APPENDIX I (a)

INDIAN PHARMACEUTICAL RESEARCH & DEVELOPMENT AFTER TWENTY YEARS INTO SIGNING TRIPS AGREEMENT: “When will India Get the Pills?”

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ABSTRACT

India has signed the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) way back in 1 January 1995. It is now almost twenty years after signing the TRIPS agreement. According to the agreement all World Trade Organization (WTO) member countries must follow intellectual property rights regulation on inventions whether process or products, in all fields of technology, without any discrimination [1]. India was allowed a transition period of ten year from 1995 to 2005 as part of harmonization process to switch over from the then existing process patent to product patent. As a result India’s Intellectual Property Rights (IPR) act 1970 has undergone three amendments in March 1999, June 2002 and April 2005 to comply with TRIPS principles.

The new IPR Act 2005 has transformed the pharmaceutical industry from process patent to product patent, so also extended the product patent protection term from seven to twenty years. Besides this, the burden of proof of the process used in developing a drug now shifts to the defending company. The new product patent policy has become a challenge for Indian pharmaceutical companies. Companies have to invest heavily on the discovery of new drug molecules now as they can no longer use the process patent protection to re-engineer patented drugs. This has put enormous pressure on Indian pharmaceutical companies to remain innovative by investing in new drug research & development (R&D) for their own survival and growth. However, the research finds that there is no significant R&D investment from Indian pharmaceutical companies to promote new drug molecule research despite twenty years into signing TRIPS agreement. The question now is “when will India get the pills?”
INTRODUCTION

“The Indian pharmaceutical industry should turn their attention to invent new drugs from molecule levels and each manufacturing unit should try to become invention centres, opined Dr APJ Abdul Kalam, former President of India” [2].

Pharmaceuticals are a significant industry in the world. They are so significant because they provide important health benefits to the humanity. However, pharmaceutical inventions i.e. bringing new drug candidates from molecule to the medication stage is extremely costly (approximately US$ 1 billion) [3] and it is time-consuming as well (it may take 15 – 20 years) [4]. Drug discovery is an arduous journey with high rate of failures too. All these have made huge impacts on the rights of intellectual monopoly on pharmaceutical inventions in the world. In this context, TRIPS agreement is important and it regulates product patent protection in all member countries of the World Trade Organization (WTO).

India was a drug import-depended nation dominated by multi-national pharma companies selling their patented drugs in the domestic market until 1970, due to which the drug price was among the highest in the world [5]. However, post 1970 IPR Act has changed the pharmaceutical landscape in India, and created a highly competitive domestic pharma industry, meeting nearly 95 per cent of the country's pharmaceuticals needs. Country gradually became self-reliant in pharmaceutical productions. India also exports quality generics drugs at affordable price to more than 200 countries in the world. India has been labelled as the “pharmacy of the world”.

However, with the introduction of WTO led Trade Related aspects of Intellectual Property Rights (TRIPS) agreement in 1995, India had to provide product patent protection for pharmaceutical inventions provided they are new, involve an inventive step and are capable of industrial application. As a result, India has changed its existing process patent act to product patent to comply with TRIPS principles. In fact, the process patent Act, 1970 has allowed Indian companies to copy patented drugs by altering the chemical process without taking consent from the original inventor, thus producing and selling cost-effective drugs to the entire world.

In pharmaceuticals, there are two distinct types of patent available: (i) the product patent, by which a drug is produced and (ii) the process patent, through which the chemical formula for the drug is engineered. The new patent protection law (TRIPS 2005) provide both product as well as process patent to pharmaceutical inventions as
medical products and treatment involves a large degree of ambiguity as to what a scientific theory or discovery is and of the underlying chemical and biological model that explains it. It is this ambiguity medical product and treatments have been increasingly patented in the world.

India’s accession to TRIPS has changed the strategic outlook of the pharmaceutical industry, for them the critical issue was the re-introduction of product patent protection. The new product patent act has restricted Indian pharmaceutical companies’ ability to produce patented drugs using reverse engineering method, on which the entire industry was based and survived. The pharmaceutical industry’s future prospects will entirely rest on its ability to find new drug molecules. TRIPS agreement, to that extent, is an opportunity for Indian companies to re-orient their R&D towards discovery of new drug molecules.

While there is a significant change in the pattern of R&D investment in the country from Indian pharmaceutical companies, it observes that their responses to new drug development is pretty mundane, they are yet to develop a new chemical entity (NCE) despite twenty years into recognizing TRIPS-compliant product patent protection. In this backdrop, it would be exciting to know the extent of financial commitment to R&D made by Indian pharmaceutical companies in the field of drug molecule development, so also the strength of drug research pipeline as it is an area of great concern not only for the industry, but the entire Indian population. The question is when do we get our pills?

It is this excitement, the authors have been pulled into examine the impact of TRIPS on Indian pharmaceutical industry and the R&D commitment of pharmaceutical companies. The parameters used are: Analysis of R&D investments, Company size and operation, Annual revenue and profitability. The study further explores the financial capabilities of leading companies and their risk appetites undertaking hugely expensive drug research. The study uses both primary as well as secondary data for the analysis.

