



BRILL

ASIAN MEDICINE 9 (2014) 236–271



brill.com/asme

Innovation System and Increasing Reformulation Practices in the Ayurvedic Pharmaceutical Sector of South India

Harilal Madhavan

Azim Premji University

harilalms@gmail.com

Abstract

This article emphasises the role of domestic knowledge capabilities and networks in shaping an incentive structure for innovation and research. I combine an analysis of in-house research activities by ayurvedic firms in South India with their inter-firm and inter-institutional relations in the establishment of a new innovation regime aiming to promote growth in the ayurvedic sector. The tensions typical of this competitive environment are discussed by paying attention to the absence of contingent regulatory practices and the recent efforts in this direction as illustrated by the use of the 'Magical Remedies Act' to curtail the claims of many firms in the market. The ayurvedic pharmaceutical company Oushadhi owned by the Government of Kerala as well as the private firms SNA Oushadhasala Pvt. Ltd. and Vaidyaratnam Oushadhasala Pvt. Ltd. (all from Thrissur district of Kerala) are analysed to delineate their research priorities and bottlenecks for innovations. The data of this ayurvedic sector is contrasted with the case of the Kani tribe and the ways in which their traditional knowledge has been reformulated into an industrial ayurvedic product. Through this exploration, the paper attempts to offer an economic explanation for increasing reformulation practices in Ayurveda.

Keywords

Ayurveda – bioprospection – innovation systems – reformulation – traditional knowledge

Introduction

Research and innovation in ayurvedic pharmaceuticals can be analysed in the context of an increasing competition with the biomedical pharmaceutical sector in India, the potential for market success and the challenges posed by the ethos and dominant parameters of science and modern medicine. In this context, the ayurvedic sector necessarily confronts two challenges: firstly, to carve out a recognisable economic space in the market and advance without challenging the dominance of science and biopharmaceuticals; secondly, to pursue ways for complying with internationally acceptable standards of trade practices, which are basically designed for biopharmaceuticals.¹ The interdependence of various stakeholders from within and outside the ayurvedic pharmaceutical sector and the geo-political context in which they operate, shape the kind of innovations that are feasible for growth and can be adapted to Ayurveda. This paper explores the innovative behaviour among ayurvedic firms in the context of recent policy developments. This, in turn, reveals the nature of reformulation practices that offers an economic explanation for the increase in the number of proprietary products on the market. Such an analysis allows to explore incentives and constraints for innovations—both endogenous and exogenous to firms—and details the relevant policy steps required in terms of the institutional linkages necessary for the sector.

Bioprospectors and herbal pharmaceutical companies are interested in traditional plant-based medical knowledge, usually referred to as ‘traditional knowledge’—TK, mainly due to two developments: a) the increasing acceptance of traditional knowledge as a lead in the search for active ingredients and multi-ingredient compounds that can considerably reduce search costs

1 India has a growing pharmaceutical sector, which accounts to about six to seven billion US \$ in 2008, representing two per cent of India's global market, and ranking fourth in terms of volume and thirteenth in value (Greene 2007). Ayurvedic pharmaceuticals form a very meagre share of the same and represent only two per cent of the global herbal market in terms of value (Madhavan 2011). The ayurvedic manufacturing industry is different from the general pharmaceutical industry, viz. source of knowledge, nature and process of drug discovery, scientific applications, fragmentation of markets, targeted consumer categories etc. It also has some similarities in terms of marketing strategies, institutional development, networking etc. The structure of the industry is analysed elsewhere (Madhavan 2009; Bode 2008). Parallel to these well-developed codified systems of Ayurveda, Unani, Homeopathy and Siddha, India's folk medicines also thrive. They have found a niche mostly in rural areas. In the context of the Kerala state, many folk and tribal healers continue to practise what their teachers had taught them, and what could be called a pre-codified indigenous system of healing that already existed in the past.

and can occasionally indicate valuable leads for developing entirely new plant-based pharmaceutical drugs; and b) from a private industry perspective, the high cost of drug discovery² and the impending patent expiration of many blockbuster drugs represent significant hurdles for future commercial viability.³ Also, the trade-related Intellectual Property requirements like product patenting have been extended to many countries that, until now, have been dominated by generics. In this context, most of the ayurvedic products have to compete, not only with other products within the herbal category, but also with these newly emerging patented biopharmaceuticals.

In the last decade, a large number of biopharmaceutical giants have begun to take an interest in herbal divisions in their drug research⁴ (for example, Ozone Pharmaceuticals, Sami Labs, Hindustan Lever Ltd. etc.), whereas many small and medium-sized ayurvedic companies lack the personnel and the means to innovate patented or new molecule developing research. It is also true that many have preferred to stay away from the production of molecular research as they stick to the traditional trajectory, brand loyalty, and specific customer base. It makes the ayurvedic industry quite different from other industries in terms of taxation, access to resources, and even in market structure. The ayurvedic companies predominantly concentrate on the production of classical ayurvedic products (based on ayurvedic textual formulations) and a new category of proprietary products, which ensure them exclusive marketing rights in a monopolistic competitive environment and at times, they even hold a product monopoly.

I discuss the incentives and disincentives for ayurvedic firms to explore the determinants of the current innovative practices in the sector. This analysis is extended to understand the regulative structures in place in order to minimise the malpractices inherent in the drug production scenario. To focus the analysis, I will discuss the Local Innovation and Production System (LIPS), which determines the nature of the innovations and the dimensions of innovativeness in the sector. I argue here that the economic incentives for radical innovations in the strict sense of molecular innovations are largely crowded out by the structure and function of LIPS within Ayurveda, hence innovations

2 It takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available as a treatment. The average cost of researching and developing each successful drug is estimated to be 800 million US \$ to one billion US \$. This includes the cost of the thousands of failures: for every 5,000–10,000 compounds that enter the research and development (R&D) pipeline, ultimately only one receives approval (CBO 2006).

3 Gehl Sampath 2005.

4 Arora 2005.

mostly take place in the form of reformulation practices in drug production. Yet, reformulations per se could be considered as a major form of alternative innovation practices within the sector. The paper will also show that systemic incentives can introduce nuances in reformulation practices as in the case of the commercialisation of the traditional medical plant knowledge of the Kani.

Three Postulations: Property Rights, the Innovation System and Trade Practices

To understand the innovation system⁵ in the ayurvedic sector, I consider three important and interrelated postulations. The first is to ascertain that there is a cost involved in the commercialisation of community knowledge. Many economic models perceive knowledge as an exogenous public good. It is assumed to be available in every economy, as in Solow's neo-classical formulation,⁶ and thus knowledge is not understood as a process or a practice. However, later theories, including the thinking of evolutionary economists, do not consider technological knowledge to be something that just happened to societies or economies,⁷ but as a process that every society needs to consciously and actively promote and nurture, for which certain socio-economic preconditions must be met. The question is whether traditional knowledge also has the same features as a determinant of growth. We can assume that there are two possible types of growth involving traditional medical knowledge as a major source of input that differ only in the presence or absence of property rights. The first type is one in which the adequate protection of patents,⁸ ownership rights, and other incentive mechanisms are available to the actual knowledge holders, whereas in the second type, no incentive mechanisms are effectively

5 The concept of 'innovation system' emerged as an alternative way to explain the innovation process, improving on an earlier view of simple linear progression of scientific research. The concept considers innovation as an outcome of interactions among firms, organisations, and institutions, in the context of historical, cultural, and socio-economic framework conditions. The innovation systems framework is useful in capturing knowledge flow in order to elaborate policy.

6 Solow 1957.

7 Nelson and Winter 1982; Romer 1986; Lucas 1988.

8 Patents in ayurvedic research are given only in very exceptional cases, if the novelty and new avenues for the uses can be proven. So far, around 34 patents have been granted mainly under the research of the Central Council for Research in Ayurveda and Siddha (CCRAS) and another 13 patents have been filed within India. In addition, many technology transfers have also been encouraged (available at <http://www.ccras.nic.in>).

established. When innovators fail to internalise (either through property rights or through other exclusive rights) the cost of (sharing) innovations, they will choose to keep their inventions secret, and hence the available knowledge and innovations will remain static. This means they will not be available for further innovations.⁹ Obviously there are other socio-economic reasons for keeping the knowledge secret in this case, such as the belief that efficacy would be lowered once it is shared, mishandling of the knowledge by others, etc.

In folk medicines,¹⁰ innovations tend to remain with the innovator due to the absence of efficient protective mechanisms and threat of mass exploitation. Consequently, current innovations do not relate to previous ones because the innovator/physician chooses to keep them secret or might possibly be indifferent to the idea of putting them into the public domain.¹¹ Therefore, innovations are continuous but non-additive or non-cumulative, production remains at the same level, the sector is static, and the production frontier does not expand. The costs of sharing knowledge include the risk associated with the loss of that knowledge, loss of livelihood, and an undermining of cultural belief. These losses need to be translated into financial costs/remuneration through contractual benefit-sharing if knowledge is to be accessed from the community. That means community-related knowledge can only be developed when there is adequate compensation for the community, which in turn, also involves administrative and procedural costs. So for a firm, it is always safer to work with knowledge from the public domain when lacking the support of a strong innovation system, where property rights are not defined. Ethnic groups protect their traditional knowledge through various mechanisms such as 'term locking'—the use of an indigenous or colloquial term for the known medicinal plants in a herbal healing system. Various examples of this can be found in ethnic groups such as the Mudugar tribe of Attappady, Kerala.¹² Hence, much of the folk medical knowledge possessed by indigenous people does not reach professionally trained ayurvedic physicians or firms involved in the clinical development of ayurvedic drugs. This also holds true for the

9 Nwokeabia 2002.

10 Unlike folk medicines, intellectual property of medical inventions is clearly defined in the bio-pharmaceutical sector, and one invention can prove to be the basis of a 'ladder' further spurring inventions and hence form a chain of added value through research. In the case of folk medicines (this includes all the practices which are not codified but orally transmitted through generations, mainly the tribal medical knowledge and knowledge of indigenous communities), a legally binding property right system is yet to be initiated, but also many cultural/therapeutic beliefs stop them from sharing the knowledge.

