TRIPS AND PHARMACEUTICAL INDUSTRY:ISSUES AND PROSPECTS

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1. INTRODUCTION

Trade Related Aspects of Intellectual Property Rights (TRIPS) were brought in with the prospects purpose of universalising the standards of Intellectual Property Rights and frame the rules of the game of the developing countries on par with the developed countries. Several factors like the continuous advancement in science, new breakthroughs in bio-technology, the growing participation of the private sector in the cost intensive research and development in the knowledge based pharmaceutical sector and the relative strength demonstrated by the developing nations in adapting the results of the scientific innovations to the local environment have prompted the industrialised nations to seek stronger protection for their innovations in all the countries.

The Paris convention of 1883, one of the oldest treaties governing the protection of industrial intellectual property was fairly liberal in protecting the Intellectual Property Rights (IPR). Under this convention, member countries were free to determine the standards of protection, the subject matter of protection and the period of protection and thus maximum divergence were observed in the case of protection of innovations in the pharmaceutical sector. Several countries fearing that the patent protection in pharmaceuticals will limit the spread of knowledge and thus prevent the scientific innovations reaching the general and the needy public, neither protected the processes of manufacturing a drug nor the final drug. This is because, once a product is patented (product patents), the same product cannot be produced by an alternate method or process during the protection period. However, if the process alone is protected (process patents), then an alternative process which is mostly `invented' around the earlier process could be used to produce a similar product, since in pharmaceuticals, a product can be produced by more than one method. Under the Paris Convention differences were observed in the term and duration of protection too. For instance, while some countries granted protection from the date of filing the patent application yet others did so from the date of the grant of patent. Many developed countries had a period of protection that ranged from 14 to 16 years.

While many of the industrially developed resource rich countries chose to reward the innovators and adopted product patents to promote further innovations, some of the developing countries realised the potential of the process patents in developing the domestic industry and adopted the same. Thus, the developing countries with process patent protection were able to take advantage of the innovations made by early innovators. When a subsequent product is based on an innovation made earlier, the late entrant enjoys the reduction in the cost of developing the product without of course sharing the benefits/profits derived by the new product with the early innovator. But the capacity to exploit the earlier innovations to its advantage depends on the technological development of the country, capacity of the domestic industry, the market size and the type of technology that is used in developing the product. Of the many countries that adopted process patents, developing countries like India, China, Korea and Brazil have developed expertise to develop new products, which were mostly around the earlier innovations of the developed countries. It is assessed that the deficiencies in India's intellectual property system alone are estimated to cost US companies around $500 million a year (Scrip's Year Book, Vol.2, 2000:316).

As per the minimum standards mentioned in the TRIPS agreement, patent shall be granted for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step and are capable of industrial application without any discrimination to the place of invention or to the fact that products are locally produced or imported. Accordingly, now patents will have to be granted in all areas including pharmaceuticals and the effective period of protection is for twenty years from the date of filing the application. With the implementation of TRIPS agreement by most of the developing countries by 2005, a stronger patent regime or product patents will be uniformly applicable on the pharmaceutical innovations among the member countries[1] of the World Trade Organisation.

The implications of TRIPS for the pharmaceutical sector are that: patents will be granted both for products and processes for all the inventions in all fields of technology; the patent term will be twenty years from the date of the application (compared to the seven years under the 1970 Act), which is applicable to all the member countries and thus rules out all the differences in the protection terms prevailed in different countries; patents will be granted irrespective of the fact whether the drugs were produced locally or imported from another country; though the grant of the patent excludes unauthorized use, sale or manufacture of the patented item, yet there are clauses which provide manufacturing or other such rights of the patented item to a person other than the patent holder. In the case of a dispute on infringement the responsibility (to prove that a process other than the one used in the patented product has actually been used in the disputed product) lies with the accused rather than with the patent holder (in the 1970 Act, the responsibility is with the patent holder). This is the broad framework, which will guide the pharmaceutical industry of India in the WTO regime.

