LEVERAGING TRADITIONAL KNOWLEDGE ON THE MEDICINAL USES OF PLANTS WITHIN THE PATENT SYSTEM: THE DIGITISATION AND DISCLOSURE OF KNOWLEDGE IN SOUTH AFRICA

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LEVERAGING TRADITIONAL KNOWLEDGE ON THE MEDICINAL USES OF PLANTS WITHIN THE PATENT SYSTEM: THE DIGITISATION AND DISCLOSURE OF KNOWLEDGE IN SOUTH AFRICA

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1 Introduction: a dialectical relationship

Traditional knowledge (TK) associated with a biological resource is an intangible component of the resource itself. Hence, it is not surprising that in countries endowed with abundant biological resources, there exists a rich source of knowledge relating to the uses of such resources for nutritional, medicinal, and agricultural purposes. Such a knowledge base has been developed and nurtured over many generations by indigenous communities, who traditionally are the custodians of biological resources. It is a well-documented fact that TK plays an important role in the global economy and is valuable not only to those who traditionally depend on it in their daily lives, but also to modern industry, especially the global biotechnology, pharmaceutical and agribusiness corporations. Yet the exploitation of TK by these industries does not usually lead to corresponding benefits to indigenous communities either in the form of attribution or compensation.¹ This has led a large number of developing countries rich in biological resources and associated TK, including South Africa,² to decry the situation whereby their indigenous communities have been deprived of benefits from the use of their TK, which has been monopolised and used by others, mainly multinational corporations, without authorisation.³ An increasing number of cases of the misappropriation of TK and the subsequent acquisition of intellectual property (IP), rights particularly patents on such knowledge, without the payment of compensation

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¹ See Mugabe Intellectual Property Protection 8, Hansen and Van Fleet Traditional Knowledge and Intellectual Property 5; and Okedji 2003 SJICL 355.
² South Africa has a unique biodiversity that has been described as an asset of international, national and local value and significance. See GN 1095 in GG 18163 of 28 July 1997 (White Paper on the Conservation and Use of South Africa’s Biological Diversity) 12.
³ See Shiva Patents 768; and Chander and Sunder 2004 CLR 1350-1352.
to the provider countries and their indigenous communities, are being reported at present.\(^4\)

The use of patents in legitimising such misappropriations of TK is due to the fact that the global IP regime as presently structured is based entirely on the traditionally western or conventional description of knowledge and its conceptions of individual intellectual property ownership.\(^5\) Within the bio-cultural context in which TK of the medicinal uses of plants (TKMUP) falls, the criteria for patenting are primarily based on the traditional western scientific narrative, with no regard to any other cultural accounts of science, thereby leading to the direct exclusion of TKMUP and other non-western scientific narratives.\(^6\) The failure of the global patent system to accord recognition to TKMUP and other TK associated with biodiversity has reinforced the distrust of the current IP regime by indigenous communities and developing countries. In addition, such failures raise the pressure for the review of the patent system’s conceptual framework in a manner accommodative of developing countries' complex and dialectical attitude to the intellectual property system.\(^7\) The scope of the proposed reform varies from the re-calibration of the patent regime to accommodate the exigencies of TK, adoption of a *sui generis* knowledge protection mechanism amenable to TK, and a limitation on the role of patents implicating TK.\(^8\)

Presently, no tangible progress has been made towards reforming the global patent regime despite the public sympathy.\(^9\) The lack of such progress is not unconnected with the fact that the configuration of global economic, technological and political power tilts heavily and favourably towards developed countries and their industrial

\(^4\) A phenomenon that has being popularly termed "biopiracy". It is widely reported that such patents have been granted on TK relating to natural products such as neem, turmeric, basmati rice, hoodia, African potato, ayahuasca, may apple, and rosy periwinkle. See Roht-Arriaza 1995-1996 *Mich J Int’l L* 921-926; and Blakeney 2000 *EIPR* 251.


\(^6\) See Oguamanam 2008 *Ind J Global Legal Studies* 496; and Oguamanam 2004 *Ind J Global Legal Studies* 146, 151-152.


\(^8\) Oguamanam 2008 *Ind J Global Legal Studies* 490-491. See also Mgbeoji 2001 *Ind J Global Legal Studies* 169, 173-175; Verma 2004 *JWIP* 782.

interests. Such interests are currently deriving maximum benefits from the commercial exploitation of biodiversity and associated TK as facilitated by the international patent system. As observed by a commentator, "it would be easier for commercial interests to self-destruct than for them to allow for the abolition of or even weakening of the patent system". In view of such reluctance to adopt the proposed reforms to the global intellectual property system, most developing countries have resorted to the adoption of a radically different strategy in their approach to intellectual property, particularly as it concerns the protection from misappropriation of their TKMUP and other TK associated with biodiversity. The adoption of such a strategic approach has positive implications in the empowerment and protection of TKMUP from misappropriation through "foisting the latter on the formal patent system in what translates into a direct encounter between the local and the cosmopolitan". For instance, the adoption of the Traditional Knowledge Digital Library (TKDL) by India has not only led to the prevention of biopiracy patents involving Indian TKMUP, but has also motivated the adoption of appropriate classification tools for TKMUP at the International Patent Classification (IPC) Union.

