International Journal of Research in Engineering and Applied Sciences(IJREAS)
Available online at http://euroasiapub.org/journals.php
Vol. 11 Issue 12, December -2021,
ISSN(O): 2249-3905, ISSN(P) : 2349-6525 | Impact Factor: 7.196| Thomson Reuters ID: L-5236-2015

TRADIONAL KNOWLEDGE IN BIO TECHNOLOGY AND INNOVATION

AUTHOR-T.SHEELA.
CO-AUTHOR-DR.R.CHOLAIRAJAN & R.KRISHNAPRIYA

ABSTRACT

The focus of the paper is to explore the economic benefits that may be derived by the traditional knowledge holder based on biotechnology innovations. The main objective of the paper is to show that holders of traditional knowledge may develop their traditional knowledge through biotechnology based innovation and that the holders of traditional knowledge may use biotechnology to advance their economic position. The traditional debate relating to traditional knowledge and biotechnology mainly discusses upon the following issues: the impact of biopiracy on the traditional knowledge, the rights of the indigenous people to access and benefit sharing, the impact of patent protection on the holders of traditional knowledge, the rights of the holder of the traditional knowledge to have an unimpeded rights over the knowledge, and the exploitation of traditional knowledge by those from outside the community or family or individual that owns the traditional knowledge. The paper takes a different perspective of the debate. The paper endeavours to explain how biotechnology can assist the holders of the traditional knowledge to innovate for gaining economic benefits; and to explore what are the obstacles in the development of biotechnology-based traditional knowledge innovation. The paper will propose methods on how developing countries and the least developed countries can develop local biotechnology businesses based on traditional knowledge. The paper endeavours to answer the following questions: what are traditional knowledge and biotechnology; how biotechnology can assist the holders of the traditional knowledge to innovate for gaining economic benefits; and what are the obstacles in the development of biotechnology-based traditional knowledge innovation. To answer to above questions the paper will offer definitions of the term "traditional knowledge," define the term biotechnology and explore the economic opportunities for traditional knowledge based innovations. To show the opportunities for innovation and economic benefits from the biotechnology innovation in traditional knowledge, the paper will use a case study to show how an innovative professor from Taiwan Province, China has developed a global business based on the traditional Chinese fermentation techniques.

INTRODUCTION

Based on the development of enzyme-based nutraceuticals products using fermentation methods that have been scientifically developed from traditional Chinese fermentation formula, using fruits and vegetables. The business has managed to develop the traditional fermentation into high technology bio-process fermentation methods using bacteria and yeasts. The traditional fermentation method is based on yeast as the catalyst and this has been modernised with the use of some additional bacteria. The formula of the catalyst is not patented and remains within the family as a trade secret. The business is now conducting further research to develop pharmaceuticals using the methods and the ingredients that the family owns with its collaborative partner in Malaysia through a joint venture. The Malaysian Government has awarded 1st Global, the Malaysian biotechnology company, a research grant worth about USD 1.4 million to develop pharmaceuticals using the innovative technology developed using the Chinese fermentation methods. The paper is arranged in the following manner. Part 1 is the Introduction. Part 2 begins by defining the two main terms here, namely 'traditional knowledge' and 'biotechnology'. Part 2 will also discuss the relationship between traditional knowledge and intellectual property. This is followed by the discussion on the economic benefits offered by biotechnology by looking at the economic data on the various aspects of biotechnology activities. Part 2 will then discuss the differences between the modern innovations

based traditional knowledge and the innovations that exploits the traditional knowledge.

Traditional Knowledge and Biotechnology

Traditional Knowledge There is no single definition of the term "traditional knowledge". Lenzerini states that there are clearly innumerable forms of traditional knowledge and that would be difficult to subsume into a single definition.1 However there are several attempts being made to define the term 'traditional knowledge'. According to WIPO, traditional knowledge is a multifaceted concept that encompasses several components. WIPO suggests that the terms "traditional knowledge" and "indigenous knowledge" could be interchangeable. What characterizes traditional knowledge is the fact that, generally, it is not produced systematically, but in accordance with the individual or collective creators' responses to and interaction with their cultural environment. In addition, traditional knowledge, as representative of cultural values, is generally held collectively. What can be sometimes perceived as an isolated piece of literature such as a poem, or an isolated technical invention such as a plant resource to heal wounds, is actually an element that integrates a vast and mostly coherent complex of beliefs and knowledge. This element is controlled and vested collectively in the community and not in the hands if the individuals who use such isolated pieces of knowledge. Furthermore, most traditional knowledge is transmitted orally from generation to generation, and thus remains largely remain undocumented.2 According to WIPO, contrary to common perception traditional knowledge is not necessarily ancient. Traditional knowledge evolves all the time, a process of periodic, even daily creation as individuals and communities take up the challenges presented by their social and physical environment. In many ways therefore, traditional knowledge is actually contemporary knowledge.

