India's Pharmaceutical Industry: A Firm Level Analysis Post Trade-Related Aspects of Intellectual Property Rights (TRIPS)

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Abstract

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) asks for global coordination of intellectual property rights (IPRs) legislation. All WTO member nations are required under the TRIPS Agreement to implement and enforce basic intellectual property rules. The establishment of pharmaceutical product patents was expected to stifle the growth of the Indian pharmaceutical industry. However, contrary to popular belief, the Indian pharmaceutical business has grown in the post-TRIPS period. In the present study, an attempt has been made to explore the post-TRIPS scenario regarding the Indian pharmaceutical industry, specifically a comprehensive firm-level analysis has been done. The period taken into consideration is from 2006-2023. The TRIPS Agreement shifted Indian pharmaceutical companies' R&D priorities, resulting in higher R&D investments. Since the TRIPS agreement came into force, the Indian pharma industry has tried to upgrade itself in terms of state-of-the-art technology.

Keywords

TRIPS, Indian pharmaceutical industry, Regulatory filings, Patents, and R&D expenditure.

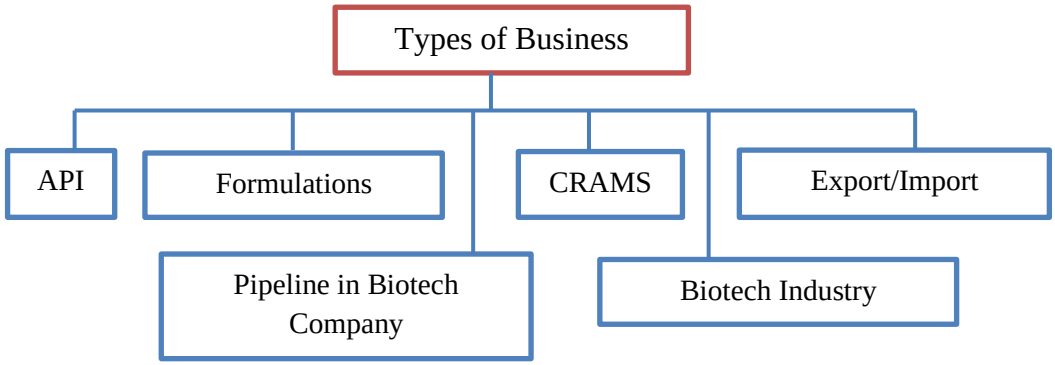
1. Introduction

Since the late 1980s, the Indian pharmaceutical sector has become one of the top medication exporters in the world and has reached production self-sufficiency. Additionally, its worldwide competitiveness has been encouraging. The pharmaceutical market in India is still growing on a global scale. This accomplishment has been credited to the industry's capacity to carry out research and development (R&D) and to create generic medications that were acquired and enhanced during the lax patent protection system made possible by the Patent Act, of 1970 from the 1970s to the 1990s. The Patent Act opened the door for improvements in indigenous Indian R&D because it recognized process patents but not product patents.

Indian pharmaceutical sector supplies over 50 percent of the global demand for various vaccines, 40 percent of the generic demand for the US, and 25 percent of all medicines for the UK. India contributes the second-largest share of pharmaceutical and biotech workforce in the world. India's domestic pharmaceutical market is estimated at US$ 41 billion in 2021 and likely to reach US$ 65 billion by 2024 and further expand to reach ~US$ 120-130 billion by 2030. (Indian Economic Survey 2021).

Globally, India ranks 3rd in terms of pharmaceutical production by volume and 14th by value (IBEF). The domestic pharmaceutical industry includes a network of 3,000 drug companies and ~10,500 manufacturing units. Indian drugs are exported to various countries in the world, with the US being the key market. Generic drugs account for 20 percent of the global export in terms of volume, making the country the largest provider of generic medicines globally. It is expected to expand even further in the coming years.

