

The Importance of Patenting Traditional Medicines in Africa: the case of Zimbabwe

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Abstract

This paper brings out the importance of creating domestic legislative structures that seek to protect traditional medicine and associated traditional knowledge (TK) in Zimbabwe. Traditional medicines are important to Zimbabwe's primary health care system, with an estimated 80% of the country's population relying on traditional herbal therapies. However, there are various challenges that are associated with integrating traditional medicines with the conventional health care system and these include the absence of clinical tests to ascertain the safety and efficacy of some of the drugs. The paper takes a scope at the current Intellectual Property Rights (IPR) system with particular emphasis on the Patent law. Due to the absence of sound policies that protect the Indigenous Knowledge Systems (IKS) in developing countries, issues of bio-piracy and bio-prospecting have been on the rise. As such there is need for developing countries to formulate their own IKS policies and patenting system that extends exclusive rights to indigenous communities for their traditional knowledge on medicinal plants so that they can benefit. The sui generis options for IKS protection that suit developing countries are discussed in this paper. A brief discussion on the important role biotechnology can play in the patenting of traditional medicines is made to understand how modern science can improve and protect the existing TK.

Key Words: Indigenous Knowledge System, Traditional medicine, bio-piracy, Patent Law, *sui generis* system.

1.0 Introduction

Indigenous knowledge systems (IKS) are a valuable global resource and efforts to secure their protection should be actively supported both at national and international level. Traditional knowledge of herbal medicines has the potential to translate into sound commercial benefits by providing leads for the development of useful products and processes in the pharmaceutical industry (WTO, 2006). The world market of herbal medicine based on traditional medicine is estimated to be over US \$60 billion (WHO, 2012). Most of the major modern drugs such as quinine, salicylic acid, artemisinin have been discovered from TK sources. There is need to protect the economic interests of the indigenous people and communities who generate and develop it. Basing on the global economic value of traditional knowledge, the holders of traditional knowledge should share in the economic benefits derived from that knowledge.

Scientists have shifted their interest toward traditional knowledge and associated genetic resources in a bid to solve some of the global health problems such as Human Immune-deficiency Virus (HIV) and cancers. The resurgence of interest in traditional knowledge and associated genetic resources has been stimulated by the importance of traditional knowledge as a lead in advancing the frontiers of science and technology (ARIPO, 2012). This article examines the importance of patenting traditional medicines in Zimbabwe and gives suggestions on statutory measures that can be adopted by developing countries to ensure the protection of IKS.

2.0 Literature Review and Conceptual Framework

2.1 Indigenous Knowledge Systems

There is no single definition of the term indigenous knowledge systems but a description of the concept gives one an idea of what it entails. The concept is referred to in different forms that includes terms like indigenous knowledge (IK), indigenous technical knowledge (ITK), ethno-ecology, ethno-botany, ethno-zoology, local knowledge, folk knowledge, traditional knowledge, traditional environmental (or ecological) knowledge (TEK) and people's science (Herman 2012). The term Indigenous or sometimes Traditional Knowledge (TK) seems to refer to that body of knowledge held by people who are not regarded as “developed” as far as modern science and civilization is concerned. Wherever this term is mentioned it is usually in relation to natives of a country or region whose history involves some kind of marginalization at one point or another from modern civilization.

According to Warren (1991), people in such communities depend on specific skills and knowledge that have been influenced by internal creativity and experimentation for their livelihoods over a long period of time (Warren, 1991 and Flavier, 1995). A major distinguishing characteristic of indigenous knowledge is that it is intergenerational. It is handed over from one generation to the next. Those who hold the knowledge hold it as it were in trust for future generations. It has been preserved, transferred, adopted and adapted in many situations due to its interaction with development processes (World Bank, 2012). Of late indigenous knowledge has gained prominence as people realize the role it has played over time in preservation of biodiversity. Basically, traditional knowledge is any knowledge, innovation, or individual or collective practice of an indigenous population or local community, having real or potential value, associated with a biological resource, protected or not by intellectual property legislation.

There is great diversity within and among communities. There is therefore no standard community that can be taken as a stereotype to represent all other communities. The relationship between a particular community and its environment or biological resources differs from what one finds in the next community. A community is defined in terms of shared social and economic relationships, the transmission of knowledge, values and customs. Some communities are said to define themselves in territorial terms or in terms of a particular natural resource or set of natural resources or in terms of shared activity (Mayet).