Traditional knowledge is embedded in traditional knowledge systems, which each community has developed and maintained in its local context. The commercial and other advantages deriving from that use could give rise to intellectual property questions that could in turn be multiplied by international trade, communications and cultural exchange. CBD on the other hand, refers to indigenous people's knowledge, innovations and practices to highlight the intellectual effort of indigenous and local communities as they relate to biodiversity conservation and sustainable use.3 Hansen and van Fleet state that traditional knowledge is the information that people in a given community, based on experience and adaptation to a local culture and environment, have developed over time, and continue to develop. This knowledge is used to sustain the community and its culture and to maintain the genetic resources necessary for the continued survival of the community. 4 Hansen and van Fleet suggest that the term traditional knowledge includes mental inventories of local biological resources, animal breeds, and local plant, crop and tree species. It may include such information as trees and plants that grow well together, and Developing Biotechnology Innovations Through Traditional Knowledge 3 indicator plants, such as plants that show the soil salinity or that are known to flower at the beginning of the rain. It includes practices and technologies, such as seed treatment and storage methods and tools used for planting and harvesting. Traditional knowledge also encompasses belief systems that play a fundamental role in a people's livelihood, maintaining their health, and protecting and replenishing the environment. Hansen and van Fleet also suggest that traditional knowledge is dynamic in nature and may include experimentation in the integration of new plant or tree species into existing farming systems or a traditional healer's tests of new plant medicines. The term "traditional" used in describing this knowledge does not imply that this knowledge is old or non-technical in nature, but "tradition based." It is "traditional" because it is created in a manner that reflects the traditions of the communities, therefore not relating to the nature of the knowledge itself, but to the way in which that knowledge is created, preserved and disseminated. The International Institute for Environment and Development (IIED) outlines certain

characteristics common to many traditional knowledge systems, in particular, the way in which knowledge, cultural values, customary laws, biological resources and landscapes are inextricably linked and together maintain the integrity of knowledge systems.5 The common characteristics are: a) Based on a number of reasons, traditional knowledge is linked to biological resource. This is because thousands of traditional crop varieties are themselves the product or embodiment of knowledge of past and current generations of farmers which have developed, conserved and improved them. Hence, indigenous societies, knowledge and resources cannot be separated. b) Traditional knowledge is linked to landscapes. This is because knowledge is often acquired from particular sites in the landscape of spiritual significance such as sacred lakes, rivers, forests or mountains. IIED contents that traditional forms of governance and belief systems often operate at landscape scales, through customary institutions for management of common property resources. Where peoples have lost their traditional territories or no longer have access to sacred wilderness areas, the processes which sustain and create traditional knowledge and beliefs are likely to be severely weakened or lost, thus putting traditional knowledge at serious risk.

Traditional knowledge is also linked to cultural and spiritual values. IIED argues that the social processes by which traditional knowledge is acquired and used, which sustain knowledge systems and give traditional knowledge its distinct character, are shaped by the unique cultural and spiritual values and beliefs of communities. Many traditional knowledge holders believe that all parts of the natural world are infused with spirit and that it is from these spirits or gods that knowledge is acquired. Spiritual values and beliefs are closely interlinked with, or expressed in, customary laws which govern the way knowledge is acquired and shared and the rights and responsibilities attached to possessing knowledge, and have a strong spiritual character. There are many definitions of biotechnology, which can be based on classical or modern biotechnology.6 Grubb defines classical biotechnology as the production of useful products by living microorganisms7 and this includes process like fermentation that produces beer or food items like the Indonesian delicacies of "tempe" (fermented soybean cakes). On the other hand, modern biotechnology began in the 1970s with the research into genetic engineering on the two basic techniques of recombinant deoxyribonucleic acid (DNA) technology and hybridoma technology.8 Modern biotechnology generally involved recombinant DNA and/or cell fusion technology.9 This involves the applications of (a) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (b) fusions of cells beyond the taxonomic family; that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.10 CBD defines biotechnology as any technological application that uses biological systems, living organisms or derivatives, to make or modify products or processes for specific use.11 While the OECD defines biotechnology as "The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."12 Biotechnology is used in several fields as in agriculture, pharmaceutical industry and medicine. Biotechnology combines disciplines such as genetics, biochemistry, microbiology, and cell biology along with information technology, chemical engineering, robotics etc., and biotechnology, globally recognized as a rapidly emerging and far-reaching technology. One Indian author states that biotechnology is described as the "technology of hope" for its promise of food, health and environmental sustainability.13 2.2 Traditional Knowledge and Intellectual Property With innovations and improvements in the field of traditional knowledge by the knowledge owner come the questions of protection, or intellectual property rights. More and more traditional knowledge holders are aware of the intellectual property issues, including the rights to protection of the traditional knowledge and at the same time the rights