In order to comply with the World Trade Organization's (WTO) TRIPS agreement, which established universal basic requirements for the protection of intellectual property, India revised the Patent Act in March 2005. Along with patents, other IPRs including copyright, trademarks, industrial designs, geographical indications, and secret information are also covered under the TRIPS Agreement. Members of the WTO are required to abide by the TRIPS Agreement's rules. The TRIPS Agreement mandated the implementation of pharmaceutical product patents as well as a minimum 20-year patent protection duration.



Source:- Author's compilation

Figure 1:- Segments of the Indian Pharmaceutical Sector

1.1. Active Pharmaceutical Ingredients (APIs)

The Active Pharmaceutical Ingredient, or API, is the main component in medications. The primary drug used to treat ailments is known as the active pharmaceutical ingredient or API. Many companies only concentrate on developing APIs. Companies typically sell three main categories of APIs: cancer, steroids, and hormones. The primary revenue stream is the oncology industry. This is primarily due to the high setup costs associated with these streams typically five or six times more than average.

1.2. Formulations

In the field of pharmaceutics, pharmaceutical formulation refers to the process of combining various compounds, including the active component, to create a final pharmaceutical product. Another common addition to the idea of formulation is the dosing form. There are two classifications for pharmaceutical formulations:

1.2.1. Oral Formulation

1.2.2. Topical Medication Form

1.3. Contract Research and Manufacturing (CRAM)

The greatest scalable business potential for Indian players is provided by contract manufacturing or CRAMS. This is because Custom Chemical Synthesis (CCS) typically uses resources at the gram or kilogram level, whereas CRAMS typically requires supplies in considerably bigger numbers, often in tons. Because CCS supplies rely on the success of the partner's research and development process, they can be somewhat unpredictable. On the other hand, CRAMS supplies depend on how well a product performs after it is commercialized.

1.4. Export/Import

With the largest number of approved pharmaceutical production facilities and a large assortment of export-ready drugs, India is well-positioned to lead the world in pharmaceutical exports. Several internal factors affect the pharmaceutical industry's growth in India. Since 2008, there has been consistent annual growth, with an additional $1–1.5 billion in income each year. India's top two export destinations for pharmaceuticals are the US and the UK. A significant portion of the industry's revenue comes from exports; India exports pharmaceutical products to more than 200 countries.

1.5. Pipelines in Biotech Companies

A drug's position in the pipeline indicates the stage of clinical trials it is either conducting or must go through to be licensed for sale or use by the general public. The pipeline as a whole displays the range of unique products or procedures that a company has either produced or is working on. An FDA (Food and Drug Administration) approved medication that has begun clinical testing is referred to as "in the pipeline."

1.6. Biotech Industry

Based on the products and services provided, the Indian biotechnology industry is currently divided into five segments. Among these are the bio-pharmaceuticals, bio-services, bio-agriculture, bio-industrial, and bio-informatics sectors.

1.7. The Rationale behind Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS agreement, which is currently the most extensive international agreement on intellectual property, marked the integration of intellectual property law within the framework of multilateral trade. Concerns from developing nations over wealthy nations' endorsement of an excessively restrictive interpretation of TRIPS sparked a series of discussions that started in 2001 and produced the Doha Declaration. Clarification on the scope of TRIPS is provided by this WTO statement, which emphasizes the significance of, among other things, interpreting TRIPS in line with the objective of "promoting access to medicines for all."

There were already several agreements in place in the field of intellectual property for the protection of intellectual property internationally, such as the Berne Convention about copyright and the Paris Convention related to industrial property rights, including patents and trademarks. But since the trade-related aspects of intellectual property have gained more attention, it has become imperative to reach a global agreement within the framework of the GATT, involving as many countries as possible, on the standards of protection for trade-related intellectual property.

The results of intellectual creativity today include inventions, designs, know-how, and artistic works. To encourage this kind of creative activity, trade secrets, industrial designs, literary and artistic works, integrated circuit layout designs, and other products are protected. Moreover, trademarks and similar symbols are safeguarded to maintain the confidence earned through commercial endeavors, safeguard customers, and guarantee equitable competition.