2.2 Intellectual Property Rights

Intellectual property rights (IPR) are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time after which the creation will be available to the public domain (WTO, 2012). These rights enable the creator to enjoy the benefits of his/her creation and act as an incentive fostering the development of new ideas in research. According to the World Intellectual Property Organisation (WIPO), efficient and equitable intellectual property systems can assist countries in realizing the potential of intellectual property as a catalyst for economic development and social well-being. The intellectual property system helps strike a balance between the interests of innovators and the public interest, providing an environment in which creativity and invention can flourish, for the benefit of all (WIPO, 2012).

Intellectual property rights as a collective term includes Patents, Copyrights, Trademarks, Geographic indications, Trade secrets and Registered (industrial) designs which can be collectively used for protecting different aspects of an inventive work for multiple protection. After a review conducted by the Convention on Biological Diversity (CBD) Secretariat, it was observed that the IPR system did not sufficiently ensure the flow of benefits back to the indigenous and local communities. An alternative '*sui generis*' IPR system known as the Traditional Resources Rights (TRR) was proposed to add on to the existing IPR system (Chitsike, 1998).

The World Intellectual Property Organisation (WIPO, 2012) defines a patent as an exclusive right granted for an invention, that is, a product or process that provides a new way of doing something, or that offers a new technical solution to a problem. According to Saha (2005), a patent is an exclusive right granted by a country to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies conditions stipulated in the law. Exclusive right implies that no one else can make, use, manufacture or market the invention without the consent of the patent holder.

The patent is available for a limited period of time, usually 20 years. Patents provide incentives to individuals by recognizing their creativity and offering the possibility of material reward for their marketable inventions. These incentives encourage innovation, which in turn enhances the quality of human life (WIPO, 2012). During the tenure of the patent, the patent owner has the right to decide who may or may not use the patented invention. Patent owners may also give permission to, or license, other parties to use their inventions on mutually agreed terms. Owners may also sell their invention rights to someone else, who then becomes the new owner of the patent. Once a patent expires, protection ends and the invention enters the public domain. Once the invention is in the public domain, the owner no longer holds exclusive rights to the invention, and it becomes available for commercial exploitation by others (WIPO, 2012).

3.0 Methodology

Information pertaining to this study was obtained through documentary research. Relevant literature from books, academic papers, journals, newspapers and the internet were used. Key informant interviews and consultations in the Ministry of Science and Technology Development were carried out in a bid to understand the government of Zimbabwe's position on the formulation and implementation of policies that govern the protection of indigenous knowledge systems (IKS). Information was gathered from government departments which include, the Patents Office in the Ministry of Justice, Legal and Parliamentary Affairs and the Ministry of Health and Child Welfare and other relevant stakeholders such as the Zimbabwe National Traditional Healers Association (ZINATHA) and the African Regional Intellectual Property Office (ARIPO).

4.0 Traditional Medicines and Zimbabwe's Health Care System

4.1 The role of Traditional Medicines in Zimbabwe's Primary health care system

Indigenous knowledge systems present cheaper and more affordable solutions to most of the human health care problems currently being faced in Zimbabwe and Africa at large. Treatment of various ailments using traditional medicines has emerged as the most significant health care alternative to modern medical practices. According to the World Health Organization, up to 80% of the world's population depends on traditional medicine for its primary health needs (Shetty, 2010). In many regions of the world such as Africa, South America and Asia where modern healthcare is not readily available or affordable, the general public continues to rely on traditional medicines which are based on locally available natural resources and cultural knowledge. In a public health context, medicine has to be readily available, accessible and affordable for it to be promoted within a particular community (Tan, 2008). Issues of quality, efficiency and efficacy of traditional medicines have been the main cause for its poor promotion in Zimbabwe's formal health care system but regardless of these issues, TM remains as the most prominent primary health care alternative in Zimbabwe.

According to a report that was released by the Zimbabwean Parliamentary Health Committee in 2010 more than 80 percent of Zimbabweans use traditional medicines (Nkatanzo, 2010). A decade-long economic crisis which sparked the flight of health professionals and decimated the country's health service has driven more Zimbabweans towards traditional medicines. Many Zimbabweans, unable to afford expensive private health care, have turned to traditional healers. Many primary health care problems like fever, upper respiratory tract infections and gastro-intestinal problems such as diarrhoea, dysentery, worm infestations, hepatitis, anaemia, arthritic conditions, and certain gynecological conditions have been managed at household level through the use of traditional herbal remedies (Nkatanzo, 2010).

