Chapter - I

INTRODUCTION

1.1 Topic of the research
The topic of the research is viz. the systematic study of the pharmaceutical industry in India which is threatened due to the new controls brought about rules and regulations of the WTO regime, especially regarding tariff policies, the TRIPS (Trade Related Intellectual Property Rights), the opening up of Indian domestic market to foreign multinationals by adopting liberalization, maintenance of professional standards of business ethics, obtaining world class quality approvals and accreditations for Indian pharmaceutical exports, adoption of ‘product patents’ in addition to ‘process patents’ and restrictions on unauthorised imitations. Till 1995 the Indian Pharmaceutical industry was governed by IPL (Indian Patent Laws) and laws controlling the production and distribution practices. After getting the membership of the World Trade Organization, which has become the apex international permanent body for reorganising and streamlining world trade and for bringing about an ideal international order in global trade ethics by making the necessary controls mandatory on the part of the member countries, the Indian pharma industry is facing new difficulties and challenges.

The Indian pharmaceutical industry was indirectly and remotely governed by the rules and regulations of GATT since 1948. The GATT adopted a lenient and mild approach in its regulations, and would revise and reframe its rules with every new round of conferences held under its ambit. As a result there was relatively much more freedom to Indian pharmaceutical industries to grow independently. Especially after the 1970s, the Indian pharma industry made a very rapid and amazingly qualitative progress. This may be credited to the intrinsic strength of cheaper scientific manpower, patronizing policies of the government the excellent competency of Indian manufactures in the field of bulk drugs and generic drugs. Further, the cost effective production process
employing unique skills of processing and re-engineering of world class brands, had added to the profitability of these concerns.

Till the year 1970, India had only 2,257 pharmaceutical units. Their number rose to 5,156 (more than double) by the 1980s, and by 1990s, their number shot up to 16,000 units. By the end of the 20th Century India had small, medium and large pharmaceutical units together totaling more than 20,000. Thus there has been a 10 fold progress in the number of industrial units, only during the last 30 years.

The Indian pharmaceutical industry employed only about 2 lakh employees in 1970s. At present it has created employment for more than 30 lakh employees. The Indian pharmaceutical industry provides drugs and medicines of competitive quality at very low prices compared to those of advanced countries and dominates domestic trade by about 85 to 90 percent.

India has achieved the fourth global rank in terms of volume of generic market, next to US, Japan and Germany.

The Indian pharmaceutical industry contributes as a ‘net foreign exchange earner’ by exporting drugs worth Rs. 14000 crores in 2003 as against India’s pharma imports worth Rs. 4000 crores only.

It has not only multiplied its exchange earnings by 20 times in the last 3 decades but has also captured the global market by penetrating new markets of 65 countries in general and markets of the US, the European Union, China and Brazil in particular.

1.2 WTO membership: Emerging problems

1) Against this background of India’s rapid progress of the pharmaceutical industry, when India had to accept the membership of WTO; there were partly legitimate and partly exaggerated fears in the confessed
quarters of captains of pharmaceutical industry, economists, policy makers, elected law makers from different political parties and the general public.

2) Since the pharmaceutical industry per se is 'capital intensive' due to requirements of huge fund allocations for activities of R & D. Indian pharmaceutical industries may not be able to survive in the environment of open business competition, owing to capital deficiency.

3) Due to the acceptance of 'patent rights' and the monopoly of MNCs in Global pharmaceutical market, Indian consumers will have to pay exorbitant prices to foreign companies. The Indian Drug Manufacturers Association (IDMA) protested that 'prices of all medicines will rise by 5 to 20 times (!) as a consequence of the acceptance of TRIPS and WTO dictates.

4) The general opinion was that acceptance of the WTO regime will lead to 'country's sell out to foreign multinationals' and cause agony to the Indian patients by compelling them to be party to this total sell out'.

1.3. **Reason for selecting the topic**

Due to the controversial nature of the burning topic of alleged 'threats to Indian pharmaceutical industry due to membership of WTO', this Researcher was motivated to conduct an objective and unbiased academic research based on the actual facts and figures of this vital issue of public interest.

Since 1993, the researcher continued his study and gathered secondary data essential for a methodological study. In the meanwhile, India's process patent practices, were officially permitted till the year 2003 because the moratorium of the years was granted by WTO for official acceptance of 'product patent regime' which was to commence in India from 2005.
The researcher therefore decided to earmark the transitional period of ten years of 1993 to 2003 for objectively examining the perceived impact of WTO regime on Indian pharmaceutical industry in the areas of viability and sustainability of Indian pharma industry, export earnings of pharma industry, employment levels, price levels of drugs and medicines in the domestic market, and general prospects of the Indian pharmaceutical industry.

