ABSTRACT

The research work, “A Study of Pharmaceutical Research & Development Post-2005 Product Patent Regime in India” is a comprehensive study undertaken to identify on the impact of WTO-led Trade Related aspects of Intellectual Property Rights (TRIPS) on Indian pharmaceutical industry and the pharmaceutical companies transformation from the existing patent law of process patent protection to product patent protection effective 1995 when India signed the TRIPS agreement with WTO. The TRIPS agreement emphasizes strong product patent protection to pharmaceutical inventions by all member countries of the World Trade Organization (WTO). This study, therefore, attach great relevance and immense value to the pharmaceutical industry, the government of India and billions of people around the world.

Healthcare is a subject of primary concern for every human being and making quality healthcare available to common public should be of utmost importance to every government in the world, particularly in India where the right to healthcare is fundamentally guaranteed under the constitution of India. It is, therefore, very important for Indian government to make affordable drug accessible to common man to protect the public health of the nation.

However, the extreme nature of drug monopoly due to the recent introduction of strong intellectual property regulation (TRIPS) has crippled the global generic pharmaceutical industry, particularly Indian pharmaceutical companies, which supplies quality drugs to the international community at a fraction of the original drug cost in the world. India was asked to toe the line of international patent protection law for all pharmaceutical inventions whether it is process or product, which restricted the production of generic version of the patented drugs. As a result, Indian companies had to re-align their business strategy putting strong emphasize on pharmaceutical research and development to survive and grow in the pharmaceutical business.

Though Indian pharmaceutical companies are aware about the significance of investment in R&D, but it has not emerged as envisaged despite two decades of TRIPS-induced intellectual property regulation in the country. It is in this context, this research has emerged as a thought
process to investigate the reasons behind the poor research and development, particularly new drug research from Indian pharmaceutical companies. The research, thus, investigated a large number of Indian and a few multinational pharmaceutical companies operating within India as well as contract research organizations on various aspects of drug research such as their capacity to invest for new drug molecule discovery, the intensity of drug research and the technology and research skills of Indian pharmaceutical companies to initiate molecular level drug research in the country.

Pharmaceuticals are a significant industry and it has a growing importance in the world, because pharmaceutical provides important health benefits to the humanity by way of inventing new products, new processes or new applications to existing product or process. Research and development, therefore, is the key to the growth of pharmaceutical industry around the world including India. Though Indian pharmaceutical industry ranks 4th globally and is growing at an annual rate of 12 – 15%, industry is yet to make use of its full potentials to create the first breakthrough in discovering New Chemical Entity (NCE). The question is when do we get our first pill? The answer should lie in how seriously government takes decision to invest and initiate massive drug research in the country through its established research institutions and universities.

For the government, drug research should become an essential component in its practical governance to protect public health. Whereas to the private sector, it is only the profit that motivates research, so they focus entirely on drugs that gives maximum financial returns such as lifestyle diseases like cancer and diabetic than the primary care drugs like HIV, TB, and Malaria etc., which are quite prevalent in tropical country like India.

The objectives of the present study is to analyse and appraise with regards to Pharmaceutical research and development post implementation of product patent protection in India with special emphasis on new drug molecule discovery. The study also includes examination of R&D capabilities, R&D investments and R&D intensities of Indian pharmaceutical as well as some of them multinational pharmaceutical companies operating in Indian market.
For this study, primary and secondary data were obtained by using questionnaire and interview methods to more than 111 Indian Pharmaceutical/Biotech companies and Contract Research Organization (CROs) located across the country. The source for secondary data were books, research journals, company websites, agency reports, newspapers, industry & trade magazines and various internet sites.

The study has used simple statistical tools such as Chi-Square test and t-Test to analyse the data and test of hypotheses. The main hypothesis has been statistically proved and justified that “There is no significant R&D investment to promote new drug molecule research in India after 20 years into signing TRIPS agreement”.

The study further summarizes the facts that Indian companies are aware about the importance of R&D, but unable to support sustained investment due to firms limited income and profitability, therefore, there is no significant R&D investment to promote new drug molecule research in the country despite strong intellectual property rights.

The study made important observation that pharmaceutical invention is expensive, risky and time consuming affair with high rate of failure making research viable only for large companies in the world with deep financial power. None of the Indian pharmaceutical companies at present fits the bill.

Hence, the study suggests that, in India, only the government can come to the rescue by seriously involving in the process of new drug discovery and development, for which it has to revive the existing public sector pharmaceutical units, research institutions and universities across the country to initiate massive drug research not only to develop and acquire the rare research technology and medicinal chemistry skills but to protect the most important issue of public health.

This research has its own limitations as well due to highly sensitive nature of drug research and the confidentiality maintained by organizations. The research also lack sufficient literature on new drug molecule research by Indian companies. Since TRIPS agreement is fairly a new
phenomenon, so many companies lacked the expertise to provide sufficiently satisfactory answers.

Researcher, in this study, finds sufficient scope for future research in this subject and the study may be extended to companies having dedicated R&D with active molecule in the research pipeline. A separate study can be done with top 25 Indian pharmaceutical companies who are into active development of new drug molecules to get a concrete view on drug research in the country. In addition, an exclusive research can be conducted for companies who are into biosimilars research which has greater prospects of finding new drugs.