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TECHNOLOGICAL UPGRADING, MANUFACTURING AND INNOVATION: Lessons from Indian Pharmaceuticals

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TECHNOLOGICAL UPGRADING, MANUFACTURING AND INNOVATION: Lessons from Indian Pharmaceuticals

Dinesh Abrol[*]

[***Abstract***: *This article describes the impact of market friendly policy measures on manufacturing in the case of Indian pharmaceutical industry. It brings out that how the results have been less than encouraging for technological upgrading and innovation making. It traces the sources of failure of technological upgrading and the lack of depth (value addition) in manufacturing to the practice of a liberal regime of trade, investment and technology. It shows how the policymakers could not succeed in getting the private sector to re-prioritize the challenge of technological upgrading and innovation making through the perusal of market-friendly policy measures for the benefit of public health and the development of home market in the case of high value added pharmaceutical manufacturing. It would not be able to revive the prospects of high value added manufacturing in India by emulating the same policies which have failed to produce results for the pharmaceuticals. Therefore, the claim is that the new industrial policy package does not have much potential to change the prospects of industrial upgrading in a radically different way.*]

1. Introduction

Several new policy measures are under the consideration of UPA government on the front of technology upgrading for the benefit of industrial revival. Suggested policy measures are encompassed in the recommendations of the report entitled "Technology and Depth" which the planning commission issued in the month of August 2012 (Planning Commission, 2012). It is important to note that this report explicitly recognises that "India is slipping in the race for the lack of technological depth in its manufacturing sector". Of course, it still does not inform us about the sources of failures of technological upgrading in manufacturing[1]. But the proposed policy initiatives aim to get the government to coordinate the private sector by using still the market friendly measures and institutions[2].

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[1] Planning Commission (2012), "Technology and Depth: Recommendations and Implementation", Government of India, Delhi, August 2012.

[2] In the foreword to the report, Arun Maira, Member Planning Commission states the perspective that "the strengthening of manufacturing sector requires institutions that can coax and coordinate actions amongst multiple independent organizations. This is not easy for governments when most or all of the actors in a sector are private organizations rather than government organizations, as they are in

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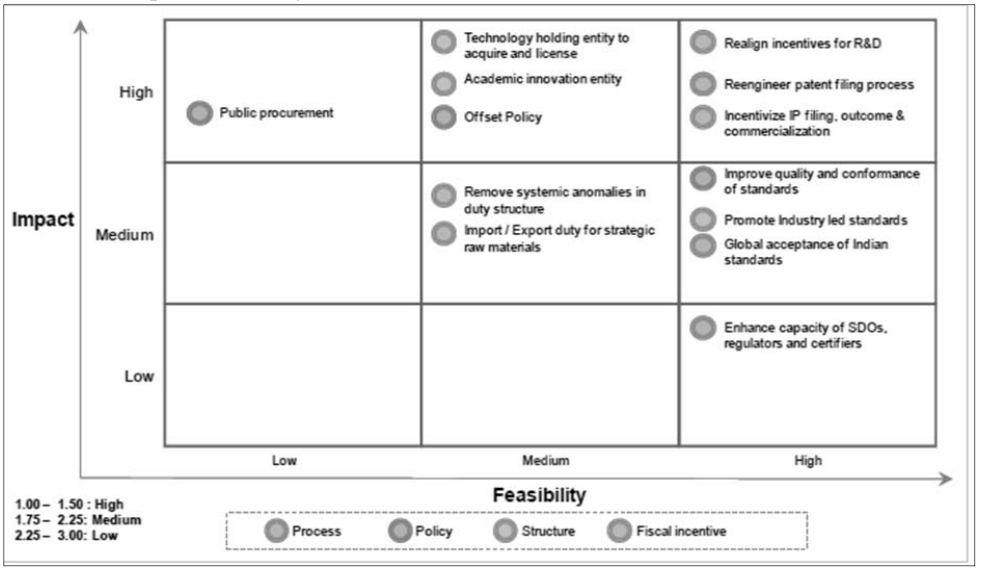
The government is being asked to provide priority to technological learning in a more concerted way through a greater push to industry led R&D, larger participation of industry in R&D, perusal of intellectual property for MSMEs, promotion of academic innovation through intellectual property, incentivisation for patent filing, creation of technology holding entity and public procurement policy, duty anomalies removal, promotion of industry led standards and for the prioritization of sectors with on-ground inputs from industry using tax incentives, grants and export duty improvement for strategic raw materials[3].

Given below is the impact feasibility matrix on the measures proposed to be implemented for technological upgrading within the framework of continuing with the policy of disinvestment, privatization, liberalization of trade and investment and deregulation.

Exhibit-7b: Impact Feasibility Assessment Matrix



India. In such situations, coordination can be brought about only through processes of coordination, rather than imposition of state authority".

[3] The report proposes that the government needs to create a public procurement policy, offset policy, duty structure anomalies removal and duty structure changes for strategic raw material, use standards for improving quality and conformance, promote industry-led standards and build global acceptance of Indian standards and create a process to prioritize areas and technologies by the country. The report divides the proposed 14 recommendations into four broad categories namely, strategic importance, quick wins, ease of implementation, indirect impact.
See Planning Commission (2012), "Technology and Depth: Recommendations and Implementation", Government of India, Delhi, August 2012, p 48.

The impact feasibility matrix has a clear message that the government should enhance its own direct intervention to maximize the impact through the implementation of stronger intellectual rights, removal of anomalies in duty structure, acquisition and licensing of foreign technology, offset policy, incentives for in-house industrial R&D and academic innovation and promotion of industry led standards. This would enable the government to deal with the failures on technology side. While the policymaking apparatus believes that this way a major hurdle would be happily removed on the front of the revival of manufacturing from the way of further progress, but should we take their current step of promoting the state intervention for the benefit of technological upgrading as breaking away from the present[4].

It is clear that the policymakers intend to keep fully intact the liberal policy regime on trade, investment and intellectual property regime. They are not seeking a radical transformation in the policy regime; only more incentives for technology upgrading are under consideration in order to give priority to manufacturing in the interest of enhancement of global integration by encouraging the industry to undertake a higher amount of exports from the knowledge-intensive segments. Most of these policy measures are going to be implemented as a part of the initiatives of 12th FYP. The government is not thinking of changing the policy regime through a legislation backed change. Changes in the policy regime would not be able to set the institutions and incentives right because the failures on the front of directionality of innovation and industrial promotion, steering and policy coordination, demand articulation would not be plugged through the proposed changes in the governmental promotion schemes. The policymakers wish to promote manufacturing through the policy measures that are not radically different from the steps under implementation for the benefit of technological upgrading in the case of Indian pharmaceutical industry.

Advocates of liberalization held the view that lack of acceleration in the pace of accumulation of technological capabilities originates from a) the absence of freedom for the large firms to pursue the prospects for profit and b) the lack of push for export promotion[5].

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[4] "Concerted action on priority areas for technological development, as well as the selection of these areas must happen through more systematic engagement of the producers and the various policy organs of government. The strength of the processes of coordination will determine the speed with which the country can develop technological depth and strength of its manufacturing (Planning Commission, 2012)."

[5] Pre-liberalisation policies increased the perceived risks of large firms in respect of the follow-up prospects of profits to be made, which in turn constrained these firms in respect of competence building and made them to innovation. Private sector firms were being stifled by anti-monopoly policy and industrial licensing system. Sellers' market operations were responsible for lack of technological improvement (Desai, 1987). Disagreement was expressed by the side opposing external liberalization on the grounds that per se government intervention & protection from foreign competition cannot be held responsible for the underdevelopment of national system of innovation (NSI) & technological stagnation (Subramaniam 1987). The side opposing external liberalization proposed in turn the promotion of internal competition, increased government procurement of

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More like the propositions promoted by Desai (1987) the current political apparatus also holds that the component of deregulation & opening up of the economy is a necessary ingredient in the policy package. Policy package is lacking in the component of sufficient promotion for the revival of industrial production. The introduction of a higher level of fiscal incentives and direct funding to private sector for research and development (R&D), participation of private sector in R&D decision making structures would do the job of technological upgrading better.

In this article we seek to analyse the evidence on the results for technological upgrading in the case of Indian pharmaceutical industry in order to bring out that how the results from the implementation of these policy measures have not been encouraging for manufacturing and technological upgrading. We assess the experience of pharmaceutical industry with a view to understand how much the policymakers could succeed in getting the private sector to re-prioritize through the proposed market-friendly policy measures the challenge of acceleration of technological upgrading. We trace the sources of failure of technological upgrading and the lack of depth (value addition) in manufacturing to the practice of a liberal regime of trade, investment and technology. It suggests that if the proposed changes in policy package are going to continue to set the larger objectives of industrial development in a market friendly manner, then the proposed market friendly measures do not have the potential to change the directions of technological upgrading in India.

Analysis of the impact of the market friendly measures of support under practice in the case of pharmaceutical sector for technological upgrading indicates that during the period of last two decades India failed to align the goals of industrial development with the goals of health and technological learning. Briefly the author also explores the challenges of realization of the synergy of linkages and possibilities available for the rejuvenation of the sectors of healthcare and pharmaceuticals in India because the levers of strategic importance got neglected and did not have a political priority. When the policy process is industry led, under the liberal policy regime the tendency of the industry was to go for the options that give them quick wins. The government has had a tendency to opt for the ease of implementation and the levers of indirect impact.

Analysis of the evidence gathered suggests that the response of domestic pharmaceutical firms has been lukewarm to the policy measures conceived for industrial promotion and innovation. Foreign firms are not interested to build technological depth to encourage high value added manufacturing. Limited success obtaining demands a rethinking in the light of the experience with the implementation of a similar policy package for the benefit of industrial development and innovation. We cannot expect the magnitude and directions of technological practising to be determined very differently from what the private sector is already able to achieve under the current trade regime of trade, investment and technology. The current policy regime favours the idea of complete freedom to industry in

products from local sources, expansion of internal markets through public investment & changed composition of growth, stronger linkages between RTD & users for major innovations.

the sphere of trade and investment which tends to encourage more the domestic firms to depend on imports of high value added intermediates, enter into collaborations with foreign firms for the deployment of existing production base for exports and rely on the location of low value added manufacturing to be profitable in business in India.

2. Achievements and Limitations of Technology and Depth

Experience obtaining from the period of last two decades on the front of manufacturing and technological upgrading in the case of Indian pharmaceutical industry tells us that our discussion needs to question the very assumptions of the current policy regime under use for industrial and economic growth. Analysis of the drugs / pharmaceutical sector is vital for understanding the contradictory impacts of the economic reforms on the patterns of performance in manufacturing because while the role of market friendly measures was export friendly for low value added exports it was not able to make the private sector technological upgrading friendly in the case of knowledge-intensive segment of the industry.

The drugs and pharmaceutical sector is a knowledge intensive and export promoting segment of the Indian chemical industry; today it accounts for 83 per cent turnover, 79 per cent exports, and 60 per cent R&D expenditure. Formulations account for 65 per cent and bulk drugs for the balance 35 per cent in value terms. While still the Indian drugs / pharmaceutical companies manufacture a wide range of generic drugs (branded and non-branded), intermediates, bulk drugs and Active pharmaceutical Ingredients (API), but it accounts also for 92 per cent of the imports of chemical sector. A large part of these imports are of bulk drugs, which is a knowledge intensive area of manufacturing. While its cumulative investment (1991-09) comes to 33 per cent of the knowledge intensive chemical sector, the foreign direct investment (FDI) inflows (2000-10) account for 71 per cent of all Indian industrial sectors. Much of this foreign investment has been of brown-field nature, which means that it has been for the acquisition of existing assets rather than for the creation of new assets and technological upgrading.