Last but not the least, very few research-based studies have been carried out on the impact of WTO on world trade, in Indian Universities. Furthermore, not a single research thesis based on the selected topic, has so far been credited to the Faculty of Commerce, University of Pune.

Right from the year 1993 upto 1997, since the publication of the proposed draft of the Secretary General of GATT Mr. Dunkel a national level debate had assumed agitative proportions pertaining to the dilemma on whether to join the WTO or not. The political as well as the economic opinion was not in favour of accepting the WTO regime, which according to the antagonists, was certainly detrimental to the budding and prospering Indian pharmaceutical industry. The Swadeshi Lobby of the BJP and its allies the leftist lobby of the ruling Congress and its allies from the so called third front who were ideologically opposed to the entry of multinational giants, the three communist parties including CPI, CPM and forward block and the captains of big Indian pharmaceutical companies, as well as the small scale drug manufacturers who had become nervous due to the threats of the competition from global pharma giants, and finally journalists of national and regional newspapers, all had recorded their opposition to the acceptance of the WTO regime. This nation-wide debate continued for a long time, even after India had formally obtained the membership of the WTO.
The gist of the arguments against the WTO membership can be summed-up as under:

1) The Indian pharma industry in general and twenty thousand small units in particular will be totally destroyed and shattered due to their inability to withstand the formidable competitive threat of global MNCs.

2) Due to the norms and conditions regarding the proven quality of the drugs and hyperstrict conditions of the US Food and Drug Administration regarding Good Manufacturing Practices (GMP), Indian Pharmaceutical experts will be severely affected causing a set back to foreign exchange earnings of Indian pharma companies.

3) Due to the removal or reduction of import tariffs, foreign drugs will become cheaper and affordable to the middle-class population of India and Indian small companies will lose even their domestic markets.

1.4 Title of the research

While preparing the synopsis and broad outline of the proposed research, it was decided that the title of the research should be short, precise, specific and logically apt. Bearing this in mind the following title was accepted as a final one.


The title itself identifies and defines the paradigms of the scope and coverage of the study, which are as under:

a) Prevailing strengths and weaknesses of the Indian pharmaceutical industry in the total global industry.

b) The nature of various strict and rigorous controls of the apex authority to supervise, monitor and maintain the order of ethics
and discipline in the global trade and their direct and indirect impact on the prospects of Indian pharmaceutical industry.

c) The objective assessment of India's gains and losses and opportunities and threats produced by the acceptance of the WTO regime.

d) A data-based and quantitative exercise of examining the truth and the substance of arguments based on perceived fears and biased prejudices, as well as, emotive overreactions which were against WTO regime, vis-a-vis, the facts and actual evidence of the 'state of affairs' concerning particularly with Indian pharmaceutical industry.

e) A broad and exhaustive survey of pros and cons of WTO regime affecting Indian pharmaceutical business.

f) The study to be logically confined to the period of 1993-2003 being the period of transition and transformation from 'Process patent regime' to 'Product patent regime'.

1.5 Hypothesis

Hypothesis which is to be tested and verified by the analytical data has been categorically stated as "The WTO regime is going to enforce Indian manufacturers to manage innovations and workout trading strategies so as to acquire strategic marketing assets".

"The overall impact of WTO regime on the business prospects of Indian pharmaceutical industry has been much more benevolent than malevolent. It has created greater trade opportunities and avenues as opposed to the misconceived notion of being a threat and detrimental to trade prospects.

1.6 Objectives of the research

1. To examine the profile of pharmaceutical industries, globally and its trade with special reference to the dominant players who
have sizeable shares in total global market. To identify the dominant regions which make large purchases of drugs and medicines by their respective purchasing powers and the health awareness. To study the trends in the growth of the pharmaceutical trade in the World in the period of the 'cold war' and the current decade of the 21st century.

2. To study in detail the growth and progress of the pharmaceutical industry in India during pre-independence and post independence decades. To account for the total value added by the Indian pharmaceutical industry, the shares of foreign exchange earnings as well as the earnings from the domestic market. To identify the dominant pharma companies and their respective shares in the total pharmaceutical business. To examine the trends of its growth especially in post 1960s as well as during the decade of economic reforms and the membership of WTO. To identify the areas and prospective potential for the progress of Indian Pharmaceutical industries, after adopting the WTO regime. To study the composition of India's exports and imports of pharmaceuticals in post 1980s.