11 Madhavan 2011.

12 Unnikrishnan 2009.

codification of knowledge, since many indigenous texts that carry the bulk of the knowledge have traditionally developed and improved formulas. For example, *Sahasrayogam*, *Yogamrutham* (Kerala origin) have never figured in any of the institutional syllabi. The 1992 Malleswara Project mentions that in the Bommiyampathy region of Attapady in Kerala alone, tribal populations make use of around 500 medications and plant knowledge that were completely unknown to the institutionalised system of Ayurveda. This also shows that considering folk medicine as a systematised knowledge has a character resembling eco-systems and customary follow-ups. Following on from my first postulation, any kind of knowledge inherent to a community or individual cannot be shared without an understanding of values attached to it and, more importantly, without a cost.

In the mainstream ayurvedic sector as well, research and bioprospection is developed into further cumulative innovations when adequate incentive mechanisms are established. At the macro level, defining knowledge rights remains a major hurdle in the development of the pharmaceutical sector. When working with public knowledge, i.e. in the case of classical formulations, 'creative reformulation' for incremental innovations can be a feasible option for the firms; and this has radically redefined the sector over the past few decades. Here, property rights are ensured by branding the product with the firm's name. These reformulations via incremental innovations may lead to a new product or process or a completely new form of the old product, which may at times qualify as a substitute to the former. It is worth mentioning that these 'below the radar'¹³ innovations are relatively effective substitutes for many high-end drugs in developing countries.¹⁴

A contractual agreement with symmetrical information and a more participatory approach to define the individual and community property may provide incentives for the community to preserve its knowledge and disclose it for further commercial validation. Therefore, it is important to establish an incentive system, which takes the communities' incentives for sharing knowledge into consideration, and encourages firms to practise effective bioprospection while using the resources sustainably. Many authors have highlighted the need for an efficient institutional (innovation) system, but scholars have generally ignored the social and normative institutions, which mainly represent the interpersonal relations and horizontal learning avenues that may strengthen values and support cumulative innovations.¹⁵ Furthermore, simply enforcing legal

13 Clark et al. 2009.

14 Kaplinsky 2011.

15 Murray and Stern 2007; Murray 2005.

rights may be a relatively blunt and costly instrument in shaping the socially complex processes of innovation since they ignore the substantive organisational and institutional context in which these interests are embedded.¹⁶

My second postulation is that the ayurvedic firm can be re-conceptualised as an organisation embedded within a broader set of formal and informal rules and a socio-economic–political environment reflecting historical and cultural trajectories. This understanding helps to avoid overemphasising research and development (R&D) in the innovation process, and encourages policy makers to take a broader perspective on the opportunities for learning and innovation in small and medium sized enterprises.¹⁷ Here, innovation is understood as a localised, context specific and socially determined process which implies, for instance, that the acquisition of technology abroad is not a substitute for local efforts. LIPS offer a distinctive framework to analyse these complex interactions within the sector. Within this framework, the processes of generation, dissemination, and use of knowledge, as well as the productive and innovative dynamics, are understood. It encompasses a wide range of economic, political, and social actors and their interactions, including manufacturers, suppliers of raw materials, equipment and other inputs, distributors and marketers, workers and consumers, organisations focused on education and training of human resources, information, research, development and engineering, support, regulation and financing, civil society, cooperatives, associations, unions and other representative bodies.¹⁸ This technique brings the innovation systems into the foreground. The innovation system emphasises innovation as an outcome of interactions among firms, organisations, and institutions, in the context of historical, cultural, and socio-economic conditions and localised learning interactions that are necessary for the build-up of critical capabilities throughout the innovation system.¹⁹ It is a holistic approach to policy in order to influence and change innovation behaviour for improving productive performance.²⁰ In innovation systems, the firm is placed at the centre and considered as the driving force.²¹ This is due to the fact that innovation is defined as ‘the implementation of a new or significantly improved product (good or service) or process,

16 Scotchmer 1991, 1996.

17 Mytelka and Farinelli 2003.

18 Lundvall 1992.

19 Lundvall 1992; Bell and Albu 1999; Metcalfe and Ramlogan 2008; Kraemer-Mbula and Wamae 2010.

20 Freeman 1987; Nelson 1988; Lundvall 1992.

21 Izuka 2013.

a new marketing method, or a new organisation method in business practices, workplace organisations or external relations'.²²

Economists and policy analysts have ignored the role of previous innovations or existing knowledge, and their exclusive focus on the 'public good' aspect of information deterred them from delving deeper into the distinctive properties of information, and particularly from the challenge of contracting for technological information.²³ In this case, the cost of using tacit information such as traditional knowledge reduces the public good argument since it is unlike other public information which can be transferred at negligible costs. So in a system in which these issues are not clarified or defined, stakeholders are unable to take the risk of venturing into an action to maximise their objective. Here, firms may not be able to invest in drugs because of the high cost involved in any drug enquiry. This lack of transparency probably results in less bioprospection activities and more proprietary and reformulated drug development in Ayurveda.

A major ayurvedic manufacturer in Kerala noted:

If we go for bioprospection, it involves not only time and money but long periods of waiting to pass through various drug developing processes, including clinical trials. There are many types of cost involved, such as the costs of finding the knowledge, ensuring the stakeholders' benefit, difficulties regarding patenting and even more ensuring continuous availability of raw materials and strong competition from many biomedical drugs. Even after we have passed through all these difficulties, if the invented drug enters the category of essential drugs, then it would be priced low. So we prefer to produce proprietary ayurvedic medicines to avoid all these headaches.²⁴

My third postulation is that, given the relevance of the other two postulations, a sector that depends on a complex innovation system and aims for a larger market presence can maximise its profits by taking the dominant trade practices into account and following them. The peripheral trade practices such as the sanitary and phytosanitary (SPS) measures²⁵ and the policies and

22 OECD and Eurostat 2005.

23 Gehl Sampath 2003.

24 Interview by the author with Managing Director, PKHL, Thiruvananthapuram, July 2008.

25 The WTO recognises internationally harmonised standards and encourages member countries to use them as a basis for their SPS measures in order to reduce distortions in market access. The SPS Agreement is consistent with the standards and guidelines of the

legislation in place, such as the Dietary Supplements and Health Education Act (US, 1994) in major markets of the US and EU, are relevant barriers of entry for ayurvedic firms, not to mention the fact that many firms have issues with good manufacturing practices, agricultural practices, and accepted preservatives etc.

Through these three important postulations we may infer that, firstly, a well-defined property right system is important in incentivising the knowledge sharing process and by and large, the firms look for alternatives and cost effectiveness that may keep them away from the complications of property and patenting issues. Secondly, differences in innovation structures may determine the probability of a break-through innovation or a social innovation being successful and thirdly, given that Ayurveda is competing with the biomedical sector, its standardisation and manufacturing procedures may have to be modelled on the dominant standardisation framework and that of the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), if the intention is to produce for the international market. The current global health challenges require a careful bridging of innovations and intellectual property with public health goals. Incremental innovations and reformulation of ayurvedic knowledge in the public domain could be a means of renegotiating a place for Ayurveda in the contemporary competitive regime, if it is adequately backed by social innovations that find solutions for many social and medical issues (for example, the Ayurvedic Kit²⁶ for nutritional programmes, products like Kamilari and Liv-52 for liver care, etc.). These new forms of innovations can be thought of as having the potential to improve the economic situation of the poor²⁷ and may address an aspect of medical innovative development that has been overlooked in the past.

FAO and WHO with respect to food additives, pesticide residues, contaminants, hygienic practices, and methods of analysis and sampling for harmonising international rules in this field of trade.

- 26 In reaction to the spread of epidemics during the monsoon, Oushadhi, in association with the Indian System of Medicine (ISM) department, plans to distribute ayurvedic Epidemic Prevention Kits (EPK). Each kit would contain the classical ayurvedic products like Shadangam Kashaya Choornam, Guluchi Choornam, Avipathi Choornam, Thaleesapathradi Choornam, Viluadi and Sudarshanam tablets.
- 27 See Kaplinsky 2011 on innovations leading to national policies to stimulate economic growth for the benefit of poor people (primarily in the economic sense of poverty) and inclusive development.