to obtain the conventional intellectual property such as patent and copyrights on the improvement made to the traditional knowledge.. "as far as possible and as appropriate, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities, embodying traditional lifestyles, relevant to the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." It could be argued that lack of protection of traditional knowledge could open the traditional knowledge to manipulation by third parties, resulting in the losses on the part of holders of the traditional knowledge. Just as intellectual property rights facilitate and encourage industrial innovation and creativity through market incentives, mechanisms to protect traditional knowledge should be designed to facilitate and encourage traditional innovation.14 The protection of traditional knowledge can take the form of defensive protection or positive protection. For the development of innovation based on traditional knowledge, one may have to look at the positive protection, where the holder of the traditional knowledge could possibly rely upon the conventional intellectual property system to provide certain level of protection to traditional knowledge. However, relying on the conventional intellectual property system alone may not provide an adequate protection for traditional knowledge holders. This is because the conventional intellectual property protection has little regard towards the protection of traditional knowledge and maintains the concern that inventions involving traditional knowledge should not be patented on the ground that they are already in public domain and thus should not qualify as new inventions. Thus, an alternative intellectual property protection system may have to be in place. A carefully designed intellectual property regime in traditional knowledge could help developing countries become full players in global agricultural markets, whilst equitably rewarding indigenous peoples for their contributions to international well-being.15 This may include developing a sui generis system which seems to be the logical answer to the need to protect traditional knowledge. National experience by countries will certainly play a very important role in the development of effective means of protection of traditional knowledge. The sui generis system could also be combined with the provision on undisclosed information in Article 39 of TRIPS Agreement. Article 39.2 of TRIPS Agreement provides that protection must be provided to information that is secret, has commercial value because it is secret, and has been subject to reasonable steps to keep it secret. Article 39 of TRIPS Agreement has a role to play in providing intellectual property protection for traditional knowledge as the unique feature of the traditional knowledge is that "traditional knowledge is not always disclosed to people external to the community of its holders, since it is sometimes kept secret, at least to a certain extent, even within the community itself."16 At the same time the sui generis system for protection of traditional knowledge may also provide simultaneous protection of the title of "ownership" by traditional knowledge holders of both the knowledge and of the resources related to such knowledge.17 This is because of the relationship of the traditional knowledge with the resources, such as plant resources forming part of the knowledge, where it has 14 IIED, note 5 above. 15 T.Cottier and M.Panizzon, Legal Perspectives on Traditional Knowledge: The Case For Intellectual Property Protection, JIEL 7(371), 2004. 16 F. Lenzerini, note 1 above, 120. On the same issue of secrecy and family ownership in the Traditional Chinese Medicine see X. Li, Overcoming market Failure and Rationalising Traditional Indigenous Traditional Knowledge Protection Regime: An Economic Approach and Case Study in China, University of St.Gallen, Bamberg, 2007. 17 F. Lenzerini, note 1 above, 120. 6 Research Papers been suggested that "biodiversity-related traditional knowledge derives its value from the genetic resources to which it applies."18 2.3 Economics Opportunity of

International Journal of Research in Engineering and Applied Sciences(IJREAS)
Available online at http://euroasiapub.org/journals.php
Vol. 11 Issue 12, December -2021,
ISSN(O): 2249-3905, ISSN(P) : 2349-6525 | Impact Factor: 7.196| Thomson Reuters ID: L-5236-2015