As a biologically mega-diverse country with associated rich TK, South Africa has also had to contend with issues relating to biopiracy and other misappropriation of such

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10 See Mgbeoji 2001 Ind J Global Legal Studies 171; and Helfer 2004 Yale J Int’l L 15.
12 This is evident in the adoption of diverse measures for the protection from misappropriation of various aspects of their knowledge forms including TKMUP. Such measures include the digitisation of TKMUP, as evidenced by India’s Traditional Knowledge Digital Library (TKDL) project, China’s Traditional Chinese Medicine Patents Database, and South Korea’s Traditional Knowledge Portal; recent attempt at incorporating innovations in CHM in Taiwanese patent law; efforts to enshrine the disclosure of origin requirements (DRs) in patent application; and developments around geographical indications (GIs). For an in-depth discussion of these measures, see Oguamanam 2008 Ind J Global Legal Studies 498-527.
13 Oguamanam 2008 Ind J Global Legal Studies 497.
resources. In response, SA was one of the developing countries that resorted to the adoption of a radically different strategy in its approach to intellectual property in the context of its application to TKMUP and other TK associated with biodiversity. This is evident in the adoption of strategic measures for the protection of various aspects of its TK forms from misappropriation, such as the National Recordal System (NRS) and the Disclosure of Origins (DRs) system. This paper seeks to explore, in the following two sections, the implications of these measures, which reflect important trends in the dialectics of SA's engagement with intellectual property, in leveraging TKMUP within the structure, content and conceptual framework of the patent system in the country. It will be argued that the implementation of these measures, which were primarily adopted as defensive anti-appropriation strategies in the context of TKMUP, currently represents a paradigmatic shift in SA's approach to and experience of the IP system, as they have effectively opened up TK to the patent system in the country.

2 The digitisation of TKMUP through the National Recordal System (NRS)

2.1 Understanding the NRS

The National Recordal System (NRS) is a defensive anti-appropriation strategy which was launched on 24 March 2013 by the Department of Science and Technology (DST) in response to the Indigenous Knowledge System (IKS) Policy adopted by the South African government in 2004. The IKS Policy laid the platform for the recognition, affirmation, development and protection of TK in the country. The NRS, which was designed as an interdepartmental instrument, strives to enable communities and guilds of traditional healers to record their mostly oral knowledge holdings for the

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17 The recent instances involve biological resources such as the *pelargonium*, *rooibos* and honey bush. For recent biopiracy cases involving South Africa, biological resources and associated TK, see Subroyen date unknown http://www.iod.wowinteractive3.co.za/PUBLICATIONS/eMag/IoD SaeZineIssue34January2011/Biopiracycanitbecurbed.asx; Sapa 2010 http://www.timeslive.co.za /business/article473765.ece/Nestle-accused-of-SA-bio-piracy; and Groenewald 2010 http:// mg.co.za/?article/2010-01-22-town-like-alice-takes-on-german-biopirate.

18 See DST *Indigenous Knowledge Systems* 15-16; GN 552 in GG 31026 of 5 May 2008 6-19; and GN 918 in GG 36816 of 4 September 2013 5.

19 The IKS indicates the need to establish a recordal system in which communities and guilds of traditional healers can record their knowledge holdings in order to assist or promote their interest in future economic benefits and social good, based on such knowledge. See DST *Indigenous Knowledge Systems* 11, 15-16.
purpose of preservation, protection, future economic benefit and social good. The recordal system, which is loosely modeled upon India’s Traditional Knowledge Digital Library (TKDL), seeks to capture, preserve, manage and disseminate TK in digital format, while simultaneously enabling processes to derive benefit from the TK. Unlike the TKDL, which captures TK in the public domain, although it is contained in diverse but usually inaccessible classical literature in different traditional or local languages, the NRS focuses on undisclosed and confidential TK rather than TK in the public domain. The NRS, which has been developed in phases, currently focuses on TK of both African traditional medicine and indigenous foods, while the protection of TK relating to arts, crafts and farming practices will be developed at a later stage. The focus on African traditional medicine and indigenous foods, which implicates TKMUP and other TK associated with biodiversity, is due to the fact that the two domains are most at risk in terms of biopiracy and other forms of misappropriation.

The capturing of the mostly oral and undisclosed TK will be done using the "IK holder cataloguing facility". This implicates the use of the catalogue sub-system to maintain a database of TK holders, together with data such as their contact details, location, the traditional authority under which they fall, and a description of their specialised TK. The catalogue system is complemented by the community register, which will be used to track registered communities within the NRS. The latter incorporates a component that stores electronic copies of any legal or contractual agreements that have been signed with community representatives. These include prior informed consent agreements, information transfer agreements, and memoranda of agreement signed by each community participating in the project and the documentation centre which facilitates the recording of TK with the communities.

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20 Fogwill et al "Software Architecture" 2.
21 Such as such as Hindi, Sanskrit, Urdu, Tamil, and others. See TKDL date unknown http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng.
22 Although TK construed to be in the public domain is also stored in the system.
The preservation, protection and accessing of the captured TK will be by means of an information and communication technology platform known as the National Indigenous Knowledge Management System (NIKMAS).\textsuperscript{28} At the core of the system, which is the first of its kind internationally, is a Digital Knowledge Repository (DKR).\textsuperscript{29} The DKR uses digital audio/visual recordings that capture, to the extent possible, the oral, visual and performed aspects of TK, and sometimes photos, to store and maintain TK in its original oral format for long-term preservation.\textsuperscript{30} This is vital in combating the erosion of TK caused by social issues and changes in technological landscape. In addition, digitising TK in its original format is critical to the issue of ownership of the captured TK as it enables the knowledge to remain accessible to the original TK holders. This in turn addresses any concern that communities may have about losing control of their cultural heritage through the conversion of such ancient knowledge into metadata.