Innovations and Reformulations in Ayurvedic Pharmaceuticals

Drugs and products developed from textual formulations cannot be patented but can obtain proprietary rights, since most of the products are simply an extension, addition, or deletion of one or more herbal ingredients in a given formula. In the case of proprietary drugs, the formulations can be 'optimised' to make them different and special. However, a specific licence has to be obtained in order to deviate from the classical text while ensuring nevertheless that the ingredients are the same as those listed there and that the processing methods are similar to those described in these authentic texts, while combinations make them different.²⁸ Thereby, alterations promoted by private sector manufacturers can also receive legal recognition. In addition, the products do not qualify for patent protection since the properties of novelty and inventive steps—the clauses necessary for product patents under the TRIPS regime—do not hold. Hence, successful exploitation of knowledge in this sector largely focuses on innovations in the control and management of 'complementary assets' or supporting systems, in particular, the process of gaining regulatory approval, specialisation in incremental research in some known products, marketing and advertisements etc. Many of these factors act as powerful barriers to entry for other firms. The market for such products are characterised by strong information asymmetries and consumers are typically unable to evaluate drug quality. Many scholars have addressed the issues of multiple product branding and the nebulous differences between varied product categories and different norms of product classification followed by different corporate companies.²⁹ I do not intend to discuss these here in detail. Even in the classical formulations, the cost can differ as quality can be largely compromised by the use of second-best plants for the extension of the market through low cost.

As the head of R&D at Oushadhi points out:

We are not able to compete with many northern firms in the case of Haridra, because the cost of Haridra produced by Oushadhi is relatively high due to the quality control. Haridra has anti-allergic, anti-inflammatory and antimicrobial properties. We sell at a high price because we use the quantity of milk along with ghee and manjal (turmeric, *Curcuma longa*) prescribed by the traditional texts, but this is not the same in the case of many branded companies and they do not add enough milk to the preparation. Also, they sell it in granule form, which saves a minimum of five

28 See D&C Act 1940.

29 Bode 2008; Banerjee 2009.

main days in production, hence the cost will be reduced and the output will go up. But Haridra should be produced in the most absorptive form (powder) for allergy and should be easily meltable.³⁰

Traditional practices are often ignored in order to minimise the production costs. In the case of ayurvedic pharmaceuticals, standardisation essentially means ensuring the basic minimum quality, while allowing firms to innovate high quality products and position them differently in the market. The absence of radical innovations in Ayurveda render the new forms of reformulations in the industry no less important; on the contrary, they are imperative for the growth of the market. Pordié and Gaudillière describe reformulation in Ayurveda as the redefinition of knowledge and preparation practices focusing on the properties of complex medicinal materials to feed the emergence of autonomous pharmacy, but carried out mostly by experts who can manipulate medicinal combinations. They also underline the fact that at times, this may overlook humoral variabilities and depersonalise the act of healing.³¹

Evidence from a number of firms in Thrissur, Kerala is analysed in this section, where enquiries were made concerning their R&D, reformulation, and innovation practices. Thrissur district has the largest growing number of ayurvedic medicine manufacturing companies in the state of Kerala, well-established medicinal plant market and delivery system and effective inter-linkages between the communities, state, firms, and other stakeholders of the sector. This data may help us to delineate the type of innovation underway in Kerala State, which is traditionally considered the home of authentic Ayurveda. The firms' reformulation practices are evident from this analysis.

Generally, the R&D activities in Ayurveda can be broadly classified into three different types. The first is product research, development, and delivery of new drugs with enhanced performance in terms of cost, safety, and efficacy. The second type is standardisation and research that produces quality enhancements. The third is medicinal plant research. The demarcation between plant research and product research is ambiguous since any product research necessarily begins with botanical research. Research investment is skewed towards the second type, i.e. mostly standardisation techniques (see table 1).

30 Interview by author with Oushadhi R&D chief, May 2013.

31 Pordié and Gaudillière 2014.

TABLE 1 *Fragmentation of research expenditure (%) in different categories (info from 27 firms)*³²

Number of firms in sample according to size	Product research	Standardisation and quality check	Plant research
large firms	43	50	7
medium firms	31	63	6
small firms	19	75	6

Various national institutions such as the Indian Council of Medical Research (ICMR), the Council of Scientific and Industrial Research (CSIR), the Department of Biotechnology (DBT), the Department of Science & Technology (DST), the Central Council for Research in Ayurveda and Siddha (CCRAS), and the Central Council for Research in Unani Medicine (CCRUM) are involved in research into AYUSH (Ayurveda, Yoga, and Naturopathy, Unani, Siddha, Sowa Rigpa, and Homoeopathy). The ICMR has carried out research in traditional medicine on the validation of traditional knowledge in the areas of diabetes, filariasis (philariasis), benign hypertrophy of the prostate, coronary artery disease, cancer, HIV/AIDS, and so on, and the fingerprinting of selected herbal preparations, agrotechnology of selected plants for various clinical trials (e.g., *Picrorhiza kurroa* and *Pterocarpus marsupium*), and the development of new molecules from plant sources.³³ There are a number of collaborative projects on a national level, but the New Millennium Indian Technology Leadership Initiative (NMITLI) and the Golden Triangle Initiative (GTI)³⁴ projects require specific mention in the context of product research in association with the industrial field.

32 Primary survey by author, November 2012. I divide the firms into three categories: large firms are those which have a sales turnover of more than Rs. 100 million and medium firms are between Rs. 50 and 100 million and small firms are those below Rs. 50 million per year.

33 Banerjee 2008.

34 The Golden Triangle Partnership (GTP) 2005 is an innovative scheme with the Department of AYUSH, ICMR and CSIR as equal partners to study ayurvedic formulations using modern tools and technologies in order to (1) validate them as safe and efficacious therapies for Indian and global use, (2) identify a few formulations as complementary agents to modern drugs, (3) help the Indian traditional drug industry to scientifically standardise the raw materials and finished products for global acceptability of these drugs.

NMITLI is the largest R&D scheme to boost public-private-partnership efforts in the country. It looks beyond today's technology and thus seeks to build, capture, and retain a leadership position by synergising the best competencies of publicly funded R&D institutions, academia, and private industry. The Government of India's GTI project integrating biomedicine, modern sciences, and traditional medicine is indicative of a trend in which traditional sciences such as Ayurveda are increasingly embracing a scientific evidence base and the spirit of robust research.³⁵ R&D investment and collaborations are relatively higher among large firms such as Oushadhi, Vaidyaratnam, and SNA Oushadhasala.

In most of the firms, research funding constitutes less than two per cent of sales turnover (table 2). The survey showed that most of the quality control labs for raw materials are considered to be research labs. And the lion's share of research money is actually spent on standardisation processes, not on product

TABLE 2 *General economic indicators of three leading firms in Thrissur district*³⁶

	2010–11			2011–12		
	Oushadhi	VRO	SNA	Oushadhi	VRO	SNA
Sales (Rs. Million)	379.3	475.3	61.1	453.1	535.1	73.1
Export % of sales	Nil	73	25	Nil	67	38
Proprietary medicines (%)	NA	19	72	NA	20	76
Fixed Capital ³⁷ (Rs. Million)	124.5	17.0	1.0	138.8	17.0	1.0
R&D expenditure % of sales	0.34	1.1	1.4	0.66	2.0	1.6

35 The Osteoarthritis project under NMITLI scheme involved a network of 16 national research institutions, modern medicine hospitals, and pharmaceutical industries from India (Patwardhan and Mashelkar 2009).

36 Author's primary survey 2012. We have not received information about one major firm in Thrissur. SNA is incorporated in the major analysis as it seems to be one of the leading innovative firms.

37 Fixed capital is that portion of the total capital outlay that is invested in fixed assets (such as land, buildings, vehicles, plant and equipment), that stay in the business almost permanently—or at the very least, for more than one accounting period.

or process innovations or research leads. The most vibrant firm in research collaboration is the public firm, Oushadhi, though research spending within Oushadhi is lower than that of other firms. In terms of their innovative activities and irrespective of their size, most of them have innovative activities and produce more proprietary products than classical categories. VRO has substantially increased the research account, especially for new product research. But new or improved process innovations are not very frequent in these small firms (table 3). However, many claimed to have made changes in product appearance to suit the market demand and to make their products user-friendly. The expenditures on advertisements of two major firms comes around 5–8% of their sales turn over.

The innovations within Oushadhi are commendable. The firm has introduced around 90 drugs to the market through various forms of innovations. The best example of process innovation is Pramehoushadhi, introduced by Oushadhi for diabetic patients in 1998, which has a turnover of Rs. 30 million per year as of 2014. It is the most demanded product by diabetic patients. Initially it was in granule form and later the market feedback led to its transformation into tablets, which was a success. Preclinical and long-term toxicity studies are conducted on Prameshoushadhi for this purpose. The challenge was to

TABLE 3 *Number of firms reporting varied innovative activities*³⁸

	New Product/ Improved products	New/ Improved process	Quality change through technology	New raw-material	Appearance changes	New organisation	Total
Oushadhi	32	14	30	5	4	4	90
VRO	27	16	5	2	4	5	59
SNA	42	13	1	0	09	0	65
other firms (50)	29	26	2	0	23	7	

38 Joseph et al. 2013, p. 14. New products are defined as any products, including classical, which are new to the market. New process is an entire change in the combination or other process through which the drug is produced.

sustain the proportionate phytochemical profiles of 500 grams in a 2.5 gram tablet. Challenges in monitoring changes through scientific parameters were also evident in the case of a burn cream when it was repositioned as a spray.

