RESEARCH PAPERS

23

DEVELOPING BIOTECHNOLOGY INNOVATIONS THROUGH TRADITIONAL KNOWLEDGE

Sufian Jusoh*

SOUTH CENTRE

JUNE 2009

* LL.M, Barrister at Law (England and Wales), Research Fellow at South Centre, Geneva, Switzerland. The views expressed in this paper are the personal views of the author and do not necessarily represent the views of the South Centre or its Member States. Any mistake or omission in this study is the sole responsibility of the author.

THE SOUTH CENTRE

In August 1995 the South Centre was established as a permanent inter-governmental organization of developing countries. In pursuing its objectives of promoting South solidarity, South-South cooperation, and coordinated participation by developing countries in international forums, the South Centre has full intellectual independence. It prepares, publishes and distributes information, strategic analyses and recommendations on international economic, social and political matters of concern to the South.

The South Centre enjoys support and cooperation from the governments of the countries of the South and is in regular working contact with the Non-Aligned Movement and the Group of 77 and China. The Centre's studies and position papers are prepared by drawing on the technical and intellectual capacities existing within South governments and institutions and among individuals of the South. Through working group sessions and wide consultations, which involve experts from different parts of the South, and sometimes from the North, common problems of the South are studied and experience and knowledge are shared.

TABLE OF CONTENTS

LIST OF CHARTS AND TABLES

ABBREVIATIONS

AMSF	Advanced Microorganism Symbiosis Fermentation Technology
CAM	Complementary Alternative Medicine
CBD	International Convention on Biodiversity 1992
DNA	Deoxyribonucleic acid
GAP	Good Agriculture Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
OECD	Organization of Economic Co-operation and Development
TM	Traditional Medicine
TCM	Traditional Chinese Medicine
TRIPS	The WTO Agreement on Trade Related Intellectual Property Rights
USD	United States Dollar
USDA	United States Department of Agriculture
UDFDA	United States Food and Drugs Authority
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

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 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.

Although there is no single definition of the term “traditional knowledge,” there are several attempts to define the term. According to the WIPO, traditional knowledge is a multifaceted concept that encompasses several components: it is not produced systematically but in accordance with the individual or collective creators' responses to and interaction with their cultural environment; as representative of cultural values is generally held collectively; and most traditional knowledge is transmitted orally from generation to generation, and thus remains largely undocumented. At the same time, traditional knowledge is not necessarily ancient but evolving 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.

On the other hand, CBD 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. In addition, according to “A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity”; 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.

Despite the existence of different definitions, there are three common characteristics of traditional knowledge. One, biological resources cannot be separated from traditional knowledge; two, landscapes provide the physical space for interaction with natural and biological resources, and for sharing of knowledge and resources between individuals and communities; and three, cultural and spiritual values where 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 that knowledge is acquired.

The paper suggests that by using biotechnology, traditional knowledge holders may obtain economic gain, through innovation and research and development based on the traditional knowledge. The term biotechnology must be seen from the wider sense and not limited to genetic engineering alone. Biotechnology includes any technological application that uses biological systems, living organisms or derivatives, to make or modify products or processes for specific use. Biotechnology combines disciplines such as genetics, biochemistry, microbiology, and cell biology along with information technology, chemical engineering and robotics etc. Biotechnology is used in several fields as in agriculture, pharmaceutical industry and medicine.

When dealing with biotechnology based innovation in traditional knowledge, one will also needs to discuss the issue of intellectual property. 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 conventional intellectual property such as patent and copyrights on the improvement made to the traditional knowledge.

The protection of intellectual property and traditional knowledge relate to the need to promote investment in the research and development in the biotechnology sector using traditional knowledge. In promoting investment in biotechnology sector, a developing country must take into account the interest of local and indigenous communities, to ensure that they benefit from the transfer of knowledge and at the same time to protect the resources from depleting.

Where the conventional intellectual property rights such as patents are not applicable, there must be mechanisms to protect traditional knowledge in order to facilitate and encourage traditional innovation. It has been argued that the conventional intellectual property protection has little regards towards the protection of traditional knowledge and the concerns 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. Therefore, the development of *sui generis* systems 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.

Nevertheless there are shortcomings in the traditional method of protection of intellectual property in relation to traditional knowledge. Indigenous 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. Due to the secrecy, it is suggested that there are possibilities of different needs concerning the protection of the traditional knowledge may arise. Be that as it may, there is a need to refer to the provision of Article 39 of the WTO TRIPS Agreement which deals with undisclosed information and trade secrets that has commercial value. Another unique feature of the traditional knowledge vis-a-vis a legal protection of the knowledge is the relationship of the traditional knowledge with the resources, such as plant resources forming part of the knowledge. Consequently, protection of traditional knowledge is intended to be the simultaneous protection of the title of ownership by traditional knowledge holders of both the knowledge and of the resources related to such knowledge.

The use of biotechnology to develop innovation in traditional knowledge sector may open doors to economic gains provided it is subject to an appropriate benefit-sharing mechanism. According to the MarketLine Biotechnology Global Industry Guide 2008, the global biotechnology market grew by 10.6 percent in 2007 to reach a value of USD 171,803 million and the compound growth between 2003 and 2007 was at 10.7 percent. Based on the Asia Pacific Biotechnology Market Report 2008, 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.

There are several segments of biotechnology that could be of interest to traditional knowledge holders to innovate further. One of such areas is in the area of TM and the CAM which include the supply of medicinal plants, botanical drug products and raw materials. Pharmaceutical companies have shown interest in natural product drug development and discovery and this is an area where there could be possible collaborations between pharmaceutical companies and traditional knowledge holders.

Another area where traditional knowledge and biotechnology may converge is in the area of agriculture biotechnology, especially in the non-genetic engineering crops. For example, 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.

Traditional knowledge and biotechnology may also converge in the field of environmental biotechnology where traditional knowledge may be used in biotechnology fields to address the issue of climate change, such as in biofuel. For example in Indonesia, fishermen use oil pressed from jatropha or jarak fruits 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. In addition there are demands for eco-friendly goods which holders of traditional knowledge can take advantage of. Corns have been 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.

Through a case study the paper will show that it is possible to innovate on traditional knowledge using biotechnology as a catalyst. The study will be based on the joint venture project between Biozyme Biotechnology Corp. of Taiwan Province, China and 1st Global Biotechnology of Malaysia. The case study is based on the development of enzyme-based nutraceutical products using fermentation methods that have been scientifically developed from traditional Chinese fermentation formula, using fruits and vegetables which is later used to develop techniques to produce nutraceuticals and CoenzymeQ10 to address heart problems. Further research to develop pharmaceuticals using the methods and the ingredients that the family owns is undergoing.

The paper also shows that the any effort to promote innovation in traditional knowledge sector using biotechnology has to receive supports from the Government as the traditional knowledge holders may lack the necessary funds to support the research and development in the innovation. The paper gives an example of how Malaysia provides various forms of grants ranging from innovation grants to pre-commercialisation of research and innovation in biotechnology in addition to other fiscal and tax incentives. The measures taken by Malaysia to support innovation and research and development can be emulated by other developing countries.

1. INTRODUCTION

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.

The case study is 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. Part 3 consists of the Case Study and Part 4 will conclude the paper and offer few recommendations.

2. TRADITIONAL KNOWLEDGE, BIOTECHNOLOGY AND INNOVATIONS

2.1 Traditional Knowledge and Biotechnology Defined

2.1.1 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

---

[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).

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.

c) 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.

[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.

2.1.2 Biotechnology

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 microorganisms[7] 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.

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).

[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.

> "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.

been suggested that “biodiversity-related traditional knowledge derives its value from the genetic resources to which it applies.”[18]

2.3 Economics Opportunity of 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 multi-national 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).

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 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 2003[25] 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.[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.

Traditional knowledge and biotechnology may also be used to address 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.

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.[33] 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).

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 companies.

---

[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).

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.

---

[41] International Federation of Pharmaceutical Manufacturers 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.

