IMPACT OF THE TRIPS AGREEMENT ON THE INDIAN PHARMACEUTICAL INDUSTRY

-A CASE STUDY OF THE PHARMACEUTICAL INDUSTRY IN THE STATE OF ANDHRA PRADESH

A Dissertation

Submitted in partial fulfilment of the requirement
for the award of the Master of Laws

By

B. SANDHYA

NATIONAL LAW SCHOOL OF INDIA UNIVERSITY
NLSIU
BANGALORE

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Under the Guidance of

N.S. Gopalakrishnan

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DECLARATION

I do hereby declare that this work has been individually carried by me under the guidance of N.S. Gopalakrishnan, Faculty member, NLSIU, Bangalore and this work has not been submitted either in part or whole by anyone for any other degree to any other University.

Place : Bangalore
Date :

B. Sandhya,
Final Year LL.M.
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CONTENTS

ABBREVIATIONS

IPRs	Intellectual Property Rights
IPA, 1970	Indian Patent Act, 1970
GATT	General Agreement on Tariff and Trade
TRIPS	Trade Related Intellectual Property Rights
WTO	World Trade Organisation
WIPO	World Intellectual Property Organisation
INPADOC	International Patent Documentation Centre
CSIR	Council for Scientific and Industrial Research
IICT	Indian Institute of Chemical Technology
NCL	National Chemical Laboratories
CDRI	Central Drug Research Institute
DST	Department of Science & Technology
BDMA	Bulk Drug Manufacturers Association
IDMA	Indian Drug Manufacturers Association

Chapter One

INTRODUCTION

The concept of property today has undergone dramatic changes. There is a trend towards treating new things as property. This change can be attributed to many factors like industrial revolution, technological and information revolution etc. The recognition of intellectual property is one such development. The legal regime is developed to recognise certain kinds of intellectual labour as property and granted certain rights in protecting such property. A universal definition of intellectual property might begin by identifying it as nonphysical property based upon some new idea or ideas[1]. Intellectual property rights are the legal expression of the privileges granted by the State to the inventors or innovators for the use of their creations[2]. Intellectual property rights (IPRs) include industrial property rights, i.e., the rights granted to any new inventive solutions. These rights can be in the form of copyright, patents, trademarks, brandnames, Industrial design etc. As the study is related to the patent system it is important to know the meaning of the patent. Patents pertain only to the practical application of knowledge, to the creation of a specific object, which may never have existed without its particular originator[3]. Patent is often defined as a statutory grant of monopoly for working an invention and vending the resulting product[4]. Patents gives exclusive rights to make use or sell a particular application of an innovation, at the same time it carries an obligation to disclose the invention to the public[5].

In the late 18th Century it was first attempted to legislate patent laws in India, basically to protect the British Industry. After independence two committees has reported on the revision of the patent law. Three comprehensive bills had been presented and two joint committees of parliament had examined the issue at length. Finally the present Indian patent Act 1970 was adopted by substituting the then existing Indian patent & Design Act 1911 basing on the Ayyangar Committee report. The provisions under the present patent Act were incorporated keeping in view of past experience where the Trans National Corporations (TNCs) patent monopoly created many problems to the indigenous firms. It also took into consideration, the national plans that have been formulated for the economic upliftment of the country, raising of the standard of living of its people basing the needs of the community, constitutional goals and objectives.

1...

The present patent Act excluded certain subject matters from the patent regime. Only a limited protection is granted, to the items covered under the Act. Compulsory licensing provisions are provided with regard to the working of a patent, and the State is also empowered to the using of a patent in the public interest. An important feature of the Act of 1970 is the special provisions regarding drug patents. The drugs can be patented only for a new method or process of manufacture and not for the product as such[6]. The life of drug patent has been reduced from 14 yrs to the maximum period of 5 to 7 years[6]. Every patent relating to processes for manufacturing drugs which is not working has to be endorsed with the words 'licences of right' after 3 yrs of the date of sealing. Besides this the Controller is empowered to grant compulsory licence of a patent in the public interest. These special provisions with regard to drugs are provided on the ground that the monopoly of TNCs in drug patent resulted in the lack of availability of essential drugs as well as the lack of knowledge to produce them[7].

But in the present context of India being a signatory to the GATT Final Act, including, Trade Related Aspects of Intellectual Property Rights (TRIPS) and the member of WTO, one has to examine the implications of the above discussed provisions. India recently attempted to amend the Patent Act, 1970 through the Presidential Ordinance and then introduced a Bill in the Parliament which is still pending before the Rajya Sabha. This also require an enquiry in the context of Pharmaceutical Patents.

The Indian Patent Act radically changed the Indian drug scene[8]. The complete elimination of product patent brought about significant changes in the Indian Pharmaceutical Industry[9]. The Industry is in a position to launch by its own new process or using old process any patented product introduced in the world market in a short period of time and at one-tenth of the price[10]. Because of the process patent the competition that followed among TNCs and the indigenous firms reduced drug prices in India below International levels[11]. There is also sharp rise in the exports of drugs and pharmaceuticals in the 1970's and 80's[12].

But while considering the overall impact of the Indian patent Act, it has been contended that the pattern is not altered very greatly with regard to foreign

2...

domination of patents in relation to the food, chemicals and pharmaceutical Industry even today inspite of the special provisions. This was contended basing on the patent applications filed between 1972-73 to 1986-87[13]. India being a developing country is still lagging behind in the area of technical advancement, resource availability and infrastructure for Research & Development (R & D) for bringing about the new inventions in this field. So it can be said that the Indian Pharmaceutical Industry achieved its growth and self sufficiency only to some extent and still far from competing with the efficient and superior TNCs gaints of the world.

Under the TRIPS the coverage of patentability extended to all inventions both process and product and in all fields of technology. This provision and the following provisions are important in relation to the drug patent. Now India will have to recognise and grant product patent. The life term of patent is increased to 20 years, the importation of product is considered as working of patents. There is no provision for automatic licensing, and the scope of compulsory licence is limited to very extreme cases of emergency and exceptional circumstances[14]. The patentee can question any use of his patent without his authorisation and the licence[15]. Art 34 provides for the reversal of burden proof in case of process patent violation. The general principle of law is that the patentee was to prove that the alleged infringer was using the patented invention. But under the reversal of the burden of proof, now it is the alleged infringer who has to prove that he or his agent is not using the patented process. Another controversial provision is in relation to the transitional period. The TRIPS provisions provides that developing countries like India would have to effect changes in their existing patent regimes during a 10 years transitial period. But it has been contended that there are number of articles taken together indicate that there is virtually no transitional period available to the developing countries[16]. Under the agreement India have to provide rights for Pharmaceutical products from day one of entering into WTO[17]. The patent Amendment ordinance in the result of such provisions in the Agreement.

It is argued that TRIPS is based on completely different philosophy, that is to protect private interest and very little consideration on social interest. This is evident from treating all the members equally notwithstanding their different economic, social status[18]. The question arises while arguing for a change or strengthening

3...

the patent regime of any country is whether it will lead to either better technology transfer or indigenous technology generation. The same question arises in relation to the pharmaceutical industry also and there are number of arguments putforth infavour or against the TRIPS agreement in relation to its impact on the pharmaceutical industry.

NEED FOR THE STUDY :

In the context of the latest GATT accord which is accepted by the countries, the scenario of the world at large and of the members will be different from that of the existing one. Traditionally GATT limited its role on issues related specifically to tariffs and trade in goods with an overall objective of free trade among its member nations. However it has been resurrected for making most far-reaching negotiations in areas which were hitherto not covered by it.

One of such issues is IPRs which the developed countries succeeded in introducing under GATT through TRIPS agreement. The provisions of TRIPs, it is argued by many, will have far reaching implications for the self-sufficiency and long-term growth performance of the developing countries, as the developing countries are at a disadvantage in respect of resource endowment, International competition etc. India being the developing country it is very important to understand the implications of the problem of IPRs in the context of International Technology (IT) and R & D capabilities.

There was much dissension and difference of opinion on different aspects of the issue of IPRs, and patent protection in particular. One of the important area where patent play a very significant role is with regard to pharmaceuticals. In India much study has been done to show and argue that how and to what extent the patent system affected the pharmaceutical industry. But these studies are generally based on the production of drugs by the industry, the drug prices, exports of drugs, including the legislative changes which has to be brought under the Indian patent Act[19].

In this background the present study has been undertaken to examine closely the real impact of the patent system in relation to the pharmaceutical industry. As

there are many factors which facilitate the industrial growth, and many indications which can show the trend of industrial growth, Innovation and Science & Technology (S & T) are inter-related and one that influences the other. These two facilitates indicate the industrial growth. In this context the legal system through the patent regime provide for the encouragement of invention and in turn to facilitate R & D and S & T development. So the aim of study is to examine what to extent this above discussed purpose has been achieved by the pharmaceutical industry through patent system and also to examine how far its provisions are utilised by the industry. It is also important to examine whether the provisions of TRIPs agreement and the Ordinance passed and the Bill introduce to enforce those provisions are going to help the Indian Pharmaceutical Industry and the R & D in this area.

Eventhough, the patent system effect the agriculture, chemical, drugs, biotechnology, etc. The study is limited to only pharmaceutical industry. There is no doubt that the effect of the TRIPs on all these sectors are very crucial to the Indian situation. But it is very wide in scope and involves many issues, and not feasible to do in terms of the time limit and collection of data etc. Since the impact of patent system in relation to the pharmaceutical industry is very important in the present scenario, the limitation of the study to that extent can be justified and relevant.

CONCEPTUAL FRAMEWORK :

In the context of the above discussion there is a need to understand the working of the Indian patent system. For this purpose it is necessary to understand the factors which facilitate R & D in relation to a industry. In particular we need to understand to what extent and how far the patent protection facilitates R & D.

The second problem is with regard to the R & D cost. One has to understand that who is providing for the R & D cost and who is benefiting from it in India. And how it will be effected by the TRIPs agreement.

Thirdly, there is also a need to re-examine the relevancy of the special provisions with regard to drugs. As the Indian patent Act made a balance between

5...

the private interest and public interest, it has to be seen whether these provisions facilitated the growth of the pharmaceutical industry and promote public interest.

Finally in the globalisation process and India being a signatory to the GATT - Final text of the Uruguay round and a member of WTO we need to examine the effect of the TRIPs agreement and the Ordinance issued by the Government on the Indian Pharmaceutical Industry. Here one has to see whether it will lead to either better technology transfer or indigenous technology generation.

OBJECTIVES :

The broad objective of the study is to examine the role of patent system with regard to the development of the Indian Pharmaceutical Industry during the period between 1972-1994.

To examine the probable impact of the TRIPs agreement and the changes brought to the Indian patent Act by the new Ordinance on the Indian Pharmaceutical Industry.

RESEARCH QUESTIONS :

1. What is the philosophy of Indian Patent Act, 1970 with reference to the pharmaceutical industry.

2. Whether special provisions incorporated in Indian Patent Act helped in the development of the Indian Pharmaceutical Industry.

Which includes the questions with regard to R & D status plus the inventions new process or new product development.

3. What is the role of Indian Patent Act in the new products development.

4. What is the status of industry in the present context of GATT. Whether they are in a position for inventing new products and new processes? or they will go for licensing agreements etc with the patentee?

In Chapter III - A brief history of the patent system is given to understand the origin and development of patent system.

Chapter IV is devoted to a study of the Indian patent system in relation to the Pharmaceuticals in the Indian context.

In Chapter V - An analysis of the provisions of the TRIPs agreement and the Indian patent Ordinance is undertaken.

In Chapter VI - A case study of the pharmaceutical industry, situated in the state of Andhra Pradesh is included.

In Chapter VII - Conclusions are drawn by critically examining the data collected.

FOOT NOTES :

1. Justin Hughes, "The Philosophy of Intellectual Property", Georgetown Law Journal, Vol.77, 1988, P. 294.

2. Tarun Kabiraj, "Intellectual property Rights, TRIPs and Technology Transfer", Economic and political weekly, Nov.19, 1994.

3. Ayn Rand, 'Capitalism-The unknown ideal' New American Library, Signet printer 1967.

4. Rajagopal Ayyangar Committee Report (ACR, 1959) Report on the Revision on the patent laws -Govt. of India, 1959.
Sec. 3,4 Sec. 87,90, Sec.100 etc. of Indian Patent Act, 1970.

5. Tarun Kabiraj, op cit P 2992

6. Sec 5 of The Indian Patent Act, 1970 provides for process innovation. Sec 53 provides that the term of 5 yrs from the date of sealing of the patent of 7 yrs from the date of the patent whichever period is shorter.

7. See generally, ACR, 1959.

8. It helped to build in India a strong base and infrastructure for the production of drugs. We are now self-sufficient in 54 essential drugs and its varied formulations. National laboratories & R & D centres of Industrial units have invented cost effective technology, prices of drugs in India are among the lowest in the world and exports have shot up tremendously. Aruna Parimi, "Dunkel text opening a Pandora's box", The Economic Times, Calcutta, March 25, 1994.

9. Indian firms began to manufacture new drugs in India much earlier after it introduced in the world market compared to the previous regime. The examples of drugs which were introduced by the Indian Companies in India within 4 yrs are salbutamd, mebendazole, naproxen, catopril, norfloxacin. B.K. Keayle, "patent regime at glance", National working group on patent laws, New Delhi', 1992.

10. Sudip Choudari, 'Dunkel Draft on Drug patents. Background and implications'. Economic and political weekly, Sept. 4, 1993.

11. Tarun Kabiraj, op. cit., P 2995.

12. BDMA, "Memorandum for change in sales tax structure for Bulk Drugs and Intermediaries", 1994.

13. Rajiv Dhawan, Lindsay Harris & Gopal Jain, "Power without responsibility on aspects of Indian patent legislation" Vol. 33 J.I.L.I. (1994).

14. See generally, Aruna Parimi.

15. B.K. Kealye & Biswajit Dhar, "Indian Pharmaceutical industry and patent regime for drug security"-National working group on patent laws, 1993, P. 5.

16. Ibid., P. 8.

17. S.P. Shukla, " Resisting the world trade organisation - Agenda for Marrakesh"

Economic and political weekly, March 12, 1994.

18. Biswajit Dhar & C.N. Rao, "Patent systems and Pharmaceutical sector", EPW No. 40, 1993.

19. See generally, Papers presented by member of the National working group on Patent Laws.

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Chapter Two

THE INDIAN PHARMACEUTICAL INDUSTRY -A PROFILE

India is one of the developing countries which has not yet been able to achieve commendable economic success even after 47 years of Independence. It has nearly 17 percent of the world population, but its share in the global output is only 1.1 percent. Compared with the population, the economy is minuscule. The two deficits, fiscal and trade, have been widening in the recent years. Poverty is widespread and inequalities in income and wealth have grown enormously[1]. It is said that the technological backwardness and inadequate attention to modernisation have also hampered mass production, cost reduction and productivity in most of the developing countries. Without the desired level of the needed foreign exchange, it is feared many of the developing countries may not be able to take advantage of new technologies in the current decade[2]. However, it is also argued that with the WTO coming into force, it will stimulate world economic growth by adding over $ 270 billion annually to global output. Openness to trade, investment and modernisation has helped many countries to accelerate their growth. The developing countries would benefit from being granted unrestricted access to the markets of developed countries and earn about $ 85 billion in additional export[3]. India is considered to have greater advantage over many other developing countries. In the context we will examine the growth and performance of the Indian Pharmaceutical Industry.

Pharmaceutical is said to be a substance used in the diagnosis, treatment, or prevention of disease and for restoring, correcting or modifying organic functions[4]. Pharmaceuticals are generally classified by chemical group, by the way they work in the body and by therapeutic use. Alkaloids were the first pure pharmaceuticals derived from natural substances plants. Records of medicinal plants and minerals date to ancient Chinese, Hindu and Mediteranian Civilisations. The ancient Physicians used a variety of drugs in their profession. During 16th Century A.D., after Western Medicine began to recover and develop,the pharmaceutical practice began to develop rapidly. Among the earliest modern pharmaceuticals were the anesthetics, Morphine, ether, chloroform, cocaine etc. The historic basis of the

11...

pharmaceuticals industry has been the discovery and manufacture of bulk drugs without which there would have been no industry[5]. Initially very few companies worldover were involved in the manufacture of basic drugs while rest others were engaged in trading activities. At the time of world war II few companies are engaged in the formulation production which simply procured bulk drugs from the innovator company and formulated them in conventional dosage forms. The manufacturers of bulk drugs was limited to meet the demands of established drugs. The chemical research activities were also restricted to semi-synthetic pencillins and sulfonanides apart from procuring active ingredient and azo dyes from the natural resources like plants and herbs,etc. by extraction. The industry has been actually expanded after World War II.

Eventhough the entry of Multinational companies (MNCs) in India dates back to the colonial era, the foreign drug companies built their base in the post-independence period. As the Hathi committee observed

> "... within a period of twenty years, multinational companies attained a position of dominance in the drug industry".

Until 1970, almost 90% of the production belongs to the foreign drug firms. As of 1973, 70 percent of the total turnover of drugs in India, that is Rs. 370 Crores belonged to the foreign sector. The number of multinational pharmaceutical companies operating in India come to 66 and the number of multinational drug companies with more than 40 percent foreign equity stood 45[6].

It has been observed that the foreign drug companies in India are not only the most profitable among manufacturing firms in the country generally but also among all types of foreign controlled enterprises including those in non-manufacturing sectors[7]. As of 1968, 33 foreign controlled drug firms on the average earned profits before tax of 24 percent on capital employed, while one firm, Roche recorded profits of 57 percent. The ratio of gross profits (GP) to total capital employed (TCE) in the pharmaceutical industry ranged from 27.7 percent to 46.3 percent during the period 1960-61 to 1969-70 as against 15.9 to 18.8 percent for all manufacturing industries. GPT/TCE and GP/Net sales (NS) for pharma industry on the average, worked out to 37.4 and 17.5, the corresponding ratios for all industries together came to 17.6 and 10.1 percent respectively. The main thrust of MNCs of drug firms is towards capitalising on drug formulations and non-drug items

12...

like cosmetics and luxury goods where technology and capital inputs are much lower and which permits promotion of aggressive salesmanship and brings in much high returns on investments. For strategic reasons like, to facilitate the practice of transfer pricing, to prevent the leakage of technology etc, the MNCs are reluctant to manufacture bulk drugs. It has been observed by the Hathi Committee that "It is glaringly obvious that multinational units are not interested in producing bulk drugs in countries like India... the MNCs operating in India produce only a small fraction of bulk drugs[8]". As it is pointed out by the committee that only 17 foreign companies manufactured bulk drugs. The committees report further observed that "we are convinced that their (MNCs) continued presence in this country is a powerful damper on the challenge of our achieving the technology goals of self-sufficiency and self-reliance".

The pharmaceutical production commenced in India way back in 1901 when a unit to manufacture formulations out of imported drugs was set up in West Bengal. The growth of this industry remained negligible upto 1947[9]. Since independence however a few Indian companies initiated the broad basing of pharmaceutical, essentially through formulations. With a large investment and a much weaker base, the industry could produce only simple formulations and a few biologicals worth around Rs. 10 Crores. Dominated by the multinational cartels, the indigenous sector of the pharmaceutical industry had very little to contribute. The mulitnational and their products continued to dominate the national scene even after two decades since independence. The States intervened and the public sector undertakings in the drug sector was followed by the establishment of the Hindustan Antiobiotics Limited (HAL) in Pumpri in 1954 for the production or antibiotics and IDPL was incorporated in 1961 which started functioning in 1968. IDPL has three manufacturing plants located at Rishikesh, Hyderabad and Gurgoan (Haryana), two wholly owned subsidiary units are in Tamil Nadu & Bihar and three joint sector undertakings are located at Jaipur and Lucknow. Three joint sectors have been set up in collaboration with the respective state industrial development corporations. IDPL played a very important role in the development of indigenous drug industry-base. The infrastructure created at IDPL plants has acted as a catalyst for the development of pharmaceutical industry in the country since its establishment.

13...

The production of bulk drugs and formulations by the indigenous sector has increased substantially in the past two decades. The data shows that the output of the Indian pharma Industry increased several fold during the two and half decades covered by the series. The annual compound growth rate works out to 12.8 percent measured in current prices even in real terms, the rate of growth , 8.4 percent[10]. The combined total of bulk drugs and formulations in the mid-seventies added up to Rs. 708 crores of this the value of formulations came to Rs. 586.67 crores or about 83 percent as against 17 percent in the case of bulk drugs. During the later half of the seventies, the proportions of bulk drugs and formulations remained more or less the same as in the earlier period[11]. In 1982-83 the production of bulk drugs and formulations (interms of value) at the price level of 1979-80 was Rs. 345 crores and 1660 crores respectively. In 1991-92 it was Rs. 900 crores and Rs. 4800 crores and in the following years showing the growth rate of 16 percent and 15 percent since three years. It has emerged as a net exporter of pharmaceuticals from a net importer. From a meagre Rs. 46 crores export of pharmaceuticals in 1980-81, now the exports have risen to around Rs. 1800 corers. It has touched a record figure of Rs. 1410 crores of exports during the financial year 1992-93 out of which the lion's share of Rs. 13819 crores is to General currency area (GCA). Exports to the GCA showed a 51 percent increase over the previous year performance. Exports to the rupee currency area (RCA) amounting to only Rs. 28.4 crores which is declined by 92% over the previous years performance[12]. The exports also increased to Rs. 1781 crores. In 1993-94 a growth rate of 26 percent. During the first seven months of 1994 the exports have shown a growth rate of 13 percent over the corresponding period last year. The government has been identified the drug industry as a thrust area for boosting exports. India has earned repute as a dependable bulk drug manufacturer in the international market and a good part of such exports have been to the sophisticated markets in western countries. About 20 bulk drug manufacturing plants have already received the US-FDA approval and a few more units are awaiting such approval. In the world, US-FDA has more stringent tests to allow the marketing of a drug in USA. A significant feature of the Indian exports of pharmaceutical products is that the basic drugs are mainly exported to developed countries while the main markets for finished formulations were the developing countries and the USSR. Some of the main areas of exports are USA, UK, Malaysia, Singapore, the Middle East and Africa.