As a result, during the Uruguay Round of the GATT in 1986, trade-related aspects of intellectual property rights (TRIPS) talks emerged as one of the major new topics of discussion.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) mandates that all WTO member nations' intellectual property rights (IPRs) laws be harmonized. All WTO members are required by the TRIPS Agreement to establish and uphold basic standards for intellectual property.

2. Review of the Literature

Enough literature is not available where all the parameters have been simultaneously covered. The researcher has tried to do a rigorous review in order to study how different parameters taken for the study play out regarding the Indian pharmaceutical industry. Mitsumori, Y., et al., 2023, the Indian pharmaceutical industry grew quickly as the Patents Act of 1970 did not protect product patents. India restored pharmaceutical industry product patents following the implementation of TRIPS in 2005. The data shows that these large Indian firms have contributed actively to the construction of NCEs and boosted their investment in research and development (R&D). Even so, R&D expenditures are still significantly lower than those of the biggest pharmaceutical companies in the world and the leading Japanese companies. The restricted pursuit of product patents by Indian pharmaceutical businesses gives rise to stringent limits.

Pai, R., 2023 in his article provides an overview of how the TRIPS Agreement affects generic pharmaceutical availability and affordability in India, as well as how India's regulatory framework conforms to international standards. It also considered the challenges the Indian pharmaceutical industry faced and the country's ratification of the TRIPS agreement. The research delineated the diverse regulations that oversee the pharmaceutical sector and concluded that the TRIPS Agreement has provided Indian pharmaceutical enterprises with supplementary expansion opportunities and facilitated technology transfer and upgrading.

Singh, K., & Azhar, N. 2022, attempted to investigate the effects of the nation's patent rules on the sales, exports, R&D investments, and profitability of the Indian pharmaceutical business. The findings show that, among other crucial factors, a firm's R&D activities are influenced by its marketing intensity, market share, export intensity, profitability, import of products intensity, and capital intensity, albeit in different directions and to varying degrees.

Festa, G., et al.,2022, due to recent corporate and institutional reforms in the pharmaceutical business, India is currently leading the world market; yet, there are a number of dangers and vulnerabilities that could impede its progress. This study provides an international perspective on the pharmaceutical sector's potential for growth and development in India by comparing it with both internal trends and external competition. The research's most important contribution is the necessity for Indian businesses to switch from manufacturing only generic drugs to developing original ones; appropriate industrial marketing tactics are crucial in this regard.

Sharmiladevi, J. C., 2020, the author analyzes the export intensity of Indian pharmaceutical companies by comparing their revenue from royalties, R&D expenses, and merchandise exports to that of foreign companies. The study makes the intriguing claim that, when the variables were taken into account, domestic businesses were performing better than their international peers. The primary cause of this is that domestic companies are investing more in research and development than multinational companies. The study by Manju & Sharma, 2020, explored the trends in the export and import of pharmaceutical products during the pre and post-TRIPS period. The study came to a conclusion that the exports of formulations are more than the imports of pharmaceutical products.

Kamiike, 2020, in his paper attempted to identify how the TRIPS agreement is influencing the Indian pharmaceutical industry and further discusses the industry's growth factors in the post-TRIPS period within the GVC framework. He concluded that the TRIPS agreement led to a change in the R&D orientation which further encouraged the increase of R&D investments and also promoted the industry to upgrade itself by adopting state of the art technologies by being part of the Global Value Chain (GVC). The paper by Chawra, 2020 studied the current scenario and opportunities on global pharma and the Indian pharma market. It stated that Indian pharma market will emerge much stronger in the transitionary phase as it has been successful in driving generics penetration globally and implementation of good policies, regulations, and low cost of labor are the key parameters that influence the industry.

Motkuri & Mishra, 2020, examine the structure and performance of the domestic pharmaceutical industry and the market's pricing policy regarding drugs. Researchers found that the changes in the recent pricing policy have a certain leverage for the industry rather than affecting it. In the interest of social welfare, government intervention through price control of essential and lifesaving drugs is a necessity for India.