However, in order to smoothen out the differences in the level of protection and to make necessary amendments in the national laws to adopt product patents,
Countries with different developmental status have been given a transitional period to bring in reforms in the desired areas and make the laws comparable with other countries. Countries with different developmental status have been given a transitional period to bring in reforms in the desired areas and make the laws comparable with other countries. Thus developed countries had one year to make the suitable amendments and for the developing and least developed countries, the time provided was 10 and 15 years respectively. As per this even US had to amend its patent law since, the effective term of protection was for a period of 17 years from the date of grant. India has to enforce the system of stronger patents from January 2005. During the transitional period of 1995-2005, India has to start accepting applications for product patents from 1995 and provide exclusive marketing rights (EMR) for the products that were granted patent protection elsewhere.

Within India, the opinion on stronger patents on the pharmaceutical industry is divided, some emanating from the country's prior experience with product patents and others from countries, which have recently adopted product patents. These evidences suggest that a country's level of IPR influences a variety of social and economic factors which range from common peoples access to medicine to the functioning of the domestic industry, investment in R&D, technology etc. Developing countries particularly, India, Argentina and Brazil were the strongest opponents of the TRIPS agreement and India was more vocal in voicing her views on issues raised by the developed countries. Now due to pressures from various

[1] In late '90s, as many as 140 countries were members of the WTO.

quarters, all the three countries have accepted the TRIPS agreement and India currently looks for flexibility within the TRIPS framework that would have positive impact on the people, industry and economy.

The universal TRIPS regime is expected to result in free flow of trade, investment and technical know-how among the member countries by resolving the barriers that exist in the form of differences in the standards of intellectual property. There is a rich amount of literature available, which has looked into the various impacts of universal IPR regime.

In this paper a modest attempt is made to highlight the issues of relevance for India that emerge from various studies on the probable impact of product patents on the pharmaceutical industry. It also presents some of the important provisions within the TRIPS agreement that are favourable for developing countries like India. These are presented in sections 2 and 3. Section 3 also presents the initiatives taken by the government of India in adopting the product patents. The last section presents the future scenario of the pharmaceutical industry.

2 Product Patents and Prices of Medicines

Much of the debate on the impact of product patents on the pharmaceutical industry in India has centred on the issues of price of the patented product and their accessibility. While it is true that a positive association is observed between stronger protection and prices of drugs, it is also true that prices decline with the expiry of patent. In the US, Frank and Salkever (1995) report a rapid reduction in the price of drugs after the expiration of the patent. Though more competition among generic drug producers results in substantial price reductions for those drugs, yet increased competition from generics does not result in aggressive response in price behaviour by established brand name products. Danson and Chao (2000) on the contrary observe that generic competition has a significant negative effect on price of the branded products in the US and other countries with relatively free pricing like UK, Germany and Canada, whereas for the countries with strict price regulation like France, Italy and Japan the number of generic competitors has either no effect or a positive effect on prices of branded products.

In India when amoxycilin was first introduced by a multinational the price of the drug was very high. However, with the local manufacturers stepping in to produce the indigenous version of the amoxycilin, the price of the same declined rapidly. It should be admitted that adoption of the process patents along with the domestic regulations that restricted the role of the multinationals resulted in the growth of the domestic industry. In the late ‘90s the pharmaceutical industry of India has reached a position of near self-sufficiency in formulations. After a long time experience of having a negative balance of trade in pharmaceutical products, India started enjoying positive balance of trade from the late ‘80s (Table 1). In production volume India accounts for 8 per cent of world’s pharmaceutical production and is the fifth largest country in the world after the US, Japan, Europe and China. The number of pharmaceutical manufacturers increased from a mere 200 in 1950-51 to more than 6000 in the ‘80s, which reached a phenomenal figure of 23,790 in 1998-99. Of this a sizeable percentage of firms belong to the small-scale sector. It is estimated that out of the 28.6 million workforces in the pharmaceutical industry, about 4.6 million is employed in the organised units and the rest are engaged in distribution and ancillary industry. These units produce drugs that are not under patent protection and are analogous to products that are already there in the market. Hence competition is severe among the pharmaceutical units in

India, which is one of the important reasons for the relatively lower prices of the medicines in India.