14...

The Indian bulk industry has made significant contributions in the manufacture of most modern drug molecules within the short period of time after it is introduced. It has also helped to introduce the respective formulations for the first-time in the country. Some of the notable examples are the Quinolone antibacterials, Ciprofloxacin and Norflodxacin, Ace-inhibitors captopril and Enalapril, H2-antaonists cimatidine and Ranitidine, anti-histaminics. Astemizole and Terfenamide and semisynthetic antibiotic cefactor, the cardiovascular drugs Nifedipine and Diltizem and even the latest anti-inflammatory drug Ketorolac, all of which are indigenously Produced in bulk and formulated in dosage forms for medical use in the country[13]. The Indian pharma industry has grown in size and strength with current investments in the order of over Rs. 1000 crores. It has also registered phenominal progress with turnover currently crossing Rs. 5000 crores.

Though, in general, the MNCs dominated the pharmacy market in India, from 1970 on wards its control started declining. From 1972-73 onwards the number of branches and subsidiaries are declined. The number of branches in the pharma industry declined from 18 in 1969-70 to 11 in 1973-74 and 6 in 1978-79. The number of subsidiaries fell from 21 to 17 during the corresponding period. On the otherhand, their total assets of the branches of multinational drug companies went up by more than two and one-half times, from a little over Rs. 10 crores to Rs. 25 crores. In the case of subsidiaries, the increase was from Rs. 101 crore to a little over Rs. 205 crores. A more detailed analysis of 15 selected materials by a sample of TNCs during 1970s has brought out that a) the actual value of imports for all materials came to Rs. 901652 b) the same quantity could be obtained for Rs. 540577 of purchased at the minimum price c) the excess expenditure Rs 361075 tantamount to overpricing of about 67 percent[14]. However the share of the foreign sector in the total production of pharmaceuticals has comedown considerably during the seventies. According to the studies done, the share of the foreign sector in the total production of formulation 53.9 percent in 1973-74 declined to 43.8 percent in 1978-79. As for the production of bulk drugs, the foreign sector accounted for 56 percent in 1973-74, but it was cut to half this level by 1978-79. As the data shows that the share of MNCs has declined to 50 percent in 1980s and now the Indian and MNCs share in the Pharmacy market is respectively the ratio of 60:40. As it could be seen that the MNCs of drug firms has a share of 40 percent in the Indian Pharmacy

15...

Market, the MNCs through their branded products controls the market. And still, the MNCs play a major role with its better resources and management skills in India.

The Indian Pharma Industry consist of large medium and small-scale units. And the small-scale sector are 90 percent of the total units. The small scale industry (SSI) has rendered significant contribution to the Indian drug Industry. It has claimed to have contributed to the increase of production of drugs, lowering of the prices and in achieving near self sufficiency in the drug production[15]. And even in exports, stated that 70 percent of total exports of bulk drugs comes from SSI. As of 1994, there are 300 units in the organised sector and 10,000 units in the small scale sector. In the recent past, however, the hundred of SSI units of drug industry have been formed into closure. The Government policy measures are blamed for it. They are the abolition of loan licensing, mandating GMP standards, taking away of incentives like SSI being out of price control. Cutthroat competition in the industry also forces the SSI to closure. Several hundreds of small-scale units manufacturing bulk drugs like ampicillin, amonycillin, erthromycin and choranphenicol are closing down because of competition resulting in undercutting due to excess production. Today some of these drugs are selling below government fixed prices. The sickness of SSI will affect the 3 lakh work force and 15% of production of pharma items[16]. Even the public sector units became sick industries and referred to the BIFR. The reasons for the sickness are considered as obsolete technology, high-wage component, low productivity , high incidence of interest load, inadequate marketing set up, constraints of working capital, constraints in rolling of working capital, excess manpower and consequently high fixed cost. Further its marketing mechanism remains weak, and it is unable to make a dent in the market against competing products. It is also criticised that the Government is not ready to take realistic approach in this matter due to political pressures from different section.

Inspite of the public sector and SSI units dismal state of affairs the large Indian drug companies are flourishing, and 75% drugs are manufactured by this sector. These companies are benefited substantially by changing the manufacturing processes for new drugs and those are exempted from price control. And also managed by the changing their product mix successfully with a large share of

decontrolled drugs to maximum profits. This was substantially adopted by the large companies like Cipla, Ranbaxy, JB Chemical, Torrent, Dr. Reddy's, Wockhardt, etc.

The pharmaceuticals is a $ 130 billion per year industry with major markets in West Europe, North America and East Asia. In 1990 the value o the pharmaceutical market was around U.S. $ 165,200 millions. In 1980, the value of total world market was around U.S. $ 62,315 millions-which has almost trippled during the decade giving an annual growth rate of 10 percent[17]. Europe was the world's leading location for production and export of pharmaceuticals with an external trade surplus of over ECU 3.8 billion in 1987. The bulk consist of product prescription drugs[18]. At present the U.S. Pharma market accounts for almost 30 percent of the total world market followed by Japan with 17.6 percent while Germany, France, Italy and U.K. account for another 26 to 27 percent. India is ranked number nine with 1.5 percent share of the total world market[19].

Though as discussed above, the Indian pharmacy sector is dominated by foreign firm, the indigenous pharma industry slowly made progress and it has followed a typical pattern, starting off trading activities moving into repacking and marketing, to formulations manufacture and distribution, further on to manufacture of bulk drugs, primarily for domestic and captive use and in more recent years, to manufacture for exports markets[20]. However we could see that the developed world predominates the pharmaceutical industry. One of the main reasons for such dominance is stated to be a complex, multi-disciplinary, risky expensive and time consuming involved in pharmaceutical research activity. Technology is the source of its strength not labour or capital. It is driven by ideas know-how and invention[21]. The pharma research requires a strong and dedicated team of organic/medicinal chemists, physicians, biologist, biochemists, pharmacologists, toxicologists, physiologists, analysts, chemical engineer, etc[22]. In general industrial research including pharmaceutical industry as it developed in the late 19th and 20th centuries involves at least four elements. First it is organised research, secondly it uses scientific methods, thirdly concerned with natural sciences and technology and finally the investigations carried on whether fundamental or applied are connected in one way or another with industry and are directed primarily towards improving

technology and maximising economic satisfactions[23]. The pharma research is carried out in two distinct areas. One is basic research with regard to develop basic or fundamental knowledge of diseases, processes which are needed for the design and discovery of a new drug molecule, and to develop new bio-assays and test systems, particularly in areas where there is no adequate therapies[24]. Secondly it is applied research with regard to carry out development work in order to take an identified molecule to the state where it emerges as a new drug economically. The introduction of a new medicines covers a number of important stages such as, the initial discovery of a viable production process and its use in manufacturing efficiently and in the highest standards of quality and finally, its marketing and supply throughout the world[25].

The major players in the field of new drug discovery are USA and Japan together contributing to over 50 percent of new drugs discovered. Other countries which have contributed to new drug discovery are France, UK, Germany and Switzerland. The major factors responsible for the discovery and development of new drugs in developed countries are considered to be their patent system pricing structure, buying power of patients and size of their global operations. Moreover, the existence of a high degree of collaborative/integrated research atmosphere between universities and industrial research laboratories are significant facts. And most of the research efforts by the leading 15 companies are directed towards cardiovaseutors, CNS agents, anti-infectives, anti-cancers, respiratory, analgesics/ anti-inflammatoxies, gartro-intestinals, vaccines/biological and therapies for metabolic disorders.

In India, since independence our policy makers made a very determined effort to start industrial research in the country in a planned manner and to ensure over the years that we attain as a large big country, a worthy place in the industrial scene based on our innovations. As a result we have now a very large chain of labs in council of scientific and industrial research (CSIR), a large establishment of the Atomic Energy Commission (AEC) and a number of laboratories associated with industries and with public utilities. As far as pharma research is considered the CSIR labs especially the National chemical laboratory (NCL) Poona, Central Drug Research Institute (CDRI) Lucknow and Indian institute of chemical Technology (IICT)

Hyderabad have contributed towards development of processes for a large number of bulk drugs. However the basic research and development has been lacking and it has been pointed out that the continuing development of formulations is not R & D in the true sense and that our industry should set up research and development for production of bulk drugs from the basic stage[26]. Besides the lack of basic research the pharma sector also lacks technological expertise and production capabilities with respect to novel and advanced drug delivery systems. The clinical trials standards also very sharply to that of the western standards. Even the drug stability testing laboratories still presents a primitive look. The number of drug control testing laboratories are very few and poorly equipped in India these are 50 while in China they are 5,000. Further, the research is more concentrated on Allopathic systems ignoring the Indian alternative medicinal systems and is directed towards curative approach rather than preventive. One of the main reasons for such lacking is considered to be the low investment on R & D. On the face of it, expenditure on R & D of a pharmaceutical industry has grown from Rs. 4 Crores in 1970-71 to Rs. 70 crores in 1991-92. Expenditure on R & D as a percentage of the turnover has hovered between one and two percent only[27]. It was split 91 percent from private companies and 9 percent from public sector industry and the total was Rs. 76.8 crores. It was represented only 1.5 percent of private sector sales and 2.3 percent of sales by the public sector. An analysis of actual expenditure in 1992-93 by 15 major pharmaceutical companies in India shows a similar position[28].

Indian	**Multinational**	
Alembic	Abbott	Hoechest
Cipla	B. Wellcome	Park Davis
Ranbaxy	Boots	Pfizer
Unichem	German Remedies	Phone-poulence
Wockhardt	Glaxo	Roche

The range of R & D (revence and capital) spending in 1992-93 was 0.9% - 3.5% of sales for the 5 Indian companies and 0.2% - 3.0% for the 10 Multinationals. Three of the five Indian Companies spent more than 2% of sales on R & D and only one of the 10 foreign companies spent so, eight of them spent less than one percent[29]. This shows the overall low level of spending on R & D by the industry. In

19...

India out of 16,000 licensed drug manufacturers only 77 of them have in-house R & D facilities approved by the Department of Science and Technology (DST) of these, only a dozen odd companies actually incur on R & D expenditure of one crore rupees and above.

Besides the low investment on R & D the following factors are considered to be influenced the pharma research in India. It has been critised that the pharma research till today is confined only to research labs in India[30]. Much of the pharma research is limited to only few research institutes and no co-ordinatioon among the research centers, universities and the pharma industry. Further, there is no proper inter-relationship between research and development division and other faculties of pharmaceutical industry. Much of the research work is related to academic side in production of large number of doctorates for which large number of topics are undertaken and much of the research done in this direction is not utilitarian and does not have practical applications to pharma industry. Most of the government research units such as CDRI, NCL, IILT etc in pharma research are involved in mundane and outdated research. No concrete results are being produced by these units[31]. For example, CDRI which is basically concerned with basic drug research only credited with the development of contraceptives named Sahali. There is no basic research involved by these institutes and their pharma research activity is mainly concerned with process innovation only. It has been said that there are no proper incentives and recognition in case of scientists pursuing pharma research unlike in other fields. It is also noted that much of the research literature available in India is not satisfactory. There is also lack of healthy work environment in most of the CSIR labs. The work environment is affected due to biases of caste, sex, age and groupism and prejudices. political pressures, Bureaucratic formalism, Dishonesty, suppression of dissent, showmanship and Psychophancy are seen as some of the important factors responsible for ailing research in pharmaceutical sciences.

However, it may be promising to note that, CDRI, claimed to have invented couple of new drugs which are under clinical trials including one Ayurvedic drug and foundout processes for the new drugs introduced now. And the earnings from export of CSIR technologies increased ten fold which was negligible until two years

ago. Several of the forex-earning breakthrough have taken place in the drugs, chemicals and civil aviation sectors. Some of the CSIRs clients include Dupont, Park-Davis and General Electric of the US, Ciba of Switzerland etc. Now the foreign exchange earnings account for one percent of CSIRs budget which may not seem much at first but look more encouraging when compared to almost zero percent two years ago. The private sector in India account for 11 percent of CSIRs cash resources, government 77 percent and public sector 11 percent. It is stated that because of the budget constraints CSIR had no option but to impress on its laboratories to realign their programmes, increase linkages with industry and rope in extra-budgetary resources. And laboratories have been encouraged to collaborate with foreign companies in the form of contract research, joint development work, sale of technology, offer of technology services and services of contract. It is noted that some of its labs like IICT, NCL have succeeded in this regard.

However, in the present context to achieve global competitiveness and ensure its sustenance, it is stated that the industry should have assured multiple skills of a high order including skills in manufacturing processes, process engineering, process R & D, innovative basic research and drug development expertise in addition to marketing skill and development. In short, the objectives should center around harnessing new technologies leading to new products and bringing them to the market in time to gain a strategic competitive edge.

It is not possible to quantify precisely the results of research or determine the incremental advancement of knowledge provided by an increase in R & D funding. But scientific literature and patent indicators are generally, considered to be the key source of information on R & D outputs. For example, as of 1992, the patent applications were in Japan 3,85,000, USA 1,90,000, Germany 1,15,000, UK 99,000, France 82,000, Italy 65,000, Russian Federation 59,000, China 59,000 etc. In India the average per year for the five years ending 1992-93 was 3,600, during the same period the grant of patents was much lower, averaging 1900 per year[32]. The domestic patents granted to Indian nationals varied from 426 patents in 1968 to 928 patents in 1976-77 that is an almost increase of 48 percent and the number of application has increased from 1110 applications to 1342 applications in the

21...

same period, an increase of about 21 percent. But on the whole the patent activity decreased from 4130 patents to 2892 in the above period a decrease of about 30 percent. It is foreign patenting which has decreased from 3704 patents to 1964 patents a decrease of about 47 percent[33]. As we could see India's patent activity is very low when compared to other countries. Besides low investment on R & D lack of better infrastructure facilities, though R & d expenditure has increased from a paltry sum of Rs. 1.10 crores in 1948-49 to an impressive sum of Rs. 1.10 crores in 1976-77 and Rs. 4,186 crores in 1990-91 in all areas of science and technology is low when compared to the developed world's R & D expenditure, other factors might have influenced the low patenting activity in India[34]. Like, lack of proper awareness of patent system, further points out that Indians are more averse to patenting, other limitations of expenditure, time, etc. involved in patenting and in some cases they prefer to keep their inventions as secrets rather than disclosing it for a patent grant.

In India CSIR has all along been the single leading applicant for patents in India originating from India by accounting to 25 percent of Indian patents[35]. CSIR including its labs, PSUs are the only major patent holders of processes in relation to drugs. The pharma industry didn't go for patenting for their claimed inhouse process innovations for new drugs and they said to be kept it secret. Even the foreign companies patenting activity has decreased considerably during 1970s and still it is very low. It was contended that India provides little encouragement for private sector research and development and none for such activities by foreign companies. And there is heavy emphasis on the role of the public sector which spent 87.4 percent of India's total R & D funds in 1990-91. Total Indian R & D expenditure in 1990-91 is as follows.

FINANCED BY	**% OF TOTAL**
Central Government	68.9
State Governments	7.9
Public Sector Industries	10.6
Private sector industries	12.6

It shows that the Central government accounts for an investment of about

69 percent which is 80 percent in the 70s. Here, the fact which is conveniently overlooked by the above contention is that atleast in pharma research the private sector generally not been in a position to spend such expenditure on R & D and though the foreign companies are in existent since late 18th Century in India they never interested in encouraging this R & D units. Even after Independence for almost three decades inspite of having product patent regime, there was no substantial results in the field of pharma research by the private or foreign sector.

However, in the present context of TRIPs agreement Indian Pharma Industry has to increase & emphasis its R & D activity including the patenting of its R & D output, using patents as technological information documents in addition to creating more awareness of the patent system etc. At least to some extent the available patent information system such as patent information system division at Nagpur which has been funded by the UNDP & executed by WIPO recently modernize it and CSIR may be helpful in guiding the pharma industry, R & D units with regard to patenting. CSIR has a separate patents unit since its establishment in 1942. Its main functions are to advise CSIR on all matters relating to IPRs to scrutinise the R & D work done, identify the innovative work which can be legally protected, drafting the necessary scientific technical cum legal documents file the applications, to safeguard the interest of CSIR and also the country by filing oppositions for the grant of patents to disseminate the information to the scientists so as to keep them abreast with the latest developments. It is claimed to have changed its outlook in the present context such as to earn money from its in house expertise, sharing the monies realised from the licensing of IPR recognising IPRs secured for consideration of promotion, issuance of commendation certificates to the scientist. Also contended that the various actions initiated in 10 years advance has helped CSIR in establishing a center of expertise in IPR.

In India, as it shows the R & D output is not upto the mark but still the R & D status promising a bit if not much in the present context. For this and to facilitate the present growth of pharma industry various policy measures has taken by the Government from time to time.

After 1970, the MNCs faced more constraints over their Indian counterparts

unlike before where the environment is more conducive to the MNCs to work in their best interests. They are also prevented from producing new drugs in India by the parent companies and their exports also restricted. There are other restrictions imposed by the government controls under various policies. The policy measures may be classified under three main heads namely[37].

(1) industrial policy

(2) pricing policy and

(3) other areas such as research, brand-names, quality control, regulation of irrational and unnecessary products etc. The government set up the pharmaceutical enquiry committee in 1953. Basing on the committee's recommendations, a series of policy guidelines for the development of the industry were laid down. Which included

(1) the development of the national chemical industry to enable it to meet the requirement of the national drug industry,

(2) the enactment of policy measures that would facilitate indigenous production of the entire range of drugs and pharmaceuticals required by the country and

(3) the promotion of research and development in national laboratories as well as within the industry. Under the industrial policy the public sector units were set up to achieve self sufficiency in the production of pharmaceuticals. The indigenous production of bulk drugs needed for formulations and the reduction of import bill thereof, were identified as priority areas. The policy resolution laid down that a wholly owned foreign subsidiary should not normally be allowed, that foreign equity participation should be kept to minimum and pure technical collaboration should be preferred. The industrial licensing policy of 1973 classified pharma industry as an industry wherein companies with greater than 40 percent direct foreign equity were eligible to participate and exempt from FERA regulations. Some more significant changes came after the submission of Hathi committee's recommendations. Under this policy and other regulation directed towards the objective of increasing the involvement of MNCs in the production of bulk drugs needed by the country. Further its foremost objective was stated to be that of developing self-reliance and providing a leadership role to the public sector.

In most countries government directly or indirectly pay most of the cost of

medicines and exercise control over prices and sometimes over the selection of the products to be prescribed. In India a price-freeze was introduced on drug products in 1962. This was modified by the drug price control order (DPCO) of 1970. It was followed by the drug policy of 1978 which modified the categorisation of the drugs and introduced a classification into four categories. This division was criticised as being made without any rational criteria[38]. The DPCO was followed in 1979 which restrict prices of bulk drugs and formulations produced by any pharmaceutical company in the organised sector. The manufacturer, importer, seller and distributor were each allowed a specific margin. At the same time, the selling prices of drugs were to be kept fixed, and not allowed to fluctuate. The steering committee report which is appointed under the National drugs and pharmaceutical development council (NDPDC) stated that the drug policy of 1978 did not seem to be facilitating rapid growth in the Indian pharmaceutical industry and which was imperative to meet the growing demand for drugs. It has been contented that the pricing policies outlined by the drug policy of 1978 and the DPCO of 1979 were never implemented. These policy measures were superseded by the new drug policy of 1986 & DPCO of 1987 basing on steering committee's report. However, those two remained unimplemented till recently, and the drug policy of 1986 was modified in 1994 and the DPCO was notified on 6-1-1995 replacing the DPCO of 1987. Its foremost objective is stated to be "ensuring abundant availability at reasonable prices of essential life saving and prophylactic medicines of good quality and to create an environment conducive to chanelising new investment into the pharmaceutical industry, to encourage cost-effective production with economic sizes and to introducing new technologies and new drugs and strengthening the indigenous capability for production of drugs. Now under the DPCO 1995 there is a single list of drugs under price control and substantial changes have been brought about so as to make the reporting system, by way of forms and information required to be submitted periodically by the industry to the Government less cumbersome. Another important provision which introduced a stipulation of time limit of two months for deciding applications for price revision of formulations and four months for price fixation/revision of application regarding bulk drugs. The government has constituted a three member committee to review the entire matter relating to capabilities assessed against the drug companies under the DPCO government can assess the liabilities moto from any source. These are some of the measures

brought under the new policy in the present context.

Initially the state policy measures are directed towards the streamlining of products in the drug industry for quality control and to better conform with the country's health needs. Later on efforts has been made to promote research and development both in national laboratories as well as within the industry to achieve substantial growth of pharma industry. The drug policy of 1978 emphasised increasing the R & D expenditure of foreign companies. It has also sought to encourage higher investment by the public sector on R & D, it was to set apart 5 percent of the net turnover. The new drug policy gives impetus to R & D through delicensing to the companies which conducted clinical trials and introduce new drugs. An exemption was also allowed under DPCO for the new drugs developed through indigenous R & D. The government has also set up a National Institute of Pharmaceutical Education and Research (NIPER) at an initial investment of Rs 25 crores. It will endeavor to promote excellence in Pharmaceutical education and research and ultimately help in toning up the academic, professional and industrial functioning in the country. The policy also address to the alternative systems of medicines. It stated that the various aspects relating to development and promotion of Ayurvedic, Unani, Sidha, Homeopathic and other traditional systems in medicines would be actively pursued and the machinery for carrying out these tasks would be adequately strengthened.

One of the important policy measure affecting the pharma industry is in relation to patents. As MNCs often resort to blocking and repetitive patenting for all known and possible processes in drug production to facilitate indigenous drug industry, the Indian Patent Act, 1970 was adopted, which made it possible to produce the patented products by local manufacturers. Under IPA, 1970 only process patent regime is provided in relation to drugs and no product patent is available and the indigenous pharma industry substantially benefited by manufacturing new processes while introducing new drugs in the market. It is noted that there are more than 20 high turnover drugs manufactured and marketed are patented ones. The Patent Act also restricted the MNCs exploitation of the local pharmacy market. Indian industry is able to reach out the patented drugs and manufacture it without waiting for the patent to expire or depend on patents to licence such new drugs. A

detailed analysis of the Patent system and its impact on the Pharmaceutical industry is undertaken in the following chapters.