The case of Oushadhi demonstrates an effective industry-academia research link. Oushadhi has created various networks such as: a) a programme for producing bio-manure from bio-waste with Kerala Agricultural University; b) development of a medicinal plant nursery with state medicinal plant boards; c) collaborative research with central government institutions such as the Central Food Technologies Research Institute (CFTRI); d) collaboration in preclinical and clinical research and prototype development with Jawaharlal Nehru Tropical Botanical Garden and Research Institute (JNTBGRI) (on a hepatoprotective drug) and Amala Cancer research centre; e) a national medicinal plant project related to linkages with various biotechnology departments of many colleges; f) various analytical research with the biosciences department of Kannur University and Institute of Applied Dermatology, Kasaragod (learning disability products and for carpal tunnel syndrome); g) production and research collaboration with Central Council for Research in Ayurveda and Siddha (CCRAS); h) network with CARE Keralam (the innovation cluster in Ayurveda) to ensure the best quality of raw materials; and also i) interdisciplinary projects and the validation of pharmaceutical products with many ayurvedic firms. The government department AYUSH has recently provided funding for Oushadhi as a Centre of Excellence for Ayurvedic pharmaceuticals (Rs. 50 million). State government grants in aid and share capital have helped Oushadhi to step into many research collaborations. The share capital of the state government increased from Rs. 2.5 million in 2007–08 to Rs. 40 million in 2011–12.

Oushadhi have exclusive proprietary rights to market 32 reformulated drugs. Shelf-life and palatability were the elementary innovations in the case of the basic ayurvedic formulations. The most innovative companies are able to come up with a large number of new products and new processes. Oushadhi is even able to bring about innovations by creating new markets (for example, ayurvedic health drinks developed with the technical support of the Central Food Technological Institute, Mysore, and Ayurvedic Kit for nutritional development). Oushadhi and Vaidyaratnam have links with many research labs, both governmental and private (for example, VR have links with NABL Mumbai for HPTLC and HPLC testing, with Mannuthi veterinary college for toxicology studies, and with Kottakkal Arya Vaidya Sala for pharmacology studies). Post-graduate student projects in microbiology, biotechnology, and chemistry are another important source of innovations (some of the projects later funded by Oushadhi). An antifungal cream, research on methods of fermentations

especially in Chyawanpash and also understanding the new controlled fermentation process of Asavarishtam (a form of fermented decoctions) and profiling of various salts used in Ayurveda with the help of modern chemistry, are some of the new possibilities Oushadhi is exploring with these projects. Student research results were used in the preparation, storage, and fermentation of this product in its commercial application. Oushadhi is emerging as one of the major institutions for clinical trials in Kerala.

My research results show that the major incentives for engaging in R&D and innovation are technology change and self-motivation of firms for creating a better market. One of the innovations of Everest Pharmaceuticals of Thrissur is a discovery of the means to increase shelf-life without preservatives. *Kashaya* has been converted into *choornams* (micro-granules) to reduce raw-material wastage and enhance palatability. The cost of these micro-fine powders proved to be lower, and multi-layered sealed packing with metallised polyester with low-density plastic is used to ensure longer shelf-life. The marketing method for this product is ethical promotion and no advertisements.

Other instances of reformulations are those emerging from industry-academia contact, in the case of Oushadhi this was via the TBGRI ethnographic expedition. A new product—a hepatoprotective and psoriasis drug—developed from community knowledge is soon to be introduced to the market. TBGRI has also entered into an agreement for a three-phase clinical trial with Oushadhi on a new liver tonic. The product is in granule form and is obtained from three plants. Two of the plants are from the *Acanthaceae* and *Cannabaceae* families; the third is a bioenhancer like the popular *Thippali*. Once the clinical trials are completed, Oushadhi will apply for a joint patent. Oushadhi also plans to conduct year-long clinical trials of the product on patients with liver disorders before launching it commercially. The results of trials on animals clearly show that the tonic can be administered as a medicine for patients with history of jaundice, hepatitis, and in early stages of liver cirrhosis. It can also be used as an antidote to alcohol-related blackouts. Since the late 1990s, Oushadhi developed into a profit-making enterprise. At the same time, Oushadhi had almost entered into the reformulated drugs based on classical categories and also started flourishing setting-up outlets all over the state and also outside of Kerala. Now Oushadhi supplies medicines to many state governments even in North India. These innovative attempts and research collaborations helped Oushadhi to recover from its financial loss from 1995 onwards.

The research capabilities of traditionally experienced physicians are used by many firms as one of the important solutions for dealing with quality

standards and treatment; as many as 19 firms have adopted this strategy.³⁹ This could even contribute to the growth of the overall system as many of the earlier innovations were informal and confined to isolated physicians. Many small firms have fewer interactions in the field. This limits their ability to learn in terms of technology transfer and adoption. Traditional physicians do help these firms to cross-check the impact of new technology. Safe, hygienic, and quality-tested reformulation of existing drugs rather than entirely new products seems to be the most pertinent strategy.

The responses from the firms showed that the most important sources of innovations are interaction with the R&D enterprises and government labs, competitive initiatives, and in-house research (table 4). Many classical ayurvedic medicines have been given a new appearance as pills and *choornams* (powders). Translating the subjective parameters (like traditional cross-checking of quality manually) into objective criteria is a cumbersome process. The important issue is the pertinence of traditional standards in the mechanisation process. Further research is needed on issues of scale to understand

TABLE 4 Sources of innovations⁴⁰

Firms	High	Medium	Low
Oushadhi	nil	R&D enterprises, govt. research organisations, universities, customers, competitors, within enterprise experiences	consultants
VR	commercial labs and R&D enterprises	competitors	within enterprises
SNA	within enterprises	competitions, consultants and research labs and R&D enterprises	Govt. research organisations and clusters

39 Conversation with the main physician at KMA Oushadhasala, Guruvayoor.

40 Based on author's primary survey, conducted during November 2012.

modern technologies in manufacturing. The use of stainless steel instead of mud vessels and measuring the putative influence on medicinal properties was a major challenge in manufacturing. Rather than promoting an increase in product varieties, the firms need to concentrate on technology transfer to obtain better standardisation. The firms hold the opinion that most of the over-the-counter (OTC) products in Ayurveda make huge profits for a maximum of 5–7 years and then disappear from the market altogether, some due to increasing competition, others due to unethical practices in production and lack of efficacy studies on new combinations. The two recent examples from Kerala are Lavana Thailam (an anti-obesity medicine) from Ayurcare and Musli Power Extra (an aphrodisiac) from Kunnath Pharmaceuticals. Very few products are able to sustain their success over a long period.

My survey reveals that the impact of regulation and standards, cost of innovations, and weak financial incentives are the major reasons for lack of viable and radical innovations in the sector. The financial incentives and perks for the researchers in ayurvedic companies seem to be much lower than that of biopharmaceutical firms. It has shown that a post-graduate ayurvedic physician is paid on average Rs. 15000–20000 monthly in the research labs, which is quite a disincentive for the young personnel in the sector. This is quite similar in both private and public sector and this actually attracts the young ayurvedic doctors to find their earnings in the newly emerging ayurvedic tourism industry, where they are paid much better. An interesting fact is that many ayurvedic post-graduates have taken management degrees to actually serve the tourism industry as marketing managers and medical tourism promoters with a therapeutic background. And most of the researchers within the firms have not received any career promotions and individual incentives, and support in terms of publications in their own name or other financial benefits are largely lacking.

In terms of interactive learning, apart from Oushadhi, the firms do not participate in many interactive innovations or knowledge transfers (Table 4). But the recent development of Confederation of Ayurvedic Renaissance—Keralam Limited (CARE Keralam), an innovation cluster in Kerala, R&D and other necessary pharmaceutical developments now work as a catalyst for increasing inter-firm relations and innovative incentives among smaller firms.⁴¹ At present, the innovation system, determined by inter-firm relations and mutual learning, seems to be under-developed in the mainstream ayurvedic market and most of the product-process innovation decisions are made in accordance with external factors such as political economy of global market, regulatory frameworks, and financial availability.⁴²

41 For details, see Madhavan 2013.

42 Banerjee 2009; Madhavan 2011.

TABLE 5 Factors inhibiting innovations: Perceptions from three firms⁴³

	Oushadhi			Vaidyaratnam			SNA Oushadhasala		
Effects	High	Medium	Low	High	Medium	Low	High	Medium	Low
Financial Factors	High	Cost of innovation	Excessive risks and availability of finance	Cost of innovation	Excessive risks and availability of finance	Excessive risks and availability of finance	Excessive risks	Cost of innovation	Availability of finance
Managerial Factors			All managerial factors are of low significance	Organisational rigidities within the enterprises would be a concern	Organisational rigidities within the low importance	Others are of low importance			All managerial factors are of low significance
Other Factors	Impact of regulation and standards/scale issues	Lack of customer response		Impact of regulation and standards and lack of customer response			Impact of regulation and Standards		Lack of customer response
Remarks	Regulation remains one of the major bottlenecks for innovation according to Oushadhi			Cost of Innovation is the major risk for Vaidyaratnam while regulation and organisational rigidities also pose challenges			Impact of regulation and standards and excessive risks are the reasons for lack of technological innovation		

43 Joseph et al. 2013, P. 45-

Formerly, India practised a dual tariff structure in which a higher rate of taxation was paid for proprietary medicines while ayurvedic medicines were subject to a lower rate. When 'ingredients tests' became the touchstone, the courts held that if the predominant ingredients in the drug are mentioned in authentic ayurvedic texts, then they should be treated as ayurvedic, irrespective of whether they were used in an allopathic or an ayurvedic system. The net result was that a uniform rate of taxation for all medicines came to be adopted.⁴⁴ Section 10 (contents of specification) of the Patents (Amendment) Act, 2002,⁴⁵ provides that the applicant must disclose the source and geographical origin of any biological material deposited in lieu of a description. Also Section 25(1) (j) relating to any opposition to granting a patent, as amended, allows for an opposition to be filed on the grounds that the complete specification does not disclose, or wrongly mentions, the source of geographical material used for the invention. This synchronised approach adopted by India, whereby the patent law and central excise tariff work in tandem, will encourage patent holders to disclose whether they have derived any benefit from traditional knowledge; they may then be required to make a contribution to the holder of the traditional knowledge pool but will benefit from lower central excise tariffs. This encourages firms to continue producing ayurvedic reformulated drugs. India's argument in WTO is on the same lines regarding the derivative drugs from traditional knowledge.