Indian pharmaceutical companies now account for over 30 per cent of all US Abbreviated New Drug Applications (ANDA) filings submitted to FDA. India has the largest number of US FDA approved manufacturing sites (100+) outside USA. While the aspects of low production costs and a very large talent pool provide India a clear edge over several developed and developing countries in the world, but the substantial part of Indian global investments are in the generic manufacturing field. India exports pharmaceutical products to more than 200 countries in the world and the bulk drug export accounts 90 per cent of Indian production with USA as its single largest export market. But 95 per cent of India's pharmaceutical market has its demand concentrated in the area of second and third generation drugs whose process technologies have become off patent in developed countries.

It is the foremost Indian sector to have taken full advantage of the product patenting facility under WTO regime. Nearly 42 per cent product patents filed at IPO during 2002-10 are from this sector with CSIR, Dr Reddy's, Dabur Research and NATCO leading the table. But India does not have any significant share in foreign oriented patent families (FOPFs) at global level. The FOPFs filed in various chemistry sub-disciplines by India, USA, Japan and China during 2002-06 shows that India is far behind China in intellectual property protection in almost all chemical sub-disciplines. Its contribution is less than 10 per cent of that achieved by China. India's best patenting performance in organics and pharmaceuticals achieved during 2002–06 are insignificant when compared to the number of FOPFs filed by the inventors from USA and Japan. India is far behind China, USA and Japan in filing FOPFs.

The Indian drugs / pharmaceutical sector are ranked 3rd in the world in terms of production volume and 14th in terms of domestic consumption value. The current Indian contract manufacturing predominantly focuses on low value and high volume intermediates, APIs and carrying out clinical trials. Strong domestic and international competition has already brought down profit margins significantly in recent times. Similarly the Indian CRAMS players are yet to look at new opportunities areas including high potency APIs, antibody drug conjugates and allied products. But the bulk of the patents taken for the production of technological outputs by the industry are not for new chemical entities and products.

3. Government Support

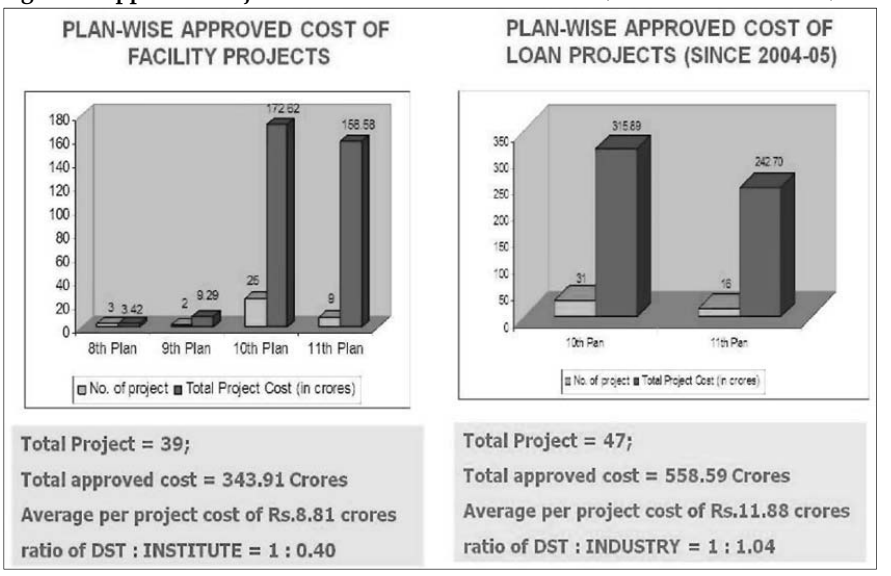
The schemes operated by different ministries / departments of the government, financial Institutions and others are intended for all categories of units *viz*., large, medium and small and even individuals in various subsectors. Considering the new challenges faced by the industry from time to time on account of liberalization and new obligations undertaken by India under the WTO, the Government of India took active interest in supporting the following initiatives for the Indian drugs / pharma industry:

- Modification of Drug Policy (1986) in 1994 to promote accelerated growth and to enhance the global competitiveness of the industry
- Recognition of the industry as the most important knowledge based industry
- Abolition of industrial licensing except for bulk drugs produced by the recombinant DNA and related technologies
- 100 per cent foreign investment through automatic route
- Extending the facility of 150 per cent weighted deduction of R&D expenditure under section 35 (2AB) of Income Tax Act till 31 March 2012
- Second Amendment to the Indian Patent act to allow product patenting in India from 1st January 2005
- Pharmaceutical policy 2002 (a) to improve incentives for R&D (b) further reduce the rigors of drug price control (c) strengthen the quality control system (d) provide incentive framework for attracting new investment into the pharma industry and new technologies and (e) reduce trade barriers for pharma exports

- Setting up Pharmaceutical Research and Development Committee (PRDC)
- Setting up Drug Development Promotion Foundation (DDPF) and Pharma Research and Development Fund
- Setting up a chain of National Institutes of Pharma Research and Education (NIPERs) to achieve excellence in Indian pharmaceutical sciences and technologies. A centre of excellence on bulk drugs will be established at Hyderabad by the NIPER in the near future.

The DPRP programme initiated in 1994 specifically addresses the R&D needs for the growth of the Indian drugs / pharma industry. The specific objectives of the programme are: Synergizing the strengths of publicly funded R&D institutions and Indian pharmaceutical industry to generate the collaborative R&D projects; creating an enabling infrastructure, mechanisms and linkages to facilitate new drug development; Stimulating skill development of human resource engaged in R&D and Enhancing the nation's self-reliance in drugs and pharmaceuticals, especially in areas critical to national health requirements.

Figure-1: Approved Projects under DPRP Scheme of DST (8 to 11 Five Year Plan)

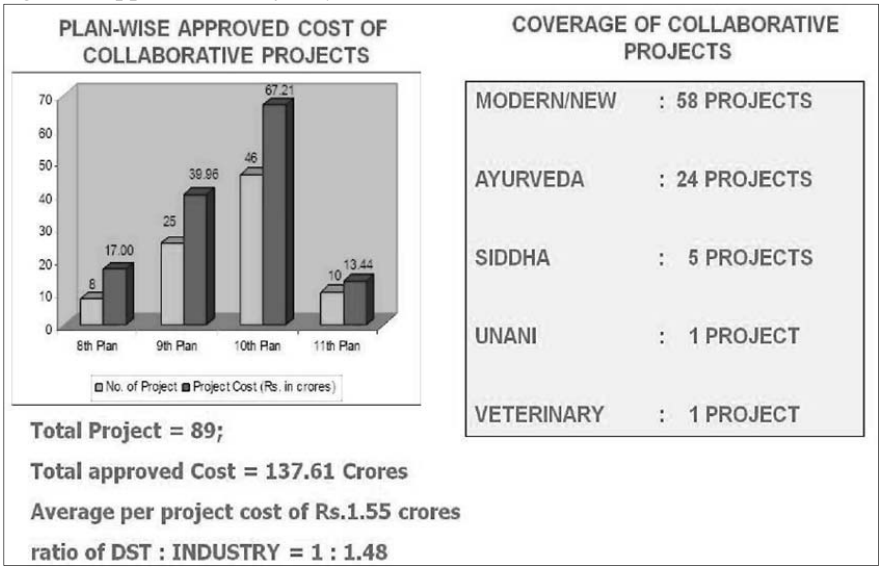


Source: R&D Impact on Indian Chemical Industry, Indian National Academy of Engineering, May 2011.

The DPRP programme supports variety of projects both in human and veterinary drugs through (i) industry-institution collaborative R&D projects (ii) creation of national facilities that are critical to the new drug development, (iii) pharma industry R&D projects, and (iv) clinical trials on neglected diseases. In case of type (iii) projects, the assistance will in the form of soft loan with 3 per cent interest with the principal payable over a period of 10 years. The programme supports both modern and traditional medicine oriented projects. The programme has so far supported 89 projects with an overall outlay of ₹137.61 crores

under collaborative project component. In addition the DPRP programme has supported 39 national facility projects and 47 pharma industry projects.

Figure-2: Approved Facility Projects under DPRP Scheme (8 to 11 Five Year Plan)



Source: R&D Impact on Chemical Industry, Indian National Academy of Engineering, May 2011.

The Technology Development Board (TDB) was established in 1996. The main objectives of the TDB are (i) to promote development and commercialization of indigenous technology and (ii) adaptation of imported technology for wider application. The TDB is the first organization of its kind within the government framework with the sole objective of commercializing the fruits of indigenous research. It provides finances in the form of soft loans and other financial assistance to innovative research and development projects. The TDB supports the following type of activities: Project funding for commercialisation of developments; Venture capital support; Seed capital support for new enterprises in the incubation centres and technology parks; Implementation of Global Innovation Technology Alliance (GITA).

The TDB provides financial support to industry for commercialization of indigenous technologies in the form of loan, equity and grant and a combination of these. Usually, the loan assistance does not exceed 50 per cent of the total project cost against soft collaterals. It carries an interest of 5 per cent and repayment is in nine half yearly instalments after one year gestation period from the date of commercialization. Usually the support does not cover purchase of land and construction of buildings. The assistance is available to industries in different sectors. But a substantial part of the funds has gone as loans for the chemical, health and medical sectors which have accounted for over 30 per cent of the total sanctioned funds over the period of establishment of technology development board.

The New Millennium Indian Technology Leadership Initiative (NMITLI) is a unique public-private partnership endeavour within the R&D domain. The Council of Scientific and Industrial Research (CSIR) is the implementing agency. The programme is based on the premise of consciously and deliberately identifying, selecting and supporting potential winners. The focus of the programme is to identify niche areas where India can gain leadership in about 10–15 years and to develop projects involving best brains of the country through a rigorous process. It builds knowledge network of partners from public funded institutions, academic institutions, Universities and private industries. Over the years, NMITLI has become the largest PPP programme in the country in the innovation space and enjoys an excellent reputation.

The main objective of the NMITLI is to catalyze innovation centered scientific and technological developments as a vehicle to attain for Indian industry a global leadership position, in a true 'Team India' spirit. The programme supports projects in all sectors of industry and provides funding to all partners. Whilst the funding is in the form of grant-in-aid to the publicly funded institutions, it is in the soft loan form to the industry repayable over a period of 10 years. NMITLI has so far evolved 60 largely networked projects in diverse areas. In the last six years NMITLI has supported 42 R&D in various fields including new targets, drug delivery systems, bio-enhancer and therapeutics for psoriasis, M. tuberculosis, pain management in osteoarthritis, insulin sensitization in diabetes mellitus type II and process of tamiflu etc. with about 287 partners, 222 in public sector and 65 in private sector with an estimated outlay of over Rs 300 crore. Although the NMITLI scheme of CSIR is apparently a major success story, but a large number of NMITLI PPPs have preferred to catalyze health innovations as a vehicle for the diseases that the domestic industry considers important for enhancing exports in Type I and Type II disease areas.

The current level of industry – University / academia / R&D institutions linkages in the case of Indian pharmaceutical sector is very disappointing. The general perception of the industry about the effectiveness of these programmes is that they have not achieved the success to the desired extent due to inadequate fund allocation (less than Rs 300-500 crores / annum for all programmes put together), long processing time, lack of remedial action on earlier programme failures, ineffective implementation, relatively lower priority assigned to R&D commercialization by the R&D institutions and suboptimal participation of private sector companies. See *Table-1* for the details.