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Annexures

Home Market Share As Percentage of World Pharmaceutical Consumption, By Region, 1960 And 1985.

	1960	1985
Germany F.R.	17.5%	7.5%
Other market econcmies	9.7%	9.7%
Sweden	0.8%	0.6%
Netherlands	0.7%	0.6%
Switzerland	0.8%	0.5%
Spain	1.5%	1.8%
Japan	6.6%	17.6%
France	7.3%	5.6%
Italy	5.1%	4.6%
United Kingocm	4.9%	2.9%
United States	45.4%	33.1%
Total	#2.320 billion	#73.277 billicn

Source : Dr. Karandikar. Indian Drug Industry After GATT, MVIRDC, World Trade Centre, Bombay, 1994

TEN LARGEST PHARMACEUTICAL MARKETS IIN THE WORLD

Sl. No.	Country	Market US $	Percentage of world Market
1	USA	33,000	30.00
2	Japan	25,000	17.60
3	FRG	10,500	9.00
4	France	7,500	6.00
5	Italy	7,000	6.00
6	U.K.	3,500	3.00
7	Canada	2,500	2.00
8	Spain	2,500	2.00
9	India	1,800	1.50
10	Brazil	1,700	1.40

Source : The Eastern Pharmacist. Nov 1992.

Drug Industry in India

(i)	Pre-Independence turnover of Pharmaceuticals	: Rs. 10 crores
(ii)	Present turnover	: Rs. 5,000 crores
(iii)	Export of Drugs	: Rs. 1,000 crores
(iv)	Number of manufacturers (own/loan)	: 19,000
(v)	Employment	: 10,00,000
(vi)	Per capita consumption of Medicines in India	. Rs. 41

(vii) Division of 1 Re. spent by the consumer .
(a) 40 paise goes for levies/taxes.
(b) 3 to 4 paise profitability of Industry.

Source : The Eastern Pharmacist, March 1992.

Pharma Companies Spending on R & D in India

Company	(Rs. lakhs) Spending
Bocts Pharmaceuticals	183.43
Cacila Laboratories	193.75
Cibatul Ltd.	145.09
Cipla Ltd.	274.26
Dr. Reddy's Labs	102.61
Glaxc India	169.28
Hincustan Antibiotics	200.00
Hinc Ciba-Geigy	277.00
Hoechst India	880.00
ICI India	192.00
Lupin Labs	765.00
Rancaxy	533.50
Sancoz (India) Ltd.	313.06
Tamil Nacu Dadha Pharma	153.02

Source . Economic Times. May 1993.

8th Plan Targets of Drug Production in India

Year	Bulk Drugs	(Rs. in Crores) Formulations
1990-91	625.00	3405.00
1991-92	675.00	3735.00
1992-93	730.00	4080.00
1993-94	800.00	4440.00
1994-95	880.00	4890.00

Source : Indian Pharmaceutical Guide 1991.

World Chemical Market ($ bn)

	Output	Exports	Home Imports	Net demand	Trade
West Europe	340	52	25	313	27
North America	275	33	22	264	11
Japan	190	20	15	185	5
E. Europe	170	15	19	174	-4
Central/S. America	54	6	15	63	9
Far East	39	14	32	57	18
India/Pakistan	25	1	5	29	-4
Africa	15	2	9	22	-7
Middle East	12	5	10	17	-5
Australia	10	1	5	14	-4
Total	1130	149	157	1138	

Source : EC & India IN 199s -Towards Corporate Synergy, 1993. in Dr. Karandhikar, **Indian Drug Industry After GATT**, MVIRDC, Bombay, 1994

LEADING PHARMACEUTICAL COMPANIES IN INDIA

Sl. No.	Company	Sales (Rs. crore)
1	Glaxo	142
2	Ranbaxy	124
3	Cadila	122
4	Alembic Chemicals	98
5	Cipla	94
6	Ambalal Sarabhai	90
7	Hoechst	89
8	Pfizer	89
9	Lupin	82
10	Boots	76

Source : The Eastern Pharmacist, Nov, 1992.

Drugs & Pharmaceutical Trends In Output, Imports & Exports

Year	Bulk Drugs	Production of Formulations	(Rs. in Crores) Imports	Exports
1974-75	90	400	46	43
1979-80	226	1150	120	71
1984-85	377	1827	215	217
1989-90	640	3420	652	856
1994-95 (Target)	880	4890	375	1780

Source : Dr. Karandikar, Indian Drug Industry After GATT, MVIRDC, World Trade Centre, Bombay, 1994

Indian Drug Industry, Growth Indicators

	(Rs. Crores)	
	1965-66	1990-91
Capital investment	140	900
Production :		
Formulations	150	3600
Bulk Drugs	18	700
Import	8.20	652*
Export	3.05	785
R & D Expenditure	3.00	60

* 1989-90

Source : Indian Pharmaceutical Guide 1991

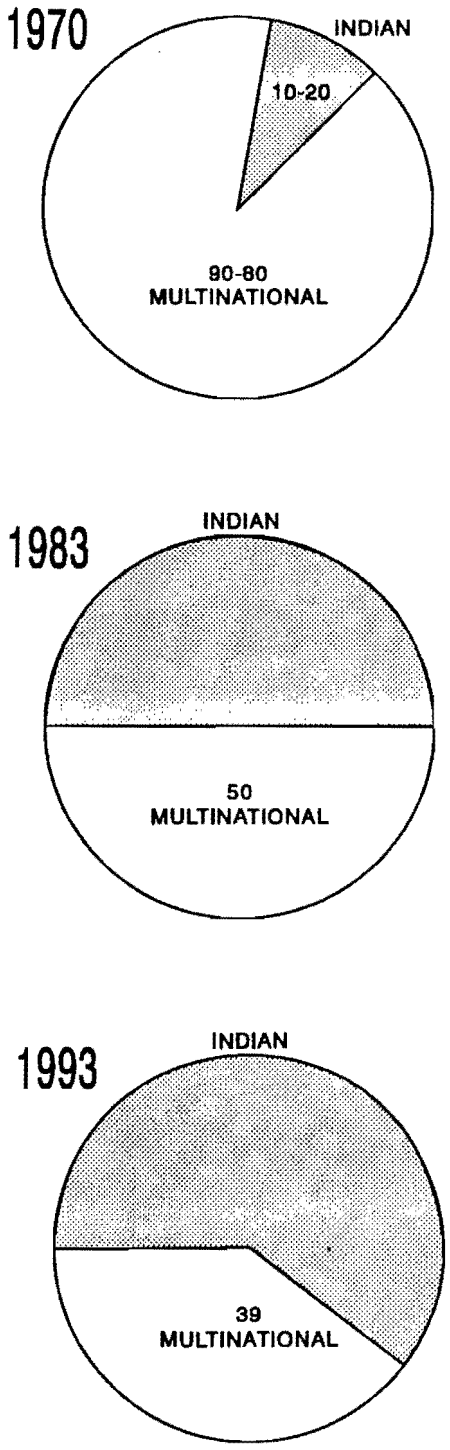
Number of Drugs Manufacturing Units in India	
1969-70	2,257
1977-78	5,201
1979-80	5,156
1980-81	6,417
1982-83	6,631
1983-84	9,000
1988-89*	16,000

Source : Indian Pharmaceutical Guide 1991.

INDIAN PHARMACY MARKET

1993

% Share by Corporate Ownership



Source : Heinz Redwood

CSIR Patent Applications filed in India during the period 1983-84 to 1993-94

Lab \ Year	83 84	84 85	85 86	86 87	87 88	88 89	89 90	90 91	91 92	92 93	93 94	Total	%
CBRI	-	1	4	-	2	-	3	1	4	2	1	18	1.1
CCB	-	-	-	1	-	2	-	-	2	-	5	10	0.6
CCMB	-	-	-	-	-	3	-	-	-	-	-	3	0.1
CDRI	14	5	3	15	11	8	8	16	34	21	12	147	9.1
CECRI	1	11	6	7	9	12	10	20	23	33	10	142	8.8
CEERI	3	2	1	2	5	2	2	5	8	4	2	36	2.2
CFRI	2	4	3	2	2	5	7	4	3	4	3	39	2.4
CFTRI	2	6	-	2	4	3	1	5	-	3	3	29	1.8
CGCRI	1	1	2	5	6	4	9	3	1	7	5	44	2.7
CIMAP	-	1	-	-	-	1	2	2	2	2	2	12	0.7
CLRI	-	-	3	3	-	2	2	14	8	2	7	41	2.5
CMERI	4	-	1	2	1	2	1	-	4	1	1	17	1.1
CMRS	1	2	1	-	-	2	6	-	-	10	6	28	1.7
CRRI	-	-	-	3	1	5	3	-	-	2	1	15	0.9
CSIU	-	2	-	-	1	-	1	1	-	2	1	8	0.5
CSIR (SCH)	1	1	-	2	-	1	-	2	-	-	-	7	0.4
CSMCRI	3	2	6	1	12	3	6	5	6	7	3	54	3.3
IICB	5	1	3	3	2	3	-	7	1	1	4	30	1.9
IICT	2	5	3	7	4	3	14	11	12	8	10	79	4.9
IIP	3	1	4	9	1	1	3	4	6	8	11	51	3.2
IMT	-	-	-	-	-	2	-	1	-	2	6	11	0.7
ITRC	-	-	-	-	-	-	1	5	-	2	-	8	0.5
MEARDO (L)	-	-	-	-	-	-	-	-	-	-	-	-	-
MEARDO (M)	-	-	-	-	-	-	-	-	-	-	-	-	-
NAL	1	4	3	5	3	-	-	-	3	-	2	21	1.3
NCL	10	12	13	8	20	26	39	41	56	42	49	316	19.5
NEERI	1	1	2	1	1	-	4	2	1	-	8	21	1.3
NGRI	2	-	-	-	-	-	-	3	1	-	-	6	0.4
NIIO	-	-	-	-	1	1	-	-	2	2	-	6	0.4
NML	4	3	11	6	3	14	15	25	12	18	9	120	7.4
NPL	-	4	2	2	5	2	3	1	4	2	4	25	1.5
RRL (BP)	-	-	1	7	2	-	6	7	5	1	1	30	1.9
RRL (BHU)	7	11	4	13	8	3	9	5	7	10	4	81	5.0
RRL (J)	-	-	-	-	-	-	8	-	4	6	13	31	1.9
RRL (JT)	2	2	3	7	16	3	5	6	12	21	10	87	5.4
RRL (T)	-	-	-	-	4	6	7	6	9	9	4	45	2.8
SERC (M)	-	-	-	-	-	-	-	-	-	-	1	1	0.1
SERC (R)	-	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL	69	82	79	113	120	119	175	202	230	232	198	1619	100.00
%	4.3	5.1	4.9	7	7.4	7.3	10.8	12.5	14.2	14.3	12.2	100	

Source : N.R. Subbaram

Chapter Three

Thus a patent grant for a few years covering either an invention or a new industry or a new trade does not restrain the people of any freedom or liberty that they had before nor does it hinder them in their lawful activity. However, disregarding the decision of the Court, the patent system was greatly exploited in an effort to secure pecuniary aid. This compelled the parliament to enact the statute of Monopolies and take away the power to give monopolies from the Crown. The statute declared all monopolies contrary to the laws of England, but provided an exception, which says that

> "any declaration beforementioned shall not extend to any letters patent or grant of privilege for the term of fourteen years, or under, hereafter to be made of the sole working or making of any manner of new manufacture within this realm, to the true and first inventor of such manufacturer, which others at the time of making such letters -patents and grant, shall not use. So as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient"[5].

More generally the terms of the section made it plain that an act of economic policy was intended and the objectives were the encouragement of industry, employment and growth, rather than justice to the "inventor" for his effort. The consideration for the grant of patent was that he would put the invention to use[6]. Until eighteenth century there were no significant changes with regard to the patent system. Only in the early eighteenth century patentee had started to enroll statements of their inventions with the Court of Chancery. Initially this practice may have been a device to help to prove against infringers what the protected invention was. But a half-century later the courts were requiring the patentee to make a sufficient statement of his invention as "consideration" for the monopoly granted to him[7].

The new patent system cheap and simple in concept, was designed to attract capital for the small ventures and out-of the way ideas being generated on the fringes of industry as much as its centre[8]. With these developments the essential features of the patent system were settled and the necessary amendments were

made to the patent system from time to time. The statutory revisions of 1907, 1917, 1932 and above all in 1949 put the law more in the form of a code and altered it in many details. However, one of the significant changes worth noting here was the restrictions upon claims to chemical substances introduced in 1919 and removed in 1949.

Practically speaking, if not a single factor the following factors together might have necessitated the crown to grant the patents. During the sixteenth century, England in comparision with France and other parts of Europe, lagged behind in economic development. So the creation of new industries required a special stimulus in the guise of monopolistic privileges. There was also the desire to reward favorites of the court, many of whom had performed valuable services. Other reason was that the sovereigns of the time, continually embarrassed by depleted exchequers, contrived many devices to replenish them, one of which consisted of granting exclusive monopolies in return for royalties, although in most instances the expense of protecting patentee from infringement left little revenue. And perhaps the desire of Elizabeth I to strengthen the political power & prestige of the nation was another factor in her willingness to create monopolies that were national in scope and subservient to the crown[9].

However, theoretically Intellectual property rights are justified on more than one count[10]. Many arguments were put forth with regard to the recognition of patents. The general purpose of patents was to promote or stimulate the progress of science and the useful arts. It has been contended that patent is a reward of inventor for his contribution to society[11]. According to John Stuart Mill it would be a gross immorality in the law to set everybody free to use a person's work without his consent and without giving him an equivalent[12]. And Jeremy Bentham asserted, "A patent considered as a recompense for the increase given to the general stock of wealth by an invention, as a recompense for industry and genius and ingenuity, is proportionate and essentially just[13]. It is also recognised that patents provides mutual benefit to the inventor and the public. The consideration to the inventor is an exclusive monopoly covering his invention for a term of years, while that to the public consists of an immediate and complete disclosure of the invention[14]. Such disclosed invention becomes common property after the expiration of the patent

term. The limited monopoly granted to inventors was never designed for their exclusive profit or advantage but for the benefit to the public or community at large was the primary object in granting and securing that monopoly[14]. This was upheld when the university of Wisoncin Alumni Association, the assignee of Harry Steerbock's patents on irradiation, refused to license manufacturers of oleomargarine and thus deprived oleomargarine consumers of health-giving vitamins. In an infringement suit involving these patents, a circuit of appeals declared in 1944 that the inequitable misuse of the monopoly of the patent warrants the denial of equitable relief. It was held "that patentee may not put his property in the patent to a use contrary to the public interest". Further, the patent is a privilege "conditioned by a public purpose"[15]. The Swan Committee in England in simple terms, explains that

> "the theory upon which the patent system is based is that the opportunity of acquiring exclusive rights in an invention stimulates technical progress in four ways; first, that it encourages research and invention; second that it induces an inventor to disclose discoveries instead of keeping them as a trade secrete; third that it offers a reward for the expenses of developing inventions to the stage at which they are commercially practicable: and fourth, that it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously[16].

As we have seen that the patents originated as a tool for the transfer of technology and establishment of new industries, at the end of the eighteenth century the theoretical foundation for the grant of patent monopoly had changed from the sole idea of industrial growth to the need for written disclosure of the invention for public interest[17]. But now it has reached a stage where much emphasis is given to the individual interest[18]. It is argued that certain conditions of economic security are required in order to encourage investment in what may turn out to be costly research programmes. So under patents certain rights and benefits are provided to the inventors in turn to the investors. It marks a shift from that the patents are for stimulation of invention to the encouragement of investment, that is from the reward of the inventor to the reward of the investor. It is argued that in order to encourage

the creativeness/improvements in relation to the industrial techniques, the patent monopoly should be given to serve full purpose[18]. It is further added that the only way the inventor can make a profit from his invention or even recover the fee for his patent is by putting it into practice; either by using it himself, and driving an advantage over his competitors by its use, or by allowing others to use it in return for royalties. Unless the use of invention is protected by patent monopoly no one will be interested in investing in the use of such inventions. Further, without such investment there can be hardly any economic development.

PATENT SYSTEM IN INDIA

"Patent system is not created in the interest of the inventor but in the interest of national economy"[19].

As discussed earlier, the English patent system originated to facilitate industrial growth. India being one of its colonies, the British administration adopted the patent system as early as in 1856, basically to protect and encourage the British trade and industry[20]. It appears that unlike the English system, the Indian patent system originated and developed through legislation[21]. On the attainment of Independence the Indian Government decided to amend the patent law of 1911 suitably so as to subserve the interest of the nation. From 1950 onwards changes were carried out so as to make the system favourable to the Indian Economic development[22]. Accordingly the patents enquiry committee in 1948 was constituted to review the patent system in India. It was headed by justice Bakshi Tek Chand and submitted its report in 1949. It was observed by the committee that

> "the Indian patent system has failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new inventions for Industrial purposed in the country so as to secure benefits thereof to the largest section of the people"[23].

The Indian Patent and designs (Amendment) Act of 1950 implemented some of the suggestions. But it was not quite satisfactory. Therefore the government appointed Justice N.R.AYYANGAR to make another report on the revision of the patent system in India. And the present Indian Patent Act, 1970 was adopted based

on the Ayyangar Committee report which was submitted in 1959. While examining the facility of adopting Patent System in India Justice Ayyangar observed that

> "the monopoly created by the Patent and the reward to the inventor by the grant of such monopoly offered advantages which had been claimed for the system only in the highly industrialised countries which had a large capital available for investment in industries and a high degree of scientific and technological education.
>
> However, he further observed that :
>
> with all the handicaps which the system involves in its application to under-developed countries, there are no alternative methods for achieving better results..... consider that the patent system is the most desirable method of encouraging inventors and rewarding them and though at present Indian inventors take a small share in the benefit of that system with the increasing emphasis on technical education and the number and quality of the research institutes that have been established in the country together with the rapid industrialisation that is proceeding, one may look forward to a time when the Indian research worker and inventor will take full advantage of the patent law. Further, the patent system has been working in India for over a century. This is therefore, sufficient justification for the retention of the patent systems[24].

The report while justifying the adoption of patent system made proposals which honours the business expectations of patent holders while providing the system as a whole with the legitimation that the public interest was strongly safeguarded. The committee examined the controversial issues and made recommendations in view of the national plans, objectives and constitutional goals. The issues are with regard to the patentability of inventions relating to food, medicine and chemical products and substances. And further patents relating to Atomic Energy inventions and those relating to defense. Secondly, the degree of patent production that ought to be offered to these inventions. Thirdly, the conditions subject to which patents in general should be open to compulsory licensing and

the terms and conditions subject to which licenses should be granted. And the countering of attempts by patentees seeking to extend the scope of patent monopoly by entering into restrictive contracts touching the use of unpatented articles[25].

On the basis of the recommendations by the Ayyangar committee the Indian patent Act, 1970 was drafted and adopted. It excluded from patentability of all inventions relating to methods of agriculture, horticulture, human, animal and plant treatment[26]. It also excludes drugs, medicines and food from product patent and allows only process patents[27]. The act keeping the social and public interest in view provides under Sec. 3 a list of matters which are not patentable[28]. Such as an invention which is frivolous or which claims anything obviously contrary to well established natural laws, an invention the primarily or intended use of which would be contrary to law or morality or injurious to public health, the mere discovery of a scientific principle or the formulation of an abstract etc. It has reduced the life term of process patents for products of great social relevance, such as for substances intended to be used as food, medicine or drugs for which seven years from the date of application or five years from the date of sealing whichever is earlier[29]. The basic philosophy of the act is enunciated in Sec. 83 of the act which provides that the patents are granted to encourages inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. The Act also made it clear that patent are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. It provided various provisions to ensure the working of patents in India. Such as compulsory licenses would be granted on application if reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention has not been available to the public at a reasonable price[30]. If reasonable requirements of public interest about availability and at reasonable price not served, government may endorse "Licenses of Right" for any patent. For process patents for food, medicines, drugs and chemical substances "License of Right" shall be deemed to be endorsed after 3 years". The controller is empowered to revoke the patents on the ground that the reasonable requirements of the public have not been fulfilled[31].

among the nations in the field of technological capabilities. The convention also allows the importation of patented product which goes against the basic philosophy of the Indian patent act, 1970. Generally foreign nationals who obtain patents in developing countries prefer to work their inventions abroad and then used the patent right to safeguard the import of the patented products into the country of grant under Paris convention[35]. It further provides that a patentee shall enjoy all the rights with regard to an imported product. The convention further requires that compulsory license shall be non-exclusive and non-transferrable even in the form of sub-license. This is a problem in developing countries, as without an exclusive license, they may be reluctant to risk their resources, particularly when it is against the liking of foreign patentee, who may license it to someone else or may itself engage in production so as to frustrate the local efforts. And the compulsory licensing under the convention can only be on the ground of non-working. Another important feature of the convention is that member countries may have to extent its patent protection to all inventions. Since India restricted its patent protections only to certain kinds of inventions felt that by joining the convention, it has to dispense with those restriction, which are provided in the Nations interest.

In the light of above said things one can understand that India did not join the Paris convention as it preconceives the equality among its partners, which is not there in the case of developed and developing countries. The Paris convention is highly titled in favour of rights of the patentees and the developing countries are unable to control the digopolistic proclivities of the foreign patentees[36]. However there had been unrelenting pressure on India to accept new intellectual property regime and to join the Paris convention by the developed countries. Especially the United States decided to invoke the special 301 to remind nations that their intellectual property laws were standing in the way of America regaining and increasing its economic domination of the economies of the World[37]. America has pushed hard to devise a new initiative within the aegis of GATT. And the developed countries succeeded in introducing the intellectual property rights under GATT through trade related aspects of intellectual property rights (TRIPs) agreement. The views of the developed and developing countries on this issue. Patent protection in particular have been quite divergent. This fact was recognised by the world intellectual property organisation (WIPO) which has unsuccessfully tried to

bring about harmonization of patent laws through a series of Diplomatic conferences for the Revision of the Paris convention spanning more than a decade and half[38].