Traditional Knowledge One must recognise that there is an abundance of economic opportunities from the working of and with traditional knowledge. The many traditional debates seen on the global level relate to how multinational pharmaceutical companies and researchers from developed countries exploit and manipulate traditional knowledge for their own commercial gains with little regard to the benefit of the traditional community or family that owns the knowledge. However, the paper argues that the traditional community or family could foster innovations and derive economic benefit from traditional knowledge using biotechnology. In order to appreciate the use of biotechnology in the development of innovation based on traditional knowledge, one has to acknowledge the growing importance of biotechnology in general in the global economy. According to the MarketLine Biotechnology Global Industry Guide 2008,19 the global biotechnology market grew by 10.6 percent in 2007 to reach a value of USD 172 billion and the compound growth between 2003 and 2007 was at 10.7 percent. In value terms, the medical and health care segments generated 69.4 percent of the global biotechnology market value. The service provider segment generated a further 14.7 percent of the global biotechnology market value. In terms of geographical market segmentations, the Americas generated 53.7 percent of the global market value, followed by 24.5 percent in Europe. It is predicted that the global biotechnology industry will grow higher, although the growth rate will be slower between 9-11 percent. The report does not take into account the current global financial crisis which may affect the ability of biotechnology companies to raise funds. Based on the Asia Pacific Biotechnology Market Report 2008,20 the biotechnology market in the Asia Pacific region grew by more than 11 percent between 2004 and 2006 with market value of USD 39.16 billion at the end of 2006. The Report states that Japan, China and Taiwan Province, China are the largest biotechnology markets in the Asia Pacific Region with a combined market share of nearly 76 percent in 2006. The Report also states that bio-pharma industry, comprising of vaccines, therapeutics, diagnostics and other products will emerge as a major segment of the Asia Pacific Biotechnology industry. Based on the two reports, it could be argued that traditional knowledge-based biotechnology products could also grow in value over the next few years. There are several segments of biotechnology sectors that could be of interest to traditional knowledge holders to innovate further. One of such areas is in the area of TM and CAM. The awareness of the economic benefit from the traditional knowledge leads to the WHO to unveil its first Global Strategy for TM and CAM 2002-2005 in January 2006. According to WHO, CAM is widely used in developed countries: 70 percent of the population in Canada, 48 percent in Australia, 42 percent in USA, and 38 percent in France. Spending on TM and CAM world-wide is significant and growing rapidly. USA, CAM expenditure has reached USD 2.7 billion per year and in Australia and Canada USD 80 million and USD 2.4 billion respectively. The global market for TM stands at USD 60 billion.21 One of the sub-sectors of the TM and CAM is the supply of medicinal plants, botanical drug products and raw materials. The World Bank reports trade in medicinal plants, botanical drug products 18 H.Ullrich, 'Traditional Knowledge, Biodiversity, Benefit-Sharing and the Patent System: Romantics v. Economics?' in F.Francioni and T.Scovazzi (eds), Biotechnology and International Law (Oxford, Hart, 2006), 201, 202. 19 MarketLine, Biotechnology Global Industry Guide, (London, 2008). 20 RNCOS Industry Research Solutions, Asia Pacific Biotechnology Market (2008-2012), (Delhi, 2008). 21 World Health Organization, the Global Strategy for Traditional Medicine, (Geneva, 2002). Developing Biotechnology Innovations Through Traditional Knowledge 7 and raw materials is growing at an annual growth rate between 5 and 15 percent.22 In India the value of botanicals related trade is about USD 10 billion per annum with annual export of USD 1.1 billion while China's annual herbal drug production is worth USD 48 billion with export of USD 3.6 billion. Presently, the United States is the largest market for Indian botanical products

International Journal of Research in Engineering and Applied Sciences(IJREAS)
Available online at http://euroasiapub.org/journals.php
Vol. 11 Issue 12, December -2021,
ISSN(O): 2249-3905, ISSN(P) : 2349-6525 | Impact Factor: 7.196| Thomson Reuters ID: L-5236-2015

