www.wipo.int/edocs/mdocs/mdocs/en/cdip.../cdip_8_inf_3_rev_2.doc> (accessed 30-10-2013).
[66] Wen and Matsaneng "Patents, Pharmaceuticals and Competition: Benefiting from an Effective Patent Examination System" *Competition Commission of South Africa* 6.

invention must not make the invention obvious to one of ordinary skill in that area.[67] In embarking on this initiative, the relevant authorities must look to the developments in international law in order to implement a structure that is capable of succeeding in its objectives and effectively working towards curtailing cases of biopiracy.

5 Local biopiracy case studies

There have been several well-publicised cases of biopiracy in South Africa, where valuable biological resources have been exploited by corporations regardless of any legal provisions designed for their protection. Both of the following cases resulted in costly and lengthy litigation procedures in order for the community's rights over their traditional knowledge to be realised.

5 1 Hoodia

The *Hoodia cactus* is a succulent that has been traditionally used to stave off hunger and thirst during long hunting trips in Khoisan communities.[68] Owing to these unique properties, development of an appetite suppressant derived from the plant has proved to be a diet pill goldmine capable of amassing huge profits.[69]

The Council for Scientific and Industrial Research (CSIR) has a broad mandate in research and development of technology in South Africa.[70] They are involved in a number of biosprospecting activities, with the intention of such activities culminating in commercial contracts for product development based on compounds identified through natural products research.[71] In 1963, the CSIR became aware of the *Hoodia* plant's traditional uses from San trackers who had worked for the South African military.[72] Following many years of development, a patent application was filed in South Africa in

[67] 6.
[68] VJ Maharaj, JV Senabe & RM Horak "*Hoodia,* a Case Study at CSIR: Science Real and Relevant" (2008) *CSIR Researchspace* <http://researchspace.csir.co.za/dspace/handle/10204/2539> (accessed 30-10-2013).
[69] D Stephenson "San Reach Landmark IPR Benefit-Sharing Accord for Diet Pill" (2003) *Cultural Survival* <http://www.culturalsurvival.org/publications/cultural-survival-quarterly/south-africa/san-reach-landmark-ipr-benefit-sharing-accord-> (accessed 30-10-2013).
[70] Stephenson "San Reach Landmark IPR Benefit-Sharing Accord for Diet Pill" *Cultural Survival.*
[71] The Global Forum on Bioethics in Research "Case Study: The San People and the Hoodia Plant" (2004) *The Global Forum of Bioethics in Research* 1 <http://www.gfbronline.com/PDFs/Fifth_Casestudy4.pdf> (accessed 14-10-2013).
[72] 1.

1995 for the use of the active components of the plant responsible for suppressing appetite.[73] The Patents Amendment Act had not yet been promulgated at this stage and therefore no declaration stating whether or not the invention was based on, or derived from, any traditional knowledge or any indigenous biological or genetic resource was required. The patent was thus granted based solely on the formalities of the deposit system as set out in the Patent Act. The CSIR then sold the right to develop an anti-obesity preparation from the extract of the *Hoodia* plant to the pharmaceutical giant Phytopharm for millions of dollars.[74] The CSIR did not consult with the San people or recognise their role as original holders of knowledge concerning the properties of *Hoodia* in accordance with the principles set out in the Convention of Biological Diversity.[75] The San community were completely oblivious of these dealings and uninvolved in the agreements between the CSIR and international partners for the commercialisation of the product. They only became aware of the happenings following the excessive media coverage when Phytopharm sold the licence to Unilever in 2001, who subsequently proceeded to market the *Hoodia* products as diet supplements.[76] In defence of these circumstances, the CSIR linked its initial reluctance to engage with the San to a concern that 'expectations would be raised with promises that could not be met', and insisted that the organisational policy on bioprospecting was to eventually share benefits of research based on indigenous knowledge.[77] Clearly, the realities of implementing this policy are complex and difficult. Wynberg suggests that *Hoodia* case demonstrates not only the value of having an integrated system to protect and promote traditional knowledge, but also the importance of so-called 'defensive protection', to prevent the misappropriation of traditional knowledge. This third option could include, for example, the compulsory disclosure of the source of genetic resources and associated traditional knowledge in patent applications, and the establishment of traditional knowledge databases.[78]

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[73] Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" *Biowatch South Africa.*

[74] C Masango "Indigenous Traditional Knowledge Protection: Prospects in South Africa's Intellectual Property Framework?" (2010) 26 *South African Journal of Libraries and Information Science* 74 77.

[75] 77.

[76] Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" *Biowatch South Africa.*

[77] Wynberg "Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant" *Biowatch South Africa.*

[78] Finetti (2011) *World Patent Information* 59.

