



BIO-PROSPECTING, IPR, TRADITIONAL KNOWLEDGE AND ITS TRADE SECRETS

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Article Received on: 10/08/12 Revised on: 21/09/12 Approved for publication: 12/10/12

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ABSTRACT

Bio-prospecting involves searching for collecting, and deriving genetic material from samples of bio-diversity that can be used in commercialized pharmaceutical, agricultural, industrial, or chemical processing end products.

Salient features of Bio-prospecting are: Conservation and sustainable use of biological diversity, Rights of traditional, indigenous knowledge holders; fair and equitable sharing of benefits arising from the research, indigenous knowledge, intellectual property, or application of biological resources. The meaningful participation in these processes by traditional, indigenous knowledge holders.

As far as Bio-prospecting & final commercial manufacturing company is concerned certain larger pharmaceutical companies operate their own Bio-prospecting units. They can develop a commercial drug from an idea to Bio-prospecting for genetic material, clinical trial, manufacturing & marketing.

Herbal medicines are not marketed as pharmaceuticals & are not regulated by FDA. These drugs lack in quality control & mostly sold as dietary supplements. Pharmaceutical industries ordinarily synthesize compounds from a limited amount of natural products & the Herbal medicine industries usually don't attempt to do so because of high cost involved for the relatively low return. Pharmaceutical Bio-prospecting involves high returns & requires low volume harvesting.

The conventional biological diversities are an international protocol which gives expression to the novel idea that the Bio-prospecting process could yield conservation & develop benefits.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) under the World Trade Organization (WTO) is the pre-eminent international agreement governing intellectual property rights. It covers a broad range of intellectual property rights, including copyright, trademarks, geographical indications, trade secrets, and patents.

Along with TRIPS a focus given to rights of traditional indigenous knowledge holder & some article related with this & regarding fair & equitable benefit sharing has been elaborately discussed.

Next in the article three approaches of Bio-prospecting for new drug discovery has been given. In case of Bio-prospecting Intellectual Property Rights are often preserved by patents which protect the rights of holder to benefit financially so indigenous knowledge holders of native healing remedies need not fear the loss of use of native biodiversities. Also Bio-prospecting provides monetary & Non-monetary benefits. Lastly the business potential of Bio-prospecting in Indian context in future has been discussed.

KEY WORDS: Bio-Prospecting, IPR, Traditional Knowledge, Trade Secrets

INTRODUCTION

Bio-prospecting involves searching for collecting, and deriving genetic material from samples of bio-diversity that can be used in commercialized pharmaceutical, agricultural, industrial, or chemical processing end products. By the early 1990s, objections to uncompensated bio-prospecting that does not share benefits with the source country became contentious. Since 1991, the convention on Bio-logical Diversity (CBD) has embodied the principles of compensated bio-prospecting globally.

Compensated bio-prospecting involves obtaining prior informed consent from the source, sharing benefits, and promoting sustainable use of bio-diversity. Where indigenous knowledge holders are involved, efforts are made to recognize and protect their rights. Benefits can take various forms, from royalties to negotiated advance and milestone payments, capacity building, facilities and equipment transfer, personnel training, sharing of research, and other forms.

Bio-prospecting involves searching for, identifying, and collecting appropriate bio-specimens. In addition, bio-prospecting uses various cutting-edge technologies to process and develop genetic material from these specimens that exhibit characteristics desirable in a commercial product. It is the genetic material, not the bio-specimen itself, that is of interest. Generally then, it would be inefficient, irresponsible, and unnecessary for bio-prospector to collect massive volumes of plants or animals for processing. Consequently, it is a misconception that bio-prospecting decimates an organism's population to near extinction and denudes entire rainforests like wholesale strip-mining for gold. Bio-

prospecting firms or their partners or clients generally need only a few specimens to extract the genetic material they need.

However salient features of Bio-prospecting are as follows-

Conservation and sustainable use of biological diversity.