One of the suggestions that the firms reiterated is the need for an inclusive innovation system based on the size of the firm.⁴⁶ The government has a 'one size fits all' policy, which hinders their ability to compete with the bigger firms. Intervention of the excise department in the quality assessment and the forest department in raw material collection was cited as the reason for the abstinence of small operators in the field. Other suggestions included a single window for information regarding quality criteria and patenting queries and a rigorous shift in policy environment for enabling the exports of small firms. They also demanded a better laboratory support, subsidised electricity, protection from wildlife laws, and stringent forest rules. It is imperative that the ayurvedic community is familiar with the differences between quality standards, regulatory affairs, R&D, and clinical standards. Many firms said that the Minor Forest Product Laws, procurement regulations and even advertisement

44 Arora 2013.

45 The Patents (Amendment) Act, 2002 is the second of three amendments to the Patents Act of 1970 to bring India's patent regime into compliance with the WTO TRIPS Agreement. This Act was introduced with the new Patent Rules, 2003, which replaced the earlier Patents Rules, 1972.

46 Mahaoushadhi Herbal Remedies, Avanoor and Kodakkatil Ayur Links, Kandanissery.

rules all present hurdles to an innovative environment within the industry. They also suggested that the regulation systems should not be based on the Ayurvedic Pharmacopeia of India (API) since it covers only a few of the formulations in the diverse canonical texts. From the interactions it was clear that a transparent institutional arrangement is pertinent in communicating and following up the regulatory regimes of various departments in this sector, which may enhance and foster innovative practices in small firms.

Local Innovations and Production Systems in Reformulation: The Kani Case

In the case of traditional industries like Ayurveda, bottlenecks such as high transaction costs and risks, weak information flows, weak institutional environments, and a number of other constraints often inhibit successful innovation systems. Using the Triple Helix model of university-industry-government relations, Leydesdorff⁴⁷ proposed configurational information to provide an indicator of synergy in Triple-Helix relations. This model enables us to distinguish knowledge functions in innovation systems. Agents are geographically positioned and endowed, but are able to exchange irrespective of these boundaries in economic relations.

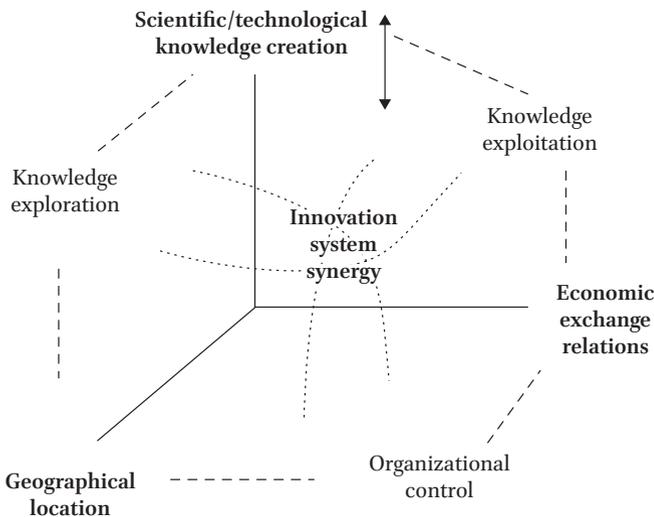


FIGURE 1 *Network of knowledge and innovation systems.*⁴⁸

47 Leydesdorff 2006.

48 Ibid.

The institutional and organisational elements of innovation systems can be called as the 'organisational control function'. 'Exploitation' is associated with the reuse of existing competences and 'exploration' with the creation of new alternatives. At the systems level, mechanisms of knowledge exploitation represent the interface between economic welfare and technological knowledge creation. This interface does not necessarily depend on geographical locations because economic welfare is created at the level of global markets, even if certain technologies originate in single regions. A more nuanced analytical understanding of institutions and markets should both demand and promote greater understanding of (a) the processes and types of institutional change needed for local systems and communities to escape from 'low level equilibrium traps', and (b) the need for pragmatic, path-dependent, and location-specific mixes of investment, in non-standard institutional arrangements as well as in the institutional environment. The case of the Kani indigenous polyherbal medicine Jeevani is an excellent example of an efficient self-motivated partnership that avoided many of these low-level equilibrium traps. A synergised institutional model could be an imperative strategy to sustain these successful partnerships, which was lacking in the case of Kani knowledge sharing.

The deal was brokered between JNTBGRI, a research institute in Kerala, India, and the Kani tribe who live in the Agastya forests of Kerala state, whose traditional knowledge of the invigorating properties of the arogyapacha plant (*Trichopus zeylanicus*) was used to create the energy boosting drug Jeevani. This case depicts the way in which various bottlenecks of bioprospection were overcome with an effective industry-academia-community network. It is clear that the issues such as search costs, incentives for revelation of knowledge, defining property rights, efficient technology transfer, and benefit sharing—the major bottlenecks of bio-prospection—were avoided through the institutional networks. The lessons from the Jeevani case open up the possibility for marginalised communities to benefit from bioprospecting deals and underlines the efficiency of an institutional approach to conservation and development problems. Although various aspects of this model have been questioned,⁴⁹ the success of drug discovery from the indigenous knowledge, the community-academia-market interaction, and the initiative for a pre-CBD (Convention on Biological Diversity, 1992) benefit sharing process constitutes to a large extent the dynamics of the innovation system. The knowledge community here interacted with outsiders, the state, and authorities on a daily basis and close commercial, personal, and social links were frequently developed between the ethnic group and outsiders. The knowledge was divulged

49 Anuradha 1998; Bijoy 2007.

after a tacit agreement with the community that the benefits would be shared, if it was commercialised. Hence, the issues of transaction cost and information access were, to a certain extent, avoided with this tacit contract.

JNTBGRI is an autonomous research organisation that was established by the Kerala state government in 1979 to conserve biodiversity. A detailed scientific investigation of arogyapacha was conducted, including chemical screening to isolate the active principles, and pharmacological screening. They realised that the classical pharmacological approach to the study of herbal drugs of isolating active principles in the form of single compounds is far from satisfactory for the understanding of traditional practices. Hence an ethnopharmacological approach was adopted to evaluate the plant from the point of view of the theoretical foundation of a well-organised system of medicine, i.e. Ayurveda. The plant was identified as *Trichopus zeylanicus travancoricus*, which had been documented before, but its traditional use and special properties were not known. A study of the leaves revealed the presence of certain glycolipids and non-steroidal compounds that had anti-stress, anti-hepatotoxic, and immunomodulatory/immunorestorative properties. The last phase of the research was conducted at JNTBGRI, where the drug Jeevani was formulated with *Trichopus zeylanicus* and three other medicinal plants as ingredients.⁵⁰ *Withania somnifera* or ashwagandha was used in the formulation of the drug; the application mentions that ashwagandha is an important drug in ancient ayurvedic literature. Toxicity, shelf-life, and clinical studies were carried out by the institute. This was a unique reformulation experience in the ayurvedic sector, different from the numerous proprietary combinations on the market. In short, this method has not used any existing combinations in the authentic texts of Ayurveda, but taken the cue from traditional knowledge and then it did seek an explanation from ayurvedic texts, i.e. it could be *vārāhi* in Ayurveda. Subsequently researching on various properties of the plants they have disseminated relevant therapeutic contact of the drug through reputed papers in journals. Later a formulation was identified through combinations of other medicinal plants, as we mentioned earlier. The research and standardisation procedure was mostly co-ordinated by government research labs with contributions from JNTBGRI, hence a synergetic innovation system emerged. This reformulation was part of an effort to obtain the marketing rights and ayurvedic principles, nomenclature, and the regulatory structures were used to obtain proprietary approval for the product.

This model is also an excellent example of a public-private partnership. The technology has been transferred to Arya Vaidya Pharmacy for which an agreement was signed between JNTBGRI and Arya Vaidya Pharmacy in 1995.