3. CASE STUDY

3.1 Introduction

The study is based on the development of enzyme-based nutraceutical products using fermentation methods that have been scientifically developed from traditional Chinese fermentation formula, using fruits and vegetables. Biozyme Biotechnology Corp of Taiwan Province, China (Biozyme) 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

Established in 1981, Biozyme is the biggest Taiwan Province, China herbal enzyme manufacturer and already has 24 years experience in producing herbal enzymes - vegetable saps and extracts and health products such as “Growell energy Liquid,” “Cordyceps Sinensis Herbal Fermentation Liquid,” and “GE Health Elements (amino acid intensive liquid formula).”

The company owns USFDA certification, Japanese selling licence, Islamic halal food certification, National Prize for customers’ favourite products, and already passed ISO 9001:2000. The yearly output of their herbal enzymes product is more than 10 million tons, with markets in the United States, Canada, Australia, Japan, Hong Kong, Singapore, and Malaysia. The total annual sale is around USD 20 million annually.

Biozyme produces its products using a combination of Chinese fermentation together with the technology developed by the company called the Advanced Multiple Micro-organism Symbiosis Technology (“AMSF Technology”). The AMSF Technology is developed through research and development activity by Professor Huang, the founder of Biozyme, with few other scientists at the Department of Food Science and Biotechnology, National Chung Hsing University, Taiwan Province, China.

Although AMSF Technology is unique to Biozyme, Biozyme faces competition from other produces in the world market producing enyzme products based on fermentation technologies. One of the competitors is Biocon of India which uses microbial process to produce therapeutic protein including human insulins. In addition, Boehrinnger Ingelheim of Austria uses microbial technology to produce higher end products such as biopharmaceuticals. In Taiwan Province, China, Chang Gung Biotechnology of Taiwan Province, China uses Chinese fermentation technology to produce certain products such as men health products. This company uses genetic engineering and animal strains whereas Biozyme does not involved genetic engineering and animal strain. In the United States, Toyo Biopharma of California produces health products from single item like cabbage or orange but does not involve in the mixture of fruits and vegetables as done by Biozyme.

3.2 The Traditional Knowledge: Chinese Fermentation Technique

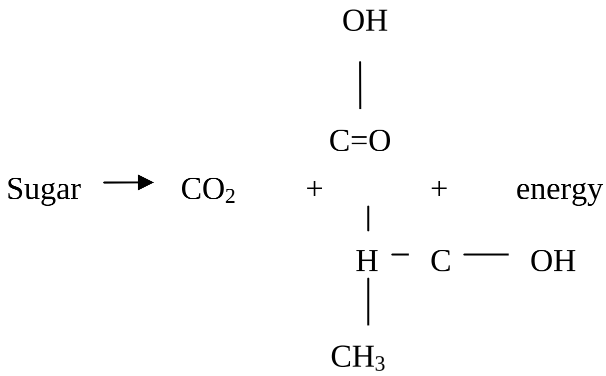
Food fermentation is regarded as one of the oldest ways of food processing and preservation. More than anything else, man has known the use of microbes for preparation of food products for thousands of years and all over the world a wide range of fermented foods and beverages contributed significantly to the diets of many people.[45] In traditional fermented food preparation, microbes are used to prepare and preserve food products, adding to their nutritive value, the flavour and other qualities associated with edibility. These processes are characterized by their limited need for energy input, allowing microbial fermentations to proceed without external heat sources.

Fermentation is one method by which organisms, including human beings, derive their energy for living when oxygen (O_2) is lacking. Normally, when oxygen is plentiful, the cells of most organisms break down sugars and starch from food to release carbon dioxide (CO_2), water (H_2O), and energy. When oxygen is insufficient, cells in organisms switch to the fermentation process to provide that energy. Cells in the human body are also able to switch to fermentation, for example during strenuous exercise, when the human body cannot take in oxygen quickly enough. Like the normal process, fermentation also breaks down sugars, releasing carbon dioxide (CO_2) and energy.[46] In addition, depending on the type of fermentation, lactic acid or alcohol is produced. These are the two most common types of fermentation naturally occurring in nature.

Breakdown of Sugar when Oxygen is available

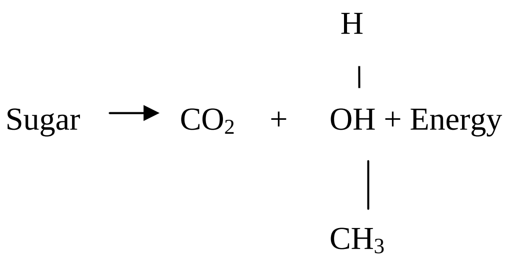
Sugar + O_2 CO_2 + H_2O + energy

Lactic Acid Fermentation



(Lactic Acid)

Alcohol fermentation



(Alcohol)

Using Biological Processes: Harnessing Single-celled Organisms to Work
Source: O.K. Achi (2005)

[45] O.K. Achi, The Potential for Upgrading traditional fermented food through biotechnology, African Journal of Biotechnology Vol. 4 (5), pp. 375-380, May 2005.

[46] O.K. Achi, note 45 above.

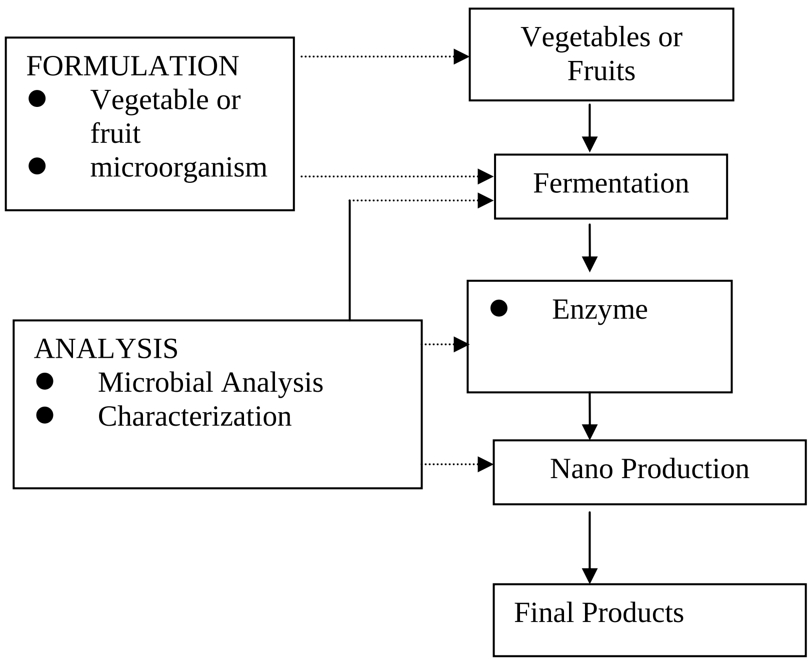
Various foods such as food and fruit juices will ferment when left on their own. Invisible to the eye, single-celled microorganisms such as yeast and bacteria are at work, breaking down the sugar molecules present.

3.3 The MSF Technology as added value to the Chinese Fermentation Technique

In 1981 the founder of Bioyzme, Professor Po-Cheng Huang realised that chemical treatments cannot cure diseases completely, but merely alleviate the symptoms. Professor Huang realised that the key to human health does not lie in treating the obvious symptoms and the organs, instead it lies in caring for the cells - the building blocks of life. His basic theory is: “Cells need to be supplied with complete nutrition and only then they can form healthy human bodies.” For this reason, Professor Huang combined essential elements from botany, nutrition, cytology and microbiology undertook research and development to develop AMSF Technology. Using this technology, components are extracted from various kinds of plants, vegetables and fruits to offer cells optimum nutrition.

3.3.1 The Working of AMSF Technology

Chart 1: Production Flow using AMSF Technology



The production of a final product using the AMSF technology is shown in Chart 1 above. The production process is explained below:

<u>1. Raw Materials (Vegetable or Fruit)</u>

Enzymes can be extracted from the tissues of vegetables or fruits. The initial biological extraction of enzymes can be processed further using chemical synthesis.

2. Advanced Microorganism Symbiosis Fermentation (AMSF)

Advanced Microorganism Symbiosis Fermentation (AMSF) is a unique technique for enzyme production. It involves the selection of special strains of micro-organism which can be cultured and multiplied symbiotically to synthesize a whole range of high end enzymes from multiple growing media derived from fruit and vegetable sources. This platform can be used in the development and manufacturing of pharmaceutical material, new drugs and health foods.