After lengthy legal negotiations involving several NGOs, a Memorandum of Understanding, detailing one of the first benefit sharing agreements, was reached between the CSIR and the South African San Council.[79] This agreement is said to be an international milestone for the protection of traditional knowledge. Key aspects of this agreement include the recognition of the San as the originators of the traditional knowledge relating to the human uses of *Hoodia*, an acknowledgement by the San of the context in which CSIR registered the patent without having first engaged the San in negotiations, and a commitment to a process of negotiating with one another in good faith in order to arrive at a benefit sharing agreement.[80] This agreement, entitling the San to receive 6-8% of the revenue from the sale of the products which will be deposited in a fund to purchase land for the San people who had been dispossessed from their lands by white settlers, was finally concluded in 2003.[81]

5 2 Rooibos

Another controversial and highly publicised biopiracy case scenario is that involving the *Rooibos* plant. In 2010, Nestec, a Nestle subsidiary, filed four international patent applications relating to compositions containing either *rooibos* or honeybush extracts for the treatment of hair and skin conditions such as acne, wrinkles and hair loss.[82] A fifth application sought patent protection for using rooibos as an anti-inflammatory. *Rooibos* is endemic to fynbos, a major vegetation type of the Cape Floral Kingdom in the Western Cape of South Africa.[83] It has have traditionally been used by the local Khoisan communities in the region for related medicinal purposes for hundreds of years.[84]

Nestec did not obtain permits to use *Rooibos* in terms of the South African Biodiversity Act. However, it claimed that it had not made any commercial use of the patents and consequently argued that it did not have to comply with the provisions of the South African Biodiversity Act, which states that before a company engages in

[79] The Global Forum on Bioethics in Research "Case Study: The San People and the *Hoodia* Plant"*The Global Forum on Bioethics in Research* 2.
[80] 2.
[81] 2.
[82] Natural Justice "Dirty Business for Clean Skin – Nestlé's Rooibos Robbery in South Africa" (October 2010) *Berne Convention Briefing Paper* <http://www.evb.ch/cm_data/Rooibos_Nestl_Briefing_Paper_update__oct__2010.pdf> (accessed 16-10-2013).
[83] Natural Justice "Dirty Business for Clean Skin – Nestlé's Rooibos Robbery in South Africa" *Berne Convention Briefing Paper*.
[84] Natural Justice "Dirty Business for Clean Skin – Nestlé's Rooibos Robbery in South Africa" *Berne Convention Briefing Paper*.

bioprospecting of indigenous biological resources it requires a bioprospecting permit, which includes a benefit sharing agreement.[85] This was held to be a fundamental misunderstanding of the law.[86] Eventually, after international media coverage, Nestec eventually took the first step towards legally accessing South Africa's biological resources and entered into benefit sharing negotiations with the government, which are currently ongoing.

This case again demonstrates how corporations tend to neglect their obligations when using resources from developing countries, and emphasises the need for a strong and effective system of traditional knowledge protection to be in place.

6 Comparative study: The Indian system and the development of the TKDL

India, like South Africa, is a 'BRICS' member of the group of advanced emerging countries. Biologically speaking, India is in the top twelve most biodiverse countries in the world, individually accounting for 7-8% of the recorded species of the world.[87] It is also megabiodiverse; and, along with South Africa and ten other countries, is a member of the Group of Like-Minded Megadiverse Countries.[88] This group aims to work together in recognizing **'**the importance of traditional knowledge of indigenous and local communities for the preservation of biological diversity, the development of that knowledge and the sustainable use of its components'.[89] Consequently, India's intellectual property structure is particularly relevant to South Africa as a comparative system.

The Indian patent law system is one that is internationally renowned for its success, and South African authorities should therefore take notice of the structure of the Indian system in terms of reforming the problematic South African non-examining patent system. It consists of a 11 step procedure. Firstly, as stated in section 7 of the Indian

[85] National Environment Management: The Biodiversity Act 10 of 2004, s 81.
[86] Natural Justice "Dirty Business for Clean Skin – Nestlé's Rooibos Robbery in South Africa" *Berne Convention Briefing Paper.*
[87] Ministry of Environment and Forests, India "India's 4th Report to the Convention of Biological Diversity" (2009) *CBD* 11 <www.cbd.int/doc/world/in/in-nr-04-p1-en.pdf> (accessed 30-10-2013).
[88] Global Contract Foundation "Cancun Declaration of Like-Minded Megadiversity Countries" (2002) *Weltvertrag* <http://www.weltvertrag.org/e375/e719/e1045/CancunDeclarationonLikeMindedMegadiversity Countries_2002_ger.pdf> (accessed 31-10-2013).
[89] Global Contract Foundation "Cancun Declaration of Like-Minded Megadiversity Countries" (2002) *Weltvertrag*.