The DKR is equipped with a rich set of annotations and metadata fields that describe or translate the TK into the formal information structures needed for legal protection and scientific interrogation.\textsuperscript{31} Hence, for research and prior art search purposes, the information can be converted into text in the six United Nations languages.\textsuperscript{32} Furthermore, the DKR has technology capabilities of allowing knowledge base conversions of indigenous names into scientific names.\textsuperscript{33} However, such an information structure, which is partially or completely incompatible with the original TK form, may be criticised as a forced assimilation of the TK into an epistemological narrative rooted in traditional western science and technology. This is due to the fact that it "imposes a data bias on the recorded IK, recontextualising it into the domains

\textsuperscript{28} Fogwill \textit{et al} "Software Architecture" 1.

\textsuperscript{29} The DKR is based on the Flexible Extensible Digital Object and Repository Architecture (Fedora) digital library technology, and enriched with semantic web technologies to support intelligent information retrieval and inference.


\textsuperscript{31} Fogwill \textit{et al} "Software Architecture" 1, 5.

\textsuperscript{32} Unlike the TKDL which digitalised its data in five UN languages, namely English, German, Spanish, French and Japanese. See TKDL, date unknown http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng.

of intellectual property rights, western law and science". Despite this criticism, it can be argued that the formal information structure is vital to the protection and promotion of TK in SA as it "...lend[s] the TK legitimacy in those domains and allows it to be protected and form an integrated part of the NRS's future-looking processes".

A sophisticated security model, the NIKMAS Security Service preserves and protects all TK stored in the DKR as well as handles all security-related interactions. Access to the stored data is through an advanced semantic search engine that will aid intelligent search across a number of possible related TK entries. The access is regulated by strict rules to avoid unduly placing undisclosed TK in the public domain, as that may encourage counter-productive outcomes such as biopiracy. Finally, the integration services of NIKMAS provide a framework and functions for integration from NIKMAS into external TK resources, websites and databases managed in various institutions and government departments.

The goals of the NRS extend beyond protection and preservation to the promotion of TK in such a way as to enable researchers and commercial entities to interrogate the recorded TK and identify those with the potential for economic or social benefit. The NRS then brokers direct access between the researchers and owners of this TK for further research or commercial development. Throughout the exercise, measures are put in place not only to ensure that the rights of the TK holders are protected, but

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34 Fogwill et al "Software Architecture" 5. For such criticism, see Oguamanam 2004 Ind J Global Legal Studies 146.

35 Fogwill et al "Software Architecture" 5. In any event, the audio/visual original recordings remain accessible to them, providing some degree of digital preservation of their knowledge and allowing them to "re-assemble" their TK more easily in terms and formats they are familiar with.

36 Fogwill et al "Software Architecture" 6-7.


38 For instance, the public is allowed open access to recorded TK that is already in the public domain, while for searches and examinations, approved scientists, researchers and patent offices are allowed limited authenticated access to confidential TK information as determined by adherence to the legal framework requirements. For the development of TK purposes, authenticated and approved scientists and researchers are given full confidential access to a single TK information on condition that all relevant legal agreements are signed, including a benefit sharing agreement. See Suchanandan 2013 http://afro-ip.blogspot.com/2013/06/explained-south-africas-national.html.


40 Fogwill et al "Software Architecture" 3.
also that adequate benefit will be accrued to the TK holders irrespective of whether the TK is undisclosed or in the public domain.\textsuperscript{41} Examples of such measures include benefit sharing agreements with indigenous communities as TK holders; restriction of access to confidential TK information; and policy enforcement by requiring researchers to obtain bioprospecting licences before accessing certain types of TK.\textsuperscript{42} In this way, the NRS acts as an honest broker between TK holders and interested third parties.\textsuperscript{43} This promotional function is very important in motivating indigenous communities to participate in activities documenting their knowledge, as in most cases, despite the potential wealth in their intangible assets, TK holders live in dire poverty,\textsuperscript{44} as is evident from the statement of Kgosi Nyalala Pilane, the traditional leader of the Batgatla-Ba-Kgafela Tribal Authority (BBKTA), a community participating in the NRS project.

It is our firm belief that our culture and identity are the pillars of our economic development journey, which is why we are participating in this project.\textsuperscript{45}

\section*{2.2 Utility of the NRS to the patent system}

The NRS also seeks to protect TKMUP from biopiracy or any other acts of misappropriation using the patent system. As a defensive anti-appropriation strategy, the NRS will serve as TK hubs to the South African patent office as well as international patent offices to enhance such protection.\textsuperscript{46} For example, the patent office (the Companies and Intellectual Property Commission (CIPC)), can utilise it for prior art searches as part of the substantive search and examination of patent service proposed under the Draft IP Policy 2013.\textsuperscript{47} In essence, the NRS will be used by patent examiners to search for prior art in order to determine whether the claims of a patent application

\textsuperscript{41} Fogwill \textit{et al} "Software Architecture" 3.
\textsuperscript{42} This supports the activities of the Department of Environmental Affairs and Tourism (DEAT) relating to bioprospecting including that of access and sharing of the benefits resulting from the bio-prospecting process.
\textsuperscript{43} Fogwill \textit{et al} "Software Architecture" 3.
\textsuperscript{44} See DST \textit{Indigenous Knowledge Systems 14}; and Carvalho "From the Shaman's Hut to the Patent Office" 19-20.
\textsuperscript{46} See Chander and Sunder 2004 \textit{CLR} 1357; Oguamanam 2008 \textit{Ind J Global Legal Studies} 498-499; and Erstling 2009 \textit{Tex Wesleyan L Rev} 315-316.
\textsuperscript{47} See GN 918 in GG 36816 of 4 September 2013 10-11.
are novel and inventive. Presently, the Patent Office which practices a formal or depository system offers only simple prior art searches. The implication is that since there is no examination of the substantive novelty and inventiveness of patent applications prior to the granting of patents in the country, the NRS is of little importance to the patent examiners in the CIPC. Nevertheless, the NRS is still important for prior art searches by patent attorneys before the filing of patent application in SA in order to minimise the chances of revocation of the resulting patent by the High Court in a patent opposition proceeding.

