COMMERCIALIZATION OF TRADITIONAL KNOWLEDGE BASED TECHNOLOGIES BY SMALL ENTREPRENEURS: AN EXPLORATION OF STRATEGIC AND POLICY OPTIONS[1]

Dheeraj Awasthy, Indian Institute of Management Ahmedabad, Tel 6327901 email: dheeraj@iimahd.ernet.in

Rakesh Basant, Indian Institute of Management Ahmedabad, Tel 6324865 email: rakesh@iimahd.ernet.in

Vivek Gupta, Indian Institute of Management Ahmedabad, Tel 6327903 email: vgupta@iimahd.ernet.in

Fax Number: 6306896

1 An earlier version of the paper has been accepted for 3rd Conference of International Entrepreneurship Forum: Entrepreneurial Innovation to be held at Bangalore from March 6th – 8th,2003

Abstract

The paper is based on the case study of an entrepreneur who has invested his career in developing a new product based on traditional knowledge. Using this case we highlight the issues faced by a small entrepreneur in the commercialization of traditional knowledge based technologies in pharmaceuticals industry. The framework developed by Teece is used to analyze the strategic options available to the entrepreneur in a weak appropriability regime. We also analyze a hypothetical scenario of strategic options available to the entrepreneur if the appropriability regime was strong. Since traditional knowledge based entrepreneurial activities have significant scope in India, it is important to explore the policy and strategic options that are available to us. In the context of the case study, the concluding part of the paper reviews these options and the associated implications for the holders of traditional knowledge.

1. INTRODUCTION

In the new economy with development of markets for risk capital, entrepreneurial innovation has come to occupy the center-stage of academic and management focus. Rightly so, as it creates a potential for Schumpeterian kind of competition which can completely alter commercial landscapes. Countries with a culture and institutions for entrepreneurial innovation create wealth and are leaders of world progress. Despite Indian entrepreneurial successes in information technology and pharmaceuticals industry on a global scale, we are still far from being characterized as an innovation-led country.

For achieving long term growth, we should look for opportunities where innovation based entrepreneurship can create global products. If we look around for successful 'made in India' brands, we see that traditional knowledge has been our forte. Many successful Indian products have their roots in our heritage, and are well respected, e.g., yoga. However, we have not been able to replicate the same success in global market in the traditional knowledge-based Indian system of medicine. Some estimates point that the global herbal market will be worth $5 trillion by the year 2050 (Padmini 2002a). It is poised to witness high growth because with increasing environmental sensitivity and knowledge of potential side effects of allopathic medicines, consumers are moving to herbal medicines.

A likely reason for failure in capturing global market in this segment is that, devoid of any protection, the Indian system of medicine did not get advantage of critical peer review that is at the root of the advancement of knowledge in the world today (Mitra and Tren 2002). A policy shift from process to product patenting regime can unleash a wide range of entrepreneurial innovations from this knowledge and lead to subsequent filing for patents. The intellectual property protection process creates opportunities for critical evaluations by experts and competitors. Such a shift could

start a positive spiral of innovation and new products development, improving our capabilities and bringing about a new innovation-product development culture in India. By encouraging ground level innovations and entrepreneurship, India can become synonymous with herbal products as France with wines and Cuba with cigars.

Currently, people who undertake such innovations lack proper understanding of the complex game of intellectual property protection and technology commercialization. These entrepreneurs are often located in communities where knowledge of patent laws is virtually non-existent. Consequently they often end up devising a wrong IPR strategy and market choice and lose their potential advantage. We highlight these and related issues in light of the case study of an entrepreneur who has invested his career in developing a product out of traditional knowledge. In the next section, we briefly discuss the role of appropriability and complementary assets in the commercialization of new technologies. Section 3 places the discussion in the context of Indian pharmaceuticals industry. This is followed by a discussion of the case of the entrepreneur. Using Teece's framework, the strategic options available to entrepreneur are also evaluated here. In the context of this case study, the last section highlights some policy and strategic issues.

2. APPROPRIABILITY, COMPLEMENTARY ASSETS COMMERCIALIZATION OF TECHNOLOGY

An innovation does not directly translate into gains for the innovator. For gains, the innovation has to go through successful commercialization- where it faces technological and market uncertainty, and imitation threats. Innovator does not appropriate all the gains resulting out of the innovation- they are shared amongst, the innovator, the follower firms, and the suppliers and customers. Three factors influence the distribution of gains among these claimants (1) the appropriability regime, (2) complementary assets, and (3) dominant design paradigm (Teece 1986). In the case of a traditional

knowledge based innovation, which is non-systemic in nature, only the first two factors are important.

