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PHARMA SECTOR: PROBLEMS AND PROSPECTS

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ABSTRACT

Pharmaceutical industry operates under natural oligopoly due to of technological requirements and needs for inbuilt knowhow over a long period. Here returns on R &D investment has got a long gestation period and uncertain as one in ten experimental drugs has the probabilities of getting into market. Human capital is to be built in house through learning by doing over a long period of time. Once the capabilities are built up Pharma cos acquire natural advantage provided through patenting. This is used as market power to prevent competitors entering into business. Even distribution of drugs to the end users is capital intensive. Human resources need both marketing as well as scientific knowledge. In the industry fringe cos operate at the lower level of the ladder, suffer from lack of capital, infrastructural constraints and high attrition among the skilled personnel.

After 53 years of building capabilities in the Pharma sector and India's compliance to patent law, TRIP, many Global players are keen to include Indian cos in the value chain in R&D segment. India also has a number of competitive advantages in this sector with pool of science graduates and the scope for cheap clinical research facilities. Though India's domestic market itself is growing at 8 to 9 percent and sector has made foray into the global market, this is dominated by 250 large and medium size firms. Nearly 8 thousand small Pharma firms are operating at a low value chain. They are facing severe constraints which are even threats to their survival.

Successful big cos are operating in the field of genetic drugs and can grow further if only they make use of global opportunities being part of R&D value chain. Private Public Partnership could be successful in grabbing favourable global opportunities and making use of India's comparative advantage in this sector. The research is based on secondary published materials and information available in the internet.

KEYWORDS

Natural Oligopoly, Technological requirements, infrastructural constraints, Trip Genetic Drugs

INTRODUCTION

Pharma products have the characteristics of public goods which provide vast social benefits from usages. For hundred years, drug discoveries and availability of preventing medicine have increased average longevity of population and improved their productive lives worldwide. Products of these industries have more or less markets all over the world without any product differentiation/adaptation. Yet challenges for the industry are enormous and have been increasing in the recent years due to regulatory mechanism and technology enabled drug testing methods. Pharma industry is basically R&D oriented and the process of R& D is complex, costly and involves long time in this industry. This industry being a knowledge based, a firm in the industry has always to be involved in building up research and development capabilities for maintaining market share. This requires large and uncertain investment. Moreover returns on investment on R &D have got a long gestation period and uncertain as one in ten experimental drugs have the probability of getting market access. Once the capabilities are built up over one or two decades, Pharma cos acquire natural advantages through economies of scale and scope. Also specific human resources need to be built in house through learning by doing over a long period of time.

There is a dichotomy in pharma industry in more than one ways. For example, the producer needs patent right for a long period to realize the expenditure incurred in drug development. Yet its full social potency could be achieved only when they are accessible by the lingerer population for which price should be reasonably low. This causes constant conflicts between the corporate, the market forces and the interests of general public. This makes the role of regulators to protect the interests of all stakeholders. The expiry of the patent causes a sharp drop in the price. However, the driving force of the industry being R&D, there is always a tension in the market economy between the need to preserve incentives for innovation by granting temporary monopoly power to the firm. The distribution systems of drugs are often complicated due to complexities of management of supply chains and existence of multiple end users with different objectives e.g. hospitals, medical practitioners and stores. Indian market developed spurious drugs prior to the regime of product patenting. Also there are the possibilities of building nexus between companies, drug distributors and medical practitioners and group interests at the costs of social cause of prevention and cure of disease could suffer. All these call for committed and effective regulatory system