Table-1: Pattern of Funding under Government R&D Support to Industry

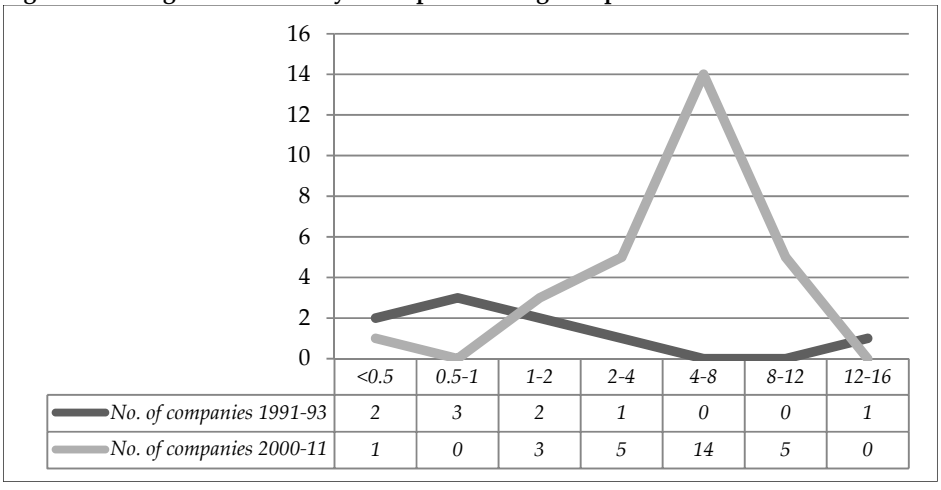
Scheme	*Disbursement per annum*
Small Business Innovation Research Initiative (SBIRI)	₹80 crore
Biotechnology Industry Partnership Program (including non-pharma sectors)	₹55 crore
Drugs & Pharmaceuticals Research Program (including non-pharma sectors)	₹70 crore
New Millennium Indian Technology Leadership Initiative (NMITLI) (including non-pharma sectors)	₹37 crore
TDB	₹21 crore
Total	**₹263 crore**

In order to provide the justification for the claim made with regard to the change being only incremental we give here below some of the details of evidence of the connection of response of the private sector with the policy regime on trade, investment and technology to offer a critical assessment of the sources of failure on the basis of analysis of the pattern of changes experienced by the area of pharmaceutical innovation over the period of last few decades in India.

4. Impact on the Prospects of Reverse Knowledge Transfer

Evidence shows that only six firms have been able to increase their R&D investments in a significant way. Even the R&D expenditure of the top fifteen Indian pharmaceutical firms that have internationalized themselves in a big way during the period of last one decade is still nowhere near the expenditure being incurred by the generic companies of Israel and Europe[6]. See *Figure-3* for the details.

Figure-3: Average R&D Intensity for Top 14 Leading Companies



	<0.5	0.5-1	1-2	2-4	4-8	8-12	12-16
No. of companies 1991-93	2	3	2	1	0	0	1
No. of companies 2000-11	1	0	3	5	14	5	0

Note: Top 14 leading Indian Pharmaceutical Industries are: 1. Ranbaxy laboratories, 2. Cipla ltd, 3. Dr Reddy's Laboratories, 4. Cadilla healthcare, 5. Biocon Ltd, 6. Sun pharmaceuticals, 7. Lupin Ltd, 8. Piramal healthcare, 9. Glenmark pharmaceuticals, 10. Torrent pharmaceuticals, 11. Strides arcolab, 12. Wockhardt ltd, 13. IPCA laboratories, 14. Orchid pharmaceuticals)

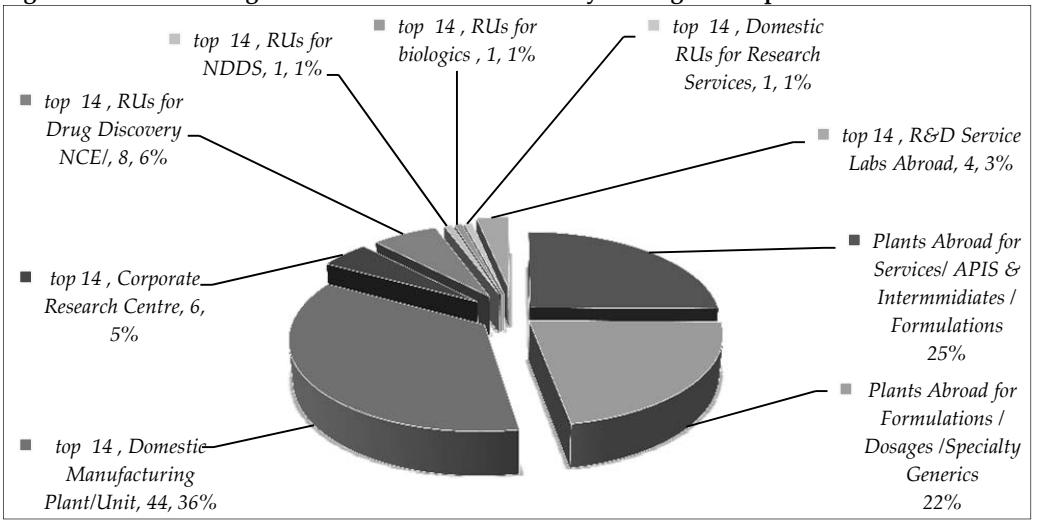
Source: Prowess Database, CMIE 2011.

The pattern of marketing and advertising expenditure and royalty payments being made to local and foreign sources shows that the in-house capability development culture and management is of conventional nature and does not show the features of any kind of

[6] Ranbaxy is now no more a domestic company and has been sold by its Indian promoters to Daichi Sankhyo, a Japanese multinational. Of course, Dr. Reddy's Laboratories, Cipla, Glenmark, Lupin, Cadila, Wockhardt, Torrent are still around as integrated Indian pharmaceutical companies which have also built substantial foreign sales.

unique or distinct institution. Similarly take the establishment of specialized R&D laboratories at home and abroad for the benefit of product development. Over the period the scale of progress being shown by the pharmaceutical firms is hardly promising in respect of reverse knowledge transfer and acquisition. Abroad these firms have done far less for the establishment of research units as compared to for the establishment of marketing set ups. Even the manufacturing plants established abroad through acquisition are practicing less complex technologies and low value added activities. R&D facilities are far more for the purpose of dossier preparation for generic entry rather than for the development of new products. The objective of gaining an entry in to the regulated markets of US and EU for the introduction of generics has remained a major focus of building the firm specific competencies for these firms. Firm specific capabilities were mainly built for the filing of drug master files (DMFs) and abbreviated new drug application (ANDA) work prior to registering products (generics). See *Figure-4 & -5* for the details.

Figure-4: Manufacturing & R&D Facilities established by leading Indian pharmaceutical firms

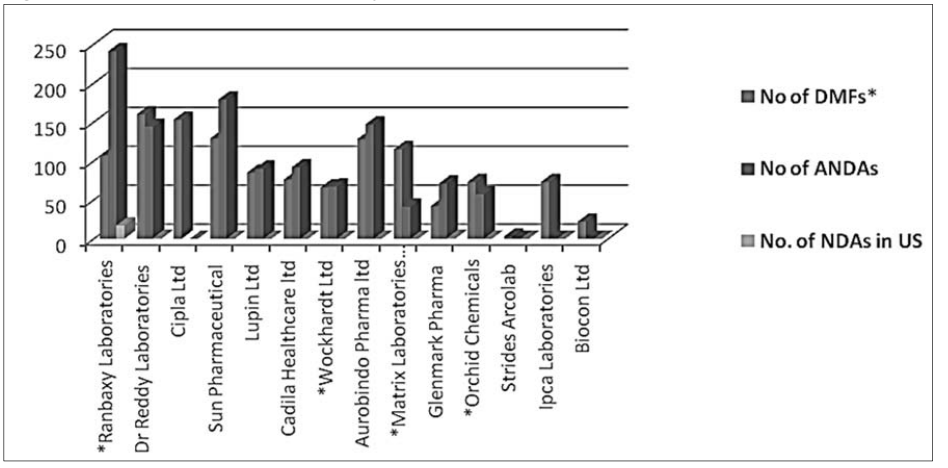


Note: Companies are now became foreign companies after the acquisition of Ranbaxy by Daiichi Sankyo in 2009 and acquisition of matrix by Mylan in 2007, acquisition of Shantha Biotecnics by Sanofi Aventis in 2009, acquisition of Nicholas Piramal (Health Unit) by Abbott Laboratories, acquisition of a part of Orchid Pharma by Hospira Inc .US, acquisition of Wockhardt Ltd (Nutritional Arm) by Abbott Laboratories.

Source: Individual Company websites, data accessed as on November 2011.

Assessment of the relationships forged while undertaking outward foreign direct investment (OFDI) for the acquisitions, alliances, collaborations and agreements indicates that these firms have failed to give priority to the objective of capability for new drug development. Investments have not been undertaken for the establishment of appropriate industrial networks using the possibilities available at home and abroad. When we analyze the details of the emerging pattern of alliances and collaborations to study the pattern of acquisition of assets by all these companies, the number of alliances, collaborations and

Figure-5: ANDAs and DMFs filed by these Firms in US



Note: As at March 2009 the sales data for Matrix, Glenmark is for the financial year 2007-2008, Sun Pharma includes in Subsidiary Caraco.

Source: No. of DMF Data from http://www.betterchem.com (Drug master file database) and no. of Abbreviated New Drug Application (ANDA) from individual company website. Data accessed as on December 2009

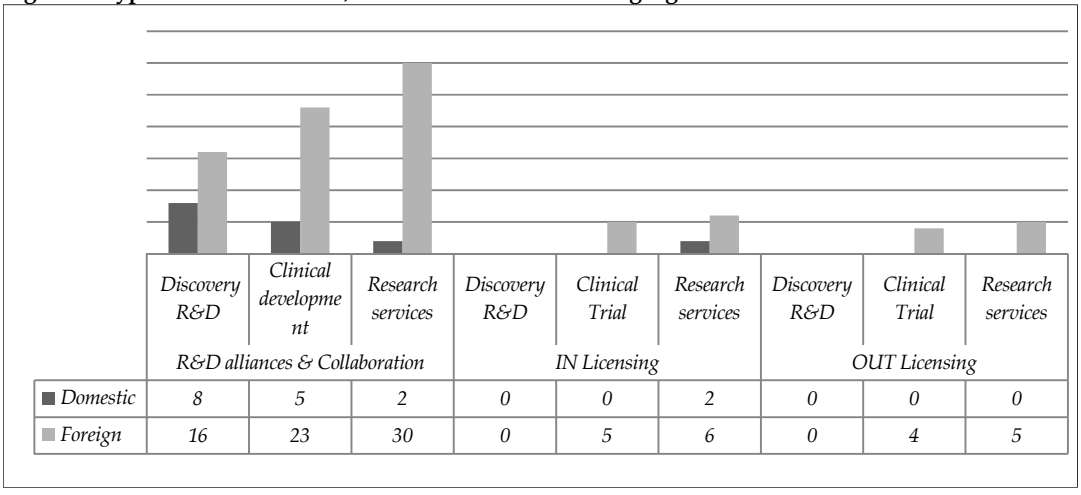
acquisitions have only remained right through skewed in the case of all the fourteen firms in favour of the purposes relating to marketing, manufacturing and supply of R&D services. Their acquisitions were mainly for the strengthening of their foreign marketing. Even a smaller number of firms are involved in the asset augmentation for the purpose of manufacturing. R&D alliances and collaborations involved still fewer firms.

Foreign firms account for the maximum number of alliances, collaborations and licensing agreements entered into by these firms during the period under observation. In the case of R&D related ties, research services function dominated the relationships forged with the foreign industry. It is also clear that these firms did very little to use the alliances, collaborations and agreements to strengthen their drug discovery. Discovery R&D was the objective of relationship forging with foreign firms in far fewer cases compared to research services and clinical trials. While these firms have hardly used the relationships capable of being established with foreign public research institutions for the strengthening of R&D function and new drug discovery and development, but even in their relationships with foreign firms it is the short term objectives which seem to have dominated. See *Figure-6, -7, -8, -9 & -10* for the details.