2.1 Role of Appropriability

"Appropriability regime refers to the environmental factors, excluding firm and market structure, that govern an inventor's ability to capture the profits generated by an innovation" (Teece 1986: p287). Appropriability of an innovation increases when the innovation is difficult to imitate either because of stringent intellectual property rights (IPR) regimes or due to the characteristics of the innovation (e.g. tacitness, complexity etc.).Appropriability regime is defined as tight if intellectual property protection is high. In tight appropriability regimes an entrepreneur could license the technology for royalty to incumbent firms, can raise cash by debt or equity or sell the patent for equity to large firms. Without adequate intellectual property rights protection, selling of such know-how suffers from market failures in information valuation. In weak appropriability regimes, incentives to innovate are very weak. Entrepreneurs especially small ones, often lack managerial resources to understand innovation risks and thus use imitation strategies in business models and products. In fact, entrepreneurs using innovation based strategies face challenges from entities following these imitation strategies in the marketplace reducing appropriability of gains from innovation.

2.2 Role of Complementary Assets

Technological know-how needs to be combined with other capabilities and assets for successful commercialization and appropriation of gains from innovation. Access to these complementary assets needed for commercialization also enhances the appropriability of an innovation. Marketing, distribution and competitive manufacturing are important complementary assets. These complementary assets can be classified as (1) Generic and (2) Specialized. An asset is defined as

generic if it can be put into any alternative use whereas a *specialized* asset is a dedicated asset to a specific innovation/transaction/use and has no or very low contingent value. The choice of integrating or collaborating for access to complementary assets in the technology commercialization process depends on the type of appropriability regime and specificity of assets required for commercial success.

3. PRODUCT INNOVATION IN PHARMACEUTICALS INDUSTRY

In the pharmaceuticals industry the commercialization of new products is a huge challenge. In what follows we discuss this process in the context of Indian pharmaceuticals industry in order to identify the complementary assets required by the innovator for successful commercialization.

3.1 KEY CHARACTERISTICS OF INDIAN PHARMACEUTICALS SECTOR

The Indian pharmaceutical industry comprises 20053 manufacturing units with the total production in the country in 1999-2000 at Rs.19737 crores. The formulations accounted for Rs.15960 crores and bulk drugs contributed Rs.3777 crores. The total capital investment in the pharmaceutical industry was Rs.2500 crores with R&D expenditure being Rs.320 crores (Bhandari 2001). In the pharmaceuticals segment the total turnover of ayurvedic/herbal products is approximately Rs. 2,300 crores, which includes major OTC products, ayurvedic ethical formulations and ayurvedic classical formulations (Rajasekharan 2002). There are around 10,000 small and big ayurvedic companies in the year 2002 as compared to 3,000 five years ago (Neti 2002). The demand for herbal products is also growing and worldwide the market grew at an annual rate of eight per cent during the period of 1994-2001(Padmini 2002a). A report recently published by ORG-MARG, shows that Indian herbal market has been growing at 25% per annum and the sales is likely to double by 2005 (Neti 2002).

The structure of Indian pharmaceuticals market changed considerably after the Indian government removed patent restrictions in 1970. India adopted a process patent regime offering very limited

protection of seven years. At the same time, increased tariffs and easy entry norms led to emergence of a large number of small pharmaceuticals companies doing reverse engineering of newly developed molecules and producing them in bulk in India. The Indian pharmaceuticals industry became a highly competitive and fragmented one. Over a period of time, some companies have acquired considerable knowledge through learning-by-doing and are today supplying in the world market. As a member of the WTO, India is bound to implement the TRIPS agreement and introduce product patents in the pharmaceuticals by the year 2005.

Another important facet of the industry is DPCO (Drug Price Control Order). This order restricts the companies selling price for medicines on a control list below as those given by government notifications. In recent years, the number of drugs covered by DPCO has declined significantly.

3.2 Complementary Assets in New Drug Approval

New drug development, approval and commercialization is a complex and long drawn process in the pharmaceuticals industry. Innovations[2] in pharmaceuticals industry are governed by the Drugs & Cosmetics Act, 1940 (Drugs Act) and the Drugs and Cosmetics Rules, 1945 (Drugs Rules). The Drugs Act and Drugs Rules also prescribe the standards and quality, and regulate the import, manufacture, sale and distribution of all drugs including ayurvedic drugs in India. Drug Controller General of India (DCGI) handles new drug approvals, which has two stages: preclinical and clinical. The preclinical studies identify effective molecule/active ingredients and tests the toxicity

---

2 According to Indian Drug Policy a new drug is defined as: (a) a new substance of chemical, biological or biotechnological origin in bulk or as a prepared dosage form; (b) a drug already approved by the licensing authority which is now proposed to be marketed with modified or new claims; (c) a fixed-dose combination (FDC) of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined in a fixed ratio; (d) all vaccines.

effects in animal testing. This stage of investigation may take anywhere between 3-5 years and costs between $100-150 million overseas and Rs 40-60 crores in India. On satisfactory completion of preclinical stage the drug is then submitted to DCGI for permission to conduct human clinical trials in phase I, II and III. This stage takes generally 5-8 years and is estimated to cost between $300-350 million abroad and around Rs 100 crores in India (Singh 2001). Indian Drugs Act allows companies to seek approvals for selling traditional knowledge based drugs without undergoing new drug approvals if they are supported by citations in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine. Once a drug is approved for marketing by the Drugs Controller General of India (DCGI), the manufacturer has the option of selling it over-the-counter– except for drugs under Schedule H of the Drugs and Cosmetics Act (Rx drugs).