Under the AMSF Technology, 12 strains of bacteria are used in the symbiotic fermentation process. Over one hundred kinds of materials can be processed simultaneously and a wider range of beneficial elements can be obtained by using 12 bacteria symbiotic culture and extraction techniques thus allowing more raw materials to be processed simultaneously and allowing more variety enzyme products to be produced. Moreover, these derivatives are small and intact molecules, in the form of nano particles, that can be easily absorbed by human body.

Beneficial microorganisms and bacteria with high fermentation activities are implanted into the raw materials, from which beneficial elements are extracted and are made into many precious enzyme products. Under this system, the microorganisms will digest the raw material and extract enzymes from the raw material during the fermentation process. The microorganisms will continue with the fermentation and extraction of enzymes upon the final production and the microorganisms will continue with its function in carrying the enzymes into the human body upon consumption of the relevant products produced using the AMSF technology.

The microorganisms assist the enzyme production by extracting nutrition from the ingredients in the production process, thus eliminating the need to add artificial nutrition to the production. For example, certain micro-organism will extract protein from the ingredients, without having to add artificial or additional protein to the process and the protein will be carried into the body upon consumption and the micro-organism will continue to function upon consumption of the products.

In summary, microorganisms act as the factory workers in the process of fermentation. Accompanying the metabolic process of bacteria, the essences of raw materials are extracted. No chemicals are added and the microorganisms alone finish the whole work. Only sugar is added as food for these microorganisms, which then is transformed into low-calorie oligosaccharide later. Consequently, the products produced using these methods are absolutely free of artificially synthesized substances.

Products produced under the symbiotic fermentation process do not require preservatives to preserve its freshness. Through this unique process, the finishing products are in high concentration liquid form. Because solution with high concentration has high osmotic pressure, the activity of living bacteria can be inhibited due to this high osmotic pressure. In addition, foreign harmful bacteria cannot survive in high osmotic environment either. For this reason, the original solutions can be perfectly preserved without any preservatives.

The efficient functioning of the micro-organism carrying the enzymes produced using the AMSF process is further assisted by the utilisation of nano technology. Basically, nanotechnology is the control of matter on a scale smaller than a few nanometers using extremely small machines or devices to assemble individual components such as atoms or molecules to form larger particles for specific functions. Through micellation in the nano technique, substances become water soluble. The diameter of the granule is smaller than 30nm, in order to make such materials to be readily absorbed by the human body.

Thus, the ingredients used in the production is processed into nano particles which contains microorganisms which continue with the extraction of enzymes and the body will easily absorb the nano particles containing the micro-organism carrying the enzymes thus increasing the effectiveness of the absorption of the nutrients into the human body.

Products produced under the symbiotic fermentation process do not require preservatives to preserve its freshness. Through this unique process, the finishing products are in high concentration liquid form. Because solution with high concentration has high osmotic pressure, the activity of living bacteria can be inhibited due to this high osmotic pressure. In addition, foreign harmful bacteria cannot survive in high osmotic environment either. For this reason, the original solutions can be perfectly preserved without any preservatives.

3.4 Malaysia – Taiwan Province, China Joint Venture to develop Coenzyme Q10 using the AMSF Technology fermentation technique

Biozyme Biotechnology of Taiwan Province, China has now set up a joint venture project with its Malaysian partner 1st Global Biotech (1st Global) to conduct research and development to use the same MSF technology to produce co-enzyme Q10 (CoQ10), peroxidase together with Vitamin K and the research will also focus on the production of pharmaceuticals for cardio-vascular problems. 1st Global will work on the AMSF Technology by conducting research and development on possible local raw materials available in Malaysia, such as tobacco, fruits and vegetables that could be used to produce raw materials for CoQ10.

These raw materials can be sourced from tobacco and fruits and vegetable farmers through contract manufacturing. The use of tobacco's enzyme will also assist the Government of Malaysia in solving the dilemma faced by local tobacco farmers that they have to cease tobacco farming after 2010. The first enzyme product research and development will relate to CoQ10 enzyme productions. The research and development centre will also assist in finding local fruits and vegetables that best suit the enzyme production industry and this will help spur the local agriculture sector.

1st Global will focus on the development of nutraceuticals and pharmaceuticals and this is to take advantage of the demand in the world market. According to the World Nutraceuticals Report to 2010,[47] global demand for nutraceuticals will grow 5.8 percent annually by 2010 and the products on demand include probiotics, soy additives, lycopene, lutein, sterol-based additives, green tea, glucosamine and chondroitin, and CoQ10. China and India will be the fastest growing markets, while the United States will remain the largest. According to this report, the world nutraceuticals industry is worth around USD 11.7 billion.

According to Claire Day, demand for the CoQ10 is growing as CoQ10 manufacturers struggled to meet demand when studies revealed that the nutrient could help combat heart disease, cancer and other age-related disorders.[48] Day argues that the latest findings have led to another surge in demand for CoQ10 supplements as studies suggest that the vitamin could also alleviate conditions such as migraine and periodontal disease, help maintain healthy vision and improve fertility in men.

Day also reports that the global CoQ10 sector was estimated to be approximately 150 tons in 2005, showing an increase of about 50 percent compared with the 2004, where the demand in Japan, the 'spiritual home' of the CoQ10 was valued at USD 135 million. Day predicts that the overall requirement for CoQ10 is expected to double in the period between 2007 and 2012, with strong growth in the United States.

CoQ10 or ubiquinone is a fat soluble vitamin-like substance which is widely used in pharmaceutical and food industry. CoQ10 is a cofactor for mitochondrion in the oxidative phosphorylation to produce 95% of the cellular energy for all the functions in every living organisms.

[47] Feredonia Group, World Nutraceuticals Report to 2010, (London, July 2006).
[48] C. Day, The Fall and Rose of Coenzyme Q10, Nutraceutical Business and Technology, Vol. 3 Nr.2 March/April 2007, 24-28.

It passes reducing equivalents to receptors in the electron transport chain, hence, serves as an important antioxidant to battle against the destructive effects of free radicals.

Peroxidase is a valuable enzyme which is recently being used or several purposes such as bio-bleaching for paper pulp making and waste water treatment in the dye industry; to reduce xenobiotic compound produced by industries such as PAH (Polycyclic Aromatic Hydrocarbons), dioxin, chlorinated phenols, synthetic dyes, nonylphenol and related estrogenic activities; and to be used as enzyme-linked immunosorbent assay (ELISA) in biomedical field.

On 18th June 2009, 1st Global was awarded a research grant worth USD 1.4 million to start research and development on the usage of Malaysian tobacco to produce CoQ10 for pharmaceutical purposes using the AMSF Technology. Although the grant is small, this provides a financial assistance for the Malaysian partner to embark on the first step in the research and development.

By using the MSF Technology, CoQ10 and peroxidase can be produced from vegetables or fruits in a large quantity at a great speed. 1st Global will begin the pilot production of Coenzyme Q10 and Peroxidase using AMSF Technology in July 2009 and the commercial production of the Q10 co enzyme products in the first quarter of 2010. The proposed pilot production will take about 6 to 12 months to complete to be followed by commercial productions.

Based on a 540 day production process, these are the steps taking place:

Step 1

The process starts with a selection of fresh fruits, vegetables and other plant based ingredients, herbs and spices. The specific ingredients for each product are chosen based on the enzyme activity, nutrition content and other health benefits. All the ingredients are thoroughly washed and tested for microbe activity, pesticides, and heavy metals and prepared for the Extraction and Fermentation phase. By adding natural sugars (creating osmotic pressure) all liquid is being extracted from the fruit and vegetables.

Step 2

The Extracting and Fermentation Stage follows, and is the beginning of the fermentation phase. At this stage certain microorganisms will be added.

Step 3

This is the Deep Fermentation stage. Other microorganisms will be added at this stage. The added microorganisms grow below the surface where ingredients are further broken down releasing additional nutrients into the liquid.

Step 4

This is the Storing Fermentation stage during which the fermented liquid matures and starts to develop a unique flavour. Other microorganisms are added at this stage. These microorganisms use oxygen and they form a thin membrane on the top of the barrel.