**Theoretical Framework**

With the introduction of a strong intellectual property rights, India has expected a drastic change in the R&D investment in the country, not only from local but multinational pharmaceutical companies as well. It has assumed with the transfer technology and research skills that the country will become world’s next hub for drug research activities including drugs specific to India borne diseases.

However, our research reveals that the introduction of strong intellectual property law has failed to bring in significant R&D investment, transfer of research skill and
technology to the country. It may be true that there was an initial spurt in R&D investments specifically from leading Indian pharmaceutical companies, but its intensity has gradually declined. At the same time, multinational pharma companies (MNCs) have failed to make any impact on the R&D investments in the country. Their entire efforts were concentrated mainly on Phase III studies on testing human subjects as it required limited skills and technology. Therefore, we assume that there is no significant R&D on promoting new drug research either from Indian pharmaceutical companies or MNCs despite 20 years into India signing TRIPS agreement.

Government cannot find fault with the private sector pharma industry for the state of low R&D investment scenario in the country, instead government should take initiatives and invest liberally in drug R&D as access to medicines and healthcare is a fundamental rights guaranteed under Indian Constitution. The reason for low R&D investments for private sector pharma industry could be many, but the significant among them are: company size and operation, lower revenue and profitability, high-cost high-risk long-gestation period of drug development, past failures in new drug development and lack of risk appetite due to promoter controlled organizations.

Data Collection and Methodology

Type of Research and Sample Design:
The study used both primary and secondary data for analysis. The secondary data has taken from the annual reports available on company web sites, research agency websites, journals and research publications. To obtain the primary data, questionnaire method was adopted; consequently 200 pharmaceutical companies were approached across India. Out of which 72 of them were returned the questionnaire duly filled which include 14 large, 28 medium and 30 small scale firms. Judgment sampling method has been adopted for the selection of the pharmaceutical companies.

Time period of the Study:
The study covers a period of nine years from 2005 to 2013, particularly post-2005 product patent implementation in the country. A period of nine year is considered appropriate to represent the trends of all three financial objectives of the firm with respect to annual sales turnover, net profit and expenditure on R&D in order to reach conclusions.

Results
Pharmaceutical invention is expensive and risky, required long term investment. The discovery process involves various phases spread over a period approximately 15 to
20 years before a drug reach finally from laboratory to market [7]. It may be due to these factors pharmaceutical inventions demands complete patent protection. This has left Indian companies to re-align their business strategy with particular emphasize on R&D investment on new drug discovery.

Other factors responsible for low R&D investment in the country may be due to firm’s small size and operation, lower revenue and profitability, high-cost high-risk nature of drug development, long-gestation period, frequent drug failures, lack of risk appetite of family-led organizations.

**Firm’s Small Size and Operation:**
The average annual sales turnover of twelve leading Indian pharmaceutical companies from 2005 to 2013 shows the figure somewhere in the region of Rs. 1108 - 5094 crores (Figure 1), which is considered to be very small from company size and operation point of view to undertake and fund new drug R&D activities as compared to multinational companies in the world. For example, Pfizer spent 9.5 billion US dollar for R&D alone, which is about 14.2% of their annual sales revenue of US$67.1 billion during 2010 [6]. The entire revenue of Indian pharma industry is equivalent to only 1/3rd of Pfizer’s 2010 revenue. In India, Ranbaxy, Dr. Reddy’s and Cipla are the largest among Indian pharmaceutical companies in terms of revenue. But their annual turnover underline the fact that they are small in size and operation, which leaves Indian companies financially incapable to invest large sums into new drug R&D unlike MNCs.

The above observations have found similarity when we analyzed the sampling responses received from 72 Indian pharmaceutical companies of large (14), medium (28) and small size (30), in which a whopping 85% of them said that it is due to small size and operation that is affecting companies earning potentials resulting in low investments in new drug R&D. Though companies are interested in spending on R&D, but in reality unable to invest due to firm’s limited capacity.
Lower Revenue and Profitability:
The average revenue and profitability of leading pharmaceutical companies (figure 2) below indicates that none of them is earning sizable profits to invest on a long term basis for new drug R&D activities. Hence, there is no significant R&D on new drug discovery. The top Indian company Ranbaxy is earning negative profit since 2011. The combined net profits of all companies will find still inadequate to discover a new drug molecule. Therefore, lower revenue and profitability affecting firms’ capacity to invest on long term project like new drug discovery. They have to simply reach size, operation and business volume before embracing significant R&D for new drug development.
Further a massive 86% of respondent from 72 pharmaceutical companies have agreed the fact that “lack of finance is the reason why companies not able to invest in new drug R&D”.

