

Role of Critical Infrastructure and Incentives in the Commercialization of Biotechnology in India

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Abstract: Commercialization is a process by which the new knowledge is converted to products and services of commercial value. The model for commercialization of biotechnology is not a linear assembly like model. Due to emerging status of knowledge and involvement of biological systems legal and ethical challenges also arise and make the commercialization process longer, costlier and risky. Despite these entry barriers, we find many countries have appreciated the potential of biotechnology to produce useful and safer products and services in many areas of human activity and have invested and reaped fruits in terms of successful products in the market. We find from these accounts the results vary with the level of maturity of the industry and priority assigned by the nations and investments made in skills and generation of new knowledge. Among the developing countries, India is one of the early investors in biotechnology. Efforts were started as public initiatives. Skill generation, infrastructure development along with knowledge generation was taken up by the Department of Biotechnology. Multi-pronged efforts established visible capabilities in the public research system. Despite these efforts for one and half decades very little has happened at the commercialization level. This gap in realization of Indian research efforts as commercial successes has been a puzzle. In this paper, the author attempts to investigate the reasons behind slow commercialization. The approach is based on the hypothesis that to achieve successful commercialization in knowledge intensive field with high rates of turn over like biotechnology, the company should have (i) high levels of capabilities in R&D and strong network, to supplement and complement skills and facilities and (ii) an environment which is highly facilitating (high levels of preparedness of the technology delivery system) through favourable policies for regulation, accessing fiscal resources in terms of finances, infrastructure and skills, fiscal incentives, enhancing awareness of the public, etc. The study involved survey of 223 companies having some interest in biotechnology commercialization. The results of the survey show that access to funds, critical technical facilities and skills of desired quality have been the major obstacles. As far as the facilitating environment and critical infrastructure for commercialization is concerned, many companies found it to be not very favourable. The incentives are inadequate and confusion in regulatory policies has discouraging effect.

Keywords: Biotechnology, developing country, India, commercialization, incentives, infrastructure.

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Introduction

Commercialization is a process by which the new knowledge is converted to products and services of commercial value. The model for commercialization of biotechnology is not a linear assembly like model. It requires constant touch with research for the paradigm is not 'expansion of scale' but 'expansion of scope'. Commercialization, in addition to this continued connection with research or knowledge generating units, requires patronage of policy makers to facilitate the process be it protection or regulation and also an environment in which required skills materials, channels of distribution and awareness of ultimate consumer. Due to emerging status of knowledge and involvement of biological systems legal and ethical challenges also arise and make the commercialization process longer, costlier and risky. Hence "patronage of policy makers" is particularly significant in the case of biotechnology though some of the above conditions are valid for any frontier technology.

Despite these entry barriers, we find many countries have appreciated the potential of biotechnology to produce useful and safer products and services in many areas of human activity and have invested and reaped fruits in terms of successful products in the market. We find from these accounts the results vary with the level of maturity of the industry and priority assigned by the nations and investments made in skills and generation of new knowledge. Among the developing countries, India is one of the early investors in biotechnology. Efforts were started as public initiatives. Skill generation, infrastructure development along with knowledge generation was taken up by the Department of Biotechnology. Multi-pronged efforts established visible capabilities in the public research system. Despite these efforts for one and half decades very little has happened at the commercialization level. This gap in realization of Indian research efforts as commercial successes has been a puzzle. In this paper, the author attempts to investigate the reasons behind slow commercialization.