Rights of traditional, indigenous knowledge holders ; fair and equitable sharing of benefits arising from the research, indigenous knowledge, intellectual property, or application of biological resources.

The meaningful participation in these processes by traditional, indigenous knowledge holders.

Bio-prospecting vs. Final Commercial Manufacture

At this point, there is a need to distinguish bio-prospecting per se from the development or actual manufacture of a commercial product. With pharmaceuticals as an example, certain large global pharmaceutical firms operate their own bio-prospecting units. In other words, they are vertically integrated and can take a product from start to finish all in-house. Specifically, they can develop a commercial drug from idea conception to bio-prospecting for likely genetic material, synthesis of active compounds, clinical trials, manufacturing, marketing and distribution. On the other hand, stand-alone bio-prospecting firms typically work mostly on the front end. They normally identify likely samples, organize sample collection, isolate and process active compounds from samples into a form usable by the pharmaceutical client. In this case, the bio-prospecting firm merely delivers processed molecules to its client. The pharmaceutical firm then decides, with no guarantee of success, whether to proceed to develop a new drug with the processed compounds.

Pharmaceutical Bio-prospecting and Phytomedicine

Related to the foregoing is another common misconception concerning bio-prospecting at least with regard to pharmaceuticals. There is a general belief that pharmaceutical bio-prospecting invariably requires, high-volume harvesting of whole organisms for final consumption, thus decimating bio-diversity.¹ This is not entirely accurate. However, high volume harvesting is always true of herbal medicine. Although it is possible to bio-prospect for potential herbal remedies, bio-prospecting for regulated pharmaceuticals has focused on the higher returns available from commercializing approved and regulated pharmaceutical drugs. Herbal medicines, on the other hand, are not marketed as pharmaceuticals and are not regulated by the Food and Drug Administration. Further, they are not standardized in dosage or strength, lack quality control, and are mostly sold as dietary supplements.

Bio-prospecting that aims to develop a regulated pharmaceutical drug ordinary does not require wholesale harvesting of plants or animals. Thus, while pharmaceutical bio-prospecting does not ordinarily endanger bio-diversity, current practices in the phytomedicine industry always pose a danger. Pharmaceutical firms ordinarily strive to synthesize compounds from a limited amount of natural products. On the other hand, producers of herbal medicines usually do not attempt to do so because of the high costs involved for the relatively low-return industry. In contrast, pharmaceutical bio-prospecting involves a high return and requires only low-volume harvesting. The point is that, although one can bio-prospect for both pharmaceutical drugs and phytomedicines, the two are not necessarily the same.

In general the phytomedicine industry harvests various parts of plants, such as stems, roots, or bark, and various animal parts, such as bones, horn, or skin, for consumption with minimal processing. These ingredients are mostly ground into powders or pastes. The plant or animal itself is usually harvested in great numbers. "Herb and phytomedicine companies pay a low price for large volumes of medicinal plant biomass from tropical ecosystems, package it in their own facilities and then sell the products at an inflated price in northern countries. Despite the CBD, the industry still enjoys a period of uncontrolled, undocumented, and poorly managed free access to medicinal plants and cultural knowledge throughout the world". In other words, the danger to bio-diversity lies more in current phytomedicine industry practices than in pharmaceutical bio-prospecting. Even so, harvesting phytomedicines does not mean only a slash and harvest approach must be used. Conservation practices can be applied to the phytomedicine industry as well. For example, forest farms can be organized to grow and harvest targeted plants for commercial use. Medicinal plants can be cultivated as fallow crops.