GATT is an international organisation set up in 1948. It has now 124 member countries including India. The main purpose of GATT is to remove trade barriers among member countries and promote world trade. The role of GATT has traditionally been restricted to international trade in goods. The eighth round of GATT negotiations started at Punta Del Este in Uruguay in 1986. For the first time in the history of GATT the issues like TRIPS, TRIMS, trade in services, trade in textiles, trade in Agricultural commodities have been included under the uruguary round negotiations which are never been under the GATT regime. The negotiations of the Uruguay round talks dragged for seven long years. In 1991 the then Director General of GATT Arthur Dunkel presented a draft agreement which is called as the text of the Dunkel Draft (DDT). However, it has been pointed out that the DDT ignores the issues raised by the developing countries in the negotiations[39]. The developing countries like India who initially opposed to the Dunkel Draft had been subjected to different kinds of pressures to the "GATT" Agreement on April 15, 1994, at Marrakesh in Morocco[40]. The Uruguay round of the GATT has created a new body, namely, the World Trade Organisation (WTO) which has replaced the GATT from Jan 1, 1995. The WTO evolves an elaborate institutional mechanism to oversee the rules besides an integrated dispute settlement mechanism on cases of bilateral trade frictions.

Since India signed the GATT Final Act and became the member of WTO, to fulfill its obligations Government passed an Ordinance on the 31st Dec. 1994 making amendments to the Indian Patent Act of 1970 in accordance with some of the provisions of the TRIPs agreement dealing with Pharmaceutical Patents. Even countries which are availing the transitional period are required to fulfill certain obligations on the date of entry into force of the WTO agreement. Therefore, the Government promulgated the patents (Amendment) ordinance, 1994 bringing about certain major changes in Pharmaceutical Patents in the Indian Patent Act, 1970. Under this new regime uniform standards are provided for the recognition and protection of IPRs for all member countries. The provisions of the TRIPs agreement are to be implemented in the national domestic laws. Under the TRIPS Agreement

39...

the developing countries like India are not allowed to have special provisions of patent system in relation to food, drugs etc. The member countries sovereign authority to adopt patent laws according to their socio & economic needs is restricted by the TRIPs agreement. In future it could also be foreseen that even this power to adopt domestic laws in relation to patents may be restricted by bringing out single universal patent law which is applicable to all.

Historically, the patent systems evolved to protect property rights in innovations which were products of manufacture. Agriculture, chemical processes and products were traditionally considered to be outside the ambit of patent laws. Living things were also excluded from patentability as these were regarded as products of nature rather than of manufacture and as such were considered to be the common heritage of mankind which should be available freely to everyone. This situation, has been drastically changing particularly as a result of the technological revolution ushered in by recent developments. This has its impact on the area of drugs as well. The new regime is going to have sustantial changes in the patent policy and law regarding pharmaceutical products.

FOOT NOTES :

1. Floyd L. Vaughan, The U.S. Patent System, Norman University of Oklahomer Press, 1956, P. 13.

2. Ibid

3. Ibid

4. Darly V. Allin, II Coke 84 b (K.B. 1602)

5. Floyd L. Vaughan, op. cit., P. 15.

6. Cornish W.K., Intellectual property: patents, copyright, trademarks and allied rights, 2nd edn, (Indian Reprint) New Delhi, 1993, P. 67.

7. Ibid

8. Ibid., P. 69.

9. Floyd L. Vaughan, op. cit., P. 14

10. For example, Justin Huges, justifies intellectual property basing on both lock's labor theory and Hegel's personality theory. Locke linked properly to the product of the individual person's labor. Locke began his justification of property with the premise that initially only out bodies are our property. Our handiwork becomes our property because our hands and the energy consciousness, and control that fuel their labor are our property. Hegel proposed a personality theory in which properly is justified as an expression of the self. Hegel points that property provides a unique or especially suitable mechanism for self actualization for personal expression, and for dignity and recognition as an individual person. And an idea belongs to its creator because the idea is a manifestation of the creator's personality or self. In Justin Hughes, "The philosophy of intellectual property". The Georgetown law Journal, Vo. 77, P.287 (1988).

11. Under the U.S. Constitution, Cl. 8, Sec 8 of Article 1 "To promote the progress of Science and useful arts by securing for limited times to Authors and Inventors the exclusive right to their respective writings and Discoveries". The purpose of the patent law has articulated by the U.S. Supreme Court in U.S. & Masonite Corporation, (62 s ct. 1070 (1942)) as the promotion of the progress of science and the useful arts is the main object of the patent system, and reward of inventors is secondary and merely a means to that end.

12. Floyd L. Vaughan, op. cit., P. 27.

13. Ibid

(a). A.R. Lall, "Importance of patenting of inventions to research and development and to industry", seminar paper, presented at National seminar on `patent system', Hyd, Nov. 28-29, 1981.

14. Ibid

15. Floyd L. Vaughus, op. cit., P. 32.

16. Justice E.S. Venkataramiah, "Law relating to Industrial property in India", IIMB Foundation day lecture, B'lore, Oct. 28 1992, P. 12.

17. Gopalakrishnan N.S., Intellectual property and Criminal Law, NLSLU, Bangalore, 1994, P.

18. Ibid., P. 213.

(b). Blanco White, Patents for inventions, Stevens, 3rd ed. 1962, P.

19. Justice E.S. Venkataramaiah, op. cit., P. 12.

20. In the British India period while legislating patent system in India under which to determine the priority of patents also extended to Britain.

21. Gopalkrishnan N.S., op. cit., P. 192.

22. Rajiv Dhawan, "Whose interest -independent India's patent law and policy" 32, J.I.L.J., 1990, P. 429

23. See generally. ACR. 1959

24. Ibid

25. Ibid

26. Respectively Sec. 4, Sec 3(4), 2(1) of IPA, 1970

27. Sec. 5 of the IPA, 1970

28. Sec. 3 of IPA, 1970

29. Sec. 53 (1) (9) of Indian Patent Act, 1970

30. Sec 84 of IPA, 1970

31. Sec. 87 and Sec. 89 (3) of the IPA, 1970

32. Dr. Nitya Nand,"Patent Laws : The Indian Experience"- National working group on patent laws (NWGP), 1992, P. 6.

33. Government of the Empire of Austria, Hundary invited to other countries to participate in an international exhibition of invention, which was held in 1873.

34. Articles 2 & 3 of the Paris Convention provides for National Treatment, Art 5 provides that a patentee shall enjoy all the rights with regard to an imported product, etc.

35. India, Zebanon, Cuba reported to the United Nations (UN) that most of the patents in their countries were foreign owned and not worked but merely for the preservation of patent rights, in Dr. S.K. Verma "The International patent system and transfer of Technology to developing Countries -A Critique", in P.S. Sangal & Kishore Singh `Indian Patent System & Paris Convention : Legal Perspectives', Delhi University, 1987, P. 28.

36. Ibid., P. 31.

37. Rajiv Dhawan,"Making the world Fit for prey GATT and Intellectual property Rights", NWGPL, 1992, P. 2.

38. B.K. Kealya, Biswajit Dhar & C.N. Rao "Dunkel Draft on TRIPS- An evaluation", NWGPL 1993, P. 2.

39. Further points out that the provisions on TRIPS in DD closely resemble the Submissions made by the America, Japanese and European business communities in 1988 to the GATT negotiating committee in Sudip Choudhari "Dunkel Draft on

Drug Patents": Background & implications", EPW, Sept. 1993, P. 1863.

40. For example in 1989, the United States Trade Representative (USTR) placed India on a "Priority Watch" list of countries which allegedly deny adequate protection of Intellectual property rights pursuit to the "special 301" provisions of the Omnibus Trade and competitiveness act of 1988. The USTR maintains that India must improve patent protection of all classes of inventions in order to avoid being named a "Priority" country which denies adequate protection of Intellectual properly rights, in Aparna Vishwanath, "Patent System and Pharmaceutical Industry", NWPL, 1993.

❑

Chapter Four

PHARMACEUTICALS AND THE PATENT SYSTEM IN INDIA

Patent is a statutory limited private property right given to an inventor for a new and useful invention. In this way, patents are intended to encourage inventions. An invention must fulfill five major requirements to be granted patent. The invention must, be a patent subject matter, be useful, be novel, that is, not have been obvious at the time it was made and must also disclose the invention known to the applicant as of the filing date in sufficient detail. With regard to the patentable subject matter the patent protection can be provided either to the specific process for manufacturing a product or it can be provided to cover the product itself, irrespective of the process involved. This distinction in the nature of patent protection is of particular relevance to the chemical industry where a product can be manufactured using more than one process route. This has significance for the late comers in the industry who can bring about innovations with respect to the processes involved in the manufacture of an already existing product[1]. It is also very significant in relation to the patentability of inventions in respect of drugs. As the pharmaceutical industry is a part of the Chemical Sector and is second in important after the organic chemical industry[2]. Since social, economic industrial and technological conditions differ from time to time and from country to country, countries adopted and changed the patent system according to their own domestic needs.

The majority of the nations in the world have provided special provisions as regards the patentability of inventions in respect of articles of food and medicines or as to the licensing and working of patents in this class, at one point of time or the other. For example the patent laws of every country in Europe contain special restrictions on patentability of articles of food and pharmaceutical products. The French law of 1844 confined patents for articles of food and medicine to process claims though permitted the patenting of chemical products. Belgium in its patents law of 1854 adopted the French model. The German law of 1877 denied patents to articles of food, medicinal products, though processes for their preparations were patentable. The Swiss law was amended in 1954 under it, inventions of medicine

including medicinal mixtures and forms of medicine and inventions of food products are not patentable, but the processes are patentable. The law in Sweden and Spain was similar. U.K. also by an amendment in 1919, introduced the same restrictions as to patenting of substances intended for food or medicine as applied to substances prepared or produced by chemical processes. Even in Japan until 1976, Pharmaceuticals, Chemicals food and beverage could be covered only by process patents. It was said that the reason why it did not adopt a patent system for substances was based on the viewpoint of national interest that such things as pharmaceuticals and foods and beverages were indispensable to the daily life of the people. With regard to chemical substances it was based on Industrial Policy, attempting to protect the chemical industry which was weak in technical development, from patent monopoly of foreign companies.

However, later the patent laws were amended by removing those special provisions and further strengthened the patent protection by the respective countries, after substantial advancement was achieved by the industry towards technological self-reliance. Eventhough USA did not adopt any special provisions in its patent laws in relation to the patentability of drug inventions, its successful pharmaceutical companies began as satellites of the West German chemical industry. It itself exploited all German patents to provide a tremendous boost to their chemical industry after the world war II[3]. Even now, as for chemical patents issued in 1991, 51 percent patents were in USA totaling 27,433 and the significant thing is that nearly a third of US chemical patents originate in Germany and Japan.[4]

As we know, initially patent system was recognised for the purpose of encouraging the establishment of the domestic industry and also to encourage inventiveness within the country. Patent protection provided only limited monopoly rights for a given period of time, since there is scope for the abuse of such rights by the patent holder. To prevent such abuse and keeping in view of the above said objectives the patent laws were adopted which strikes a balance between the private interest and public interest. Indian patent law of 1970 is one such model law which protects both private and public interests and which is adopted after much deliberation in view of the past experiences under the patent Act of 1911. The special provisions in relation to the drug patenting were introduced by the 1970

Act. One of the objectives for including those special provisions is to protect and to encourage the Indian pharmaceutical industry. Which has hardly any status at that time and the transnational corporations enjoyed a monopoly and dominated the Indian sector. The patents Act of 1911 did not categorically state what was patentable. The interpretation was that any new process for manufacturing a drug (Whether old or new) was patentable. A new drug was also patentable provided the process of manufacture was described in the patent. The process, however in such a case was not required to be new[5]. And the life of the patent was for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee[6]. The TNCs took full advantage of these provisions and the indigenous firms have been legally prevented from manufacturing most of the new drugs introduced by the TNCs[7]. The patentee while patenting a new drug could describe all the known and possible processes to prevent others from manufacturing such patented product by non-patented process[8]. Eventhough the law permitted others to manufacture a new drug by developing or using a process not mentioned in the patent, in practice, TNCs could prevent or delay the use of these new processes developed through indigenous efforts. This was evident in the case of **M/s. Farbwerke Hoeches Vs M/s Unichem laboratories**[10]. The plaintiffs, Hoechest, a TNC alleged that defendants have wrongfully and with full knowledge infringed their patent by manufacturing, preparing and selling tolbutamide in accordance by the use of invention of plaintiffs said patent as claimed in claims 1 and 11. Their patent was in respect of the manufacture of new sulphonyl meas, salts of those compounds and of antidiabetic preparations containing such compounds. One of the compounds comprised is Tolbutamide. The defendant which is an indigonous firm admitted the manufacture of Tolbutamide but claimed that this was according to the process of another patent held by Haffkins Institute, Bombay under a license. Haffkins Institute, a public sector firm, worked out a process for manufacturing tolbutamide from locally available raw materials. The High Court of Bombay held that Plaintiffs patent was valid and entitled to the relief for an infringement action. The court reached this conclusion despite the fact that its patent did not specifically mention Haffkine's process and its description was open-ended. The Court interpreted that "claim 11 is wide enough to cover all the methods of eliminating sulphur from thiouroes, where the desulphorisation is effected by means of hydrogen peroxide or by the

use of any other substance. Therefore claim 11 as well as the wider claim of the plaintiffs patent have been infringed by the defendants".

The same patent was also sought to be used for preventing Bengal Chemical and pharmaceutical works (BCPW), an indigenous firm, from manufacturing another drug, chloropropamide[11]. BCPW developed a new process for manufacturing it and obtained a patent in 1956. In 1961, BCPW received a letter from Hoechest alleging that the former had infringed upon the latter's patent under which Pfizer had been given a license to produce it. Denying the allegations, BCPW sought legal action when it continued to receive such threats[12]. Hoechest and Pfizer filed a suit in 1962 in the Calcutta High Court against BCPW. This time the judgement was in favour of the indigenous firm. It was held that BCPW'S patent was an independent one, not in any way influenced by Hoechest's patent which, in fact, did not relate to the manufacture of chloropropamide at all[13]. The Court observed that the Hoechst's patent was widely described to cover a large and unspecified number of products or processes. It also contained according to the Court inadequate and misleading information which prevents and distorts the diffusion of knowledge. Sometimes a mere threat of legal action may be enough deterrent to the indigenous firms in many cases of patent dispute. Hindustan Antibiotics (HAL), a public sector firm claimed that it had developed an indigenous process for manufacturing oxytetracycline HCl[14]. A plant was set up and production began in 1961 without any external technical help. In the same year a TNC, Pfizer too started manufacturing the same drug[15]. Pfizer claimed the infringement of their patent rights which compelled the BCPW to suspend production and decided not to contest the Pfizer.

The Indian firms were also forbidden from processing a patented drug into formulations or importing it. For example, a TNC was importing a drug at Rs. 8 per 20 tablets. It sued an indigenous firm, CIPLA, when the latter started importing it at Rs. 2 per 40 tablets[16]. chloramphenical and metronidazole are among the other drugs for which the TNC took legal action to prevent the indigenous firms from formulating[17]. Basing on the recommendations made by the patents enquiry committee a special provision was made by an amendment in 1952 dealing specifically with drugs food etc. regarding compulsory licence. The provision

empowered the controller to grant a compulsory license to any applicant unless there are good reasons for refusing. Even this did not help the indigenous firms to get licences from the foreign patentees, when they were reluctant to give it. For example the Haffkine institute applied for a compulsory licence and the foreign patentee offered to give the licence voluntarily on the basis of royalties to be fixed through negotiations. They demanded high rate of royalty of 25%. It took more than four years to reduce it to 10 percent which was still higher than the limit of 5 percent stipulated by the Reserve Bank of India. However, by that time it decided to abandon the scheme. Neo pharma Industries another indigenous firm entered into a technical collaboration agreement with an Italian firm for the technology to manufacture chloramphemicol. A licence was sought form Park Davis, which held the relevant patent in India. But whereas the Subsidiary company in India pointed out that the matter was beyond its jurisdiction, the parent company in the US insisted that Neo Pharma should first discuss with the local company. It took more that two years to decide as to who would negotiate. At last when the negotiations started with the parent company, they did not formally refuse to grant a licence but simply sat over the proposal. Finally when a compulsory licence was sought Park-Davis went to the Court and obtained a stay order.

As mentioned earlier, the life of patent was for 16 years under the Act of 1911 which could be extended to a maximum of another 10 years in certain cases. During this period others are legally prevented from manufacturing the patented products. Patent terms are designed to stimulate innovation by providing a period of exclusive marketing rights during which the company can recover research and development (R & D) cost as well as a reasonable return on the investment. It has been argued that the patent term was decided arbitrarily across the board to products in all industries, without considering the different costs and varying periods of time in which those cost can be recovered through market sales[23]. The use of an arbitrary patent term unrelated to the period of exclusive marketing power needed to recover R & D costs has enabled chemical and pharmaceutical companies to reap windfall profits. High profits in turn, have enabled the leading companies to solidify market power, charge prices above competitive levels and engage in a wide range of anticompetitive practices[24] High profit levels are earned by subsidiaries of foreign drug companies in India. For example between 1962 - 1994 foreign-owned

subsidiaries earned an average net profit of 28% of net worth[25]. Such high profit levels enabled foreign-owned subsidiaries to recover the investment of the parent company within two years while the foreign controlled subsidiaries did so within four years[26]. In India drugs were sold at unreasonably high prices despite the fact that Indian per capita income is among the lowest in the world. As the kefauuer committee, a committee of the US senate reported in 1959 that "Prices of certain drugs and antibiotics in India were amongst the highest in the world and that in drugs, India was one of the highest priced nations"[27]. The Indian drug price index, calculated on the basis of prices in eight age-old static drugs rose by 41.9% between 1961 and 1970. Furthermore, it has been shown that brand-name products of foreign controlled companies in India are priced 150-300 percent above the formulation prices of Indian public sector companies[28]. One of the major reasons for allowing foreign companies in India is that it will facilitate R & D technological development and transfer it to the domestic industry. However, as the Hathi Committee points out that the main thrust of MNCs continue to be towards capitalising on drug formulation and non-drug items like cosmetics and luxury goods where technology and capital inputs are much lower and which permit promotion of aggressive salesmenship and brings in much higher returns on investments. MNCs in India produce only a small fraction of bulk drugs[29]. And they have not contributed to development of local pharmaceutical industry either through substantial investment in R & D within the country or through transfer of relevant technology[30]. According to the Committee estimates the expenditure on R & D activity by the industry in India is about 1.1 percent of the total turnover by the industry. The expenditure is woefully inadequate when looked at from the angle of total turnover by this industry, vis-a-vis expenditure incurred on R & D in the developed countries and the turnover attained[31]. The drug production was low, and India was a net importer of drugs. The imports was being twice the value of exports. As we could see there was no research activity worth the name[32].

The above discussion shows that the MNCs enjoyed a monopoly status. They charged higher prices, reap higher profits and held dominant market share. In doing so, they took advantage of the patent Act of 1911 and also used promotional devices, exaggerated and unjustified claims regarding the therapeutic value of their product and means such as transfer pricing. This has dampened the growth of the

many new drugs which are introduced by the foreign companies in abroad were introduced in Indian market by the indigenous drug companies within short span of time. Process patenting aims not to inhibit research in the development of alternative process and it allows the development of processes appropriate to domestic environment and socio enconomic conditions and resource endowment. This led the Indian drug firms to develop alternative innovative process in a competitive environment and has resulted in lowering cost of production and in lowering prices for the product. This has given the Indian firms a competitive edge over rivals, as the foreign companies can't do the same in India because of the restrictions put by the parent companies. The data shows that the drug prices are very low in India when compared to other countries. Eventhough government policy of drug price controlling might have helped to keep the prices low, process patenting has also played a major part to keep it low. Irrespective of this the industry made efficient profits. There are some instances where the drugs were sold at much cheaper and lower prices than prescribed by the drug pricing policy.

There are also adequate provisions relating to "Licences of right", "Compulsory licensing" & "revocation of patents". These provisions ensure that either the patent holder will have to exploit the patent himself or he will have to sub-license to others so that public is not deprived of the benefits of the new technological advancement. The idea is that when the state grants patent rights it expects some obligations from the patent holders. However, there are hardly any compulsory licences granted of any patents including pharmaceutical patents. In actual practice only one compulsory license has been granted so far in 19 years and as on 31st March 1989, only 15 applications were pending with the controller for grant of a compulsory license[34]. As in the case of compulsory licences, the provisions of license of right also has hardly been used in actual practice in the country[35]. For example, not even a single application filed for license of right in 1984-85. Since the coming into force of the patents Act in 1972, the total number of patents worked in the country by utilisation of the license of right by any person other than the patent owner has perhaps not exceeded 25[36]. It shows that the actual use of a patent by a non-patentee still remains hazardous. The main reasons are firstly the patent owner can involve the applicant in lengthy litigation and procedures. The patentees can continue to prevent or delay the use of their patents by others by refusing to

negotiate and then proceeding to the court in case of any intervening action by the controller. For example, in **Catalysts & chemicals India (West Asia) Ltd** Vs **Imperial chemical industries Ltd**. the Catalysts and chemicals India (West Asia) Ltd. tried to enter into an agreement to get license to use a patent which is held by the imperial chemical industries Ltd. It is a company based in London who filed for patent in India in respect of 'Catalyst and Hydrocarbon Steam Reforming process using them' under the patent Act of 1911 in 1958 and it was accepted by the patent office in 1963. After the adoption of patent Act, 1970, the patent office made the endorsement in the entry of the above patent, which is deemed to be endorsed "Licenses of right" under Sec. 87 of the Act. However, the patent holder refused to give the license under the mutual agreement. So the Catalyst and Chemicals India (West Asia) Ltd made an application to controller general of patents office for settlement of the terms under Sec. 88 (2) of the patent Act, 1970 in respect of the above mentioned patent[38]. It also made an application under Sec. 88 (4) of the Act of 1970 for permitting it to work the patented invention on such terms as the controller might think fit to impose pending his decision under section 88 (3). It was made on march 29, 1976, and on May 28, heard both parties and, on June 4, passed his order under Sec. 88 (4) of the Act permitting the catalyst and chemicals India (West Asia) Ltd to work the aforesaid patented invention subject to the terms set out in the order pending the decision under section 88 (3) of the Act of 1970. The imperial chemical industries Ltd on Aug 6, 1976 moved the High court under Art. 226 of the constitution of India and obtained a stay order against the Controller's order under Sec. 88(4). Finally, the Court decided not to interfere with the impugned order passed by the controller. However, by the time of final hearing in July 1977 the patent was about to expire i.e. In Aug. 1977. So the Court further held that in any event any order by the Court relating to the working of license in respect of the aforesaid patent is likely to be for a very short duration.