Foreign firms are apparently gaining in terms of financial gains and control far more from the R&D and marketing relationships than that these companies could forge for R&D and marketing functions through OFDI. Take the examples of out licensing and in licensing agreements being signed by these companies. In the case of in-licensing agreements payments to foreign firms are on a recurrent basis and are guaranteed returns. Imbalance is also evident at the level of number of agreements entered into by these companies for marketing and research. Marketing as a purpose dominates the agreements. However,

when we also analyze the impact of agreements entered into for R&D purpose by these companies on the capability building, there is an imbalance evident. In-licensing agreements in R&D area are for bio-equivalency studies. In respect of product development, the area of bioequivalence is not a gap that has to be filled through in-licensing agreements. However, this is not the case when one analyzes the out-licensing deals because the agreement pertains to the clinical development of earlier phases and pre-clinical toxicology studies, etc.

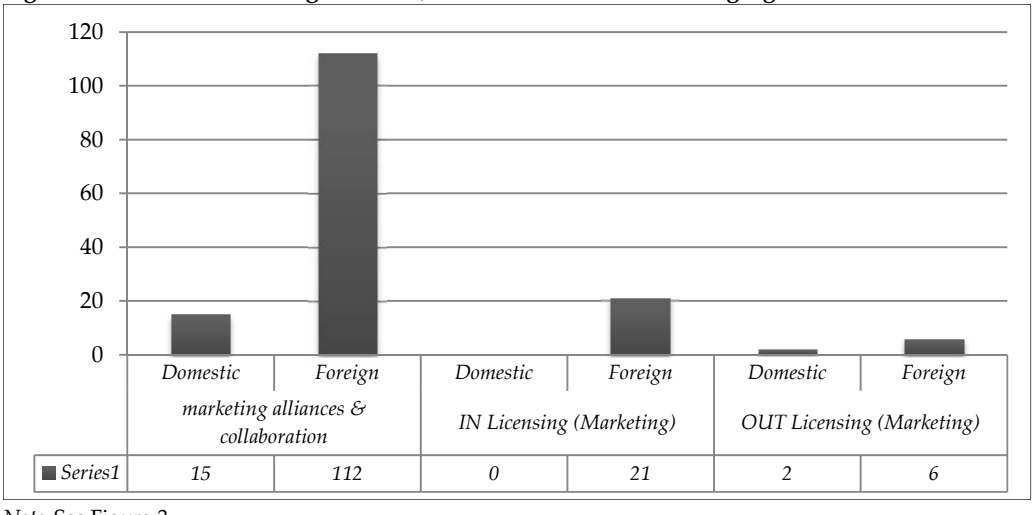
Figure-6: Type of R&D Alliances, Collaborations & Licensing Agreements 1999-2011



	R&D alliances & Collaboration			IN Licensing			OUT Licensing		
	Discovery R&D	Clinical development	Research services	Discovery R&D	Clinical Trial	Research services	Discovery R&D	Clinical Trial	Research services
Domestic	8	5	2	0	0	2	0	0	0
Foreign	16	23	30	0	5	6	0	4	5

Note: See Figure-3
Source: Individual company website press releases, news, archive etc, data accessed as on November 2011.

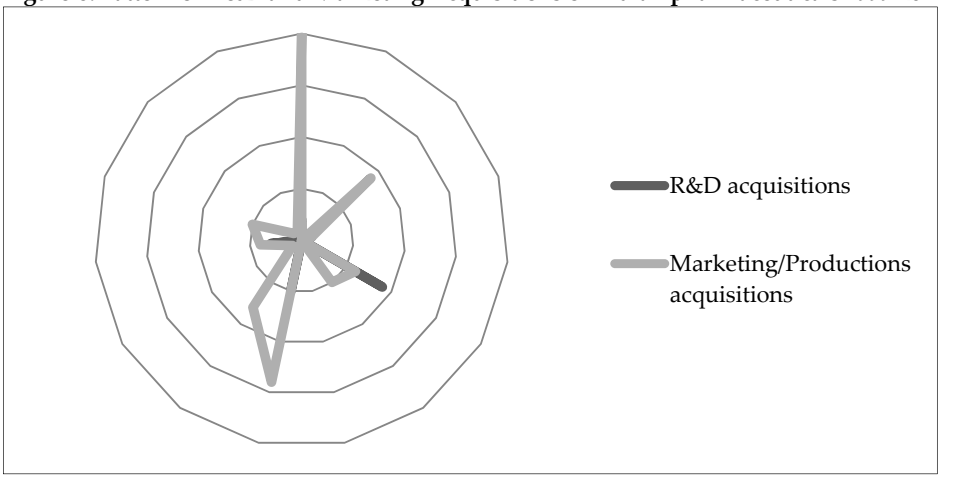
Figure-7: Pattern of Marketing Alliances, Collaborations and Licensing Agreements 1999-2011



	marketing alliances & collaboration		IN Licensing (Marketing)		OUT Licensing (Marketing)	
	Domestic	Foreign	Domestic	Foreign	Domestic	Foreign
Series1	15	112	0	21	2	6

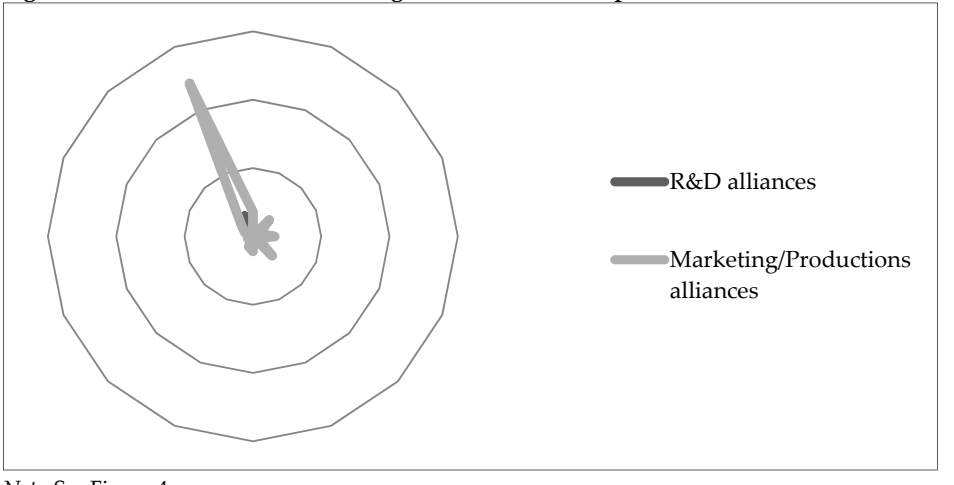
Note: See Figure-3
Source: Individual company website press releases, news, archive etc, data accessed as on November 2011.

Figure-8: Pattern of R&D and Marketing Acquisitions of Indian pharmaceuticals 1999-2011



Note: See Figure-3
Source: Individual company website press releases, news, archive etc, data accessed as on November 2011.

Figure-9: Pattern of R&D & Marketing Alliances of Indian pharmaceuticals 1999-2011

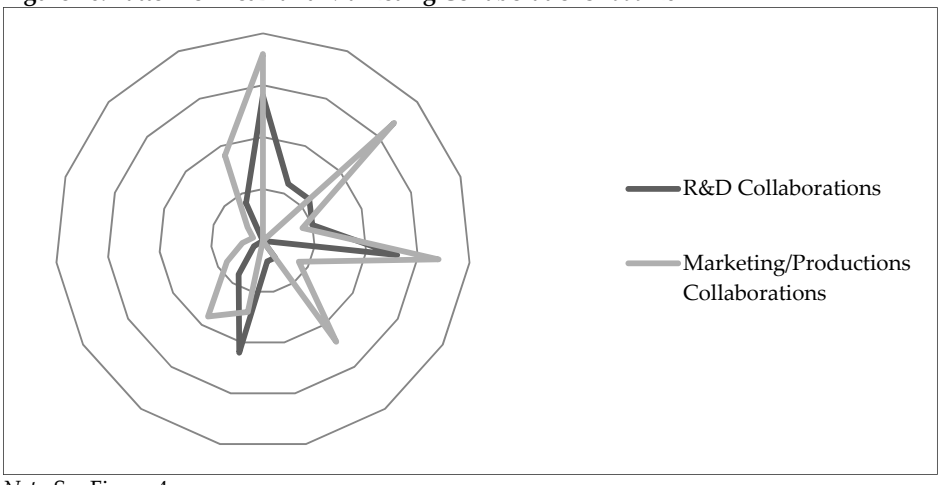


Note: See Figure-4
Source: Company annual reports and websites, accessed April 2010.

Compared to the acquisition of manufacturing and distribution arms abroad by each and every firm only a smaller number of firms have acquired firms abroad with the motive of upgrading R&D capabilities in the sample. Even as far as the number of acquisitions made for boosting the drug discovery R&D purpose is concerned it is a tiny number reflecting the overall bias of OFDI connections in favour of lower priority being given by the firms to the objective of reverse knowledge transfer and acquisition. R&D acquisitions were mostly for the acquisition of research service facilities needed to be established for the benefit of generic entry. Research services function has dominated the acquisitions made. It is clear

that so far the main objective of acquisitions has been limited to getting facilities in the host country for the preparation of dossiers and undertaking laboratory work.

Figure-10: Pattern of R&D and Marketing Collaborations 1999-2011



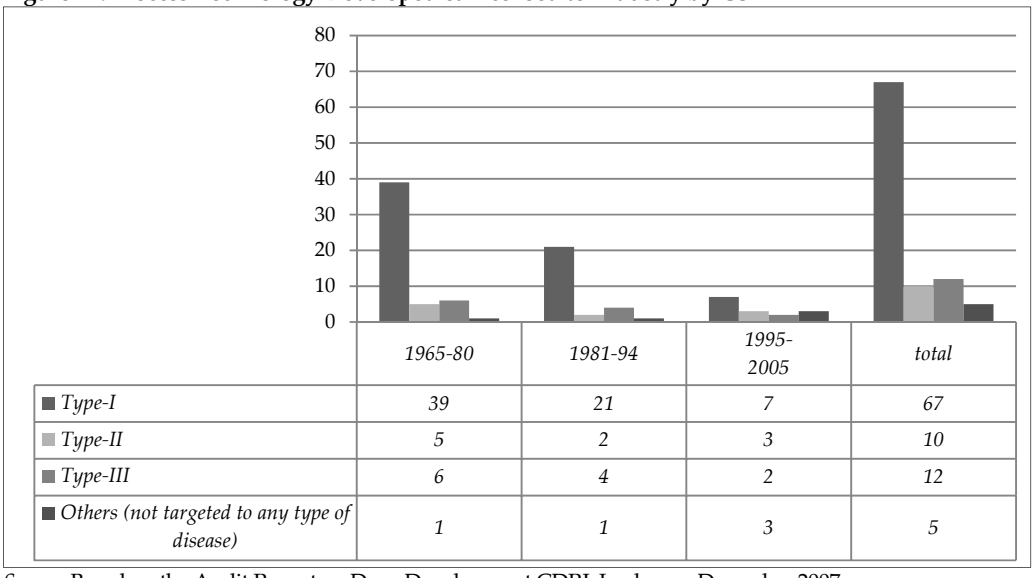
Note: See Figure-4
Source: Company annual reports and websites, accessed April 2010.