**Long Gestation Period:**
Drug discovery and development stage indeed is a very lengthy process, takes approximately 15 – 20 years for a molecule to become medication [7]. As shown in (Figure 3) [7], a vast number of chemical compounds are identified and screened in the initial stage of discovery journey. A selected few compounds then goes to pre-clinical testing before they embark on clinical studies on animals and human subjects. Food and Drug Administration (FDA) review and approval are taken before actual marketing of the new drug. The entire process takes almost 10 – 15 years and it cost the organization anything between US$ 1 – 1.2 billion, which most Indian companies find difficult to finance due to lack of funds.
The long, risky and expensive R&D investment with uncertain outcomes pause serious threat to Indian pharmaceutical companies for going ahead with new drug research, which is amply clear from table shown below (Figure. 4) that only a few companies are engaged in new drug research.

Source: PhRMA, based on data from Center for the Study of Drug Development, Tufts University, 1995
### Figure 4. Compounds of Indian Companies at Different Stages of Development

<table>
<thead>
<tr>
<th>Compound</th>
<th>Therapeutic Area</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dr Reddy’s</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRF 2593</td>
<td>Metabolic disorders</td>
<td>On-going. Phase III</td>
</tr>
<tr>
<td>Several Compounds</td>
<td>Respiratory disorders</td>
<td>On-going. Phase I</td>
</tr>
<tr>
<td>DRL 17822</td>
<td>Metabolic disorders / Cardiovascular disorders</td>
<td>On-going. Phase I</td>
</tr>
<tr>
<td><strong>Ranbaxy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RBx 11160 (Arterolane)</td>
<td>Anti-malaria combination drug</td>
<td>On-going. Phase III Studies in India and Thailand</td>
</tr>
<tr>
<td>Unnamed</td>
<td>Respiratory problems</td>
<td>On-going. Completed Phase I in collaboration with GSK and received related milestone payment from GSK</td>
</tr>
<tr>
<td><strong>Glenmark</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GRC 10693</td>
<td>Naturopathic Pain, Osteoarthritis &amp; other Agonist inflammatory pain</td>
<td>On-going. Entered phase II trials</td>
</tr>
<tr>
<td>GRC 8200 (Melogliptin)</td>
<td>Diabetes type-2</td>
<td>On-going. Entered phase III</td>
</tr>
<tr>
<td>GRC 3886 (Oglemilast)</td>
<td>COPD, Asthma</td>
<td>On-going. Phase II Completed</td>
</tr>
<tr>
<td>GRC 4039 (Revamilast)</td>
<td>Rheumatoid arthritis, multiple sclerosis and other inflammatory disorders</td>
<td>On-going. Entered phase II</td>
</tr>
<tr>
<td>GBR 500*</td>
<td>Multiple Sclerosis and inflammatory disorders</td>
<td>On-going. In phase I</td>
</tr>
<tr>
<td>Compound</td>
<td>Disease/Condition</td>
<td>Status</td>
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<tr>
<td>------------</td>
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</tr>
<tr>
<td>GRC 15300</td>
<td>Osteoarthritis pain, Naturopathic Pain, Skin Disorders</td>
<td>On-going. In phase I</td>
</tr>
<tr>
<td>GBR 600*</td>
<td>Anti-platelet, Adjunct to PCI/ Acute Coronary Syndrome</td>
<td>On-going. Completed preclinical trials</td>
</tr>
<tr>
<td>Crofelemer</td>
<td>Anti-diarrhoeal</td>
<td>Successfully completed phase III. In-licensed from Napo Pharmaceuticals, USA.</td>
</tr>
<tr>
<td></td>
<td><strong>Lupin</strong></td>
<td></td>
</tr>
<tr>
<td>LL 2011#</td>
<td>Anti-migraine (Amigra)</td>
<td>On-going. In phase III.</td>
</tr>
<tr>
<td>LL 4218</td>
<td>Anti-psoriasis (Desoside-P)</td>
<td>On-going. In phase II</td>
</tr>
<tr>
<td>LL 3858/4858#</td>
<td>TB (sudoterb)</td>
<td>On-going. In phase I</td>
</tr>
<tr>
<td>LL 3348</td>
<td>Anti-Psoriasis (Herbal Desoris)</td>
<td>On-going. In phase II</td>
</tr>
<tr>
<td>Unnamed</td>
<td>Diabetes type 2</td>
<td>On-going. In preclinical</td>
</tr>
<tr>
<td>Unnamed</td>
<td>Rheumatoid arthritis</td>
<td>On-going. In preclinical</td>
</tr>
</tbody>
</table>

Note: * Biologics; # these molecules are phytopharmaceuticals (origin from plants).

Source: Company Websites

**Past Drug Failures of Indian Pharmaceutical Companies:**

Drug discovery is a lengthy and an arduous process beset with failure at any phase of its discovery journey. Report suggests the average rate of success of a new drug hitting the market is approximately 11% i.e. only one in nine compounds make it to the final stage\(^\text{[12]}\). For instance, *Balaglitazone* – a new anti-diabetic molecule from Dr. Reddy’s has nose-dived in the phase III development stage due to the side-effect profiles of the *glitazone* family compounds. Dr. Reddy’s has invested a large amount of money over 6 - 7 years to develop the anti-diabetic molecule with no success\(^\text{[13]}\). Similar fate with Glenmark’s GRC 15300 – the new chemical entity of novel chronic pain management drug candidate failed at the Phase II stage\(^\text{[14]}\).