Besides this, there are other reasons for the absence of the grant of compulsory licenses. Firstly, the law requires that the applicant has to establish the ability to work the invention to public advantage as well as his capacity to undertake the risk in providing the capital tor the working of the invention. Secondly, the application for compulsory license can be made only after the expiration of three years from the date of sealing of the patent. Lastly the commercially working of a patent usually

requires the underlying secrete know-how, and without the cooperation of the patent owner, this may not be readily forthcoming[39].

But as far as pharmaceutical patents are concerned non-utilisation of the licensing provisions does not have much affect. The patent filing is very low in India and till now only a very few process patents are filed in India. In India, Europe and USA the process pantent filed include amitriptyline, catapress, norfloxacin, Colchicine, doxyoycline, Indomethacin norfloxacin, ranitidine[40]. Actually, the drugs are produced in India by the Indian drug firms by alternative innovative processes. These process have been made out through reverse engineering rather than by getting patent information and know-how from patent holder by way of licenses etc. Indian drug firms are not particular with regard to patenting their innovative processes because of various reasons. Like, shorter life term of drug patents & it involves 2 to 3 years time and expenditure in patent filing. They prefer to keep their processes secret rather than going for patenting. Since they have to disclose it and in infringement suits the burden is on them to prove the infringement, they felt that keeping it secret may be more benefitial. As we know one of the important purpose of the patents documents are to act as a major source of scientific and technological information. But, it has been felt by the scientists especially who are doing drug research that it is very difficult to get the information by breaking patents, if not it is impossible. However, the licensing provisions in the 1970 Act helped to control and prevent the abuse of the rights by the patent holder, especially the MNCs of drug industry to create monopoly and prevent others from manufacturing the drugs.

The Indian drug industry has taken full advantage of the process patent regime and other provisions as mentioned above in the Indian Patent Act. This can be inferred from the growth rate of the industry, its production, its exports & imports, drug prices etc. It further shows the increased contribution to the Indian drug market by the indigenous drug firms which was dominated by the foreign companies before 1970s. For example, the national sector drug industry's contribution in 1991 was 80 percent of the bulk drugs and 70 percent of the formulations produced in India. The production of bulk drugs rose from Rs. 18 crores in 1966 to Rs. 200 crores in 1992 and formulations worth Rs. 150 crores in 1956 rose to Rs. 4200 crores in 1992. And direct investment in the drug industry increased from Rs. 225 crores in

1973 to Rs. 110 crores in 1993. In addition there has been a tremendous boost to the ancillary industries. Even the exports have grown from Rs. 194 crores in 1986 to Rs. 1145 crores in 1992 and now exceed imports on this area. The question is whether this will continue even in the context of TRIPs Agreement and the changes that has to be introduced in the Patent Act. This is examined in the subsequent chapters.

FOOT NOTES

1. Biswajit Dhar, "Patent system and GATT", NWPL ,1993.

2. Organic Chemical Industry accounts for 19% of the Chemical sectors turnover in Western Europe. In 1988, Pharmaceuticals share is 15% followed by plastic material 13% inorganic 8%, in Dr.Karadikar, Indian Drug Industry after GATT MVIRDC, World Trade Centre, Bombay, 1994, P. 58.

3. Background paper presented at National conference of scientists on science & technology & patents, NWGPL, New Delhi, 4th Dec, 1989.

4. Dr. S.M. Karandikar op. cit., P. 57.

5. N.R. Ayyangar Report on the Revision of the Patents Law, Delhi, Govt. of India (GOI) 1959.

6. Sec. 14 & 15 of the patents and Designs Act 1911.

7. Sudip Choudhari, "Dunkel Draft on Drug patents, background & implications", Economic and political weekly (EPW), Sept. 4, 1993. P. 1861.

8. Ibid., P. 1861.

9. Ibid.

10. Journal of the patent office technical society, Vol. 2 No.1 1968, pp. 59

11. Sudip Choudhari, op. cit., P. 1861.

12. Ibid., P. 1861

13. Ibid.

14. Ibid. P. 1862

15. Ibid.

16. see the evidences of K.A. Hamid of CIPLA Joint Committee on the patents Bill, 1965, Vol. 1, P. 154,in Sudip Choudary, op. cit., P. 1861.

17. Ministry of Petroleum and Chemicals, Report of the committee on Drugs & Pharma Industry, (Hathi Committee) Govt. of India, New Delhi, 1975, in Sudip Choudary, op. cit., P. 1861.

18. Ibid., P. 1862

19. Ibid.

20. Ibid.

21. Ibid.

22. Aparna Vishwanath,in her study shows that the uniform 17 years patent term avail in U.S. does not correspond to the years of revenue needed to recover R & D costs in particular industries, but is instead, an arbitrary figure which remains unchanged since 1870. Moreover, studies which have attempted to calculate appropriate patent terms are based on assumptions which promote the interests of Chemical and Pharmaceutical Industries in extending the patent monopoly period. And the use of an inaccurate patent term has enabled pharma and chemical industries to reap windfall profits in both sales in US and India. Aparna Vishwanath, "Patent system and Pharmaceutical Industry", NWPL, 1993.

23. Ibid., p. 66.

24. The study further points out that high profit levels have enabled the leading chemical and pharmaceutical companies to obtain a disproportionate share of market power. For example, around 25 companies based on the US, Europe & Japan dominate the International Chemical Market in terms of world population and trade. Similar concentration of market power in the pharma industry is revealed by the fact that in each industralised country the largest four corporations accounts for 50% production, V.N. Centre on TNCs, TNCs in the Pharma Industry (1983) p.7, Aparna V., op. cit., P. 70.

25. Ibid., P. 69.

26. Ibid., P. 69.

27. A.V. Ganesan, "Role of Industrial Property in international Arrangements for Economic co-operation; Experience & perspectives, the Indian Experience", International forum on the role of Industrial property in Economic co-operative Arrangements, New Delhi, 1989.

28. Aparna Vishwanath, op. cit., P. 71.

29. P.C.K. Parikar, P.M. Pillai and T.K. Sunder "International Environment Multinational Corporations and Drug Policy", centre for Development Studies, Trivandrum, 1989, P. 31.

30. Ibid.

31. Ibid., P. 33.

32. Ibid., P. 52.

33. The Patents Enquiry Committee reported in 1950 that the foreign patentees did misuse or abuse their rights e.g. by importing the patented products rather

than manufacturing it here fixing prices at high levels.

34. A.V. Ganesan., op. cit., P. 5.

35. Ibid

36. Ibid., P. 6.

37. Sudip Choudary, op. cit., P. 1863.

38. Sec. 88(2) of the Patent Act of 1970 provides that if the parties are unable to agree on the terms of the license, either of them may apply in the prescribed manner to the controller to settle the terms thereof". Sec. 88 provides that "the controller shall after, giving notice to the parties and hearing them and after making such enquiry as he may deem fit, decide the terms on which the license shall be granted by the patentee. And Clause 4 provides that "The controller may at any time before the terms of the license are mutually agreed upon or decided by the controller, on application made to him in this behalf by any person who has made any such requisition as is referred to in sub-sec (1), permit him to work the patented invention on such terms as the controller may, pending agreement between the parties and decision by the controller, think fit to impose.

39. A.V. Ganesan., op. cit., P. 5.

40. Dr. Nitya Nand,"Patent laws: The Indian Experience",NWGPL, 1992, P. 9.

41. Y.K. Hamid,"Patents and the Pharmaceutical Industry -A Review" September 1993, P. 4.

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Annexures

PRODUCTION				
Year	Bulk Drugs Rs. in Crores	Growth Percentage	Formulations Rs. in Crores	Growth Percentage
1980-81	240.00	6.2%	1200.00	4.3%
1983-84	355.00	9.2%	1760.00	10.0%
1986-87	458.00	10.1%	2400.00	23.4%
1989-90	640.00	16.4%	3420.00	8.6%
1991-92	900.00	14.2%	4800.00	12.0%
1992-93	1150.00	16.0%	6000.00	15.0%
1993-94	1340.00	15.0%	6900.00	15.0%

Source : BDMA, 1994.

EXPORTS			
Year	Bulk Drugs Rs. in million	Formulations Rs. in million	Growth Percentage
1984-85	292.00	995.00	1287.00
1985-86	333.00	1065.90	1399.50
1986-87	871.60	1021.20	1892.80
1987-88	1397.10	882.50	2279.60
1988-89	2428.70	1572.90	4001.60
1989-90	3505.00	3142.00	6647.00
1990-91	4134.00	3714.00	7348.00
1991-92	7226.00	5087.00	12313.00
1992-93	8566.00	5537.00	1410.30
1993-94	10000.00	7718.00	17808.00

Source : BDMA, 1994.

Drug	Year of Introduction		Interval in years
	World	India	
Ibuprofen	1967	1973	6
Salbutamol	1973	1976	3
Mebendazole	1974	1976	2
Cimetidine	1976	1981	5
Lorazepam	1977	1978	1
Ranitidine	1983	1985	2
Norfloxacin	1984	1988	4
Acyclovir	1985	1988	3
Ciprofloxacin	1985	1989	4
Astemizole	1986	1988	2

Source : The Eastern Pharmacist, Feb 1993.

Drug Prices in International & Domestic Markets

Product	(In Indian Rupees) Domestic Price	International Price
Cimetidine 200 mg.	6.77	36.40
Ranitidine 150 mg.	16.15	121.67
Captopril 25 mg.	15.45	58.56
Nifedipine 10 mg.	3.82	29.90
Diltiazem 60 mg.	15.26	40.89
Atenolol	11.29	61.15
Haloperidol 5 mg.	13.58	41.16
Naproxen 250 mg.	12.76	31.07
Rifampicin 150 mg.	9.01	46.88

Source : The Eastern Pharmacist, Feb 1993

Indigenously developed new drugs despite US patents

Name of Therapeutic group/drug	Year when patent expired in U.S.
Cardiovascular	
Nifedipine	1989
Quinidine	1973
Nadolol	1996
Metoprolol	1995
Atenolol	1994
Propranolol	1990
M-Dopa	1984
Prenylamine	1984
Clonidine	1985
Guanethidine	1982
Minoxidil	1992
Diltiazem	1991
Prazosin	1990
Verapamil	1986
Digoxin	1978
Hydrochlorthiazide	1985
Clofibrate	1983
Anthelmintic	
Tetramisole	1983
Albendazole	1995
Pyrantel	1990
Mebendazole	1992
Fenbendazole	1993
Tinidazole	1988
Bephenium	1981

Source : National Seminar on Patent Laws (22.11.1988) held by National Working Group on Patent Laws.

Comparative Drug Prices

	Pack	India (Rs.)	Pakistan (Rs.)	Times Costlier	USA (Rs.)	Times Costlier	UK (Rs.)	Times Costlier
Anti-bacterial Cephalexin 250 mg.	4 s	11.98	----	----	55.63	3.64	16.50	0.38
Norfloxacin	4 s	15.20	30.00	0.98	99.14	5.52	----	----
Anti-inflammatory Diclofenac 50 tabs.	10 s	7.62	45.00	4.91	105.60	12.86	47.49	5.23
Anti-ulcerants Ranitidine 300 tabs.	10 s	26.16	210.00	7.03	348.70	12.33	234.07	7.95
Cardiovasculars Atenolol 50 tabs.	10 s	5.60	63.25	10.29	89.38	14.96	50.19	7.96
Enalapril Maleate 5mg.	10 s	9.50	24.00	1.53	86.62	8.12	75.77	6.98
Anti-viral/fungal etc. Acyclovir 3% cream 5mg.	10 s	98.00	133.30	0.36	271.98	1.78	229.55	1.34
Anti-anxioytics Alprozolam	10 s	3.55	----	----	54.40	14.32	18.72	4.27
Anti-cancer Vincristine 1mg Vinblastine 10mg.	 Vail Vail	 28.80 108.00	 113.40 96.39	 1.52 0.05	 1068.32 1102.0*	 37.10 10.20	 252.72 277.83	 4.62 2.02

Source : The Eastern Pharmacist-October 1993.

Some of the Bulk Drugs Exported From India
Name of the Bulk Drug
Ampicillin & its salts Sulfamethoxazole Cephalexin & its salts Trimethoprim Ibuprofen Amoxycillin & its salts Chloramphenicol & its salts Ranitidine Cloxacillin & its salts Mebendazole
The Eastern Pharmacist, Feb 1993

Year	No. of Patent Applications	%age of Indians	Applications by Foreigners
1856	33	-	100
1900	492	9.0	91
1920	1037	9.5	90.5
1940	741	28.8	71.2
1947	2370	9.3	90.7
1960	4503	14.7	85.3
1970	5142	21.7	78.3

Source : NWGPL

Year	Patents held by	
	Indians	Foreigners
1968	3274	35120
1969	3408	36257
1979	3065	19795
1985	3008	13162

Source : NWGPL

Chapter Five

THE TRIPS AGREEMENT -AN ANALYSIS IN THE INDIAN CONTEXT

The TRIPS agreement calls for fundamental change in the Indian Patent Act, 1970 and also in the International Patent System especially in the area of pharmaceuticals. The experiences of the developing countries shows that with the relatively more flexible Paris convention in comparision to the TRIPS agreement they could achieve a little industrial growth. This seems to be not the case[1]. This can be shown by the global pharmaceutical market which is divided into three categories[2]. Firstly the pharma industry located in the developed countries controlling perhaps more than 90% production of the world. There are about 30 MNCs controlling the industry and enjoy monopoly due to their patent system. Secondly, pharma industries located in about 15 developing countries who are almost self-sufficient in producing formulations to meet the country's requirements. In almost all the countries except India is produced by the National Units under licence, the major production of the drugs is either controlled directly by MNCs or from MNCs who directly and indirectly dictate the selling price. Due to local production and due to IPA, 1970 the drug prices are cheapest in India. The price difference ranges from 500% to 2000%. In third category, about 90 developing and under developed countries like African, Eastern, South American, Gulf etc. mostly depend on imports and there is no local pharmaceutical production. These countries have nothing to protect and still get exploited by paying 2000 percent more price either by joining the Paris convention or adopting the American or European Patent Law. The indirect pressure through World Bank and IMF seems to be the controlling mechanism in these countries[3].

In the light of the above experiences India did not join the Paris convention. As the views of developing and developed countries are quite divergent. And WIPO has unsuccessfully tried to bring about harmonisation of patent laws. However, in the Uruguay round negotiation of GATT, irrespective of the opposition by the developing countries, the TRIPS agreement was included[4].

The TRIPS agreement consist of seventy-three articles divided into seven parts.

It seeks to protect IPRs with respect to copyright, trademarks, geographical indications, industrial designs, patents, integrated circuit designs, the protection of undisclosed information and the control of uncompetitive behaviour in contractual licenses. The study examines only the provisions in relation to the patents under the TRIPS agreement. These provisions are an important departure from the traditional patent rights particularly in respect of national treatment, patentability its coverage and duration of patent life, working of a patent etc.

These provisions have important ramifications in three areas. They are in relation to the patentable subject matter, term of patent and conditions governing working of the patents. Art. 27 of the TRIPS agreement provides that patents shall be available for any inventions whether products or processes in all fields of technology. The product patenting prevents the development and marketing of the product by another process without license. In case of pharma industry, no longer the domestic drug firms are allowed to produce the patented drugs by alternative process without license and payment of royalty. It affects the applied research, the production and availability of patented drugs at reasonable price. The product patents discourage investment in R & D for processes for existing products impeding the achievements of a socially desirable scientific and technical optimum[5]. It further prevents the development of processes appropriate to domestic environment and socio-economic conditions and resource endowment. Whenever a product is protected by property rights, all other processes for its production can only be protected through dependent patents, which require the authorisation of the Principal patent. Consequently, the monopoly privilege is more extensive than intended, since it confers a monopoly on all possible new innovations, along the lines of the original protected invention[6]. Art. 28 (1) (b) further provides for product-by-process protection. It says that in case of process patent, the patent holder can prevent others from using, offering for sale, or importing for these purposes the product obtained directly by that process. It means that the process protection is extended to the product when it comes from the patented process. Another thing which has been contended that the product innovation is far more costly compared to process innovation and the product patent regime envisages that a country is in a position to innovate new product and India is not in such position.

As we could see, the majority of the countries have excluded certain fields of technology from patent regime. The excluded fields might be different from country to country and its adoption from time to time. In general these are agricultural machinery, fertilisers, chemical products, nuclear inventions, biotechnology, pharmaceutical products etc. In India also some kinds of nuclear inventions, plant varieties, biotechnology, a method of agriculture or horticulture, any process for treatment of human beings or any process for treatment of animals or plants to render them free of disease or to increase their economic value or that of their products, etc. have been excluded from patentability[7]. The changes include in Art. 27 of TRIPS agreement will have great implications on the drug research and the pharma industry. Modern biotechnology gives the scientist the tools to probe the biochemistry of various diseases. The pharma industry uses biotechnology techniques to produce naturally -occurring human proteins in commercial quantities[8]. Biotechnology plays a major role in the areas such as (1) increase in bulk drug production by microbial methods (2) immunological agents (3) diagnostics, detection of diseases and various physiological conditions of the body (4) production of bioactive molecules, regulatory proteins (5) improved drug delivery systems[9]. In USA, when the biotechnology industry is broken down by market sector, it is found that more companies are specialising in health care than all other market segments. The US pharma companies are moving towards greater symbiosis with biotechnology companies. At present 12 products are approved by FDA in last seven years are being sold. More than 20 are awaiting at review at FDA and at least another 135 in Clinical trials[10]. However, it is noted that these technologies entered into India soon after but remained confined to only a few leading research laboratories. Indian industry is still in its infancy in this field. Over the last few years the department of biotechnology have expended around Rs. 50 crores per annum on biotechnology related products, processes, human resources development, assisting the building up of infrastructural facilities[11]. There is a need to adopt a careful plan towards the development of industrially viable cost effective and needed products for this country. Even medicinal plants as a source of therapeutic agents are important, particularly in respect of an estimated $1.5 bn pharmaceuticals[12]. Though India has longstanding traditional medicine, it is not encouraged much. A recent study in Kerala shown that more than 80 percent of educated individuals preferred modern medicine to traditional system[13]. MNCs

are already introduced new drugs which are made by plant extracts available in India unlike Indian drug industry. It has been contended that in the present context, a substantial proportion of research and development should be in the development of natural products, primarily those extracted from plants, in countries where much expertise already exists, such as China and India[14].

The TRIPS agreement also provides the patent protection for longer duration. It is 20 yrs uniformly applicable to all patents. The patent term of 20 yrs can in effect be extended by further 20 yrs term in relation to the drug products as the product holder can seek a process patent on the expiry of the product patent, claiming novelty of the process to be patented. Even for the existing products which have been long outside the purview of patents, process patent can be obtained by claiming novelty of the process, this way monopoly can be perpetuated with regard to the drug patents. It has been argued that the small and medium-sized enterprises which consist 90% of the Indian drug industry is going to suffer the most because of the rapid obsolescene of technology. No patented technology will last long even for first term of 20 yrs. Further it stops the Indian drug industry of catching up efforts with the technological leaders.

The TRIPS agreement provides that patented products whether produced locally or imported will have to be treated at par without discrimination. Art. 27 provides that the patents shall be available without discrimination as to the place of the innovation and whether products are imported or locally produced. This is a major and fundamental departure, from the existing system. Working of patented invention in the patent granted country is one of the basic tenets of the patent systems. Under the IPA, 1970 the provisions of compulsory licensing, sub-licensing or licensing of right are provided to ensure the working of a patent of certain important patented inventions. However it was contented that the agreement uses the term non-voluntary use and prescribed the onerous conditions for getting license. This would go a long way to guarantee that the system of compulsory licences is eliminated[15]. Art. 31 provides that the other use of the patent other than allowed under Art. 30 can be allowed only with the authorisation of the right holder[16]. Cl. (a) of Art. 31 states that such authorisation shall be considered on its individual merits. Further it can be allowed according to the Cl. (b) only after 4 yrs of filing or

agreement also provides for judicial review over revocation and forfeiture of a patent. All these provisions, it appears, make it difficult to get a license by Indian drug manufacturer from the patentee. It has been pointed out that no drug manufacturer would come forward to take a compulsory license when he is not sure about the reasons for which the license has been issued to him and how long would circumstances exist besides the above mentioned conditions. It was also contented that in effect the MNCs could continue with their policy of providing technology to developing countries only for the exploitation of their local markets.

Another important provision of the agreement is in relation to the 'burden of proof'. Art. 34 provides that there will be a presumption of an infringement of the process patent when another person manufacture the same or identical product. The process patentee need only make reasonable efforts to findout the process used. In the traditional patent infringement legislation, the patentee or plaintiff has to prove that the alleged infringer was using the patented invention, but now it is the infringer who has to prove that he is not using the patented process. This provision extended patent protection even to the identical product that means the rights of the patentee are enforceable even if the product by a rival manufacturer is not the "same product". In a product patent regime the patentee's rights are confined to the particular product he has patented, under the agreement it extended even to identical product[17]. This will prevent the drug manufacturers to involve in process research. It will discourage investment on R & D for alternative processes because three is always a potential threat that the investor may be sued for infringement of the patented process. According to keayle and Dhar the process patent regime practically becomes infructuous and non-operative. The industry will have to largely depend on imports[18]. This does not augur well for the future of local enterprises in India.