Ray et al., 2019, building on the previous discussion the authors made an effort to investigate the development of the Thai and Indian pharmaceutical industries' markets and exports. It is believed that the government must create an action plan for establishing the pharmaceutical industry's brand. Additionally, as new sectors of the business have emerged, including contract manufacturing, contract research services, bio-pharmaceuticals, and Indian medical systems, a "brand India" has progressively developed around the Indian pharmaceutical sector.

Rentala et al., 2017, expanding on this theme it is necessary to consider a study in which the authors tried to use export efficiency as a metric of firm performance to assess the export efficiency of the Indian pharmaceutical industry during the temporary TRIPS and post-TRIPS periods. The findings showed that once India joined the WTO, the export efficiency of the sector increased, and that the industry's efficiency peaked during the post-TRIPS era. This has been made feasible by the industry's ability to provide premium goods at affordable costs.

The study by Khurana, 2017, investigated the role and impact of FDI in India and specifically studied the pharmaceutical sector. The study concluded that FDI has positively impacted the Indian pharmaceutical industry and has not only made India self-reliant but also a net exporter of generic medicines.

Lajipathirai & Sekhar, 2017, their study, identified various strategies that would fit in pharmaceuticals to market they are Over the Counter (OTC) products and to make an in-depth analysis of OTC product's potency, safety, and availability. They came at a conclusion to organize the pharma industry, and those manufacturing OTC drugs.

Regarding the impact of R&D expenditure, regulatory filings and patents granted, the study by Banerji & Suri, 2017, concluded that Indian pharmaceutical exports are driven collectively by regulatory filings as well as total patent granted. It implied that in post-TRIPS era and after the start of the product patent regime; the Indian pharmaceutical firms have increased their R&D expenditure in order to enhance patenting activity and at the same time leveraged the opportunity of supplying generics to lucrative generic markets like the USA and Europe.

Abrol & Singh, 2016, analyzed the post-TRIPS scenario in India and focused on the impact of the approach adopted by the government for the formulation of post-TRIPS innovation policy to address the steering and coordination of policies for upgrading in-house R&D, publicly funded R&D, intellectual property, domestic industry, and health system. Results indicated that the link between domestic firms and public sector research organizations is the weakest link of the domestic pharmaceutical innovation system in India.

Rentala et.al, 2014, to estimate the export competitiveness of the Indian pharmaceutical industry, the researchers attempted to comprehend the significance of various technological capabilities and other business resources in this work. By contrasting the outcomes of the fixed effects model and random effects model, the ordinary least squares (OLS) regression approach was used for study analysis. According to the findings, R&D spending by Indian pharmaceutical companies still has to rise to significantly affect export performance. Improvements in technology will make it easier for Indian pharmaceutical companies to launch novel research compounds on foreign markets and will render the Indian pharmaceutical sector more competitive worldwide.

Goldar, B., 2013, the study's underlying hypothesis is that the export competitiveness of the Indian pharmaceutical sector increases with R&D expenditure. The author developed a number of factors for the analysis, such as companies started after 1995, multinational firms, foreign equity, machinery age, R&D intensity, technology imports, bulk medication producers, and exports. The results demonstrate that export performance rose after 1995, or when the patent laws were modified. Furthermore, the question of whether bulk medication makers exported more than other producers was looked into.

Akhtar, 2013, attempted to analyze the balance of trade, bulk drugs, and TRIPS in the context of the Indian pharmaceutical industry. Results showed that 70 percent of the bulk drugs requirement is fulfilled by the domestic industry. In addition to catering to the needs of domestic demand, it is also the leading supplier of bulk drugs and formulations globally.

The study by Bedi et al., 2013, studied the impact of a restructured patent regime on the R&D expenditure and the patenting activity of Indian pharmaceutical companies. The results witnessed that there has been patenting activity after the advent of TRIPS.