Irrespective of the competition, because of the socio-welfare implication of the pharmaceutical prices, all over the world other than in the US, the prices of medicines are subject to government regulations. However, the methods used to regulate prices differ from country to country. In USA and Canada, the cost is charged in full to patients. Even in the US, a law allowing the pharmacists to import the drugs from Canada that would be cheaper by 30-50 per cent was proposed but was not passed due to pressures mainly from the industry quarters (Sanfransisco Chronicle, January 1, 2001). (Industry observers however note that the high rate of return made possible by the free pricing policy of the US government is responsible for half of the new drugs that are invented there). In some nations the government meets part of the bill. Most of the governments list the drugs, which qualify for reimbursement and the extent to which they do so. In most OECD member countries, price is fixed according to the therapeutic value of the drug, its cost of production and the price of similar drugs.

In France and Italy, the manufacturers price must be approved for a product to be reimbursed by the social insurance programme. The UK price system favours domestic firms that would locate corporate headquarters and R&D in UK. Among multinationals it favours those that have significant sales to National Health Service. Further in UK no attempt is made to control the prices of individual drugs. Instead annual arrangements are made with companies to determine the total sum to be paid by the National Health Service for its products. This assures the firms a reasonable rate of return. Germany follows reference pricing of pharmaceuticals. This classifies drugs into groups with similar therapeutic purpose and sets a common reimbursement price for all products within a group. The consumer pays the difference between the reference price and the manufacturers price. Hence demand is highly elastic at above the reference price. In all these countries majority of the people are also covered by some health security schemes.

In the absence of such health security schemes and with the very low purchasing power of the people in India, the government of India has brought certain essential drugs under the price control. The price control along with the amendment of patent laws in early ‘70s resulted in a declining impact on prices. Three factors have contributed to the lower costs of production viz :(1) the process development capacity of the units; (2) severe competition among the firms and (3) relatively lower costs of production. Based on India’s own experience and on a selective comparison of prices of a few drugs in countries where product patents is in force, intellectuals forewarn that the stronger protection would result in increase in the prices of the drugs and thus medicines will be inaccessible to common people. Their comparison of patented drugs introduced elsewhere in the world shows that prices of the drugs had increased manifold after the protection. This fear about the rise in the prices and the probable exploitation by the multinationals among the developing world grew high when the vested multinationals tried to prevail on the South African government to stop the passing of the bill to permit parallel import of the HIV-AIDS drugs which would ensure the availability of those drugs at a lower rate.

The other side of the argument on prices of the drugs is that, developing countries may not be affected by the increase in the price of the drug due to low participation of patented drugs (Watal, 1996; Lanjouw, 1998). This is because so far the dynamic domestic players in India have managed to introduce substitutes of the patented product within four or five years after

their appearance in the world market. This `lag' is to observe, the feed back on the product in the international and other markets (Lanjouw, 1998). Thus, the welfare loss of non-introduction of a patented drug is minimised by the introduction of such drugs though after a lag, so far made possible by the weaker regime, will not be possible in the product patents regime. It is also possible that the monopoly would adopt a discriminatory pricing strategy to fully exploit the different markets.

One of the major advantages of the universal system is that, it would facilitate access to new medical products. While the welfare loss due to the possible price increase in the post WTO regime is highlighted in most of the studies, the welfare loss due to the non-introduction of new-patented drugs in India due to the weak protection regime is not discussed adequately. In this context, one of the advantages of the product patents is that the stronger patents will provide access to the latest inventions in drugs, which the developed world will not shy away from introducing in India. It is observed that, though Pakistan also has process patent regime, some of the new drugs that were introduced in Pakistan by the MNCs were not introduced in India at all even though these MNCs were present in the country (Basant, 2000). This is because the MNCs feared about the competition from the counterfeit products in India, whereas in Pakistan MNCs are stronger than the domestic firms.