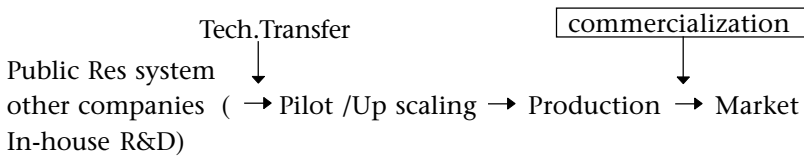
Commercialization in the Innovation Process

In the innovation process, commercialization is a relatively costly and difficult phase. It is the process of taking new knowledge, process or product beyond R&D phase and actually introducing it into production or in the market place. The location of this process is in the business sector and the R&D results may be self generated or outsourced. There is a widely quoted 'rule of thumb' that for every dollar spent on research 10 dollars are spent

in development and 100 dollars for commercialization. The ratio thus is R:D:C 1:10:100. This magnitude becomes one of the major inhibiting factors to commercialization in developing countries. Though this ratio varies among industries, it is largely true for large process-oriented projects where pilot plants and lot of regulatory compliances are required.

Though commercialization occurs through the companies, many a times the technology to be commercialized is developed outside the company. The major sources are public research system or other companies within or outside the geographical boundaries through different instruments of technology transfer. The nature of impediments vary depending on the nature, characteristics and maturity of the technology or knowhow transferred to the company.

Thus the typical commercialization process can be depicted as:



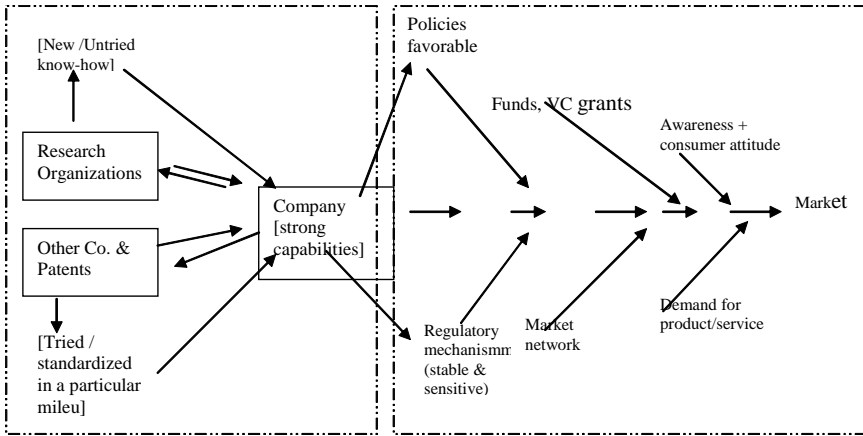
The efficiency with which the knowhow transferred to a company goes through the intervening phases to commercialize different products /services depends primarily on two factors:

1. The inherent capacity of the firm to absorb new knowledge and proceed with further steps and
2. Factors external to the company like policies, market, network, and supportive infrastructure & financial mechanisms. Thus, it seems to be a combination of strength/competence (technical, managerial and marketing) of the company, which is commercializing the technology and environment congenial for this which leads to successful commercialisation. Thus, the whole process can be schematically depicted (Figure on next page).

The status of knowledge in the field, organization of knowledge generation and transfer processes and implementational strategies adopted by different countries are important factors which influence and lead to different results. In this paper we restrict our study to the status of commercialization of biotechnology in India.

Theoretical Framework and Methodology

According to Batherham (2000) companies which want to succeed in new



Thus the commercialisation process to succeed requires

- Sound research base
- Technologically Competent companies
- Congenial and encouraging environment

economy need to invest in new skills and technology and align themselves with research institutions that perform basic research. According to an Australian report (Anonymous 2002), success factors in the commercialization path are listed as R&D products and services, IP protection, market analysis, regulatory issues, alliances and collaboration and availability of capital. This partially compares well with our identified factors. Furman *et al.* (2002) observe common innovation infrastructure include: (1) cumulative technological sophistication, (2) human capital resources available for R&D activity and (3) resource commitments and policy choices such as investment in education and training, IP protection, openness to international trade and R&D tax policies. Of Furman *et al.*'s list we consider R&D tax policies as part of incentives.