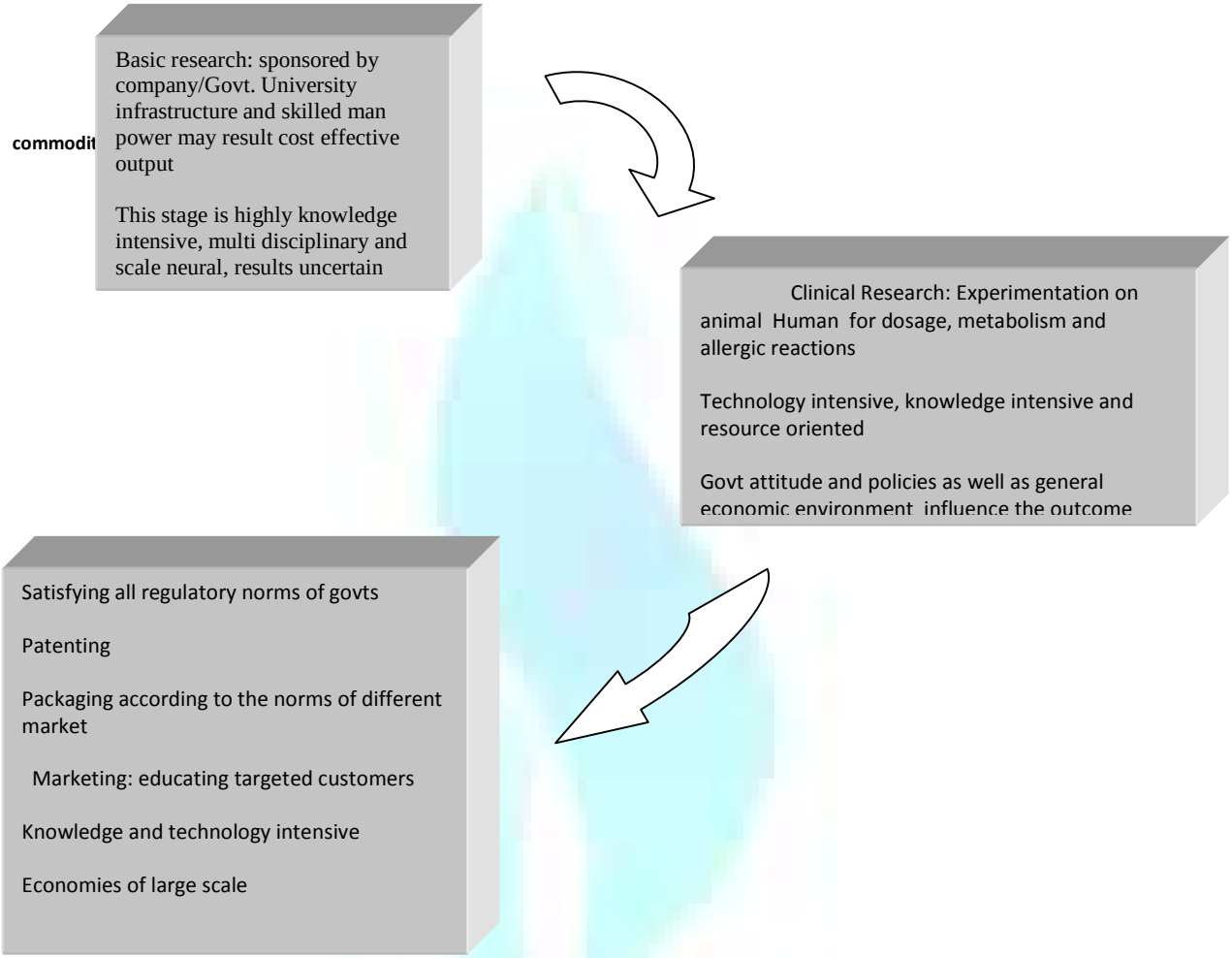
The paper will analyse various characteristics of pharma industry including the problems of drug development, and explain the strategies of firms in the industry, role of govt. The paper will also look into the present global demand for drugs and role of other participants in the market. Then the paper analyses challenges that Indian Pharma sector has been undergoing in the overall optimistic environment that has arisen through globalization and changes that pharma sector in the developed economies

RESEARCH AND DEVELOPMENT: AN ESSENTIAL PART OF THE SURVIVAL OF THE FIRM

R&D in Pharma sector: Problems and General practices: Development of new molecules for medicine is long drawn process. It takes at least sixteen years to complete the process of R& D and consequent drug development to bring the product to the market. Process involves financial commitments which may not result into profitable venture.