The NRS can also be utilised to oppose patent grants in foreign countries where the subject matter of the patent application is based or derived from SA’s TKMUP. The basis for such opposition will be the citation of NRS references as prior art, particularly in countries like the United States, where oral disclosure other than within its territory is not allowed. In essence, just like the TKDL, which has been successfully utilised by India in pre-grant and post grant patent opposition proceedings in foreign countries, the NRS can be utilised to ensure that SA’s TKMUP is not unjustly commercialised in foreign countries. Such an objective is achievable as the NRS is designed to facilitate access to foreign patent offices to conduct searches on the TKMUP documented in the system. In this way the NRS acts as a bridge between the local TKMUP and a patent examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent examiners.

To aid such searches by the international patent offices, the NRS will adopt appropriate classification tools similar to those of the TKDL, namely the Traditional Knowledge...

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48 A limited power of examination conferred on the examiner under the Patent Act relates only to the form or documentation. See s 34 of the Patents Act 57 of 1978; and regs 40-41 of GN R2470 in GG 6247 of 15 December 1978 (Patent Regulations).

49 Aggrieved TK holders including traditional healers can approach the court to seek a revocation of the resulting bad patent. See s 61(1) (g) of the Patents Act 57 of 1978 above.

50 See s 102(a) of the US Patent Act 35 USC 2006.


Resources Classification (TKRC). The TKRC is a modern classification system created under the TKDL and fashioned after the framework of the International Patent Classification (IPC). It seeks to improve on the problem associated with the classification system regarding the documentation of traditional knowledge. This Indian initiative resulted in a detailed and improved IPC structure relating to traditional medicine, as is evidenced by the inclusion of a new main group, A61K 36/00 with 207 subgroups covering different categories of plants. Thus, adopting a similar classification system in SA will effectively make the NRS an integral part of national and international patent administrations, like the TKDL database.

Perhaps the only issue relates to whether confidential or undisclosed TK in NRS database constitutes "prior art" under patent law. This is particularly important with respect to TKMUP, which, despite the communal ownership structure, is generally confidential in nature. This is due to the fact that the use of such knowledge is usually restricted to certain members of the community, mostly traditional healers. It should be noted that the NRS intellectual property objective is to prevent placing undisclosed TK into the public domain in order to prevent unauthorized uses as well as to enhance SA's competitive advantage in the global economy. Such an objective is in consonance with the WIPO Agreement Concerning the International Patent Classification (1971). It provides a hierarchical system in which technological or innovation categories are divided into a range of sections, classes, and subclasses for easy identification in prior art examination. Most national patent offices including the CIPC (albeit to a limited extent to the level of subclasses, but not to the level of groups and sub-groups) as well as the International Bureau of the WIPO and the Patent Corporation Treaty (1970) (PCT) rely on the IPC for prior art searches. The IPC divides technology into eight sections with approximately 70,000 subdivisions. Each subdivision has a symbol consisting of Arabic numerals and letters of the Latin alphabet. See WIPO date unknown http://www.wipo.int/classifications/ipc/en/general/preface.html.

with the objectives of the recently launched Bio-economy Strategy.\textsuperscript{59} The strategy seeks \textit{inter alia} to utilise the nation's rich biodiversity and associated TK in establishing SA as a world leader in research, development and the manufacture of pharmaceutical products such as active pharmaceutical ingredients, vaccines, African traditional medicines and herbal medicines.\textsuperscript{60} The South African \textit{Patents Act} describes prior art or "the state of the art" to comprise of:

All matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.\textsuperscript{61}

By this description, oral or written TKMUP once disclosed, whether in SA or elsewhere, is regarded as being in the public domain.\textsuperscript{62} The implication is that such TKMUP or any invention based upon it or principally derived from it cannot be patented.\textsuperscript{63} However, the absolute novelty principle under the Act is triggered only when information about an invention, knowledge or technology has been disclosed to the public, or the invention has been used secretly and on a commercial scale in the country.\textsuperscript{64} This raises a peculiar problem for confidential or undisclosed TKMUP captured within the NRS, as any invention based on such knowledge is patentable in SA. This is unlike the situation in India where TKMUP is construed as being in the public domain and hence, there is an absolute prohibition on the patenting of any "invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components".\textsuperscript{65}