accounting for about 50 percent of the total exports. Japan, Hong Kong, Korea and Singapore are the major importer of TCM taking 66 percent share of China's botanical drugs export.23 Pharmaceutical companies have shown interest in natural product drug development and discovery and this is an area where traditional knowledge holders may want to work or collaborate with these companies. For instance, in Europe, AnalytiCon Discovery has stressed on drug discovery based on natural product chemistry. In the Asia-Pacific region, MerLion Pharmaceuticals in Singapore has comprehensive structures and capabilities necessary for natural product based drug discovery.24 In addition, the growing popularity of the traditional knowledge based natural products lead to the introductions of new regulations affecting nutraceuticals and herbal based products such as the Dietary Supplement Health and Education Act in 1994 in the United States. For European countries, safety and quality, licensing of providers and standards of training, methodologies, and priorities for research, have rapidly become issues of great importance. The USFDA has recently published the International Conference on Harmonization guidance Common Technical Document addressing concerns related to quality of medicines that also includes herbals. The United States has also established the National Center for Complementary and Alternative Medicine to conduct scientific research in the area of CAM. Its mission is to explore complementary and alternative healing practices in the context of rigorous science, support sophisticated research, train researchers, disseminate information to the public on the modalities that work and explain the scientific rationale underlying discoveries. The centre is committed to explore and fund all such therapies for which there is sufficient preliminary data, compelling public health need and ethical justifications. Apart from TM and CAM, traditional knowledge may also be used to explore innovation in other areas of biotechnology. One such area is in agriculture biotechnology. Agriculture biotechnology may involve both the use of genetic engineering and non-genetic engineering. According to the International Service for Acquisition of Agri-biotech Applications (ISAAA), in 2008, there were 25 countries planting biotechnology crops, rising from 6 in 1996 and 18 in 200325 but these figures relate to the genetically engineered crops which are not relevant to the discussion on the traditional knowledge. However, there are efforts to use non genetic engineering biotechnology in agriculture. In Cuba, there have been some efforts to develop non-genetically engineered seeds under the Programme for the Local Agrarian Innovation since 2000 involving farmers themselves. Under this programme, farmers learn how to produce new seeds using traditional methods and these seeds will be shared among farmers.26 The farmers have developed varieties of sweet potatoes, mandioca and beans. At the same time a research is being conducted at the University of Bern to produce a kind of strong enough plant to resist the drought in Ethiopia using tissue culture methods, instead of using genetic engineering. climate change concerns, such as in biofuel. It is well known that biofuel originates from agriculture products such as corns and soybeans, rapeseeds, sugar cane, palm oil and jatropha. For example in Indonesia, fishermen use oil pressed from jatropha or "jarak" as fuel to the motor boats. This usage can be considered traditional knowledge and this can be further developed with new technology to improve the efficiency of the oil. Modern biotechnology combined with traditional knowledge may be combined to pursue research and development in biofuel. The United States Agriculture Secretary puts biofuel development as a part of the agriculture agenda in the United States. This includes advancing research and development and pursuing opportunities to support the development of biofuels, where United States Department of Agriculture needs to ensure that the biofuels industry has the necessary support to survive recent market challenges while promoting policies that will accelerate the development of next-generation biofuels.28 In addition, there are demands for eco-friendly goods which holders of traditional knowledge can take advantage of. For example corns may be used to produce biotechnology plastics which can also be used to

produce by-products like golf balls and cups. In addition, herbals can be used to produce herbal cosmetics through biotechnology processes. Fruits may be used to produce enzymes and enzymes products such as those which are subject to the case study in this paper. The raw materials for these eco-friendly products are mostly found from naturally occurring and sustainable sources. 2.4 Modern Innovations Based on Traditional Knowledge v. Innovations Exploiting Traditional Knowledge The above discussion shows the global economic value that one can expect from innovation in biotechnology, providing opportunities for traditional knowledge holders to capture some part of the market.29 Innovative modern products based on traditional knowledge have to be differentiated from innovations or inventions exploiting traditional knowledge. In the first case, the traditional knowledge holder would be involved, directly or indirectly in the production of the traditional knowledge based products, whereas in the second case, the traditional knowledge holder does not play any role apart from transferring the knowledge to someone who works in the knowledge. This part will explain the differences between modern innovation based on traditional knowledge and the innovations exploiting traditional knowledge. The purpose of the discussion is to differentiate the two approaches and the same to explain that innovation based on traditional knowledge is not the same as the innovation exploiting traditional knowledge. 2.4.1 Modern Innovations Using the Traditional Knowledge It has been suggested that innovations of modern products using the traditional knowledge need not arise from the organised or formal systems of knowledge.30 Nevertheless, there are efforts in India, China and other countries to bring the informal sector of traditional knowledge into the modern sector, or in other words to modernise the products produced through traditional knowledge. 28 United States Department of Agriculture, 'Secretary of Agriculture Vilsack Lays Out Priority, Extends Comment Period For Payment Limitations Rule'
http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2009/01/0026.xml (Last accessed 24 June 2009). 29 K. Aparna Bhagirathy, Using Traditional Knowledge for Commercial Innovations: Incentives, Bargaining and Community Profits, SANDEE Working Paper No. 11-05, 2005. 30 R.T. Krishnan, Transforming Grassroot Innovators and Traditional Knowledge into a Formal Innovation System: A Critique of the Indian Experience, Indian Institute of Management, Bangalore (2005), 1. Developing Biotechnology Innovations Through Traditional Knowledge 9 In India, in 2000, the Government set up the National Innovation Foundation to identify, recognise and support grassroots innovations and traditional knowledge. This is the extension of the Honey Bee Network created in 1980s to identify the grassroots innovations and traditional knowledge in India and share the traditional knowledge back with the innovators themselves through documentations and dissemination in different languages.31 The Honey Bee Network was later formalised into The Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) and The Grassroots Innovation Augmentation Network (GIAN). The Government of India set up the National Innovation Foundation in recognition of the work of the three initiatives. These initiatives documented more than 20,000 innovations and traditional knowledge which are either of contemporary origin or based on outstanding traditional knowledge primarily from Indian.32 It is found that many of the inventions are relatively simple and can improve efficiency in the traditional sector such as for farmers and farm workers. It is contended that the efforts to bring improvement by the modern science into the traditional knowledge sector have been slow due to the differing perceptions, communication styles, and different priorities and co-ordinations. It is found that many of the inventors in the traditional knowledge sector are possessive of their inventions and suspicious of any effort to help them.34 At the same time, many of the inventions are not designed for manufacture, causing problems in bringing the inventions to