As mentioned earlier, of the two major factors affecting the process and pace of commercialization we look at the factors external to the company, i.e critical infrastructure and incentives. The other factor relating to the companies' capability has been dealt with in the earlier studies (Visalakshi and G.D.Sandhya 2000, Ramani and Visalakshi 2001, and Visalakshi 2004). The infrastructure critical to BT commercialization, according to us, include skill, funds and supportive institutions and industry, market and required policies in place.

While listing out the various factors we realize some of the factors serve as part of infrastructure as well as new rules/amendments serve as incentives. For example, as strong IP law operative in a country could

become part of infrastructure while an amendment which favours inclusion of living modified organism could be an incentive for biotech research and commercialization.

Incentives

Incentives are measures that are put in place to induce people and organizations to generate positive outcomes. In the case of science and technology, the different types of incentives can be classified in the following categories: fundamental incentives, institutional and infrastructural incentives, financial and fiscal incentives, budgetary incentives, legal and regulatory incentives, government procurement incentives, honorific incentives, and knowledge-base incentives.

The fundamental incentives are those which may be stated as initial conditions for socio-economic development, such as those provided by a market economy which includes free competition, private property, openness to the global economy, efficient bureaucracy and a stable democracy.

Institutional and infrastructural incentives could be made more efficient, particularly those for technological innovation (such as science parks), transfer, extension, diffusion, popularization, information, networking (including professional associations) and international cooperation. While institutions and infrastructures for R&D need to be modernized, strengthened and better linked to industry, infrastructures for information and communication technologies are particularly important for any developing countries since these technologies can substantially improve productivity and efficiency in all sectors of the economy and support technology transfer and networking. Hence the need to put into place incentives for their application and diffusion.

The financing of technological change is of paramount importance for developing countries which lack a full-fledged financial system and which attract little foreign direct investment and commercial credit. The strengthening, privatization and diversification of the financial system should be a high priority in order to increase the availability of venture capital and small credit to farmers and the informal sector. Financial incentives in general and incentives for foreign direct investment in particular need to be reinforced in view of the globalisation of the economy, by removing or reducing constraints in respect of percentage of local equity, local inputs and repatriation of dividends. A more positive approach to multinational corporations is needed if they are to contribute to endogenous technological capacity building.

The use of fiscal incentives, such as tax exemptions, rebates, reliefs, holidays, and accelerated depreciations, can be used to promote R&D, linkages with industry, application of technology, training, return of national expatriates, use of foreign consultants, strategic technology import, etc. Many countries have established or are in the process of setting up Export Processing Zones, essentially with tax incentives and facilities for the transfer of technologies, such as more freedom to hire expatriate experts.

Budgetary incentives, except scholarships, are more and more regulated by the new WTO agreements, particularly investment allowances, modernization grants, industrial subsidies and export compensations. This should be to the advantage of countries which cannot compete with the industrialized countries in subsidizing industry.

Legal and regulatory incentives are essential to protect intellectual properties and technologies, to enforce minimum technological standards, to facilitate the hiring of essential foreign experts (residence and work permits, tax holidays) and to discriminate technology imports. In Africa this type of incentives has also been used to enhance the status of researchers. Legal and regularity incentives need to be reviewed from time to time to adjust to changing circumstances. For instance, technology flows are more and more regulated by the market than by bureaucratic regulations although some regulations are needed.

Government procurement can provide important incentives to local industries to upgrade their technological capacity. India is currently not bound by the WTO disciplines on government procurement policies, and can, therefore, use such policies for the benefit of indigenous enterprises. Honorific incentives, such as prizes and awards, are public recognition of excellence and have proved to be particularly cost-effective in promoting innovation and technological improvement.

Incentives to strengthen the knowledge base, such as basic education, encouragement to take science disciplines, technical training, apprenticeship, sabbatical leaves, study tours, participation in international seminars, etc. are extremely important for any socio-economic development. Incentives are the tools which can be used to manage technological change and are vital for socio-economic development.