Patents Act, [90] a patent application must be filed with the Indian Patent Office, which is subsequently published in the official journal of the Patent Office.[91] The application is then referred to the examiner who decides whether the subject of the patent applications fulfills the patentability criteria as provided for in India's Patent Act.[92] In terms of section 13, the examiner also investigates whether there is any publication in the world or any other claims before the date of the claim. He or she then issues a report.[93] Once the report is issued, there is scope for third parties to participate in the proceedings if they wish to oppose the patent, by making submissions on why the application should not succeed.[94] The South African patent process holds no such scope for pre-grant opposition. The examiner then issues a final report either granting or rejecting the patent application.[95] At this stage, third parties can again forward reasons as to why they believe the grant should be revoked.[96]

Despite the thorough nature of the 11 step procedure, the Indian government has nonetheless been involved in several expensive and lengthy litigations over patents given to ancient traditional medicine plants from India.[97] These included a patent granted in the USA on the use of turmeric in wound-healing, as well as a patent granted to the firm Grace in Europe for the use of neem extract.[98] Turmeric, a herbaceous perennial plant of the ginger family, has been traditionally utilised for centuries in India to heal wounds and rashes.[99] The Council of Scientific and Industrial Research challenged the patent and eventually won their case on the fact that the novelty requirement was not fulfilled.[100] The patent was consequently revoked. The neem patent was granted in 1994 to the US corporation W.R. Grace Company, as well as the US Department of Agriculture, as a method for controlling fungi on plants.[101] Extracts of neem seeds have been known and used for centuries in Indian agriculture to protect

[90] 39 of 1970.
[91] S 7.
[92] Indian Patents Act 39 of 1970, s 12.
[93] S 12.
[94] S 25.
[95] S 43.
[96] S 63.
[97] V Chouhan "Protection of Traditional Knowledge in India by Patent: Legal Aspect" (2012) 3 *Journal of Humanities and Social Science* 35 38.
[98] M Hirwade "Traditional Knowledge Protection: An Indian Perspective (2012) 32 *Journal of Library & Information Technology* 240 243.
[99] RK Gupta & L Balasubrahmanyam "The Turmeric Effect" (1998) 20 *World Patent Information* 185 185.
[100] 185.
[101] Hirwade (2012) *Journal of Library & Information Technology* 243.

crops against hundreds of pests and fungal diseases that attack crops.[102] The patent granted on neem was eventually revoked by the European Patent Office in May 2000, after several years of proceedings instituted by international NGOs and representatives of Indian farmers.[103] In both cases, the patents were granted due to lack of good documentation, and were eventually cancelled once the appropriate documents arose.[104] Shortly before the time that the Traditional Knowledge Digital Library was established, the TKDL expert group estimated that approximately 2000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world.[105] This alerted the Indian authorities to the need that there was a need to do something to protect traditional knowledge from being misappropriated in the form of patents on non-original innovations, and quickly.

In 2001, India became the pioneer of an exceptional and proprietary industrial mechanism to protect Indian traditional knowledge from biopiracy, in the form of a searchable database known as the Traditional Knowledge Digital Library (TKDL).[106] This system is completely unique to India.[107] The goal of the TKDL is to identify all traditional use of India's biological resources, sourcing from numerous books in local languages; while its primary overall objective is the defensive protection and prevention of misappropriation of the currently disclosed Indian traditional knowledge. TKDL contains 34 million pages of formatted information on millions of medicinal formulations, in multiple languages.[108] Previously, much of India's traditional knowledge only existed in Sanskrit, Hindi, Arabic, Urdu and Tamil.[109] Similarly to South Africa, this language barrier made the knowledge inaccessible to patent examiners.

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[102] S Sahai, P Pavithran & I Barpujari "Biopiracy: Limitations Not Innovations" (2007) *Biopirateria* <http://www.biopirateria.org/libros/07-3%20Biopiracy%20Imitations%20not%20Innovations.pdf> (accessed 30-10-2013).

[103] D Debnath "Analysis: The Fight for Traditional Knowledge to Conform to the Need of Documentation" (1 May 2013) *Social Science Research Network* <http://ssrn.com/abstract=2259044 or http://dx.doi.org/10.2139/ssrn.2259044> (accessed 30-10-2013).