\textsuperscript{59} See DST \textit{Bio-economy Strategy}.  
\textsuperscript{60} See DST \textit{Bio-economy Strategy} 4, 6.  
\textsuperscript{61} Section 25(6) of the \textit{Patents Act} 57 of 1978. Also see \textit{Ensign Bickford (South Africa) (Proprietary) Limited & Ors v AECI Explosives and Chemicals Limited} (O) unreported case number 4/95 (SCA) of 21 September 1998 22-23; and \textit{Schlumberger Logelco Incorporated v COFLIXIP SA 15} (O) unreported case number 256/01 of 6 September 2002 15-16 paras 20-21.  
\textsuperscript{62} This would place such provisions of the South African \textit{Patent Act} in conflict with that of the United States which, as earlier noted, provides that oral disclosure other than within its territory does not constitute prior art. Nevertheless, both provisions of the South African \textit{Patent Act} and that of the United States are justifiable under international patent law. This is because the \textit{Patent Cooperation Treaty} allows its state parties to adopt national laws determining the criteria of prior art and other substantive conditions of patentability provided that they do not constitute requirements as to the form and contents of applications. See A 27.5 of \textit{the Patent Cooperation Treaty} (1970).  
\textsuperscript{63} Section 25(1) and (5) of the \textit{Patents Act} 57 of 1978.  
\textsuperscript{64} Section 25(8) of the \textit{Patents Act} 57 of 1978.  
In a nutshell, the intellectual property issue raised by the digitisation of confidential or undisclosed TKMUP in SA relates to how information or data stored in the NRS can be utilised for prior art search in order to prevent biopiracy, without affecting their potential for commercialisation in the country. Presently, for the purposes of searches and examinations, NRS allows limited authenticated access to confidential TKMUP to approved scientists, researchers and patent offices as determined by adherence to the requirements of the legal framework between the parties. This restrictive strategy of using disclosure sparingly and to selected parties allows the disclosed limited information about the confidential TK to be regarded as "prior art" for the purpose of determining the novelty of an invention under patent law without unduly placing detailed information about the confidential TK in the public domain. The only drawback is that since the patent examiners are allowed access only to limited details on the confidential information, such incomplete disclosure still leaves open the possibility that patent claims on the undisclosed aspects of the TK will be considered valid.

The above discussion of the NRS shows that the digitisation of TKMUP in SA has given new momentum to the leveraging of TKMUP within the patent system. For instance, NRS calls attention to the growing importance of TKMUP as a knowledge form by fuelling an epistemological encounter and dialogue between TKMUP as a local knowledge form and its more cosmopolitan western counterpart through the direct attempt to increase TKMUP’s stake particularly within the international patent system as a prior art. Such recognition of disclosed TKMUP as a prior art calibrates or levels the TKMUP with the traditionally western or conventional scientific or medicinal knowledge which when publicly disclosed or patented is prima facie prior art under

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69 See Oguamanam 2008 Ind J Global Legal Studies 503.
This creates a semblance of psychological parity in favour of TKMUP vis-
a-vis the extant recognition of the conventional scientific knowledge under the patent regime.\textsuperscript{71} The only difference is that while theoretically TKMUP that is regarded as prior art may be freely accessible as it is part of the public domain, the conventional counterpart, which is usually patented, is protected for the period of any applicable patent. However, it is doubtful if the TKMUP in the public domain is "an open-access resource from which either individuals or groups may, without normative let or hindrances, withdraw units of the resource".\textsuperscript{72} Indeed, under the South African \textit{Biodiversity Act},\textsuperscript{73} and its \textit{Bio-Prospecting, Access And Benefit-Sharing Regulations},\textsuperscript{74} any use of this knowledge for bioprospecting would require the prior informed consent of the indigenous community which has developed or nurtured it.

Furthermore, by linking TKMUP with the patent system, the NRS has made it feasible for patent examiners to discover TK-related prior art, thereby enhancing the integrity of the patent system and the overall empowerment of TMKUP. This is because the NRS will be of significant importance to the patentability of traditional medicinal innovations and other scientific innovations based on or derived particularly from previously undisclosed TKMUP.\textsuperscript{75} In addition, since the NRS usually demonstrate its source of information, the system will help in ensuring in instances of the patenting of inventions based on or derived from stored TKMUP, that the TK holders are appropriately compensated for the use of their knowledge.\textsuperscript{76} It is therefore not surprising that the South African government assigned a key role to the NRS in the implementation of the Bio-economy Strategy for South Africa.\textsuperscript{77}

\begin{thebibliography}{9}
\bibitem{Oguamanam2008} Oguamanam 2008 \textit{Ind J Global Legal Studies} 503.
\bibitem{Oguamanam2008} Oguamanam 2008 \textit{Ind J Global Legal Studies} 503.
\bibitem{MunzerRaustiala2009} See Munzer and Raustiala 2009 \textit{Cardozo Arts & Ent LJ} 54
\bibitem{BiodiversityAct} Section 82 of the \textit{National Environmental Management: Biodiversity Act} 10 of 2004.
\end{thebibliography}
3 Disclosure requirements (The disclosure of the origins of TKMUP)

3.1 The disclosure of the origins of TKMUP in South Africa

The system requiring the disclosure of the origins of TKMUP was adopted in response to the IKS policy, which indicated the need to amend SA’s patent law in order to formally require the declaration of the use of TK or the transfer of materials arising from the indigenous use in the prior art declarations in respect of patents. Disclosure of Origins is provided under subsections 30(3A) and 30(3B) of the Patents Act requiring the mandatory disclosure of the origin of TK and evidence of benefit sharing for an invention that is based on or derived from TK. These provisions require any patent applicant in SA to disclose any TK actually used in the course of developing the invention, and the actual source or origin of the TK; as well as to provide evidence of prior informed consent and/or an undertaking of equitable benefit-sharing with the TK holders. These requirements apply irrespective of whether the TK is confidential or in the public domain, captured in the NRS or any other database in the country, or has not yet been captured. The mandatory provisions which were inserted into the Act by virtue of the Patents Amendment Act 2005 seek to ensure some accountability or integrity in the use of TKMUP within the patent system by preventing the granting of bad patents, which often implicate the misappropriation of biological resources and associated TK in South Africa.