Step 5

The last phase is the Ripe Concentrate Stage where the liquid continues to mature. Flavour and composition are closely monitored during this stage to ensure maximum benefit of the finished product.

The whole production process is according to HACCP and GMP standards and is followed very carefully with a Standard Operating Procedure.

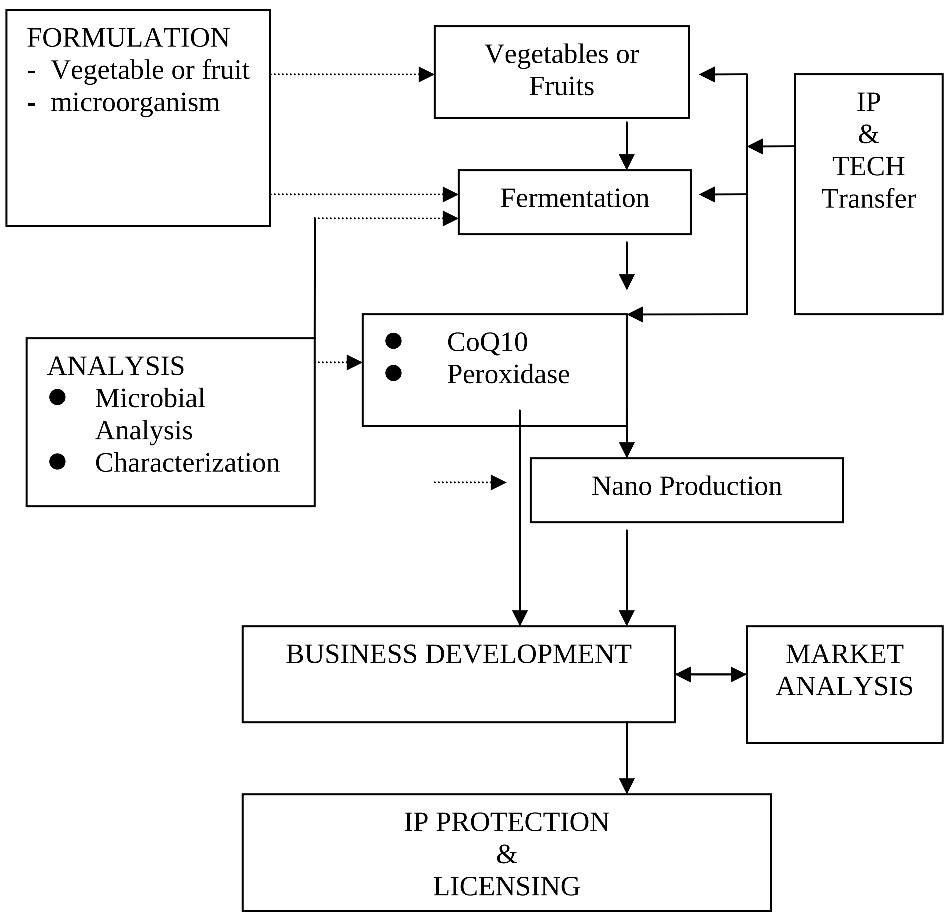
The research and development and the commercial scale production of CoQ10 and peroxidase is highly sustainable as the price of CoenzymeCo10 and peroxidase are very high at the world market with the cost of production at around 42 percent and 50 percent respectively. According to the estimate by Bioyzme, the selling price for CoQ10 is within the range of USD 2 million per ton and USD 1.6 million for peroxidase.

The project will bring high foreign earnings due the fact that it is geared towards export market. However, the weakening of US Dollars against major currencies may affect its earning power in the non USD markets like Europe which trades using Euros. This impact may be cushioned by the fact that the company will arrange a long term sale contract with Biozyme International of Taiwan Province, China.

The Malaysian project offers several added values such as the increase usage and additional economic values of local vegetable and fruit crops. By using local vegetables and fruits the project will be able to assist local agriculture producers to increase their productions and will add to another option in their marketing; the increase of biological use of an organism through nanotechnology; and the capability to reduce health care cost for a number of acute and chronic diseases. The project also plans to use expertise at local universities through contract research by local researchers and this will assist in increasing innovations at local research institutions.

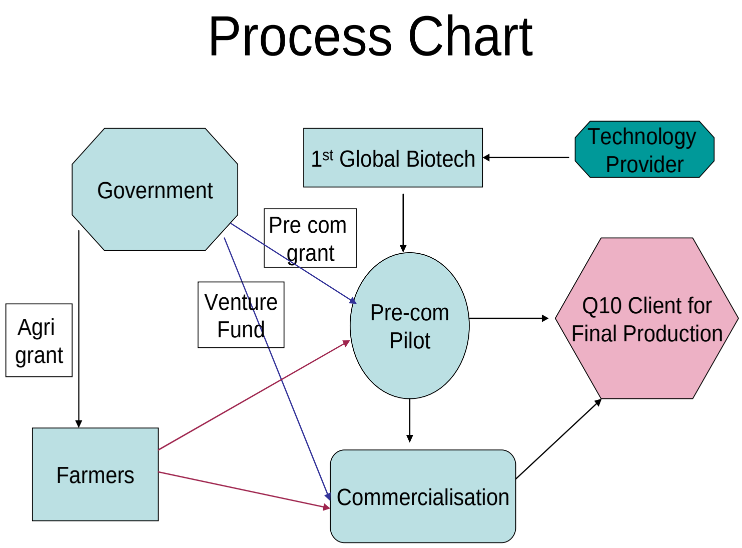
Overall the project is reflected with the following structure:

Chart 2: Structure of the AMSF Project in Malaysia



The following chart explains the impact of the project on the Government and the society:

Chart 3: Impact of Government Grants



Based on Chart 3, although the Government may provide grant and venture fund for the project's pre-commercialization and commercialization stage the funds are not for the company's sole usage. The benefit from the funding will trickle down to the farmers who will provide the upstream raw material production for the company, especially the tobacco farmers who are facing a dilemma in the future. Fruit and vegetable farmers may also benefit from the project in the event that the company decides to expand the raw material from tobacco to certain agriculture produce.

The impact of the project to the farmers will be felt once the production of 10mt starts in 2011. But the farmers will be informed in advance of the potential purchase of the products. They will also be guided and assisted. The farmers will be required to produce the leaves and other raw materials which will then processed to produce the required raw materials.

Assuming that 30 percent of the cost is for the actual purchase from the farmers of the unprocessed raw material, the financial benefit on the farming community will be around USD 4.4 million per annum. This amount will then will trickle down to the rural communities such as small businesses.

1st Global also intends to start production of the following products using the MSF technology on the contract manufacturing basis where the products will re-resold to Biozyme.

Growell energy liquid

Its ingredients are 75 kinds of vegetables and fruits, seaweed DHA, lecithin and spirulina peptide. These products are suitable for pregnant women, young children, growing up children. It helps in increasing memories, concentration, reducing pressure and fatigues.

GE Health elements – amino acids intensive liquid formula

Its ingredients are vegetables, fruits, glucosamine 1500 mg, amino acids 95 mg, pineapple enzymes and L Calcium Lactate. This product helps to keep bones and joints in good condition. It is suitable for athletes, elderly people and those suffering from degenerative arthritis and osteoporosis.

Nightpeace herbal fermented liquid

Its ingredients are vegetables, fruits, Siberian ginseng, chamomile, hops, Vitamin B complex and tryptophane. This product is a plant-based liquid supplement that supports sleep naturally.

3.5 Malaysia's Biotechnology Funding Mechanism

The above discussion shows that the 1st Global received research and development funding from the Malaysian Government. This is part of the overall scheme in Malaysia to provide funding for research and development in biotechnology.

There are several options for government-backed fund or financial incentives available to the Malaysian joint venture company. The Government backed fund is being set up as part of the Malaysian National Biotechnology Policy which was launched on 28 April 2005. Thrust Six of the National Biotechnology Policy is to apply competitive 'lab to market' funding and incentives to encourage committed participation from academia and the private sector.