Abrol et al., 2011, Considered the tactics used to foster learning, innovation, and the development of competencies as well as to forge connections and synergies within the Indian pharmaceutical sector in the aftermath of Trade Related Intellectual Property Rights (TRIPs). The study concluded that businesses and the Indian government have selected globalization routes that have particular consequences for innovation. The results of their R&D investment operations show a considerable shift in pharmaceutical companies, both domestic and foreign.

3. Objectives of the Study

3.1 To explore the performance of the Indian pharmaceutical industry after the implementation of TRIPS.

3.2 To analyze the performance of leading pharmaceutical firms of India during the post-TRIPS period based on selected parameters (sales, net profit, R&D expenditure, regulatory filings).

4. Significance of the Study

There have been many previous studies that have envisaged the performance of the Indian pharmaceutical industry based on different parameters but on a firm level, there has not been any comprehensive study taking many parameters together. Hence, this paper attempts to shed light on the performance of leading firms in the Indian pharmaceutical industry in the form of a comprehensive firm-level analysis.

5. Research Methodology

The overall structure of the study involves descriptive analysis of the research problem and the nature of the study is such that it requires secondary data. The data was mainly retrieved from the annual reports of the companies taken for the study. The parameters considered to evaluate the performance of the firms are sales, net profit, R&D expenditure, and patents granted in terms of ANDA and DMF filings. The time period taken for the study is from the F.Y 2006-07 to 2022-23. The basis of the selection of the duration of study is that in India, TRIPS formally came into force in 2005.

6. Data Analysis

Data has been collected through various government organizations like the Dept. of Pharmaceuticals, India Brand Equity Foundation (IBEF), newspapers such as Pharmabiz and Pharmaexcil. The annual reports of selected companies have a major share in data collection and accordingly, growth has been calculated and the rest of the study has been descriptively analyzed.

Up until the middle of the 1990s, the Indian pharmaceutical industry's R&D efforts were concentrated on the creation of novel methods for producing drugs. Changed by the TRIPS Agreement. The TRIPS Agreement has altered the R&D priorities of the Indian pharmaceutical business in addition to raising R&D spending levels. Pharmaceutical businesses in India are expanding their R&D spending to develop new products.

The pharmaceutical sector is very focused on R&D. Continuous R&D for the creation of novel medications and technology is necessary for the pharmaceutical industry to experience sustainable growth under the TRIPS Agreement's pro-patent framework. In order to compete against fierce competition in the international pharmaceutical industry, Indian businesses have upped their R&D spending. R&D is becoming more of a focus for the businesses. The new R&D priorities include R&D for bio-pharmaceuticals, NDDS (novel drug delivery systems), and NDDR (new drug development research).

In the years following TRIPS, Indian pharmaceutical firms not only boosted their R&D spending, but also became more intensely focused on R&D. As their R&D experience grows, Indian pharmaceutical businesses' technological capabilities have been continuously rising. Strong R&D technology is helping Indian pharmaceutical businesses expand their foothold in the global pharmaceutical industry. In the post-TRIPS era, India's pharmaceutical sector is climbing the value chain.

The current study has taken into consideration key parameters such as-

6.1 Sales

6.2 Net profit

6.3 R&D Expenditure

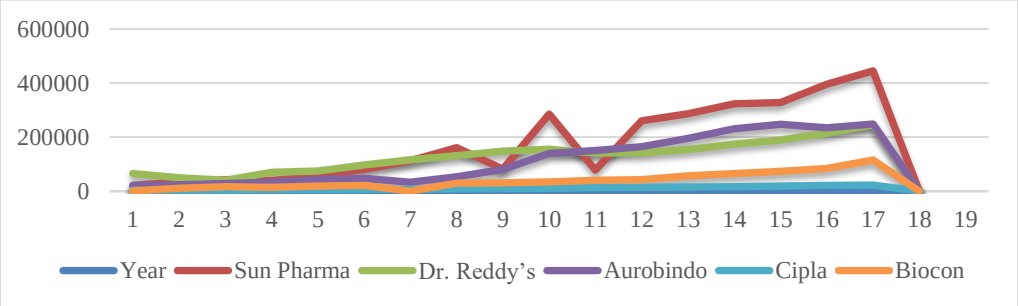
6.4 Patents granted in terms of ANDA and DMF filings