5. Impact on New Product Development

Bulk of the "innovative outputs" still belongs to the areas of dosage / formulation/ composition of matter and process related R&D. Their patenting activity continues to be largely tilted in favour of the development of processes, new forms of substances, dosages and formulations, new drug delivery systems. The number of patents granted to these companies for the new chemical entities (NCEs) is small. Assessment indicates that attempts are still limited to the activity for product development being confined to the development of analogue molecules. The chemistry driven process research capable of giving non infringing processes for the manufacture of active pharmaceutical ingredients (APIs) and identifying and characterizing the impurity profiling pertaining to APIs have been the priority objectives. The other area of R&D pertains to formulations where Novel Drug Delivery System based products (NDDS) are also introduced. The focus on new chemical entity (NCE) development is quite recent for the emerging Indian multinationals. See *Figure-11 & -12* for evidence on the nature of technological performance.

At the moment there is only a small amount of activity going on in respect of new chemical entities (NCEs) in DRL, Glenmark, Lupin and Sun [Pharmaceuticals for the benefit of foreign markets. Analysis undertaken of the R&D objectives confirms that the Ranbaxy Laboratories had the highest level of achievement with regard to filing of patents for all kinds of inventions except in respect of NCEs. In the case of NCEs Dr. Reddy's Laboratories has the highest level of achievement. Even the higher end competitive strategies adopted by Indian pharmaceutical firms differ in terms of their emphasis.

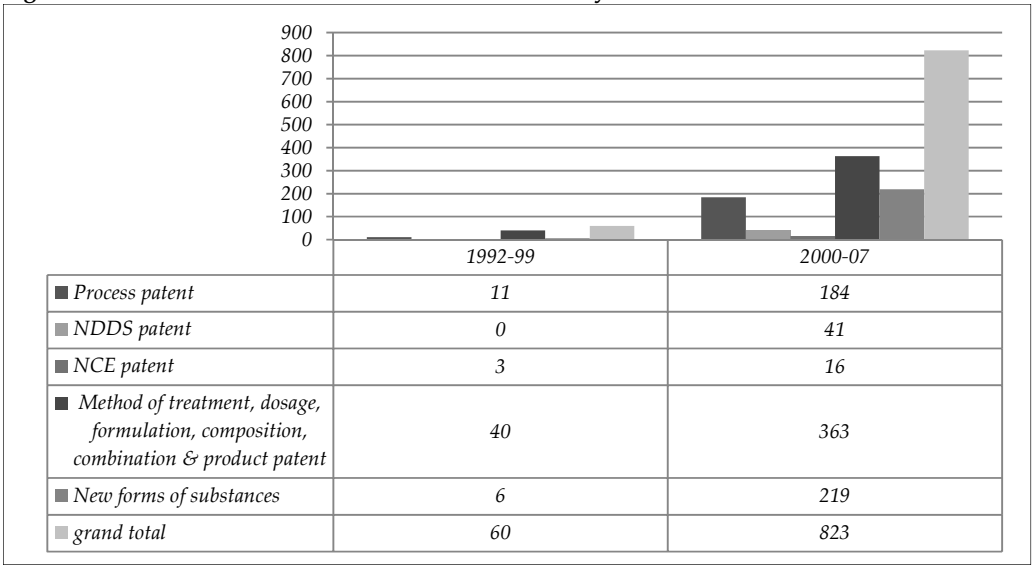
Figure-11: Process Technology Developed & Licensed to Industry by CSIR



	1965-80	1981-94	1995-2005	total
Type-I	39	21	7	67
Type-II	5	2	3	10
Type-III	6	4	2	12
Others (not targeted to any type of disease)	1	1	3	5

Source: Based on the Audit Report on Drug Development CDRI, Lucknow, December 2007.

Figure-12: Evolution of Domestic Pharmaceutical Industry Patents in USPTO 1992-2007



	1992-99	2000-07
Process patent	11	184
NDDS patent	0	41
NCE patent	3	16
Method of treatment, dosage, formulation, composition, combination & product patent	40	363
New forms of substances	6	219
grand total	60	823

Note: NDDS-New drug delivery system, NCE-New Chemical Entity

Source: Emerging patterns of pharmaceutical Patent innovations, data collected from USPTO of 1992-2007 and Patent Classification (Process, product, NDDS, Method of treatment, NCE, Dosage, Formulation, Composition, New forms of substances (Salt, Polymorphs, Derivative, Amorphous, Analog, Conjugate, Crystalline, Esters, Isomers, Metabolite, Solvates) is done by using *International Patent Classification* (*IPC*).

Glenmark Cipla and DRL are into actively focusing on specialty generics[7]. Only a few of them are still trying to gain related drug discovery abilities. In India, the firm specific processes for new chemical entities (NCE) based drug discovery started in 1994 with Dr. K. Anji Reddy of Dr. Reddy's Laboratories (DRL), earlier working an important public sector unit namely Indian Drug Pharmaceutical Limited (IDPL), setting up the first new drug lab at Hyderabad as a distinct facility for drug discovery work.

Although there are at least 10-12 Indian Pharmaceutical companies that are working on the development of new products in the sector of drugs and pharmaceuticals, and an estimated 60 new compounds are known to be in various phases of development and testing, but not too many of these compounds are expected to be successful and are being abandoned and discontinued or further R&D work. Out of 47 compounds analyzed over 20 compounds were abandoned by these companies at various stages of development (Abrol, Prajapati and Singh, 2011). The current portfolios of NCEs under development through these firms are mostly at their early stage of development at the moment and the drug that is in final phase is not a high burden disease.

Even now the emerging Indian pharmaceutical multinationals remain compelled to depend on the capabilities of their competitors in respect of pre-clinical and clinical research. None of the Indian pharmaceutical companies is engaged in the entire process of drug development. No Indian company claims to have all the resources to pursue the cutting edge and take a new compound through all stages up to marketing. While costs of conducting research in India are lower compared to the developed market economies because of low cost scientific manpower, the fact is also that at this stage India is still weak in respect of the early stage of drug discovery capabilities. Even this happens to be the case with regard to the capabilities for the stage of drug development.

Dr. Reddy's Group was the first domestic company to file the first two product patent applications for anti-cancer and anti-diabetes substances in the U.S. For the further work on product development DRL licensed out its diabetes molecule to Novo Nordisk in 1997. This molecule had to be dropped later at the stage of clinical trials due to toxicity issues. But it is also clear that Dr. Reddy's Group still does not want to engage autonomously in drug development. It is interested in selling its rights to the partners abroad for the reason that it does not have the capacity to invest further and stopping after the stage of drug discovery work. Examples of Wockhardt joining hands with Rhein Biotech GmbH, Germany, Ranbaxy shaking hands with Eli Lilly and Schwartz Pharma AG for development work, Cipla undertaking custom synthesis, collaborations with Japanese and Swiss firms, indicate the limitations of and opportunities available to Indian firms.

[7] A company not only obtains a patent on active ingredient involved in the new drug but also have secondary patents relating to the same active ingredient, such as, new formulations and compositions, e.g., new dosage forms; new salts, esters, etc. of existing ingredients; new uses and new process for manufacturing.

Almost all the emerging Indian companies are pursuing the strategy of R&D collaborations to lower their costs and risk factors. Strategy pursued is to find a new drug within an existing family that has been discovered-finding a compound that is analogous to a discovered compound like DRL where originally Sankhyo was doing work on Giltazones. This strategy cuts down on the risk. A company can reduce some of the uncertainties of new drug research though this may not produce a drug as big as a blockbuster. The second strategy is out licensing where the Indian company takes some leads to pre-clinical stage. Then it may strike a deal with MNC who will have the right to market the compound in a particular market if all tests are cleared. The Indian company gets milestone payments for each stage of clinical trials the compound clears. Companies like Ranbaxy, DRL and Glenmark are all following the out licensing the route. DRL has tried a deal with Novratis too for further work on an anti-diabetic compound DRF 4158. Ranbaxy entered into a deal with Bayer for Cipro NDDS and RBx 2258 (BPH). Glenmark has tried a deal with Forest of North America and Tejin of Japan for compounds that could provide treatment for asthma. However, the level of success obtained by these companies through the routes currently under perusal has not yet yielded the desired results in respect of new product development.

Not only domestic pharmaceutical firms have been ready to out license clinical development of their new chemical entities to the firms that have considerable market operations in the sector of drugs and pharmaceuticals in India, but also they are entering in to in-licensing deals for undertaking bio-equivalence studies in case of formulations and dosages. In–licensing arrangements are being used to build up the portfolio for the purpose of growing in the domestic market. For example, Nicholas Piramal has had arrangements with Roche for launching products of Roche dealing with cancer, epilepsy and AIDS. Glenmark has in-licensed Crofelemer, Napo's proprietary anti-diarrheal compound. Wockhardt has had arrangements for the in-licensing of Syrio Pharma SpA for dermatology products. Ranbaxy has had arrangements with KS Biomedix Ltd for EMRs to market Trans MID in India with an option to expand to China and other South East Asian Countries.

6. Impact on Academia-Industry Interactions

Domestic ties with research institutions and academia have received a least amount of attention from the emerging Indian pharmaceutical multinationals. Although domestic firms are the major beneficiaries of R&D services sourced from public sector research laboratories, but there are very few alliances for undertaking collaborative drug discovery and development related R&D work between domestic firms and public sector research institutions. Just two firms used the domestic R&D institutions for the purpose of R&D alliances.

Evidence is quite clear that what really dominates at present the scene of alliances and collaborations is the marketing activity related relationships. Some of the Indian pharmaceutical firms have preferred to rely only on marketing alliances abroad instead of

setting up subsidiaries or production facilities. We also note with some concern that most of these firms have also chosen to enter into alliances, collaborations and agreements with the foreign firms having presence in the Indian market. By forging a close relationship for the supply of contract research and manufacturing services with the very foreign actors which have a global presence quite a few of these firms are making clear that they do not have any plan to compete with the Big Pharma in future in either the domestic or the foreign markets. Lupin had a marketing alliance with Cornerstone to market Suprax. DRL has an alliance with Pilva, for development and marketing of oncology products in Europe; DRL and Glaxo-Smithkline have a multi-product agreement; DRL is collaborating with Pharmascience Group for development and marketing of generic products in Canada; Glenmark's supply and marketing agreement with Lehigh Valley. Certainly some of these marketing alliances reflect an element of strategic choice. At the moment DRL, Glenmark and Lupin are seemingly the examples of strategic elements guiding them in their relationships, but it is not the case with most of the firms whose relationships we have analyzed.

In a very few cases domestic R&D institutions have been targeted for in-licensing agreements. In some cases the global pharmaceutical companies are out-licensing their products to Indian firms. This relationship brings about regular royalty payments at minimum investments with a wider geographical coverage for their products. Strides Acrolab Ltd has entered into a number of such deals with companies in United States, United Kingdom, Japan and Europe. Clinical outsourcing is also being treated as a lucrative strategy by some of the Indian firms. Cadila Healthcare has entered into alliances with Atlanta Pharma, Schering AG, and Boehringer Ingelheim. Lupin has a licensing agreement with Cornerstone Bio Pharma Inc for clinical development of NDDS for an anti-infective product.

Ranbaxy entered into a few collaborative research programmes involving global pharmaceutical firms, e.g. with MMV, Geneva for an anti-malarial molecule, Rbx 11160; with GlaxoSmithKline for drug discovery and clinical development for a wide range of therapeutic areas; with University of Strathclyde, United Kingdom in new drug delivery system (NDDS); Ranabaxy has a collaborative relationship with Eli Lily, Pfizer and Novartis in drug discovery and with Vectura, a drug delivery company for the development of platform technologies in the area of oral controlled release system. Ranabaxy, Reddy's Laboratories, Lupin, Glenmark, Torrent, Sun pharmaceutical, Cadila and Biocon figure prominently in the agreements, collaborations and alliances entered into for the R&D purpose. But there are only a few examples of collaborative R&D programmes which follow one or another kind of risk sharing involving joint venture or collaboration with another pharmaceutical company in order to develop and commercialize a product. They are largely entering into one-way relationships which are hardly going to give them advantage in the long run.