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78 See DST Indigenous Knowledge Systems 16.
79 “(3A) Every 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 is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. (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 claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.”
81 Patents Amendment Act 20 of 2005.
Like the NRS, the adoption of DRs in SA is reflective of the dialectics of developing countries’ approach to the intellectual property system, especially in the context of their approach to TK. Unlike the NRS, the significance of the DRs in mitigating the patent system’s disdain for TK is perhaps marginal, both in terms of its approach and impact. For instance DRs, which have been popularly adopted by developing countries have no extra-territorial application. This is very important as most patents utilising TK are filed in developed countries, the main market for biotechnology products and processes. Hence, a bioprospecting company may seek to circumvent these mandatory patent provisions in SA by patenting inventions based or derived from SA’s TKMUP in a developed country where such a requirement does not apply or is not mandatory.\(^{83}\) In such instances, although the validity of the patent is not in issue,\(^ {84}\) it is doubtful if the company would be able to enforce such a patent in South Africa.\(^ {85}\)

In addition, because of the centrality of the disclosure of prior art to the patent law, DRs are of no relevance in determining the inventiveness of any invention based on or derived from TKMUP. Despite this, DRs add pressure to the IP system at both the national and the global levels for creative re-examination of the patent system’s conceptual framework in terms of its having to accommodate TKMUP and other TK associated with biological resources.\(^ {86}\)

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\(^{83}\) Presently, strong opposition and skepticism have trailed the introduction of DRs. Opponents representing mostly developed countries and their industrial interests have found the requirement to be an extra burden on patent applicants in so far as it seems to be out of proportion with the problem that it seeks to solve. In addition, questions have been raised concerning the compatibility or incompatibility of the requirement with treaties regulating the global patent system. Hence, some developed countries do not require such disclosure in patent applications, while those that have enacted laws incorporating the requirement, like the EU, do not make compliance mandatory, as obtains in South Africa and other developing countries. See Oguamanam 2008 *Ind J Global Legal Studies* 518-520; Carvalho "From the Shaman's Hut to the Patent Office" 30-36; Carvalho 2005 *J L & Pol’y* 148; and Erstling 2009 *Tex Wesleyan L Rev* 309-315.

\(^{84}\) Proposals aiming at explicitly incorporating the requirement into global patent treaties such as the TRIPS Agreement and PCT have not been successful. The compatibility of the requirement with state parties' obligations under these treaties is therefore vague, despite the argument of developing countries like South Africa that their actions are not inconsistent with their obligations under these patent treaties. Thus, until there is a definite judicial pronouncement, patents obtained in contravention of the requirement in most developing countries that adopted the requirement would not be valid in such countries.

\(^{85}\) The refusal to allow the enforcement of such a patent can be justified under the "same treatment principle" enunciated in the *Paris Convention for the Protection of Industrial Property*. See A 2 of the *Paris Convention for the Protection of Industrial Property* (1883).

\(^{86}\) Oguamanam 2008 *Ind J Global Legal Studies* 517.
3.2 Implications for TKMUP within the patent system

DRs can help in leveraging TKMUP within the patent system in SA. This is evident from the fact that the requirements as provided under the Patents Act ensure that in appropriate cases, any TKMUP holder\textsuperscript{87} whose knowledge contributed substantially to an invention has co-ownership right in the resulting patent.\textsuperscript{88} Thus, any applicant for a patent in which TKMUP forms a substantive part of the invention must in addition to furnishing the Registrar with a copy of the bioprospecting permit\textsuperscript{89} also provide "...proof of co-ownership of the invention for which the protection is claimed".\textsuperscript{90} Failure to provide this information in the patent application, which in essence acknowledges the substantive inventive contribution of the TK holder to the invention, is a violation of the Act.\textsuperscript{91} Requiring this mandatory proof is a mechanism aimed at minimising the misappropriation of TKMUP by ensuring that the rights of inventorship and ownership of any resulting invention accrue only to those who deserve them.\textsuperscript{92} As aptly stated by Carvalho:

\begin{quote}
... when traditional knowledge holders inform bioprospectors of the result of their own inventive activity and those results are later claimed in a patent application, there is no doubt that the original inventors are entitled to be recognised as co-owners of the resulting patents ...\textsuperscript{93}
\end{quote}

The entitlement of TK holders to co-ownerships of inventions derived from TKMUP under the Patents Act is not unique to SA, as it is in accordance with internationally

\textsuperscript{87} By virtue of the provisions of both the Patents Act and Regulations on Bio-Prospecting, Access and Benefit-Sharing, this would mean an indigenous community whose TKMUP contributes substantially to an invention. (See the Patents Act 57 of 1978 s 2; and Regulations on Bio-Prospecting, Access and Benefit-Sharing reg 8). This applies despite the increasing emergence of traditional healers as the principal repositories and custodians of all forms of TKMUP including general plants medicinal knowledge which has long been abandoned by their larger communities. (See WIPO 2001 http://www.wipo.int/edocs/pubdocs/en/tk/768/wipo_pub_768.pdf 220, citing Prof Penny Bernard of the Anthropology Department, Rhodes University, Grahamstown, South Africa.)

\textsuperscript{88} Sections 29 and 49 of the Patents Act 57 of 1978 (recognising co-ownership or joint ownership in a patent).

\textsuperscript{89} Issued in terms of Ch 7 of the National Environmental Management: Biodiversity Act 10 of 2004.

\textsuperscript{90} See reg 33A(2)(e) of the Patent Regulations published in GN R2470 in GG 6247 of 15 December 1978 (as amended by GN R1226 in GG 30593 of 14 December 2007 (Patent Regulations Amendment)).

\textsuperscript{91} See s 61(1) of the Patents Act 57 of 1978; and Carvalho 2005 J L & Pol'y 148.