3.5.1 Bionexus Status

1st Global has also made an application to the Malaysian Biotechnology Corporation, a government agency tasked with promoting biotechnology in Malaysia, for a bionexus status under the bionexus network set up by the Government of Malaysia under the National Biotechnology Policy. The vision underlying 'BioNexus Network' is the creation of a web of biotechnology companies and organizations that leverage on existing facilities, infrastructure and capabilities of universities and research institutions throughout Malaysia, not confined within pre-defined geographical parameters.

To be eligible for the bionexus status, the applicant has to fulfil certain criteria. The criteria are that the applicant is a provider of a product or services based on life sciences, or substantially utilise biotechnology processes; the applicant possesses research capability(ies) in focus areas; and the applicant employs a significant percentage of knowledge workers as part of its total workforce.

The process flow for a bionexus status application is as follows:

Step 1: Pre Application

> A Company interested to apply for the BioNexus Status is encouraged to contact BiotechCorp to discuss on the proposed biotechnology businesses and activities. At this stage, the Company can get clarification on the BioNexus eligibility criteria, as well as associated benefits and incentives.
>
> The Company is required to complete the Pre-Application Form to register interest. The Company will be assigned an Account Manager from Biotech Corp, who will advise and guide the Company on the application process.

Step 2: Internal Assessment

The Company commences the application process by completing the BioNexus Status Application Form (to be provided by the Account Manager), and submitting its biotechnology/life sciences business plan, financial projections and other relevant documents.

Step 3: Formal Application

Upon complete submission and a RM2,000 application fee in the form of a bank draft payable to Malaysian Biotechnology Corporation Sdn Bhd, the Company will be provided with a Letter of Acceptance.

Once the Letter of Acceptance has been issued, the application will be reviewed and evaluated, following which presentation will be made to the BioNexus Approval Committee.

Step 4: Approval

An approval is only given after the relevant ministries agree to the recommendation made by the BioNexus Evaluation Committee.

If the application is approved for the BioNexus Status, the Company will receive the BioNexus Status Approval Letter; whilst the unsuccessful Company will receive a notice on the rejection of its application and the Company's bank draft will be returned.

Step 5: Post Approval

Issuance of BioNexus Status certificate.

A company granted a bionexus status in Malaysia would be eligible for certain direct benefits and incentives. A company with the bionexus status would be guaranteed certain rights under the Bill of Guarantee. The Bill of Guarantee guarantees freedom of ownership, freedom of source of funds globally, freedom to bring in knowledge workers, eligibility for competitive incentives and other assistance, eligibility to receive assistance for international accreditations and standards, strong intellectual property regime, access to supportive information network linking research centres of excellence, access to shared laboratories and other related facilities.

Companies conferred Bionexus status may apply for the tax incentives from the Malaysian government. Tax incentives include 100% income tax exemption for 10 years commencing from the first year the company derives profit or Investment Tax Allowance of 100% on the qualifying capital expenditure incurred within a period of 5 years; tax exemption on dividends distributed by a BioNexus company; exemption of import duty and sales tax on raw materials/components and machinery/equipment; double deduction on expenditure incurred for R&D; double deduction on expenditure incurred for the promotion of exports; and a company that invests in its subsidiary, which is a BioNexus Status company, is granted tax deduction equivalent to the amount of investment made in that subsidiary provided that the investing company owns at least 70% of that subsidiary. A BioNexus company is given concessionary tax rate of 20% on income from qualifying activities for 10 years upon the expiry of the tax exemption period. A company or an individual investing in a BioNexus company is given a tax deduction equivalent to total investment made in seed capital and early stage financing. A BioNexus company undertaking merger and acquisition with a biotechnology company is given exemption of stamp duty and real property gains tax within a period of 5 years until 31 December 2011. Buildings used solely for the purpose of biotechnology research activities are given Industrial Building Allowance over a period of 10 years.

Bionexus companies are also qualified for certain grants such as the Bionexus Fund. Bionexus fund is to fund seed or start up biotech companies, to assist towards the development and commercialization of biotechnology projects and R&D findings of priority and core areas, in particular projects and findings that are central to achieving the objectives of the national biotechnology policy.

To be eligible for the Bionexus fund, the applicant must be Bionexus Status companies, within bionexus status area, majority owned Malaysian companies, the applicant must have ownership of or beneficial use of any intellectual property necessary to commercialise the innovation, the innovation has commercial potential and the majority of the applicant's business activities, employees or assets must be within Malaysia or transferred to Malaysia within reasonable period. The maximum funding per company is RM2.5 million (approximately USD 700,000). The grant shall be disbursed based on approved budget and made out at the beginning of each agreed milestones. The grant shall be utilized within two years from the date of approval.

The funding shall cover expenditure relating to the setting up of a biotechnology company which includes: recruitment of interim professional management, initial market development efforts, intellectual property filing and registrations, market feasibility studies, preparation of further investment documentations, Malaysian compliance and regulatory costs, protyping costs.

The other fund available is the R&D Matching Fund, which objective is to provide matching fund for R&D projects which can develop new or improved products and/or processes and/or technologies and lead to further development and commercialisation within the Malaysia's Biotechnology focus areas. The maximum funding per project is RM1.0 million. The grant is a matching grant, hence, BiotechCorp would match "dollar-for-dollar" spent on the project up to the approved grant and based on the agreed milestones. The grant shall be utilized within two years from the date of approval.

The expenditure covered by the matching fund are: the provision of sites or premises (including the acquisition of land), the construction and adaptation of buildings, and the provision of services and other works; the provision of plants, machinery, equipment and materials; the payment of fees or other remuneration to technical advisers consulted in connection with the project; salary and wages of contract researchers directly involved in the project; the travel and subsistence expenses of persons engaged in the project or in identifying products or process development prospects within the industrial undertaking; overhead charges associated with the project concerned.

The third fund available for the Bionexus status companies is the International Business Development Matching Fund. The objective of this fund is to promote the expansion of BioNexus Status Companies into the global market. The maximum funding per project is RM1.25 million (approximately USD 350,000). The grant is a matching grant, hence, BiotechCorp would match "dollar-for-dollar" spent on the project up to the approved grant and based on the agreed milestones. The grant shall be disbursed upon actual claims. The maximum disbursement period is four years from the date of approval. The funding shall cover expenditure in relation to a particular business development within Malaysia's Biotechnology focus area and has been or will be incurred on: country pre-clinical and clinical trial expenditures; and product registration cost, intellectual property registration cost.

3.5.2 Ministry of Science Technology and Innovation Technofund

The grant approved by the Malaysian Government for 1st Global is called Technofund, to fund the pre-commercialisation stage which involved the pilot plant.

TechnoFund is a competitive funding to undertake development of new and/or cutting edge technologies in five technology clusters namely biotechnology, information and communication technology (ICT), Industry, Sea to Space, and Science & Technology Core. These technologies must have the commercial potential to create new businesses and generate economic wealth for Malaysia.

The process may involve the following activities:

a. The acquisition of technology (foreign and/or local);
b. Up-scaling of laboratory prototype or development of commercial ready prototype;
c. Development of pilot plant (pilot plant is used to generate information about the behaviour of the system or to provide valuable data in order to reduce the risk associated with the construction of the full-scale plant. Therefore pilot plant should be smaller than production scale plants and based on the "rule of thumb", the amount involved should not exceed 10 times at the lab scale);
d. Pre-clinical or clinical trials/field trials for demonstration and testing purposes; and
e. TechnoFund serves as a bridging fund to address the funding gap which exists between the earlier basic research stage and the commercialization stage.

TechnoFund aims to:

a. Stimulate the growth and successful innovation of Malaysian technology-based enterprises by increasing their level of research and development and commercialization;
b. Increase capability and capacity of Malaysian Government Research Institutes and Institutions of Higher Learning to undertake market driven research and development and to commercialize the research and development outputs through spinoffs/ licensing;
c. Enhance global competitiveness and research and development culture among Malaysian technology-based enterprises;
d. Increase contribution to Malaysia's economy through economic wealth creation and exports;
e. Foster greater collaboration between Malaysian enterprises and Government Research Institute and Institutions of Higher Learning; and
f. To encourage institutions, local companies and inventors to capitalize their intellectual work through patent registration.