Incentives can be non-fiscal which may include infrastructure development for industry use like incubators and technology parks, or expanding access to skills through academia-industry interaction, supportive policies for regulation, intellectual property protection,

licensing and product approvals, establishment of testing facilities and standards and creation of awareness of public about biotechnology.

Indian Efforts in Biotechnology

Among the developing countries, India is one of the early investors in biotechnology. Efforts were started as public initiatives. Skill generation and infrastructure development along with knowledge generation were taken up by the Department of Biotechnology (DBT). Multi-pronged efforts established visible capabilities in the public research system. Despite these efforts for one and half decades very little has happened at the commercialization level. With its existing strengths of research capabilities and infrastructure there is a growing expectation from Indian industry to commercialize biotechnology products. There are around 200 firms working in different sectors like healthcare, agriculture, etc. Though there are about dozen products marketed in the country, only a few products are commercialized based entirely on indigenous efforts. This gap in realization of Indian research efforts as commercial successes has been a puzzle and to fill this gap DBT has been making various efforts in the form of policies, schemes and support for the past decade with very little success. Outputs of Indian biotech research have been predominantly published in journals and presented in conferences. Though around 40 technologies have been claimed to be transferred with the efforts of DBT, hardly any product has come out of these transfers. Human resource generation in India was initiated and continues to be under DBT's functions. Though the number of training institutions has increased, there is a severe shortage of manpower perceived by the BT industry in terms of both quality as well as quantity.

Even though India has invested in BT for about two decades (amounting to over 10 billion rupees) and has created over 300 research groups and more than 40 institutions training around 1000 post graduates and post doctoral fellows, the outcome has been only few products. Currently around 200 companies are involved in BT related activities, most of which are small in size. Of these, around 50 companies are involved in modern biotechnology (which includes recombinant DNA and cell fusion, like hybridoma technology techniques). All this portends to some grave problems that are encountered in commercializing BT in India. In this article, the author looks at the role of critical infrastructure and incentives in the context of commercialization of BT and Indian experience on this.

In order to find out the factors, which may not hit the casual observer or could be inferred from the large data available at different sources on Indian biotechnology, but that come in the way of commercializing biotechnologies in India, a detailed and in-depth study was necessary. This paper presents the results of the study undertaken during 2003-2004.

Studies by Visalakshi *et al* (1993) which analyses four cases and Ghosh (1996) (analysed 17 cases) throw light on the effort of commercialization in BT in the late 1980s and 1990s. Obstacles to commercial success identified by these studies are the following:

- 1) Institutions involved in R&D did not go beyond basic and applied research and had no funds or skills to do development, up-scaling, etc.
- 2) Joint development of products by research institutions and industry were very rare or non-existent, for reasons of confidentiality etc.
- 3) Reward system which was in place does not encourage post R&D phase activities by the investigating or technology managers to get involved.
- 4) Industry lacs the skills to absorb the technology developed by R&D institutions and to set up production facilities.
- 5) Lack of sufficiently strong patent protection discourages investment by industry in serious basic research.

While some of the problems identified by the above studies have been addressed, others continue to play a part in influencing commercialization of R&D results. The changing patent laws, evolving regulatory framework, and coming into being of new business efforts in the post-genomic era, etc. have created a need to have a look into the status of Indian biotechnology and its commercialization and draw sufficient insights for further action.

Sample Selection and Description

The sample was derived from various lists like the one by Biotechnology Consortium of India Ltd (BCIL) and added to the list companies from other sources. We had a list of about 350 companies involved in BT and BT related activities in the country. Of these 52 companies did not have valid contact information. Some of them we learnt later as not existing any more and some are still in the initial stage of formation.

Of the remaining companies, about 222 in number, the project team could visit 162 companies located in Ahmedabad, Aurangabad, Bangalore,

Chennai, Delhi, Hyderabad, Jalna, Mumbai, Pune, Surat and Vadodhara. We collected the required information for the remaining 60 companies from secondary sources.