After assessing the role that traditional medicines are playing in addressing health care problems, the Zimbabwean Parliamentary Health Committee in 2010 recommended the government of Zimbabwe to create a regulatory framework in terms of intellectual property rights, guidelines on traditional medicine research as well as guidelines for the manufacture and distribution of traditional medicines as a complement to the conventional medicine. In their report, Parliamentary Health Committee members alluded to the fact that Zimbabweans recognize and value the importance of traditional medicine as a source of alternative treatment. Hence, the need for government to set up statutory instruments that would ensure traditional medicines becomes a part of Zimbabwe's health care system (Nkatanzo, 2010). The promotion and integration of TM into the mainstream health care system is of significant importance because TM encompasses a large group of health care systems, practices and products that are evidence-based and effective (Abbott, 2009).

4.2 Challenges Associated with the Integration of Traditional Medicine into Zimbabwe's Health care system.

In Zimbabwe, the use of traditional medicines has been associated with witchcraft and traditional health practitioners have been labelled as witch-doctors. This negative stereotype of the traditional health system dates back to the colonial times when European missionaries introduced the western health care system. People were no longer confident in their own traditional health care system because of the stigma that had been attached to its use. During the colonial era colonial administrators and missionaries often discouraged the practice of traditional health care and frequently persecuted traditional practitioners. However, despite all this most Africans continued to rely on traditional medicine since it was the only convenient form of health care available. Government clinics and hospitals provided health care to government officials and a small African elite living in urban areas. Mission dispensaries and hospitals offered modern health care to a small fraction of the Africans living in rural areas (Dejong, 1991). What this basically meant was that a larger population who happened to be residing in the rural areas was relying mostly on traditional medicine. This shows the important role traditional medicines and their associated practices have played in Zimbabwe's primary health care system particularly in addressing the health problems affecting the rural folk. In 1980 after Zimbabwe gained its independence, traditional medical practitioners received formal recognition for their work. An association to register these health practitioners called the Zimbabwe National Traditional Healers' Association (ZINATHA) was formed (Mapara, 2009). However, despite their recognition being made formal, traditional medical practices have been sidelined from formal incorporation into the country's health care system.

There are various perspectives that exist regarding integration of traditional medicine with the conventional (modern) health system. From a utilitarian point of view, knowledge of traditional herbal medicines can be validated and absorbed into the modern medical system. There are several examples of drugs like Artemisia for malaria and salicylic acid for fever that have been integrated into the conventional (modern) health system (Shetty, 2010). In an integrated system, traditional medicine is officially recognized and incorporated into all areas of health care provision. This means that it is included in country's national drug policy, providers and products are registered and regulated, therapies are available at hospitals and clinics (both private and public), treatment with traditional medicine is reimbursed under health insurance, relevant research is undertaken, and education on traditional medicine is available (Payyappallimana, 2009). Countries in Asia such as China, Republic of Korea and Vietnam have used an integrated health care system that incorporates traditional herbal medicines (WHO, 2002). These countries therefore serve as models that can be used by Zimbabwe and other developing nations to come up with an integrated health care system that includes traditional health practices. The major challenge in this case would be the formulation and enactment of a national drug policy that unequivocally recognizes the role of TM in the health care system while lobbying for extensive scientific research in TM to ascertain safety and efficacy.

The major concern on TM therapies is that they are not always safe and effective, and their use can present unique challenges to national health authorities. Poor regulation and oversight, as well as a lack of comprehensive national policies on traditional medicine, may result in consumer confusion and the marketing of potentially dangerous or ineffective therapies. High-profile cases of adverse effects from herbal supplements have demonstrated the potential dangers of poorly regulated traditional medicine. *Ephedra Sinica*, for example, was banned in the United States after deaths occurred from use of this herbal medicine for weight loss and athletic enhancement, with disregard to its traditional dosage and contraindication (Payyappallimanas, 2009). This clearly shows that a regulatory environment that does not enforce good manufacturing practices and that fails to adequately monitor claims of health benefits can encourage the use of ineffective treatments.

