



Knowledge Origin, Innovations and Growth in Ayurvedic Bioprospection: References from Kerala

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Abstract

The recent manufacturing interest in traditional medical systems and biodiversity sectors is directly related to the profitable innovations that traditional knowledge can generate. In this context, this study attempts to understand the nature of knowledge origin and innovative process in the drug discovery process in both traditional knowledge and textual ayurveda based drugs. The analysis has been broadly contextualized in the premise that the traditional knowledge innovations are non-additive in character due to the lack of proper incentive structure available with knowledge holder, and hence this knowledge, which largely serve as a tacit raw material for bio-prospection involves huge costs in internalizing in to the production. While the firms have the option of cheap cost drug discovery from ayurvedic public knowledge, they are less incentivized to go for major bioprospection.

Keywords: Traditional medicine, ayurvedic companies, bioprospection, intellectual property rights, innovations

JEL Codes: B52, O31, O32, O34

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Introduction

Trends such as globalization, fast product cycles, high competition, product commoditization, and higher technological usage and more technological innovations and its management is pertinent especially in the case of healthcare sectors, and it is true in modern pharmaceutical sector as well as ayurveda. With the present growth of the industry based on ayurveda like systems of alternative medicine brings a strong alternative for the health care choice of the people. The recent manufacturing interest in traditional medical systems and biodiversity sectors is directly related to the profitable innovations that traditional knowledge can generate.

Bio-prospectors and pharmaceutical companies involved in plant-based drugs research are interested in Traditional Knowledge (TK)² as an information source for two reasons: (a) it provides valuable leads in the search for *active compounds* required for producing pharmaceutical drugs and can considerably reduce search costs; and (b), it can provide valuable leads for developing entirely *new* plant-based pharmaceutical drugs from medicinal properties of plants that were hitherto unknown. Pharmaceutical research and development involves several years and considerable investments. Any project involving plant-based medicines requires identifying the useful active compounds from the plants. There are costs associated with bio prospecting, searching for the medicinal plants and identifying active ingredients. TK about medicinal plants can provide prior information and increase the hit rate in identifying active

² *Traditional Knowledge* can refer as the WIPO uses it, "-----the tradition based library, artistic or scientific works, performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information, and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific or artistic fields. Indigenous knowledge, on the other hand is understood by the WIPO to be the traditional knowledge of indigenous peoples. Hence 'Indigenous knowledge is therefore part of the traditional knowledge category, but traditional knowledge is not necessarily indigenous' (WIPO, Intellectual Property Needs and Expectations of Traditional Knowledge holders, WIPO report on fact finding missions on Intellectual property and Traditional Knowledge (1998-99)).

compounds. On another level, TK also provides information about medicinal properties of plant species, the uses of which is unknown outside the community or region. Thus, TK improves the potential for developing new pharmaceutical products³. Here, the leads from textual indigenous systems like ayurveda also have huge significance as far as the drug discovery is concerned. The recent decade has seen an emergence of large number of biopharmaceutical firms and many modern pharmaceutical giants have started their own divisions for herbal drug research, which incorporates two types of drug discovery i) traditional knowledge derived drugs, which is derived from the contractual sharing mechanisms with the knowledge owning communities (for example *Jeevani* developed from the knowledge of *Kani* tribes in Kerala) and ii) drugs based on ayurvedic textual formulations and modifications on which thereafter. But very less is known about the recent trends, developments and the intricacies of the drug research in ayurvedic pharmaceutical companies.

Here, in this study, we propose to answer some related questions like what is the difference in drug discovery in ayurvedic firms from modern drugs, what kind of innovations and direction of research is active in this sector, what created the recent growth of ayurvedic market-whether led by innovation or just because of the growth of just complementary assets, what is the incentive for knowledge owning communities to disclose their knowledge for bio-prospection etc. Here we are not trying to analyze the various issues of protection of traditional medical knowledge and the other protection mechanisms in detail, since this area is already well documented by many social scientists. We attempt here to argue the prospect of the sector, from the view of bioprospecting firms and communities, the major stakeholders of ayurvedic manufacturing.

³ Bhagirathy, Aparna (2005) *Using Traditional Knowledge for Commercial Innovations: Incentives, Bargaining and Community Profits*, SANDEE Working Paper 11-05

This paper has been mainly organized in five sections; first we contextualize the problem by broadly discussing the theoretical aspects of traditional medical knowledge innovations and growth of the sector. Second, we analyze the complex process of R&D, drug discovery and innovative efforts in the current bioprospections in comparison with ayurvedic industry. Third section we analyze the disincentive for the firms to enter into the bioprospection due to various costs involved in. In the fourth section, we analyse the present available and developing incentive system and regulatory mechanisms in brief and notes its inadequacies. Fifth section briefs two examples, one TK bio-prospection product another traditional formulae developed product form Kerala, a state where traditional knowledge has a long footage, to see the product development and incentive structure involve before we conclude with noted points. In the following first section, we are trying to discuss the traditional knowledge innovations in the framework of cumulative innovation model and research.

I. Traditional Medical Knowledge, Innovations and Growth

Many economists and economic models had envisaged technological knowledge as if it were an exogenous public good. It is assumed to be available to every economy as in the Solow type, neo-classical formulation (for instance, Solow1957), rather than understanding technology as a process, as knowledge-in-practice. Technological knowledge, however, is not something that just happens to societies/economies. It is a process that countries need to consciously and actively promote and nurture, and for which certain socio-economic preconditions must be met.

Here, we depict two types of traditional medicine sector growth model, which uses traditional medical knowledge to produce output. In the first type, adequate protection like patents, ownership rights and other incentive mechanisms available and in the second type, where no incentive mechanisms are efficiently established, as in the case of traditional medical sector. As the innovators fail to internalize the cost of their innovations, they will rather prefer secrecy and the available knowledge and innovations with them will remain static⁴. Here innovations are random event, with full uncertainty as the unequal time period shows in the first figure. In the first figure, the innovations are additive and continuous, where the innovator knows exactly the prior innovations available to him, so that he can add on to it or produce incremental innovation. It shows the positive path for the evolution of continuously growing sector and this is shown in the shifting up word production frontiers. The past innovations help as a precedence to current and future innovations. The output grows with every innovations and the horizontal periods are not equal, which shows the effect of innovations are not similar, some time it can be even drastic innovations, which changes even the pattern of production. The distance between t_1 , t_2 , t_3 etc are also not equal, shows the innovations are not predetermined and it can happen at any time at any quantity, which may lead to quality or quantity enhancement and sometime both.

The second figure, shows the case of traditional medical knowledge sector, where because of the absence of efficient protective/incentive mechanisms the innovations rather preferred to be remained as secret. Apparently, the current innovations doesn't relate to the previous innovations because of the secrecy or indifferent attitude of the innovator to put it in the public domain.

⁴ Innovation is all about the production of information, and it has the character of a public good. It would be underprovided for within the society since the social returns to research investments exceeds the private returns faced by an individual, and to rectify it from the view point of social welfare, and to obtain optimal production of information, there is a need to internalize at least some part of the social benefits. The patent protection gives this kind of incentives to production by creating deliberate trade-off between the monopoly rents of the producers of the knowledge and the consumer welfare of the society at large.

Hence, though they will be continuous but non-additive and hence the production remains the same and the sector, static. This could be extended to an economy, also which is predominated by the traditional knowledge. So in the traditional medicine sector, research would be developed in to further cumulative innovations and bioprospective results only when adequate incentive mechanisms are provided.