The sample had a mix of small, medium and large companies. The ownership of the companies in the sample covered all types like public, private, MNCs and joint venture companies. The nature of activity was from research alone to research, production and marketing. The nature of technology used varied from modern biotechnology, traditional biotechnology and marginal biotechnology. The areas of operation spread to agriculture, health, industrial biotechnology, instrumentation etc. Product segments in which the selected companies were active are given below:

1. Agriculture

- (a) Aquafeed
- (b) Animalfeed
- (c) Biofertilizer
- (d) Biopesticide
- (e) Seeds (Hybrid)
- (f) Seeds (Transgenic)
- (g) Plant nutrients and others

2. Healthcare

- (a) Biotherapeutics
- (b) Diagnostics
- (c) Drugs/therap.
- (d) Probiotics
- (e) Vaccines

3. Industrial BT

- a) Enzymes

4. Services

- (a) Instruments
- (b) Res. Biology & reagents
- (c) CRO
- (d) CLRO
- (e) Bioinformatics/ genomics

The information sought pertains to

- Earlier efforts at commercialization of BT
- Problems faced
- Experience based opinion on incentives/facilitators of commercialization.

A questionnaire was devised which had basically three sections. An elaborate section was on the capabilities in terms of technologies transferred from various sources to the company and the types of problems faced in adapting and commercializing the same. The last section was on incentives they required to overcome problems/impediments. A suggestive list based on other country experiences was annexed. The data collection was done by both mail and by personal interviews using semi-structured questionnaire.

Analysis

Problems Faced by Companies during Commercialization

Based on the responses given by the companies visited and involved in biotechnology we have been able to find constraints to successful commercialization of biotechnology in the Indian context. We observed that they can be grouped under following categories: policy, fund/finance, skill, infrastructure, linkage, market/consumer and external influence like activities by countries outside the India.

List of factors which affect commercialization are of two types. One set of factors were recognized as common to many companies irrespective of their size, type of products they deal with, nature of their activities, nature of technology used and level of biotechnology involved. The other set includes factors which are specific to companies based on products or size, etc. As the techniques used is linked to the product, many a times we did the analysis as per product groups, e.g. biopesticides, vaccines, etc.

Table 1 gives the constraints identified by companies across the board under different categories.

Table 1: Constraints Identified as Affecting Commercialisation of Biotechnology

Category	Actual constraints
Funds	a) VC funds by state are stringent and difficult to get. b) Private VC companies are risk averse. c) Current funding pattern is not meeting entrepreneurs' needs. d) VC's are insensitive to specific features of BT. e) There is lack of awareness of banks about requirements of BT. f) Financial crunch stops collaborative projects as public R&D charges exorbitantly for facilities the services.

Table 1 continued

Table 1 continued

Fiscal	<ul style="list-style-type: none"> a) Tax holidays for BT are not there. b) Insensitive duty structure, Non-existent sales tax concessions, exemptions etc.
Skill	<ul style="list-style-type: none"> a) Public R&D outcomes are not amenable to commercialization. b) Academics lack entrepreneurial capability. c) There is mismatch between manpower generated by public system and industry's needs. d) The manpower generated is more of technicians (good at repeating work) than being creative/ innovative.
Policy	<ul style="list-style-type: none"> a) Non clarity about status of new business propositions – CROs, CLRo's, diagnostics, etc. b) Complicated and long licensing procedures. c) Non exclusive licensing discourages technology transfer.
External factors	Dumping of cheap products by certain countries discourage new ventures.
Market	Prohibitive cost of creating and developing market in India and abroad.
Infrastructure	<ul style="list-style-type: none"> a) Lack of incubators. b) Lack of concessions for power usage. c) Lack of consultancy support for establishing new ventures.
Linkage	<ul style="list-style-type: none"> a) Procedural problems discourage interaction with public research. Institutions. b) Lack of confidence, common language and transparency in interaction with academic partners. c) Lack of awareness of research institutions about requirements of industry and product development.
Organisational	<ul style="list-style-type: none"> a) Lack of appreciation of applied research work and efforts to attitudes transfer technology. b) Lack of entrepreneurial capability among public institute scientists. c) No encouragement for industry public R&D interaction. d) Lack of rewards to scientists (patents in the name of organization and not inventor).