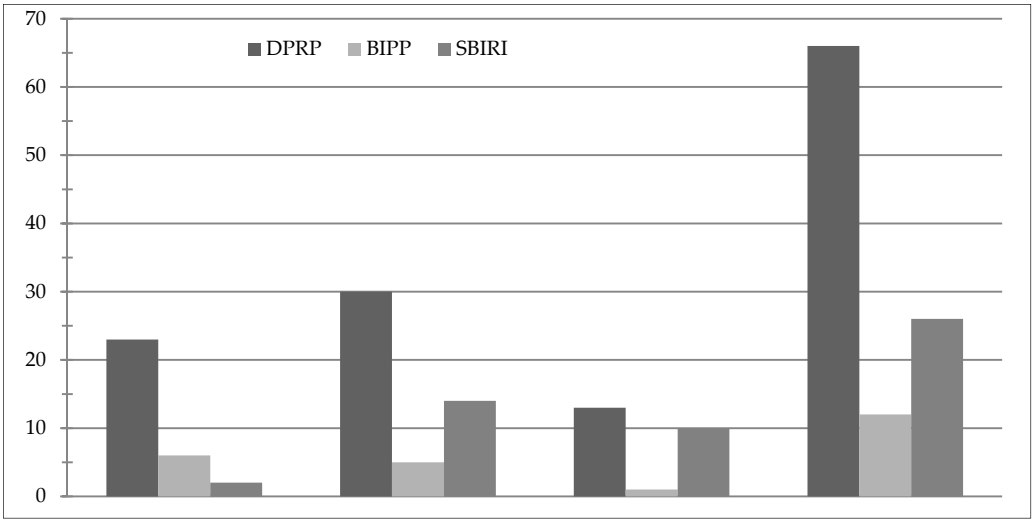
Torrent has entered into a collaborative research programme for the drug discovery in the area of treatment of hypertension with AstraZeneca. Dependent or potentially

compromising relationships would not benefit the firms as much and can the affect the national system of innovation adversely when pressures are being mounted on the industry to accept TRIPS plus provisions of data exclusivity and so on. Of course, there are still some exceptions. Cipla has entered into a collaborative programme of risk sharing type with a domestic company set up by a non-resident Indian namely Avesthagen Laboratories to produce biogeneric drug for Arthritis, N-Bril. Although Avesthagen has an ongoing collaborative programme with Nestle, BioMereleux, France and other companies, but the relationship of Cipla with Avesthagen is unlikely to prove compromising and can be handled independently.

7. Impact on Articulation and Development of Domestic Demand

The emerging Indian pharmaceutical multinationals consider the domestic market to be of small size and not sufficiently attractive for taking up the development of new products in the drugs and pharmaceutical sector. Most of the compounds belong to the category of Type I diseases in which there exists the demand. In the absence of stimulus for augmentation of home demand within the country the conditions continue to favour the target of low value added products required by the global markets. It is this imbalance in the policy design which is now reinforcing skewed research priorities in the public sector research system too. From the point of view of prevailing public health situation this certainly does not suit the country on whose shoulders the domestic industry still depends (See *Figure-13, -14, -15, -16, -17 & Table-2, -3).*

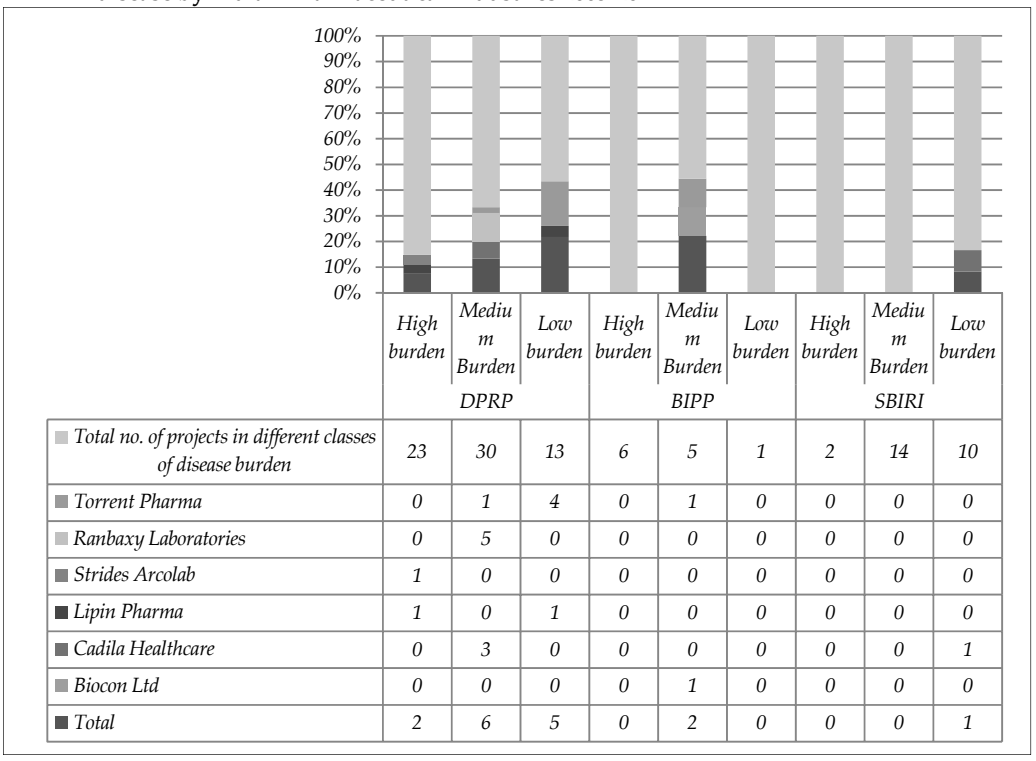
Figure-13: Pattern of R&D projects obtained by the firms from government funded programs & schemes in terms of their burden of disease orientation



Note: DPRP- Drugs & Pharmaceuticals Research Programme; BIPP- Biotechnology Industry Partnership Programme, SBIRI-Small Business Innovation Research Initiative

Source: DPRP, BIPP, SBIRI website, data accessed as on November 2011.

Figure-14: Firm-wise pattern of Government agencies Programmes/Schemes funded burden of disease by Indian Pharmaceutical Industries 2005-2011



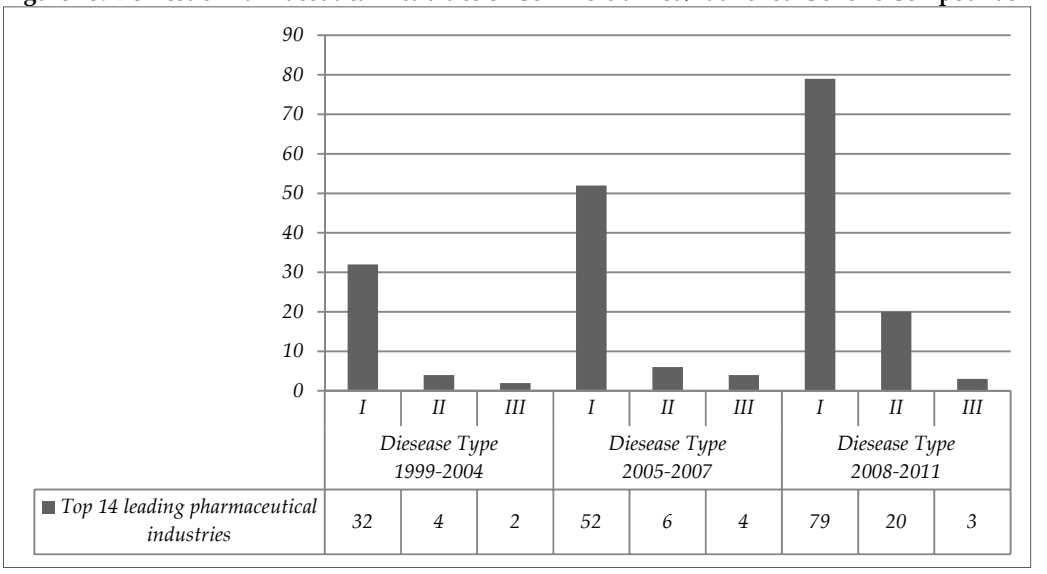
	DPRP			BIPP			SBIRI		
	High burden	Medium Burden	Low burden	High burden	Medium Burden	Low burden	High burden	Medium Burden	Low burden
Total no. of projects in different classes of disease burden	23	30	13	6	5	1	2	14	10
Torrent Pharma	0	1	4	0	1	0	0	0	0
Ranbaxy Laboratories	0	5	0	0	0	0	0	0	0
Strides Arcolab	1	0	0	0	0	0	0	0	0
Lipin Pharma	1	0	1	0	0	0	0	0	0
Cadila Healthcare	0	3	0	0	0	0	0	0	1
Biocon Ltd	0	0	0	0	1	0	0	0	0
Total	2	6	5	0	2	0	0	0	1

Note & Source: See Figure-13.

There is evidence of the shift of R&D priorities. Analysis of the evidence processed by us shows that all the important developments that we see in respect of the creation of R&D capabilities for new drug discovery and development within the Indian firms have a global market favouring R&D orientation. As the situation has stood so far their pharmaceutical research is largely directed to the needs of the regulated markets of United States and Europe. Even the high burden disease areas of the Indian nation have not been able to attract the locally bred firms. Analysis indicates the preponderance of medium burden disease areas: Cancer (3.4), Tuberculosis (2.8), HIV/AIDS (2.1), Malaria (1.6), Respiratory diseases (1.5), Blindness (1.4), Diabetes (0.7) being covered more by the firms in their relationships with the academic institutions and industry networks.

Analysis of evidence on the development of new chemical entities (NCEs) through the alliances formed for drug discovery and clinical trials formed with foreign firms shows that the focus is on medium burden diseases which include areas affecting both, developed and developing countries like Cancer, Tuberculosis, HIV/AIDS, Malaria, Respiratory diseases, Blindness and Diabetes. Concern about the shift in R&D priorities is quite prominent when we analyze the pattern of coverage of diseases in the case of alliances and collaborations that these firms have entered into with the foreign firms for the purpose of drug discovery

Figure-15: Domestic Pharmaceutical Activities of Commercialized/Launched Generic Compounds



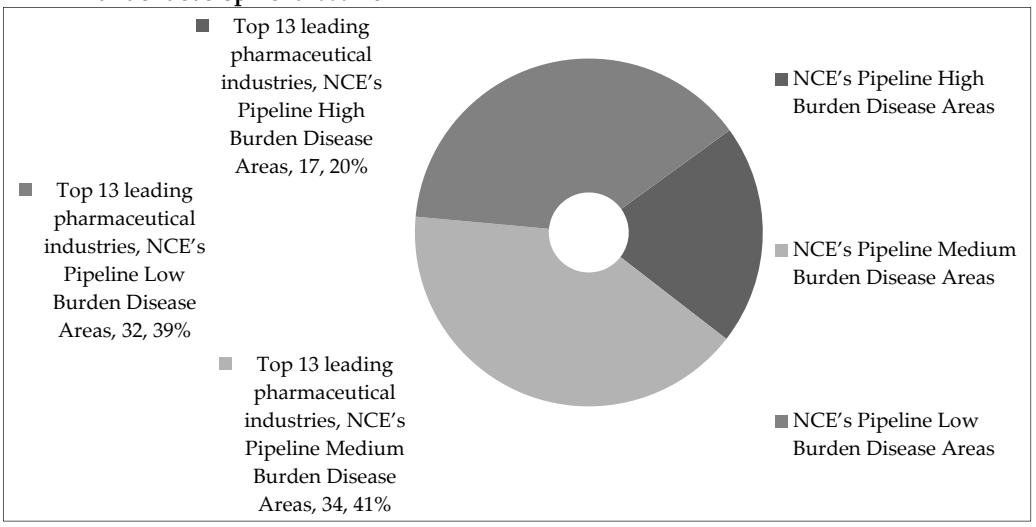
Note: Type-I Disease -- Diabetes, Cancer, Metabolic Diseases, Hepatitis, Influenza, Cardiovascular, Infectious Diseases, Inflammatory Diseases, Allergy, Respiratory Diseases; Type-II Disease -- HIV/AIDS, Tuberculosis, Malaria; Type-III Disease -- Leishmaniasis, Trypanosomiasis, Lymphatic filariasis, Leprosy, Diarrhoea.