New Chemical Entities (**NCEs)** also known as New Molecular Entities, NMEs) are compounds which emerge from the process of drug discovery (Wikipedia). After successful development of molecule, this has to be tested on animals to ascertain safety, toxicity and metabolism in humans. Drug development process also makes recommendations of the doses and schedule to be used. Thus R&D in Drugs needs to pass through following stages.

DIAGRAM 1: INNOVATION (NEW CHEMICAL ENTITY)



R&D in the pharma industry is multi-faceted and draws upon the expertise of molecular biologists, synthetic and analytical chemists, genomics and proteomics specialists, pharmacologists and medical practitioners. In the process of R &D, first the target for the development of Molecules are fixed up, then in the next step of drug development, experimentation on animal and human go through three stages before the formulation is consideration for registration on the basis of statistical trial data. After successful registration the product is launched in the market for which awareness campaign among the prescribers are to be launched. According to Zinnov report, of 5 thousand to one million drugs entering into discovery process only one enters into the final marketing process and it costs one billion US$ in the developed market.

Clinical trials are conducted to allow safety and efficiency data to be collected for health interventions (e.g., drugs, devices, therapy protocols). These trials can only take place once satisfactory information has been gathered on the quality of the non-clinical safety, and Health authority / Ethics Committee approval is granted in the country where the trial takes place. Depending on the type of product and the stage of its development, investigators enroll healthy volunteers and/or patients into small pilot studies initially, followed by larger scale studies in patients that often compare the new product with the currently prescribed treatment. As positive safety and efficacy data are gathered, the number of patients is typically increased. Clinical trials can vary in size from a single center in one country to multicenter trials in multiple countries. Due to the sizable cost a full series of clinical trials may involve, the burden of paying for all the necessary people and services is usually borne by the sponsor who may be a governmental organization, a pharmaceutical company. A clinical trial is often managed by an outsourced partner such as a contract research organization or a clinical trials unit in the academic sector. After drug development, these drugs need to be packaged in accordance to the specification of the regulatory authorities and submit DMF documents to make an entry into the market. Break up costs during different stages of Drug R&D as observed by Zinnov report.

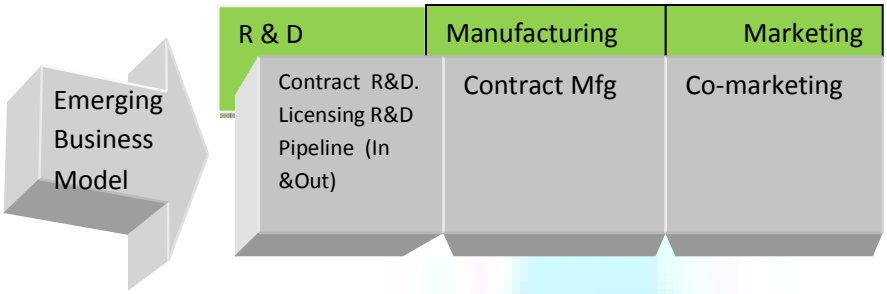
Table 1

Stage of R&D	Percentage of cost
Discovery stage	26.9
Non Clinical stage	19.5
Regulatory stage	4.1

Other	11.3
Clinical Development stage Phase I, II, III, IV	38.2

Since three different parts of Pharma products are characterized by three different management and technical styles, it is possible to break them in different organizational set up which improves the efficiency of operation and this also. Thus the industry has developed the following model of Business to cope up with challenges at all levels.