The use of traditional medicines is widely practiced in Zimbabwe and this has been attributed to long-standing traditional beliefs in the efficacy of these herbal remedies. The active constituents of most of these TMs have not been clinically tested. Herbal remedies prepared from the extracts of plants such as *Euphorbia*, *Solanum*, and *Datura* species have been found to contain various potentially toxic agents that are detrimental to human health (Tagwirei et al., 2002). To enable traditional medicine to be integrated into Zimbabwe's health care system without the fear of poisoning there is a need for extensive clinical testing of all herbal remedies to be carried out to ascertain their safety and efficacy.

Another issue that should be noted on the integration of TM into the conventional health care system is that it poses a potential threat to biodiversity. The widespread use of TM coupled with the rapidly expanding international market for herbal products can eventually result in loss of biodiversity. The production of herbal pharmaceuticals requires large quantities of medicinal plants, which results in over collection of these plants. The end result is that these plants become depleted in the natural environment. In 1997, a particular species of African potato that was found to combat AIDS disappeared completely from its native land, the Democratic Republic of Congo, two years after its medicinal value was discovered (Zhang, 2004). To avert this problem the most ideal solution would be to engage in extensive agricultural activities aimed at producing these herbal plants in large quantities required on the international market.

5.0 Biopiracy and Bioprospecting

Bioprospecting is generally described as the search for naturally occurring chemical compounds and biological material. Biopiracy on the other hand is biological theft that involves the illegal collection of indigenous plants by corporations who patent them for their own use without fair compensation to the indigenous people in whose territory the plants were originally discovered (American Heritage Dictionary, 2009).

Traditional knowledge has played a significant role in the Research and Development programmes of industry and continues to be a substantial factor in the commercialization of natural products. The growing interest in traditional medicines as well as their economic importance has stemmed up a wide range of public policy issues including those associated with intellectual property protection (ARIPO, 2012). Bio-prospecting of African biological resources by big pharmaceutical companies and research institutions has witnessed an upsurge. This spate of interest in TM has been mostly generated by the fact that therapeutic moieties based on medical plants used by traditional health practitioners offer a relatively high success rate while the synthetic route for developing new medicinal agents has a relatively lower success rate.

Bio-piracy continues to be a major issue in Zimbabwe and the rest of Africa at large. In 1999 a patent on a powerful fungicidal ingredient was granted to a research professor at the University of Lausanne in Switzerland. This patent was based on traditional Zimbabwean knowledge and on the root of the tree "*Swartzia Madagascariensis*." This leguminous tree is found throughout tropical Africa and produces phytochemical compounds used for medicinal purposes. The leaves have been reported to cure scabies and cutaneous infections while the bark has been preferably used to cure toothaches. The roots of this tree contain a very strong antifungal ingredient while extracts from the flowers can be used as insecticides to decrease the transmission of dengue, an infectious disease transmitted by mosquitoes. *S. Madagascariensis* has proved to be of enormous economic importance with its estimated market value being over US\$1 billion (Mutandwa and Moyse, 2003). Knowledge of this tree and its medicinal value had been kept by the indigenous communities who happen to be, in essence, the sole custodians of this tree.

Prior to the granting of this patent the American pharmaceutical company, Phytera and the University of Lausanne signed an addendum to a material transfer and confidentiality agreement. In this agreement the two parties agreed to a royalty payment of 1.5% of Phytera's net sales of the fungicidal ingredient derived from *S. Madagascariensis*. This agreement was made in clear violation of the principle of "prior informed consent" contained in the Convention on Biological Diversity which states that: "Access to genetic resources shall be subject to prior informed consent of the contracting party providing such resources" (Mutandwa and Moyse, 2003). In this case the concerned stakeholders, that is, traditional healers, local communities and the state of Zimbabwe were not correctly informed prior to the Swiss University's prospecting of Zimbabwe's biological resources and traditional knowledge (Mutandwa and Moyse, 2003). There were no mutually agreed terms for a fair and equitable benefit sharing mechanism that would encompass all the relevant stakeholders. The Researcher was obliged to share 50% of any royalties with the National Botanic Garden of Zimbabwe and the University of Zimbabwe. The University of Zimbabwe and the Zimbabwe National Traditional Healers Association (ZINATHA) were not involved in these negotiations between the University of Lausanne and Phytera. In this case, Zimbabwe as the country of origin of the biological resource did not benefit much from the arrangement.