From the above table, one can make out that funds and skills are major problems. Lack of understanding specificities of BT and its products appear to be coming in the way of devising facilitating policies which would encourage commercialization of biotechnology.

When the list of constraints was analysed to see any relationship with size of the company, we find finance related problems are more for small companies and policy related problems are faced mainly by large companies.

Companies with well established R&D facilities in their own companies have found accessing skill from public research system as a problem, while companies with less developed or no R&D of their own find lack of structures facilitating linkages with public R&D as a major obstacle.

It is observed that companies involved in marginal biotechnology had no problems of regulatory policies. Some of the companies involved in traditional biotechnology faced policy related problems like duty structure, definition/categorization of products, etc. Policies related to regulation and IP protection were felt as not clear and arbitrary which affected their activities and strategies for the companies engaged in modern biotechnology (MBT). These companies also felt the problems related to consumer awareness and market development.

The nature of the problem faced by companies attempting commercialization of vary with different product segments

Diagnostics have predominantly policy and policy derived market problems. Similar is the case with the production of new seeds including transgenics and biopharmaceuticals

Finding finance and developing market seems a major problem of support/service companies like instruments and reagent companies.

Probiotics, micronutrients, tissue culture, biopesticides and biofertilizers companies have common problems related to market in terms of awareness of competition and spurious products leading to loss of confidence. They all also have infrastructure problems in terms of QC, standards, testing facilities, etc.

Vaccines, enzymes and biopharmaceutical companies find problems in terms of in low level academia-industry interaction.

Unique Problems

Enzymes companies are unique in that the non stringent environmental regulation is a road block in creation of markets. Bio informatics companies want more stringent IPR laws in place that are implemented vigorously.

Biopharma companies are constrained greatly by lack of USFDA compliant infrastructure for clinical and pre-clinical trials.

Companies dealing in instruments find lack of recognition for their linkage with biotechnology and absence of special treatment as problems faced by them.

Biopesticide and biofertilizer companies feel pressure of chemical

companies lobby working against their good. They also find the registration process lengthy and cumbersome.

Diagnostics companies find lack of sera panel availability and rules for public procurement requiring companies to be in market for 2 years coming in the way.

Thus, there are many factors identified which are creating problems for commercialization of BT. The problems common to all are few and related to procedures and weak infrastructure, while those specific to various type of products are many. One could see some dependence of problems to size, viz. small companies have more finance related problem than large ones, which have can muster, enough resources.

Based on the opinions of companies, incentives which could facilitate the process of commercialization have been drawn. We found they could be grouped under the heads - fiscal, infrastructural, policy/procedures and skill.

List of incentives felt as required by the companies attempting commercialization basically fell into four categories: (1) fiscal (2) infrastructure related, (3) policy-related and (4) skill-related.

Fiscal

1. Incentives like tax benefits for export (as IT companies get) and reinstatement benefit which has been withdrawn for manufacturing companies who export.
2. Tax benefits/ holidays.
3. Favourable exchange rate for export.
4. 50% subsidy for capital expenditure in BT.
5. Duty free import of machinery.
6. Sales tax to be reduced in case of over competition (reducing greatly profit margin).

Infrastructural

1. Encouragement to collaborate with research institutes.
2. BT instruments, reagent manufacturers/suppliers need special treatment.
3. Testing, standards institutions to be created for recombinant therapeutics, regulatory data generation for transgenic, standard animal houses for preclinical, clinical facilities or at least identification and authorization of such facilities outside the country for compliance data generations.