[104] Debnath "Analysis: The Fight for Traditional Knowledge to Conform to the Need of Documentation" *Social Science Research Network.*

[105] VK Gupta "Protecting Indian Traditional Knowledge from Biopiracy" (2011) *WIPO* <http://www.wipo.int/export/sites/www/meetings/en/2011/wipo_tkdl_del_11/pdf/tkdl_gupta.pdf> (accessed 30-09-2013).

[106] Gupta "Protecting Indian Traditional Knowledge from Biopiracy" *WIPO*.

[107] IJ Kidd "Biopiracy and the Ethics of Medical Heritage: the Case of India's Traditional Knowledge Digital Library" (2012) 33 *Springer Press* 175 179.

[108] 179.

[109] 180.

The TKDL has proved to be a highly successful means of defensively protecting Indian traditional knowledge and preventing its misappropriation by third parties.[110] Once the knowledge is recorded in the TKDL, it legally becomes public domain knowledge.[111] Under patent law, this means that it is part of prior art, which constitutes all information made available to the public in any form before a given date that may be relevant to a patent's claim of novelty and inventiveness.[112] If an invention has been described as prior art, a patent on that invention is invalid. The TKDL thus comprises a tool to assist patent examiners in carrying our prior art searches, as it helps such examiners root out the applications that clearly do not satisfy the novelty requirement at an early stage. Patent examiners merely have to check the database to reject any patent application that may be a mere copy of traditional knowledge. Without such a database, the process of revoking a patent can be a complex, lengthy and expensive affair, as demonstrated in the Indian case studies of turmeric and neem.[113]

In addition, the national patent laws of most countries, including India, allow for third parties to file a submission questioning the novelty and non-obviousness of a patent application before a patent is granted.[114] There is thus a need to ensure that patent applications that wrongly claim rights in prior act are readily identifiable so that these third party observations can be filed and are made easily searchable.[115] The TKDL enables prompt and cost-effective corrective action in the form of cancellation or withdrawal of patent applications relating to India's traditional knowledge as a result of third party observations.

The TKDL therefore represents a successful effort to ensure that foreign patent offices do not grant patents for applications founded on India's wealth of traditional knowledge, and accordingly, as a unique source of India's traditional medical wisdom, is a powerful weapon in the country's fight against biopiracy. It has to date resulted in the successful opposition of hundreds of patent applications filed around the world.[116]

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[110] Gupta "Protecting Indian Traditional Knowledge from Biopiracy" WIPO.
[111] Hirwade (2012) *Journal of Library & Information Technology* 246.
[112] 246.
[113] WIPO "Protecting India's Traditional Knowledge" (June 2011) *WIPO Magazine* <http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html> (accessed 10-20-2013).
[114] WIPO "Protecting India's Traditional Knowledge*" WIPO Magazine*.
[115] WIPO "Protecting India's Traditional Knowledge*" WIPO Magazine*.
[116] Finetti (2011) *World Patent Information* 58.

However, one potential problem is that the Indian system seems to not be of such developed application in the country itself.[117] It is argued that some Indian patents filed by certain multinationals were wrongly granted.[118] An example is the 2007 patent filed by an Indian company called Avesthagen for a composition of *jamun* and cinnamon extracts, which the Indian government had persuaded the European Patent Office to refuse.[119] This appears to be either a double standard or an oversight on the part of the authorities.

7 The National Recordal System

An initiative is currently underway to replicate the Indian TKDL system in the form of a National Recordal System, which aims to document and digitize traditional knowledge-related information.[120] According to the CSIR, this system has the ultimate goal of creating opportunities "for benefits to flow back to the communities".[121]

The NRS was launched on the 24th May 2013 by the National Indigenous Knowledge Systems Office of the Council of Science and Industrial Research in response to the IKS Policy adopted by Cabinet in 2004.[122] It has been developed in phases, with the first phase focusing on African Traditional Medicine (ATM) and Indigenous Foods (IF) for implementation, because these two domains are most at risk in terms of intellectual property exploitation and biopiracy.[123] The NRS allows for the recording of indigenous knowledge in the local languages.[124] It is the first system of its kind internationally because it records indigenous knowledge in its original oral format, linking it to a complex metadata schema, and providing the necessary mechanisms for both positive