3. To examine the developments in Indian pharma policies, Indian laws governing the practices of the industry and the trade, various controls, quality and pricing policies, patent legislations, rules and regulations, changes in Indian legislation and controls during the membership of the WTO.

4. To study the impact of direct and indirect controls of GATT, WTO and WHO on Indian pharma business.

5. To make exhaustive study of the positive and negative impact of TRIPs, on India's pharmaceutical business.

6. To make objective assessment of the pros and cons, advantages and disadvantages, benefits and losses and the opportunities and threats caused by the new regime of the WTO.
1.7 **Scope and importance of the study**

The pharmaceutical industry has remained a grey area in academic research especially in the disciplines of economics, commerce and management science. It has emerged as the fourth foreign exchange earner next to textiles, gems and jewellery and software and IT services. The Indian pharmaceutical industry has emerged as one of the fastest growing sector especially during the last 3 decades having average rate of growth of not less than 15 percent. Having an advantage of highly skilled scientific manpower, innovative and adoptive efficiency and comparative cost advantage, it is poised to be ranked as one of the Top Ten leading industries of the World in the coming score\(^1\). This research therefore is appropriate and its timing is so perfect that it will enlighten the people engaged in Indian pharma industry such as the policy makers, the government the academics from pharmacy, biotechnology, economics and management, as well as the general public.

The study will explore a number of areas which hitherto have been neglected in the mainstream of the academic research and will make an original contribution bearing practical utility and benefit owing to its applied nature.

The outcome of this work will enlighten particularly the management students, new researchers, pharmacists, professionals and policy makers, in general.

1.8 **Methodology and the sources of data**

The entire study will obviously be based on the secondary data and the empirical evidence. The data will be systematically processed, analysed and interpreted so as to derive logical findings of the research.

\(^1\) A "score means 2 decades or 20 years"
This seems to be the scope for research since the pharmaceutical industry in India has no independent status as it has been clubbed with the chemical industry; it is very difficult to obtain separate data for the same. Probably due to this reason, very few researches have been conducted in this area, so far.

The main data sources are as under:

1) The U. N. Handbook of statistics
3) The data published regarding World's exports and imports by the U.N.
4) WTO reports, periodical publications.
5) The statistics published by 'the World's Chemical Market'.
6) World Health Organisation - Reports (WHO)
7) General Agreement on Trades and Tariffs - GATT - Reports.
8) Economic Survey - published by Ministry of Finance, Govt. of India.
9) Scrip's Year Books.
10) Confederation of Indian industries - Publications, Reports, data
11) Federation of Indian Chamber of Commerce and Industries - Reports.
12) Centre for Monitoring Indian Economy (CMIE) monthly and special issues.
13) Sector profile of the pharma industry - SOMO
14) Fortune 500 companies - status report
16) Statistical Outline of India (Tata E. R. Publication)
17) Reports of the Drugs Price Control Committees.
18) Indian legislations regarding Drug Controls, Patents, Prices etc.
19) Indian Drug Manufacturers' Association: Reports and representations
20) Essential reference books, research papers, Inquiry Committees' reports, journals and periodicals; Ministry of chemicals and pharmaceutical, Govt. of India : Annual reports and related literature.
1.9 Limitations of the study

The statically and periodically the data may vary five to ten percent between official government reports and industrial trading reports.

The study is limited for the period of ten years that is between 1993 and 2003. Estimated statically errors may range between five to ten percent in either direction.

1.10 Chapter scheme

Chapter I Introduction, objectives, hypothesis, methodology and scope and coverage of the study.

Chapter II Review of literature: Profile of global pharmaceutical industry and trade.

Chapter II Indian pharma industry and business.

Chapter IV Indian pharma policies, laws, controls, rules and regulations.

Chapter V Direct and indirect controls of WTO, GATT and WHO on Indian pharma business.

Chapter VI Impact of WTO on Indian pharmaceutical business.

Chapter VII SWOT analysis (Strength, Weakness, Opportunities and Threats) of prospects of Indian pharmaceutical industry during TRIPS and WTO regime.

Chapter VIII Recommendations for achieving competitiveness and future of high tech pharmaceutical business.

Chapter IX Main findings, testing of the validity of the hypothesis and final conclusion.