To further confuse the issue, a pharmaceutical bio-prospecting company may "crossover" into a phytomedicine company. A crossover example is the transformation of Shaman Pharmaceuticals into Shaman Botanicals. The former was a pioneer in formulating principles of benefit sharing, sustainable use and conservation of bio-diversity, preservation of indigenous knowledge, and informed prior consent. In fact, the framework of principles established in Shaman Pharmaceuticals contracts predated and served as a model for the Convention on Biological Diversity. Originally, Shaman Pharmaceuticals was interested in developing an anti-diarrheal drug to treat AIDS patients. Indigenous knowledge holders directed it to the sap of the Croton lechery

tree found in the Amazon. From this, Shaman pharmaceuticals developed SP-303/Provir and actually received favorable results from their single pivotal Phase III study on December 22, 1998. However, the Federal Food and Drug Administration required further testing, at which point Shaman Pharmaceuticals declined to proceed for cost reasons. It continues today as Shaman Botanicals with the same protocols selling Shaman Botanicals-Normal Stool Formula as a dietary supplement with the active compound in Provir. Shaman Botanicals claims its failure does not mean the end of ethno-botany as an approach to drug development. Rather, it blames the extremely difficult and expensive drug development process in the United States².

Regulations of Bio-prospecting

Regardless of the history and different philosophies regarding bio-prospecting, the new global reality prevents nations from continuing to permit unregulated bio-prospecting. In 1992, the convention on Biological Diversity (hereafter "CBD") was signed by 150 nations to address the international bio-prospecting issue. Also in 1992, a parallel approach embodied in the international Co-operative Bio-diversity Groups (hereafter "ICBG") took shape.

Convention on Biological Diversity

The CBD was opened for signature on June 5, 1992, at the United Nations Conference on Environment and Development in Rio de Janeiro in Brazil. This international protocol gave expression to the novel idea that the bio-prospecting process could yield conservation and development benefits. Carried out properly, the process could provide economic incentives for the conservation of bio-diversity as well as for local and regional development.³ The CBD is an international agreement that applies to sovereign nations. It was not meant to address bio-prospecting in non-sovereign entities such as individual provinces in France or individual states in the United States.

It should also be noted that the CBD is widely considered an unenforceable protocol that relies on voluntary compliance among the parties. As a well-known observer notes, although the CBD is a legal document: "It lacks bite. There is no way to enforce it."⁴ According to another observer: "Distrust is a problem. Some people think that bio-prospecting agreements are inherently unfair and out priced for indigenous peoples from the outset.

International Intellectual Property Rights Regime

The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) under the World Trade Organization (WTO) is the preeminent international agreement governing intellectual property rights. The TRIPS Agreement was agreed to during Uruguay Round, which began in 1986 and ended in Geneva in 1993 and was signed in 1994 in Morocco. The TRIPS Agreement establishes uniform minimum standards for protection and enforcement of intellectual property rights by WTO members. It covers a broad range of intellectual property rights, including copyright, trademarks, geographical indications, trade secrets, and patents.

The TRIPS Agreement is binding on all WTO members, many of whom are also parties to the CBD. Therein lies the problem. The two conventions conflict. Patent offices in the home countries of bio-prospecting firms or end-users may grant patents over genetic resources of a source country without consent or benefit sharing. The TRIPS Agreement does not require them to do otherwise. Source countries have incentives to promote CBD objectives, but the TRIPS Agreement can be used to undermine efforts at national benefit sharing legislation. CBD inspired national legislation

requiring benefit sharing and prior informed consent can be challenged in bilateral discussions, and ultimately at the WTO, on the basis that they unreasonably prejudice” the interests of the intellectual property right holder.⁵

For example, a recent review by the Center for International Environment Law and the World Wide fund for Nature noted that more study is needed on resolving the CBD-endorsed transfer of technologies protected by intellectual property rights. The review points out that the CBD is voluntary in nature. In other words, the problem remains intractable because the CBD lacks teeth. In contrast to CBD provisions, the WTO has a binding dispute settlement mechanism where one party may impose trade sanctions on another party.