4. Increasing awareness of VCs and financial institutions about BT business.
5. Establishment of quality standards and testing/ certifying facilities.
6. Land allocation on priority basis and at concessional rates (China gives it free of cost.)
7. Awareness creation (support) for BT products among consumers, bureaucrats, policy makers and implementing agencies.

Policy-related

- 1) Ban on import of BT products (diagnostics, vaccines drugs, etc.) when domestic capacity to produce exists.
- 2) VCs to be equipped with technical people for approval of proposals in BT.
- 3) VCs should have more freedom from CAG to take decisions in BT (despite high risk and long gestation).
- 4) Industrial R&D should be supported by public funds without strings of collaboration with public research organizations which charge exorbitantly.
- 5) Matching grant for people who want to put up incubators, or establish incubators for small and entrepreneurial ventures.
- 6) Harmonized system of classification of BT products which form the basis of tax structures for excise, import, etc.
- 7) Single window regulatory/licence clearance.

Skill-related

- 1) Facilities for field demonstration new agri BT products to be enhanced.
- 2) Industry academic interaction to be encouraged.
- 3) Skill generation through cooperation and consultation with industry.
- 4) Consultancy/guidance for starting new ventures in BT.
- 5) Facilitation of technology scouting.

From the above list, we can observe that they are corollary of the constraints faced. The incentives accordingly fall under fiscal, skill, infrastructure, awareness creation, easing procedure licensing, trade and regulation. Similarly there are incentives related to size product made technology used, etc.

Smaller companies look for more grants, loans and infrastructural support while companies which are big and established look for tax related incentives and lax regulatory but stringent IP laws. Across size,

companies feel a need for an incentive in awareness creation for consumers, establishment of testing facilities and standards, clarity among bureaucrats and policy makers about biotechnology.

Discussion and Conclusion

From the above analysis it comes out clearly that having a robust infrastructure and creation and existence of vibrant incentive structures can make a difference to outcomes of developing countries efforts to commercialize new knowledge. These become still more critical in knowledge intensive areas like biotechnology. In the case of developing countries, the companies in which commercialization occurs usually lacks capabilities at optimal level and hence depends on the technology delivery system (TDS) (Porter *et al* 1980) for its better performance. It is also observed that preparedness of TDS complements sub optimal capabilities in the companies (Visalakshi and Sandhya, 2000) in the case of Indian biotechnology. Our study brought out in an indirect way that problems and insufficiencies in these two factors become an impediment to successful commercialization. The major problems relate to skills and funds. The findings coincide with those of a study done in Australia (Anonymous 2002.) It is felt more by smaller companies as they are at start up stage and have no assets to prove their credibility or no revenue coming their way to plough back. This insufficiency also affects hiring people with suitable skills. This to an extent is taken care of by linkages with local public sector research institutions or universities. Some of the small companies have been promoted by technical persons who have contacts with these institutions and use facilities available with them for their work till their infrastructure gets set up and established.

For large companies while funds are not the major problem, there are problems in matching the skills with their requirements. They find the policies that delay the expected rate of return on their investments to be an impediment.

Incentives as they exist are less attractive and awareness of these also is very low and in many cases these schemes are under-utilized. Because of an overall precautionary approach lots of strings are attached to these grants-in-aid and soft loans types of funding of innovation in new areas. These conditions prohibit some of the companies to make use of them. For example, to be eligible for the grants/loans a company needs to tie up with a public research institution which always does the projects on time over

run. The other factor which discourages tie up with public and academic institutions is the exorbitant costs for services and facility usage. Policies relating to IPR and regulation are still in the process of evolving.

Thus, the whole situation has a great negative effect on the pace of commercialization. Public research system and companies in India have for historical reasons remained isolated from each other. Now there is realization of mutual dependence due to new policies and global aspirations. Still there is certain level of hesitation from either side in working together in a collaborative mode.

It is expected that factors like efforts of the government, enthusiasm by the industry, robust infrastructure, incentives, and improved capabilities of the companies will result in large scale commercialization of many products at a faster pace.

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