There are two types of Technofund, Type A being the pre-commercialisation and Type B being IP acquisition for Laboratory Scale. Type A activities comprise development of pilot plant/upscaling of laboratory prototype or development of commercial ready prototype/pre-clinical or clinical trials/field trials for demonstration and testing purposes and not for commercial production purposes. Type B comprises acquisition of intellectual property (academic/laboratory scale prototype) from overseas or local sources and must be further developed to precommercialization stage.

1st Global qualified under both types where the company would conduct pre-commercialisation of the products and process based on the MSF Technology or upscaling of the laboratory work from Taiwan Province, China.

To qualify for the funding, an applicant has to show that it has complied with the requirement of either one of the two types of fund. The applicant must be companies incorporated in Malaysia; and the applicants are encouraged to collaborate with one or more research institution or institutions of higher learning (public or private). In any case, the company or any industry partner(s) must have a minimum of 51 percent equity held by Malaysian and should jointly contribute to financial or non-financial resources to the project. Applicants must have mutual agreement or understanding with collaborators prior to the signing of the TechnoFund Agreement and to submit the agreement to

Ministry of Science, Technology and Innovation. There shall be no changes or substitutions for the collaborator, unless with the prior written approval of the Ministry.

At the same time, the project will have to meet the following criteria:

a. Project Leader and the project team must be competent enough to undertake the proposed project. The curriculum vitae and supporting documents of the Project Leader and each project team member must also be attested and submitted.

b. All categories of companies must have a minimum of 51 percent equity held by Malaysians.

c. Company entity/collaborator must also have minimum paid up capital in cash of RM10,000.00 (USD 2,800) except for start-up and spin-off companies.

d. None of the company directors or project team members have been convicted for any fraudulent activities; or the company ever been into bankruptcy, liquidation or receivership.

Quantum of Funding is up to a maximum of the total project cost or RM5 million (equivalent to USD 1.4 million) whichever is lower based on merit of the case and reasonable justification. For projects with intellectual property acquisition (Type B), funding is up to a maximum of 100 percent of the total acquisition cost or RM2 million (equivalent to USD 566,000) whichever is lower. The total project cost should not exceed RM5 million (USD 1.4 million) based on merit of the case and reasonable justification.

The maximum project duration allowed is up to a maximum of twenty-four (24) months; and if involve intellectual property acquisition, the duration of the project and funding may be extended by another six (6) months.

The application process will take about one month where the parties are required to submit the application forms, business plan and 10 copies of the CD consisting of the hard copies. All applications will have to be assessed by the Technical Committee consisting of technically qualified persons before being referred to the Approval Committee chaired by the Ministry of Science, Technology and Innovation’s Secretary General.

Approval of application takes into consideration, amongst others, the following criteria:

a. The proposed project must be within the scope of TechnoFund;

b. Applicants must submit project proposals under one of the technology clusters;

c. Able to demonstrate potential for commercialization of new and/or cutting edge technologies;

d. Applicants must belong to the relevant target group according to the type of funding applied for;

e. Project teams should consist of qualified and competent members in technical and commercialization aspects;

f. Applicants should show proof of financial capability to finance any portion of project cost not funded by TechnoFund; and

g. Project proposals must contain the following elements:-

    a. Proposed project has potential economic benefit to Malaysia and enhancement of Malaysia’s competitiveness.

    b. Project objectives must be realistic and the methodology to be used must be appropriate.

c. Project costs must be reasonable and justifiable taking into consideration that the proposed activities are for precommercialization stage only. Applicants must fulfil other conditions stipulated under the guidelines and policies of TechnoFund.

In the case of 1st Global, the Technical Committee of the Technofund in its evaluation stated that it would be difficult for them to conduct due diligence on the MSF Technology as it is not patented. However, it was explained to the Technical Committee that the AMSF Technology consists of formulation and therefore it would not be viable to apply for patent as this would require full disclosure of the process which would compromise the traditional knowledge owned by the company which form the trade secret.

This is an important issue to be addressed as it is understood from the above discussion that many traditional knowledge will face difficulties in complying with the conventional intellectual property system such as patent as the traditional knowledge would involve many characteristics that may not fit into the conventional intellectual property system. For example in the case of AMSF Technology the technology cannot be patented as this would require disclosure of the trade secret.

The insistence of patent by the Technofund Technical Committee proves a dilemma for the 1st Global and it was not easy to convince the Technical Committee otherwise as it was of the view that the AMSF Technology should be patented in order to allow due diligence to take place. However, it is suggested that the Technical Committee can always visit the Biozyme facilities in Taiwan Province, China in order to ascertain how the MSF Technology being applied by the holder of the technology. The Technical Committee should also recognise that trade secrets are also part of the intellectual property as provided by Article 39 of the TRIPS Agreement.

3.5.3 Other Government-backed funds

The Malaysian company may also apply to other fund, if there is need be. In addition to the fund from the Bionexus through the Malaysian Biotechnology Corporation, there are additional source of funding from Malaysian Technology Development Corporation (MTDC), Malaysian Life Science Fund (MLSF) and several other funds under the Ministry of Science, Technology and Innovations.

MTDC was set up by the Government of Malaysia in 1992 to spearhead the development of technology businesses in Malaysia. Its initial role was to concentrate on the promotion and commercialisation of local research and invests in new ventures that can bring in new technologies from abroad. From those investment activities, MTDC has evolved to become a venture capital outfit.

Table 1: MTDC Funds

Fund Name	Fund Size	Purpose of Funding	Maximum Amount
Non ICT Venture Fund	RM 1 billion (USD 283 million)	Investment in Venture Capital	No Specific Limit, range from RM 3 million (USD 850,000) to RM 50 million (USD 14 million)
Technology Acquisition Fund	RM 100 million (USD 28.3 million)	Acquisition of foreign technology	RM 2 million (USD 566,000)
Commercialisation of Research and Development Fund	RM 155 million (USD 32.5 million)	Commercialisation of local research and development	RM 4 million (USD 1.132 million) or 70 percent of the project cost.

The Malaysian Life Sciences Capital Fund (MLSCF) was founded in late 2006 and is a life sciences venture fund specializing in early stage investments in the areas of agriculture, industrial and healthcare biotechnology. Co-managed by Malaysian Technology Development Corporation Sdn Bhd (MTDC) and Burrill & Co., the fund has USD150 million in committed capital. The purpose of the funding is to invest in early to mid-stage companies that are involved in healthcare, industrial and agriculture biotechnology, where the maximum investment in a company is USD 8 million.

Malaysia Debt Ventures Berhad (MDV) is an innovative financier and development facilitator for Biotechnology, ICT and other high-growth sectors in Malaysia. Incorporated on 23 April 2002 as a wholly owned subsidiary of the Minister of Finance Inc., MDV has been entrusted to manage funds of RM2.5 billion (USD 700 million) for the financing of projects in these industry sectors. It provides equipment and infrastructure financing, working capital financing and contract and project financing.

The other option is to obtain a loan from the SME Bank, which acts as a development financial institution to nurture and meet the unique needs of small and medium enterprises (SMEs). The bank offers fixed asset financing, working capital financing and cost of technology transfer up to RM5 million (USD 1.4 million).