Figure 1: Production frontiers of continuous and additive growth ladder model

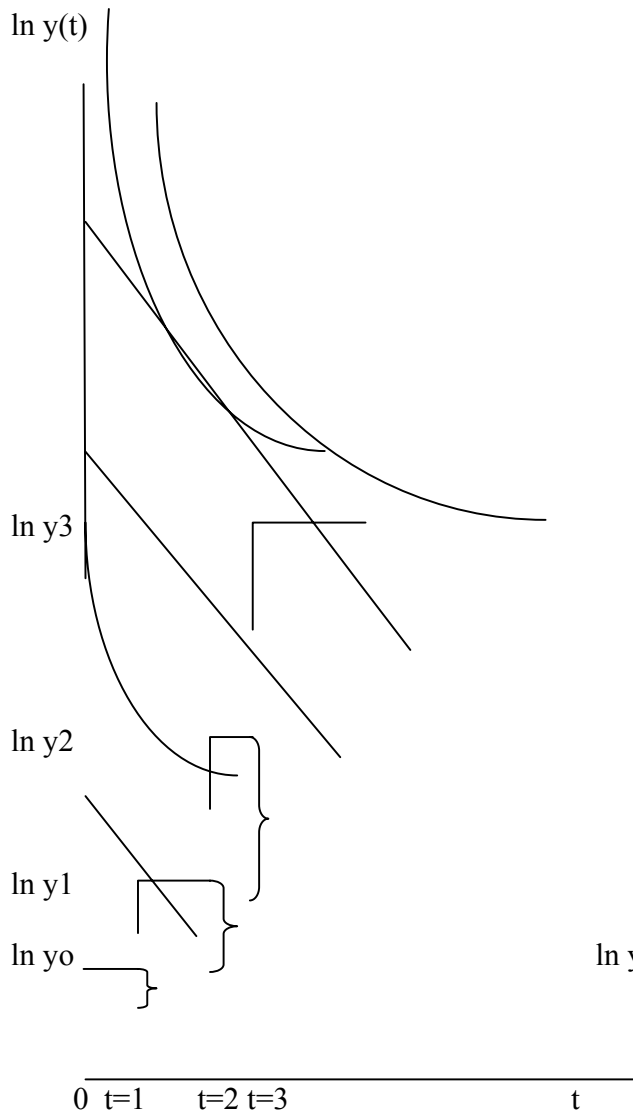
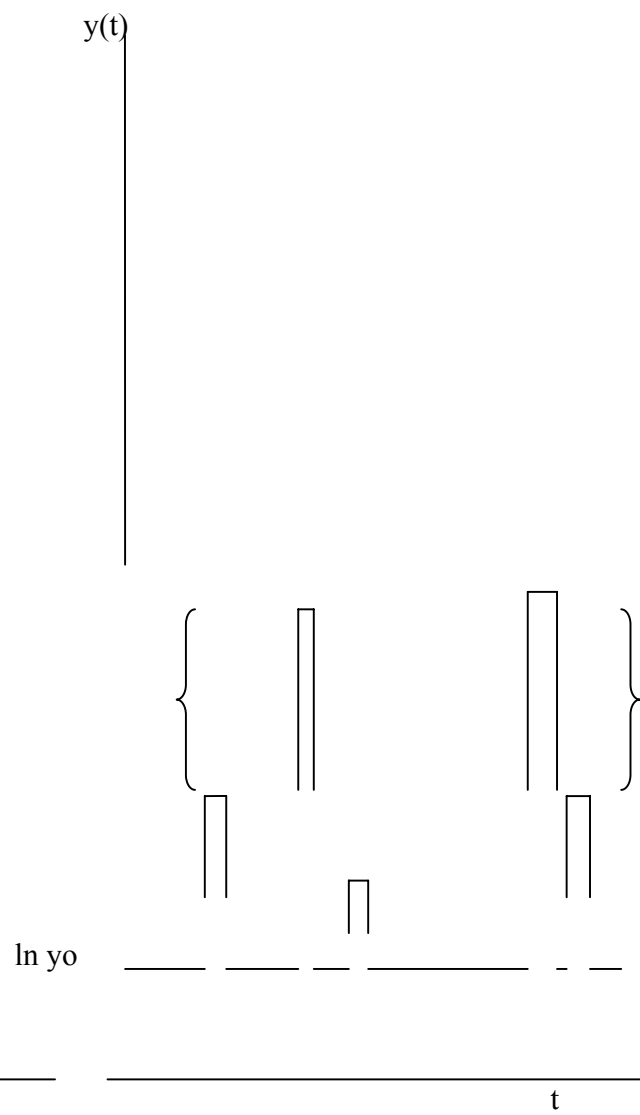


Figure 2: Continuous but Non-additive Growth Model



Commercial innovations of this traditional medical knowledge with care on preservation of resources should be promoted. The social value of this knowledge depends upon the value of future innovations facilitated by this medical knowledge. There exists a market for valuable traditional medical knowledge as a resource base for developing new pharmaceutical and biotech products. Contractual agreements with minimum asymmetry of information can provide incentives for the community to continue to preserve its knowledge and disclose it for commercial exploitation.

II. R&D, Drug Discovery in Ayurvedic Formulations

Natural products extracts of therapeutic relevance are of paramount importance as reservoirs of structural and chemical diversity. A recent review on national pharmacopoeias from several countries reveals at least 120 distinct chemical substances from different plants that have utility as lifesaving drugs⁵. This has been achieved through chemical and pharmacological screening of only 6% of the total plant species (Patwardhan et.al 2005)⁶. Untapped, hidden wealth in the flora needs to be unearthed and explored to cure diseases like AIDS, cancer, diabetes, etc. Recently, NIH has started extensive research for anti-inflammatory compounds from turmeric, ginger and boswellia with the aid of Ayurvedic knowledge. Screening of different plants for novel anticancer compounds is also in progress with reference experiential data from traditional systems. Botanical immune-drugs from traditional medicine can provide newer opportunities to bioprospect diverse and synergistic chemical moieties, which in combination might act on

⁵ Goswami A, Barooch PK, Sandhu JS. (2002) 'Prospect of herbal drugs in the age of globalization—Indian scenario', *Journal of Scientific and Industrial Research* 61:423–43

⁶ Patwardhan, B; Warude, D; Pushpangadan, P and Bhatt, N (2005) 'Ayurveda and Traditional Chinese Medicine: a Comparative Overview', *Advance Access Publication, e CAM*, 2(4) 465- 473

multiple targets and improve the therapeutic spectrum⁷. Controlled clinical trials are important to develop evidence for safety and efficacy. Results from clinical trials are encouraging, but lot more clinical research is required to establish validity of the system. Ayurvedic preparations have been successfully evaluated for treatment of bronchial asthma, rheumatoid arthritis, ischemic heart disease (Patwardhan et.al 2005).

2.1. Process of R&D in Traditional knowledge based Drugs

Many plant derived drugs presently we have, is attributed to the input of traditional medical knowledge (Taylor 1965, Lewis 1992 etc.). It has been estimated that by consulting traditional knowledge, depends on the disease condition, the bio-prospectors can increase their success ratio by 400 percent⁸. Many times traditional ayurvedic knowledge can directly help in analyzing the properties of a plant as in the case of *Jeevani*, which we would analyse later in details and others like *piper futokadsura* (use for broncho asthma), *cinchona pibescen* (anti-malarial) *cloes forskoli* (cardiovascular drug) are directly from traditional use.

Drug discovery process in this case, involves many stages, starting from screening of plants based on the traditional knowledge to the development of drugs and its marketing⁹. In the first step of searching for knowledge for useful innovations, either random screening or targeted screening could be applied. In the targeted approach prior information available is being used. There are mainly three kinds of targeted surveys, i.e. phylogenetic surveys, ecological surveys

⁷ Patwardhan B, Gautam (2005) Botanical immune drugs: Scope and opportunities. *Drug Discovery Today*:495–502.

⁸ Any extract from a species will contain hundreds of thousands of different chemicals that may result in a pharmaceutical lead. Thus the probability of success will be raised and producing a promising lead of 1 per 1000 samples (Gehl Sampath 2005).

⁹ To get a detailed view see Gehl Sampath (2005)

and ethno-botanical surveys¹⁰. In the first type, close relative of the plants, which have already given good results will be scrutinized while in the second type, plants growing in special habitats will be scrutinized and in the third plants used by indigenous people in their medicine will be analyzed.

The second step includes drug discovery and pre-clinical development, which is a time taking and complex process. Selected samples are dried and extracted and then screened to detect the therapeutic properties in the samples. If any show valuable properties those extracts will be again screened, and then isolate the pure chemicals from the sample and ensuring that they are active and non-toxic. Potential therapeutic agent will be elucidated in the repeated trials and then the molecules, which show positive results in animal models, will be considered for drug development process. This also involves some short-term toxicity analysis within a programmed schedule, ensuring the good manufacturing practices. If an extracted molecule passes through all these stages, then it could be filed for patent application.

The third step includes various phases of double blinded processes starting with the toxicity analysis, experiments in human being and its pharmacokinetic and pharmacodynamic activities and if the drug is proved to have less toxic and more efficacy, then move towards next stage of approval, but all these takes more than five years to be completed. In the fourth stage, the data on its trial and error regarding efficacy forms the basis for the approval of major authorities. Then the promotional aspects like marketing including the advertisement strategies could be charted out with the experts in the firm.