Zimbabwe challenged this arrangement through NGOs which included the Community Technology Development Trust (CTDT), ZINATHA and the Southern and Eastern Africa Trade and Information Network (SEATINI) demanding that an Access and Benefit Sharing agreement be negotiated including all the main stakeholders in Zimbabwe and that the contract between the University of Lausanne and Phytera be cancelled and the patent withdrawn. This case is one of many other cases of biopiracy that have seen Africa being hoodwinked of its rights to exclusive ownership of its natural resources and rich biodiversity.

Another case of biopiracy that has occurred in Africa is that of the Rosy Periwinkle. The Rosy Periwinkle, known by the botanical name *Catharanthus roseus* (also known as the *Vinca rosea*) is a herb native to the island of Madagascar. It is a branched perennial shrub with oval shaped leaves and white or pinkish flowers each featuring five lobed petals. In 1954, an American pharmaceutical company, Eli Lilly, extracted two alkaloids, Vinblastine and Vincristine, from the Rosy Periwinkle, which were believed to have anti-cancer activity. Traditionally, the Periwinkle had been used as an anti-diabetic, but after subsequent testing, Eli Lilly discovered that it had anti-cancerous properties as well. Eli Lilly was granted a patent for isolating the two alkaloids and took credit for the Rosy Periwinkle. The firm patented drugs made from the Rosy Periwinkle and went on to make millions of dollars with the drugs, but the people of Madagascar never received any compensation for their traditional knowledge of the herb's healing abilities (CWRU, 2012).

The discovery of Vinblastine and Vincristine from the Madagascan Periwinkle, prompted the U.S National Cancer Institute (NCI) to initiate a programme for the systematic testing of plants for anticancer activity. Between 1960 and 1982 The United States Department of Agriculture (USDA) and the NCI collaborated in the collection and testing of approximately 35,000 plant samples collected mainly from temperate regions in some sixty countries. (CWRU, 2012) This US programme of bioprospecting was a clear act of bio-piracy. This exercise was undoubtedly carried out in developing countries that had no laws protecting their indigenous knowledge. This case study showcases the extent to which bio-piracy has been stemmed up by developed countries in their bid to usurp genetic resources in Africa and the entire developing world for their own economic gain.

Despite the formulation and enactment of laws concerning benefit sharing, only an extremely small percentage of a company's profits are given to the nation from which the resource is derived. This was evident in Zimbabwe's case of the *S. Madagascariensis* where the state was given a mere 0.75% of profits from the exploitation of its natural resource (Mutandwa and Moyse, 2003). Benefit sharing holds that profits obtained from patents on indigenous resources must be shared between the patent holders and the indigenous communities from which the materials are derived. This entails the equitable sharing of profits between all relevant stakeholders so that in the end everyone benefits.

Zimbabwe has not yet established a sound legislation which adequately addresses the issues of access and benefit sharing for biological resources found in her territory. This means that anyone can access biological resources as well as indigenous knowledge and develop products and patent without remitting any meaningful royalties to the indigenous communities. Developing countries like Zimbabwe need to develop relevant and robust legislative policies that address issues of IKS protection and ABS as well as prevent developed nations from having free access to genetic resources and indigenous knowledge.

Developed countries are accruing enormous benefits from biological resources which they acquire from developing countries but they are reluctant to develop benefit sharing schemes with developing countries. In a bid to entrench their position on the global arena and assert their economic dominance, developed nations have crafted international laws which protect themselves. The challenge for developing countries is on how to protect their biological resources from being accessed freely by developed countries as well as press for sharing of benefits derived from the use of these resources.

5.1 Nagoya Protocol on Access and Benefit Sharing

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (Nagoya Protocol) is an international instrument that was adopted in October 2010 under the auspices of the CBD. Its objective is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity (CBD, 2011).

To advance fair and equitable benefit sharing, the Nagoya Protocol also addresses appropriate access to genetic resources and transfer of relevant technologies. According to Suchanandan, (2012 In: The Herald, 2012) the reason why developing countries are being preyed upon by the rich countries is because they are not implementing the necessary instruments to protect their resources and ensure locals benefit. The Nagoya protocol therefore presents developing countries with a legislative framework they can adopt to ensure protection of their IKS and genetic resources (The Herald, 2012). Zimbabwe has not yet ratified the Nagoya protocol but has set up a legislative framework, Environmental Management Act (EMA), in accordance with CBD's Article 8(j). EMA coordinates national environmental management activities which mandate the issuance of Access and Benefit Sharing guidelines but it has failed to adequately address the issue of ABS of natural resources.