the commercialisation stage. The Indian initiatives also faces several challenges such as the lack of funding and this contributed to the difficulties in securing the protection of intellectual property rights for the innovators. Another challenge is to bring the innovations in the traditional knowledge sector into commercialisation which requires market study, finance and maintenance and support for the products. The successful promotion of the modern adaptation of traditional knowledge can be attributed to the acceptance of the TCM and Traditional Indian Medicine.

TCM and Traditional Indian Medicine have undergone transformation from a mere traditional healing processes to accepted methods of preventing and curing various types of illnesses. The transformation in the role played by the two types of traditional medicines necessitates innovations in the manner of production, usage and marketing and at the same time requires the change of mindsets among the stakeholders involved in the sectors.35 According to a study by Patwardhan et.al., China has overcome difficulties facing Traditional Chinese Medicine by modernizing its traditional medicine profession with government-sponsored GAPs and GMPs.36 All manufactures of TCM are mandated to comply with guidelines laid down by China's State Drug Administration (SDA) by 2004 and farms producing raw ingredients must comply with SDA-imposed standards by 2007. For marketing of herbal medicine in China, special requirements such as quality dossier, safety and efficacy evaluation and specific labelling criteria are required. New herbal drugs must be approved according to the Drug Administration Laws. In India, new rules delineating essential infrastructure, manpower and quality control and licensing requirements in the Traditional Indian Medicine or ayurvedic came into force from 2000 and form part of the Drugs and Cosmetics Act, 1940. Under this law, ayurvedic patent and proprietary medicines need to contain only the ingredients mentioned in the recommended books as specified in 31 For a description of the Honey Bee Network, see A.K. Gupta et. al, Mobilizing Grassroots' Technological Innovations and Traditional Knowledge, Values and Institutions: Articulating Social and Ethical Capital, Futures, 35 (2003) 975-987. 32 A.K.Gupta, et. al, note 31 above. 33 A.K. Gupta et. al, note 31 above. 34 A.K. Gupta, et. al, note 31 above. 35 T.Hesketh and W.X. Zhu, Health in China: Traditional Chinese medicine: one country, two systems, BMJ 1997;315:115-117 (12 July). 36 For a comparative analysis of traditional medicine between China and India, see B. Patwardhan, D. Warude, P. Pushpangadan and N. Bhatt, Ayurverda and Traditional Chinese Medicine, A Comparative Overview, Evid. Based Complement Alternat Med. December 2(4) 465-473, (2005). 10 Research Papers the Act. Under this law, any new herbal medicine safety and efficacy data are mandatory. Depending on nature of herbs and market availability, different requirements exist for submission of clinical trial and safety data. The study by Patwardhan et.al also shows that formal training in traditional medicine in India and China helps in ensuring quality standards in health care delivery. 37 The study also finds that China has been successful in integrating TCM in the national health care system, where science-based approaches were utilized and inculcated in the education of TCM with emphasis on research. In India, a separate department for Indian Systems of Medicine and Homeopathy now known as AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homoeopathy) was established in March 1995 to promote indigenous systems. Priorities include education, standardization of drugs, enhancement of availability of raw materials, research and development, information, communication and larger involvement in the national system for delivering health care. The Central Council of Indian Medicine oversees teaching and training institutes while Central Council for Research in Ayurveda and Siddha deals with interdisciplinary research. The Governments of China and India have also encouraged research and development in the field of traditional medicine. Chinese medicine became successful in crossing philosophical barriers through constant reworking of the basic system. The first compound derived from Chinese herbal remedies