Diagram 2

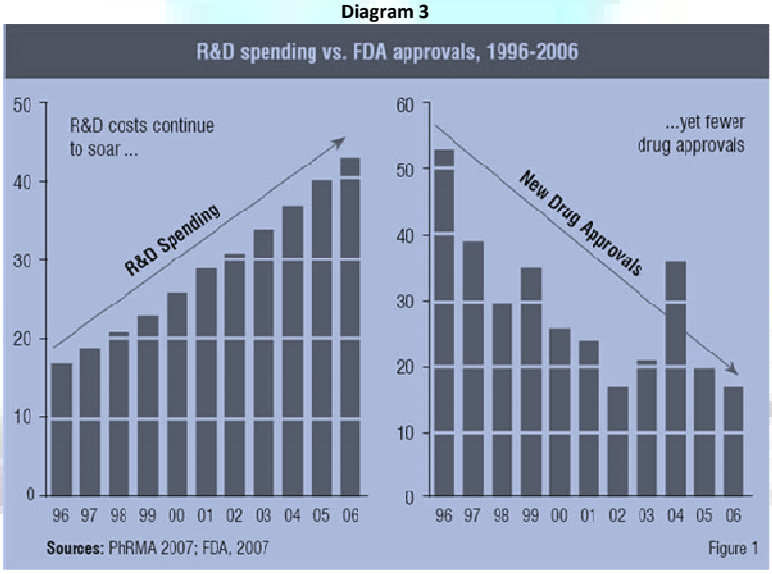


Source: Frost & Sullivan

Change in the Pharma Research Environment and need for looking into global opportunities Costs and time of new Drug discovery

A major concern is that compliance to regulations by the FDA has turned low returns to investments in R&D. For instance, the rate of return in the late 1970s fell by a third to its 1960 levels, and the cost of discovering and developing new drugs increased 18-fold (Business Week, February 21, 1977). During the 1980s, the pharmaceutical industry received a boost from the Reagan administration that lengthened the patents on prescription drugs and hastened the pace of approving generic drugs to substitute for drugs with expired patents. The immediate result in the 1980s was that R&D expenditure in drugs was about 10% of the industry's sales, versus 3% for all manufacturing industries.(S&P Industry Survey, January 1985, H16). But the FDA's Center for Drug Evaluation and Research (CDER) still regulates the industry brand name, generic prescriptions and OTC drugs, placing a heavy time delay on production. The time it takes to develop a new drug has almost doubled from its 1960 levels. The actual trend is 8.1 years in the 1960s, 11.6 years in the 1970s, 14.2 years in the 1980, and a stable 14.9 years during 1990-1996 (Pharmaceutical Industry Profile, 2000, VI). CDER claimed that with the user-fee approach in the mid-1990s, where the applicant pays the government for its review, they have doubled the number of new drugs approved and halved the review time (FDA Consumer, September-October 1997, 21). Other policies such as the streamlining of the IND and the International Conference on Harmonization also reduced review time. However, the review time continues to generate concern. Diagram below shows how R&D spending has been increasing over time while new drug approvals have been declining.