6.0 Science, Technology and Innovation (STI) Policy

Three decades after attaining independence, no sound policy governing the protection of indigenous knowledge systems had been formulated in Zimbabwe. This time gap left the country's traditional knowledge vulnerable to unscrupulous scientists from developed countries that were busy siphoning information without prior consent of the indigenous communities. In 2002, the government of Zimbabwe drafted an STI policy but this policy lacked clarity on protection of traditional knowledge. Just recently, a second Science and Technology policy was drafted by the government of Zimbabwe with help from UNESCO and the African Technology Policy Studies (ATPS) Institute. The STI policy stipulated the need to develop a national database on IKS with a view to identifying aspects that can be exploited using modern S&T for national benefit. The policy underscored the need to promote research on potential applications of IKS to future national developmental challenges. The policy also included the development of courses on IKS that are suitable for inclusion in the school curricula (STI Policy, 2012).

In a key note address at the commissioning of the STI policy the President of Zimbabwe, Robert Mugabe, underscored government's commitment to see to it that this policy is implemented. In his address the President reiterated the need for sound policy formulation to foster rapid and sustainable socioeconomic development. He also pointed out to the fact that the absence of effective policies on Science and Technology which translate into concrete plans for effective exploitation of natural resources was one of the factors that has led to dissipation of Africa's natural resources (STI Policy, 2012).

While this policy is seen as a step in the positive direction towards protecting Zimbabwe's indigenous knowledge systems, this policy will only prove its worth when fully implemented. There is need for the policy makers to give a clear and detailed plan that will elucidate on how this STI policy is going to be implemented. The policy is a mere outline of what intends to be done but it is not specific on the course of action that will be taken to ensure that each of the stated goals is achieved. The policy seems to generalize on the issue of indigenous knowledge systems and does not give any concrete plans or statutory suggestions on how protection will be conferred to IKS. It is still too early to spell doom for this STI policy that has only been in effect for a few months now but much still waits to be seen on how each of its specific goals will be achieved. In the past, failure to formulate and implement policies aimed at protecting Zimbabwe's traditional knowledge has left large multi-national bio-pharmaceutical companies with the unimpeded opportunity to exploit indigenous knowledge for their own gain. These bio-pharmaceutical companies have reaped enormous capital benefits that should have been channeled towards the development of Africa.

While much blame may be placed on policy makers who have failed to swiftly formulate policies as well as monitor the implementation of these policies, many factors such as lack of capital resources and funding to implement the policies also come into play. In an address, the Prime Minister of Zimbabwe, Morgan Tsvangirayi alluded to the fact that funding for the implementation of the STI Policy was absolutely necessary and that the government of Zimbabwe had already made a commitment to invest at least 1% of its gross domestic product on research and development (STI Policy 2012). However, looking at the current economic melt-down in Zimbabwe, 1% of GDP is just but a drop of water in the desert. Despite this exuberant exhibition of commitment by policy makers in Zimbabwe, their hands remain tied behind their backs due to lack of adequate funding for policy implementation. The issue of funding therefore stands out as the biggest problem hampering the implementation of policies aimed at protecting Africa indigenous knowledge systems. This problem is not endemic to Zimbabwe alone but to more than 80% of developing countries on the African continent.

7.0 Traditional Medicine and Intellectual Property Protection

According to the current IPR system, IKS (including traditional medicines) are not eligible for intellectual property protection. The current global IPR regime recognizes individual ownership of intellectual property rights. This makes it inadequate to cater for TK which can be collectively owned by a family or community. Limitations that arise in the protection of TK by the current IPR system are centered on the criteria used to grant eligibility for patent protection. The requirements include novelty, inventive step and commercial viability. Traditional knowledge does not meet any of these requirements because it is not new, it has no inventive step and the restriction of ownership within families and communities does not make it commercially viable. The families or communities in possession of specific TK take pride in keeping it secret and are reluctant to divulge any information that they feel exposes their knowledge to thieves (Wekundah, 2012). Another issue of concern is that TK is held in perpetuity, that is, owners of this knowledge pass it down to their descendants who in turn pass it down to succeeding generations. This means that if exclusive rights of ownership of a particular TK are to be awarded to a certain community or family, these rights will be extended to all the succeeding generations of that community or family. Under the current global IPR system, patent protection is given over a specified period of about 20 years. Perpetual protection of IKS on the other hand has no time limit which makes it difficult to protect using the current IPR system. This leads us to the question, "What can be done to improve the current global IPR system so that it can adequately cater for the protection of IKS?"