Worldwide companies build complementary assets for getting faster approvals for new drugs. These assets include clinical trial laboratories, relations with specialized companies offering clinical trial services, knowledge management and analytics systems and regulatory knowledge. For example, Hoffman-Laroche has invested millions in developing a KM system for helping file and manage new drug approvals with FDA(Seemann 1998). The expertise in drug approval process entails cumulative learning, path dependence and high uncertainties. It is extremely difficult and expensive for a small entrepreneur to develop and/or access assets required for new drug approval process.

Under such circumstances, most of the entrepreneurs in the herbal marketplace tend to operate in OTC segments and get approvals citing authoritative scriptures. The government regulator does not impose any stiff regulation in such cases and hence entry is quite easy.

3.3 Complementary Assets Relating to Marketing and Distribution

A large variety of complementary assets that fall in this broad domain e.g. brands are important for commercialization of new drugs. This sub-section discusses some of these.

3.3.1 Brands

Brand is an intangible complementary asset and requires time, investments and continuous feedback to develop. Brands are important complementary assets in pharmaceuticals markets as (1) in OTC drugs category consumers buy on recall or chemist's advice (2) in prescription drugs category doctor's prescribe drugs by brand names. According to Datta (Datta 2002) companies use mass media advertising for building OTC brands with marketing expenses accounting for 50-55% of company's expenses in first year. Morepan pharmaceuticals has spent more than Rs 5 crore in popularising the Dr Morepen brand. Similarly in herbal OTC segment companies such as Himalaya, Dabur, Paras and Zandu have built a strong brand image.

Prescription drugs brands (schedule H drugs) are not advertised through any mass media communication. Company's build specialized information distribution channel for building the prescription brands. They also provide doctors with a variety of gifts, table accessories and samples for increasing the brand salience.

3.3.2 Specialized Information Distribution Chain

In ethical formulations (schedule H drugs) doctors are the key decision makers who prescribe medicines by their brand names. Companies develop an information distribution channel comprising medical representatives (MRs) to visit doctors and inform them about company's products, its pharmacological benefits and action. Over a period of time, the role of consultants and specialized doctors has increased substantially with increasing referrals from general practitioners. This change requires companies to employ more qualified MRs to talk to specialized doctors.

As discussed earlier, MRs also provides doctors with a variety of gifts and samples for increasing the brand recall. With increasing competition companies have started using these gifts as means of penetrating the market or gaining the market-share. There has also been a consistent decline in ethics in medical profession where some doctors have started to seek direct or indirect monetary benefits from companies or retailers (Srivastava 1999). Moreover, often doctors stop prescribing a drug when a discontinuity occurs in MR visits. With all this, the role MR has changed from mere information provider to the one who identifies the preferences of the doctors and manages them.

The MRs also liaise with local retailers and distributors persuading them to push more products of the company.

3.3.3 Physical Distribution Chain

A typical drug distribution chain is: company→ clearing and forwarding agent (C&F) → stockist → retailer → consumer. In many places intermediaries such as sub-stockists and freelance wholesalers also exist who serve small retailers with limited capital. With drugs changing many hands before final delivery, the distribution structure in pharmaceuticals industry is very complex and has high costs.

The drugs are dispensed through specialized drug stores which mandatorily have a medically qualified (diploma holder) person at the shop. The drug retailers in India act as quasi monopoly despite their large numbers due to high unionization. The All India Organization of Chemist & Druggist (AIOCD) protect the drug retailer's interest and margins by issuing boycott calls, demanding no-objection letters from companies for introducing new drugs into the market. But unionization is not the only reason for the retailer's power. They enjoy power in the distribution chain also because (Subba Rao 1998):

- Retailers act as important information sources for companies to identify successful doctors and their prescription preferences.
- Retailers maintain product availability near the prescribing doctor to translate the prescription into a sale.
- Many patients often rely on retailers for medical advice. As a result, powerful drugs are routinely, and illegally, sold over the counter by pharmacists thereby making them strong influencers.
- Retailers at times also substitute prescribed drug with available substitutes or high margin drugs.
- At many places retailer-company-doctor nexus exists where retailers and companies exercise due influence over doctor's prescription of brands.

Companies understand the bargaining power of retailers and keep them happy by offering discounting deals at least once a month to retailers over and above the fixed commissions for various drugs (Pearl and Stecklow 2001).

Recently, Government of India has created a sub-committee to develop an OTC drugs list with rules and specifications (Datta 2002). Once an official list of OTC drugs is made, these drugs could be mass marketed through general purpose stores which may reduce the bargaining power of drug retailers.