50 Anuradha 1998.

The duration of the licence was seven years. JNTBGRI received a 2 per cent royalty on the drug sales. An effective drug discovery was possible in the case of Jeevani, due to an effective interaction between various institutions—JNTBGRI, the Kani trust, and Arya Vaidya Pharmacy, Coimbatore. This is an example of community-academia-market interaction for effective ayurvedic drug formulation and marketing, stemming from community-based knowledge. The ethnic groups have benefited in different ways, notably in medicinal plant production (USD 1,500 in a year).

Defining property rights is often a concern in the case of benefit-sharing models. Here, this problem was surmounted with the formation of Kerala Kani Samudaya Kshema Trust (KKSKS) and on September 1997, the due amount of USD 13,000 was transferred to the account of the Trust, of which USD 12,500 was 50 % of the licence fee and the rest was the first instalment of the royalties. The KKSKS is left to decide whether to utilise only the interest ensued over the licence fee and royalty. Up to 2003, a sum of USD 2,500 was obtained in royalties from the sale of the drug. This was passed on to the trust, in addition to many other benefits in kind.

The raw material department was probably the only area where this model ran into trouble. It failed to incorporate the forest department in sustainable cultivation, which later impacted upon the larger sustainability of the model itself. Even though it has been argued that the benefit-sharing mechanisms in the case of the Kani were not prolonged—possibly due to the raw material planning, information asymmetry of the market, political interference etc.—Jeevani's reformulation method has now led to a number of pipeline products, notably for diabetics and asthma. Now Jeevani will be marketed by Oushadhi for the next seven years, but with another innovation in appearance, i.e. a change to powder form. This procedure is yet to start its function. A new contract is also ready to be signed with the forest department for the cultivation in its own micro forest habitat.

Recent Policy Initiatives in Regulatory Practice

Initiatives Concerning Standards

A recent WHO survey showed that around 90 countries, less than half of WHO's Member States, currently regulate herbal medicines. Moreover, there are disparities in regulation between countries, which has serious implications for international access to and distribution of such products.⁵¹ This makes

51 WHO 2004.

production norms difficult for the industry. In the last decade, the central government and AYUSH initiated a number of policy regulations to ensure the safety and efficacy of ayurvedic drugs and to reduce non-scientific practices in ayurvedic proprietary products. There is a constant demand for scientific validation of the principles on which the Ayurveda, Siddha, and Unani (ASU) systems are founded, particularly of the efficacy and safety of the therapeutics. Such a demand has motivated a large number of investigations in clinical research and drug standardisation studies. Although such projects have been pursued over decades, the outcomes have been limited.⁵² Chapter IV A (regulation of ASU drugs) of the Drugs and Cosmetics Act 1940 (D&C Act 1940) suggests that drug licences are a state matter and that firms can obtain them from any responsible state institution. Proprietary drugs need special licences as they differ from classical drugs in terms of their combinations, even though the processing methods and the ingredients are the same. But for many reasons most of these policies are not seriously implemented. The absence of required drug officials is one of the major problems. For example, in Kerala, there are only three AYUSH drug inspectors in the entire state to deal with quality control of thousands of new ayurvedic drugs. Lack of quality enforcement of ingredients and gaps in the fulfilment of procedures prescribed in classical drugs leave enough room for the manufacturers to tweak the formulations and make incorrect shelf-life claims. Chandra shows that through interactions with licensing authorities from states with a large number of manufacturing units and very few officials, it was apparent that the approval is granted on the basis of the manufacturer's claims.⁵³ A large number of licences were issued even before batch assessments or label checks were carried out.

Some recent policy changes have been introduced: batch-wise testing for heavy metal content, labelling leniency (the label can be presented according to the exporting country's rules) to improve the export market (2000), a strengthening of state pharmacies and drug testing authorities, 'essential drug lists' in Ayurveda for a standardised supply of medicines to government dispensaries and hospitals etc. Kerala is the only state which has an ayurvedic drug controller. But efforts in this direction, with more monitoring officers and transparency in regulation procedures, is warranted. The raw-drug trade is currently completely handled by private players, while the avenues of co-operative models need to be explored.

The 2008 amendment to the D&C rules stipulates that firms keep raw material records for the previous year to show their actual consumption of raw drugs.

52 Chandra 2011.

53 Ibid.

Very importantly, administrative orders have been issued to ban misleading prefixes and suffixes in classical and proprietary ASU medicines. In effect, this particular order prevents the branding of classical medicine. The manufacturing companies were given a one-year transition period to sell the products they had already manufactured, starting from October 2013. By attaching a prefix or suffix, the companies are branding the classical ayurvedic products for their economic benefits (e.g. Dabur Chyawanprash, Himalaya Chyawanprash etc.). Many companies sell Chyawanprash Sugar Free, Chyawanprash Ginger, and other such products, which are not mentioned in classical ayurvedic texts. Another two important enforcements are: firstly, shelf-life/date of expiry—the D&C rule (161B) in 2010 ensures that the medicine is within the limit of longevity, and secondly, the introduction of a new category called ‘ayurvedic cosmetics and supplements’ to support exports in 2010. The second enforcement requires all clinical trials to be registered and botanical names to be mentioned on the product labels. The table below explains the recent policy changes that the industry and the State of India are currently debating. Various sub-committees with different terms of reference have been formed to deal with the manufacture, clinical trials, and safety of the pharmaceuticals. The initiatives are evidence of an increasing regulatory control over malpractice in the name of Ayurveda.

TABLE 6 *The sub-committees with different terms of reference on regulation*⁵⁴

Sub-committees under Ayurveda Siddha Unani Drugs Technical Advisory Board (ASUDTAB)	Terms of references
1. Subcommittee to examine Schedule ‘Z’ and other relevant notification	Introduction of Schedule ‘Z’ in Drugs & Cosmetics Rules 1945—related to requirement & guidelines for permission to manufacture ASU drugs for sale or to undertake clinical trials
2. Subcommittee to evaluate the proposed Retail Sale Licence for ASU drugs	Introduction of Retail sale licence for ASU medicines containing Schedule E (I) drugs (poisonous substance) of the Drugs & Cosmetics Rules 1945

54 Ibid.

Sub-committees under Ayurveda Siddha Unani Drugs Technical Advisory Board (ASUDTAB)	Terms of references
3. Subcommittee to review the Model Laboratory Practices for testing of ASU drugs	Amendments in Drugs & Cosmetics Rules, 1945, for introduction of Schedule-T-1 related with 'Good Laboratory Practices & Requirements of premises & equipment for testing of ASU Drugs'
4. Subcommittee to amend First Schedule of Drugs & Cosmetics Act, 1940, for the list of Authoritative ASU books	Frame the Amendment of the list of authoritative books in the First Schedule of Drugs & Cosmetic Act, 1940, with details of writer, publisher, year of publication etc.
5. Subcommittee to examine shelf-life of ASU Medicines	Review of shelf-life of Siddha and Ayurvedic drugs mentioned in respective formularies and under Rule 161-B, 2 (ii) of the Drugs & Cosmetics Rules to harmonise the shelf-life of drugs to rectify ambiguities between Formularies and legal provisions

One of the affirmative actions that the state authorities have taken recently is to use the existing Act to regulate the sector. For example, in Kerala the government clamped down on the dubious claims of three companies promising magical remedies. In 2011, under the Drugs and Magic Remedies Act 1955 concerning 'objectionable advertisements' the Kerala Drugs Control authorities initiated legal action against the distributors of five ayurvedic companies including Dabur India Ltd. for their sale of products using misleading advertisements.⁵⁵ This could be the first case of its kind where the rules were effectively used against ayurvedic giants. In 2012, the Kerala Drugs Controller took action against the ayurvedic giants for violating provisions of the Drugs and Cosmetics Act & Magic Remedies Act and almost Rs. 20 million worth of products were seized. The manufacturing companies found to be violating the provisions concerned Dhathri Ayurveda Pvt. Ltd., Cochin Ayurvedic Centre (Indulekha hair oil), and Sreedhareeyam Ayurvedic Medicines Pvt.

55 Kunnathoor 2011.

Ltd. The advertisements for Indulekha Bringha Complete Hair Oil, Dhathri Fair Skin Cream, and Sreedhareeyam Smartlean were found to be misleading. It was also claimed that these products were being sold at exorbitant prices. Warnings were issued under section 33 E of the DCA for false or misleading claims and section 4 of the Drugs and Magic Remedies Act 1954⁵⁶ for objectionable advertisements.

In order to ensure standards for traditional medicines, the Department of AYUSH with support from the Quality Council of India (QCI), has introduced two brands: Premium mark and AYUSH mark. This is part of the voluntary product certification scheme that the Department of AYUSH has been exploring for selected AYUSH products to enhance consumer confidence. The scheme is based on a criteria for certification. It has two levels: a) AYUSH Standard Mark which is based on compliance to the domestic regulatory requirements; b) AYUSH Premium Mark which is based on GMP requirements according to

TABLE 7 *Violations of DMRA captured by Kerala drug controller department*⁵⁷

Product	Marketing company/Outlet	Producer Company
Dabur Sree Gopal Thailam	Tali enterprises in Kozhikode	Dabur India
Primafit capsules	Fortune Herbals Sulthan Bathery	Fort Herbals, Palakkadu
Kamagold capsules	Ultra Marketing Kannur district	Laborate Pharmaceuticals, Panipat
Balovita Massage Oil	Anu Pharma Kasaragod	Balona Herbals, Moovattupuzha
Herbuosutra capsules	Distributor of Vedic Pharma Kozhikodu	Vedic Pharma, Kochi

56 Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which (a) directly or indirectly gives a false impression regarding the true character of the drug or (b) makes a false claim for the drug or (c) is otherwise false or misleading in any material particular.