¹⁰ Cox, Paul, A (1990) "Ethnopharmacology and the search for new drugs" in D J Chadwick and Arsch J eds., *Bioactive compounds from plants*, Cambridge, Cambridge University Press, pp. 40-65

2.2. R& D process in the Classical/modified ayurvedic Drugs

But in the case of ayurvedic drugs developed from classical formulae, the process is much less complex and smaller than the drug developed through bio-prospection from traditional botanical sources. Under the Western pharmaceutical industry paradigm, the first aspect of drug discovery is the shaping of the compound, and the core of the compound is a chemical believed to have a profile of biological activities for clinical use (Hara, 2003, p. 170)¹¹. But botanical inventions are plants that contain tens or even hundreds of compounds that have potential therapeutic value. In short, the innovations could be many types

- (1) Traditional formulas: formulas that have appeared in the traditional text or concentrated products made from those texts (might have lost its novelty so innovation includes the changes in delivery model and finding new uses).
- (2) Non-traditional formulas: formulas that have not appeared in traditional text (they might be long existing family secret recipes that might not have lost their novelty as long as the secret has not been disclosed to the public).
- (3) Botanically derived drugs or herbal extracts (including mixed or pure compounds; they could be derived from plants in traditional or non-traditional formulas).

Currently, the dominant Western drug discovery process from natural products has four goals (Fabricant and Fansworth 2001)¹²: (1) to isolate bioactive compounds for direct use as drugs; (2)

¹¹ Hara, T. (2003) *Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development*, Edward Elgar, Cheltenham

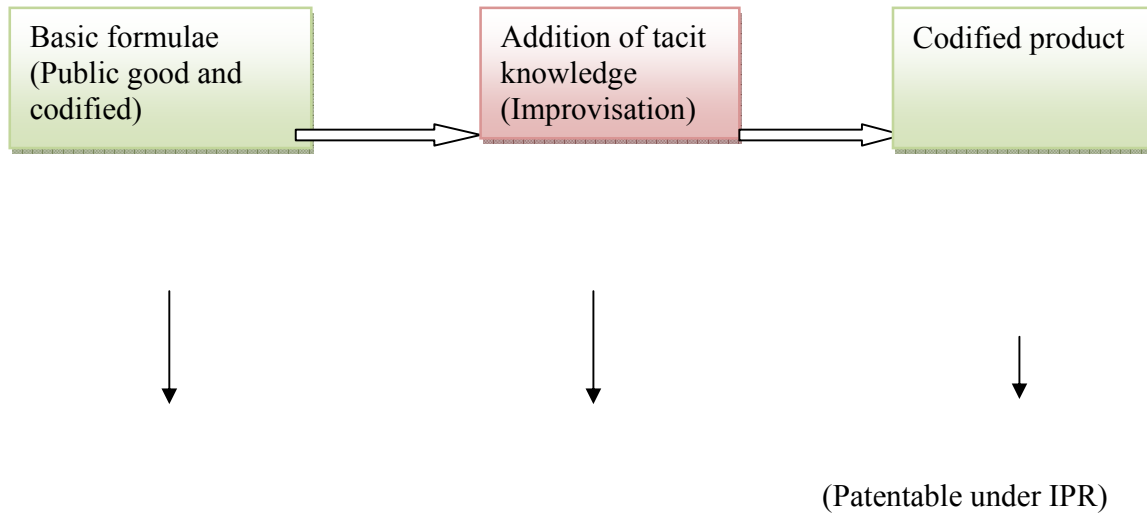
¹² Fabricant, D. S. and Fansworth, N. R. (2001) 'The Value of Plants Used in Traditional Medicine for Drug Discovery', *Environmental Health Perspectives*, 109(supplement 1), 69–75

to produce bioactive compounds of novel or known structures as lead compounds for semi-synthesis to produce patentable entities of higher activity and/or lower toxicity; (3) to use agents as pharmacologic tools; and (4) to use the whole plant or part of it as a herbal remedy.

Here we are interested in knowing a related matter i.e., what is the situation of innovations from the textual Ayurvedic knowledge. The drugs and the products developed from the textual Ayurvedic formulation are not liable to get patent rights, but only proprietary rights, since most of the products are only extension/addition/deletion of some molecules in the given formulae. And more over, these are the knowledge in the public domain, hence does not qualify for novelty and inventive steps, the clause necessary to get a product patented under TRIPS regime. So entirely new products only capture a part of the innovative activities. 'Inventing around' the existing molecules, the introduction of new combinations among them, or new ways of delivering them etc. constitutes major components of innovative activities of ayurvedic firms. So successful exploitation of economic benefits from innovation in this sector stems from innovations in controlling and managing other 'complementary assets' especially, the process of gaining regulatory approval, specialization in incremental research in some known products, marketing and other distributive efforts like advertisements etc., in which some of them usually works as powerful barriers to entry into this industry.

Though Schumpeterian innovation works to an extent in this industry, even in the same product category, profit is determined mostly by the brand name of the company, sometime the traditionally acquired fame and name over a long period of service. Though product basic formula is same modifications are made according to the incremental innovation done within the

firm. The industry is characterised by strong information asymmetries. Consumers are typically unable to properly evaluate the quality of the drug, and this industry is undergoing a strong shift in the product pattern from the medicines to ayurvedic nutraceuticals and cosmetics.



(Not patentable) (Cumulative innovations: patentable/proprietary rights)

It has been argued widely that traditional ayurvedic knowledge doesn't qualify for the protection under the intellectual property regime, as it lacks novelty and inventive steps, which is a basic criterion for any innovation or knowledge to be patented. Since this type of knowledge that has already produced, one could argue that there is no need to protect this right through intellectual property protection. This is because knowledge once produced; it turns to be a public good, which has the characteristics of non rivalry and non excludability. The diffusion of information among the members of the society can be achieved at negligible marginal cost and this optimal equilibrium price for such information is close to zero. So a simple economic logic can argue

that the already produced this medical knowledge is such an information category, which should be made available freely to the potential users, firms and other researchers. This economic analysis would prevail if the knowledge could be provided at negligible costs. Needless to say, the traditional knowledge would pass the test of efficiency only when the answer to this question is in the negative, as argued by Gehl Sampath (2003)¹³. This argument makes ayurvedic medical knowledge to qualify for protection under the intellectual property regime, but it is critical to understand the contribution that an intellectual property right to traditional knowledge can have towards (a) drug research and (b) bio-diversity conservation.

But the present practice of innovation in many firms is mostly in the form of new packages and products with slight alterations in the basic formulae. A survey regarding some firms in the ayurvedic sector showed that there is lack of technological innovations in this category¹⁴. On the contrary, drug, which comes to the market is with small alterations in the combination and sold with the brand name most of the firms possess. And it is noted that in most of the firms, the expenditure on R&D is much less than the expenditure on marketing and advertisement. Here, generally the new product formulations are being made as a reverse innovation path, with the feed back from the market. Packaging, presentation, finding new markets are the new ways of innovations mostly adopted in this category.

¹³ Gehl Sampath, P (2003) "Defining Intellectual Property Right on Traditional Knowledge: a process oriented perspective", UNU MERIT, The Netherlands.

¹⁴ Centre for Development Studies (2005) *Innovation in Indian Industries*, report Prepared for Department of Science and Technology, p 24

III. Cumulative Innovations and Disincentives for Bioprospection

Though absence of additiveness is less among the traditional innovations as we mentioned earlier, the modern biotech drug research is cumulative in nature. Scholars have long regarded the development of innovative ideas as a cumulative process; individuals “stand on the shoulders of giants”, improving, challenging, and recombining ideas to extend existing bodies of knowledge. For the purposes of this paper, we define cumulative innovation as the incorporation of prior knowledge into a new innovation, and we focus on settings in which different types of stakeholders attempt to use that knowledge for multiple purposes that may cross sectoral, national and community boundaries¹⁵.

Cumulative innovation requires at least three types of institutional challenges: disclosure, accessibility, and validation. First, disclosure is required; in order for others to be able to build upon an innovator’s knowledge, they must know of it. Second, to use knowledge developed by someone else, one must understand how the original knowledge developed and have access to the various inputs (tools, materials, information, techniques) in order to make use of it. Lastly we suggest that one must be able to replicate and validate the original knowledge before being able to effectively modify it or recombine it to create new knowledge¹⁶. Many authors have flagged the need for an efficient institutional system, like Murray (2004) argues that Scholars have

¹⁵ Scotchmer (2005) contributes in this direction by distinguishing among several different types of cumulative innovation: Type I and Type II cumulateness rely on prior innovations but in the first instance prior innovations are “incorporated” or integrated into the next generation innovation and are thus observable-in-use. In the second instance prior innovations are merely used to forward a new innovation. An example of a Type I accumulation of innovation occurs when a piece of previously developed software is incorporated into a new software release. In contrast, Type II innovations use and build upon prior innovations in tools and methods but these innovations are not observable-in-use and are thus not integral to the product. For example, in biotechnology, an innovator may make use of tools, measurement systems, or cell lines in order to probe the development of a novel drug.