In another example, the TRIPS Agreement grants WTO members several exceptions to offering patent protection to other members. A member may exclude inventions from patentability under four exceptions:

- 1) In order to protect the public order (Article 27.2).
- 2) Plants and animals other than microorganisms are accepted, (thus, patents must be granted over microorganisms as well as non-biological and essentially biological processes for the production of plants and animals (Article 27.3(b)).
- 3) Members can provide limited exceptions to the exclusive rights conferred by patents subject to certain qualifications (Article 30).
- 4) Members may permit use of the patented invention by third parties without the authorization of the patent owner in certain circumstances (Article 31).

The upshot of is that: “So far, the scope and utility of these provisions in ensuring compatibility with CBD objectives remains unclear at the WTO. “23 A separate TRIPS review of Article 27.3(b) also remains inconclusive.”⁶

Rights of Indigenous Knowledge Holders

Article 8(j) directly addressed two of the concerns raised in H.C.R. No. 146-“rights of traditional, indigenous knowledge holders” and meaningful participation in these processes by traditional, indigenous knowledge holders.

Parties must, as far as possible and as appropriate:

- (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for 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;⁷

Articles 10(c) and (d) also address the issues involving indigenous knowledge holders expressed in H.C.R. No. 146-rights and participation of indigenous knowledge holders. These provisions require parties, as far as possible and as appropriate, to:

- (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;
- (d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced;⁸

Fair and Equitable Benefit Sharing:

Article 15-7 requires a party to take legislative, administrative, or policy measures to fairly and equitably share benefits with the source party from the research and

development of commercial or other uses of genetic resources.

Handling of Bio-technology and Distribution of Benefits. Article 19 contains four provisions under the rubric of distribution of benefits as follows:

Each Contracting Party shall take legislative, administrative or policy measures, as appropriate to provide for the effective participation in bio-technological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from bio-technologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from bio-technology that may have adverse effect on the conservation and sustainable use of biological diversity.

Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.⁹

To summarize, Article 19:

Encourages participation in bio-technology research for the source country promotes fair and equitable access by the source country to results and benefits of this research, on mutually agreed terms, encourages establishment of procedures for “advance informed agreement: to safely handle the transfer of modified living organisms derived from bio-technology that may harm conservation or sustainable use of bio-diversity.

Requires disclosure of information on the safe handling of such organisms and their potential adverse impact Financial Resources.

Article 20 addresses how the objectives of the CBD are to be supported financially by the parties. Article 20-1 states that each party is responsible for financially supporting the CBD’s objectives in accordance with its national plans, priorities and programs. Obviously, the CBD can have no control over a country’s national plans or priorities.

Article 20-2 requires “developed country parties” to financially assist “developing country parties” to implement the CBD on a grant or concessional basis (provided for in Article 21).

Article 20-3 notes that financial assistance can also be made through bilateral, regional and other multilateral channels.

Article 20-4 recognizes that the success of developing countries in implementing the CBD depends on how effectively developed countries provide financial assistance and transfer technology. This provision further recognizes that economic and social development and eradication of poverty are the first and overriding priorities of the developing country parties.

Article 20-5 directs parties to give special attention to the needs of "least developed countries".

Article 20-6 gives special consideration to countries in special situations resulting from the dependence on, distribution, and location of bio-diversity, such as small island states.

Finally, Article 20-7 gives special consideration to developing countries that are the most environmentally vulnerable, such as those with arid and semi-arid zones and coastal and mountainous areas.

Financial Mechanism

In order to implement the financial assistance above, Article 21 sets up a funding mechanism under the Conference of the Parties ("COP"). The COP is to determine the institutional structure, policy, strategy, program priorities, and eligibility for access to financial assistance.

The COP also determines the amounts needed where contributions must be predictable, adequate, and timely. Voluntary contributions are also welcome. The COP reviews the effectiveness of the financing mechanism two years after its start and on a "regular basis" thereafter.

BIOPROSPECTING AND ITS APPROACH TO NEW DRUG DISCOVERY

The three approaches have been applied to bio-prospecting for drug discovery, although they can also apply to other end uses (industrial, agricultural, and chemical processing).