57 Kunnathoor 2011.

WHO Guidelines and product requirements with flexibility to certify against any overseas regulation provided, these are stricter than the former criteria. Under this scheme, each manufacturing unit would obtain a certification from an approved certification body (CB) which is accredited to appropriate international standards by the National Accreditation Board for Certification Bodies (NABCB) and will be under regular surveillance of the certification body. However, there are very few takers for these products. The Ayurvedic Pharmacopoeia Committee has produced voluminous literature on standards, but there is no reference material available in the market, which actually reduces the relevance of the whole exercise.⁵⁸

Even now, what is left to discuss in the manufacturing of ayurvedic medicine is an effective price control of drugs. Even though tax exemptions are given, it is not reflected in the prices of classical drugs and hence medicines are not cheaply available as before. This may be for various reasons, like the use of more and more technology, increasing depletion and import of medicinal plants, increasing labour costs, impact of the wellness element, and a steep increase in domestic demand etc. The lack of an effective pricing strategy *per se* is a reason for the increase in drugs. In Kerala, the earlier pricing strategy was path dependency, following the major firm, i.e. Kottakkal Arya Vaidya Sala. Now the method has been moved into cost plus pricing strategy, in which the margin is solely determined by the firm. An effective price control of various categories would have, no doubt, a greater public health impact.

Initiatives Concerning IPR

In another significant move, the government of Kerala released an Intellectual Property Rights (IPR) policy document in 2008. Since the constitutional powers of the Indian state government in the matter are limited, the document reveals the state government's approach to certain selected issues of practical importance for Kerala in the context of the new IPR regime, while eschewing general *obiter dicta* on that regime.⁵⁹ The document argues that traditional medical knowledge obviously cannot be transformed into private property and nor can it be put in the public domain. However, putting it in the public domain, while preventing direct private patenting of existing knowledge, cannot prevent their indirect private appropriation through any kind of claimed 'improvements'.

58 Chaturvedi 2013.

59 Patnaik 2008.

The basic elements of the legal arrangement suggested in the documents for the protection of traditional knowledge are the following:⁶⁰ a) all traditional knowledge, including traditional medicine, the practice of which sustains livelihoods, must belong to the domain of 'knowledge commons' (common people who hold the knowledge, not any enterprises or larger entities), and not to the 'public domain'; b) in the case of community knowledge, this custodian will be deemed to have rights over the knowledge, while in the case of knowledge that is spread out, the Kerala state will be deemed to have rights over the knowledge; c) no entity that is registered as a medium or large enterprise may be deemed to have any rights over traditional knowledge; d) the right-holders will have two kinds of rights: firstly, the right, where applicable, to a 'brand name' or a name associated with the unique practice of an institution or community or family, such as 'Kottakal massage'⁶¹ and secondly, the right to the use of the knowledge; e) everybody else, other than the right-holder to the knowledge, who wishes to use it, will have to do so under a 'commons licence'; f) any use of traditional knowledge or practice in violation of the 'commons licence' within or outside the state of Kerala will be considered a violation of the rights of the right-holders and will invite prosecution.⁶² All rights holders of traditional knowledge will be deemed to be holding their rights under a 'commons licence'. Under this licence, the right holder permits others the use of the knowledge for non-commercial purposes. If any development is made using that knowledge, it will have to be put back into the 'knowledge commons' and cannot be patented anywhere. For commercial use by others, an agreement would have to be reached with the rights holders. To operate this legal arrangement, a body named the Kerala Traditional Knowledge Authority (KTKA) is proposed, with which all practitioners of traditional knowledge of the first category will have to be registered.

This document, not yet officially implemented in Kerala, raises important policy debates in the context of our discussion. For example, a) given that some of this knowledge, such as Ayurveda, is not just confined to Kerala, how can the State arrogate all rights over it? Consider the case of the Kanis and arogyapacha; this tribal group is not confined to the state of Kerala, but extends over to the state of Tamil Nadu. Would the Kanis on the other side of the fence face prosecution, if they grow and use arogyapacha? b) Importantly, there is a

60 Intellectual Property Rights Policy for Kerala (2008) URL: <<http://www.wipo.int/edocs/lexdocs/laws/en/in/ino48en.pdf>>, last accessed 4 November 2013.

61 Reference to Shamnad Basheer's writing, URL: <<http://www.Spicyip.com>>, last accessed 1 July 2008.

62 Patnaik 2008.

complete bar against patenting any ‘improvement’ or other advancement of such knowledge by either the community or any of their licensees. In a scheme that resonates with the open source licensing movement, any improvements made using that knowledge have to be ploughed back to the ‘knowledge commons’, the question here is, would families or communities that desire to work with industry to capitalise on their closely guarded knowledge subject themselves to such restrictions, knowing that an open source approach may make the deal a bitter one for the industry? c) In the case of community or family-owned traditions, does this policy offer sufficient incentives for these families or communities to disclose their closely held (and in most cases, almost ‘trade secret’ like) knowledge?⁶³ The incentive structure for reformulation as in the case of the Kani may be annulled in the context of implementation of this regime. We have seen that both economic incentives without an institutional structure and a full-fledged innovation system without symmetrical information flow and incentives can harm the ‘below the radar’ reformulation structure of the sector. How far the clusters such as CARE Keralam can successfully circumvent or challenge these new issues and entice reformulations is a difficult question to answer.

In another important initiative, the Patent Cell (Traditional Knowledge—Innovation Kerala Project) in Kerala was formed in 2003 under the Directorate of Ayurveda Medical Education with the objective of protecting the traditional knowledge in Ayurveda. The Patent Cell has published a book with the title *Keraleeya Oushadha Vijnanam* (Information on Kerala’s Drugs) by using the data obtained from ancient palm leaf manuscripts. It was proposed to establish a centre for traditional knowledge innovation in Kerala. An amount of Rs. 10 million is provided for the strengthening and continuance of the scheme during 2014–15.

Conclusion

In a strict economic sense, the innovation system for drug discovery in Ayurveda is not yet well developed and is still battling with the issues of standardisation, inefficient regulatory structures, inadequate human resources etc. The non-additive⁶⁴ character of innovations in Ayurveda is partly explained by the nature of its innovation system, especially the ill-defined property

63 Basheer 2008.

64 Traditional medical knowledge innovations, especially the improvements in practice and new formulations respective to the individual and ecological differences, may not be

rights and lack of institutional co-ordination. Recently, most of the developments in the ayurvedic medicine sector, importantly, are mediated through drug reformulations. This is because the firms are less incentivised to invest in technological research due to the various costs involved in the complex process of bioprospection and partly due to the difficulty of valuating biological resources and identifying the social costs.⁶⁵ Evidently, many incremental innovations in the form of reformulations work as forms of alternative pharmacy, which in turn address the 'pro-poor' health needs neglected by mainstream drug research. Research should be initiated in tropical drugs and regional epidemiology, where Ayurveda could play a crucial role. The universalisation of India's health agenda envisions an effective inclusion of indigenous medicine, and reformulation practices if adequately regulated have a huge potential for an inclusive public health strategy through South-South cooperation and various regional network models.

This paper reiterates that innovations with a social purpose can be generated through multiple local learning processes through mutual interactions between various institutions and effective use of regulations within the system. The various socio-political and cultural contexts (which could be termed as Institutions A) and policy organisations, processes, and regulations (Institutions B) on the one side, along with science and technology initiatives in the manufacturing regime and market and demand on the other side decide the nature of interactive relations between firms among themselves and firms and the state. This 'Local and Production Innovation System' (LIPS) would form and mediate the firm's behaviour in pricing strategy and also in forms of market creations. Hence I argue that, in the mentioned context of ayurvedic medicine, the 'innovation system' that has emerged is effective for a reformulation regime as envisaged by various evidences.

Malpractices in the name of reformulation can be tackled using the Magical Remedies Act and subsequent new regulatory regimes as in the case of Kerala. Three important postulations explain the nature of innovations in the mainstream ayurvedic sector—the cost of knowledge transfer, firms, and pharmaceuticals as the leads for development and dominant trade practices as a determinant of firm behaviour. On the other side, we have examples like Oushadhi, whose efficiency is demonstrated by their research results in a number of reformulated medicines via interactive learning and inter-firm knowledge transfers and the Kani people's knowledge where multiple

known to the other innovators as the property rights are not defined and confined to the informal settings.

65 Madhavan 2008.

stake-holder interactions worked to form a new reformulation regime. These examples should contribute to the learning process of macro research programmes. The cluster approach in Ayurveda is an initiative for a mutual growth model. In recent decades, the Indian government has initiated various protection environments, such as the Traditional Knowledge Digital Library (TKDL), and the Ministry of Environment and Forests established a National Biodiversity Strategy and Action Plan (NBSAP) and National Biodiversity Act 2002.⁶⁶ However, growth of the sector may be hampered if incentives are not prioritised. Many developing countries with large traditional knowledge resources cannot capture or even enter the market, due to the absence of innovations and lack of existing incentives. Research in the sector should also grow beyond new forms of marketing or modifying product appearance to work towards a growth-ladder model learning. Reformulations such as Jeevani could be genuinely enhanced with the co-ordination of an effective institutional system in the way that I have proposed here.

