SUMMARY AND
CONCLUSION
5.1 Summary of results:

The Indian pharmaceutical companies are opting for ‘off patent’ drugs to generate large generic volume.

It is noticed that out of 30 top Indian pharmaceutical companies, only 3 companies (like Ranbaxy, Dr. Reddy’s Laboratories and Glenmark Pharmaceuticals) have challenged the process patents of the block buster drugs and total 8 companies (like Cipla, Ranbaxy, Piramal Healthcare, Zydus Cadila, Sun Pharmaceuticals, Lupin Laboratories, Dr. Reddy’s Laboratories and Glenmark Pharmaceuticals) that is more than 25% Indian pharmaceutical companies intend to follow this strategy.

The Indian pharmaceutical companies are building up their infrastructure Research & Development (R&D) for the contract / collaborative research activities.

The analysis confirms that about 50% of the Indian pharmaceutical companies will go for the manufacturing of Active Pharmaceutical Ingredients (APIs) & dosage form facility.

With the analysis it is clear that the Indian pharmaceutical companies have increased their focus on “Domestic market”.

5.2 Discussion:

Indian pharmaceutical companies are opting for manufacturing and marketing of ‘off patented’ drugs as this will help them to generate large generic volume.

There is a steep reduction in the price of medicines, when it becomes off patented. Even in major cases, it has been found that in United States of America (USA) the price reduction was as high as 90%.

During the years 2011 and 2013 almost Rs.3,60,000 crores (US $ 80 billion) drugs are getting off patented, which is quite significant and is a big opportunity for Indian pharmaceutical companies.
Almost all governments in Europe and United States of America (USA) have started sourcing generic drugs in order to keep the health cost low.

Almost all Indian pharmaceutical companies are working in a big way in generic business to grow fast.

Generic manufacturing is an area where India has been able to establish a firm foothold. With a market share of 31% in the total Abbreviated New Drug application (ANDA) approvals and estimated 50% in the total Drug Master File (DMF) filings in the year 2009, India is likely to continue holding a dominant position here.

The normal life of any product patent is invariably 20 years and as the pipeline of new drugs is getting exhausted at major multinational companies like Pfizer, GlaxoSmithKline, Astra Zeneca, and others, there is a stiff competition from the multinational companies against the challenge of the process patent. Few Indian companies like Cipla, Dr. Reddy’s and Glenmark have challenged the process patents of few blockbuster drugs though the litigation cost is high, but the gains are highly significant and is lucrative enough for major Indian pharmaceutical companies to opt for this, as there capacity for taking risks have also increased.

In November 2009, India’s largest drug maker revenue wise, Ranbaxy Laboratories Limited, introduced the generic version of GlaxoSmithKline Plc’s (GSK) skin medicine Valtrex (Val acyclovir) in the United States of America (USA). Ranbaxy had a 180 day marketing exclusivity for the generic. Before its exclusivity ended, Ranbaxy achieved a record 74% market share. Piggy backing on more than expected sales, Ranbaxy’s holding company Daiichi Sankyo co. Ltd., recently revised its earning forecasts upwards. Majority of the Indian pharmaceutical companies are building up their Research & Development (R&D) infrastructure for doing contract research work for major multinational companies as we have good scientific capabilities and cheap manpower helping to get a major slice of contract research.

The contract research business is to the tune of Rs.2,25,000 crores (US $ 50 billion).

The industry’s Research & Development (R&D) spending increased 17 fold in 11
years from Rs.140 crores in the year 1995 to Rs.2,380 crores in the year 2006. However, this amount is insignificant in comparison with the billion dollar investment needed to complete studies and reach commercialization for a single molecule. Indian pharma lacks the financial muscle to develop such drugs, which is why companies such as Glenmark Pharmaceuticals Ltd, rely on out licensing of molecules to fund their research pipeline. This is a long term story in terms of value creation. There have been capabilities built in this space but for it to translate into a revenue model will take time. The challenge is not a discovery, it is about the number of products that move to “phase-III” and finally make it to the market.

New drug discovery and development has not reached its full potential in India. However, the number of compounds in the Indian pipeline and in the advanced stages has increased. It is, therefore, not appropriate to say that India has failed in New Chemical Entity (NCE) innovation.

India is developing as a major manufacturing hub for the world. As the cost of drugs produced in India is significantly cheap on an average any drug can be produced in India at 40 % of the cost of western countries.