The high rate of failure associated with drug development is a major threat to the
financial health of Indian pharmaceutical companies. Organizations like Ranbaxy, Dr. Reddy’s and Glemark have learnt big lessons, now treading on the discovery path cautiously. This has led to the declining R&D intensity (Figure 5) in Indian companies after an initial spurt.

![Figure 5](image)

**Source:** Ace Equity

**Lack of Risk Appetite due to Promoter-led Organizations:**
It has been a well-known fact that promoters-led business houses are financially very sensitive and their appetite to risk taking is extremely calculative and limited to those area where investments and threats are low at the same time returns are high $^{[15]}$. But, new drug research is a high-cost, high-risk segment where success is uncertain due to lengthy process coupled with frequent drug failures. Most Indian operators are family-led business houses (figure 6), so it’s quite natural for them to avoid high risk area of drug discovery.

<table>
<thead>
<tr>
<th>Figure 6. Shareholding Pattern of Top Indian Pharmaceutical Companies 2013</th>
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<tbody>
<tr>
<td><strong>Name of the Company</strong></td>
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<td></td>
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<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>1. Ranbaxy</td>
</tr>
<tr>
<td>2. Cipla</td>
</tr>
<tr>
<td>3. Dr. Reddy’s</td>
</tr>
<tr>
<td>4. Lupin</td>
</tr>
<tr>
<td>5. Aurobindo</td>
</tr>
<tr>
<td>6. Sun Pharma</td>
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<td>10.</td>
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<td>11.</td>
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<td>12.</td>
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</tbody>
</table>

*Source: Ace Equity*

**Conclusion**

Indian pharmaceutical companies lack the ability to take high risk – high cost route of new drug development as they are financially weak. They are still small in size, operation, revenue and profitability as compared to MNCs, who has financial depth, so afford to take risk until they achieve success in a high risk – high profit segment of drug research. The expensive and risky nature of drug development coupled with long gestation period and frequent drug failures are some of the important reasons why Indian pharmaceutical companies found indecisive and sluggish in drug R&D. Indian pharmaceutical companies, in the present set-up, are not financially well placed to absorb the shock of drug failure which may impact the financial health of the organization.

Another reason could be lack of risk appetite due to the status of family-owned and operated. In other words, promoters of such organizations are self-convincing and contented with the existing level of earnings. Further there is no extraordinary incentive in sight for Indian companies to take such a huge risk to promote new molecule research. However, pharmaceutical companies are well aware about that discovery of new drug molecule is the only way out for their long term survival in the business, especially after the implementation of strong patent law. The question is when will India get the pills?

**Recommendation**

A strong intellectual property regime is not a bad idea for the nation, but industry has to be ready in terms of finance, technology and research skills to take advantage of the new patent regime. Presently, Indian pharmaceutical industry lack in all these critical areas of drug discovery. In this context, I would like to propose the following recommendations:

a) Create large companies to match size, operation, revenue and profitability to leverage investment in new drug R&D.

b) Revive public sector pharmaceutical units and encourage them to undertake aggressive drug research programs to address local as well as global disease patterns.
c) Undertake massive drug research programs through established Universities and Government research institutions across the country to harness skills.

d) Promote and incentivise pharmaceutical innovation in the country.

e) Barring essential drugs, limit control on drug pricing to push investments on R&D.

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THE INTRODUCTION OF POST-2005 PRODUCT PATENT REGIME IN INDIA: “TRIPS – a bitter pill for Indian Pharmaceutical Industry”

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Abstract:

India has signed the international treaty on Trade Related aspects of Intellectual Property Rights (TRIPS) during 1995, to be implemented after a transition period of ten year. The TRIPS agreement regulates all WTO member countries to follow ‘product patent’ protection for pharmaceutical inventions. India was following ‘process patent’ protection until 2005 when TRIPS came into existence. Under product patent protection, India can no longer manufacture and market patented drugs, which they could during process patent regime. Incidentally, India exports quality and affordable drugs to more than 200 countries in the world.

TRIPS agreement has compelled Indian pharmaceutical companies to re-align their business strategy with special focus on R&D of new molecules for its long term survival and growth. It was implicitly assumed that the introduction of strong product patent regime would result inflow of quality investments in pharma R&D both from domestic as well as multinational companies.

Against this background, this paper makes a moderate attempt to understand the financial capabilities of leading Indian pharmaceutical companies and their capacity to invest in new drug R&D. The study uses primary and secondary information relating to firms sales turnover, net profit and R&D spending for a period between years 2005 to 2013. The result of the study provides a view that Indian companies do not have the size, operation, revenue and profitability to invest in new drug R&D to sustain and succeed in the long run.