\textsuperscript{93} See Carvalho 2005 J L & Pol'y 146.
accepted principles of patent law.\textsuperscript{94} For instance, joint inventorship is recognised under the United States \textit{Patent Act} even in instances "where the inventors did not physically work together or at the same time, make the same type or amount of contribution, or make a contribution to the subject matter of every claim of the patent".\textsuperscript{95} What is required is that each of the inventors must have worked on the same subject matter and must have made some contribution to the conception of the invention as it is claimed in the patent.\textsuperscript{96} Similarly, in the United Kingdom it has been held in \textit{Re Staeng Ltd's Patents} that a person who generated the idea for an invention (a new method of securing electric cables) had made a sufficiently substantive inventive contribution to be treated as a co-inventor, as it was unlikely that the main inventor would have turned his mind to the question without being prompted by the initial idea.\textsuperscript{97} A famous example where a TKMUP holder was acknowledged as a joint inventor in Africa involves the patenting of the anti-sickle cell drug "NIPRISAN".\textsuperscript{98}

Due to the communal nature of TKMUP in SA, it is doubtful if a traditional healer would be acknowledged as a joint inventor in a patent application where TKMUP disclosed by such a healer contributed substantially to the invention. This applies irrespective of whether the TKMUP is existing knowledge or an innovative TK developed by a traditional healer. With regard to the latter, while a traditional healer may innovate, what makes his/her innovation "traditional" is that it is created in a manner that reflects the traditions of his/her indigenous community and hence is regarded as community-held.\textsuperscript{99} In essence, the innovation is developed according to the rules, protocols and customs of a certain community in the country.\textsuperscript{100} The implication is that the innovating traditional healer claims no ownership rights over the "new" knowledge

\begin{flushleft}
\textsuperscript{94} See Carvalho 2005 \textit{J L & Pol'y} 148; Erstling 2009 \textit{Tex Wesleyan L Rev} 324; and Eisenberg 2000 http://www.yale.edu/ocr/pfg/guidelines/docs/inventor_owner.pdf.


\textsuperscript{96} See \textit{Ethicon v United States Surgical Corp} 135 F 3d 1456 (Fed Cir 1998) (holding that a contribution to one claim is enough).

\textsuperscript{97} \textit{Re Staeng Ltd's Patents} 1996 RPC 183. Also see s 116 of the \textit{US Patent Act} 35 USC 2006 (providing that it is not necessary for a co-inventor to make a contribution to the subject matter of every claim of the patent).

\textsuperscript{98} See Wambebe 2007 http://www.uclan.ac.uk/genbenefit.


\textsuperscript{100} See Carvalho "From the Shaman's Hut to the Patent Office" 7.
\end{flushleft}
as his achievement is primarily regarded as a community service.\textsuperscript{101} Hence, he cannot patent his TK invention except with the permission or consent of his community.\textsuperscript{102} The same applies to the acquisition of co-ownership rights in instances where the innovative TK contributed substantially to an invention.

The disclosure requirements under the Act also ensure compliance with the provisions of the \textit{Biodiversity Act} relating to the prior informed consent of TK holders and the fair and equitable sharing obligation with TK holders. Such provisions of the \textit{Biodiversity Act} apply irrespective of whether the TKMUP involved is in the public domain or not. With regard to TKMUP in the public domain, it should be noted that it is not only publicly disclosed oral or written TKMUP that is regarded as being in the public domain. Also included as TKMUP in the public domain are TKMUP that is not exclusively known by the indigenous community that has developed or discovered it, and any TKMUP that is widely shared among a number of indigenous communities and with respect to which there is no clarity as to which specific community developed or discovered the knowledge.\textsuperscript{103} Thus, irrespective of whether TKMUP is in the public domain or not, the Patents Act requires applicants for patents in respect of TK-based inventions to provide evidence of the bio-prospecting permit used in the research leading to the development of the inventions. In addition, the applicants are required to provide evidence that prior informed consent of the TK holders had been obtained as contemplated in section 82(2)(a) or 82(3)(a) of the \textit{Biodiversity Act}; and evidence of

\textsuperscript{101} It has been argued by some experts that TKMUP should not be treated as community property in isolation, as in some cases individuals can distinguish themselves and are recognized as informal creators or inventors separate from the community. (See WIPO 2001 http://www.wipo.int/edocs/pubdocs/en/tk/768/wipo_pub_768.pdf 219) However, despite the recognition as informal creators or inventors, the innovating traditional healers are expected to use the knowledge for the benefit of their communities. This effectively puts the innovating healer in the same category with warriors and sometimes great hunters, whose skills are also employed in the service of their communities. See Khalil "Biodiversity and Conservation of Medicinal Plants" 242.

\textsuperscript{102} This does not mean that an innovative traditional healer cannot patent his invention or contribute his knowledge towards an invention in exchange for co-ownership rights. In such instances, the knowledge is not regarded as TK but as contemporary knowledge. Specifically for patenting purposes it will be regarded as local or contemporary knowledge that is derived or is otherwise based on TKMUP. The only drawback for the innovative traditional healer is that such inventions must satisfy the disclosure requirements provided under the \textit{Patents Act} before they can be patented.