¹⁶ Murray, F (2005) *Reconceptualizing the Institutional Foundations of Cumulative Innovation*; Paper prepared for Princeton Conference on Intellectual Property Rights.

generally ignored the social and normative institutions that may also support cumulative innovation. Furthermore, the enforcement of legal rights alone may be relatively a blunt and costly instrument in shaping the socially complex processes of innovation as they ignore the more substantive organizational and institutional context in which these incentives are embedded (Scotchmer 2004, 1997). Stern (2004) argued for a more detailed examination of the institutions that support cumulative innovation.

A combination of institutions and incentives can reinforce these three basic requirements for cumulative innovation. First, there should be incentives for the disclosure itself and institutions to support disclosure and dissemination of inputs into knowledge accumulation. Second, when using someone else's creation in a new form or derived work, one should be able to recognize or reward first generation innovators without too much difficulty. Third, there should be incentives to make critical tools and innovation inputs accessible to later innovators. Lastly there should also be incentives and institutions that support validation. In this context, traditional knowledge used for a drug discovery or drug development should be rewarded. And as a tacit form of knowledge, it qualifies for any kind of mechanisms for protection. The role of tacit knowledge as an important raw material for further innovations has been largely ignored in the economic writings. Arrow (1962) and Nelson (1959), tended to look innovation as isolated activities and as an investment decision of the profit maximizing firm and the impetus for this investment decisions in expected returns. The role of already produced innovations or existing knowledge is undermined and Zechauser (1995) notes that the focusing on the public goods aspect of information has deterred economists and policy analysts from delving more deeper into distinctive properties of information, including most particularly, the challenge of contracting for

technological information¹⁷. And it is to be noted that the cost involved with using the tacit information like traditional medical knowledge melts down the public good argument unlike the other public information, which could be transferred in negligible costs.

Hence here, we face two dead locks, one, the cost of acquiring a community knowledge, which is categorized in the traditional medicine by the firm and the incentive structure available to them to go for such internalization and two, the less incentive structure available to the community to disclose their knowledge. In this section, we have shown that the acquiring of this tacit knowledge involves a substantial cost, which makes two points clear, one this knowledge is liable to be protected and second, from the firms' point of view what kind of incentives available to them to bear the cost or most importantly any other institutions can bear the cost of internalising this knowledge.

3.1.1 Knowledge Secrecy and Hindrance for Bioprospection

In most of the high technology sectors, path dependency of research is very important, for which in turn, information asymmetry should also be avoided. Innovations on the products and process eschews on the available research so that it would be cost efficient (less transaction cost), and additional value could be added, and those process or products could be patented. Here, to explain the problems with the innovations and growth in the traditional medicine sector and lack of bio-prospection, we make use of the S-motivation model and growth ladder model, used by Nwokeabia (2008) in the case of studying industrial revolution in Africa¹⁸ in the case of traditional medicine sector. Here, this is used to understand why there is secrecy and

¹⁷ Emphasis by Gehl Sampath (2003)

¹⁸ Nwokeabia, H.U. (forthcoming) *Indigenous knowledge: an exit strategy from Africa's economic dependence*, United National Economic Commission for Africa.

concealment and hence less bio-prospection in the case of traditional medicinal knowledge and knowledge in plant varieties.

For example, if we consider a situation where human capital is the major resource in the production process and assume that a society's fixed stock of medical practitioners has two competing uses. It can produce physical and other goods; second, it can be used in research. We express the relationship as follows:

$$Y = F(L, \dots) \quad (1)$$

The above represents an aggregate production function, where output (Y) is a function of human capital (L) and other factors. L is further disaggregated into two parts:

$$L = x + n \quad (2)$$

Where, x is the amount of labour that equals practical force and generally accessible capacity per person used in the production of physical goods, and n is the amount of labour used in research. When n amount of labour/knowledge is used in research, innovation arrives randomly at a rate expressible as λn , where $\lambda > 0$ is a parameter indicating the productivity of the research. The productivity of research λn , has a Poisson distribution. Mathematically, Poisson process means that at the time T , the possibility of λn occurring is a random variable whose distribution is exponential with parameter λ . The innovator may find another invention/innovation in the process of solving the particular health problem at a time unknown to him. Even by allocating a

large amount of his time and resources, it is still uncertain to the innovator when the next innovation may take place. In the above sense, the probability is that a new innovation will occur sometime within the short or long interval between T and $T + dt$ ($T + dt$ stands for change in time). The probability that an invention/innovation will occur within dt from now (when $T = 0$) is approximately νdt . In this sense, ν is the probability per unit of time that the event will occur now, or the “flow probability” of the event.

So within this earlier framework above, it is sure that in any economic system any new innovations will replace the monopoly of the old sector until replaced by another. So openness in the sector can lead to successful challenging of the same time to time and can successfully destroy the monopoly rent of the previous.

Now relating this to cost of innovation, we assume that research costs/expenditures are financed at the proportional rate that is equal to the resources and labour force committed to research. If we also measure the costs and benefits in units of final outputs, the marginal cost is the amount over and above initial investment. The marginal benefit is the product of the value of innovation (Vt) and the (private) marginal effect of research input in a sector. As soon as this innovation is put to use, its profit yielding function makes it possible for the owner to realize more money than the invested principal. If the interest rate is constant/neutral, then the value can be expressed as:

$$V_{j_{mj}} = \sigma_{j_{mj}} \cdot 1 - \sigma \exp(-rT_{j_{mj}}) \sigma / r > 1 @ T_0, \quad (3)$$

where, $V_j m$ is the value that represents the market worth of the m th innovation. This value depends positively $V_j m$ on and $\sigma_j m_j$. The m represents the medical sector. When we include the expected net income from the use of the innovation, we get a different function; here V_{mk} is the exponentiated profit rate at the time t . In the case of business stealing, therefore, the loss will then be expressed as:

$$1 - \sigma n - V_{j m_j} = 1 - \sigma n - \left(\sigma_{j m_j} 1 - \sigma \exp(-r T_{j m_j}) \sigma / r \right) < 0 @ T = t + dt \quad (4)$$

Which, by virtue of the initial state of net income at time t is less than zero (<0). The above equation implies that the innovator loses both his initial investment and the expected profit. The double loss of both investment cost and expected income is thus a driving force to hide the new idea or innovation in the absence of institutional and other legal support. This scare of multiple losses led to secrecy in the case of grass root innovators and traditional knowledge holders, unless an institutional system, in place to adequately incentivise this revelation.

3.2 Process of knowledge search in ayurvedic pharmaceuticals

It is necessary to distinguish between two different demand scenarios, the specific and the non-specific demand scenario, which may cause very different effects (see Simpson, Sedjo, and Reid, 1996 and Rausser and Small, 2000). First, in a random search scenario (which we will name 'non-specific demand'), i.e. the sequential testing of large numbers of leads in no particular order, firms will seek for more or less unspecified resources (genetic resources, bioactive compounds) worldwide. Thus, potential suppliers will be competitors worldwide (or perhaps in a larger geographical region). In this case, competition between suppliers will tend to reduce

prices. Non-specific search (also called 'brute-force'-search, Rausser and Small, 2000) will, however, be the exceptional case, because it is a nearly cost-maximizing approach to discovery. Although the difference between specific and unspecific demand is sometimes compared to oil drilling where knowledge about 'promising' sites may command significant information rents (Rausser and Small 2000: 175), the case of bioprospecting is different: If economically feasible, oil companies are interested in the exploitation of the resource wherever it is found. As a consequence, discovery of a promising drilling site will potentially affect the sequence of sites exploited but not the *exploitability* of other sites. The situation in the case of genetic resource discovery is different. Once a firm has obtained the information incorporated in a certain species, there is no reason for it to ask for the same species from another site, as they are redundant now. Thus, owners of land parcels will regularly find themselves in a situation of 'winner-takes-all'-competition. If firms search more specifically ('specific demand'-scenario) for certain compounds or genetic information, it is more likely that they will have to focus on a small geographic region which is expected to contain plants with desired qualities.

Bio-information can be used globally through partnerships, trade and other forms of cross-border transfer-pricing arrangements, if tacit knowledge held communally can be converted to articulated information under a system of flexible property rights (Mathur 2003). This could raise the value of traditional knowledge by enabling it to be priced to correspond to its true international market value. This presents new opportunities to holders of traditional knowledge for cross-border partnerships in the international trading system. However, institutions that would yield dispersed benefits do not emerge easily and there is a profit to be made if local knowledge has a use and commercial value beyond its local context. This problem can be

narrowly postulated in the specific context of valuing traditional medical knowledge using a modified version of the Ruitenbeek Korup model (Ruitenbeek, 1989):

$$CPV_i = a.EPV_j \text{ Where,}$$

EPV_j = Expected Production Value of a Patented End-product 'j'

CPV_i = Capturable Production Value of active ingredient, 'i' and

'a' is variable with value < 1

As Mathur notes, "a" tends to be very small in the beginning of the innovation cycle when biological resources are being researched and screened for further development or synthesis (Mathur 2003). For most part of the twentieth century, it was erroneously believed that plant genetic resources for drug uses are exhausted, and the value of "a" was so small that it was close to zero. The discovery of Vinca alkaloids with anti-cancer properties and the recent interest in traditional plant resources that have a human medicinal-use history have caused people to rethink about the value of "a". However, the value of "a" is not easily fixed because biological resources are unquestionably of vast value which defies empirical or normative evaluation and humanity is very far from completing even a basic catalogue of all terrestrial and marine species (Wilson, 2002).