Key Words: Product patent, R&D, Pharmaceutical companies, financial resources
1. Introduction:

India is a signatory to the World Trade Organization’s international treaty on Trade Related Aspects of Intellectual Property Rights (TRIPS), which regulates patent protection to be followed by all members of WTO, on pharmaceutical inventions whether it is products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.

Pharmaceuticals are a significant industry in the world with the growing significance of providing important health benefits to the humanity. Besides, pharmaceutical inventions are extremely costly and it takes several years to develop new drugs from molecule stage to medication. This had profound impacts on the rights of intellectual monopoly to protect pharmaceutical inventions.

In pharmaceutical industry, there are two distinct forms of patent available (i) the product patent, by which a drug is produced and (ii) the process patent, through which the chemical formula for the drug is engineered. Since there is a large degree of ambiguity as to what a scientific theory or discovery is, it is unclear of the extent to which a new medicine, or a new biologically engineered product is or is not independent of the underlying chemical and biological model that explains it. Through this ambiguity medical products and treatments have been increasingly patented in the world.

However, for pharmaceutical companies in India, TRIPS regulation was a significant blow to their business strategy because, under product patent companies cannot produce patented drugs, which they used to by altering the chemical process of the drug until 2005. Thus, the introduction of new product patent legislation has effectively ended 35 years of India’s reverse engineering skills though the industry has perfected the art of science and technology to produce quality drugs at affordable price to the poorest of the world. TRIPS now provide industry a rare opportunity to invest in new drug discovery, which hitherto was bare minimum due to the fact that country was practicing liberal process patent act before TRIPS implementation.

Our research, therefore, will focus on the financial side of Indian pharmaceutical companies post 2005 product patent implementation whether they have the capacity to pump in large sums into R&D to develop new drugs as part of business strategy to survive and grow.

2. Theoretical Framework:

India has implemented the TRIPS agreement with the expectation that a strong intellectual property regime will embolden the environment of R&D in the country, particularly of new drug inventions leading to increased R&D investments from local as well as multinational pharmaceutical companies. India expected inflow of quality foreign direct investment (FDI), transfer of skills and technology from multinational pharmaceutical companies not only in the area of new drug discovery but for innovation and development of existing drugs that are more specific to Indian
conditions.

The strong intellectual property regime has mandated Indian companies to re-work their business strategy making R&D an integral part of development, in which discovering new molecules would provide long term growth. However, Indian pharmaceutical companies lack the required financial depth to fund large R&D investments into new drug molecules due to factors like small size of operation, lower revenue and profitability. Hence there is no appreciable R&D investment from Indian pharmaceutical companies to promote new molecule research despite 20 years into signing TRIPS agreement by the government of India.

Government cannot isolate private sector industry alone responsible for drug discovery in the country. It’s not pharmaceutical companies but Indian constitution that guarantees access to medicine and qualitative healthcare to its citizen as a fundamental right. Therefore, if private sector find incapable for investment, it should be the government through its various agencies must consider investing in new drug discovery as strong intellectual property rights without adequate R&D investments will hamper the prospect of pharmaceutical industry in India. It may even force private sector companies to surrender to MNCs, who then take over control of the Indian pharmaceutical market triggering a pre-1970 like situation where drug accessibility and affordability was a big concern.

3. Methods:

**Type of Study:** This research is basically an analytical study of cross sectional financial performance of leading Indian pharmaceutical companies and a handful of MNCs operating within India. The analysis is based on primary and secondary data taken from the annual reports available on official web site of the companies, research agency websites, journals and research publications. The primary data for this study were collected from 72 pharmaceutical organizations across the country, which have been provided with a set of sample questionnaires to get their response.

**Sample Design of Research:** A sample of twelve leading Indian pharmaceutical companies listed on BSE index and seven MNCs operating within India have been selected for the purpose of the study. The sample selection is purely on the basis of convenient sampling.

**Time period of the Study:** The study covers a nine year period from 2005 to 2013, specifically the post-implementation of product patent regime in India. A period of nine year is appropriate to represent the trends of all three financial objectives of the firm with regard to annual sales turnover, net profit and expenditure on R&D.

4. Results:

Pharmaceutical innovation is highly time consuming (15-20 years) and very expensive (approx. US$1 billion) due to various phases involved in the drug discovery process. Despite spending huge amount of money on new molecule research, there is no guarantee that the molecule will turn out to be a successful medication. The nature of drug discovery is such that it has every possibility to fail at any stages of its discovery journey. For instance, *Balaglitazone* – the much hyped
new chemical entity, an anti-diabetic molecule of Dr Reddy’s Laboratories have nose-dived in the phase III development stage due to the side-effect profiles of the glitazone family compounds. Dr. Reddy’s has invested a large amount of money over 6 -7 years to develop the anti-diabetic molecule with no success. Another case is Glenmark’s GRC 15300 – the new chemical entity of novel chronic pain management drug candidate failed at the Phase II stage. Therefore, companies with lack of adequate financial capital, size, operation and profitability will find tough to sustain in the area of new drug discovery.