6.1. Sales

Table 1:- Sales (In millions)

Year	Sun Pharma	Dr. Reddy's	Aurobindo	Cipla	Biocon
2006-07	21,320.5	65,095	21,722.3	3207.95	990
2007-08	34605.6	50,006	24,092.8	4338.21	10,902
2008-09	42,723	40,419	28,852.5	4010.38	16,732
2009-10	39,040	70,277	33,196	4960.60	14,931
2010-11	57214	74,693	42,299.9	5,359.52	18,576
2011-12	80195	96,737	47250	6,323.84	21,483
2012-13	112,999	116,266	33,872	7,020.7	25.380
2013-14	160,804	132,170	53,785	8,279.33	29,332
2014-15	82,287.7	148,189	80,951	10,173.39	31,429
2015-16	285,177	154,708	139,552	11,345.44	34,602
2016-17	78,636.9	140,809	150,899	13,790.10	40,787
2017-18	261,000	142,028	164,998	14,630.24	43,359
2018-19	287,000	153,851	195,636	15,219.25	56,588
2019-20	323,000	174,600	230,985	16,362.41	65,286
2020-21	3,28,375	1,89,722	2,47,746	19,160	73,603
2021-22	3,95,760	2,14,391	2,34,555	21,763	83,967
2022-23	4,45,202	2,45,879	2,48,554	22,753	1,15,501
Compounded Annual Growth Rate	**17.31%**	**10.47%**	**15.70%**	**10.91%**	**15.90%**

Source:- Annual Report of the Selected Companies



Source:- Annual Report of the Selected Companies

Figure 1:- Sales

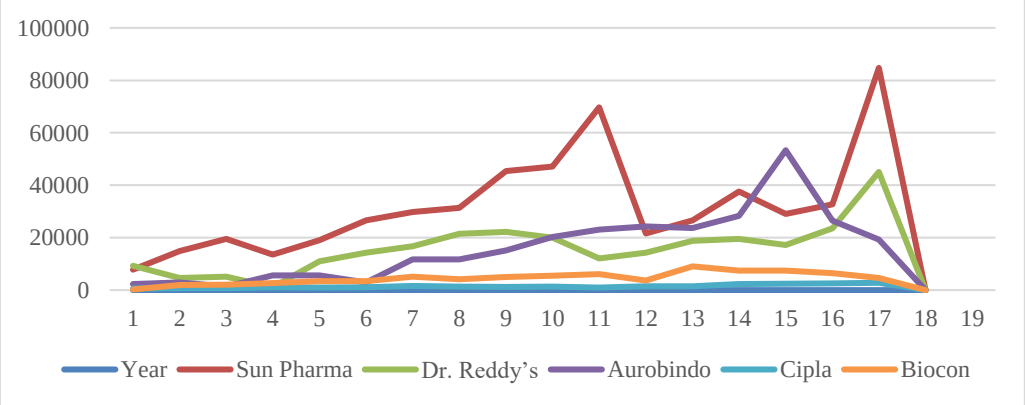
In the above table/graph, it is evident that the sales growth rate of Sun Pharma has surpassed by a whopping 17.31 percent as compared to other selected firms. Following Sun Pharma, Biocon has a growth rate of 15.90 percent. That has been followed by Aurobindo (15.70 percent), Cipla (10.91 percent), and Dr. Reddy's (10.47 percent). The reason for Sun Pharma to have topped the charts is that it continues to focus on improving manufacturing efficiencies and optimizing costs.