Bibliography

- Anuradha, R. V. 1998, *Sharing with Kanis: A Case Study from Kerala, India*, New Delhi: Kalpvriksha Mimeo.
- Arora, P. 2005, 'Healthcare Biotechnology Firms in India: Evolution, Structure and Growth', *Current Science*, 89(3): 458–63.
- Arora, S. 2013, 'Failure of WTO Talks on Patents and Enhanced Protection for Traditional Knowledge: Are there any Alternatives Available to India?' URL: <<http://www.taxindiaonline.com>>, last accessed 25 November 2013.
- Banerjee, M. 2008, 'Ayurveda in Modern India: Standardization and Pharmaceuticalization', in D. Wujastik and F. Smith (eds), *Modern and Global Ayurveda. Pluralism and Paradigms*, Albany: State University of New York Press, 201–14.
- . 2009, *Power, Knowledge, Medicine: Ayurvedic Pharmaceuticals at Home and in the World*, Hyderabad: Orient Blackswan.
- Basheer, S. 2008, 'Break with Tradition', *The Indian Express*, 5 July, 4.

66 In the case of traditional knowledge associated with the use of biological resources, the Biological Diversity Act 2002 offers some scope for protection of resources. Section 3 of the Act indicates 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 utilisation or for bio-survey bio-utilisation'. URL: <http://www.nbaindia.org/act/act_english.htm>, last accessed 13 April 2012.

- Bell, M. and M. Albu 1999, 'Knowledge Systems and Technological Dynamism in Industrial Clusters in Developing Countries', *World Development*, 27(9): 1715–34.
- Bijoy, C. R. 2007, 'Access and Benefit Sharing from the Indigenous People's Perspective: The TBGRI-Kani Model', *Law, Environment and Development Journal*, 3(1): 1–23.
- Bode, M. 2008, *Taking Traditional Knowledge to the Market—the Modern Image of the Ayurvedic and Unani Industry 1980–2000*, Hyderabad: Orient Longman.
- Chandra, S. 2011, *Status Report on Indian Medicine and Folk Healing*, Report to the Department of AYUSH, New Delhi: Govt. of India.
- Chaturvedi, S. 2013, 'The Dynamic of Traditional Medicine Industry', in Chaturvedi, S. and R. K. Srinivas (eds), *Health Sector Challenges, Traditional Medicines and India China Collaboration*, New Delhi: RIS, 173–99.
- Clark, N., J. Chataway, R. Hanlin, D. Kale, R. Kaplinsky, L. Muraguri, T. Papaioannou, P. Robbins, and W. Wamae 2009, *Below the Radar: What does Innovation in the Asian Driver Economies Have to Offer other Low Income Economies?*, INNOGEN working Paper No. 69, UK: The Open University.
- Congressional Budget Office (CBO) 2006, *Research and Development in the Pharmaceutical Industry*, Washington DC: Congress of the United States.
- Drugs and Cosmetics Act. 1940, The Drugs and Cosmetics Act and Rules, New Delhi: Government of India.
- Freeman, C. 1987, *Technology and Economic Performance: Lessons from Japan*, London: Pinter.
- Gehl Sampath, P. 2003, *Defining Intellectual Property Right on Traditional Knowledge: A Process Oriented Perspective*, Discussion Paper, The Netherlands: United Nations University MERIT.
- . 2005, *Regulating Bioprospecting: Institutions for Drug Research: Access and Benefit Sharing*, Netherlands: United Nations University Press.
- Greene, W. 2007, 'The Emergence of India's Pharmaceutical Industry and Implications for the US Generic Drug Market', *Office of Economics Working Paper No. 2007-05-A*, Washington: US International Trade Commission.
- Izuka, M. 2013, 'Innovation Systems Framework: Still Useful in the New Global Context?', *Working Paper Series*, The Netherlands: United Nations University-MERIT.
- Joseph, K. J., D. Abrol, and H. Madhavan 2013, 'Local Innovation and Production System in Indigenous Medicine: The Case of Ayurveda in Kerala, India', *RISSEI Project Preliminary Report—India*, March (unpublished), Rio de Janeiro: Rio de Janeiro Federal University.
- Kaplinsky, R. 2011, 'Bottom of the Pyramid Innovation and Pro-Poor Growth', Washington: Innovation and Growth, PRMED Division of the World Bank.
- Kraemer-Mbula, E. and W. Wamae (eds) 2010, *Innovation and the Development Agenda*, Ottawa: International Development Research Centre.

- Kunnathoor, P. 2011, 'Kerala Drug Control Dept. Start Drive against Cosmetic Traders for Violating Magic Remedies Act', *Aayurbhishak*, Chennai, 16 January, 136.
- Leyesdorff L. 2006, *The Knowledge-Based Economy: Modeled, Measured, Simulated*, Boca Rota: Universal Publishers.
- Lucas, R. E. 1988, 'On the Mechanics of Economic Development', *Journal of Monetary Economics*, 22: 3–42.
- Lundvall, B. A. (ed.) 1992, *National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning*, London: Pinter Publishers.
- Madhavan, H. 2008, 'Knowledge Origin, Innovations and Growth in Ayurvedic Manufacturing: References from Kerala', (unpublished) paper given at *Sixth Globelics Conference*, Mexico State Technical University, Mexico, 22–24 September.
- . 2009, Commercializing Traditional Medicine: Ayurvedic Manufacturing in Kerala, *Economic and Political Weekly*, Vol. XLIV(16): 44–51.
- . 2011, 'Growth, Transition and Globalisation of Traditional medicine: Case of Ayurvedic Pharmaceuticals in Kerala', Unpublished PhD thesis, Thiruvananthapuram: Centre for Development Studies.
- . 2013, 'Towards a "Pharmaceutical Vicious Circle": Revisiting Kerala Ayurvedic Sector', *International Institute of Asian Studies Newsletter*, 65: 32–5.
- Metcalfe, S. and R. Ramlogan 2008, 'Innovation Systems and the Competitive Process in Developing Economies', *The Quarterly Review of Economics and Finance*, 48: 433–46.
- Murray, F. 2005, 'Reconceptualizing the Institutional Foundations of Cumulative Innovation', paper prepared for *Princeton Conference on Intellectual Property Rights*, Princeton.
- Murray, F. and S. Stern 2007, 'Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis', *Journal of Economic Behavior & Organization*, 63(4): 648–87
- Mytelka, L. K. and F. Farinelli 2003, 'From Local Clusters to Innovation Systems', in Cassiolato, J. E., H. M. M. Lastres, and M. L. Maciel (eds), *Systems of Innovation and Development, Evidence from Brazil*, Cheltenham, UK: Edward Elgar, 249–72.
- Nelson, R. R., and S. G. Winter 1982, *An Evolutionary Theory of Economic Change*, Cambridge, MA and London: Belknap Press.
- Nelson, R. R. 1988, 'Institutions Supporting Technical Change in the United States', in G. Dosi et al. (eds), *Technical Change and Economic Theory*, London: Pinter Publisher, 312–29.
- Nwokeabia, H. 2002, *Why Industrial Revolution Missed Africa—A Traditional Knowledge Perspective*, working paper 01/02, Addis Ababa: Economic Commission for Africa, UN.
- OECD and Eurostat 2005, *Oslo Manual—Guidelines for Collecting and Interpreting Innovation Data*, Paris: OECD.

- Patnaik, P. 2008, 'An IPR Policy for Kerala', *People's Democracy*, xxxii (26), July, 12.
- Patwardhan, B. and R. A. Mashelkar 2009, 'Traditional Medicine-Inspired Approaches to Drug Discovery: Can Ayurveda Show the Way Forward?', *Drug Discovery Today*, 14: 804–11.
- Pordié, L. and J.-P. Gaudillière 2014. 'The Reformulation Regime in Drug Discovery: Revisiting Polyherbals and Property Rights in the Ayurvedic Industry', in *East Asian Science, Technology and Society*, 8(1): 57–79, DOI: doi:10.1215/18752160-2406053.
- Romer, P. M. 1986, 'Increasing Returns and Long-Run Growth', *Journal of Political Economy*, 94: 1002–37.
- Scotchmer, S. 1991, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law', *Journal of Economic Perspectives*, 5: 29–41.
- , 1996, 'Protecting Early Innovators: Should Second-Generation Products be Patentable?', *The Rand Journal of Economics*, 27: 322–31.
- Solow, R. 1957, 'Technical Change and the Aggregate Production Function', *Review of Economics and Statistics*, 39: 307–20.
- Unnikrishnan, E. 2009, 'Ayurvedavum Aadhunikaavalkaranavum' (in Malayalam), *Malayalam Varika*, 12 September, 42.
- WHO 2004, *WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems*, Geneva: World Health Organization.
- Yamashita, T. and Ram Manohar, P. R. 2007, 'Memoirs of Vaidyas: The Lives and Practices of Traditional Medical Doctors in Kerala, India (1)', *Electronic Journal of Indian Medicine*, 1: 45–62.