to enter the western market was ephedrine, an amphetamine like stimulant from ma huang (Ephedra sinica). The next was artimisinin, a potent antimalarial from qinghao (Artemisia annua). In 2003, Chinese researchers launched a phase II trial to test the efficacy of a drug called kanglaite from iijen (Coix lachryma-jobi) for treating non-small-cell lung cancer. This is the first drug from TCM to enter clinical trials in the United States.38 India has progressive research institutes like the Central Drug Research Institute (CDRI), Central Institute of Medicinal and Aromatic Plants and National Botanical Research Institute at Lucknow, Regional Research Laboratories (RRL), at Jammu, Bhubaneshwar and Jorhat, National Chemical Laboratory at Pune, which routinely undertake research on medicinal plants. Most of them are involved in standardizing the herbal medicines and isolating active compounds. Few selected crops rauwolfia (producing chemical compound reserpine for antihypertensive), turmeric (producing curcumin for anti-inflammation) and ashwagandha (withaferin A for anti-inflammation) have been taken for improvement yet there is a need for research on quality planting materials for farmers, conservation of endangered species and to prevent exploitation of the natural resources.39 Apart from China and India, the same effort to diffuse technological innovations among small farmers has also taken place in Bolivia.40 The Bolivian Government through the Bolivian Agriculture Technology System provide funding to promote applied research and technology transfer agricultural development. The foundation promotes innovation through a network of technology providers, farmers and private sector agents. 2.4.2 Innovations Exploiting Traditional Knowledge This part refers to the use of traditional knowledge by non-traditional knowledge holders to create new products based on the traditional knowledge. It has been acknowledged that traditional knowledge and genetic resources have often been the targets of pharmaceutical companiesDeveloping Biotechnology Innovations Through Traditional Knowledge 11 Biogenetic materials are not only found in the rainforest but also in the marine and coastal environment,41 hence the wider exposure of traditional knowledge to the modern sectors including the pharmaceutical industry. It has been suggested that a growing number of molecules found in the coastal areas demonstrate interesting pharmaceutical properties have been identified and some of which are already at the clinical trial stage. Examples include anti cancer compounds, antivirals, antibiotics, antifungals and hormonal modulators.42 It has also been acknowledged that coastal genetic resources have yielded cosmetics and products such as enzymes, toxins and microbes for industrial and biotechnology use.43 There are many discoveries based on natural resources that have been transformed into medicines. Some examples include anticancer drugs from the Pacific Yew Bark Tree marketed as Taxol, anti Malaria product COARTEM by Novartis, Aspirin from Salix SPP and diabetes treatment from venom of lizards.44 There are many incidents where traditional knowledge has been exploited and patented without proper acknowledgement and benefit sharing arrangements with the holder of the traditional knowledge. One of the famous examples is the patent on turmeric, which was granted to two Indian Nationals at the University of Mississippi Medical Centre on “use of turmeric in wound healing” in 1995. This patent received an objection from the Indian Council of Scientific and Industrial Research which argued that turmeric has been used for thousands of years for healing wounds and therefore the medicinal use was not novel. The United States Patent and Trademark Office upheld the objection. Another example is the European Patent granted to WR Grace and USDA for ‘a method for controlling fungi on plants by the aid of hydrophobic extracted neem oil’. Neem is a tree normally found in South and Southeast Asia and has properties as natural medicine, pesticide and fertilizer. The European Patent received several objections on the ground that the fungicidal effect of extracts of need seeds had been known for centuries in Indian agricultural to protect crops. The patent was revoked in 2000 by the EPO for want of novelty and prior disclosure, on the ground that

'all features of the present claim have been disclosed to the public prior to the patent application.' The third example which relates to the failure to offer benefit sharing is the beneficial use of hoodia cactus. Hoodia cactus has been used by San people in the Kalahari Desert in South Africa to stave off hunger and thirst on long hunting trips. Scientists at the South African Council for Scientific and Industrial Research studied an earlier report and this resulted in the patent on Hoodia's appetite suppressing element P57 which was then licensed out to Phytopharm. Phytopharm was later acquired by Pfizer. The San people protested this and later reached an agreement with the South African scientists for a share in the royalty.