Indian pharmaceutical companies are one of the most brilliant and competitive industries in the world using right technology, innovation and cheap manpower coupled with large English speaking, literate population which gives comfort to the multinational companies and keep Indian companies ahead in the race. India has maximum number of United States Food & Drug Administration (USFDA) approved plants (Source: Indian pharma cos top US FDA list, The Economic Times, Aug 2007).

Even major World Health Organization (WHO) and Clinton Foundation initiatives are being executed through Indian pharmaceutical companies. Indian generic manufacturing supplies to over 80% of donor funded Acquired Immunodeficiency Syndrome or Acquired Immune Deficiency Syndrome(AIDS) medicines to developing countries in the last 7 years, confirms India’s status as the ‘Pharmacy of the World’.

From the year 2003 to 2008, the number of Indian generic manufacturers supplying
anti–retroviral (ARVs) increased from 4 to 10 while the number of Indian manufactured generic products increased from 14 to 53. Ninety-six countries out of 100 purchased Indian generic anti–retroviral (ARVs) in the year 2008. According to the study, in year 2008, India produced generics accounted for 91% of pediatric anti–retroviral (ARV) volume.

Reverse engineering has been one of the greatest boons to the Indian pharmaceutical industry and is a form of innovation that Indian pharma companies have mastered. But the story of Indian pharma companies does not end at developing and manufacturing generic versions of branded or patented drugs. In fact, that is where it starts. Its strength in generic manufacturing gave India the confidence to challenge patents of some of the world’s largest pharmaceutical companies. To add to that, India has fast become the hub of research and development outsourcing. It has emerged as a leader in Novel Drug Delivery System (NDDS), custom synthesis of new molecules, and much of the work done by Indian contract research and manufacturing firms is being patented by multinational companies.

According to government statistics, pharma exports were worth Rs.39,358 crores in the year 2008-09, grown at combined annual growth rate of 21.25%. It also accounted for 1735 Drug Master Files (DMF) according to the year 2008 US Food and Drug Administration (FDA) data, as against 1054 from the United States of America (USA) domestic companies and more than the combined total of European and Japanese companies. In the year 1998, India filed only 3 Abbreviated New Drug Applications (ANDAs). In the year 2009, it filed 181 Abbreviated New Drug Applications (ANDA) (Source: Pandye, P., Innovation has helped drug firms take on Big Pharma, Mint, Sep. 2010).

The understanding of market dynamics and adapting to them quickly is a huge strength that India has. This is illustrated in the number of Drug Master Files (DMF) filings alone that Indian pharma has with United States of America (USA) drugs regulator.

The Indian pharmaceutical industry has crossed annual turnover as Rs.49,500 crores (US $ 11 billion) in the year 2009-2010 and growth is at the rate of 12%. The Indian
pharmaceutical market has almost doubled in the last 5 years and is expected to again double in next 5 years. Hence, the Indian pharmaceutical companies are balancing their focus on both domestic as well as international market.

5.3 Conclusion:

Strategies such as greater level of Research & Development (R&D) activities, patent filings, contract manufacturing, contract research, inorganic growth strategy through acquisitions, co-marketing and co-licensing arrangements have helped the Indian pharmaceutical industry to surge as a global player. However, challenges are also ahead for the Indian pharmaceutical industry with changes in global trends and Trade Related Intellectual Property Rights (TRIPS) compliant patent regime in India.

5.3.1 Strengthening of Research and Development (R& D) activities:

Research & Development (R&D) is crucial for the growth of pharmaceutical industry; thus success of pharmaceutical industry depends more on successful Research & Development (R&D) activities. This factor has more relevance for India since new product patent regime has been introduced to comply with Trade Related Intellectual Property Rights (TRIPS) agreement (Source: Nauriyal, D.K. “TRIPS-Compliant New Patent Act and Indian Pharmaceutical Sector: Directions in strategy and R & D”, *Indian Journal of Economics and business*, special issue China and India, 2006 and “Pharmaceuticals: Getting the Dose Right,” *Pharmacy Choice*, Nov 2006). Many Indian pharmaceutical companies have realized the need to enhance their Research & Development (R&D) activities well in time and accordingly, raised the Research & Development (R&D) spending considerably (“From Copycats to Innovators,” *India Report, Focus reports*, Sept 2006 and Drugs & Pharmaceuticals, CII). In the year 2005-06, Indian pharmaceutical industry had spent over Rs.2,475 crores (US$ 550 million) in Research & Development (R&D) activities (both under current and capital account). This accounts for around 5% of total sales of the industry. Likewise, clinical trials in India cost approximately Rs.90 crores ($20 million) while the cost abroad would ranges between Rs.1,350 crores (US$300 million) and Rs.1,575 (US$350 million) (Source: Ibid). Though the industry level Research and Development (R&D) intensity is well above the average, Research & Development (R&D) intensity in manufacturing sector (estimated to be 1%), compared to
developed countries, such as United States of America (USA), Germany, it is very low. In United States of America (USA), pharmaceutical companies spend more than 17% of their sales on Research & Development (R&D) activities. In Europe, pharmaceutical Research & Development (R&D) accounts for 18% of their total industrial Research & Development (R&D) expenditure. The biggest spenders among the European countries are the United Kingdom (UK), Germany and France. Thus, it is important for Indian pharmaceutical industry to scale up their Research & Development (R&D) intensity to strengthen their position in the global market place.