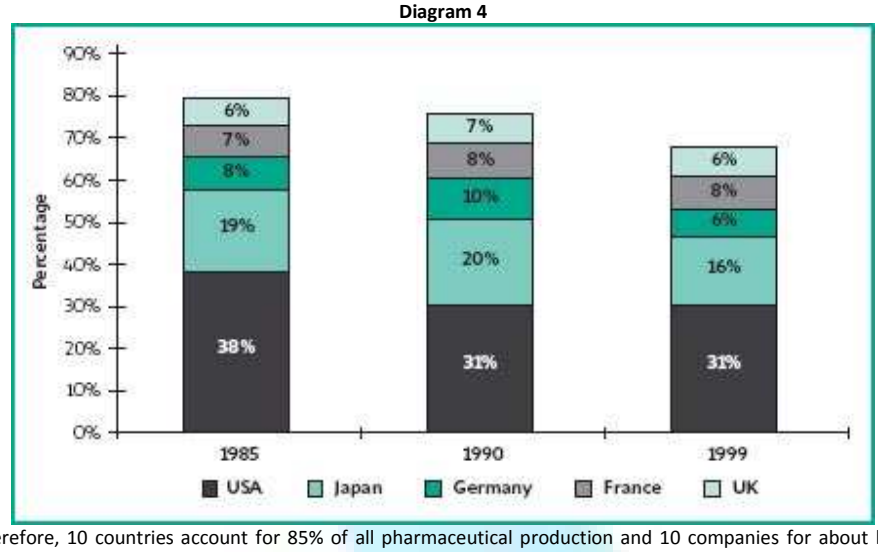
Diagram 3



Expiry of most of the patents: Pharma cos are facing another challenge in recent years due to expiry of large number of patent. Between 2007 to 2012 the top fifty companies would face loss of $115 billion worth of drugs due to expiry of patent. The industry needs cost effective way to produce drugs at the same time keeps privacy of its formulation and bring a drug faster by six months which can reduce the cost considerably. Pharma giant Bristol Myer Squibb lost 85% of its market share on Glucophage, after its patent expired in 2002. Pfizar is also facing the same problem for its anti cholesterol drug Lipitor which fetches it's a third of revenue. Patent expiry is a beneficial thing for the developing countries as these drugs are available at a cheaper price through development of genetic drugs.

Change in the International Economic Environment and Pharma Industry: Two-thirds of the value of medicines produced globally is accounted for by firms with headquarters in just five countries - the USA, Japan, Germany, France and the UK. Production is also concentrated in a few key products and in a relatively small number of companies, which often have factories and offices in many countries other than five centres.
Concentration is also apparent when the medicines market is analysed by therapeutic class and individual medicines or products. Sales of medicines in the top 10 therapeutic classes account for over 30% of global sales, and sales of the 10 best-selling medicines account for US$ 40.2 billion or 13% of global market share.

Diagram 4



In value terms, therefore, 10 countries account for 85% of all pharmaceutical production and 10 companies for about half of all sales. The medicines in the top 10 therapeutic classes account for one-third of all sales and the 10 best-selling medicines for one-eighth of the world pharmaceutical market.(http://apps.who.int/medicinedocs/documents/s6160e/p007a.jpg.) The combined share of these countries fell from 78% of total pharmaceutical production in 1985 to about 67% in 1999 while both Switzerland and Italy increased their output to about 4.5% each, just behind Germany and the UK, and just outside the top five. Since 1985, the top 10 medicines producing countries have accounted for 84%-88% of world production. The USA remains the biggest single producer (by value), accounting for almost one-third of total production, and Japan the second biggest. Together, these two countries produced 57% of the world's pharmaceuticals in 1985 and 47% in 1999. The USA lost some of its market share to Japan and Germany between 1985 and 1990. During the period 1985 to 1999, the market share of the UK was 6%-7%, while that of France remained at 7%-8%.
Challenges for MNCs in recent years:

1. FDA has become very, very strict in approving new molecules. The trend shows that the number of new molecules approved by the FDA every year has been falling
2. Huge cost due to expiry of most of patents in coming years. Many pharmaceuticals with high sales histories fear losing their patent protection and face competition from generic copies. There has been evidence that sales can decrease by as much as 75 percent in the year preceding patent expiration
3. So 1/6 of the global sales, or more importantly 1/4 of the US sales for large pharmaceutical companies, will vanish in the next three to four years. That's one challenge in three or four years.
4. A second challenge is the rising cost of health care, which most developed countries can't afford. US has 15-16% of GDP is spent on healthcare. In Europe, in Australia, in Canada, the government pays for healthcare and they are broke too. All across the developed world, Japan, Europe, even the US, the population is aging. And aging population means less productive people contributing to the pool and more people using the healthcare services, which insurance companies or the government have to pay for. This means that there will be some kind of a control on costs, which will include pharmaceutical industry, either the pressure on prices or in Europe it's very difficult to get new products on the formulary which the government reimburses.
5. Developing nations in their compliance to WTO has enter into new patent laws (TRIP) form 2005. This has made these countries an attractive destination for R&D specially clinical research and get patenting. Firstly clinical research is less costly and less time taking due to availability of people ready for trial medicine.
6. Developing economies in their earlier process patenting regime have developed capabilities of producing formula and genetic drugs . In the situation of most of recent patent being on the brink of expiry and high bleak prospects of new drugs being coming to the market MNCs are attracted to forge ties with Pharma cos of developing nations to produce genetic drugs.
7. On the other side, developing economies through liberalization and globalization introduced economic reforms encouraging foreign firms to enter into domestic market. Though developed economies concentrated in some of the medicine, they were too costly for the developing economies. Moreover, drug development in the tropical diseases such as malaria, typhoid, Polio, aids were costly and time taking in the developed countries due inaccessibility and difficulties of clinical trial. While drug development for diseases of developed nation has reached point of saturation, there is expanding market for drugs for tropical diseases. These drugs can finally be developed only in the developing countries. Developing economies such as India, China, Brazil have developed resources to attract Pharma MNCs entering into these countries to collaborate with domestic companies.