It is also possible that higher prices charged by the MNCs may not really affect the consumers because; the research activities undertaken by the MNCs are totally different and not pertain to the LDC market. Hence it can be said that the percentage of population affected by the price rise would be very less. SenGupta (1998) presents a different picture. His analysis shows that prices of `older drugs', which are not patent protected are much higher in India compared to other countries, while prices of drugs that are patent protected or recently off patent are cheaper in India compared to the prices of drugs in the same set of countries. This anomaly he attributes to the price control mechanisms that are in operation in India. Basant 's (2000) comparison of various medicines from 14 MNCs operating both in India and Pakistan show that about 70 per cent of the various medicines are cheaper in Pakistan than in India.

A related issue is the wider use of cost effective generic drugs. In US and some parts of Europe, the pharmacists are authorised to dispense generic drugs in the place of a prescription drugs, which will cost less than the prescription drug. Thus, the consumers have the option to choose between the generic and the branded drug. However, if the doctor writes it as `dispense as written' then the pharmacist cannot change the drug. In India, the `Over the Counter' market is restricted to a few common medicines and prescriptions bearing the generic name are also uncommon. Unlike the other consumer items, in the case of drugs, the consumer goes by what has been prescribed by the physician. Hence, in the post WTO regime, the physicians will play a crucial role in choosing between a patented drug and a generic drug, in cases where alternatives are available and help the consumers from being exploited by the market forces.

The drug prices in India were brought under control based on the recommendations of the Hathi committee, which observed that since the drugs industry has a social responsibility, it should operate much above the principles of trade for profit. However, due to the repeated plea of the industry that the drug production was becoming unprofitable, in 1986, government reduced the number of drugs under control from 347 to 166. Yet in spite of the price reductions in India, over a period of 15 years from 1980, there has been a general rising trend

in prices especially of essential life-saving drugs (Rane, 1995). Recently, whereas the finance ministry under which the Drug Price Control Order (DPCO) is monitored has announced the decision to reduce the number of drugs under the price control, the report on pharmaceutical pricing set up by the government, after studying the scenario in different countries where some form or the other of price control exists, has recommended that drugs should be under the price control. The Pharmaceutical Policy 2002 indicated a drastic reduction in the number of drugs under price control. According to the industry sources, the new DPCO would cover about 34 bulk drugs and their formulations under control (Lalitha, 2002a).

Despite the price controls, monitoring and enforcing such prices has been very poor in India (Rane, 1996) where, significant differences persisted between the prices charged by different manufacturers for the same formulation. Mostly companies with substantial market power charged higher prices and the impact of DPCO did not percolate to the consumers at all (Chaudhuri, 1999). While stressing the fact that the present price controls will be applicable on patented products too and such controls would definitely benefit the customers, Watal (1996) warns that costs of establishing and maintaining an effective price control over all patented drugs may be very high.

There is nothing in the GATT treaty, which prevents India from continuing to use price regulation to protect the consumers against exploitation through high prices. The drug price control mechanisms prevalent in India are applicable on the patented drugs too. Under the Drug Policy (1994) of India, a drug is subject to price control if annual turnover in the audited retail market is more than Rs.40 million. A drug turnover above this minimum revenue level may be exempted if there are at least 5 bulk producers and at least 10 formulators, none with more than 40 per cent of the audited retail market. Any bulk drug with a turnover above Rs.10 million with a single formulator with 90 per cent or more of the market is also subject to price control. Given this last criterion, all patented drugs would be subject to price control, unless they are widely licensed, a highly unlikely scenario (Watal, 1996).