\textsuperscript{103} See DEAT \textit{South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework} 13.
a benefit-sharing agreement between the applicants and TK holders as contemplated in section 82(2)(b)(ii) or 82(3)(b) of the *Biodiversity Act*.\textsuperscript{104}

These provisions, which reinforce the mandatory provisions of the *Biodiversity Act*, seek to ensure that TK holders give their informed consent to any exploitation of their TKMUP by bioprospectors, as well as that they derive benefits from any invention resulting from the bioprospecting activities. This is very important to TK holders who are not considered inventors or co-inventors for the purpose of the patent law, as their TKMUP is not part of the inventive processes as such. In fairness they must be acknowledged as the originators of the experience and data that allowed a patentable medicine to be developed.\textsuperscript{105}

4  Conclusion

The adoption of both the disclosure requirements and NRS as defensive anti-appropriation mechanisms in SA is indicative of developing countries' skeptical and often dialectical approach to the intellectual property system, especially in the context of its application to TK.\textsuperscript{106} Nevertheless, such measures have ultimately albeit unconsciously fuelled an epistemological dialogue and encounter between TKMUP as local knowledge and its more cosmopolitan Western counterpart. This is evident in their direct attempt to increase the TK stake within the patent system, thereby empowering and opening up TKMUP to the patent system. That such a paradigmatic shift in the country's approach to the patent system, particularly in the context of TKMUP, has occurred is evident under the 2008 Policy Framework for the Protection of Indigenous Traditional Knowledge through the Intellectual Property System. The Policy embraced the patent system as one of the best IP tools for protecting traditional knowledge, as the scope for ownership and commercial sharing is great.\textsuperscript{107} Hence, in SA it can be argued that the traditional excuse that intellectual property rights are hopelessly irreconcilable with traditional knowledge is no longer applicable. Such a shift in attitude may not be distanced from the realisation that there is a need for SA

\textsuperscript{104} See reg 33A (2) (b) and (d) of the *Patent Regulations* (GN R2470 in GG 6247 of 15 December 1978).

\textsuperscript{105} See Gervais 2005 *Mich St L Rev*.

\textsuperscript{106} See DST *Indigenous Knowledge Systems* 15-16.

\textsuperscript{107} GN 552 in GG 31026 of 5 May 2008 14.
to actively engage the patent system in response to a combination of factors such as economic globalisation, progress in genetic research, and increase in incidences of biopiracy. These factors would make non-engagement with the patent system an ill-judged option for the protection of TKMUP and other biodiversity-related TK in the country.108

The above anti-appropriation measures, when fully implemented, could potentially reduce or eliminate biopiracy and any acts of misappropriation of TKMUP in SA and beyond. For instance, the impact of the DRs in addressing the misappropriation of TKMUP is evident from the recent increase in the negotiation and signing of benefit-sharing agreements with indigenous communities by bio-prospecting companies seeking to commercialise products based on or derived from indigenous biological resources and associated TK.109 The fact that some of these companies may not necessarily wish to patent their inventions in SA points to the potential extraterritorial application of the DRs, although the compliance of such companies with the requirement may arguably be motivated mostly by the need to avoid adverse public opinion in their target developed countries rather than the need to have the subsequent patent enforced within SA. With respect to the NRS, its efficacy in mitigating instances of biopiracy particularly within SA may be affected by the formal or depository nature of the patent system as currently practised within the country. The situation will improve greatly once the substantive search and examination system is established, as proposed under the Draft IP policy.


109 Some of these agreements relate to the commercialisation of products based on indigenous plants such as the *Sceletium tortuosum* (Kanna, Kougoed), *Pelargonium sidoides*, and recently, *buchu*. See Chennells 2013 *LEAD Journal* 169-170.
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LIST OF ABBREVIATIONS

AIPJ Australian Intellectual Property Journal
BBKTA Batgate-Ba-Kgafela Tribal Authority
Cardozo Arts & Ent LJ Cardozo Arts and Entertainment Law Journal
CHM
CIPC Companies and Intellectual Property Commission
CJLT Canadian Journal of Law and Technology
CLR California Law Review
DEAT Department of Environmental Affairs and Tourism
DKR Digital Knowledge Repository
DRs Disclosure of Origins
DST Department of Science and Technology
EIPR European Intellectual Property Review
Fedora Flexible Extensible Digital Object and Repository Architecture
GIs Geographical indications
Ind J Global Legal Studies Indiana Journal of Global Legal Studies
IKS Indigenous knowledge systems
IP Intellectual property
<table>
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<td>International Patent Classification</td>
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<td>NIKMAS</td>
<td>National Indigenous Knowledge Management System</td>
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LEVERAGING TRADITIONAL KNOWLEDGE ON THE MEDICINAL USES OF PLANTS WITHIN THE PATENT SYSTEM: THE DIGITISATION AND DISCLOSURE OF KNOWLEDGE IN SOUTH AFRICA

EP Amechi*

SUMMARY

Traditional knowledge (TK) plays an important role in the global economy and is valuable not only to those who traditionally depend on it in their daily lives, but also to modern industry, especially the global biotechnology, pharmaceutical and agribusiness corporations. Yet the exploitation of TK by these industries does not usually lead to corresponding benefits to indigenous communities either in the form of attribution or compensation. Such misappropriations of TK are aided by the fact that the global intellectual property (IP) regime as presently structured is based entirely on the traditionally western or conventional description of knowledge, as are its conceptions of individual intellectual property ownership. In response to the fact that their calls for the reform of the global patent system have not be heeded, most developing countries, including South Africa, have resorted to the adoption of a radically different strategy in their approach to intellectual property, particularly as it concerns the protection of their TK from misappropriation. This is evident in the adoption of strategic measures in South Africa for the protection of various aspects of its TK forms from misappropriation, such as the National Recordal System (NRS) and Disclosure of Origins (DRs). This paper seeks to explore the implications of these measures in leveraging TK within the structure, content and conceptual framework of the patent system in South Africa. The focus is on TK associated with the medicinal uses of plants (TKMUP).

KEYWORDS: traditional knowledge; medicinal uses of plants; national recordal system; prior art; disclosure of origins; patent

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