6.2 Net Profit

Table 2:- Net Profit (In millions)

Year	Sun Pharma	Dr. Reddy's	Aurobindo	Cipla	Biocon
2006-07	7843	9,327	2290.8	607.64	200
2007-08	14,869	4,678	2,907.8	701.04	1956
2008-09	19,491.7	5,168	1,285.4	771.02	2038
2009-10	13,511	1,068	5634	1082.59	2,696
2010-11	19074	11,040	5635	989.57	3,399
2011-12	26567	14,262	2,938.6	1144.24	3,384
2012-13	29,831	16,776	11,728.5	1544.85	5,089
2013-14	31,414	21,512	11,720.9	1388.41	4,138
2014-15	45,394	22,179	15,163.5	1,181	4,974
2015-16	47,159	20,013	20,251	1,360	5,504
2016-17	69,644	12,039	23,017	1,006	6,121
2017-18	21,616	14,341	24,232	1,411	3,724
2018-19	26,654	18,795	23,647	1,528	9,053
2019-20	37,649	19,498	28,310	2318.17	7482
2020-21	29,038	17,238	53,338	2,405	7,405
2021-22	32,727	23,568	26,471	2,517	6,484
2022-23	84,736	45,067	19,277	2,802	4,627
Compounded Annual Growth Rate	**11.49%**	**15.21%**	**12.55%**	**9.05%**	**5.53%**

Source:- Annual Report of the Selected Companies



Source:- Annual Report of the Selected Companies

Figure 2:- Net Profit

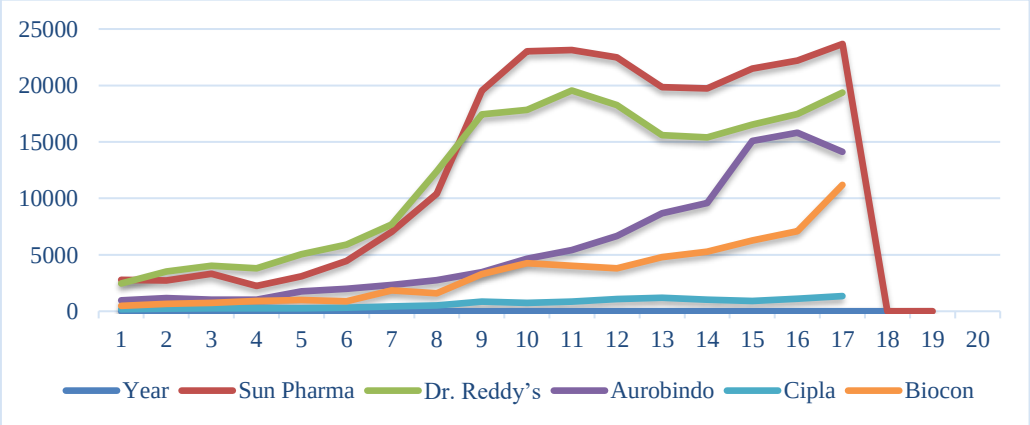
In terms of Net profit, the highest growth rate has been recorded by Dr. Reddy's (15.21 percent), Followed by Aurobindo (12.55 percent), Sun Pharma (11.49 percent), Cipla (9.05 percent) and the lowest is by Biocon (5.53 percent).

6.3. R&D Expenditure

Table 3:- R&D Expenditure (In millions)

Year	Sun Pharma	Dr. Reddy's	Aurobindo	Cipla	Biocon
2006-07	2,787	2,463	967.1	175.73	479
2007-08	2,725.2	3,533	1175.1	234.01	646
2008-09	3,320	4,037	1032.3	251.50	744
2009-10	2,242	3,793	1014.8	250.69	915
2010-11	3096	5,060	1757.2	259.79	995
2011-12	4449	5,911	1989	323.83	879
2012-13	7,042	7,674	2333.4	425.14	1860
2013-14	10,418	12,402	2,753.2	517.51	1580
2014-15	19,550	17,449	3,465.5	844.14	3,284
2015-16	23,025	17,834	4,644	741.46	4,267
2016-17	23,138	19,551	5,428	859.91	4,019
2017-18	22,489	18,265	6,665	1074	3,804
2018-19	19,847	15,607	8,683	1204	4,796
2019-20	19,736	15,410	9,580	1,013.35	5271
2020-21	21,499	16,541	15,096	924	6,270
2021-22	22,194	17,482	15,814	1,122	7,105
2022-23	23,676	19,381	14,115	1,344	11,194
Compounded Annual Growth Rate	**14.47%**	**11.22%**	**16.81%**	**11.54%**	**19.51%**