While it is clear from the above arguments that the patented products can be subject to price controls yet it is not very clear, whether the products that enter the country through the `Exclusive Marketing Rights' (EMR) route will also be under these price controls. As per the TRIPS agreement, during the transitional period, developing countries like India will also have to provide `Exclusive Marketing Rights' for products patented elsewhere (any other member country) till the patent application for that product is approved or rejected in India. Kumar (2001) points out that while there is a possibility of getting a product produced locally, if we accept the product patents, under EMR, the import monopoly is sanctioned before examining whether a product is worthy of patent or not. Actually in the TRIPS agreement, the scope and effects of EMRs are not specified[2]. EMR has no legal precedent

[2] The TRIPS concept of EMRs appears to have been drawn from US law. The Hatch-Waxman Act of 1984 requires *inter alia* that an innovator drug be granted at least five years of market exclusivity after it is approved by the drug administration before equivalent competing products are approved. This provision was meant to benefit drugs that have either no patent protection or had less than five years patent protection left at the time of approval. Another market exclusivity provision contained in the same law delays generic entry by three years when a new application that requires clinical tests is approved as for instance in the case of a new dosage form of an existing drug or a second use for a known substance. In addition under the Orphan Drug Act, a drug designated as `orphan' drug i.e., one dealing with a rare disease conditions affecting less than 200,000 persons in the US, is entitled to a market exclusivity of seven years. Another

anywhere in the world but for one case in Argentina. Though as of May 1999, 13 WTO members like, Argentina, Brazil, Cuba, Egypt, India, Pakistan, Turkey, Uruguay, Kuwait, Morocco, Paraguay, Tunisia and the United Arab Emirates have notified the establishment of a mailbox, yet only India and Argentina have gone for EMR. In India no EMR so far has been granted. There is an interesting case of EMR in Argentina. The Argentine patent office confirmed EMR on a US company, since the said application satisfied all the stated conditions. However, the patent examination later revealed that the patent application did not cover a new legal entity but which was already in the public domain and a patent for this product was granted in Luxembourg where patents are granted without prior examination (Correa, 2000).

Hence, to avoid abuse of EMRs, developing countries should ensure that EMRs if granted (a) apply only to new chemical entities, since the rationale of the said article is clearly to provide protection to such entities and not to a simple new form or formulation of a known product and (b) require that a patent in any other WTO Member country that serves as a basis for the EMRs be granted in a country with a serious examination procedure (Correa, 2000). But India should allow introduction of products under EMR only after they are certified that the product is suitable to the Indian environment and the consumers. Hence, one way to reduce the monopoly powers enjoyed by such drugs could be to improve the speed of processing the EMR applications and decide on their patent status soon so that domestic controls can be enforced on such drugs.

2.2 Product Patents and Research and Development

One of the advantages of the universal patent regime is that private venture capital firms become willing to invest in technology based start up companies; technical knowledge flows more readily from university laboratories to the market place and local firms become willing to devote substantial resources to internal research (Sherwood, 1993). Available evidence show that patents are important for chemicals and particularly for pharmaceuticals basically because of the huge R&D costs incurred by the firms (Nogues, 1990). Also, the purpose of the patent is to provide a form of protection for the technological advances and thereby reward the innovator not only for the innovation but also for the development of an invention up to the point at which it is technologically feasible and marketable.

The higher cost of the R&D proves to be an effective entry barrier for new firms and hence only firms with large flow of funds become responsible for industrial inventive activity (Grabowski, 1968). In developing countries, only a few firms have sophisticated R&D facilities and others benefit mainly from the spillovers of the resultant R&D. But, in order to move on to the higher echelon, firms need to invest in R&D. More often small firms shy away from investing in R&D because, R&D is based on trial and error. Though small firms are also capable of innovations, for successful commercialisation of the innovation, size of the firm matters. For instance, cost of developing one new drug in the US increased from $54 million in 1970 to $231 million in 1990. Recent studies indicate that 1 out of 5000 compounds synthesized during applied research eventually reaches the market. Other

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sponsor's application for marketing approval of the same drug for the same use may not be granted during this period of seven years. These provisions in US law first inspired the original US proposals behind Article 39.3 of TRIPS, and later in the TRIPS negotiations, formed the basis for the EMR proposals (Watal, 2001: 120-121).