So the cost of accessing the biological resources (which is very scarce) and traditional knowledge also going up, which leads to many firms to turn towards the basic ayurvedic knowledge in the public domain, and if not, more of an uncharted area of bio piracy.

3.3 Another Disincentive for firm: Cost of Allocative efficiency

In theory, firms will employ factors of production in accordance with their relative scarcity until marginal costs meet marginal revenues. This means that additional bioprospectors, R&D-resources etc. will only be employed if their marginal costs meet their expected marginal contribution to the firm's revenue. It will be more difficult for the firm to generate valid expectations in the case of random search for genetic resources. In addition, experience has shown that it is difficult to establish accurate expectations about likelihoods of commercial values of final products even at stages at which a plant or an active compound is considered to be commercially interesting. Thus, firms will normally use rules of thumb for their decisions to employ additional factors of production. First steps of pharmaceutical bioprospecting are very risky investments for the industry. Only at the later stages of R&D, when the success of the final product becomes more probable, the firm's interest in the preservation of a certain area is likely to increase.

Royalties are unlikely to produce economically efficient outcomes. As royalties depend on a large number of parties and factors, information asymmetries are highly probable. Especially in the early stages of the product's R&D, it is almost completely unknown both to the firm and to the supplier whether the biological information provided by the sample will become a contribution to a new product, let alone whether this product will become a commercial success. At later stages of the product development, firms obviously have better information about the genetic information's contribution to the product and about its success probability. Thus, as time passes, the information asymmetries favour the firm's interests. In both cases royalties will tend to be low. During early phases it is rational from the firm's standpoint not to pay high sums for

an input good which is almost unknown with regards to its commercial relevance. Because both parties are almost systematically ignorant about the samples' 'real' values, the amount of royalties paid is not an outcome of a market failure due to information asymmetries. Instead, both sides will build their ideas about the adequacy of royalties based on their experiences and expectations. Still, market power may be a factor of significant importance here. At later stages, firms will deliberately underestimate the value of the input good provided by the host country, especially its contribution to the final product. Once the firm possesses the genetic information required, the host country is in a weak position for the enforcement of its property rights. The fact that many contracts stipulate room for renegotiations at later stages of R&D if the parties gain new information about the likelihood of a genetic information's future commercial applicability does not solve the general problem of information asymmetries. Furthermore, firms may even try to renegotiate if they can argue that the final product is such a distant prospect compared to the initial genetic information, that the supplier should no longer be entitled to receive the original share of the net sales. Rational providers thus have to calculate expectations about the periods in which the product that is based on their genetic information yield sales (denoted by j to k), about the likelihood that the genetic information can be successfully transformed into a marketable product (pS), and about the amount of net sales in each period during which they are expected (μNS_t). As potential royalty payments are promised for a possibly distant future, rational providers will discount them to their net present value. If they have personal expectations about acceptable net present values of royalties they may have received (R) when the product leaves the market one day, they can calculate their 'royalty factor' (RF) being the percentage share of the assigned net sales:

$$R = P_s \cdot RF \left(\frac{\mu_{NS,j}}{(1+i)^j} + \frac{\mu_{NS,j+1}}{(1+i)^{j+1}} + \dots + \frac{\mu_{NS,k}}{(1+i)^k} \right) \quad (1)$$

$$R = P_s \cdot RF \sum_{t=j}^k \frac{\mu_{NS,t}}{(1+i)^t} \quad (2)$$

$$RF = \frac{R}{P \sum_{t=j}^k \frac{\mu_{NS,t}}{(1+i)^t}} \quad (3)$$

R may represent the income to be earned by the supplier of a genetic resource in order to be indifferent between alternative forms of land use. If R is smaller, the supplier may prefer to destroy plants on his piece of ground to harness it for agricultural cultivation, cattle breeding, mining, etc. In other words, if the firm wants to exploit the genetic resources, it has to offer at least R . In many instances, agricultural cultivation and the utilization of the land as a source of genetic information are completely exclusive forms of land use, because the firm may have to secure its re-supply of genetic resources in later periods in the case that commercial utilization becomes likely and the sample is not yet synthesizable. In these cases (for example, ten Kate and Laird, 1999: 72), the firm has to rely on ongoing *in situ*-extraction of samples at later stages of its R&D. As time preference rates will often be high (for example, if providers are poor) R will almost automatically be too low to sustain genetic resources on the allotment. As a consequence, royalty arrangements are often combined with other forms of monetary and non-monetary benefits, for example salaries for the supply of raw materials, which compensate time preference effects by assigning sources of immediate income to the provider (Rubin and Fish, 1994; Rosenthal, 1996). Let y denote any other form of benefit paid to the provider in addition to the royalty payment. If, in the simplest case, y is an up-front payment, equation (3) changes to

$$R = y + P_s \cdot RF \sum_{t=j}^k \frac{\mu_{NS,t}}{(1+i)^t} \quad (4)$$

$$RF = \frac{R - y}{P_s \cdot \sum_{t=j}^k \frac{\mu_{NS,t}}{(1+i)^t}} \quad (5)$$

With a higher time preference rate, the landowner must be offered a higher up-front payment (or analogously, higher - discounted - milestone payments or salaries) or must be assigned a higher royalty factor in order to provide him with a sufficient incentive to leave his parcel of land uncultivated. As a consequence, royalty payments will tend to be crowded out by other forms of ‘benefit-sharing’ among poor people, who often have a higher time preference rate than the rich.

So these technological advances, which take place in three stages, primary stage of invention, secondary stage of innovation being embedded in the product and process and the third stage of diffusion, involves a cost for the bio-prospecting firm and the sharing communities as well. In the primary stage, experimentation and observation is needed to capture the exogenous information, this calls for a combination of physical, human and natural capital and valuation of this natural capital become pertinent. In the second stage and the third stage the information is developed could be embodied in a product or disembodies, i.e. in movement of human capital. Matter of confusion exists over whether the property rights would be given to the initial stage, i.e. communities, research firm at the secondary stage or both together. The question of importance is the debate of how to ensure both the primary stage and the secondary stages of R&D, and their associated capital inputs, receive enough competition to generate incentives for

their continuing efficient operation. How are the returns to innovation to be appropriated and apportioned is a question, which many of the international as well as national organizations are grappling with. There are enough developments, as we mentioned, in the recent period and a huge chunk of research is going on in this area and hence we are not entering into this area of discussion, but only briefly outline some of those in the next section. But our intention here is to show that in spite of all these developments, many international firms feel it largely difficult to deal with the complex system of property rights and many celebrated models of benefit sharing has been suffering from controversies. This is not intended to look down many of the efforts for equitable sharing, but to make this less complicated and cheaper, so that many more firms will be interested to take chances. This has resulted in the growing market for ayurvedic cosmetics and nutraceuticals, which only need a slight alteration from the classical formulae, some time even disregarding the basic root tradition from which it originates, with a proprietary ownership, which is easily gettable from the local inspecting authorities.

IV. A Brief View on National and International Initiatives

As Mathur (2004) notes, it is intriguing when certain kinds of knowledge sharing and knowledge transfers of economic value are neither mediated by the market nor by the state. The problem of protecting traditional medical including ayurvedic knowledge under the intellectual property system is perennial due to the lack of clarity in valuation of traditional knowledge and plant genetic resources and the uncertainties regarding enforceability of a special category of property rights.

The economics of innovation and exhaustible natural resources have also puzzled economists for a long time. Informal cross-border spill-overs in missing markets are an endemic feature when borders are porous (Mathur 2004). When intermediation among economic agents is not mediated through market transactions, it is customary to consider state intervention, however transitory, as a policy measure. The need for policy intervention is greater when network externalities for pure public goods exhibit non-convex production and revenue functions due to increasing returns caused by technology standards and innovations based on science and technology (Datta-chaudhuri, 1990; Mookherjee, 2003, p.130). The market for traditional knowledge and plant genetic resources is precisely such a case. Here, government failure can be a more worrisome problem than market failure⁵. National and international priorities may conflict and lead to different solutions if international pecuniary external economies are not addressed in national policy choices. The problem acquires new dimensions of complexity when cross-border spillover effects of missing markets require interventions without disturbing the harmony of national policies with international regimes when nations compete with each other in the arenas between national governance policies and international economic relations (Mathur 2003). The larger incompatibilities within the international sharing and property right system are thoroughly exposed by Mathur (2004).