Ministry of Science, Technology and Innovation

In supporting the development of biotechnology industry in Malaysia, Ministry of Science, Technology and Innovation provides the numerous grants for biotechnology as follows:

Table 2: MOSTI Funds

Fund Name	Fund Size	Purpose of Funding	Maximum Amount
Science Fund	RM 550 million (USD 156 million)	Development of new products or processes up to proof-of-concept; enhancement of research capability	RM 500,000 (USD 141,000)
Inno Fund	RM 80 million (USD 22.6 million)	To encourage participation from micro entrepreneurs / individual and groups from the community in the service and product	Enterprises – RM 3 million (USD 849,000) and Community Groups RM 1 million (USD 283,000)
Technofund	RM 680 million (USD 192.5 million)	Pre-commercialization on activities, comprises development and up-scaling of new and novel technologies from lab scale prototype up to commercial ready.	Up to a maximum of the total project cost or RM5 million (USD 1.4 million) whichever is lower
Agro - Biotechnology R & D initiatives	RM 80 million (USD 22.6 million)	R & D in strategic areas of agro-biotech that will lead to modernization and transformation of the agricultural sector	Up to a maximum of the total project cost or RM2.5 million (USD 707,000 million) whichever is lower

Genomic & Molecular Biology R & D Initiatives	RM 100 million (USD 28.3 million)	Generation of intellectual properties and technologies for application in modern bio-manufacturing of high value products such as biocatalyst, fine chemicals and diagnostics	Up to a maximum of the total project cost or RM5 million (RM1.4 million) whichever is lower
Pharmaceutical & Nutraceutical R & D Initiatives	RM 90 million (USD 25.4 million)	To develop 'proof of concept' products or service developed by local scientists to comply with the international standards imposed by the regulatory authorities such as good research practice (GRP) and good laboratory practice (GLP)	Up to a maximum of the total project cost or RM5 million (USD 1.4 million) whichever is lower

3.6 Analysis of the Case Study

There are several observations can be made from the case study. There are several lessons to be learned from the case study. One, the case study shows that it is possible for the holder of the traditional knowledge to innovate and add value and gain economic advantage from directly working on the traditional knowledge rather than having to resort to letting 'outsiders' to work on such knowledge.

In the case study, the traditional knowledge is identified as the Chinese fermentation technology as modified by Professor Huang. The knowledge belongs to Professor Huang and his family and commercialised through his company Biozyme and its international associates in the United States, Europe and Malaysia.

Professor Huang has added value to the traditional knowledge using the AMSF Technology which he researched and developed through collaboration with a university in Taiwan Province, China. What happens here is the non systematic production of fermented products has been turned into a systematic production of enzyme-based products that could be further developed into nutraceuticals and pharmaceuticals using plants resources within Taiwan Province, China. The technology could be adapted to produce similar products using vegetables and fruits in other countries. It shows that the value added traditional knowledge can be replicated and bring benefits not only to the traditional knowledge holder but also to the country through increased export and also to the society at large.

The value added AMSF fermentation technology used by the Biozyme fits within what is stated by WIPO that "contrary to a common perception, traditional knowledge is not necessarily ancient. It is evolving 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." This is because the AMSF technology is not ancient but contemporary that fits within the need of the contemporary society.

Two, the case study also shows that it is possible for the traditional knowledge holders to collaborate with others, in this case between Biozyme and 1st Global, to share the availability of raw materials and to transfer the technology under licence using the conventional licensing agreement. The transfer of technology shows that there is a possibility to have a South-South transfer of technology based on the traditional knowledge, and this will assist the economic development and increase the competitive edge of the South countries, for example in the field of alternative medicine.

Three, the case study shows that the government has a role to play in encouraging the development of innovation within the traditional knowledge. Governments can offer various forms of support such as grants and tax incentives. Support is needed from the government as the traditional knowledge owners may lack the necessary capital to develop the ideas and the innovation to the commercial level. The efforts taken by the Government of Malaysia shows how a government can support the traditional knowledge holders by offering the various incentives and grants to encourage investment and transfer of technology. In the case, the transfer of technology from Taiwan Province, China to Malaysia is facilitated indirectly by the availability of the grants and the incentives, to encourage the Malaysian joint venture company to acquire the value added AMSF technology.

Four, the case study also shows that those traditional knowledge holders must comply with the various international standards such as the GMP in the production of the traditional knowledge products in order to gain acceptance to the market, to meet the regulatory requirement and to attract consumer confidence. Biozyme has complied with the various standards such as GMP and has made sure that all productions comply with the modern requirement. It is important for the traditional knowledge holders to adapt to the modern standards in order to break into the market and to further enhance the standing of the innovative traditional knowledge products. This shows that the efforts taken by the Government of China and the Government of India to encourage research and development and the adoption of high standards of production receive support from the industry.

Five, the case study also shows the difficulty to adapt the traditional knowledge with the conventional intellectual property system. The fermentation technology where the AMSF technology is based on is not patented and so is the MSF technology as this is considered a formulation and thus a trade secret. Patenting the trade secret would have disclosed the formulation to the public domain and this is not desirable. At the same time any patent application could be attacked on the ground the fermentation technology is already in the public domain and not disclosing the formulation of the AMSF technology would result in the partial disclosure and this could lead to the rejection of the application.

However, for a research grant approving committee, it would be more difficult to conduct a technology due diligence on a trade secret as compared to conducting a due diligence on a patented technology. This was the concern of the Technical Committee of the Malaysian Technofund that the AMSF Technology when it argued that it would have been better for the AMSF Technology to be in a patented format. Nevertheless, the AMSF Technology is an extension of a traditional knowledge and therefore, is in a unique position as compared to the conventional technology. This also shows that there is a need for a grant approving committee to be able to find creative way to conduct due diligence on trade secret under Article 39 of TRIPS. This requires an appreciation of the peculiarity of the traditional knowledge which necessitates the new method of protection and a new paradigm shift in the way policy makers think about intellectual property protection.

4. CONCLUSION AND RECOMMENDATIONS

Based on the above discussions, the paper is able to reach several conclusions.

One, traditional knowledge is difficult to define as they may be owned by the community or by the family and they may not be ancient. In the case study, the knowledge to process certain types of fruits and vegetables into enzyme based products is owned by the Huang family and this is further based on the ancient method of Chinese fermentation.

Two, biotechnology, either traditional or classical, may assist the innovation and economic development of local community through the innovation and value-added activities on the traditional knowledge. There is a big potential for developing countries to develop biotechnology by utilising traditional knowledge based inventions to enhance their economic competitiveness and their share of global market of biotechnology. The abovementioned discussion shows that the Government of China, the Government of India and the international community and international organizations such as the WHO are fully aware of the economic potential from the innovation and value-added activities from the traditional knowledge. The different initiatives taken by China, India and the WHO to assist the holders of the traditional knowledge to modernise the production methods show that with government assistance, traditional knowledge holders can exploit the knowledge to the fullest.

Three, the biotechnology can assist the innovation and economic development of traditional knowledge holders. In fact some of the traditional knowledge is actually part of biotechnology and this shows that biotechnology is not necessarily a modern matter. The policy of the various policies by China and India and Malaysia shows how government can encourage the development of the traditional knowledge using biotechnology and to further develop biotechnology related traditional knowledge. The case study shows that biotechnology related traditional knowledge can be further developed into high end products such as nutraceuticals and with research and development and further investment into pharmaceuticals.

Four, there are various obstacles facing innovation in the biotechnology-based traditional knowledge or to use biotechnology to add value to the traditional knowledge. One of the main obstacles is the funding required to conduct research and development and later the commercialisation on the traditional knowledge. Many traditional knowledge owners live in rural areas with little access to capital. Even those with the capital such as 1st Global and Biozyme Biotechnology joint-venture from the case study find that capital is still a big issue. Thus, there is a need for sharing of resources and capital among the various parties. Two, there is a need for policy makers to understand that in some cases, trade secrets may offer a higher level of protections to traditional knowledge compared to patents. Nevertheless, the traditional knowledge itself may remain a trade secret but the follow-on innovation in the chain of traditional knowledge improvement process could be patented if they fulfil the patentability requirement. Importantly, a *sui generis* right needs to be conferred to traditional knowledge holders who stand on the upstream of traditional knowledge innovation chain to ensure their equitable benefits sharing in the follow-on innovation. Three, in the event that there is a collaboration between the traditional knowledge holders and a third party innovator or investor to commercialise the products based on traditional knowledge, there has to be a proper mechanism for benefit sharing between the third party and the third party innovator or investor. The benefit sharing arrangement has to be in the form of commercial arrangement between the parties and it is not enough for such arrangement to contain in the patent application alone. The commercial arrangement between the traditional knowledge holder and the third party innovator or investor must have pertinent provisions such as the monetary gain or any form of gain in favour of the traditional knowledge holder, how the benefit is to be transferred from the third party inventor or investor to the traditional knowledge holder and the terms or duration for such benefit to endure to the traditional knowledge holder.

Based on the above, the paper is now able to develop several recommendations for the developing countries.