estimates indicate that of 100 drugs that enter the clinical testing phase 1[3], about 70 complete phase 1, 33 complete phase II, and 25-30 clear phase III. Only two-thirds of the drugs that enter phase III is ultimately marketed. This suggests that attrition rates are especially severe in earlier research stages. Compounds that overcome clinical trials of Phase II have a relatively good chance of becoming new drugs. However, as phase III is the more costly R&D stage, one failure out of three produce may still imply a considerable loss of resources (Gambardella, 1995). Though global investment in the R&D has been increasing rapidly, R&D efforts need not necessarily result in new products and innovations. According to a US FDA report 84 per cent of new drugs placed on the market by large US firms during the period 1981-88 had little or no potential therapeutic gain over existing drug therapies. Similarly in a study of 775 New Chemical Entities introduced in to the world during the period 1975-89, only 95 were rated to be truly innovative (Lanjouw, 1998).

Because of these reasons and due to the protected policy regime, the R&D investment in India has been very low and started picking up only in the early '90s as evident from Table 2[4]. Of the Rs.1, 800 crores spent on R&D in 1998, 35 per cent belongs to the public and joint sector and that of the private sector is about 65 per cent (IPR, September 2000). In spite of the growing investment in R&D, R&D as percentage of sales ratio stagnates around 2 per cent. Further of the 1261 Department of Science and Technology recognised R&D units, 256 have spent more than Rs. 1 crore every year. 350 have spent between Rs.25 lakhs and Rs. 1 crore and the remaining below Rs. 25 lakhs (Report on Currency and Finance, 1998-99). This indicates that most of the R&D investment was perhaps directed towards process improvements and adapting the technology to local conditions thus resulting in technology spillovers rather than in new product developments. For instance, the UK multinational Glaxo was faced with several local competitors on the first day when its subsidiary marketed its proprietary drug Ranitidine in India (Lanjouw, 1998), because the competitors enabled by the weaker patent regime were ready with the indigenous version of Ranitidine. The more recent case of adapting the technology developed elsewhere to local conditions enabled by the process patent regime is the case of viagra introduced by Pfizer. A patent for this drug was granted by the US patent office to Pfizer in 1993. The company spent about 13 years and several millions of dollars to develop the drug. Apparently what took Pfizer 13 years and millions of dollars in R&D to perfect, the Indian firms have managed to do in weeks, for a fraction of costs. Of the 30 raw materials used in this drug, 26 are available locally. Utilising the information that was available on the Internet, US patent records and industry literature some of the Indian firms started their work on the indigenous version of viagra, which was available in the market within weeks of Pfizer formally launching the product. However such reverse engineering is not possible with products that have got patents after 1995. Absence of stronger protection in the chemical and pharmaceutical sector in developing countries like India is cited as one of the reasons that holds back foreign investment especially from countries like the US, Japan and Germany (Mansfield, 1995). However, with the change in

[3] Phase 1 is for the evaluation of drug safety for clinical pharmacology and toxicity in human volunteers. Phase 2 is for the clinical investigation for treatment effect and phase 3 is the full-scale evaluation of treatment where the drug is administered on several hundred patients and normal subjects. Phase 4 is the post-marketing surveillance to elucidate uncommon side effects.

[4] Prior to the '90s, the government R&D was much higher than the private R&D (Bowander 1998, Lakhwinder 2001), which started changing since the early '90s. Another point to be observed is that R&D facilities that do not satisfy all the criteria set by the Department of Science and Technology (DST) are not recognised by DST. Hence to that extent there could be a certain percentage of under estimation of R&D investment.