5.3.2 Novel Drug Delivery System (NDDS):

Pharma market is governed by Intellectual Property Rights (IPR). Invariably, the innovator company takes patent for active ingredient as well as packaging.

The new entrant can penetrate the market only if that comes out with Novel Drug Delivery System (NDDS). This brings novelty, recognition and acceptability to the competing product and Indian pharmaceutical companies have started working in this direction.

5.3.3 Market penetration: Acquisitions in least developed countries:

Least Developed Country (LDC) is the name given to a country which, according to the United Nations, exhibits the lowest indicators of socioeconomic development, with the lowest Human Development Index ratings of all countries in the world.

A country is classified as a ‘Least Developed Country’ if it meets three criteria:

1. Low-income (three-year average GNI per capita of less than Rs.40,725 (US$905 million), which must exceed Rs.48,870 (US$1,086 million) to leave the least developed countries list)
2. Human resource weakness (based on indicators of nutrition, health, education and adult literacy)
3. Economic vulnerability (based on instability of agricultural production, instability of exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, handicap of economic
smallness, and the percentage of population displaced by natural disasters).

The classification currently (as of 29th January 2009) applies to forty-nine countries.

During the last decade, the activities of the Indian pharmaceutical companies have expanded globally. Enhancement of activities has not only been limited to exports but also by way of the industry's presence in manufacturing / marketing activities in various countries. Many Indian pharmaceutical firms have made a number of acquisitions in various countries. More than two-third of these acquisitions have been in the developed country markets of Europe and United States of America. However, there lies the scope for further penetration in other countries, especially least developed countries. Under the Trade Related Intellectual Property Rights (TRIPS) agreement, such countries have been granted with longer transition period (up to 2016) to become Trade Related Intellectual Property Rights (TRIPS) compliant. Indian generic producers can play a big role in these markets, through acquisitions and penetrate further in such markets.

5.3.4 Leveraging Biotechnology:

Bio technology is the new buzzword. Intermittently biological products are replacing chemical synthesis products in all likelihood.

The most selling product by the year 2012 will be a biological product and out of the first 10 pharmaceutical products 6 will be from biology. Biotech is the key area of the strategic focus and a key input of the road map for the future.

Biopharmaceuticals have witnessed significant growth in recent times. The size of the world biopharmaceuticals industry has been estimated at over Rs.2,70,000 crores (US $60 billion) in the year 2005 with more than 200 drugs being marketed. India is being recognized as one of the important players in the biopharmaceuticals market. Many Indian pharmaceutical firms are going for convergence with biotech industry for development of new drugs. However, it is indeed very important to accelerate the level of convergence and the pace. By the year 2010, more than Rs.45,000 crores (US $10 billion) worth of biopharmaceutical products is expected to lose patent protection
in developed country markets. Recently, United States of America (USA) has passed Food and Drug Administration (FDA) Revitalization Act to allow drug makers to sell generic version of biopharmaceuticals after 12 years of exclusive marketing rights by the innovator company. This will give ample opportunities for Indian pharmaceutical firms to tap this large bio-generic market.

5.3.5 Patent Filing:

Knowledge is the currency of future and it is very essential for all Indian pharmaceutical companies to build intellectual property right hence more thrust has been given on patent filing. Indian companies need to intensify their patent filing activities to have technological competitiveness in order to remain globally competitive.

Indian pharmaceutical industry has comparative advantage in Research & Development (R&D) due to its high intellectual base and low cost of Research & Development (R&D).

5.3.6 Contract research:

Looking into India’s strength in higher education and availability of large number of science institutes coupled with relatively cheap and competitive large English speaking scientific man-power, India has become the most preferred destination for contract research.

5.3.7 Contract manufacturing:

India has established itself as a major technological centre backed with reverse engineering and improvements in chemical synthesis. The Indian pharmaceutical companies have started putting up their manufacturing base and by taking the respective country’s regulatory approval, they are exporting to that country and have developed a substantial lead in this.