4.1 International Development on Property-right Assignment

Several international organizations have recognized the importance of TK and have been involved in a variety of programs to promote the preservation of TK. Some of the key agreements and initiatives are listed below.

- In what was one of the earliest initiatives, in 1982, the World Intellectual Property Organization (WIPO) adopted the Model Provisions for *National Laws on the Protection of Folklore against Illicit Exploitation and Other Prejudicial Actions* (now widely known as the Model Provisions), along with the United Nations Educational, Social and Cultural Organization (UNESCO).
- The Food and Agricultural Organization (FAO) introduced in 1989, provisions for the sharing of benefits arising out of the use of genetic resources and the protection of traditional knowledge as part of the *Farmers' Rights in the Revised International Undertaking on Plant Genetic Resources*.
- The Convention on Biological Diversity (CBD), in 1992 established a common international platform for countries by providing a framework to regulate the access to biological resources and the associated TK and to reward communities for their contribution to conservation and sustainable use of the same (Article 8j)¹⁹.

While none of these agreements is binding, each provides a forum for discussion of TK and establishes guidelines for action by member countries. Different possibilities and modifications under experiments are given regarding property rights.

¹⁹ Article 8j mandates that member States: "...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 benefits arising from the utilization of such knowledge, innovations and practices."

Table 1: Mechanisms of Protecting Traditional knowledge

Possibilities	Further Modifications	<i>Sui generis</i> alternatives
Customary law	Formal recognition of customary law	----
Contracts; breach of confidence, unfair competition, etc.	Access and benefit sharing agreements	Biodiversity management regulations with provisions on traditional knowledge; access legislation
Intellectual property law	Certificate of origin; declaration of informed consent; extended grace period; waive fees; etc	New intellectual property categories

Access and benefit sharing is consequently becoming an important issue in the global environmental regulation realm as the CBD is the only agreement trying to put in place a new governance scheme for the use of all genetic resources. However, and even if an agreement on ABS has been negotiated for several years already; the ABS issue still seems to lead to a dead end one. On one side developed countries are reluctant to put in place any national or International framework whereas, on the other side, the developing world is forcefully hoping to be soon able to share the benefits from the use of genetic resources.

The inadequacy of the current incentive mechanism leads to sub-optimal investment in biodiversity as a source of innovation. As Goeschl and Swanson (2002) states, one can underline three kinds of insufficiencies that result from ABS regimes, based on incentives relying on the existing IPR mechanisms: First, the IPR mechanism is insufficient for investment in products with a short life span. It creates an underinvestment in GRs with high adaptability. Second, the IPR mechanism creates a trend of monopolization and is therefore not compatible with the requirements of an innovation process based on diversity. Third, the IPR mechanism acts at the level of individual companies and does not create an incentive to invest in the other levels of value creation whose benefits are diffuse. It produces an underinvestment in the other levels of value creation, particularly at the level of the ecosystem and its local or indigenous users. The interest of demonstrating this triple insufficiency from the point of view of a dynamic approach is to show the necessity of abandoning a conception of efficiency based on a static allocation of resources, in order to progress towards a conception that better accounts for the collective character of the innovation process and the relationship between economic growth and the autonomous dynamics of the natural evolution of genetic resources.

4.2 Initiatives and Experience in India

Various suggestions have been advanced to extend protection to knowledge, innovations and practices. These include (i) documentation of traditional knowledge; (ii) benefit sharing models with public/private sector partnership; and (iii) other initiatives.

(a) Documentation through TKDL and other Sources

In India, preparation of village-wise Peoples' Biodiversity Registers (PBRs) and Community Biodiversity Registers (CBRs) for documenting all knowledge, innovations and practices has been undertaken in a few States. In the first such initiative, the concept of Community Register (CR) was launched by the Foundation for Revitalization of Local Health Traditions (FRLHT) amongst South Indian NGOs in 1994. There have also been some initiatives that focus on accrual of rights on individual innovators rather than of communities, such as *Srishti* and *Honeybee*. These efforts to prepare PBRs and CBRs were later taken up by the respective State Governments also and now, for example in the State of Karnataka, these are being prepared with State funds and assistance also.

For preventing instances of biopiracy in future, a need was felt for developing digital databases of prior art related to herbs, which are already under public domain. Thus an exercise was initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as Traditional Knowledge Digital Library (TKDL). Such digital database would enable Patent Offices all over the world to search and examine any prevalent use/prior art, and thereby prevent grant of such patents and bio-piracy. The preparation of TKDL is being done in conformity with the classification system being developed by WIPO, so that it is easily used by patent examiners the world over in order to prevent bio-piracy. It has also been recognized that documentation of traditional knowledge (TK) is one means of giving recognition to knowledge holders. But mere documentation may not enable sharing of benefits arising out of the use of such knowledge,

unless it is backed by some kind of mechanism for protecting the knowledge. Documentation of traditional knowledge may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form in which it exists.

(b) Developing Benefit sharing models with public/private partnerships

Some limited efforts have been made in India for registration of biological resources and associated traditional knowledge. For example, the *Honeybee* database established ten years ago in India is a facility for registration of innovations by innovators. The database can be accessed for adding value to these innovations and sharing benefits with the knowledge providers and innovators. Thus the *Honeybee Network* involves documentation, experimentation and dissemination of indigenous knowledge. The network has probably the world's largest database on grass root innovations, having now about 10,000 innovations, with names and addresses of the innovators (individuals or communities). Through the Honeybee Newsletter, grassroots innovations have been disseminated to more than 75 countries. For example, this database has entries on traditional use of fish and fish products, improving crop productivity etc. More important efforts have been made, however, for public/private partnerships to ensure benefit sharing. Despite their criticism on account of inadequacy of the rewards to the innovators, it is a path worth pursuing so that some critical mass of opinion on what should be an equitable reward emerges.

(c) State support and other initiatives

Another relevant aspect relating to TK is the need for value addition to this knowledge for converting it into economically profitable investments or enterprises. Many of the innovators however do not have the capacity for value addition. Thus there is a need for providing institutional support through public funding in scouting, spanning, sustaining and scaling up of grass root innovations and to enhance technical competence and self reliance of these innovators, through establishment of green venture promotion funds and incubators. It was also proposed as part of the 1999-2000 national budget of India that a National Innovation Foundation would be set up. This foundation, with an initial corpus of Rs.200 million (about US\$ 4 million), is intended to build a national register of innovations, mobilize intellectual property protection, set up incubators for converting innovations into viable business opportunities and help in dissemination across the country. Apart from this, the Ministry of Environment and Forests has established a National Biodiversity Strategy and Action Plan (NBSAP), which is undertaking a number of activities including identifying access and benefit sharing methods that are easy to follow and take into account the concerns of the innovators.

In the case traditional knowledge associated with the use of biological resources, the Biological Diversity Act 2002 offers some scope for doing so. Section 3 of the Act provides that all foreigners must get previous approval of the National Biodiversity Authority to “obtain any biological resource occurring in India or knowledge associated thereto, for research or for commercial utilization or for bio-survey bio-utilization”. The term foreigner here refers to a person who is not an Indian citizen (or is a non-resident citizen as defined in Clause 30 of section

2 of the Income Tax Act of 1961), or a body corporate, association or organization that is not incorporated or registered in India (or even if registered or incorporated in India, has any non-Indian participation in its share capital or management).

The first fundamental motivation for IPR is that they provide an incentive for private agents to engage in innovative activities. Thus, theory predicts that stronger IPRs should increase the propensity for R&D and therefore innovation. In the general pharmaceutical industry, there are evidences that, stronger patent protection might actually hinder technological progress. This is the case whenever incentives for innovation with a monopoly are lower than in more competitive markets. Earlier theoretical literature suggested that the threat of a new firm entering the market would ‘force’ the incumbent monopolist to have a high rate of innovation (Arrow 1962; Dasgupta and Stiglitz 1980 and 1981; Gilbert and Newbery 1982). But then it was recognized that, given the “sunk cost” nature of research expenditures, an incumbent could deter competitive entry with only a limited amount of research, so that innovation with a monopoly could be substantially lower than with more competition (Dasgupta and Stiglitz 1981 and 1982; Dasgupta *et al.*, 1982; Farrell *et al.*, 2003). Even more important, strong patent protection can significantly slow down technological progress when innovation is sequential or cumulative, that is, it builds on previous innovations (Scotchmer, 1991; Merges and Nelson, 1994; Bessen and Maskin, 2000). Strategic use of patents and litigation costs further deters innovation. This practically leads to lot of hidden costs in the industrial technological developments and efficient bioprospection. Finally, strong patents can distort the directions, in addition to the rates, of innovation. It has been argued that for a localized and more indigenous knowledge system, a *sui-generis* system is more adaptable (Damodaran 2003). A well-written local contract can serve the

purpose better than assigning the property rights globally. Though we have a few examples on the successful benefit sharing mechanisms, some discrepancies are seen in some of them as we move towards the details. In the next section we discuss a celebrated model of bioprospection and try to point out the discrepancies in the model and highlight the less incentives for firms, to go for traditional knowledge bioprospection.