Source:- Annual Report of the Selected Companies



Source:- Annual Report of the Selected Companies

Figure 3:- R&D Expenditure

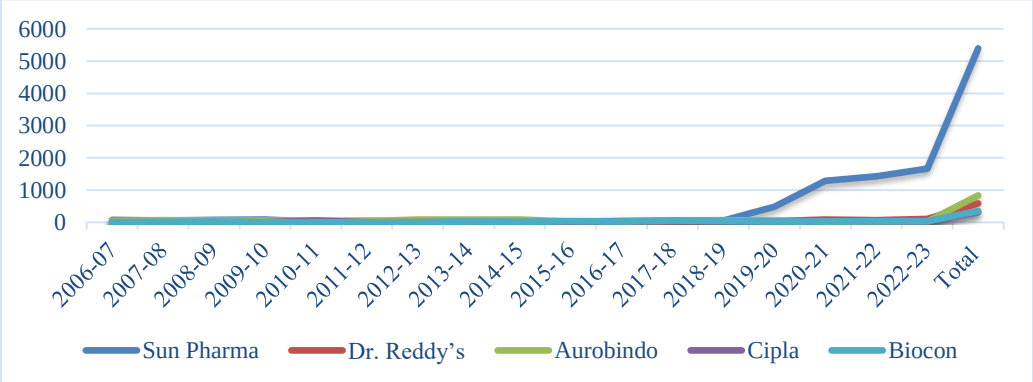
The highest expenditure on R&D from the year 2006-07 to 2022-23 has been done by Biocon (19.51 percent). Followed by Aurobindo (16.81 percent), Sun Pharma (14.47 percent), Cipla (11.54 percent) and, Dr. Reddy's (11.22 percent).

6.4. Patents in terms of ANDA and DMF Filings

Table 4:- Patents in Terms of ANDA and DMF Filings

Year	Sun Pharma	Dr. Reddy's	Aurobindo	Cipla	Biocon
2006-07	70	14	40	0	0
2007-08	59	13	69	0	14
2008-09	76	31	55	0	25
2009-10	81	25	52	0	0
2010-11	18	21	57	59	0
2011-12	22	41	36	0	0
2012-13	20	27	81	7	0
2013-14	26	21	84	14	23
2014-15	20	13	87	8	17
2015-16	22	18	21	5	34
2016-17	33	21	30	32	27
2017-18	40	31	46	34	57
2018-19	51	34	63	32	33
2019-20	483	30	55	20	28
2020-21	1287	81	18	42	25
2021-22	1420	63	19	33	34
2022-23	1665	100	20	23	32
Total	**5393**	**584**	**833**	**309**	**349**

Source:- Annual Report of the Selected Companies



Source:- Annual Report of the Selected Companies

Figure 3:- Patents Granted

In terms of patenting activity, Sun Pharma has the largest basket of patents with 5393 DMF and ANDA filings in all these years. Followed by Aurobindo (833), Dr. Reddy's (584), Biocon (349), and Cipla (309).

6. Conclusion

The pharmaceutical sector grew globalized as a result of the TRIPS Agreement. The pharmaceutical value chain has been regrouped and expanded into new markets such as India. After the introduction of the TRIPS agreement in India, companies have adopted newer and sustainable methods of R&D. India already has a reputable position globally when it comes to generics and formulations so the key was to encourage R&D so that more can be contributed to this field. By increasing their R&D expenditure and ANDA/DMF filings, they were able to make quality products and as a result, patents were granted. TRIPS agreement opened a world of opportunities for India and helped it to maintain its reputable position globally.

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