The first is random testing in which the greatest diversity of different specimens as possible is sampled. This is the shotgun approach and is expensive as well as inefficient.

The second is the bio-rational approach, which is more useful and efficient. This approach targets specific organisms based on their biological characteristics. For example, observing bacteria thriving in hydrothermal vents suggests they have heat and salinity tolerances.

The third approach, which is also non-random, is ethnobiological. This approach elicits traditional (or indigenous) knowledge to guide samples selection. The ethnobiological approach is less expensive and more focused. Yet, this approach is "used only by a small segment of bio-prospectors."¹⁰ The implication is that the myriad complex problems, including control of intellectual property rights over indigenous knowledge, make this last approach unattractive and problematic.¹¹ Shaman Pharmaceuticals (now Shaman Botanicals) is the best known of bio-prospecting firms to have adopted the ethnobiological approach. The advantage of relying on indigenous knowledge holders is that they: know the correct species, its location, the proper time of collection (some plants are poisonous in certain seasons), the solvent to use (time and conditions to be left on the solvent), and finally, posology (route of administration, dosage).¹²

How indigenous remedies are prepared also offers clues as to the chemical compounds involved however, problems involving intellectual property rights that are integral to this approach abound. This is the wellspring of opposition to ethnobiological bio-prospecting. Clearly, indigenous peoples fear the loss of their right to profit sharing. In addition, they also fear the loss of ownership of native bio-diversity and the right to carry on their traditional practices.

Intellectual Property Rights

In general, intellectual property rights are rights to make, use, and sell a new product or technology that are granted, usually for a period of 17-20 years, solely to the inventor or the entity that files a claim on the inventor's behalf. They generally

take the form of patents, trademarks, or copyrights and have traditionally fallen under the domain of national law.¹³

In the case of bio-prospecting, intellectual property rights are often preserved by patents, which protect the right of the holder to benefit financially. There are confusing misconceptions about, as well as genuine philosophical objections to, patents, including the morality of patents relating to life forms.¹⁴ In the United States, living or dead plants found in nature cannot, themselves, be legally patented. However, if a plant breeder made a horticultural or genetic change, the change is considered an invention and can be patented.

It is important to note that patents on living organisms in pharmaceutical bio-prospecting are uncommon. Typically, patents are granted for scientific advances during the isolation and modification of chemical derivatives and analogs of compounds originally isolated from a plant for an identified use.¹⁵ In this sense, indigenous knowledge holders of native healing remedies need not fear the loss of use of native bio-diversity. Another misconception is that patents relating to traditional knowledge somehow infringe on the right to perform indigenous cultural practices. In fact, indigenous rights to use tangible and intangible cultural resources in both traditional and innovative ways are not affected by patents.¹⁶

Nonetheless, the world of intellectual property rights, especially in the international bio-prospecting arena, is both arcane and complex. For example, the Agreement of Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization sets minimum requirements for the protection of intellectual property rights.

These include novelty, non obviousness, and usefulness. Indigenous knowledge, however, fails the novelty requirement.

For example, using a certain plant root to treat diarrhoea-as part of indigenous knowledge is not a novel or an original use. Knowledge of that particular treatment was known or used by others.¹⁷ Thus, most countries' patent offices do not provide for the protection of indigenous knowledge. Neither do they require benefit sharing from bio-prospecting.¹⁸ National and international legislation on intellectual property rights and bio-prospecting are still being discussed and continue to evolve.