Entry strategies of MNCs in the Pharma sector of developing economies: Usually MNCs enter into a country through four routes: Trade, Single venture and Joint Venture and Merger and Acquisition. Of these four, a firm chooses one strategy whichever is more cost effective. When MNCs initially were looking for markets in the developing region, traded drugs through licensed agents. Pharma MNCs in the developed

economies traded drugs in India and China by providing distributional rights of drugs to the local agents (linsence). As these economies started growing , demands for medicine expanded and foreign companies found it profitable to start production base in these economies mainly to cater to the domestic market.

Following table gives the summary of entry strategies of Pharma MNCs in the developing countries.

Table 2

Strategies	Challenges
Launching their own genetic version of patented drugs through their own genetic subsidiary or by giving exclusive rights to their preferred manufacturer	Genetic version will have face competition across the globe especially from India and China
Filling for an incremental by altering ingredient or delivery mechanism	Additional time and cost involved
Introducing Line extension or repositioning drugs	Consumer's association with successful brand names diminishes and hence gaining acceptance in the market will take time

Indian Pharmaceutical sector:

Indian Pharma sector have been a dynamic sector after 53 years of building capabilities. The patent law TRIP have given them leverage and many Global players have been offering to include Indian cos in the value chain in R&D segment. India also has a number of competitive advantages in this sector. India has a pool of science graduates who are capable of learning through in house experience. India has scope for cheap clinical research facilities. Though India's domestic market is itself is growing at 8 to 9 percent and Indian Pharma sector has made foray into the global market. Yet structure of the industry is oligopolistic nearly 250 firms controlling 70 per cent of the market. While leaders of the industry controls 7 per cent of the market. Nearly 80 thousand small Pharma firms are operating at a low value chain. Even at that stage they are facing severe constraints which are threats to their survival. Most of the big cos are successfully operating in the field of genetic drugs. These cos would do well if they make use of global opportunities being part of R&D value chain. Private Public Partnership usually has been successful in those sectors which results scale economies in the long run and needs heavy capital investment over a long period

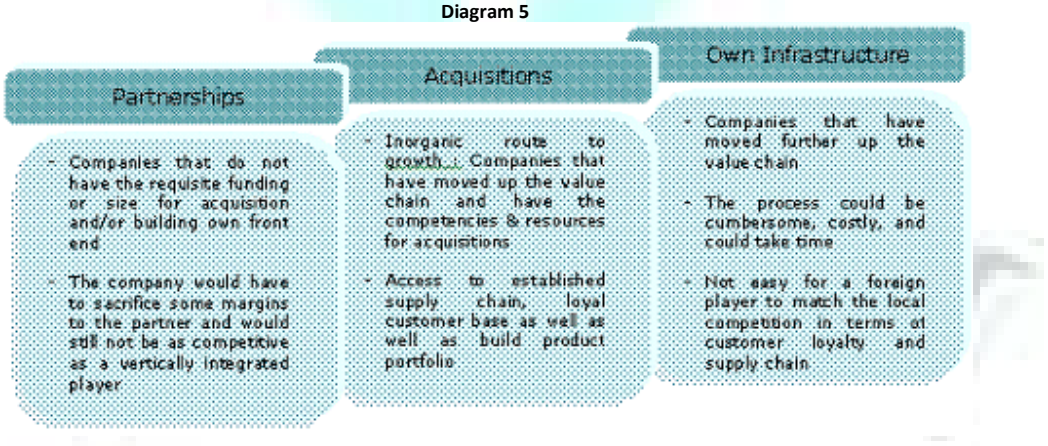
There are three levels of integration that are currently being sought in Indian Pharma industry