Today India has maximum number of United States Food & Drug Administration (USFDA) approved plants out of United States of America (USA).
5.3.8 Co-marketing alliances:

With the increase in domestic market Indian companies have increased their focus on domestic market and invariably majority of Indian pharmaceutical companies are having therapeutic group wise market divisions which have put pressure on their balance sheets plus European and American companies are giving thrust to their respective local market. This has opened opportunities of co-marketing alliance where depending upon the respective companies market strength they go for a tie up to sell other companies products as well.

5.3.9 Product infringement strategy:

The patent infringement cases need to be tackled by the Indian firms through proper understanding of the patent laws to move to greater compliance and reap the benefit of higher price as the product is still patented and the buyer is willing to pay premium.

The growth path of the generic players is witnessing turbulence with increasing number of Intellectual Property Rights (IPR) related litigations. Legal cost associated with challenging of patent infringement cases turn out to be very high for many pharmaceutical companies. Problems associated with increasing number of patent infringement cases should be tackled by the Indian firms through proper understanding of the patent laws and move towards greater compliance. Another approach, which has already been adopted by many pharmaceutical companies is 'out of the court settlement', which may prove to be much cheaper and faster to resolve patent related disputes. There are various methods of settling patent cases out of the court. In some cases, there may be reverse payments, in which the innovator company prefers to pay a lump sum amount to keep away the generic manufacturer from the market. In some other cases, both innovator firm and generic player agree to sell the product at a price fixed by the innovator and erode competition.

5.3.10 Safety and superior product quality:

Ensuring safety and quality of products, produced and marketed by the pharmaceutical industry is another major concern. In recent times, a number of Food and Drug Administration (FDA) approved blockbuster drugs like “Vioxx” (developed
by Merck Inc.) had to be withdrawn from the market as questions were raised regarding their safety standards. In addition to safety and quality, in the Indian context, the problem of spurious drugs has become a cause of concern. It is alleged that a large percentage of the world's spurious drugs are produced in India. It is estimated that in the domestic market about 20% of drugs sold are alleged to be spurious. The problem is more acute in remote and rural areas. Traditionally, antibiotics antiprotozoals, anti-malarial, anti-hormone and steroids are most likely candidates for faking. Of late, even lifestyle drugs (such as nutritional, anti-diabetes, anti-hypertensive and cancer drugs) are also allegedly produced. Though, spurious drugs may not endanger the life, they can be ineffective in curing the patients. Reusage of drugs past their expiry date is yet another menace. Filling spurious drugs in used medicine bottles is also allegedly prevalent. This calls for stricter safety and product quality regulations for the industry. The Indian government has recently introduced death penalty for someone found involved in such activities.

5.3.11 Diversification of market:

Being a non-existent entity before the year 1970, to one of the most respected entity in the global pharmaceutical world, Indian pharmaceutical companies have come up a long way and have evolved itself, when it has faced the problem.

Earlier, it was reverse engineering and then came infringement of process, now product patent and the future lies in biotechnology. All visionary companies are diversifying in biotech, especially bio-similar and recombinants and the need is to come out with niche products to create differentiation and to grow in the business.

5.3.12 Product pricing strategy:

Pricing strategies for launching of pharmaceutical products have never been more of a key issue as it is right now. It is crucial to consider optimal pricing strategies while determining the viability of launching a drug as the competition has become very stiff.

Globally, there is a trend of falling bulk drug prices. According to industry sources, bulk drug prices have been falling over the years due to highly competitive environment (Source: “Government to enforce 5-per cent cut in prices of 75 drugs”,

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domain-b.com, March 2007). Till few years ago, competition from China used to drive the falling of global bulk drug prices. However, recently the prices of Chinese bulk drugs have been showing an increasing trend. This may primarily be due to phasing out of incentives and support mechanism to Chinese pharmaceutical industry by the government. At present, the intense competition amongst Indian bulk drug manufacturers in various markets is the prime driver of falling cost of bulk drugs in the global market (Source: Kumar, S. “India to extend price controls on drugs,” BMJ Journal, Aug 2004).

The Indian pharmaceutical industry is in the process of developing many potential new pharmaceutical products for world markets. While some of them are in the early stages of development, others are well on their way to commercialization. Business wisdom dictates that early assessment of a product's concept and its potential to generate acceptable investment returns is crucial when deciding allocation of funds for undertaking Research & Development (R&D) activities. In addition, there are flexibilities provided under the World Trade Organization (WTO) to control prices through compulsory licensing and parallel importation. Therefore, it is crucial to consider optimal pricing strategies while determining the viability of launching a drug. The need for viable pricing strategies increases in an era of rising Research & Development (R&D) costs.