V. Two Cases from Kerala: Empirical Details

In this section, we talk about two cases of innovations, one, case of *Jeevani* (a celebrated benefit sharing model from Kerala), which has been developed from the traditional knowledge of *Kani* tribe, and second, *Pankajakathuri breath easy*, a product developed from the traditional ayurvedic knowledge to see that why firms are more disincentivised in the first case than the other.

5.1 Nature of R&D in Kerala Ayurvedic Sector

In Kerala, the R&D in ayurvedic industry is mainly concentrates on: (1) Clinical research (2) Process related research and (3) Medicinal plant research. Clinical research is aimed at evolving new methods and procedures for dealing with acute ailments such as cancer, rheumatic arthritis etc. Process related researches broadly cover activities like bioactive research, standardization, development of new product etc. One important factor hinders the drug invention, is the high cost of R&D and at the same time after the successful clinical trials they are priced low. On the other hand, if it is in nutraceuticals category, clinical validation is not mandatory, only the clearance from local authority is needed and as an OTC product it could be priced at a very high rate. So incentive for converting even the medicine into nutraceuticals is common in this sector.

However, there are more efforts to discover new drugs since 2005, product patent have become very important and there is improved incentives for innovations. The leading manufacturing firm, Arya Vaidya Sala, Kottakkal has recently set up a Medicinal Plant Research Centre with a view to satisfy a long felt need for an institution for conservation and study of medicinal plants used in ayurveda. AVS has research collaboration with many national and international institutions like, Council of Scientific and Industrial Research, International Development Research Centre etc. Presently India has National and state medicinal plant boards.

Ayurvedic firms, encourage research mainly on: one, standardization of ayurvedic medicines, two, analysis of medicines with an objective to identify the active ingredients, and three clinical trials of new dietary range of medicines. Co-operation between research institutes and firms will improve the supply of raw material and quality of products. AVS and Pankaja Kasthuri signed an agreement with Tropical Botanical Garden and Research Institute (TBGRI) and Arya Vaidya Pharmacy received financial help from National Health Institute of USA to develop and consolidate scientific collaboration between researchers at the Ayurvedic Trust, Coimbatore and top US universities.

Table 2: R&D Expenditure to total sales in percentages

	1994-95	1997-98	1999-00	2001-02	2004-05
KAL	0.5	0.6	0.4	0.6	1.04
Nagarjuna	0.5	2.04	1.1	0.9	1.06
Kottakkal	0.6	0.3	0.4	0.9	1.12

Source: Compiled from annual reports of firms

For most of the companies the R&D investment is less than one percent of their sales turn over (Table 2). This has to be improved as R&D forms an important factor in the sustenance of the industry. But in absolute terms, there is an increase in R&D in most of the firms. AVS's R&D expenditure increased from Rs. 13.19 lakhs in 1992-93 to Rs.42.79 lakhs in 2001-02. In contrast, the pharmaceutical industry as a whole spends more than two percent of its income on R&D (M.D Nair 2003). Primary information on Pankaja Kasthuri shows that their R&D expenditure is three percent. Oushadhi, a public enterprise, has invested Rs. two crores for R&D in 2006.

Many institutions like, Department of Science and Technology, Indian Council for Medical Research, Central Council for Research in Ayurveda, Technical Information Forecasting and Assessment Council, Ministry of Science, Department of Bio-technology, Ministry of Environment and Forests etc. are actively involved in the research related to herbal medicine and products. Recognizing the profound influence of R&D on the prospects and opportunities for the growth of Indian pharmaceutical industry (including all the medical systems), the Department of Science and Technology, Government of India has also mounted a programme for drug development during 1994-95. So far the GoI has invested Rs. 32 crores as its share under this programme and the industries have contributed Rs. 45 crores making a ratio of 2.2:1. Recently, government allotted 150 crores for R&D in this sector. But the academia-industry interface in this sector remains to be low.

5.2. Jeevani Case: Transfer of Technology Model

A lead provided by a tribal community, *Kani tribe*, inhabiting the Southern- Western Ghat region of Kerala State in India, relating to the anti-fatigue properties of a wild plant *Trichopus ceylanicus* has led to bioprospecting and development of a scientifically validated drug “Jeevani” by the Tropical Botanic Garden and Research Institute (TBGRI), Thiruvananthapuram.

Many pharmaceutical firms approached TBGRI for getting the license for the production of “Jeevani”. After negotiations with various interested parties, the manufacturing license of “Jeevani” was transferred to the Aryavaidya Pharmacy, Coimbatore Ltd. for a license fee of Rs. 10 lakhs for a period of 7 years with 2.0% royalty at ex-factory sales price. Council for Scientific and Industrial Research (CSIR) norms were adopted for the technology transfer in November 1995. The TBGRI in consultation with the tribal community has worked out an arrangement for benefit sharing. According to this arrangement, the TBGRI has agreed to share 50% of the license fee and royalty with the tribal community. In order to meet the demand of regular supply of plant to the manufacturing unit, it needs to be grown in large quantities. Since, it is a shade loving plant, it has to be cultivated as an understorey vegetation of trees in the forests, local tribal have been encouraged to take up cultivation of *Arogyapacha* with the active cooperation of Integrated Rural Development Programme (IRDP) and Forest Department. Cultivation of these plants provides protection to the associated trees species. In addition to secure economic uplift of the tribal people in terms of employment and additional income. Thus modern economic working of the local knowledge and use of plants leads to conservation of the plant species as well as its associates. This case study clearly establishes that conservation and sustainable utilization are dependent on long-term benefits.

Table 3: Comparison of the First and Second ABS Agreements between Stakeholders

First agreement	Second agreement
Parties were the TBGRI and the AVP	Parties included Kanis, the TBGRI and the AVP
Entered into force on November 10, 1996	Yet to be implemented
Valid for a period of 7 Years	Would be valid for a period of 7 Years
License fee of Rs. 10,000,00	License Fee 20,000,00
Royalty to be paid at 2 % for 10 years	Royalty to be paid at 4 % for 10 years

Source: Chaturvedi, 2007

In 2004, the new Director at the TBGRI constituted a Business Management Committee (BMC), with a membership of seven persons, two from its faculty, three outside experts and two representatives of the *Kani* Trust. As the Table shows, the BMC decided to set minimum conditions for the ABS arrangement. It suggested the license fee be doubled to Rs. 2.1 million and that the royalty payment also be doubled to 4 per cent.

5.2.1 Growing discrepancies in the Model

The major discrepancy in the model is the management of biodiversity conservation. It has been documented that when the rwa material price has increased from Rs.25/kg to Rs75/kg many have

started cultivation²⁰ of *Trychopus zylanicus* in the Kani tribe since their opportunity cost of the same is much lower due to the lack of employment opportunities. Mere market creation for biodiversity resource need not always facilitate conservation. In fact, in this case unregulated biodiversity prospecting and drug development could speed up the destruction of the resource. The incident of overexploitation of wild *T. zeylanicus* can be noted as an example for this when in 1996; the subsequent over-harvesting forced the Forest Department to ban the cultivation (Dedeurwaerdere et.al 2005).

In this situation, even with a clear incentive for the tribe members involved in the contract to adopt sustainable management practices, there could be no guarantee that other groups would not free ride on the contract through exploitation of the wild variety or, alternatively, that the company would not look for other providers of the same plant under less restrictive conditions. The basic trust shown by the actors of this model is very important, as it may not be able to be replicated in other situations²¹. As Dedeurwaerdere notes, the property right holders of the physical asset, the forest administration and the members of the tribal community, seem to have been involved only marginally in the drafting of the terms of the contract and the legitimacy of the agreement is not recognized with the same intensity by all the actors. In particular, different perceptions subsist between the younger and the older tribal members, the latter caring more about the loss of cultural identity. And many of these contracts come into existence without

²⁰ The 50 households who first cultivated the herb witnessed a significant increase in income given the low opportunity cost of family labour. As a result more households began to cultivate in the second season. The price offered by AVP increased from Rs 25/kg of fresh leaves to 75/kg through effective bargaining by the Kanis during the second harvest.