7.1 Convention on Biological Diversity

The Convention on Biological Diversity (CBD) was the first international agreement to acknowledge the role and contribution of indigenous and local communities in the conservation of biodiversity. It is a progressive instrument when it comes to establishing legal statutes to protect and regulate biodiversity at national level. The CBD contains important provisions that recognize the rights of indigenous and local communities and the important role they play in the conservation of biodiversity especially in regard to genetic resources and benefit sharing (Chitsike, 1998). Article 8(j) of the CBD is subject to national legislation and states that countries who are signatories to the CBD should enact legislation that respects, preserves and maintains knowledge, innovations and practices of indigenous and local communities (Wekundah, 2012).

7.1.1 Environmental Management Act

Zimbabwe has made initiatives for Article 8(j) of the CBD by establishing the Environmental Management Act (EMA) of 2003 which provides for a comprehensive national access and benefit sharing framework. Under EMA's Access to Genetic Resources and Traditional Knowledge Regulations, this statutory instrument advocates for an equitable access regime and benefit sharing mechanism for traditional medicinal plants, as well as intellectual property rights that recognize the contribution of indigenous knowledge to primary health care and development of modern medicines (CBD, 2012). However, documentation on traditional knowledge, innovations and practices in Zimbabwe is poor. This has been one of the greatest barriers to realizing the full potential of EMA in addressing the issues of IKS protection and ABS of genetic resources. To ensure the successful implementation of EMA, there is need to develop a system for inventory of traditional systems and practices.

7.2 Trade Related Intellectual Property Rights (TRIPS)

This treaty was established by the World Trade Organisation and serves to strengthen intellectual property as one of its three trade pillars, the others being trade in goods and trade in services. TRIPS has set minimum standards for countries to abide by in the protection of IPRs and according to its provisions, member states are not obliged to extend patent protection to plants and animals. Article 27.3(b) of the TRIPS Agreement however, urges member states to provide patent protection for plant varieties by formulating and implementing a *sui generis* system (a system of its own kind) which is better designed to suit national interests whilst taking into account the protection demands of informal and local communities. In the context of the TRIPS Article 27.3(b), all member states must establish some form of intellectual property protection that best suits their interests but those who do not wish to introduce patent rights have the choice to provide an alternative protection protocol (Garwe, 2008). Under TRIPS, the formulation of tailor-made legislation (*sui generis*) to protect traditional herbal medicines is of paramount importance because it accords governments the opportunity to draft national policies on IPR that have international recognition. This affords effective protection for IKS at national level as well as conferring protection to the indigenous communities who generate this knowledge.

7.3 Comprehensive Biodiversity Legislation

This is an encompassing legislation which deals with the protection and sustainable use of biodiversity. Taking such a broad approach would ensure that issues such as access to genetic resources, biosafety, IPRs and communal rights that involve biodiversity will be collectively addressed. The aim of this approach is to enforce coherent all-encompassing policy measures in the national context that favour national interests (Seiler, 1998 and Wekundah, 2012). For many legislators, this is an ideal approach as it can assure greater consistency. On the other hand, the corporate sector may not be in favour of it as it creates too many cross-sectoral pressures. There is a risk that a comprehensive biodiversity legislation approach may not be able to provide specific mechanisms for local communities to protect and promote their interests (Grain, 1997).

The Community Intellectual Rights and Collective Rights approach seems favorable for developing countries such as Zimbabwe because it is centered on collective patent rights being given to a community that is in possession of the traditional knowledge. The establishment of community trust funds to ensure the equitable distribution of royalties would be an important accession to this approach. Community intellectual rights enable the communities to protect their knowledge on TM as well as establish a platform enabling these communities to directly benefit through the remittance of royalties by firms who wish to commercially exploit their knowledge. However, the CIR legislation approach tends to focus more on commercial rights and benefit-sharing objectives and draws on existing IPR concepts, rather than fully reflecting indigenous peoples' needs and aspirations. Taking a more comprehensive approach, which entails not only legal protection of TK rights, but in-situ conservation of TK systems, securing land and resource rights, empowerment and self-determination would be ideal in that it addresses the indigenous people's needs and aspirations (Swiderska, 2004). Zimbabwe seems to have taken this comprehensive all-encompassing biodiversity legislation approach as seen by the enactment of the EMA to oversee the protection of biodiversity and address issues of Access and Benefit Sharing (ABS) of natural resources. Zimbabwe therefore, needs to come up with a hybridized *sui generis* approach where Community Intellectual Rights and Collective Rights are included in the Comprehensive Biodiversity Legislation to ensure full protection of traditional herbal remedies.