The agreement further provides a transitional period to the developing countries to adopt the TRIPS agreement in their domestic laws. Art. 65 Cl. (2) of part VI of the agreement provides that any developing country is entitled to delay for a further period of four years in its application of the Agreement. And cl. (4) further provides that a developing country which is by adopting the TRIPS agreement has to extend its product patent protection to areas of technology which are not protectable under

its domestic laws may delay adoption of provisions of sec. 5 which deals with patent, for an additional period of 5 yrs. In case of some developing countries the transitional period comes to 10 yrs. This transitional period of 10 yrs is applicable to India and pointed out that it is an incentive to overcome difficulties and to become competitive in the International market. However, Art. 70 (8) provides that patent applications for pharmaceutical and agricultural chemical products would be accepted by national authorities after the agreement comes into force irrespective of whether the national law provides for the grant of product patents or not. In the case of developing country like India can take 10 yrs to change over to a product patent regime in these areas. As per Art. 70 (9) India has to provide exclusive marketing rights for new products in these areas on fulfillment of certain conditions. This totally defeats the purpose of transitional period.

It is also important to take note of the provisions regarding trade secrets and exclusive marketing rights. Art. 39 provides that any secret informations of know-how of commercial value shall be safeguarded. Further, Cl. (3) provides that in case of pharmaceutical or agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data made to the governments or its agencies has to be protected these informations against its disclosure and against unfair commercial use. While the grant of a patent ensures that the innovation covered by the patent is disclosed, Art. 39 provides that the information pertaining to an innovation can be kept secret. Another important provision is that of Art. 70 (9). A product patent applicant, under Art. 70.8 shall be granted exclusive marketing rights (EMRS) for a maximum period of five years. It provides that EMRs will be granted for five years or until a product patent is granted or rejected. For getting EMR the inventor has to obtain a product patent the invention in another member country after the agreement came into force. They have to also obtain market approval in that country and the country in which it applies for EMR. It has been pointed out that granting of EMRs makes international patent grants interdependent[19]. Further stated that the EMRs provided are qualified by the provisions of Art. 39 the latter providing grounds that he may provide to the concerned authorities for getting such rights. It has been contended that these provisions goes beyond any patent law in any country at any period of time[20]. An applicant for a patent does not have any rights over his invention till he is granted

a patent. These provisions gives rights far greater than that enjoyed by a patentee and that too even before the grant of patents by the country[21].

The above discussion shows some of the negative implications of the TRIPS agreement in our country in relation to drugs. Someother opined that product patenting as provided under TRIPS agreement is an effective means to protect the interests of the product innovations in India[22]. It is argued that drug product innovation involves longer time and expenditure and only through stronger patent protection can the investor recover the cost and risks the investment in research and development. However, doubts have been raised over the question of R & D expenditure by the drug firms in the developed countries[23]. Besides it is also points out that when process patenting is available the inventor makes out all-out efforts for every conceivable operable synthesis often based on insignificant change of the compound. It is a waste of resources. This type of 'detour' research does not contribute to the development of the local industry[24]. Further it was opined that in India only 10 to 15% of patented drugs are marketed so there can be hardly any effect on Indian drug sector. But it is argued that the 15% refers to the number of drugs in the market and not to the turnover of the drugs available in the market. According to the publication of US pharmaceutical manufacturers association, today out of 100 most prescribed drugs in USA, 95 are patented drugs[25]. Finally, with regard to the drug prices it is argued that under process patent regime the drugs are made available at cheaper prices with the cost-effective processes. And under product patent regime prices will go up as the innovator or owner of patent desire to recoup their expenses or increase their profits. Anyhow it is pointed out that it never leads to the conclusion that prices must rise to the levels comparable to other nations as aggregate demand and elasticity factors and income distribution are important factors in making any comparisons. But it is felt that the combination of physician decision-making, imperfect information and third party payment makes drug demand stronger and less price-elastic than it might otherwise[26]. Other factors in determining the drug prices are the expenditure involved in introducing the new drugs to the physicians, the cost of clinical trials before the drugs is finally marketed and the competition from the generic imitators[27].

It is also stated that the world over behaviour of drug markets indicate (1) the

latest therapeutic equivalents with high shares of patented drugs dominate the market (2) product patent expiry has minimal downward effect on drug prices and market shares[28]. Even after the patent expiry the branded products may dominate the market and branded drug prices might go up; for example, India's two top brands, Burroghs Wellcome's Septran and Alembic's Althrocin are over two decades old, and command tremendous equity in medical perpetual space. These are the contententions put forward with regard to the probable implications of the TRIPS agreement on Indian drug scene.

THE PATENT (AMENDMENT) ORDINANCE, 1994

The patent ordinance provides for a means for filing of applications for product patents for new pharmaceuticals products and also for grant of exclusive marketing rights (EMRs). The measures have also been incorporated in the amendments to ensure that governments ability to intervene in public interest is preserved. Sec. 39 of IPA, 1970 which placed some restrictions on application for patents outside India has also been deleted. It has amended Sec. 5 of IPA, 1970. It lays down that anyone can apply for a product patent but the controller will not be acting on such applications until December 31, 2004. However, the priority rule applies and an applicant has priority over subsequent applicants and is also eligible for EMRs . Thus a foreign patentee can file an application for new invention on or after 1 Jan 1995. Eventhough his application will be processed only after 10 yrs. Once it is accepted his patent term applies from the date of filing of the patent application.

Under the amendment the grant of EMRs for patent applicants subsequent to Jan, 1, 1995 is provided subject to the following conditions : 1) The applicant has to file an application in India for grant of patent. 2) He has to file an application and obtain patent for an identical invention in any convention country and he has to obtain marketing approvals from the appropriate authority in India. When an application for a product patent is accompanied by an application for EMRs, the controller has the power to refer the application to the examiner to make a report as to whether such invention can be considered as invention under sec. 3 and sec. 4 of the patent act, 1970. The union industry ministry which is the nodal agency to monitor the implementation of the modified patent act, does not expect to provide any EMRs to the companies for at least next five years[30]. Because it is stated that

the procedure for EMRs is expected to take up a long time.

The ordinance make a difference between the Indian and foreign inventors. It provided that for an invention made in India the inventor only get a process patent for applying for EMRs. Furthermore, the domestic inventors are excluded from the conditions of filing the patents in a convention country and to obtain marketing approval[31]. He has the option of obtaining a process potent for an identical invention. It is seen as a positive move towards protecting Indian interests[32]. These provision might help the Indian drug industry in a way that they can get process patent in relation to a new drug product and get EMRs as provided. And they will get the monopoly over that product through EMRs in the transitional period and by the time the patent is accepted or rejected as the case may be for that drug product. It can also give some advantage in the cases of similar inventions made in India and abroad in a short gap. Other positive aspect is that foreign companies may be willing to invest in India, as it is easy to get process patents and they can also get EMRs, instead of waiting to get product patents. If this happens to be the R & D sector of the drug industry in India will be benefited.

Further in the public interest, the ordinance provides that the provisions of "compulsory licensing" under the patent act would also be extended to the new provision on EMRs. And the government also can impose price control on any substance which is the subject of an EMR by stating reasons in writing[33]. However, in practice implementing these provisions will have all kinds of constrains. It is also pointed out that the ordinance puts much hurdles to the foreign patentees in getting EMRs, as it made a difference with a foreign patentee to the Indian and also have to apply in a convention country and get a patent before filing in India. One has to wait and see how these provisions are going to work and help the Indian industries. To find out the attitude of the industry a study has been conducted and the results included in the following chapter.

FOOT NOTES :

1. Dr. B.S. Chimni "TRIPS for Self-Reliance -problems with the TRIPS Text", NWPL, 1993, P. 53.

2. I.A. Modi, "Patent Issues in TRIPS", The Eastern Pharmacist, October, 1994, P. 35.

3. Ibid.

4. B.K. Kealya, Biswajit Dhar & C.N. Rao, "Dunkel Draft on TRIPS -An Evaluation", NWPL, 1993, P. 2.

5. Dr. Chimney, op. cit., P. 57.

6. Ibid.

7. Sec. 3 Cl (h) (i) of IPA, 1970.

8. Dr. Karandikar 'Indian Drug Industry After GATT' MVIRDC, World Trade Centre, Bombay, 1994, P. 97.

9. Ibid.

10. Ibid., P. 98.

11. Dr. P.C. Dandiya "Biotechnology in Drugs and Pharmaceuticals", The Eastern Pharmacist, April, 1993, P. 14.

12. Dr. Karandikar, op. cit., P. 103.

13. Ibid.

14. Ibid.

15. Dr. Chimney, op. cit., P. 60.

16. Art. 30 of the TRIPS Agreement provides for limited exceptions to the rights conferred by patent.

17. B.K. Keayla, op. cit., P. 7.

18. Tarun Kabiraj 'Intellectual Property Rights, TRIPS and Technology Transfer', EPW, Nov. 19, 1994, P. 2994.

19. B.K. Keayla, op. cit., P. 9.

20. Ibid.

21. Ibid, P. 10.

22. Tarun Kabiraj, op. cit., P. 2994.

23. [illegible], For example, it is stated that the R & D budget is the hiding place for promotion disguised as research and clinical studies that are designed to produce noise instead of new products. Inflated R & D budgets are then used to justify for a product prior to the time it gets on the market, or a claim prior to the time it is approved, then medical education will almost be budgeted somewhere in phase 3 research... So all the communications associated with that products can easily be cross-charged into the R & D budget, so those figures in the kinds of reports that PMA issues to be expenditures for actual research when they are not -they are promotional- related expenditures using medical education. David jones, former executive director, Ciba Geigy. Before the U.S. Congress, Senate, Committee on Labour and Human Resources, Dec. 11, 1990. In Dr. Hamid Y.K. "Patents and the Pharmaceutical Industry - A Review, International Conference on Patent Regime proposed in the Uruguay Round, New Delhi, September, 1993, P. 3.

24. Tarun Kabiraj, op. cit., P. 2994.

25. Dr. Hamid, op. cit., P. 4.

26. Tarun Kabiraj, op. cit., P. 2995.

Projection of Indian Drug Industry based on Investment Scenario of the ten leading Indian Pharmaceutical Ilsted Companies

Year / Description	at %age of turnover (Rs. in crores)	1992-93	1993-94	1994-95	1995-96	1996-97	1997-98	1998-99	1999-00	2000-01
	1	2	3	4	5	6	7	8	9	10
Sales	15.6%	3787	4376	5056	5842	6751	7801	9014	10415	12035
Gross Profit	14.5%	549	634	733	847	979	1131	1307	1510	1745
Interest	4.4%	165	190	220	254	294	339	392	453	524
Depreciation	2.1%	80	92	107	123	142	165	190	220	254
Profit Before Tax (2-3-4)	8.0%	304	352	407	470	543	627	725	837	968
Taxes	3.2%	121	140	162	187	216	250	288	333	385
Profit After Tax (5-6)	4.8%	183	212	245	283	327	378	436	504	582
Dividend Outgo	1.8%	68	79	91	105	122	140	162	187	217
Plough back of Funds (7-8+4)	5.1%	195	225	260	301	348	402	464	536	620
Capital Expenditure	3.1%	117	136	157	181	209	242	279	323	373
Cumulative (10)		117	253	410	591	800	1042	1321	1644	2017
Existing R & D Expenditure Industry can make	2.0%	76	88	101	117	135	156	180	208	241
Additional R & D Expenditure Industry can make	2.8%	106	123	142	164	189	218	252	292	337

Source : The Eastern Pharmacist-October 1993

17. B.K. Keayla, op. cit., P. 7.

18. Tarun Kabiraj 'Intellectual Property Rights, TRIPS and Technology Transfer', EPW, Nov. 19, 1994, P. 2994.

19. B.K. Keayla, op. cit., P. 9.

20. Ibid.

21. Ibid, P. 10.

22. Tarun Kabiraj, op. cit., P. 2994.

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24. Tarun Kabiraj, op. cit., P. 2994.

25. Dr. Hamid, op. cit., P. 4.

26. Tarun Kabiraj, op. cit., P. 2995.

27. Ibid.

28. Dr. Karandikar, op. cit., P. 112.

29. Art. 33, 70 (8) (i) (iii) of the TRIPS Agreement.

30. T.S. Viswanath "Marketing rights unlikely for Companies", Economic Times, Jan 8, 1995, P. 1.

31. Shailandra Kumar, 'Lawyer hail patent -Act Amendment', ET, Jan. 1995.

32. Ibid.

33. Sec. 24 D(2) of the Ordinance.

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Annexures

Patents and Market Shares of Indian and Foreign Companies In India

Sl. No.	Name of the Company	Ownership	Total No. of patents (1972-89)	Patent Companies patents under Indian name	Market Share (As on Year end 1989)	
					Drug formulations	Bulk drugs
1	Glaxo India Ltd.	Foreign	3		6.0	
2	German Remedies	Foreign	Nil	2	2.0	
3	Bayer India	Foreign	4	44	0.5	
4	Boots Co. (India) Ltd.	Foreign	23	8	1.6	3.49
5	E Merck (India)	Foreign	6	1	1.2	
6	Hoechst (India)	Foreign	228	168	4.5	
7	Pfizer India	Foreign	4	103	2.5	0.67
8	Rallis India	Foreign	2		1.7	
9	Sandoz Ltd.	Foreign	3		1.5	
10	Searle (India)	Foreign	17		1.4	
11	Cynamid (India)	Foreign	7	16	0.9	
12	Hindustan Ciba-Geigy	Foreign	66	30	2.1	
13	Eskayef	Foreign	1		1.8	
14	Burroughs Wellcome	Foreign	3		1.9	
15	Parke Davis	Foreign	2		2.1	
16	Reckitt & Colman (India) Ltd.	Foreign	35	2	0.5	
17	Warner Hindustan	Foreign		57	0.8	
18	Hindustan Antibiotics	Public Sector	27	NA	36.88	
19	Indian Drugs & Pharma	--"--	14	2.9		
20	Ranbaxy Laboratories	India	8		2.1	
21	Unichem Laboratories	India	10		1.2	
22	Alembic Chemicals	India	Nil		3.0	0.99
23	Cipla	India	Nil		2.1	
24	JB Chemicals	India	Nil		1.4	
25	Lyka Labs	India	Nil		1.4	
26	Ambalal Sarabhai	India	Nil		4.0	71.00
27	Jayant Vitamins	India	Nil		0.9	

Source : Economic and Political Weekly, May 1993.

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Source : The Eastern Pharmacist-October 1993										

Promising Biotechnological Products and Market Size in North America

Compound	Use	Market size ($ mn)
Atrial natriuretic factor	Diuretic	60-100
Epidermal growth factor	Wound recovery	160
Erythropoietin	Anaemias (Kidney failure) blood enrichment	300
Factor VIII	Haemophilia	200
Follicle stimulatory harmone	Infertility	180
Human growth factor	Stature correction	250
Interferon alpha	Cancer	70
Interferon beta	Cancer/infections	20
Interferon gamma	Cancer/arthritis	50
Interleukin-2	Cancer/infection	300-500
Ripocortin	Anti-inflammatory agent	50
Monoclona antibodies (2)	Cancer therapy/infection Prophylaxis	1000
Tissue plasminogen activator	Degradation of blood clots	400-800

Source : Dr. Karandhikar, **Indian Drug Industry After GATT**, MVIRDC, Bombay, 1994.

Percentage share of Indigenous Production of Drugs covered under Patents Abroad in Total Production

Drugs Groups	IDMA estimates (%)	Government of India estimates (%)
1 Antibiotics	40 23	16.00
2 Antibacterials	98 80	NA
3 Cardiovascular Drugs	40 18	51.00
4 Non-steroid anti-inflammatory Drugs (NSAIDS)	22.16	20.00
5 Tranquillisers	74 42	17.00
6 Anti-asthmatics	47.53	11.00
7 Systemic antifungals	25 66	NA
8 Anti-leprotics	69.96	NA
9 Anti-convulsants	65.93	NA
10 Antipeptic ulcer drugs	65 92	NA
11 Oral anti-diabetics	55.30	NA
12 Anti-histamines	21 42	NA
13 Cytostatics	32 41	NA
14 Contraceptive hormones	88 79	NA

Source : For IDMA -Intellectual Property Rights and Patent Protection 1992.

For Govt. of India -Answer to Question No. 235 in the Rajya Sabha by the Minister of State in the Ministry of Chemicals and Fertilisers, Government of India, dated March 12, 1992. In Dr. Karandhikar, **Indian Drug Industry After GATT**, MVIRDC, 1994.

Biotechnology Products, Forecasts.

Therapeutic products	Market value of ($mn)	Area	Year	Leading company	Share of leading Co. in the USA (%)
Erythropoietin	225 (130/ 95)	United States/ Europe	1991	Amgen	85
Interferon (alpha)	200	United States	1990	Biogen/Genentech	...
Human growth harmone	100	United States	1990	Genentech	...
Hyaluronic acid	350		1995	Biotechnology General	60/75
Superoxide dismutase	200	United States	1990	Biotechnology General	...
Mab for septic shock	240	United States	1995	Gentocor	10
Growth factors	500	World-wide	1995	...	...
Growth factors	7000	World wide	2000	...	..
Epidermal growth factors	150	United States	1990	Chiron	60
Tumor necrosis factor	150	United States	1990	...	...
Interleukin-1	100	United States	1990	Immunex/syntex	90
Interleukin-2	400	United States	1990	Getus Immunex Biogen Amgen	40 40 10 10
Interferon (beta)	75	United States	1993	Cetus	55
Interferon(Gamma)	140	United States	1995	Biogen	45
Atrial natriuretic factor	185	United States	1995		
Insulin 1	115	World-wide	1990	Lilly/Genentech	...
Factor VIII	300	World-wide	1990	...	...
Tissue plasminogen activator	500	World-wide	1990	Genentech	..
Pro-urokinase	50	...	1993	...	...
Pro-insulin	150	World-wide	1990	Lilly/Genentech	...

Source : Dr. Karandhikar, '**Indian Drug Industry After GATT**', MVIRDC, Bombay, 1994.

Chapter Six

PHARMACEUTICAL INDUSTRY & PATENT LAW: A CASE STUDY

An Examination of the implementation of the Indian patent Act 1970 assumes a great importance in the context of the TRIPS agreement. An attempt is made in this chapter to understand the role of IPA, 1970 in relation to the growth of Indian Pharmaceutical Industry. It is true that there are many factors which contributed to the growth of indigenous pharma industry and it appears that patent act has played a significant role in this regard. An attempt is made to find out whether the provisions are utilised by the pharma industry to its advantage. The study may be useful in view of the strategic planning to be adopted by the pharma industry to meet the challenges of the TRIPS agreement. Because of various difficulties faced in getting access to various pharma industries, the study is limited to the bulk drug industry in A.P. The bulk drug segment has the most critical role to play in the development and growth of the Pharma industry. This segment of the industry had a rapid growth in 1970s & 1980s to reach the present stage of the investment of about Rs. 1000 Crores. The bulk drug industry is the producer of the active ingredient basic drugs through the use of various chemicals, raw materials and drug intermediates. It is a highly technology oriented industry with research as the backbone since the focus is on introduction of newer and newer molecules/basic drugs. The requirement of capital investment is also high along with trained technical manpower, sophisticated equipments, quality control instruments etc. The bulk drug industry consisting of large, medium and small scale units providing direct employment to 2,00,000 persons and indirect employment of another 2,00,000 persons. It is regarded that encouraged by the patent laws and the drug policies of the government, the industry both in private and public sector produces 90% of the country's requirement of drugs. And the more than 50 percent of our production is exporting to highly competitive and quality conscious markets of the developed as well as developing countries. It is claimed that the industry is highly efficient, professionally managed and can produce quality drugs at competitive prices. Our technological base has also reached a stage where even new compounds are made expeditiously and are offered at prices lower than those prevailing internationally[1].

The Indian Bulk Drug Industry consists of 600 manufacturing units spread throughout the country. However, out of these 600 units 238 units are situated in the state of Andhra Pradesh. The contribution of the bulk drug industry of A.P. to the total Indian bulk drug industry is shown below. It is said that after the establishment of IDPL, a public sector undertaking during late 60s in Hyderabad, a congenial atmosphere was created to establish drug industries, besides generating many trained personnel[2].

BULK DRUGS INDUSTRY	**INDIA**	**ANDHRA PRADESH**
Number of Units	600 (including A.P.)	238
Production Figures:		
1992-93	Rs. 1045 Crores	Rs. 350 Crores
1993-94	Rs. 1650 Crores	Rs. 500 Crores
1994-95 (Estimated)	Rs. 2200 Crores	Rs. 750 Crores
Exports :		
1992-93	Rs. 856 Crores	Rs. 217 Crores
1993-94	Rs. 1000 Crores	Rs. 250 Crores
1994-95	Rs. 1300 Crores	Rs. 300 Crores
No. of people Employed :		
(Direct & Indirect)	4,00,000	50,000

SOURCE -BDMA, 1994

In A.P. most of the bulk drug units are situated in Hyderabad and its near by places. Now Hyderabad is being called as the capital of Bulk Drugs.

This study basically covers all three segments large, medium and small-scale of the bulk drug industry. In addition, the public sector unit, multi national company and Research Institution are also covered. A very few researchers/Scientists, academicians, some personnel who are familiar with the patent system and the TRIPS agreement like the former director of WIPO and some pharma consultants,

members of the drug associations, etc are also interviewed for the study. The researcher has gone to all the possible sources to collect the data. The sampling method was used for identifying the data.

PUBLIC SECTOR UNIT : The philosophical justification of setting up and continuation of public sector in a mixed economy like India is noted in the ideology of socialistic pattern of society as envisaged under the Indian constitution[3]. In particular, the arguments putforth for the establishment and the continued operation of public sector acts as an instrument for success of planning, infrastructure creation, balanced regional growth, reduction in concentration of economic power, development of key, basic, strategic industries, model employer, contribution to public exchequer, promotion of standard of living, argumentation of employment opportunities, strengthening foreign exchange resources position etc[4]. As mentioned elsewhere there are around 16,000 manufacturing units in the pharma industry and out of which about 250 units are in the organised sector. 16 central/ state public sector units are engaged in the production of drugs and formulations and vaccines. The capital investment in public sector is 25-30% of the total capital investment in the pharma industry. The bulk drug production in public sector is about 20% of the total production of bulk drugs in the country[5].