- Back-end manufacturing capability (API/formulation)
- Product integration (ANDA pipeline), and
- Front-end (marketing and distribution) in the developed world

The US and European generics companies are scouting for alliances/buyouts at the back end of the chain, which would allow them to offset any manufacturing cost advantage held by companies in the developing markets. The Indian companies are looking at the front-end integration as building a front-end distribution set-up from scratch could take significant time. The product side integration is common to both sides, with weaker US/European generics companies looking at anyone that could offer a basket of products. This is because the US/European pipeline is weak while Indian companies are aspiring to grow rapidly, want to achieve critical mass quickly, and are looking for geographic expansion.

The Indian companies excel as far as the back end of the pharmaceutical value chain is concerned i.e. manufacturing APIs and formulations. Over the past few years the Indian pharmaceutical companies have also stepped up their efforts in product development for the global generic market and this is visible with the DMF filings at the US FDA. About 30% of the new DMF filings at the US FDA are being filed by Indian companies. What the Indian companies are short of the front-end distribution and marketing infrastructure in the developed world. The current stress is on bridging this gap through any / or all of the following strategies. The type of strategies employed would depend on the companies' existing capabilities, available resources, nature and scale of expansion planned and on the targeted geographical market.

Diagram 5



Indian companies have preferred to stay away from NMC business segment, which entails substantial investment in terms of money, time and other resources coupled with very high risk of failure. The Indian companies also lack experience in developing their own molecules, especially the experience to take the molecules through the advanced stages of development. The Collaborative Research model can mitigate the risks of failure and bring in the required investment.

CRAMs is expected to go through cycles. Indian Cos should make use of these opportunities of collaboration with ethical cos to improve their research capabilities and finally become self sufficient. This approach coupled with govt.'s assistance can usher in a new era of drug discovery. The Key here is to reduce the costs of production through alternative avenues of production. The contract research and manufacturing services provide this opportunities. MNCs can reduce the costs of drug production by 30 to 50 per cent of the original cost. Low cost nations like India

and China have been growing CRAMS by 40%. India has 75 drug manufacturing facilities approved by FDA. Companies like GSK, Pfizer, Aventis and Navartis have started crucial trial and R&D activities in India. According to Indian Patent office 80 per cent of Indian patent were registered by foreign cos of which 33 per cent was pharma cos.

R&D Initiative in India by Major MNCs

GSK want to make India as the hub of R& D. They want to emphasize on collaborative research with GSK-R&D U.K. already it has centres in India which carries out research in the following areas such as technology absorption, process improvements development of in house technology and development of in house capabilities of clinical trial. Pfizer has already invested more than $ 13 million on R& D in India for clinical trial. It has conducted more than 20 clinical trials.

Aventies plans to make India as research hub and shift the major part of research of its global R&D operations to India and has a plan for setting up base for clinical trial and already developed infrastructure for clinical trial.

Austra Zeneca has already R&D in Bangalore for infectious disease in the developing countries. It wants to scale up R&D facilities with investment of $ 40 million. It also has base for clinical trial for various diseases.

Eli Lilly plans to make India as the primary hub for R&D.This co. has been involved in clinical trial since 1995..it conducts Phase II, III and IV .

Navertis exploring collaboration with Indian firms in R&D

Roche is considering to make its clinical trial bas for cancer drugs.

Reasons for looking for India as the hub of clinical trial: Some industry outlook

Bristol_Myers to reduce research and development costs and improve patient recruitment rates. It is very difficult to achieve unless the clinical development shifts to India. Pfizer finds it important to reduce time for drug development as this co is cancer research and time is important for patients cure. GSK sees outsourcing R&D to achieve the goal to improve service and reduce costs.