²¹ In the first phase of the model, actually TBGRI and Kani tribe has only a confidential agreement, which was completely based on the trust and faith.

much attention towards other authorities like forest department and state government, which can also bring some discrepancies in the systemic development.

Given all these factors, it is very difficult to get into a contractual relation with the knowledge communities unless the manufacturing companies develop a mutual understanding, respecting the customary laws or by a third party mediation like state or research institute. And the success of the *Jeevani* case lies in that.

5.3 Case of *Pankajakasthuri* – Drug developed from Classical formula

Understanding the pulse of the consumers without losing the basics of the traditional knowledge, Pankajakasthuri Herbals India Ltd. (PKHIL), (Trivandrum-based leading Ayurvedic pharmaceutical company in the cosmeceutical market of Kerala) started mass scale production and emerged to be one of the major such companies in India. Sree Dhanwanthari Ayurvedics of 1988 rechristened when it became a private limited company in 1996. Now PKHIL, founded by Dr. J. Hareendran Nair has grown from a local outfit to a company with a reach outside India. And it is set to mark its entry into the Kingdom of Saudi Arabia (KSA) with the export order it has acquired, enabling it to ship its products for diabetes and blood pressure in to the Kingdom.

Initially Dr. Nair (professional Ayurvedic doctor) began practising Ayurveda in the traditional form, but over time he began to experiment with new Ayurvedic formulation for respiratory ailments, as he was getting more and more patients with respiratory ailments. The basic idea needed for developing the formulation was available in age-old Ayurvedic texts. Hareendran began his experiments on a trial and error basis by testing various combinations and began to

collect the impact of each of them. The efficiency and effectiveness of each one of them was also looked into. After 4 years his experiments began to yield fruits. Starting with small-scale, but intensive research at his clinic, Dr Nair made a breakthrough with his Ayurvedic cure for asthma and launched a drug under the name *Pankajakasthuri*, with the backing of the State government. This was the turning point of the company. Even now Pankajakasthuri granules, which is well packed with the help of the modern techniques, holds the monopoly power in the granule market and forms 60 percent of the turnover of the company. The innovative aspect of the product (Pankajakasthuri) was that unlike traditional Ayurvedic drugs, which are administered in the form of *lehyams* or *Kashayams* (various decoctions) this was in granule form and could easily be consumed by the patient. Moreover it also retained all the traditional characteristics. Dr. Nair then applied for patenting his drug and a proprietary patent was awarded as per the existing Indian patenting norms. Thereafter Pankajakasthuri began to be known as the trademark of the firm. The beauty conscious consumers of Kerala, a large chunk of Ayurvedic research papers regarding properties of Ayurvedic substances to enhance beauty, and the size of Indian cosmetics industry around Rs.840 crores a year were the main factors which made Dr. Hareendran to diversify in to this sector. His initial aim was to acquire a market, which extends at least one-percent of the total cosmeceutical market. The firm has developed various Ayurvedic cosmetic products like *Kaveri fairness cream, Kaveri milk cream, Pankajakasthuri dandruff oil* etc.

Backing on a knowledge based on Ayurveda, research projects undertaken by him have led to the formulation of drugs for the treatment of diseases like asthma, diabetes and hepatitis B, on which the effect of allopathic medicine has been limited. The company has also diversified and marked an entry into the competitive soap market with four herbal soaps, apart from making inroads into

foreign markets. It is now being marketed in the new name *Breath Easy* and in Malaysia marketing is done through *Oze Marketing Limited*. Now the company has different category products diversified in to the sections like OTC, FMCG and ethical products. A new-found and surging interest in the cures offered by Ayurveda and awards²² won for pioneering work in this field has helped to grow and strengthen PKHIL's hold in the herbal drug sector.

PKHIL had achieved a 100% growth rate during the fiscal 2005-06 and in the succeeding years. Riding on the resurgent interest in Ayurveda, the company has scored with its innovative product range. The crux is that company is successfully mixing mechanisation with the traditional Ayurvedic knowledge. According to him even the allopathic doctors prescribe Pankajakasthuri for Asthma and other bronchitis disorders. "It would have been easy for us to export all our products under the edible food category, as they all are nothing but herbal formulations. But we waited as we are particular to export a capsule or even a granule of our products only under the drugs category license from the respective governments", says Dr. J. Hareendran Nair. The clinical trials and the toxicological study are done in KEM hospital Mumbai and some of the laboratory quality test is done in Tropical Botanical Garden and Research Institute of Thiruvananthapuram.

In 1999, the department came out with two more wonder drugs; *Ilogen excel* Tablets for diabetes and *Somatone* Capsules for hypertension. And since then, the progress has been consistent and continuous. *Ilogen-Excel* and *Somatone* has helped PKHIL to achieve a turnover of Rs.6.52

²² *Best rural entrepreneurs award* by National Integration Society of India in 1994-95, *Best herbal medicine award* for Pankajakasthuri granules from the Kerala State Consumer Protection Centre in 1996-97, *best herbal soap in Kerala* in 1997-98 for Kerala Upabhokthru Vedi for Kasthuri herbal soap and *JeevanRaksha Award* in 1997-98 from Human Aids and Cancer Control Society of India and best state entrepreneur awards of various years.

crores in the past financial year (1999 - 2000), as against Rs.3.25 crores the year before. In 2004 it stands around 25 crores of rupees with 18 panchakarma centres all over the world with 23 different products. PKHIL believes that advertisement has a major role to play in sales maximisation as it spends around 25 percent of its turnover to advertisement and the feedback is phenomenal. A close look in the product pattern of PKHIL shows, there is a shift from actual ayurvedic medicine to nutraceuticals and recently a shift again from nutraceuticals to concentration in the cosmeceutical market. This actually represents the nature of whole industry, happened due to the change in the demand and the trend in consumerism.

The company already has a presence in Malaysia, Singapore and other Middle Eastern Countries. Now around 15 percent of the company's turnover is from the exports. An import license for the company's Pankajakasthuri granules, for the treatment of asthma, was received from the government of Singapore in May 2000. The Malaysian government had also granted export license to Pankajakasthuri under the drug category in 1998. Similar approvals are awaited from the US and Japan. Pankajakasthuri proved to be the most effective remedy for asthma and all types of breathing disorders and soon gained immense popularity. It is all set to start Panchakarma hospital in St. Petersburg in Moscow and in UAE. Dr. Nair did not stop his enthusiasm there and he began to develop Ayurvedic drugs for other ailments like diabetics, high blood pressure, urinary disorders rheumatism etc. However these products could not be marketed easily, as advertising through any mass media is not allowed for the Prescription drugs brands (schedule H drugs) as allopathic. Hence Pankajakasthuri adopted the ethical method to sell the same similar to the practice adopted by pharmaceutical giants of modern medicine i.e. through

prescription from physician to the patient. These kinds of complementary assets needed for the marketing has been well adopted by the Pankajakasthuri Limited.

This case shows the growth of a company, from a single product, which has derived from the traditional formula. This is mainly caused by the impacts of the complementary assets and better positioning of the product, to tap the increasing demand. This doesn't have the complexities of earlier example both in drug discovery and related and unforeseen costs.

Concluding Remarks

The current global market for herbal products, which includes medicines, food supplements, herbal beauty and toiletry products is estimated at around US\$ 62 billion. Out of this, the market for herbal medicine alone estimated at around US\$ 5 billion (EXIM 2002)²³ and now it may be around US \$ 12 billion. In this the income from bio-prospect market might be a having a handsome share. Here, we broadly aimed to outline the knowledge origin, bio-discovery and nature of innovative efforts in the traditional medicine, especially ayurvedic sector, with some special reference from state of Kerala, India. This explains the non-additive character of these innovations due to the lack of incentive system to reveal the knowledge, which leads to a static growth in the sector as such. The analysis shows that much of the development in the sector in India is mostly mediated from the drug developed from traditional formula, and the actual bioprospective efforts are less. This is due to the firms are less incentivised to invest in this, reasoned by various costs involved and the complex process of drug discovery. This is partly due to the difficulty in the valuation process of biological resources too. Apparently, the firms have

²³ Gautham; Raman; Kumar (2002), *Exporting Indian Health care*, EXIM bank, Quest publications.

the cheapest option of developing a drug from classical formulae with necessary modification, and it is easier to get the proprietary rights and make huge profit with the help of market promotion methods. The complexities in the property right assignments and the vulnerabilities of the benefit sharing models have added to this phenomenon. In an era, where, we see a huge growth in herbal drugs and products, many developing countries with large traditional knowledge resources, couldn't capture or even enter the market, is mainly due to this lack of technological innovation in this sector due to the existing disincentives.

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