5. Financials:

5.1 Annual Sales Turnover:
The average sales turnover of top Indian pharmaceutical companies for nine years from 2005 to 2013 shows the highest sales revenue being at Rs. 5,094 crores (Chart 5.1.1), which is less than the approximate amount spent for discovering a single new drug molecule in the world. For example Pfizer spent US$9.5 billion for R&D alone in 2010, which is 14.2% of its annual revenue of US$67.1 billion. The entire revenue of our pharma industry is equivalent to 1/3rd of Pfizer’s 2010 revenue. Ranbaxy followed by Cipla lead the pack among Indian pharmaceutical companies in terms of revenue. The analysis clearly indicates that, in India, virtually no pharmaceutical company is financially strong enough to invest huge amount for the discovery of new drugs.

![Chart 5.1.1 Ave. Sales Revenue during 2005-13](source)

**Source:** Ace Equity

5.2 Average Net Profit:
The largest pharma company Ranbaxy has minus net earnings. The highest net earner is Sun pharmaceuticals. Cipla, Dr. Reddy’s and to some extent Lupin is making net profit on an average Rs. 500 – 900 crores (Chart 5.2.1 & 5.2.2). These figures suggest that the earnings are not substantial enough for Indian companies to concentrate on new drug R&D. The entire earnings of all twelve companies put together will still find insufficient to discover a new drug molecule. Therefore, companies in India are not capable of large R&D investments. They have to reach size, operation and the financial volume in order to consider R&D for discovering new molecule.
5.2.1 Ave. Net Profit 2005-13

Source: Ace Equity

5.2.2 Ave. N/P percentage to sales

Source: Ace Equity

5.2.2 Ave. sales v/s Net profit v/s N/P percentage 2005 - 2013

Source: Ace Equity
5.3 Average R&D Spending:
Ranbaxy and Dr. Reddy’s are the two major Indian pharmaceutical companies found most active in the area of drug research and development including new drug discovery as they have several new molecules at different stages of development. Lupin and Cadila is catching up with R&D including new drug research. Company to watch out next for active R&D is Glenmark as they have quite number of new molecules in the pipeline. Sun Pharmaceuticals is another company looking to build up its R&D investments in India.

![Average R&D expenditure % to Sales Turnover 2005-13](chart)

**Source:** Ace Equity

However, the combined average expenditure on R&D by twelve leading Indian companies is just 8.66% as compared to MNCs who spends anything between 15 – 20% of their sales turnover. Since drug development is a high cost – high risk area, even a single failure will dent Indian company’s financial health; from there recovery would be difficult unless companies have adequate financial resources. Top three pharma companies have reduced their R&D intensity after an initial surge (chart 5.3.2) when they have realized the drug failure affecting their financial performance. It clearly indicates that after an initial surge R&D intensity of Indian pharmaceutical companies is declining gradually due to inadequate financial supports and frequent drug failures.
The above observations have found similarity when we analyzed the sampling responses received from 72 Indian pharmaceutical companies of large (14), medium (28) and small size (30), in which 66% of the respondent ‘strongly agreed’ that lack of finance is the reason why companies unable to invest into new drug R&D. To another question, a whopping 87% of them said that it is due to small size and operation that is affecting companies earning potentials resulting in low investments in new drug R&D. We can, therefore, safely assume that though there is a strong R&D interest among companies, but the firm’s capacity is limiting the R&D intensity. At the same time, the financial performance of MNCs operating in India (Chart 5.3.3 to 5.3.5) shows negligible R&D interest despite their robust performance in sales and profitability from Indian market.
6. Conclusion:

Indian pharmaceutical companies lack the financial depth to take the high risk – high cost route of new drug research and development. They are still small in size, operation, revenue and profitability as compared to MNCs, who take financial risks and get amply rewarded with new drug discovery.

New drug research is lengthy and expensive. The drug process is so rigorous and extensive that there is always a risk of failure looming large on pharmaceutical companies. Indian pharmaceutical companies, at present, are not financially well placed to absorb such a huge cost and shock of drug failure due to smaller operation and profitability.
Therefore TRIPS, in the present scenario, is a bitter pill to swallow for pharmaceutical industry in India. Similarly, strong intellectual property regulation is serving neither the industry nor the country particularly in the area of quality FDI, skill development and transfer of research technology. Whereas industry’s influence over manufacturing and marketing of generics version of patented drugs at affordable cost have been knocked off completely triggering a wide-spread issue of drug accessibility and drug affordability in the world because more than 200 countries in the world depend on India for their medications.