A wholly Government owned company "Indian Drugs & Pharmaceuticals Ltd (IDPL, a large-scale) was incorporated in 1961 with a view to establish production facilities for drugs and pharmaceuticals in the state sector. Initially the company had three plants one of them is the synthetic drugs plant at Hyderabad.

The Hyderabad unit is a major bulk drug and Vitamin producing centre in Asia. It established with the Russian Collaboration. Russians transferred technology for 16 drugs some Sulphas, Vitamins, Analzines and some trained chemical engineers. Its actual production started in 1965. It has emerged as the mother factory providing bulk drugs to the rest of the Pharmaceutical Industry's downstream operations. The infrastructure created, acted as a catalyst for the evolution of pharmaceutical industry in the state. It is claimed to have fulfilled the initial tasks set before it, that is, to make available adequate quantities of high quality bulk drugs in the essential life saving range to the industry and thereby establishing the infrastructure for the

manufacture of bulk drugs from basic stages using multi stages complex technologies. However, in the recent past this unit became sick and referred to the BIFR[5]. Its turnover has slumped from Rs. 13 crores to Rs. 3 crores and number of bulk drugs which it produces come down to seven from sixteen.

For the purpose of study an enquiry is made with regard to R & D in the unit. As it was felt that a strong scientific and technological base is a must for industrialisation and in the absence of such a base the country has to rely on import of technology which in crucial cases may not be accessible. R & D was given important place in the programmes of the Company. Organised R & D laboratories were commissioned in the plants much earlier than the main production blocks.

The available Russian technologies were assimilated with capital intensive R & D , IDPL concentrates in manufacturing equivalent or substitute in therapeutic action to products covered under patent. IDPL has contributed a lot in developing the self-reliance in the manufacture of drugs in the country. The technologies for the products which were inducted in the product-mix subsequently were developed by the in-house R & D. It played the pioneering role through its R & D absorption and assimilation of technologies. Production of a number of bulk drugs was taken up and about 20 more bulk drugs were added to the product-mix to the original product-mix of 16 bulk drugs[7].

The unit has eight laboratories and about 50 people were working. It spends Rs. 2 crores of its annual turnover on R & D. To its credit it developed a drug which works on central nervous system (IDPH-84185), one muscle relaxant (an ointment). The details of these two were made published in 1981. It has also developing three more drugs, anti-piratic , anti-histonamic and anti-analyzee, for which three phases are over. For anti-histonamic it went for patenting, the compound is named as IDPH-8261, 82 indicates the year and 61 indicates the compound number which they invented. However, the plant does not have any patent cell, it consulted a legal firm (Dabur Company) in Calcutta to file patent for the unit and payed legal fee as charged for the patenting work. The R & D personnel of the unit uses the facilities in Indian Institute of Chemical Technology (IICT) centre for cellular microbiology (CCMB) and other universities. However, the research efforts are not

upto the mark in the recent past. Almost it come to standstill and number of reasons are shown for the poor R & D results of the unit. Even before sickness affected the industry, in early 1980s plant had a technology transferred from Italy which is not appropriate one for the unit to adopt it. It is being critisised as a wrong step in its R & D progress and pointed out that such technology transfer has drastically affected the R & D efforts in the plant in terms of its expenditure as it spent Rs. 5 Crores on R & D at that time. There are other problems which hampered the good results of the R & D in the plant. This include severe procedural hassels, for example for each and every small thing researchers need in their research work, they have to take prior approval of the management, and purchase department. It is also difficult to keep their research work as secret since they have to inform the progress of the work from the top to bottom of employees in the plant. This forces the researcher to disclose the name of the new compounds and formulas to every one and in many occasion it is leaked to the competitors. It is also pointed out that there are no incentives given for the research work in the unit. The researchers find better opportunities in the private sector. And most of the researchers after gaining some experience in the unit leaves the unit and joins somewhere for better salaries etc. Some of them establish their pharma production plants with their experiences, contacts etc. gained while working in the unit. Now, there are many instances where the employees of the unit selling out the formulations etc. outside and making money out of it for them. Other factors like indecisiveness, corruption, adhocism, mismanagement, a distorted product profile are considered to be the reasons which lead to the sickness of the Industry.

As one can find out that the IDPL -Hyd. unit primarily established to produce the drugs from basic stages and to facilitate the growth of pharma industry in India, thanks to the Russians who transferred the essential technologies, the unit made good profits atleast upto 1977. The provisions of 1970 Act are utilised to the extent that some of the drugs in addition to 16 drugs started production were developed by in-house R & D. Patent activity, though not much, has been done by the unit as mentioned earlier. Initially capital expenditure is directed towards R & D unit and later only revenue expenditure was included. It is stated that the R & D of pharma products of new chemical entities (NMEs) has become more expensive due to increasing stringent scientific and clinical criteria. So a facility has been created

for the pharmacological and toxicological testing of NCEs. Which are synthesised at the R & D centre, Hyderabad unit. There are only, 4 or 5 such facilities in the country and this national asset should be used for discovery of new drugs[8].

PRIVATE SECTOR :

The public sector unit, IDPL has provided infrastructure facilities and a base for technological skills gave birth to many indigenous private pharma industry, especially in the state of A.P. The IDPL unit is called as Mother Industry. As mentioned earlier many of the personnel worked in IDPL came out and established their own pharma industrial units. Now some of them are placed as India's top pharma industries[9]. Dr. Reddy laboratories Limited (DRL) is one such Company. It's Chairman was involved with the process development work and implementation of new technology in synthetic drugs plant of IDPL, Hyderabad till 1973. The company started as a small unit one decade back with the production of Methyol Dofa, which is in common use, now reached the stage to produce variety of drugs. Now, it has highest position in the production of ciprofloxin of quinolan group. It is the largest manufacturers of some drugs and the only manufacture of six life saving drugs in India. The US-FDA approved their three bulk drugs manufacturing facilities comparable with the best in the world. Dr. Reddy laboratories (DRL) is the flagship company of a group companies. The group consist of Global Organics Ltd, Cheminor Drugs Limited (CDL) etc. The group had established a substantial growth in turnover and profitability. As of march, 1994, DRL has achieved a turnover of Rs. 135 crores, an increase of 35% over 1993 Other group companies CDL & Globe Organics Ltd. have also registered a 30 percent growth[10]. The group had also established a substantial lead in the export of anti-ulcerants, fluro-quinolones and anti-hypertensive compounds. The group had launched six new products during 1991-92 and raised the group turnover to Rs. 200 crore.

Synthesis of patented molecules has been part of the success and growth of this company unlike other units which normally waited for diffusion of the new technology through consultants and job transfers. It was the third largest manufacturer of Ibuprofen in the world until the product was phased out, the largest manufacturer of ranitidine after the patent manufacturer and the second largest vendor of ciprofloxacin. This Industry has introduced many new drugs in India and

also exports to the countries not covered by patent laws. They finds out new alternative processes to produce such drug through their in-house R & D expertise.

Products currently manufactured by the Dr. Reddy Group are :

Amoldipine Besylate
Astemizole
Cetirizine ACI
Ciprofloxacin HCI USP XXII
Ciprofloxacin Lactate
Dilitiazem HCI USP XXII
Domperidone
Enalapril Maleate USP XXII
Enrofloxacin base
Famotidial USP XXII
Finasteride
Ibuprofen BP 93/USP XXII
LopamidoL
Ketorolac Tromothamine
Lomefloxacin HCI
Lansoprolole
Norfloxacin USP XXII
Omeprazole Pellets
Omeprasole Powder
Onchansetron HCI
Pefloxacin
Ranitidine HCI USP XXII
Salmeterol Xinoafate
Terfenadine USP XXII

Under special request
Clozapine
Fluconazole
Fluxetine HCI
Sumatriptan
Terazosin HCI

Most of the above listed drugs are US patented drugs for which DRL through its original research found out alternative processes and started manufacturing it. For example, as claimed by its chairman, Ranitidine, Ciprofloxacin, ditiazem, famotidine, norfloxacin are products introduced by the DRL, through the research done at DRL by way of process innovation. They got exemption for these products under the scheme for providing decontrol of products based on indigenous research. Ciprofloxacin a new generation substitute for chloramphicol also introduced by the industry. In 1992, commercial trial production of, ketorolac, a new generation painkiller was started from the basic stages. Ketorolac is a discovery of syntex of US, was launched in the US in 1991 administered in oral and injectible forms. Another drug, sumatripan an anti-migraine drug under formulation in 1994 will be the first to gain process technology, after the original inventor.

The research work at DRL is directed towards process innovation only not for product innovation or NCEs. The R & D unit at DRL has seven Ph.Ds and 70 chemists working. It spends about 1.73% of its annual turnover on R & D. It doesn't have any patent cell in its unit. It didn't go for patenting its new processes, they prefer to keep it secret. They hardly used the patents as technological breakthrough for finding out new processes. They did this through "reverse engineering" technology. That is once the product is introduced, by examining/breaking it the researcher will find out the compounds which consist of the product. Some of the products they made with very slight modifications in the processes and started manufacturing. Dompronde, Ranitiden, Cymoterdem etc. are some of them. Also by using cheap chemicals in the manufacturing process, made it cost-effective than the original manufacturer. The Indian environmental standards also helped them to substitute the chemicals in the alternate processes and to get better results. For example, in ciprofloxin making, DRL uses sodium Hydride in the place of sodium Mythoxide which yield 5% loses. The use of sodium Hydride is more risky as it may cause fire. In these units there was infact accidents, but they still continues its use by paying less compensation to the injured persons and manages to cover it up. Another example is the use of some gases like Benzin which causes cancer. Use of Benzin is not allowed and banned in the Western Countries, but still we are using it in India. The DRL is well managed to introduce eight new products within short span of time while they made good profits.

DRL has been one of the first Indian Companies to reconstruct its future plans in the light of the TRIPS agreement. It has promoted a research foundation, Dr. Reddy's Research Foundation (DRF) as early as in 1992 which in addition to the process research, started its work early 1993 for discovery of new medicines from natural products and also by drug design. Development of NCE's is one of the major activity being undertaken at this facility. Considering the importance of patents for new inventions, steps are also taken to ensure this. In view of the huge financial resources required for basic research, it is under taking drug design, synthesis of new compounds and preliminary screening in the first phase. After patenting the compounds the company would like to license some of these compounds discovered by DRF to leading companies in the world and have collaborative arrangements for undertaking phase I, II & III clinical trials[11]. However, since the

facilities of Dr. Reddy's group are US-FDA approved and are described as world-class by leading MNCs, would like to restrain the option of manufacturing these compounds in the group facilities itself. It is expected that the DRF will file patents for new compounds in the fields of analgics and anti-inflamatory drugs soon. The work is also being carried out on anti-fungal and anti-cancer compounds. A few new compounds have already been submitted to the National cancer Institute (NCI), US, for screening. DRF has an agreement with NCI for the screening of anti-fungal, anti-cancer and anti-viral properties. And work on newer quinolones, anti-diabetic drugs in the euglycaemic category has been also taken up.

Until now, it seems that the DRF found out three new molecules one is from natural product (microbiology) two from bio-technology, these three compounds are in the process of patenting. To claim priority they filed patent applications when the invention was at an embryo stage. According to DRF's chairman it takes 6 months to 1 or 2 years to findout new molecules. According to him it involves 1/5th to 1/10 th of world cost of developing new molecule in India. Dr. Reddy group companies spent approximately Rs. 20 crores from Oct. 1991 to 1995 for the establishment of DRF and have plans to invest another Rs. 20 crores. DRF running costs involves around four to five crores of rupees. DRF employs around 30 scientists (Ph. Ds) and 100 to 150 researchers. It has various labs for natural products, microbiology, biotechnology, Biochemistry. A pharmacology lab is also now coming up. Generally these labs headed by the scientists, DRF personnel uses the facilities of IICT, National Institute for Nutrition (NIN), Central University etc. and it pays the fee to these Institutions. It is stated that they pays around one lakh rupees per month to these Institutions.

Besides improving its research base, DRL also chalked out innovative plans for the future in the context of TRIPS agreement. Such as, it set up a subsidiary unit (RCI) in USA to manufacture patent expired drugs & pharmaceuticals. By taking advantage of the low manufacturing costs in India, they are planing to do the 90% of the job in India and 10% finishing work in USA. It is felt that during the next couple of years several drugs will fall outside the purview of the US patent regime and they have a staggering market of $ 15 billion. With just five MNCs producing these drugs today, the prospects for dynamic new entrants are immense[13]. The

It has six manufacturing locations, manufactures 27 bulk drugs out of which three products are approved by USFDA. It also covers 15% of total antibiotics production in India, around 50 formulations. It employs around 1880 personnel. It has 5 bulk drug units & two formulations units. SOL has introduced new drugs in the market such as pentoxifylline, Fluconazole, Fanotidine by finding alternative processes. It has R & D unit to do process research work. It is claimed to have spent, till now, Rs. 3 crores of capital expenditure on R & D and a sum of 1 crore and Rs. 1.25 crore are ear-marked for 1994 and 1995 towards capital expenditure. However, it is stated that on general average it spends 0.7% of its sales turnover on R & D. The R & D unit employs 55 personnel for process research work including quality control. There are over a dozen Ph.D. Scientists. It has also on-going agreements with IICT and NCL for developing process technology for specific products. However, it did not go for any patent protection for the new processes invented by them. They are not involved in any new product development or NCEs. It does not have any patent cell also. The company is not involved in any patenting activity.

In the present context it is going for modernisation of its plants and creation of additional manufacturing facilities and to set up R & D centre for synthesis and development of new drugs and for modernisation and expansion of the bulk drug manufacturing units at Hyderabad and Karnataka. The total cost of expansion and modernisation is Rs. 9 crores[16]. It is also planning for a joint venture to establish one Bulk drug plant with Broomington Pharma Co. of Mexico. Out of the total 40 lakhs 50 thousand dollars investment SOL Pharma Co. has an equity share of 20 lakhs dollars[17]. Another joint venture in association with a European firm for making five to six bulk chemicals is also under consideration. The company is also eying the large US and Canadian Market but the cost of setting up unit in North America is prohibitive according to them. However, SOL Pharma is investing about $ 4,00,000 in two overseas formulation ventures to be located in Nigeria and Malaysia. It is also plans to go for joint venture in Russia. The Russian project will be a formulation plant for which large demand exists there. All these collaborations are expected to be finalised soon. It has finalised a marketing tie up with Betab of South Africa for marketing specialised formulations.

It can be said that all the plans with which the company is going ahead involves mainly the collaboration agreements with foreign companies. It is also giving much thrust to the production of intermediates and its exports in the context of TRIPS agreement. Though it is stated that they are taking steps to improve R & D and modernisation plan including the development of new products, it is not clear how they are going to do it. According to the Company's management there are three areas which has given prime importance in the context of GATT agreement. Firstly, continuous thrust will be given to the intermediates production for exports. Secondly, it will go for alliances on collaborative terms, licensing agreement in case of new drug products, thirdly emphasis will be given to "Custom synthesis" quality specifications, etc. which are steps involved in drug production.

MNC : Larger corporations commands immense political economic and technological power and they transcend the jurisdictions nationally and multinationally. They possess decisive market power, sometimes collusively with their gaint brethren and sometimes unilaterally. These companies control major resources and are considered too big to fail despite their own mismanagement or corruption. Park-Davis Ltd. is one such US based multinational drug company having its subsidiary unit in India that is Park-Davis (India) Limited which is incorporated as long back as in 1898. Its parent company has merged with another large company in 1988. The parent Company also involved in the production of consumer goods. The Indian company is only engaged in the production of formulations. However, its Bombay plant is involved in the production of one bulk drug that is Chromycil. The unit is not involved in any basic research and the R & D is only developmental in nature. The R & D unit is mainly concerned with the quality assurance of the products. This unit did not get any technology from its parental company for the new drug products which was invented by the parent company. Most of its products are available in the common market and out of patent protection. They are being sold by the company under its brand name like Cloromycin, hemiflbron etc. Now its warner lambert research institute is engaged in the basic research work. Two new drugs, one for heart disease and another for memory disease, has been found out and they are now under clinical trial. In the coming years the Indian unit is expected to get technologies for the new drugs to produce in India.

SMEs : Small and medium-scale enterprises (SMEs) of the drug industry are generally restricted its production and exports to one or two particular drugs. They have hardly given any priority for R & D and maintains minimum R & D necessary for the purpose of quality control, quality improvement etc.

Neuland Laboratories Ltd : It is a medium-scale unit established around 1986. Initially it is a leading manufacturer of salbutamol sulphate and its intermediates with a turnover of Rs. 8 crores. Recently they have started manufacturing hetorlac tromethan, enalpril maleate, ranitidine hydrochloride, norfloxacin and Ciprofloxacin. It has bought process technology for Tromethane, Enalpirm Maleate from IICT by paying Rs. 10 lakhs. The management policy is to go in for manufacture of wide range of fluoroquinolone bulk drugs with emphasis on exports and are outside the ambit of DPCO. It has taken steps to obtain ISO-9001 certification. About 50 percent of income is projected to be earned from exports, and the company has export obligations. It has around 600 people working in it having two manufacturing units. It has an R & D unit with 10 people working including 4 Ph.Ds. They spent 1 to 2% of their sales turnover on R & D. Being a medium-scale, it is provided with sales tax benefits and state subidy on established units. The management has taken the positive attitude towards the TRIPS agreement. It has plans of manufacturing the drugs which are going to be off-patented after 20005. It is also setting up a formulation unit with an investment of Rs. 3 crores initially and plans to expand it later. This formulation unit is expected to start its production in the first three months of 1996. Overall it is expected to do with Rs. 60 crores of annual turnover in 1995-96 with a net profit of Rs. 6 crores. It is also planing to go for rights issue to collect the funds nearly Rs. 9 to 10 crores needed for the production of new bulk drugs and working capital. It is also planning to invest Rs. 3 crores towards R & D and also planning to take four more Ph.Ds. However, regarding patenting they don't have any plan ahead, except in relation to the need of recognising patented drugs which are going to enter into generic market. They also don't have any legal or patent cell in their unit.

SUVEN PHARMACEUTICALS LIMITED

This medium-scale unit was promoted by Mr. Venkat Jasti in 1989 for the manufacture of bulk drugs and drug intermediates. It was converted into a public

Ltd. company in 1995. The unit has production capabilities for the manufacture of bulk drugs, based on intermediates which are for captive consumption. It manufactures the bulk drugs namely theophylline used in the treatment of Bronchial Asthma, Caffine is a bulk drug used as central nervous system stimulant pentoxyfyllinne used as a vasodilator. It also produces seven more intermediatory products. It is claimed to have personnel consist of well trained supervisors, operators, maintenance staff and allied staff with several years of experience in the production of multistage synthetic drugs, fabrication and erection of machinery for chemical plants. The total strength of the staff is 75 permanent employees. For the domestic market of its products the clients list includes Cipla, Geoffry Manner, Natco Labs, Sun pharmaceuticals, SOL pharma, Cheminor Drugs, etc. According to the management there would be increasing focus on export markets where it has already made some headway. As per the company estimates the exports performance for 1995 is expected to be 65.1% of sales. As of 1994 December its income stated to be around rs. 509.40 lakhs, and the profit of the unit is shown to be around Rs. 88.38 lakhs. It has gone for public issue recently, and it is proposed to set up a unit for new bulk drugs and drug intermediates. They also have plan to export the capacities of existing products. The technology for the existing and proposed products is claimed to be developed in-house by the company in its R & D laboratory which is managed by eight qualified and dedicated scientists under the leadership of Dr. S. Ramachandran, who is a renowned synthetic organic chemist. The basic engineering as supplied by Mr. A. Raja Rao for Chief General Manager of IDPL who has executed many bulk drugs, intermediates and agro-chemicals projects for reputed Indian companies. Dr. Hargovind Rathore, one of the Directors of the Company is actively involved in R & D management, commercial development and technology development of a medium scale company in USA working as a president and chief Executive officer of that company. He is also actively involved in technology and process developmental activities of this unit.

According to the management of the company, since the fine chemical intermediates used in pharmaceutical, agrochemical, photo chemical and dyestuff industries are outside the product patents, in the post GATT scenario it could foreseen that the business opportunities are unlimited in the production of fine chemical intermediates. Also the average number of intermediates required for

may be able to competent in the world market. However, expresses doubts over large investment on R & D.

C-WELL DRUGS PVT. LTD. : It is a small-scale unit. It manufacturers two generic drugs Ibuprofen and CPM. It produces 180 tons of Ibuprofen and 24 tons of CPM. Its investment is around 70 lakhs of rupees. Its total staff including technical and non-technical is 175. It also accounts 20% of exports out of its production. Recently, it has employed Dr. Sattur who is a former Deputy Director of IICT whose specialised area is drug development to look after R & D in the unit. Till now it hardly spent or did anything towards its R & D. Now it is spending Rs. 25 lakhs on R & D. However, the main purpose of this R & D is directed towards the quality improvement/ development of its drug in the light of thrust to be given to the exports. It is also planning to employ three organic chemist in its R & D section. The state has provided tax exemption on R & D expenditure and also customs free on the equipment etc. Dr. Sattur sees the TRIPS agreement as a threat to the survival of small-scale units while pointing out the lack or inability of research work in small-scale units. It was felt that there are no safeguards available through the state machinery. He also points out that the management is yet to understand the real implications of the TRIPS agreement and there is no collective initiative taken within this industry to adopt necessary steps in the context of the TRIPS agreement.