Source: Data collected from individual website & latest annual report of individual pharma companies and Cygnus research, data accessed as on November 2011.

and clinical research. Markets for which the capability development is being undertaken with the help of foreign firms are those diseases where the developed world has more interest. High burden disease areas of the Indian nation are of lower interest. However, the domestic industry is also known to be complaining of government funding for the direct benefit of R&D in industry being rather small. Bit has been seen that they are not even utilizing the existing schemes in a big way. Medium burden diseases are a major focus of the projects submitted by the industry. This is because of the attraction of these diseases on account of markets being more attractive due to the worldwide emphasis on many of those diseases at the level of R&D funding.

To come to the impact of OFDI connections on the lack of balance R&D priorities it is starkly visible in the case of use of government schemes by the emerging Indian pharmaceutical multinationals. More than half of these firms have chosen to ignore the schemes formulated by the government industrial research financing altogether. There were only six firms out of fourteen firms that took projects funded by the government for the development of facilities and activities required to be undertaken for the development of new drugs. But even they accounted for just 15 projects in the portfolio of 104 projects sanctioned by the government. Domestic firms have not come forward to use the government schemes for R&D and innovation of therapeutics for tackling the priority diseases.

Figure-16: Pattern of Coverage of different types of disease burden for New Chemical Entities under development 1999-2011



Note: Data available on the Burden of Disease from GOI; 1-High Burden diseases: Infectious diseases / Injuries (16.1), Maternal & prenatal problems (11.6), Cardiovascular (10.0), Brain disorders (8.5), Diarrhea (8.2), Childhood disease (5.4); 2-Medium Burden diseases: Cancer (3.4), Tuberculosis (2.8), HIV/AIDS (2.1), Malaria (1.6), Respiratory diseases (1.5), Blindness (1.4), Diabetes (0.7), 3-Low Burden Disease / Conditions: Oral diseases (0.5), Leprosy (0.1), Otitis Media (0.1), Inflammatory diseases, Arthritis, Bone disease, Otitis Media, Ulcer, Psoriases, Depression, Hypertension, Allergy, Hepatitis, Prosthetic hyperplasia, Others (25.4).

Source: individual Company website Press releases, News, Archive etc, data accessed as on November 2011.

Figure-17: Status of outcomes of product innovation by stage of development & disease Therapeutic area-wise disease focus of new chemical entities under development

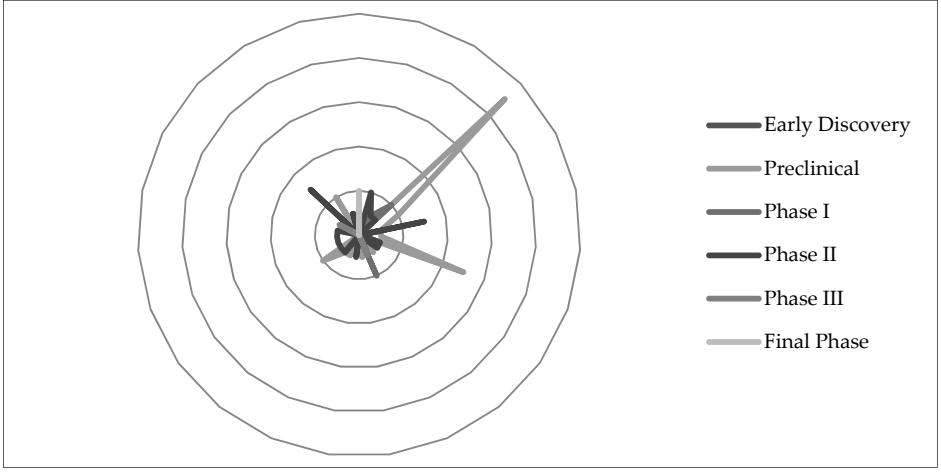


Table-2: Number of compounds under clinical development in different therapeutic areas by foreign companies 1999-2009

Name of companies	*Tuberculosis*	*Malaria*	*Diarrhoea*	*Hepatitis*	*Total*
GlaxoSmithKline Pharmaceutical	-	-	-	1	1
Novartis India Ltd	-	-	-	1	1
Grand total	-	-	-	2	2

Table-3: Pattern of inventive output based on classification of pharmaceutical patents 1992-2007

Diseases	*Pattern of Public patenting*										*Total*
	Process	*Composition*	*NCE*	*NDDS*	*Formulation*	*Method*	*Combination*	*New forms of Substance*	*Derivative Product*		
Malaria	3	4	-	-	-	1	1	2	-	-	11
TB	1	5	-	-	-	-	-	-	-	-	6
Diarrhoea	1	-	-	-	-	-	-	-	-	-	1
Hepatitis	1	1	-	-	-	-	-	-	-	-	2
Total	6	10	-	-	-	1	1	2	-	-	20

Lack of interest in the schemes from the emerging Indian pharmaceutical multinationals is the case even when the government has agreed to cede to the collaborating firms the ownership of intellectual property rights (IPRs). Some of these firms have now been sold by its promoters to foreign firms. It is obvious that the national links of these firms are only getting weakened rather than being strengthened. Certainly the OFDI connections of the strategies of the emerging Indian pharmaceutical multinationals are affecting adversely the plans that the policymakers have for the development of the national system of innovation for the benefit of Indian pharmaceutical industry.

8. Proposals from the Industry Side

Innovation in late industrializing environments has required the public sector to play a role in the development of private sector of science based industries is a commonly accepted proposition; however the role & contribution of publicly funded activities is externally determined. In India the public sector industry supported the private sector; In India, the public sector has played a historic role in the development and diffusion of talent. But the role and contribution of public sector research laboratories have been historically determined through public policy. But if there is an understanding that public sector science has no achievements to show in respect of product innovation then the policymaking results can only become myopic in orientation, which is visible from the proposals being made by the domestic private sector industry. We can already see that public sector laboratories are being made to starve for both leadership and funds. No steering and coordination, the new health research policy was proposed in 2001-02 but it is yet to be put on the statue books by the government. But there is a lot of enthusiasm for the introduction of market oriented, industry led R&D where the proposed alignment is emphasizing even far more myopic objectives than the nation has been subjected to by the

policymakers. Policymakers are being pushed into introducing the Bayh Dole Version of IP Culture which means only much more private orientation of R&D.

Continuing, the Indian private pharmaceutical sector would not be able to go far without the public sector science contributing to process innovations. Even today the industry wishes to have public support in respect of knowledge and finance. But how much and where all this support has to go is a critical question for the policymaking. Below we assess briefly the proposals made in the 12th FYP for R&D. The routes for financing of pharmaceutical innovation are: Government Grants for R&D; Private investments in R&D; Venture Capital/Angel funding. Public funding in pharmaceutical R&D has not been sufficient in the past. While ₹360 crore per annum may be required to fund only one NCE program in an optimistic case, Funds disbursed by the Government per annum for the last few years for supporting innovation (not exclusively focused on pharma) amount to ₹263 crore, excluding fiscal incentives.

However the future directions of public funding for R&D are proposed to be developed in PPP mode whose directions are not strategic enough to give priority to the objectives that should be receiving support under PPP model of R&D funding for industry led R&D. In the 12th FYP the Department of Pharmaceuticals has proposed to set up 5-6 Innovation Centres at the identified pharmaceutical clusters[8]. Financing of bulk drug R&D and Promoting SPV type funding for innovation is envisaged under the cluster support programme. API R&D Laboratories; Formulation R&D, Bio-analytical Laboratories, Formulation Bioequivalence Centers; Stability Centers; Toxicity Study Centers; Kilo Plants; Pilot plants required for test batch preparations required for regulatory dossiers for APIs & Formulations Common Infrastructure such as: Industrial gases such as Steam, Compressed Air, Nitrogen, Fluorine, etc., Separate Warehouses for raw material and finished goods storing, Cold Storage Facilities; Solvent tanks; Boiler house, Effluent Treatment facilities such as CETP, etc., Pharmaexil has proposed global market orientation as a key objective for the innovation policy and has been given acceptance.

A venture capital fund of ₹1,000 crores is proposed to be created to be operated by Exim Bank. Innovation parks have been identified to be set up with the help of public grants and cheap loans in the vicinity of 5-6 pharmaceutical clusters. Technology Up-gradation, Raw Material Bank & Physical Infrastructure; R&D Infrastructure, Margin Money Subsidy for credit from Banks; Shared services in foreign countries such as warehouses, liaison offices, support for regulatory. Special interest rates for cluster projects have been proposed. But the problem is that in their proposals DMFs and ANDAs won the battle[9]. Not that this

[8] Fully private owned model: 50 per cent grants-in-aid by government subject to a maximum of ₹100 crores. 25 per cent loan by Venture Capital Fund or Bank with 3+5 years tenure and 25 per cent of fund by cluster developer. Alternately jointly operated by private sector and government has been preferred to public sector operated innovation park.

[9] 50 per cent of DMF, ANDA filing expenses (paid to foreign regulatory authorities) incurred could be reimbursed upon showing the exports to such country for a value twice that of investment of the

contd…

objective does not support, but whether the private sector operated innovation park objective would be able to undertake the management of objectives of technological learning. Proposed orientation in the case of soft infrastructure is for the enhancement of institutional funding for intangible assets such as IP, ANDAs, DMFs, Patenting of pharmaceutical innovation, etc. Pharmaexil has proposed that "End-to-End R&D" facilities are required to be developed for drug registrations. Special Purpose Vehicles for cluster may provide funding to entrepreneurs for viable projects and soft infrastructure in venture capital mode[10].

Approximate costs of such DMFs, ANDAs, Novel Drug Delivery Systems (NDDS), patenting proposed to be supported by the government without putting any kind of binding constraints are provided here below:

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concerned product. There is no need to cap this as it will be directly related to product sales; 50 per cent of bioequivalence expenses incurred could be reimbursed upon demonstrating an export sale value of at least ten times the investment.; Phase 1 clinical trial expenses should be funded through SPV upon screening that the preclinical work is satisfactory; 50 per cent grant for patent libraries and patent departments to support SSIs to promote their research capabilities ; 50 per cent grant for five years for warehouses set up by clusters in foreign locations to support SSIs exports; 50 per cent grant for five years for liaison/sales/marketing/distribution offices set up to support SSIs of clusters. 50 per cent grant for setting up of NIPER or reputed university affiliate courses to develop the industry university interaction and practical training at clusters. 50 per cent reimbursement of legal expenses in defending patents for two products sponsored by the cluster SPV upon demonstration of at least six times the export sales for the given product in the given country.