7. Recommendation

Industry can exert only a limited influence over government’s decisions, which discuss, negotiate and decide the future of the nation. Organizational entity has no option but to abide by the international regulations as part of government’s commitment to the world regulatory body. A strong intellectual property regime is not an evil per se, but it will do well only when industry attains certain level of competitiveness with regards to finance, research skill and technology particularly in the area of pharmaceutical inventions. As far as Indian pharmaceutical industry is concerned, they are quite fragile in these critical areas. New drug research is a high cost – high risk segment where companies, especially family owned, will find little or no interest unless there is a quick and guaranteed return on their investments. In this context, I would like to propose the following recommendations as to:

f) Since government cannot go back on their commitment to the world regulatory body, the only option left to it is to actively involve and invest directly into new drug R&D.

g) Considering private sector invests only where they get quick returns, government should revive its public sector pharmaceutical units and undertake active R&D for both primary care and specialty diseases.

h) Government must encourage public-private-partnership (PPP) model of investments into drug R&D and undertake research through established research institutions and universities in the country.

i) Since there is no option, either with the government or the private sector, but it is essential to invest in drug R&D. In this critical stage, government should stand as a guarantor and promote venture capitalists to fill the vacuum and infuse capital into pharmaceutical R&D.

8. Bibliography/Webliography/References

1. Indian Planning Commission Report 2010
2. WTO agreement on Trade Related Aspects of Intellectual Property Rights
4. [http://www.livemint.com/Companies/RdthRWQs9wY8NC8h2jVMAP/Sanofi-junks-Glenmarks-painkiller-molecule.html](http://www.livemint.com/Companies/RdthRWQs9wY8NC8h2jVMAP/Sanofi-junks-Glenmarks-painkiller-molecule.html)
10. AceEquity
Dear Sir,

Thank You for your valuable time and effort in completing my study. Please click on the response button which most closely describes your answer. The data collected for this study will strictly be confidential and will not be subject to any commercial use.

*Company Name:

*Company Address:

*Annual Turnover:

*No. of employees:

*Name of the respondent:

*Designation:

*Education:

*E-mail ID:

*Contact Phone No:

*No. of years in the industry:

*No. of years with the Company:

*No. of years in the current position:

Comment on survey if any:
PHD Questionnaire
(Pharma-Biotech Companies)

Section A

This section comprises of all close ended question. Request you to please spare a few minutes to give fair and honest answers.

1. Would you describe the size of your organization as
   - Large
   - Medium
   - Small

2. Introduction of WTO-2005 TRIPS agreement was not in favour of the pharmaceutical industry in India.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

3. Pharmaceutical industry is not well equipped yet to deal with the strong intellectual property regime in the country.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

4. Strong intellectual property right without adequate R&D investments into new drug discovery will hamper long term prospect of the pharmaceutical industry in India.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

5. There is no significant R&D investment from Indian pharmaceutical companies for new drug molecule research despite strong product patent regime in force.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree
6. Lack of financial resources is the reason why Indian pharmaceutical companies are not able to invest large sums into new drug research.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

7. The small size and operation is affecting pharmaceutical companies earning potentials for large R&D investments for new drug research.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

8. Our R&D centre has active new drug molecule research program.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

9. We earmark more than 15% of our sales turnover towards new drug research alone.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

10. Currently we have several new drug molecules in our research pipeline.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

11. Majority of the research in the world are concentrated on lifestyle diseases due to better returns.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree
12. Lack of technology and research skills is the reason why many Indian companies outlicense their new drug molecules to big MNCs outside India.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

13. Implementation of strong IPR regime has not resulted into quality FDI in the country for new drug molecule research.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

14. A large part of the R&D investments into the country is intended to conduct Phase III clinical studies on human subjects, which require only minimal technology and research skills.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

15. Research at the basic molecular stage will help acquire research technology and medicinal chemistry skills.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

16. Implementation of strong intellectual property regime has failed to result in transfer of technology and research skills into the country.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

17. Strong intellectual property regime is favouring more to MNCs than Indian pharmaceutical companies.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
• Disagree
• Strongly Disagree

18. Acquisition of top Indian companies by pharma MNCs may kill the generic drug competition leading to high medicine price in the country.

• Strongly Agree
• Agree
• Neither Agree nor Disagree
• Disagree
• Strongly Disagree

19. Public sector pharmaceutical companies should be revived to play crucial roles in research and development of drugs that is specific to tropical country like India.

• Strongly Agree
• Agree
• Neither Agree nor Disagree
• Disagree
• Strongly Disagree

20. Government must consider investing in developments of new drug molecules due to high risk - high cost nature of drug research.

• Strongly Agree
• Agree
• Neither Agree nor Disagree
• Disagree
• Strongly Disagree

21. India possesses the required infrastructure and scientific aptitudes to conduct new drug research in the country.

• Strongly Agree
• Agree
• Neither Agree nor Disagree
• Disagree
• Strongly Disagree

22. India being a low-cost country can considerably reduce the time and cost of developing new drug molecules.

• Strongly Agree
• Agree
• Neither Agree nor Disagree
• Disagree
• Strongly Disagree

23. India need to strengthen its existing regulatory environment to allow flawless conducts of clinical trials in the country?