5.3.13 Regulatory / policy reforms:

Policies that influence Indian pharmaceutical industry can be broadly categorized into healthcare policy, industrial policy and health safety policy. Some of the concerns of the industry, regulators and end users are addressed through such policy framework. These include: accessibility and affordability of medicine by common man, ensuring quality and efficacy of medicines, strengthening the growth of generic medicines, promoting Research and Development (R&D), technology transfer, strengthening industry-institutional linkages and capacity development.

It may be noted that reforms are required at regulatory / policy level too. At present, both central and state governments regulate Indian pharmaceutical industry. While the state regulatory authorities are responsible for regulating manufacturing, sales and
distribution of drugs, the national regulator approves new drugs and clinical trials, a control import of drugs and also coordinates among the state bodies. A task force, headed by Dr. Pronab Sen., set up by the Government of India (for exploring options other than price control for achieving the objective of making life saving drugs available at affordable levels) has also recommended that in the long run functions of drug regulation and price control should be with the same agency, so that an integrated regulatory system exists in the economy.

Strengthening of regulatory system is also required in the context of new patent regime. There is a need to simplify procedures and shorten the timeline for various approvals. Strengthening of regulatory system with respect to data protection is also crucial. Such measures will help in attracting Research and Development (R&D) outsourcing to India. With India emerging as a major hub for contract research, particularly clinical trials, it is important to ensure good clinical practices in the country. Most of such issues are addressed in draft pharmaceutical policy (Source: “New policy adds 354 to the list of controlled drugs,” domain-b.com, July 2006).

5.3.14 Skill development:

Pharmaceutical industry is highly Research and Development (R&D) intensive. In order to remain globally competitive the industry requires pool of highly skilled man-power. India has already made its mark in scientific research in the world, with large pool of scientific man-power. The education system in India with wide network of universities providing quality science education has helped immensely in this regard. However, with the changing composition of economic growth there is an emerging trend of students not preferring science stream for career opportunities. This may lead to shortage of qualified manpower in highly research oriented economic activities such as pharmaceuticals. The problem of skilled professionals migrating to developed countries is also prevalent in India. It is estimated that Organization for Economic Co-operation & Development (OECD) countries are likely to witness shortage of skilled professionals in the years to come. In such a scenario, 'Brain Drain' to Organization for Economic Co-operation & Development (OECD) countries is likely to increase from developing countries like India. This would increase the shortage of skilled professionals in the domestic market, especially in knowledge oriented sectors like
pharmaceuticals. Thus it is important to devise policies that would attract more students to the science stream. Many countries give both financial and fiscal incentives in the form of grants and preferential loans, to encourage students to opt for science streams. Establishing strong industry academia linkages will also play a significant role in this regard.

5.4 Sum-up:

The pharmaceutical industry is one of the success stories of Indian manufacturing sector. Favorable government policies along with industry / firm level initiatives have helped the industry to post high growth rates over the years. Many Indian pharmaceutical companies have not only shown good performance domestically but have also been able to establish their foothold in overseas markets. Despite challenges posed by the World Trade Organization (WTO) regime, the growth momentum has continued in this sector. The strategies being adopted by the industry are however to be strengthened along with an appropriate policy framework for shaping the future of the Indian pharmaceutical industry.
5.5 Limitation of the research:

The study was restricted to drug companies manufacturing products used for human consumption.

The word ‘Strategy’ has multiple definitions and the proposed definition is with respect to survival and growth in the business environment.

The study did not consider change in international political situation and its impact on global marketing scenario.

The study did not consider the diseases caused due to natural calamities like earthquake, cyclone and flood.
5.6 Scope for further research:

Looking into the shift in the manufacturing base from developed countries to mainly India and China there is a huge potential for the pharmaceutical industry.

In the present study we have considered only top 30 pharmaceutical companies but while doing the research, researcher thinks following is the scope for further research:

A separate study can be done only on the niche companies who are targeting niche products based on strategy and may be presently smaller in size but can be potential growth drivers in time.

Super speciality is also an area which requires special focus as it also promises huge dividend in the future.

An exclusive study can be done only for the manufacturing capability on Indian pharmaceutical companies as this is the strength area of Indian companies.

Tropical diseases and their research in the Indian context will also be an area concerning us as multinationals are not very keen to develop cure for tropical diseases which does not give huge rewards and invariably does not fit into their strategy.