Aside from indigenous knowledge, some bio-prospecting programs recognize "know how." For example, when indigenous knowledge is involved and an invention is patented, if the provider of indigenous knowledge cannot be recognized at the level of an inventor, the contribution is treated as valuable "know how." Subsequently, in any related publications and in the patent, the contribution must be credited as "prior art." (Prior art may be very broadly defined as the entire body of knowledge from the beginning of time to the present.)¹⁹ Prior art citations formalize the contribution of such knowledge but do not claim any monopoly rights to use. According to one observer, the absence of a prior art citation may constitute grounds to deny or invalidate a patent.²⁰ The concept of prior art further illustrates the convoluted nature of the intellectual property rights regime. To begin with, an invention essentially deals with something new, something unknown. Since it is difficult to define an invention by describing something that is still unknown, the alternative is to state what is not an invention.²¹

BIO-PROSPECTING AND BUSINESS MODEL

The CBD attempts to address the need for equitable sharing of benefits from bio-prospecting and concerns about loss of global bio-diversity.

The Convention has three goals:

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.²²

Monetary payments can include bio-prospecting fees and fees for each sample obtained. The bio-prospecting firm can dedicate a percentage of the research budget to locally preferred use including diseases endemic to the local population. Monetary benefits have also been used to fund conservation programs, universities, and other groups. Monetary benefits can also be applied to develop alternative income-generating schemes. Furthermore, a negotiated agreement may also commit the firm to obtain future supplies of bio-diversity from the host country.²³

Non-monetary benefits include the acknowledgement of contributions in publications or joint authorship and joint research. More substantially, it may provide training and increase scientific capacity by building a technology infrastructure. Portions of monetary benefits can be specifically set aside to fund conservation programs and actions to promote sustainable use of bio-diversity. The bio-prospecting firm also often provides free access to its technology, equipment, products, and research results. In certain cases involving the use of indigenous knowledge, a negotiated agreement may also provide for co-ownership of intellectual property rights. "Since 1993, over 1,400 developing country collaborator's from 12 countries have received formal training in degree as well as technical training programs from the ICBG."²⁴

According to one source, monetary and non-monetary benefits can be described generally as follows:²⁵

Monetary Benefits

Advance payments: These are used primarily to set up trust funds for the disbursement of small community grants for development projects such as medicinal plant cultivation and marketing, tool purchases, written educational materials, shaman apprenticeship programs, and travel and workshops to build alliances among local community leaders.

Royalty earnings: This constitutes a percentage of income from product commercialization stipulated in research and benefit-sharing agreements.

Non-monetary Benefits- Capacity building through training, equipment transfers, development of infrastructure to conduct bio-medical research, manage natural resources, region-specific disease research that gives priority to local interests in addressing relevant diseases, e.g. malaria cure for African countries.

Long-term collaboration between various conservation, health, bio-technology, educational organizations and workers of both host and bio-prospecting countries. Negotiated Bio-prospecting Agreements. Currently, a negotiated agreement is the preferred tool used to provide compensation (which also underwrites sustainable use and conservation capacity building and programs) for access to bio-diversity. Specific terms of compensation, are-left to the

parties to agree upon but agreements are beginning to incorporate the principles embodied in the Convention on Biological Diversity. Negotiated agreements that provide balanced rights and benefits for both parties are preferred over the more problematic working out of intellectual property rights.

Prior Informed Consent

Although not stated as a principle in the Convention on Biological Diversity, the granting of prior informed consent has also become standard in negotiated agreements.

The concept of informed consent was originally conceived with regard to protection of the personal safety of human subjects participating in medical research. Until recent years, informed consent in ethno-biological research was generally interpreted to mean verbal disclosure to the individual regarding the potential uses of his or her knowledge.

Today, the possibility that financial benefits may result from this research necessitates complex arrangements with source communities and a very thorough information sharing process. Beyond in-depth discussions with local resource providers, this process can include sharing related contracts and facilitating legal advice during negotiations. It frequently also requires sharing (disclosing) project descriptions, lists of collections, lists of collections, and progress reports on research for review by the individuals, participating organizations, and national government authorities.

The principle of disclosure and informed consent, broadly interpreted, can also be a valuable tool for building consensus among stakeholders. Public workshops involving representatives from potential indigenous collaborators, government agencies, environmental NGOs, and researchers can simultaneously provide information, solicit input, and build consensus for the primary objectives of a project. Thus, prior informed consent now acts as a process through which all parties lay the foundation for the terms of multi-party bio-prospecting agreements.