8.0 Challenges associated with patenting traditional medicines in developing countries

One of the major challenges in patenting traditional medicines lies in the fact that the current IPR systems were designed by developed countries and are based on private rights. Collective knowledge or rights are only recognized if the community is a company. This prevailing western model of IPRs is detrimental to developing countries and their communities because it excludes all innovations that take place in the intellectual commons, for example in traditional communities (Chitsike, 1998). Traditional communities come from and are characterized by a background of sharing, where genetic resources are treated as common property. Since time immemorial, Africa's people have depended on free and open access to that diversity of food, fuel, medicine, shelter and economic security, exchanging and trading of such resources among themselves. In the African context, knowledge and experience are communally owned and so the concept of property rights does not exist. During the colonial period many colonial authorities in African countries removed rights to resources from communities and vested them in individuals as a prerequisite for legal protection (Kameri-Mbote, 2000). What this meant was that as long as resources are not owned by an individual or company there were no binding ownership rights and access to such resources was open to all. It seems the current global model of patent law has these colonial sentiments that do not recognize the collective ownership of resources by communities. There is a dire need for developing countries to come up with their own model of a patent system that will accord communities the rights to be exclusive owners of their traditional knowledge and resources.

In a bid to achieve intellectual property protection for traditional medicine, countries like India have established Traditional Knowledge Digital Libraries aimed at preventing misappropriation. The Indian TKDL contains formulations used in traditional medicine. The database was created following a public outrage over the patenting of an Indian traditional herb, turmeric, in the United States. Zimbabwe has espoused the Indian TKDL model and this is evident in Zimbabwe's STI policy which echoes on the need to develop a national database on IKS. Establishing a national database on IKS would make information on traditional medicine publically available thus protecting against misappropriation but it also makes it more difficult for communities to benefit financially from traditional medicine. Once information on traditional medicine becomes public knowledge it becomes more difficult to protect it and anyone can use it without the consent of the communities who own that knowledge.

In most developing countries the knowledge on traditional medicine is not publicly available, and attempts to obtain patent protection may prove problematic because of disclosure requirements. Disclosure requirements tend to be a problem because traditional knowledge may be a form of 'trade secret' for which disclosure is ordinarily detrimental to the trade secret holder. According to the current international patent law, patent applications require disclosure.

China has enacted patent laws that require disclosure of the source of genetic resources in domestic patent applications (Abbott, 2009 and China Daily, 2009). This move was taken to foster the protection of its traditional medicine and biodiversity resources for commercial exploitation. Apart from shielding its large domestic market for pharmaceutical and traditional medicine products based on native biological materials against uncompensated exploitation by foreign companies, China has extended its interests into promoting exports of biological resource-based inventions to foreign markets (Abbott, 2009).

There is need for Zimbabwe and other developing nations to formulate domestic patent laws aimed at protecting their traditional medicines and biodiversity. By enacting these laws, developing countries will be able to commercially exploit their own natural resources and foster economic growth realized from exploitation of these natural resources, in this case, traditional herbal medicines. Basing on the Chinese patent law model developing countries need to adopt patent application processes that include the disclosure of the source of origin of genetic resources and TK used in the invention, as well as evidence of prior informed consent and benefit sharing. This could help prevent inappropriate patents and facilitate benefit sharing that is based on mutually agreed terms.

10.0 Conclusion

Developing countries need to step up efforts to protect their indigenous knowledge on herbal medicines as it plays a major role in the primary health care system. Traditional medicines have the potential to boost the economies of many countries on the African continent if statutory measures are put in place to govern their protection. Zimbabwe needs an efficient and equitable intellectual property system guided by a sound intellectual property policy and should adopt a *sui generis* system and formulate an IKS policy that is specific on the protection of TM. A patenting system that accords collective rights of ownership to communities should also be established and the aspect of benefit sharing should be addressed at national level to ensure that local communities benefit.

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