• Strongly Agree
24. **India will remain to be the supplier of high quality low cost drugs to the world even under tough product patent regime.**

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

25. **Indian pharmaceutical companies will eventually overcome the tough product patent act to become one of the top drug discovery nations in the world.**

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree
Section B

INTERVIEW GUIDE

This section comprises of all open ended question. Request you to please spare a few minutes to give your most appropriate statements to the questions.

1. What is the future of Indian pharmaceutical industry under the product patent regime?

2. Do you think our pharmaceutical industry is capable of developing new drug molecules in the near future? Please specify

3. What do you think that we lack in becoming one of the top drug discovery nations in the world?

4. Do you anticipate a strong IPR regime will lead to the problem of drug accessibility and affordability in the country?

5. What roles do you want our government to play to create a strong research based pharmaceutical industry in the country?

6. Globally, there is a declining tendency in doing R&D on tropical diseases. Isn’t it a dangerous trend which may lead to serious health crisis in world?

7. Any other information you would like to share?
Dear Sir,

Thank You for your valuable time and effort in completing my study. Please click on the response button which most closely describes your answer. The data collected for this study will strictly be confidential and will not be subject to any commercial use.

*Company Name:

*Company Address:

*Annual Turnover:

*No. of employees:

*Name of the respondent:

*Designation:

*Education:

*E-mail ID:

*Contact Phone No:

*No. of years in the industry:

*No. of years with the Company:

*No. of years in the current position:

Comment on survey if any:
Questionnaire
(Clinical Research Organizations)

Section A

This section comprises of all close ended question. Request you to spend a few minutes to give fair and honest answers.

1. Would you describe your organization as
   - Indian Company
   - Multinational Company

2. Introduction of WTO-2005 TRIPS agreement was not in favour of the pharmaceutical industry in India.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

3. Pharmaceutical industry is not well equipped to deal with the strong intellectual property regime in the country.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

4. Strong intellectual property right without adequate R&D investments into new drug discovery will hamper long term prospect of the pharmaceutical industry.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

5. There is no significant R&D investment from Indian pharmaceutical companies for new drug molecule research despite strong product patent in force.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree
6. The competency of Indian scientists is as comparable as to the best available in the world.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

7. Majority of our clinical research business comes from MNCs is intended to conduct Phase III clinical studies on human subjects.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

8. Majority of the research work in the world are concentrated on life style drugs rather than primary care diseases like TB, Malaria etc.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

9. Infrastructure, quality human skills and cost efficiency is the chief reasons why MNCs prefer India for their clinical trial activities.
   - Strongly Agree
   - Agree
   - Neither Agree nor Disagree
   - Disagree
   - Strongly Disagree

10. Indian companies lack adequate financial resources to develop new drugs.
    - Strongly Agree
    - Agree
    - Neither Agree nor Disagree
    - Disagree
    - Strongly Disagree

11. Implementation of strong IPR regime has not resulted into quality FDI in the country for new drug molecule research.
    - Strongly Agree
    - Agree
    - Neither Agree nor Disagree
    - Disagree
    - Strongly Disagree
12. Pharmaceutical companies can no longer rely on business based on products going off-patent in the world after the introduction of product patent.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

13. India possesses required infrastructure, scientific skills and financial resources to undertake new drug research in the country.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

14. India offers a rich and growing pool of skilled, talented and experienced medical professionals who can undertake drug research at any level.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

15. India quite capable of developing new drug molecules on its own.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

16. Our scientists have the competency to master the skill of biology as well as medicinal chemistry required at pre-clinical stage studies.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

17. Government must consider investing in developments of new drug molecules due to high risk - high cost nature of drug research.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
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18. Public sector pharmaceutical companies should be revived to play crucial roles in research and development of drugs that is specific to tropical country like India.

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- Agree
- Neither Agree nor Disagree
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19. India being a low-cost country can considerably reduce the time and cost of developing new drug molecules

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

20. India need to strengthen its existing regulatory environment to allow flawless conducts of clinical trials in the country?

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

21. The Supreme Court verdict denying patent protection to Novartis cancer drug ‘Glivec’ may not adversely affect the innovation & investment climate in the country.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

22. Strong intellectual property regime is favouring more to MNCs than Indian pharmaceutical companies.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

23. Acquisition of top Indian companies by pharma MNCs may kill the generic drug competition leading to high medicine price in the country.

- Strongly Agree
- Agree
- Neither Agree nor Disagree
24. **India will continue to be the supplier of high quality low cost drugs to the world even under tough product patent regime.**

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree

25. **India pharmaceutical companies will eventually overcome the tough product patent act to become one of the top drug discovery nations in the world.**

- Strongly Agree
- Agree
- Neither Agree nor Disagree
- Disagree
- Strongly Disagree
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5. What roles do you want our government to play to create a strong research based pharmaceutical industry in the country?

6. Globally, there is a declining tendency in doing R&D on tropical diseases. Isn’t it a dangerous trend which may lead to serious health crisis in world?

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