3.3.4 Complementary Manufacturing Assets

Given a weak appropriability regime and high power of channel members in the supply chain, it is the manufacturing competence that is critical for a company's success. Process competencies are critical in pharmaceuticals industry for increasing yield and attaining high qualities at low costs. There are many small manufacturers who do contract manufacturing of a variety of drugs and provide these assets in the market on rent. Since these complementary assets are available on rent in the market, they are somewhat generic in nature for a new entrant.

4. COMMERCIALIZATION OF TRADITIONAL KNOWLEDGE BASED TECHNOLOGIES – A CASE STUDY[3]

Magic Drugs (P) Ltd. is a small entrepreneurial pharmaceutical company dealing in herbal medicines located in Central India. It is owned by a senior dermatologist Dr. A. V. Malik and his son Mr. Kapil Malik. Presently it has two innovative products in the market based on a plant extract. These products were sequentially launched in 1998 and 1999 in the prescription drugs market in Central India. During late 2001 Magic Herbs reached a plateau in the product sales and

---

3 The name of the company and actors has been disguised to maintain confidentiality.

was barely able to break even. Unable to sustain their expenses, the company CEO, Mr. Malik called off the services of its entire sales staff.

Despite having innovative products, Magic Drugs was struggling to find a clear strategic path for itself. Dr. Malik was trying two options (1) get some equity funds to invest into his company (2) sell the product line to other companies.

4.1 THE STORY OF INNOVATION

Dr Malik's journey of innovation began in late 1940's when he was an MBBS student. Dr. Malik's niece had developed a boil on her forehead. So, he took the young girl to his professor who advised him to bring back the girl after a week for surgery. Next week when he went back to pick-up her niece, he was surprised to see that the boil on her forehead had disappeared. Being a medical student he became curious. His cousin told him that she applied a plant leaf given to her by a tribal who frequented their house. Dr. Malik became quite interested in the plant, but he did little work on it till he became a skin specialist himself. On pursuing his work on it he found that the plant was mentioned in ancient texts for treatment of ulcers in animals. He started using the plant in his medical practice and found good results. He used the plant for treating a variety of skin ailments and some of the difficult conditions to avoid surgery. Because of his inquisitive and scientific nature, most doctors in his surroundings would refer difficult cases to him which he was able to cure with the help of this plant.

Encouraged by the results he developed a process of extraction and converted the plant extract into a cream form. Initially, he dispensed this cream freely to his patients. The drug was giving significant result even when other allopathic treatments failed. According to Dr. Malik no such

product wherein a single ointment cleansed the wound and promoted tissue regeneration was found in modern medicine. In fact, such a concept did not exist in modern medicine. Dr. Malik also found many new uses of the drug in treating leg ulcers, traumatic ulcers, minor cut, wounds etc. The results of this drug were positive and he received compliments for the same.

Dr. Malik also presented his results in domestic and international conferences. He was however very cautious with his invention and did not publish the details in any scientific journal for of fear of imitation[4].

4.2 THE STORY OF COMMERCIALIZATION

Many colleagues of Dr. Malik repeatedly asked him to make the drug available in the market for mass benefit. In its original form the plant had a foul small so he started working on the drug to convert it into a more usable form. He developed a product in a cream base packed in tube of 25g size. He launched a company named Magic Drugs (P) Ltd along with his son for marketing the product. He had limited funds for investments in the company. Dr. Malik himself prepared the raw material extract and supplied it to an outsourced manufacturer to convert into a cream base and package it in tubes.

Prior to commercialization, Dr. Malik approached a patent lawyer to get patents on his innovation. Dr. Malik did not have knowledge about patent procedures. With a lawyer's help he received a process patent for his drug in India in 1996. Dr. Malik asked his patent lawyer that he also wants an international patent on the drug for signaling the strength of his product in the domestic market. His lawyer, who had worked in South Africa in the past, told Dr. Malik that it will be easy and cheap to

---

4 It was not clear how effective this strategy was as the details of this innovation was available in patent documents.

seek a product patent in South Africa which will be applicable in the entire African continent. With this lawyer's help he received a product patent for 20 years for the drug in South Africa in 1997. He contacted around half a dozen big pharmaceutical companies for partnerships and government agencies for further innovation and product patenting in the US market but got no positive response. Presumably this was also a failure of information valuation as he was very afraid of imitation threats. Later when he wanted to patent the drug in US, he was advised that it was not possible to seek US a product patent since the drug was already in the market. In 1999, Dr. Malik launched another variant of the drug in the form of an oral formulation which was useful in a variety of mouth and gum diseases.

Dr. Malik also started developing a marketing and distribution network for the company. He appointed a clearing and forwarding agent (C&F) – based in a major city in central India and appointed 25 stockists spread across all the major cities of central India. Dr. Malik decided to sell his drug through ethical selling route because the therapeutic uses of the drug were in curing serious ailments. Magic Drugs adopted an ethical promotion strategy and appointed a team of MRs for reaching doctors. These MRs were primarily fresh commerce graduates as they were available at low salaries. There was high turnover of MRs who left the company as soon as they gained some experience, treating the company as a training ground. Since the company did not carry a large product line, the sampling and network cost overheads for the company were very high. The situation got aggravated further as Magic Drugs was not able to achieve the desired sales in the market.