The Indian pharma industry is still trying to come to terms with the new patent regime. It is estimated that the Indian companies will lose close to USD 1 billion in potential revenues, since many of the drugs currently produced will become protected by patents. A curious phenomenon has also resulted, with the industry clearly divided into two segments – Indian manufacturers and MNCs. The Indian companies continue to play to their traditional strengths in generic and bulk drugs, and focus on the medium and lower ends of the consumer market. On the other hand, the MNCs have chosen to maintain their focus on the high end of the market

There are three ways in which Big Pharma is playing its hand in India, while working with an assortment of partners.

- **Generic takeovers** Why let Indian generic companies launch cheap versions of Big Pharma's drugs going off-patent? Partner or buy them, and keep the spoils in the family.
- **Product-development partnerships** With Bill Gates and others picking up the research tab, there's insulation from failure. And manufacturing and supply contracts, though low- or no-margin, are huge and assured.
- **Vaccines** India has the market (a few trans-Yamuna colonies in Delhi equal the population of Finland) and the R&D (at least 25 outfits are engaged in world-class research

Already, Big Pharma is circling other generic majors, including Wockhardt and Dr Reddy's Laboratories. Sanofi-Aventis has acquired a controlling stake in vaccine maker Shantha Biotechnics. And Pfizer has reportedly sent feelers to a bouquet of generic companies. "Big Pharma is eyeing only those generic companies with a global market and high quality standards. Not just any company," says Arun Bhatt, President, Clininvent Research, a leading contract-research organisation.

According to analysts, the stage for Pharma MNCs to enter into Indian market through Strategic Partnerships has opened through tie up of joint venture/ in licensing deals and marketing / research and manufacturing. Mumbai base Glenmark 's tied up with Shasun Chemicals and drugs Ltd to develop, register and sell 12 genetic drugs in US.

The strategy being followed by Indian Pharma companies, prior to implementation of product patent in India, was to launch their brands of existing molecules patented before 1995. In case of molecules patented between 1995 & 2005, Indian Pharma companies have launched their brands. The MNC's holding patents for molecules discovered during 1995 to 2005 have filed patents under the Exclusive Marketing Rights (EMR) mailbox provision. These applications are being scrutinized by Indian patent office and if it grants patents to these molecules, then Indian Pharma companies selling their brands of these molecules may have to withdraw their brands or pay some 'royalty' to the MNC Pharma companies. Thus there has been a great change in the marketing strategy of pharma companies. Before 2005 there was a mad rush of Pharma companies to launch as many brands possible of patented molecules, but now after 2005 patented molecules cannot be copied hence Indian companies are trying to introduce new molecules. This, they are trying to do so by various means like in licensing, collaborations & joint ventures, purchase of MNC companies.etc. Introduction of new molecules is also a preferred strategy because Pharma companies in order to enhance their image in the eyes of Doctors want to introduce latest molecules so that they are seen as progressive R&D focused companies.

CONCLUSION

This paper after reviewing the world wide challenges of the Pharm industry, attempted to high light reasons for high concentration of this industry in few developed economies. Recent economic down turn, changes in the regulatory frame works and saturation of production of medicines for developed economies along with costs of drug development in America and European Economies are reasons for MNC to look for collaborative efforts in the developing economies. Favorable environment created through liberalization and WTO compliant patent rules in the developing economies have attracted MNCs to enter into Contract Research and production of genetic drugs as well as getting patents for new drugs.

Some developing economies such as India have developed capabilities in those fields. Collaboration with MNCs has been helping domestic cos to enter into international market with brand names though Indian cos are only operating in the genetic drugs and bulk formulations. Though Indian Pharma cos are responding to the favourable environment, success of this sector is possible only if govt. proactive in providing partnership, support proving infrastructure for millions of small Pharma cos to survive and grow. India is a better place to invest on Drug development of Communicable diseases and some NGOs are active in this endeavor.

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