IICT : Indian Institute of Chemical Technology, is one of the CSIRs labs situated at Hyderabad, previously it is called as Regional Research Laboratory. It is one of the premier research institute wherein 300 scientists are working. Till 1994 the institute has published more than 1,336 papers and produced 136 Ph.Ds. It is claimed to have developed 205 technologies out of which 140 technologies are commercialised. Till now, 89 patents are filed by the institution. It is stated that the Institute's research work mainly found on multipurpose pilot plants for scale-up studies, calibre to transfer commercial technology packages, pioneering indigenous development of vital drugs needed by the country, development of Green technology, CFC substitutes, company based chemicals etc. It is also regarded as the best school of organic synthesis and its stature is unassignable in antibiotics, immunosuppressacts, chiral synthesis etc. Since its work is considered to be pioneering in indigenous development of vital drugs and its commercially viable

and cost-effective approaches make it possible to manufacture drugs at costs lesser than the international prices. Anti-bacterials anti-virals, anti-histannes, anti-cancer, anti-ulcer agents, analgesics, anti-inflammatory agents cardio vascular drugs are some of the drugs which are indigenously produced. For example, IICT developed a mefloquiul drug for treating the dreaded cerebral malaria, took a heavy toll in Rajasthan and Northeastern parts of the country last year, while recognising the need to provide mefloquine and make it available at an affordable price IICT initiated a new, simpler technology[18]. This enabled them to develop a process to produce the drug with cheaper starting materials and non-hazardous chemicals. The process has been licensed to two Bombay based drug companies and one of them commercialised it. They are expecting the permission from the controller for its introduction into the market. In 1992, IICT Scientists developed the anti-AIDS drug AZT for which the British company Burroughs wellcome has a patent. This drug is commercially produced by Cipla without profit for Rs. 15 per capsule. Each capsule of AZT in the United States costs about $3 and a patient has to take three to four capsules a day. Scientists at IICT also have successfully produced the abortion pill RU-486 thereby breaking the world monopoly of the French pharmaceutical firm "Roussel". According to its Director, the RU-486 technology was given to an Indian drug firm for commercial production. The cost is expected to be much lesser than the imported drug which costs Rs. 600 per dose. The IICT has an impressive client list that includes Abbott Labs of the US, which is paying $100,000 for advisory consultancy and knowhow on synthesis of molecules as therapeutic agents. Park-Davis has paid $40,000 for IICT knowhow on screening plant extracts for pharmacological activity. The Brazil-based Labogen which has paid $25,000 for IICT's process for making the anti-aids drug AZT Labogen is also buying IICT's technology for the drug omeprazole. It is also claimed that in the context of TRIPs regime the institute has already initiated the process for developing patented technologies. To face the new challenges it is now planning to develop new molecules using its strong chemical base and capitalising its innate talent and track record.

The IICT has reputed and furnished library which also contains necessary patent information for scientific research. It has enough infrastructure facilities to provide access to the patent abstracts. It has data base with an American patent information

centre, Dialace through satellite connection, and also to International patent documentation centre (INPADAC). The IICT's library facilities including the patent information are allowed for the use by the Industry. The large-scale industries are charged Rs. 50,000 per year for using the library. Medium and small-scale units pay Rs. 25,000 and Rs. 10,000 respectively per year. In cases of providing additional passes it charges Rs.5,000. However, for Ph.D scholars and research scholors it does not charge any fee. It is stated that now, IICT is able to cover 30 to 40% ot its annual budget on its own.

There is, at least, a basic awareness of the patent system within the scientific community of IICT. If they want to file for a patent they can send it to the CSIRI patent Division not taking any pains of patenting by themselves. The CSIR's patent division will do the search in relation to its patentability etc. and take further action to file it to the Indian patent office. This helps in completing the steps for patenting within the stipulated time. By the use of the computers installed in the unit and with the availability of the computer facilities in most of the CSIR laboratories a system has been developed by which the exchange of documents are being effected through floppies. This procedure not only helps in avoiding repetitive retyping of the documents which contain highly scientific expressions but also in expediting various actions. According to its deputy director, there is a dual ownership on patents filed by IICT, between the scientists who are inventors in relation to the patented invention and the institute. The inventors get part of the remuneration received by the IICT through licensing patents. The IICT generally enters into agreement with third parties for various activities like transfer of technology, know-how, etc.

Besides these existing research facilities, applied chemtech India Ltd. (Actil) is poised to become the country's first dedicated research firm for inventing and patent new basic drug molecules. It was formed with a corpus of Rs. 10 crores and has gathered a team of research scientists from the country's premier chemical and pharmaceutical research institutes to develop and patent new drug molecules which will find use in the Indian context[19]. The research group comprises of scientists from the IICT, Centre for cellular and molecular Biology (CCMB) and academicians from international institutes. They are working on chemical light, a basic constituent

of major cardio-vascular drugs at the company's research facilities at Hyderabad and Bombay. According to the Managing Director, Actil is working on a number of areas to develop new molecules that the Indian drug industry can use without the fear of infringing into the product patents of various drug molecules developed abroad[20]. The company is also working on alternatives in the fields of new generation cardio vascular drugs such as AC inhibitors and antibiotics like macrolides. It has developed an alternative for esmolol, the international patents for which is held by ICI. It has also identified a number of off-patent drugs abroad which could aid in the manufacture of high tech intermediate manufacturing in India. The company intends to set up a pilot plant in Hyderabad to produce the new molecules and is in the process of setting up a clinical testing arrangement with the CSIR's Central Drug Research Institute in Lucknow[21].

The researcher also met a few number of scientists who are working in different research Institutes. The overall view of these scientists can be summed up as follows. For the majority of Scientists it is a question of survival/existence to be within a scientific community than for any special interest in research. Of course, there are some dedicated researchers who are sincerely interested in their research work, but those accounts for very small percentage. According to the former Deputy Director of IICT, eventhough, India has a third largest technical manpower in the world but it is only interms of quantity and not in terms of quality. We have many M.Scs and Ph.Ds but they donot have any exposure in the research work. There is no accountability of the researchers, further, there is no proper environment to work in the research Institutions. It has been found out that the work environment in these research Institutes is affected due to biases of caste, sex, age and groupism among scientists. One of the views held that in most of the government research Institutes in Pharma Research are involved in mundane and outdated research and scientists really interested in pursuing research aren't given a nod and asked to carry out work on unrelated and uninteresting topics to the scientists and it has naturally sap their talents[22].

Even in the private Research Institutes for example, in DFR, the researchers work in their labs is subject to the approval of its heads. The Scientist who heads the labs only directs the researcher's work and effort is put by them. Generally for

any breakthrough in this research work the credit goes first to the president of DFR next general manager then the concerned scientists who is heading the lab. Sometimes the researchers names may be included in the publishing papers of such research work. In certain cases, some cash awards may be given to the scientists and it depends on the scientist to share cash award with the researchers working in his lab. In a particular instance, in DFR, the scientist received Rs. 10,000 out of which around Rs. 5,000 to 6,000 he kept to himself and the remaining he shared with researchers by giving Rs. 1,116 each. It is also said that the basic pay for the researchers provided for Rs. 3,500 even for scientists it is around Rs. 5,000 to 7,000 but for the General Managers it is around Rs.17,000 to Rs.20,000. They also felt very insecured about their jobs in the private sector. For example, in DFR a senior Chemists who was working for 7 years and whose work was appreciated by all including the president of DFR was fired out within an hour when he had some differences with the manager. The scientist and researchers signs an agreement while joining in DRF. The general terms and conditions are that they have to keep everything secretive and anything the researchers want to discuss in relation to their work is subject to the acceptance of the scientists.

As far as patents are concerned there are hardly any instances of individual Indian scientist filed for patents. There may be some exceptions like that of Mr. Sampitroda who helds a number of patents in India and abroad in the area of Electronic Engineering and Communication. However, out of the interviewed scientists if not all, but some of them atleast uses the patent documents as source of scientific and technological information for in carrying their research work. But it is said that it is very difficult to get the true information from the patent documents if not it is impossible. In their words it takes a hell lot of time to break a single patent. And also pointed out that, for example, US patents are considered to be very vague and it is very difficult to break it. It was felt that it is impossible to break a Japanese patent as you can't understand what it contains. Only 10% of it may be able to read and understand. However, the German patents are considered to be the best and easy to read the documents. It is said that by 100 percent you can remake the invented process or product basing on German patent.

It is said that the major drug companies in the world spends an average 15 percent of its sales turnover on R & D. It employs 1,000 Ph.D scientists in addition to the 2,000 staff members in this R & D units. They have separate patent cells to look after its world-wide patenting. The total cost of patenting in foreign countries is about $10,000 in addition to the renewal fee. On an average the cost of patenting in each country is about 5 to 6 lakhs of rupees. However, it is pointed out that in India it costs 5% of the above mentioned cost. It can be seen that the Indian industry employs very less number of scientists when compared to the major companies in the world. There is little patenting activity by the industry and they don't have any separate patent cell. It is pointed out that even in Korea almost 700 industries have their own patent cells. And it is suggested that India atleast should follow the Korean experience.

In this context it is interesting to look at the views of Indian Industries. The large scale industry's view was expressed by DRL's Chairman thus :"If you can't fight them, we could at least join them". All the major Indian drug companies including Ranbaxy, Lupin, Cipla are doing joint-ventures with the foreign companies. The gain through the joint ventures is considered to be the technology transfer from foreign companies to Indian. However, according to Mr. Bedi from SOL Pharma Ltd. the foreign companies never gives/transfers any technological information. The same view was also held by Dr. D.N. Reddy from Central University of Hyderabad. Everyone accepts that in joint-ventures there is threat of taking the control of the Indian industry by the foreign company. But some points out that with the appropriate measures Indian Industry can withstand it. They could also foresee the possibility of the Indian Company taking over foreign company if it manages well over the foreign company. However, it has been pointed out that in the joint-ventures anything can happen, it may be advantage or disastrous to the Indian Industry depending on how they manages it. It is also pointed out that SMEs will close down in the absence of adequate safeguard to protect them. But according to some industry personnel these industries can still survive as the large-scale industry can't make or produce everything by themselves. SMEs can surviving by making ancillary products necessary for the large-scale industry. It was argued by one of Pharma consultants that small-scale sector in the drug industry are commercially and economically unviable[23]. It is pointed out that in this sector there

is lack of testing facilities, it leaves out hazardous chemical substances without effluent treatment system, and the GMP standards are not followed. It is interesting to note that most of these small-scale units are setup with low capital investment and with high working capital. It is also pointed out that notwithstanding the MNCs threat to the SMEs this sector is being killed by the Indian large-scale industry as well. For example, it is shown that Ibuprofen is sold at Rs. 380 which is less than the raw material cost i.e., Rs. 480 by the large scale industry. It was suggested by Prof. D.N. Reddy and Dr. Shahid Ali Khan that the SMEs should be encouraged to adopt the Korean experience. The research done by the Universities can be allowed to be exploit by the industry. It is further suggested that state should help this sector in the present context especially in India as it is the soul source which generates more employment than gaint corporation.

The drug industry including some of the large-scale units are having plans to give major thrust to the intermediatories production in the context of globalisation. As it expected that the intermediaries will have great market. It was also suggested that the Industry should give importance to the alternate Indian medicine systems. The available natural resources have to be used by the Indian industry to take certain advantages in introducing new drugs. However it is said that the MNCs have already started exploiting the natural resources in this regard. For example, Lillily a multinational drug firm patented the extracts of a plant called Vinca Rosia which is a tropical plant. It is pointed out that the treasure house of Ayurveda posses immense opportunities and the immediate need is the tapping of latents in this area. However, till now very few firms are engaged in the production of alternate medicine. Some of them are Dabur India, Alembic, Hamdard (Unani), Cipla's medicinal plant at B'lore, Kottakal and in A.P. only a small unit in Chittor District. In the present context it is very important to strengthen the Indian medicinal system. We have to bring the conventional medicine system in to an unconventional way to be adopted by the society.

Uniformly it was opined by everyone that IDPL and IPA, 1970 has been the two major factors which contributed to the growth of Pharma Industry. Inspite of being agreeing to the fact that the process innovation is the major contributing factor to its growth which is encouraged under IPA, 1970 by providing only process patent

regime, now, the majority of the section of the industry supports the stronger patent regime under the TRIPS agreement. It is interesting to note that some industries opposed in the begining the inclusion of TRIPS agreement under GATT regime. According to Dr. Shahid Ali Khan IPRs are necessary to create and enable socio economic development. In his words patents are sophisticated instruments to encourage creativeness. It is a recognition of industrial property leads to qualitative products and more creativeness in addition to generating more employment. According to him the TRIPS agreement will prove advantage to India but only thing is we have to take certain measures. He advocates for joint ventures and common research between universities and SMEs like in South Korea. And emphasis also made to strengthen the Indian Judiciary to protect IPRs effectively. A different view was taken by Dr. D.N. Reddy. According to him, the TRIPS agreement will be disadvantage to India in the larger interest. The terms of the agreement are unjustified. And the creation of patent monopoly and the inclusion of the TRIPS agreement under GATT is against the basic principles of the liberalisation. No technology transfer will be made and the world will be divide into efficient and inefficient nations. He advocated the adoption of state mechanisms to protect the Indian Drug Industry. Mixed views are expressed in relation to the terms of the TRIPS agreement. According to them it is unjustice to create the patent monopoly for 20 long years as it was felt that the efforts of scientific research should reach the society as soon as it is made. And argued that one can't say that it takes 10 years for the drug research to reach the market and it depends upon various factors. It is pointed out that the drug prices may be increased under the product patent regime and it is indicative of the economic growth. It is also opined that the product patent regime will inspire the Indian Drug Industry to improve and re-direct its R & D. It is recognised that it will be difficult for the industry in view of the present R & D Structure but given the transitional period it was felt that by way of group management, re-orienting its research in relation to the Indian medicine system and emphasising the research on third world diseases the Indian Industry can manage well and possibly come up with new drug products. It is also felt that with an exception of few members the industry in general are not quite clear/aware of TRIPS provisions with regard to transitional period, EMRs etc. The Industry also till now doesn't have any legal infrastructure which will be necessary in the context of patenting activity and patent litigation which could be foreseen in the present

context. However, it is said that they will take necessary measures in this regard in the coming years. Over all it was felt that there are certain disadvantages as well as advantages. Under the product patent regime there is bound to be a shrinking of our existing markets for the products. Launching of new molecules would become increasingly difficult for Indian Industry inspite of the transitional period because of practical difficulties. To introduce new molecules into the markets would be very expensive and it will not be possible to start manufacturing the drugs with their cost effective manufacturing techniques. Since Indian organisations do not have global access to the rich advanced nations, their capability of deploying required resources for basic research and development to invent the new molecules could be very much limited. One of the main advantage of TRIPS and GATT is the opening up markets in the advanced country for Indian products. However, it is added that the Indian industry need to update their manufacturing technologies, improve their manufacturing facilities in line with international standards. It is stated that in the long run the Indian industry will be enable to position themselves to capture market share in the developed nations. Also argued further that Indian industry will have excellent opportunities for entering into strategic alliances with multinational organisations for doing contract research, contract manufacturing and obtaining the franchise of their research products in view of our abundant wealth of scientific talent. And such arrangements will boost the image of the organisation, would enhance the competence of the quality standards thereby enabling the Indian organisations to withstand the competition from advanced nations with regard to the quality.

FOOT NOTES :

1. BDMA, "Memorandum for change in Sales Tax structure for Bulk Drugs and intermediaries, 1994.

2. Ibid., P. 3.

3. B.F. Rao, Chairman, IDPL, "Role of Public Sector in Pharmaceutical Industry", The Eastern Pharmacist, June 1993, P.41.

4. Ibid.

5. Ibid., P. 42.

6. The Eastern Pharmacist-September 1992, P. 89.

7. Ibid., P. 43.

8. B.E. Rao, op cit., P. 43.

9. Andra Jyothi, Telugu Daily -Jan 13, 1995.

10. The Eastern Pharmacist-March 1994, P. 99.

11. Ibid.

12. Ibid.

13. The Eastern Pharmacist-May 1993, P. 79.

14. The Eastern Pharmacist-Feb 1994, P. 81.

15. The Eastern Pharmacist-Nov 1992.

16. Ibid.

17. Andhra Jyothi, op. cit.

18. News Times, Daily, 3rd April 1995.

19. The Eastern Pharmacist-Dec 1994, P. 94.

20. Ibid.

21. Ibid.

22. For Example, Dr. Sattur, Former Deputy Director, IICT, explained that though he emphasised the basic drug research it wasn't given any importance in the institute's research work.

G. Vidya Sagar, "Pharma Research -Short comings and Remedial Measures", The Eastern Pharmacist-March 1994, P. 43.

23. Dr. M.N. Reddy, Banjara Hills, Hyderabad.

Chapter Seven

CONCLUSIONS

Indian pharmaceutical industry is at the cross roads in the present context of the TRIPS Agreement. Though IPA, 1970 has been encouraging the Indian pharma industry's growth by facilitating the process innovations, the industry is not in a position to innovate new products. Now, there is hardly any patent activity by the industry. This low patenting activity is the result of the provisions of IPA, 1970 in relation to the burden of proof, short term of patent, time and expenditure involved in patenting, etc. in addition to the lack of patent awareness, resources and legal infrastructural facilities.

The indigenous Pharma industry will be at a disadvantageous position under the product patent regime in the context of the TRIPS Agreement. In view of the joint venture projects by the large-scale industry and more emphasis on the intermediaries production and other ancillary pharma products by the SMES, the industry may survive in the global market. But, here we could foresee the dominance and control by the foreign companies and Indian industry playing subservient role.

However, it has been quoted that "challenges can be stepping stones or stumbling blocks". Now under the TRIPS Agreement some of the provisions can be taken advantage by the industry to face the challenges of new GATT regime. The transitional period is provided to ease change by allowing time for reorientation for pharma industry. The Indian Patent Ordinance states that until Dec 31, 2004 the controller will not be acting on the patent applications filed according to Art. 70.8 of TRIPS Agreement from 1 Jan 1995 though the priority counts from the filing date during the transitional period. The Ordinance also makes a difference between the Indian and foreign inventors to protect the Indian interest which is not envisaged under the agreement. In the case of products with EMRs, the government can intervene in the public interest for restricting supplies and causing a price increase. The Agreement also provides that members can adopt measures to promote the public interest in sectors of vital importance to their socio-economic and technological development. But all these measures should not derogate the provisions of the TRIPS Agreement. There are certain problems that may be faced

oking the compulsory licensing provisions, as importation is allowed as working of patent. It is also difficult to interpret the conditions to grant compulsory license such as reasonable requirements, reasonable terms, conditions etc. Further the agreement is vague in defining the precise circumstances in which compulsory license shall be permitted or banned as it is difficult to determine economic value of the license as the doubts can be raised for instance, R & D cost to be recovered from a single market, what kind of profits or royalty over the costs would have to be offered. The applicant for compulsory license is not sure about the reasons for which the license has been issued to him and how long would those circumstances exist in the light of Art. 31 and drug manufacturers may not be willing to go for licensing.

In the case of patentability, it is not clear to what extent enforcing patent rules in case of plants, tree or cattle will be possible. The agreement says patent protection extend to all fields of technology but to what extent it is patentable is not defined. In case of pharmaceuticals, IPA, 1970 defines that a substance capable of using as a medicine and it gives an inclusive definition. And it also excludes the process for medicinal, surgical, curative, prophylactic or other treatment of human beings, plants and animals. It also provides that a mere discovery of any new property or new use for a known substance or of the mere use of a known process is not patentable. But in other countries it is not the same case[4].

There is going to be uncertainty in enacting laws embodying the TRIPS agreement by member countries, the manner in which these laws to be interpreted, administered and enforced. It may be able to exploit the TRIPS provisions to our advantage but the important point is that it is a short term manoeuvre and not a form of long term strategy, and foreign patentees will be able to fight back with every resources at this disposal to protect their interest[5].

Anyhow, besides these difficulties, India need to adopt certain measures while creating more awareness of patent system. There is a need to improve our legal expertise in drafting, filing patents, using patents as Scientific & technological information documents and patent litigation. There is also need to encourage and ensure the proper disclosure of inventions through patents. We also need to

improve our infrastructure facilities in the Indian Patent office. Since we follow the examination system, we need a highly developed and upto date documentation system which not only should contain patents filed and granted, both domestically and all over the world, but also non-patent technical literature. We also need to use the handy and useful instrument of "opposition" more diligently and effectively, to promote a healthy growth of inventions and industries in India. Further it is suggested to encourage the inventors and to set up a National Association of inventors and affiliate it to the International Federation of Inventors Associations (IFIA)[6]. Besides these, the pharma industry, the Government, Universities and Research Institutes has to work collectively and efforts should be made to promote basic drug research by improving our work culture through strategic planning. The SMEs also be encouraged by following Korean experience of using university research on free licensing to these units. It is important in the present day context to incorporate and integrate alternate systems of medicines as part of modern therapeutic artmamentarium. The objective of the industry should be to reduce costs and thereby assure global competitiveness through innovative technology development and consequently through productivity improvements. In case the above steps are seriously and immediately taken the adverse impact of TRIPs Agreement on the pharmaceutical industry and the Indian consumers can be regulated.

FOOT NOTES :

1. Dr. B.S. Chimni,"TRIPS for self reliance -problems with the TRIPS text", NWPL, 1992.

2. Sec 3(i) of IPA, 1970.

3. Cl. (d) of Sec. 3 of IPA, 1970.

4. For example, in US the Pharma Patents were allowed where a new use discovered for an otherwise old products in the form of "As a new therapeutic compound `X'. And the Patents Act, 1952 under Sec. 100 (b), provides that if a new property or a new use of a known compound is unobvious, a claim can be made to a process for using compound, e.g. for the method of treatment of human

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beings against diseases. In journal of the Patent Office technical society, Vol. 19, 1985.

In the recent instance, Burroughs Wellcome (BW) has got through approval of a set of five patents on AZT, the drug for AIDS. A basic point is that the compound AZT or Zidorudine was first synthesized in 1964 and the patent claim is of a "creative insight" by BW in its use for HIV virus treatment. The small firms want to market generic versions of AZT and contend the grant on the ground of it being a compound synthesised and known since years. Also the work on its synthesis was in association with National Institute of Health, and as such NIH should be co-owners of the patents. NIH also support this view and claim that patent approvals cannot be exclusive. Thus seems to likehood of prolonged legal battles ahead. In The Eastern Pharmacist, Jan, 24, 1995.

5. Heinz Redwood, New Horizon in India consequences of Pharmaceutical Patents, 1994.

6. Mr. Shahid Ali Khan "Intellectual property rights and socio and economic development" , paper presented at IJO conference, Hyd, Feb,1995.

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3. Gopalakrishnan N.S. Intellectual Property and Criminal Law, NLSIU, Bangalore, 1994.

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5. Blanco White, 'Patents for Inventions', Stevens, 3rd, Ed., 1962.

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