Promoter/developer should have minimum net worth of ₹1,000 crores, should be in business for at least 5 years., should have a history of successfully implementing large pharmaceutical supporting industrial projects with knowledge in safety, environmental management capability such as pollution control equipment and Common Effluent Treatment plants, etc., cluster should have the scientists supporting research who have patented products or filed DMFs or ANDAs and achieved regulatory approval of facilities, such clusters should have very high chance or generating R&D due to the intrinsic competitive advantage and hence sector VC funds, banks should be encouraged to provide intangible asset funding or / and float SPVs. Clusters should provide end to end infrastructure from concept to complete filing of a product /patent and support including the regulatory agencies' inspection, Not more than ₹100 crores grant for a cluster. Minimum 25 per cent should be the contributor of cluster promoter.

All these requirements have been proposed without suggesting any kind of binding constraints on the investors in terms of output orientation in terms of disease orientation. Quality is the other most important aspect that needs to be addressed for the country to achieve higher growth trajectory. Investment support from banks in such intangible assets is scant. Proposal is therefore to treat quality on par with R&D; proposal made and accepted suggests treating entire investment in quality on par with R&D in terms of import duties and weighted deductions. Proposes considering investments for Quality Control equipment at par with R&D capital goods purchases. Any outsourcing for the purpose of R&D should be eligible for deductions under R&D expenditure. A special scheme for green chemistry projects for API's is recommended.

- Average cost of DMFs -- ₹1.5 crore to ₹4.5 crore
- Average cost of ANDAs -- ₹4 crore to ₹20 crore
- Cost of developing Non infringing NDDS Products -- ₹4 crore to ₹20 crore
- High cost of filing patents in specific markets abroad
- Each Intellectual Property generation costs between ₹5 to ₹20 crores and each patent costs approximate ₹1 crore.

However, it needs to be noted that there are already 4 schemes specifically dedicated to R&D Projects and another 14 policy measures in place which are directly associated in funding of pharmaceutical R&D, innovation/incubation, venture capital, R&D infrastructure financing, promoting of business in foreign countries, under various departments/wings of Central Government such as Ministry of Commerce & Industry, Office of Development Commissioner (MSME), Department of Scientific and Industrial Research and Department of Economic Affairs, which are also being operated by the government without putting any kind of binding constraints on the objectives in terms of the disease orientation and stage of development of the R&D work to be taken up by the pharmaceutical industry.

Further, it also needs to be that IDPL & HAL are closed, fermentation plants had to be stopped and as on date all these plants and connected machineries are lying unused for more than a decade and have almost become unusable. Public sector in the case of pharmaceutical industry needs support; Urgent need is to revive IDPL, Hindustan Antibiotics (penicillin G plant) bulk drug manufacturing facility. There is also the paucity of Biological strains (Bacterial/Viral) available in our country. Available Strains are having the poor yielding capacity. Need to develop the infrastructure & techniques of R& D facility within Cell Banks to improve the availability of Cell Lines and Strains. But the government is being pushed in the direction of supporting the private sector for APIs without putting any type of binding constraints[11].

All of these requirements have been proposed under the PPP model without suggesting even any kind of binding constraints on the investors in terms of output orientation in terms of disease orientation. Quality is the other most important aspect that needs to be addressed for the country to achieve higher growth trajectory. Investment support from banks in such intangible assets is scant. Proposal is therefore to treat quality on par with R&D; proposal made and accepted suggests treating entire investment in quality on par with R&D in terms of import duties and weighted deductions. Proposes considering

[11] There is also the proposal that government could declare funding of R&D as a "priority" sector and fix some minimum per cent of total lending for this exercise. Banks can float a series of SPV s to meet the finance needs of this discipline. These SPVs will be funding the R&D efforts of 30-40 pre-approved companies. The manufacturing cycle is long especially in APIs/Intermediate sector. Each chemical process has multiple steps – At least 5 steps and up to as many as 25 steps to reach the end product taking several weeks to finish production. For most API companies; working capital tends to be between 120 days to 180 days.

investments for Quality Control equipment at par with R&D capital goods purchases. Any outsourcing for the purpose of R&D should be eligible for deductions under R&D expenditure. A special scheme for green chemistry projects for API's is recommended.

Take the proposal for encouraging R&D in drug discovery institutions. The perspective is that industry requires policies to ensure return on investments that would allow re-investible profits and it also requires actual development of eco-system for R&D in India at industry, academia and institution levels in given Global Scenario; Policy makers have been asked to recommend that India be made a global hub for contract research, and that DHR, DoP, DBT, DST, DSIR, ICMR, CSIR, AYUSH, and Post Graduate Medical Research & Teaching institutions shall form a consortium for this purpose. The proposal is that the consortium shall be responsible for pooling funds & other resources and to set priority areas of Pharmaceuticals and related Medical Research for funding. Additionally it is also proposed that the consortium shall be able to encourage the R&D initiatives of both industry and academia.

9. Summing Up Remarks

Evidence indicates that mostly the achievements of technological upgrading are attributable to the decisions taken in favour of delaying the implementation of external liberalization by a decade. In case of the pharmaceutical sector, the Indian policymakers were compelled to delay both, the implementation of external liberalization and the enforcement of strong intellectual property rights, liberalization of investment and technology on account of the opposition from various quarters. At least this delay helped the industry to export low value added pharmaceuticals and achieve the limited results that the sector has been able to contribute in respect of technological learning and innovation making. Fortunately, only in the beginning of 2002, the policymakers went ahead to get the domestic pharmaceutical firms to aggressively pursue the foreign markets and sources of knowledge for the betterment of learning and innovation making.

Analysis made of evidence available on the performance of the private sector industry in the knowledge-intensive sectors indicates that the results for technology and depth have been disappointing. Results of the response of industry and institutions to the policy regime on trade, investment and technology, have been disappointing in respect of technological learning, innovation making and value addition in manufacturing. This is in spite of the introduction of incentives in the form of tax benefits for R&D, stronger IPRs, encouragement to outward foreign direct investment (OFDI) and tax rebates for export promotion. The policy regime on trade, investment and technology has been either encouraging the domestic firms to participate in the emerging global value chains at the lower value end or attempting to insert the foreign firms into national productive structure without putting the much needed binding constraints on their operations in favour of technology upgrading for the realization of goals of public health. Policies on trade, investment and technology have been permitting the firms to pursue through their new business models the capture of existing assets and values rather than the creation of new

assets and values in the knowledge-intensive sectors in the name of sustaining the inflows of FDI and exports to the regulated markets.

Assumption of the policymakers was that progress would occur by subjecting the links between science and industry demand the domestic pharmaceutical industry to competition at home and abroad, and external liberalization. Links between public sector science and emerging Indian pharmaceutical multinationals remain weak and the barriers to diffusion of knowledge into the national system will persist. This is the case even when most of the Indian pharmaceutical companies fulfil now the criteria of "resource rich" large firms. The OFDI based relationships of these firms are lacking in emphasis on the products needed for high burden diseases of the country. Goal misalignment and weakened national identity are manifest; most of these firms have preferred to invest more in hospitals and pathology laboratories.

Till this day for the domestic as well foreign firms the strategic intent to invest remains weak in autonomous product innovation; the OFDI related learning connections have only ended up developing an excessive focus on the acquisition of complementary resources for production and marketing to the detriment of the institutionalization of the processes of building of firm-specific capabilities and strengthening of the national system of innovation. During the post-TRIPS period the potential sources of firms' location advantage available at home could not be mobilized appropriately for the benefit of technology seeking motive by the emerging Indian pharmaceutical multinationals; they have failed to use the foreign and domestic sources of knowledge effectively for the augmentation of firm specific assets and the establishment of product innovation specific interactions and linkages within the national borders.

There has been the emergence of sub optimal conditions for product innovation in the form of typical systemic failures on account of the perusal of a myopic pathway and lack of balance in the interactions and linkages emerging with the national system of innovation. The contribution of the OFDI learning connections to development of the firm specific technological capabilities is at present marginal for new product development. Not many resources could be leveraged from the acquisitions and strategic alliances entered into by these firms for the upgrading of processes of drug discovery and development. Even after the elapse of almost two decades the learning and innovation making activities of these companies are successfully occurring only in respect of the development of non-infringing processes and low end incremental innovations required to be undertaken for the attainment of successful entry of domestic firms in to the regulated generic pharmaceutical markets of United States and Europe.

Sub-optimal conditions are attributable to insufficient augmentation of firm specific assets and lack of establishment of interactions and linkages within the national borders. In the case of emerging Indian pharmaceutical multinationals, their acquisitions, alliances and collaborations remained focused on gaining the access to complementary resources needed for marketing and production of off-patent generic pharmaceuticals. Linkages formed with foreign firms have failed to take-off as a significant external mechanism of technological

learning. Path dependent systemic failures can be observed to have impacted on the co-evolving national system of innovation through the subcritical in-house product innovation capabilities, underdevelopment of local learning networks and lack of attention to domestic demand.

Assessment of the motives and outcomes of their international acquisitions, strategic alliances, collaborations and agreements confirms that the gains of these companies continue to relate far more to marketing and production of generics rather than R&D to be undertaken for product innovation. The emerging Indian pharmaceutical multinationals have not been able to acquire the firm-specific technological assets needed for the successful conduct of R&D activities for drug discovery and development from their interactions and linkages with foreign firms. Lacking in the strategic intent to build the interactions and linkages for the learning activity within the national borders the emerging pharmaceutical multinationals have ended up creating a set of sub optimal conditions for the conduct of product innovation and the country has lost a precious opportunity.

Learning by doing in an environment of global competition is not a self-sustaining process. The new environment would not be able to result in the accelerated export quality generic production in pharmaceuticals. Merely by encouraging them through the tax incentives for R&D, government grants for R&D, stronger IPRs, freedom for alliance making and collaborations and so on the government cannot hope to achieve the required results on the front of technological upgrading. Analysis shows that because the government chose not to intervene in the process of acquisition of resources and capability building by putting any kind of binding constraints on the private sector while pursuing the policy regime on trade, investment and technology the domestic pharmaceutical industry could not be shifted away in practice from the promotion of low value added exports to prioritizing technology and depth. Although a lot for competence building and learning is possible by using the channel of reverse knowledge transfer via knowledge acquisition related collaborations, alliances and networks in the pharmaceutical sector but the outward foreign direct investment (OFDI) for the emerging Indian pharmaceutical multinationals was encouraged without prioritizing the reverse knowledge transfer. OFDI activities should be encouraged when they meet the criteria and expectations associated with the learning connections of the acquisitions, alliances and collaborations.

Finally, policymakers should not be allowed to operate anymore on the basis an understanding that the past innovation patterns in the case of pharmaceutical sector were imitative and not creative enough due to weak intellectual property rights and closed economy environment and that India would be able to use the opening up process for the creation of external learning mechanisms to develop new pharmaceutical products. There is an urgent need to strengthen the system of public sector science to play its due role in drug discovery, preclinical and clinical research. There is the need to orient the public procurement policy in favour of the perusal of advanced market commitments and public funding of clinical trials in the case of national priorities. Similarly it is necessary to get the firms to build their firm specific assets and ties with the public sector science with a view to

strengthen the national system of innovation for the benefit of both foreign and domestic markets.

It is also quite clear that all of this cannot happen with the liberal policy regime remaining intact and guiding the industry in the same direction through further incentives. This kind of policy support would be essentially myopic in scope. Since the policymakers in planning commission report are only committing to provide more incentives for R&D, acquisition of technology and knowledge, stronger IPRs, more FDI and innovation prizes with the liberal policy regime orientation being intact, it is not difficult to see that how India would not continue to have more of myopic outcomes for technological learning in the future. Certainly the government needs to fill the gaps and intervene on the front of R&D, engineering and production in terms of both, supply as well as demand side. Export promotion and internationalization need to be pursued in a balanced way without ignoring the investments and processes to be put in place for the perusal of technological learning for product innovation at home and abroad.

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