1. The governments may develop a string of policies to develop innovations by the traditional knowledge holders, to provide for socio economic benefit to the society and the country. Such policies include:

    a. The government's direct involvement in the financing of the research and development and commercialisation of biotechnology based traditional knowledge into added value products which are able to bring high income to the community.

    b. The government's direct involvement may come in the form of creating grant schemes for research and development, grant scheme for purchase of technology as added technology to the traditional knowledge, venture funds and debt funds for the commercialisation stage, export assistance scheme for export promotions.

    c. Government granting direct fiscal benefits from the increase in the number of business activities. On one hand, Governments may provide some direct fiscal incentive to those involved in the biotechnology based traditional knowledge business by providing some tax exemptions or tax holidays. On the other hand Governments may collect more tax due to increased in individual income through increased employment and the higher amount of salary. Governments may lose on the corporate tax but may gain from the income tax and indirect tax such as sales tax and value added tax. For example in the United State the combined corporate and academic investments in biotechnology totalled USD 231.7 billion over the past five years and this investment is investment is fuelling a biotechnology industry that supports directly and indirectly 7.5 million jobs for an average investment per job of USD 30,900. These jobs paid an average of USD 71,000 per year or USD 355,000 over five years.[49] Despite the global financial crisis, in the United States, venture capital firms invested USD 577 million or 19.20 percent of all total investment in the first quarter 2009.[50]

2. The financial investment, fiscal incentives and other supporting policies must be clear, easy to be understood by the stakeholders, transparent and with proper guidance from the relevant approving authority.

    a. The time taken to process the application including the approval and rejection should not take time. For example in Malaysian a Bionexus status would be processed within six weeks from the date of the complete application with guidance provided from the early stage to ensure only applications with potentials are processed. The Technofund application process takes about eight weeks to be processed including approval or rejection of the application. However, the Technofund application lacks the necessary guidance from MOSTI on what entails an application with potential for success which could result in a lengthy process.

    b. The process must be transparent with little room for abuse and corruption and with proper appeal process. This means various levels will perform different role. For example the Bionexus application is processed by the Malaysian Biotechnology Corporation who refers a complete application to the Evaluation Committee consisting of parties from various organizations and departments such as the Ministry of Science and Ministry of Agriculture. The Evaluation Committee will make

---

[49] For further detail see R. Guilford-Blake and D. Strickland (eds) Guide to Biotechnology 2008, (Washington DC, BIO, 2009).

[50] PriceWaterhouseCoopers, Money Tree Reports, Investment by Industries Q1 2009, https://www.pwcmoneytree.com/MTPublic/ns/nav.jsp?page=industry (last accessed 25 June 2009).

recommendations to the Approval Committee and the Approval Committee is not bound to accept the recommendations from the Evaluation Committee.

3. The fiscal and financial package is not a guarantee of success without proper guidance on other related fields such as how to meet the clean and acceptable production methods such as GMP and HCCP. Clean and modern production method is not the factor for success but it will be able to provide easier access to market by meeting strict entry requirement into certain countries and to provide a higher level of confidence to consumers. The clean production method will provide a guarantee of safety and quality.

4. Creating special pool of potential traditional knowledge that could be developed. The owner of the traditional knowledge that does not have the capacity and the capability to add value to the knowledge can be encouraged to share the knowledge with interested entrepreneurs to develop the products and to market such products. Foreign investments may also be encouraged. The Government can devise a sui generis protection method for the owner of the traditional knowledge. This is because the promotion of traditional knowledge such as traditional medicine depends on whether the practitioners and the holders of the knowledge will be able to protect traditional knowledge.

5. Creating a data bank, in undisclosed or disclosed manner depending on the ownership, where traditional knowledge could be identified. At the same time data bank will also serve as protection of traditional heritage for the use of future generations. Data in the data bank with a clear identification of the owner of such knowledge will facilitate licensing of such knowledge for commercialisation and this will allow a creation of value chain of such knowledge.

6. While regulation in general is to be encouraged, excessive regulation of traditional medicine can lead to suppression of valuable forms of traditional medicine and resistance from traditional medicine practitioners. Regulatory options range from professional organizations imposing standards on their members, to recognition of these standards, either directly or indirectly, by the government, including statutory support for bodies which impose standards or formal government registration of practitioners by law.

7. Governments may set up an advisory centre to provide advice to various parties on the issue of innovation and commercialisation of traditional knowledge. The advisory centre may provide advice on the intellectual property protections, intellectual property management and the best method and best practice in the commercial arrangement for benefit sharing between third party investor and inventor and the traditional knowledge holders. The advisory centre may also provide advice at subsidised rates to those who cannot afford to hire professional advisors such as legal advisors and patent agents and this will provide better protection for the traditional knowledge holders and may even encourage the traditional knowledge holders to be more involved in the innovation based on and commercialisation of traditional knowledge.

REFERENCES

- O.K. ACHI, The Potential for Upgrading traditional fermented food through biotechnology, African Journal of Biotechnology Vol. 4 (5), pp. 375-380, May 2005.

- D. ACOSTA, Innovation Gives Boost to Small Farmers, IPS, 9th Jan. 2009, http://ipsnews.net/news.asp?idnews=40727 (last accessed 26.2.2009).

- K. APARNA BHAGIRATHY, Using Traditional Knowledge for Commercial Innovations: Incentives, Bargaining and Community Profits, SANDEE Working Paper No. 11-05, 2005.

- B van BEUZEKOM, Biotechnology Statistics in OECD Member Countries: Compendium of Existing National Statistics, Ad Hoc Meeting on Biotechnology Statistics, OECD, Paris, 2001, 3-4 May.

- 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)

- T.COTTIER and M.PANIZZON, Legal Perspectives On Traditional Knowledge: The Case For Intellectual Property Protection, JIEL 2004.7(371).

- C. DAY, The Fall and Rose of Coenzyme Q10, Nutraceutical Business and Technology, Vol. 3 Nr.2 March/April 2007, 24-28.

- FEREDONIA GROUP, World Nutraceuticals Report to 2010, (London, July 2006).

- R. GUILFORD-BLAKE and D. STRICKLAND (eds) Guide to Biotechnology 2008, (Washington DC, BIO, 2009).

- P.W. GRUBB, Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice and Strategy, (Oxford University Press, 3rd Ed., 1999).

- 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.

- 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).

- 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).

- T.HESKETH and WEI XING ZHU, Health in China: Traditional Chinese medicine: one country, two systems, BMJ 1997;315:115-117 (12 July).

- 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.

🕮 INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATION, Biodiversity Resources, Traditional Knowledge and Innovation in Health, (Geneva, IPFMA, 2003).

🕮 C. JAMES, Global Status of Commercialised Biotech/GM Crops, 2008, The First Thirteen Years, 1996 – 2008, ISAAA Briefs 2009, (ISAAA, Ithaca, N.Y, 2009).

🕮 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).

🕮 A.KUMAR, Indian Biotech Bazaar, A Swot Analysis, Biotechnol J, May 4: 2, (5) 543-535. 2007.

🕮 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.

🕮 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.

🕮 MARKETLINE, Biotechnology Global Industry Guide, (London, 2008).

🕮 PRICEWATERHOUSECOOPERS, Money Tree Reports, Investment by Industries Q1 2009, https://www.pwcmoneytree.com/MTPublic/ns/nav.jsp?page=industry (last accessed 25 June 2009).

🕮 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).

🕮 ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, 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).

🕮 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).

🕮 RNCOS Industry Research Solutions, Asia Pacific Biotechnology Market (2008-2012), (Delhi, 2008).

🕮 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.

📖 UNITED NATIONS DEPARTMENT OF ECONOMIC AND SOCIAL DEVELOPMENT, Biotechnology and Development: Expanding the capacity to produce food, (United Nations, New York, 1992).

📖 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).

📖 N.VIETMEYER and J.LAMBERT, Medicinal Plants: Rescuing a Global Heritage, the World Bank, 1997.

📖 WORLD INTELLECTUAL PROPERTY ORGANIZATION, 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.

📖 WORLD INTELLECTUAL PROPERTY ORGANIZATION, 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).

📖 WORLD HEALTH ORGANIZATION, the Global Strategy for Traditional Medicine, 2002.