[117] Forster "Patents and Traditional Knowledge" *ENSight*.
[118] Forster "Patents and Traditional Knowledge" *ENSight.*
[119] Forster "Patents and Traditional Knowledge" *ENSight.*
[120] C Saez "South Africa to Launch National Traditional Knowledge Recording System" (10-05-2013) *Intellectual Property Watch* <http://www.ip-watch.org/2013/05/10/south-africa-to-launch-national-traditional-knowledge-recording-system/> (accessed 10-10-2013).
[121] Saez "South Africa to Launch National Traditional Knowledge Recording System" *Intellectual Property Watch.*
[122] Saez "South Africa to Launch National Traditional Knowledge Recording System" *Intellectual Property Watch.*
[123] Saez "South Africa to Launch National Traditional Knowledge Recording System" *Intellectual Property Watch.*
[124] Saez "South Africa to Launch National Traditional Knowledge Recording System" *Intellectual Property Watch.*

and defensive protection.[125] Five documentation centres have already been established in South Africa in order to record the indigenous knowledge, with the envisage that by 2015-2016 all nine provinces will host centres to facilitate the capturing, cataloguing, validation, preservation and dissemination of indigenous knowledge in participating communities.[126]

Central to the success of the NRS is the National Indigenous Knowledge Management System (NIKMAS), an information and communication technology platform which supports the NRS processes.[127] These processes include the cataloguing of the holders of IK, recording, verification and classification, as well as authentication.[128] The system is unique in that the indigenous knowledge is recorded in its original oral format, which is then linked to a complex metadata schema; thus providing the necessary mechanisms for both positive and defensive protection.[129] It is the first of its kind internationally.[130]

The project has two main uses. Firstly, the Department of Trade and Industry and the Intellectual Property Commission can use the system for prior art searches as part of its search and examination service, making the NRS a critical element in preventing the granting of patents in error and biopiracy cases.[131] In doing so, the NRS adheres to a strict set of rules in terms of granting access to the system. Firstly, all information that is documented on the NRS, must be accompanied by prior informed consent agreements, information transfer agreements, and a Memorandum of Agreement that is signed between each community participating in the project and the Documentation Centre

[125] Department of Science and Technology "Indigenous Knowledge Recording System Launched" (28 May 2013) *Sabinetlaw* <http://www.sabinetlaw.co.za/science-and-technology/articles/indigenous-knowledge-recording-system-launched> (accessed 14-10-2013).
[126] Department of Science and Technology "Indigenous Knowledge Recording System Launched" *Sabinetlaw*.
[127] Department of Science and Technology "Indigenous Knowledge Recording System Launched" *Sabinetlaw*.
[128] Department of Science and Technology "Indigenous Knowledge Recording System Launched" *Sabinetlaw*.
[129] Department of Science and Technology "Indigenous Knowledge Recording System Launched" *Sabinetlaw*.
[130] Department of Science and Technology "Indigenous Knowledge Recording System Launched" *Sabinetlaw*.
[131] D Hanekom "Opening Address by the Minister of Science and Technology at the Launch of the National Recordal System for Indigenous Knowledge" (24-05-2013) *South African Government Online* <http://www.gov.za/speeches/view.php?sid=36766> (accessed 31-10-2013).

which facilitates the recording of IK with the communities.[132] Secondly, the NRS will create legal certainty.[133] This is because it will provide a benefit sharing framework which will assist in the identification and location of knowledge holders in the permit granting process set out in the Patents Amendments Act, where applicants for patents are required to lodge declarations stating whether their inventions are based on or derived from any traditional knowledge or any indigenous biological or genetic resource.[134]

8 Conclusion

Intellectual property systems are clearly vitally important policy instruments held by countries in the general context of traditional knowledge protection and specifically, the prevention of biopiracy. There are several questions behind the establishment of an appropriate patent law system to protect the traditional knowledge relating to biological resources in South Africa that remain open. The current national regime appears to substantially fail in protecting traditional knowledge, in that it seems to facilitate the exploitation of traditional communities and incite substantial social costs, rather than resulting in equitable and effective protection.

As a megadiverse country rich in traditional knowledge, it is essential that the relevant South African authorities take action in order to bring the patent law up to international standards in this department, although the lack of appropriate skills and resources in the country may be a temporary obstacle. The 11 step patent law system of India appears to be a successful and relevant example of such a standard. The development of searching and examining capability in the patent system is a fundamental first step towards advancing the protection of South African traditional knowledge; and the National Recordal System, as inspired by the Indian TKDL, is an ambitious and beneficial enterprise that seems to be guiding the law in a more positive direction.

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[132] Hanekom "Opening Address by the Minister of Science and Technology at the Launch of the National Recordal System for Indigenous Knowledge" *South African Government Online*.
[133] Hanekom "Opening Address by the Minister of Science and Technology at the Launch of the National Recordal System for Indigenous Knowledge" *South African Government Online*.
[134] Hanekom "Opening Address by the Minister of Science and Technology at the Launch of the National Recordal System for Indigenous Knowledge" *South African Government Online.*