Since the drug treated serious ailments with a plant extract, the company faced a difficult situation of convincing doctors about the efficacy of the drug. The product brought a unique concept of cleansing as well as healing the wound—something which is not heard in allopathic practices. It was difficult for allopathic doctors to accept the claims. After initial introduction of products in the market Dr. Malik realized that allopathic practicing doctors prefer medicines which are backed by clinical trials and scientific reports. Magic Drugs had not invested in clinical trials so far as it was not legally mandatory for their drugs (herbal drugs) to undergo clinic trials.

Dr. Malik had a venture capitalist friend in United States. He wrote to him for helping him to sell the drug. The venture capitalist talked to a dermatologist friend in the US about the proposal. The US based dermatologist estimated a huge market potential for such a drug in US but cautioned that it required scientific trials to back such claims. Facing a credibility challenge for the drugs in the Indian market and looking at a potential US market, Dr. Malik decided to invest in formal scientific trials for the drug in 2001. The first set of clinical trials was done on animals for toxicity and drug claims. Subsequently, human trials on volunteers for two different usages of the drug were done in a local medical college. Being a reputed doctor in the city, Dr Malik got an easy access and support in local government medical college for conducting human trials. The reports showed that his drug had superior healing powers and unique properties as compared to simple anti-bacterial ointments for both usages.

4.3 LESSONS FROM THE CASE STUDY

The case study presents a situation where the inventor entrepreneur with traditional knowledge based innovation is trying to commercialize and appropriate rents on his technology in a weak appropriability regime. Dr. Malik has already gained some experience in trying to commercialize his product. His efforts to create a marketing channel have met with limited success. We use the

framework (see figure 1) proposed by Teece (Teece 1986) for analyzing the current situation of the entrepreneur and identify options available to him.

4.3.1 Requirement of Complementary Assets for Commercial Success

The entrepreneur requires access to specialized information distribution channel for ethical selling and specialized marketing assets like brands for OTC selling. For distributing physical products, he requires access to generic drug distribution channels, which act as quasi monopoly because of unionization. The entrepreneur also had to invest in scientific trials for market acceptance, although the Indian laws did not require such investments. Moreover, it is not clear if clinical trial regimes that are acceptable for allopathic drugs would automatically be usable for herbal drugs. In this case, these were required as a signaling mechanism.

The entrepreneur tried to create specialized information channel at low cost. However, he failed in his attempt as Magic Drugs lacked organizational capabilities and finance for developing such a channel.

4.3.2 The Need for Specialized Complementary Assets

Information distribution channel for contacting doctors is a specialized asset which has low value in other uses. The same channel can be used for a variety of drugs if the company has a large portfolio. Other assets like brands carry an image and identify certain unique propositions for the consumers. In general, brands may be specialized or generic depending on the situation; medicinal brands are usually specialized. A recent attempt of extracting contingent value of the Disprin brand failed miserably in the marketplace. The brand owner company tried to bypass a DPCO rule by changing medicinal content of the drug, which was not accepted by consumers. The company had to revert to its old positioning strategy. The incident shows that the specialized medicinal brands have limited

alternative use value. The manufacturing assets required for producing the low complexity drug, are however, generic. Retailer chain is a somewhat generic complementary asset and is contractible in market although on skewed condition due to high bargaining power of the retailers. The margins are fixed. It is impossible for a company to integrate such distribution resource within the company and thus contracting is the only choice.

4.3.3 Issues Relating to Appropriability Regime

Indian patent act 1970 creates a weak appropriability regime because it only recognizes process patents for a limited period of 7 years. These patents do not help in shielding the innovator's interests from imitators who can rapidly enter into the market with small changes in the manufacturing process of the drug. In cases of complex technologies, imitation costs could be as high as 70% of innovation costs providing an effective shield to the innovator (Mansfield, Schwartz, and Wagner 1981). In this case however, the technological complexity of the product is low. Hence, the entrepreneur faces a situation of weak appropriability.

4.3.4 Criticality of Specialized Assets

For ethical selling information distribution channel is a must. Magic Drugs experienced a decline in sales after it withdrew its channel by removing the current set of MRs. In OTC segment the company requires to create specialized brands for selling the drug.

Alternatively, the company can enter the OTC segment without upfront investment in specialized brands by giving higher margins to the retailers. In this segment the competition is high which may force the company to invest into manufacturing assets in future. Given the small share of manufacturing costs to total costs, the scope for such a strategy may be limited.

4.3.5 Cash Requirements

The company lacked finances to support an aggressive marketing plan. Initially, it started with only one product and introduced the second research product at the end of the year 1999. The entire cost of Magic Drugs marketing activities was shared by these two products only (refer table 1 for break up of major costs and margins). The rough gross margin after accounting for channel and manufacturing costs is around 25% which is barely enough to cover administrative and medical representatives' expenses. The high overheads resulted in negligible profits for the company.