1 F. Lenzerini, Traditional Knowledge, biogenetic resources, genetic engineering and Intellectual Property Rights, in D.Wuger and T. Cottier, (eds), Genetic Engineering and the World Trade System, World Trade Forum Series, (Cambridge, CUP, 2008), 118-148, 119. 2 WIPO, WIPO International Forum on "Intellectual Property and Traditional Knowledge: Our Identity, Our Future", Muscat, 21-22 January 2002, http://www.wipo.int/arab/en/meetings/2002/muscat_forum_ip/iptk_mct02_i3.htm (last visit 2 January 2009). See also WIPO, Intellectual Property Needs and Expectations of Traditional Knowledge Holders, WIPO Report on Fact Finding Missions on Intellectual Property and Traditional Knowledge (1998 – 1999) Geneva, April, 2001. 3 See CBD, Art. 8(j). 4 S.Hansen and J.W. Van Fleet, A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity, (American Association for the Advancement of Science (AAAS) Science and Human Rights Program, Washington, DC., 2003).

5 International Institute for Environment and Development, Andes (Peru), Dobbo-Yala Foundation (Panama), University of Panama, Chinese Centre for Agricultural Policy, Southern Environmental and Agricultural Policy Research Institute, Kenya Forestry Research Institute, Centre for Indigenous Farming Systems (Bhopal), Ecoserve (New Delhi), Herbal and Folklore Research Centre (Andhra Pradesh), Protection of Traditional Knowledge and the Concept of 'Collective Bio-Cultural Heritage', in Ad Hoc Open-Ended Inter Sessional Working Group on Article 8 (j) and Related Provisions of the Convention on Biological Diversity, Fourth meeting, Granada, Spain, 23-27 January 2006, UNEP/CBD/WG8J/4/INF/18, 24 November 2005. 4 Research Papers 2.1.2 Biotechnology.

10 Cartagena Protocol on Biosafety 2000, Art 3(i). See also an explanation of the techniques in B van Beuzekom , Biotechnology Statistics in OECD Member Countries: Compendium of Existing National Statistics, Ad Hoc Meeting on Biotechnology Statistics, OECD, Paris, 3-4 May 2001. 11 The International Convention on Biological Diversity 1992, Art.2. 12 OECD, Definition of Biotechnology, available online at http://www.oecd.org/document/42/0,3343,en_2649_34537_1933994_1_1_1_1,00.html (last visited 17 January 2008). 13 See A.Kumar, Indian Biotech Bazaar, A Swot Analysis, Biotechnol J, May 4: 2, (5) 543-535. 2007. Developing Biotechnology Innovations Through Traditional Knowledge 5. 27 22 N.Vietmeyer and J.Lambert, Medicinal Plants: Rescuing a Global Heritage, (the World Bank, Washington DC, 1997). 23 World Health Organization, note 21 above. 24 T. Okuda, Trends in natural product-based drug discovery, and roles of biotech ventures and biological resource centers, http://www.wfcc.nig.ac.jp/NEWSLETTER/newsletter35/a4.pdf (last accessed 4 January 2009) 25 C. James, Global Status of Commercialised Biotech/GM Crops, 2008, The First Thirteen Years, 1996 – 2008, ISAAA Briefs 2009, (Ithaca, ISAAA, N.Y, 2009). 26 D. Acosta, Innovation Gives Boost to Small Farmers, IPS, 9th Jan. 2009, http://ipsnews.net/news.asp?idnews=40727 (last accessed

26.2.2009). 27 D. Acosta, note 26 above. 8 Research Papers Traditional knowledge and biotechnology may also be used to address.

Protection of traditional knowledge is in line with the provision in Article 8 (j) of the CBD. Article 8(j) requires each Contracting Party states that: 6 P.W. Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice and Strategy, (Oxford, OUP, 3rd Ed., 1999), 224. 7 P.W. Grubb, note 6 above, 225. 8 S.N. Cohen, A. C. Y. Chang, H. W. Boyer, and R. B. Helling, "Construction of Biologically Functional Bacterial Plasmids in Vitro.", 70 Proceedings of the National Academy of Sciences, 3240 (1973) 9 United Nations Department of Economic and Social Development, Biotechnology and development: expanding the capacity to produce food, (United Nations, New York, 1992).

37 B. Patwardhan et.al, note 36above. 38 B. Patwardhan et al., note 36 above. 39 B. Patwardhan, et. al., note 36 above. 40 F. Hartwich, M.M. Perez, L.A. Ramos, J.L. Soto, Knowledge Management for Agriculture Innovation: Lesson from Networking Efforts in the Bolivian Agricultural Technology System, Knowledge Management for Development Journal, 3(2) 21-37 (2007).

International Federation of Pharmaceutical Manufacturs association (IPFMA), Biodiversity Resources, Traditional Knowledge and Innovation in Health, (Geneva, IPFMA, 2003). 42 IPFMA, note 41 above. 43 IPFMA, note 41 above. 44 IPFMA, note 41 above. 12 Research Papers