Milestone Payments

In some cases, host countries and their commercial collaborators also make provision for milestone payments. These are payments made upon completion of certain key, definable, and scheduled performance events in a project, as agreed to by the parties. Milestone payments usually precede final commercialization of a product. In theory, they can be made even though a product does not eventually succeed commercially. For example, a bio-prospecting firm makes some or all milestone payments to the host country as the firm progresses in its process of identifying and isolating an active anti-cancer compound. Upon finishing its work as contracted and delivering the compound to a pharmaceutical firm, problems may arise. For example, the pharmaceutical firm may encounter insurmountable problems with the compound's toxicity in animal and human clinical trials. Thus, although milestone payments during the bio-prospecting process were made, no anti-cancer drug may ever result.

Capacity Building Supports Development

Capacity building is considered the most important component of non-monetary compensation by some. There is great flexibility and opportunity for creativity in this area. Capacity building provides the means to achieve various goals in the host country. It can strengthen a country's science and technology infrastructure by providing training to technicians, graduate, post-graduate and postdoctoral students, and faculty of educational institutions. Individuals are trained in biotechnology as well as in relevant area such

as biodiversity conservation and management. Depending on individual circumstances, provision can also be made for stimulating local economic development.

Equipment transfers to host country collaborators come both through government funding and directly from commercial partners. Laboratory equipment related to the preparation, extradition, storage and microbiological screening of specimens is commonly transferred to the source country. Other equipment purchases may include herbarium storage cases, computers, software and field equipment to aid with biodiversity description and management. Infrastructure development effort include vehicle purchases, renovation of laboratories, herbaria, and medicinal clinics and improvements to community managed enterprises such as ecotourism lodges. Future business potential of Bio-prospecting in Indian context-

The tribal's in the country occupy about 18.74% of the total area of the country, mainly in the hilly and forest areas of 19 states and union territories. India stands 7th in biodiversity and having 16 different bioclimatic.

There are more than 10000 plant species are available in India, out of which,

Medicinal – 8000

Edible – 3500

Fibre – 550

Gums resin – 425

Pesticides- 325

Others – 1000

Courtesy – Department of AYUSH ²⁶

CONCLUSION

By linking at natural resource and the most ancient medicinal treatise VEDAS which is time tested and sustainable, there is an enormous potential with respect to bio-prospecting as per following-

India can give potential product leads in Pharma especially in chronic metabolic disorders, life style diseases, infection diseases and psychiatric disease.

Coupling of technology with 'VEDA' wisdom can unveil many blockbuster drugs. VEDA agricultural practices can be coupled with tissue culture techniques to yield maximum with minimum input.

VEDA alchemy or chemical techniques can be combined with chemo genomics and bio and nano engineering to create new life style products.

VEDA knowledge about plants and environment can be successful in mitigating Global Warming and earn good carbon credit markets for India.

However following modifications and or policy amendments are to be considered,

CBD should be as proactive approach and not reactive as mandatory.

Sui generis synchronization is among 1st world, 2nd world and 3rd world countries. Clear specifications for Patent criteria like novelty.

Incremental innovation criteria can be introduced in TK patents.

This can bring confidence in putting huge capital for industry at initial stages of bio-prospecting and offer them fair returns.

This shall strengthen further for opening multi channels of capital and create market drive for applied research and development.

Bioprospecting business model should get processed through institutional mechanism in order to bring homogeneity in stakeholders.

Promote Bioprospecting as a national campaign in order to retrieve the best out of natural resources and TK.

Appropriate Coding and Decoding techniques programmes for TK in order to explore Trade Secretes hidden in them balancing with making Tribes Stake holder and founder member of research programmed but not just idea offered.

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Source of support: Nil, Conflict of interest: None Declared