4.3.6 Competitive Position of Imitators/Competitors

As discussed in previous sections, Indian pharmaceuticals industry is highly competitive. A typical company has imitation as its core strategy and is looking for any viable opportunity to exploit. The large companies are multi-market, multi-product companies with developed specialized chains, historical distributor relations and experience in handling doctors. These companies are able to distribute their overheads over large number of products and thus have better cash profits.

The entrepreneur tried establishing contractual relations with the incumbent firms but was unsuccessful. The companies he contacted did not show any interest in his drugs or in establishing contractual relations with his company. Despite this, there has been no imitation attempt of his drug so far in the market by any other company.

Overall, the current situation of the entrepreneur can be summarized the following manner (Table 2)

In such a scenario, the entrepreneur is in a weak position where any further investment made has high risks.

5. SOME STRATEGIC AND POLICY IMPLICATIONS

The discussion so far suggests that traditional knowledge based innovations in a weak appropriability regime have limited chances of yielding gains to the innovator entrepreneur. This situation is well discussed by Teece:

> "The only clear circumstance where in the inventor can succeed alone is when (1) the technology is well protected by intellectual property law, (2) the technology can be transferred from the inventor to an organization, and (3) the inventor already has great wealth. The circumstances where these factors occur together is likely to be relatively rare." (Teece 1996: p 211)

In case of a standard knowledge innovation, patent protection is the only surety that an innovator has for appropriating benefits. The key lesson for the entrepreneur in this area is to focus on developing the right IPR strategy failing which odds against their success in the marketplace are very high. In the absence of a product patent regime in India, the entrepreneur seems to have used his options reasonably well though it does not offer him any protection. If the entrepreneur had enough knowledge about patents, he would have sought product patents in the US market before launching the product in India. While patentability of the product in the US market still needs to be ascertained, the potential seems to be high, given the product patent granted in South Africa. This would have enhanced appropriability for the entrepreneur and allowed him to create a global product.

In pharmaceuticals, given the high cost of creating and maintaining specialized assets only multi-product companies have chances of success. A product patent may have facilitated access for the entrepreneur to such complementary assets more easily and on better terms. With an exclusive patent, the patent-holder had various options:

> "In the case where the individual inventor has a patent but little else, then the patent holder's options include: (1) licensing of technology to incumbent firm who already have the necessary complementary assets in place; (2) using the patent as collateral to raise debt funds to help develop an organization to exploit the technology; (3) exchanging the patent

> for equity in a startup, equity-funded firm; (4) exchange the patent for equity in an established firm."(Teece 1996: p210)

Teece clearly demonstrates a superior position then current case for individual entrepreneurs working on traditional knowledge in case he holds an exclusive product patent. While clearer property rights facilitate such transactions, it is not clear if significant marketing and distribution investments would not have been necessary to launch the drug in external markets. Clinical trials for these markets may also have created fresh challenges.

Though untried by our entrepreneur, an important initiative can be a creation of shared information distribution channel by a network of entrepreneurs which offers a well measured, dependable information distribution service for small entrepreneurs. However, such initiatives require high degree of transparency and pose significant organizational problems relating to incentive, compatibility, free rider issues etc.

The only option then, which seems viable for our entrepreneur, is to enter the OTC market and compete like any other manufacturer without any superior advantage. As discussed earlier, given the role of the retailer in influencing sales, OTC seems to be a much easier entry route by parting with higher commissions, but scaling and competition issues remain.

Overall, the case study provides interesting insights to evaluate various policy options to encourage traditional knowledge based entrepreneurship. Key issues raised by the case study relate to legal appropriability regime, complementary assets for commercialization in pharmaceuticals industry, opportunities of innovation in traditional knowledge market and lack of awareness of legal opportunities of protection among persons having access to traditional knowledge.

There are country level disparities in policy action on these issues. A study on herbal patents granted in the US found that the patent holders are largely individual inventors. Typically, such

inventors own only one patent and China has the highest number of herbal patents for a single country (Gupta 1999). China seems to have recognized the importance of herbal patents and has encouraged, through various means, filing of such patents in their country and abroad. This is one of the reasons that China has a share of around US $ 3 billion of the US$ 61 billion global herbal market, whereas India's share is not even US $ 100 million(Kalam 2001). India is yet to enter in the same in any significant manner. The most crucial and important policy decision to encourage this process is a shift to a product patent regime[5]. However, mere provision of law will not suffice to enforce patent rights. The government must also create mechanisms for speedier judgments and high penalties for patent infringement thus creating a tight appropriability regime. This will reduce the transactions costs of the type mentioned above.

Patenting, however, is an expensive process. Policy instruments could be used to encourage investments by venture capitalists in this area. This may help many start-up ventures to access complementary assets for commercialization. Clear property rights on herbal products may attract VC investments. Clear IPRs and VC participation also create an environment where buying and selling of intellectual property will take place providing exit options to many innovator entrepreneurs.

Government can also invest in creating complementary assets in development of new drugs which provides rented facilities to entrepreneurs. This could take the form of clinical trial facilities. There

---

[5] It is recognized that conventional IPR system (for example, patenting etc.) may not always be suitable to protect traditional knowledge based inventions. However, it is our view that while the debate on alternative system of protection continues, it may be strategically important to exploit to potential or prevalent IP protection system.

is also a need to create incubation centers for supporting entrepreneurial innovation. China has 180 and South Korea 200 business incubators but the figure in India is at a dismal 12 (Padmini 2002b). Alternatively, innovative policy instruments to encourage partnerships between such innovators and existing research and medical institutions would be very useful.

A system of rewards for the owners of traditional knowledge can provide incentives for creating databases of such knowledge. Such databases would provide the pool from which entrepreneurial activity could flow. Clear property rights and a well functioning capital markets may also encourage doctors, biologists etc located in remote areas to experiment with the traditional knowledge in the region and facilitate innovation based on such knowledge with intellectual property that is commercially viable. If the government is able to devise a policy which ensures payback to the innovator and also to the community which preserved this knowledge, the government can use its current assets (doctors) to come up with innovations in this field. IP literacy could be a good starting point to unleash the creative process to tap traditional knowledge for entrepreneurial endeavors.

The absence of imitators in the case is difficult to interpret. In the IPR regime prevalent in India today, one should see a plethora of substitutes emerging for a successful product. The "non-success" of the entrepreneur, may, therefore, provide an explanation for the absence of "me-too" formulations. Whether the lack of success is due to absence of market potential or the inaccessibility of the required complementary assets to the entrepreneur still needs to be assessed. If one believes in the curative properties of the drug and the absence of substitutes, lack of access to complementary assets seems to be the logical explanation. At the same time, the innovation was not able to convince many large companies to invest in his product. It is not clear if the lack of interest of large companies emanated from limited market potential of the drug, the possibility of the drug

competing out their own formulations or information asymmetry arising out of the innovation's fear of imitation. It is obvious, however that information asymmetry and appropriability related issues could have become tractable if property rights were clearly defined. For any traditional knowledge based innovation, therefore, the role of product patents in reducing transaction costs and facilitating access to complementary assets needs to be emphasized.

6. REFERENCES

Bhandari, Mohan (2001), "Overview of Pharmaceutical Industry in India," in Indian Pharma Industry: Isuues and Options, 53rd Indian Pharmaceutical Conference 2001, FICCI (Ed.). Delhi: Saket Publications.

Datta, Nandita (2002), "No more a sneeze," Vol. 2003: Outlook Money.

Gupta, Anil K (1999), "Strategic Opportunities In Managing IPRs: Biodiversity, Drug Industry And Emerging Options," http://www.sristi.org/papers/B13.htm.

Kalam, Dr APJ Abdul (2001), "Transforming India into a Knowledge Society," in CII/WEF India Economic Summit 2001. New Delhi.

Mansfield, E., M. Schwartz, and S. Wagner (1981), "Imitation Costs and Patents: An Empirical Study," Economic Journal, 91, 907-18.

Mitra, Barun and Richard Tren (2002), "Protecting Patents, Saving Lives," The wall street journal online, http://webreprints.djreprints.com/622551008405.html.

Neti, Ramakrishna (2002), "Herbal Healthcare : Sprouting again," in Chartered Financial Analyst.

Padmini, Jayashree (2002a), "CSIR to commence clinical trials on herbals," in Express Pharma Pulse.

---- (2002b), "Knowing one's "Intellectual Property" rights," in Express Pharma Pulse.

Pearl, Daniel and Steve Stecklow (2001), "Drug Firms' Incentives Fuel Abuse by Pharmacists in India," in The Wall Street Journal. New York.

Rajasekharan, P.E. (2002), "Export of Indian medicinal plant products," Science Tech Entrepreneur, 54-60.

Seemann, Patricia (1998), "A Prescription For Knowledge Management: What Hoffman-Laroche Case Can Teach Others," in Managing Organisation Knowledge Vol. 2003: Center for Business Innovation Journal, http://www.cbi.cgey.com/journal/issue1/features/apresc/apresc.pdf.

Singh, Pradeep K (2001), "Introduction to Research & Development in Pharmaceutical Industry," in Indian Pharma Industry: Issues & Options, 53rd Indian Pharmaceutical Conference 2001, FICCI (Ed.). Delhi: Saket.

Srivastava, R K (1999), "Pharmaceutical Promotion and Ethics," Vol. 2003: Indiainfoline, http://www.indiainfoline.com/phar/feat/rkch.html.

Subba Rao, S VR (1998), *Handbook of pharmaceutical marketing in India*. Bangalore: Panther publishers.

Teece, David J (1986), "Profiting from technological innovations," Research Policy, 15 (6), 285-306.

Teece, David J. (1996), "Firm Organization, industrial structure, and technological innovation," Journal of Economic Behavior & Organization, 31, 193-224.

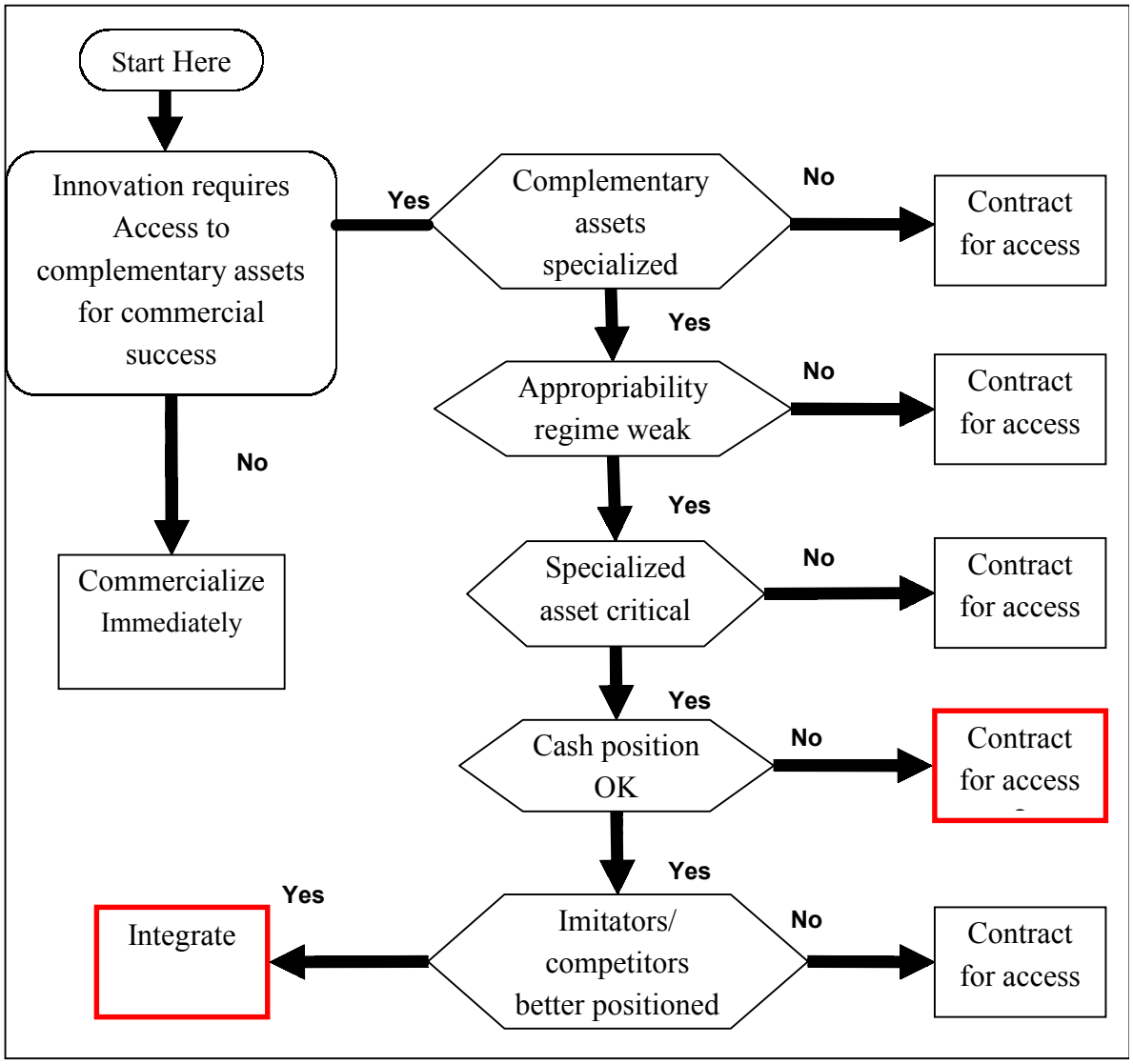

Figure 1 – Framework for integrating/contracting decisions in technological innovations (Source: Teece, 1986)

Table 1 – Breakup of Costs and Channel Margins

C&F Margin	5%
Stockists Margin	10%
Chemists Margin	20%
Sampling Cost	10%
Promotion Cost	10%
Communication Material	5%
Manufacturing Cost	15%

Source: Company sources

Table 2 – Entrepreneurial Situation vis-à-vis Appropriability and Complementary Assets: A Summary

Appropriability Regime	**Type**	**Protection Available**
Patents	Process	Weak
Trade Secrets		Weak
Product (Technology)	Self Prepared (Tacit) but low complexity	Weak
Complementary Assets	**Type**	**Protection**
Manufacturing	Outsourced	Generic
Distribution	Chemists	Co-Specialized
Marketing	MRs	Specialized
Marketing	Brands	Specialized