scenario, domestic companies, which had invested in biotechnology, were finding the lack of protection as a problem to commercialise their innovations (Lanjouw, 1998), because in DNA recombinant technologies, novelty is the product. The process of discovery is complicated, but once the product is obtained, its propagation can be achieved in many ways (Reddy and Sigurdson, 1997). Globally now factors favour the internationalisation of R&D as the multinationals review their core competencies. This is resulting in vertical disintegration of R&D, product development, and clinical trials, manufacturing and marketing activities. The severity of the US regulatory bodies has also been one of the strong factors in encouraging US firms to set up R&D and manufacturing facilities else where (Kumar 1996). Recent research done in this area also suggests that besides the level of IPR in a country, factors like the host country's policy on foreign direct investment, availability of human resources and physical infrastructure, market size, play an important role in the decision to locate the R&D activities by a multinational enterprise (MNE) in other countries (Kumar 1996 and 2001). Contrary to the perception that stronger IPR is necessary for attracting R&D investment, an insignificant relationship between patent protection and location of R&D activity emerges in the analysis of Kumar. On the other hand factors such as availability of technological resources and infrastructure were found to be more important in attracting or improving R&D (Mehrotra 1989, Kumar 1996) than the IPR protection. For instance, problems like non availability of basic tools of DNA recombinant technology and lack of technology and expertise among the local recipients to develop diagnostic kits on a mass scale have been faced by units which have set up their R&D facilities in India (Reddy and Sigurdson, 1997). Even in the weaker patent regime of India, MNEs such as Ciba, Hoechst, ICI, Uniliver, Cadbury and Astra had set up their R&D, though they protected their innovations by patenting them in their home countries. Basically as Kumar (1996) observes, if the overseas R&D is not directed to new product development but is restricted to local adaptations and providing support to local production of MNE, then IPR will not have much influence on the decision to locate R&D by an MNE.

Rising R&D costs imply that only giant corporations with formidable R&D, marketing and financial capabilities will be able to afford extensive new drug developments and commercialisations. Since it is difficult for each unit to invest in R&D, to economise on scarce R&D resources and to avoid the probable duplication, pooling of R&D resources and mergers of firms have been identified as possible solutions. Where joint efforts of firms were involved as in the case of Japan, clear logistics have been worked out. `In Japan the locus of ownership of intellectual property rights flowing from a consortium is determined by the nature and degree of governmental subsidy. Under the hojokin formula, the government provides 40-60 per cent financing, using conditional loans whose repayment are tied to profits. Under the itakusi formula, the government provides full contract financing of research. This formula was used in the case of ICOT, and under this patents belong to the Ministry of International Trade and Industry, which can be licensed to the members of the consortium and foreign firms' (Ordover, 1991 P 51). Mergers and amalgamations are also taking place to pool the resources and R&D advantages, which reduce the duplication of research and wastage of resources. Hence to avoid such costs and to take advantage of the resources, several consolidations of firms have occurred in the US in the 1980's. In India also several mergers started taking place from 1995 onwards. Some of these mergers were: Crossland Research Laboratories merged with Ranbaxy Laboratories in 1995; Sandoz (India) was merged with Hindustan Ciba-Geigy to form Novartis (India) in 1996; Sumitra Pharma was merged with Nicholas Piramal in April 1995; Cadila Healthcare had acquired the business of Cadila Laboratories, Cadila Chemicals, Cadila Antibiotics, Cadila Exports and

Cadila Veterinary Private Ltd in June 1995; John Wyeth (India), Wyeth Laboratories and Wyeth (India) Pvt Ltd were amalgamated with Cyanamid India in April 1996 and now is known as Wyeth Lederle Ltd. Tamilnadu Dadha Pharma was amalgamated with Sun Pharmaceuticals Industries in April 1997. Nicholas Piramal, Boehringer Mannheim, Piramal Health care were merged in April 1996. Roussel India (Erst) was merged with Hoechst Marion Roussel in April 1997 (CMIE, Industry, Market Size and Shares, August, 2000).

There has been an apprehension that in the wake of globalisation the focus of research in the LDCs could change and the major R&D firms may be more involved in drug discovery that addresses the global diseases and neglect the research that is more relevant for the LDCs. In this context, the concern is will the developing countries such as India benefit by the global R&D efforts or the R&D efforts that might get stimulated within the country? A study done in the context of India observes that of the firms that are both Indian owned and subsidiaries of multinationals, 46.2 per cent of the research funds are targeted at LDC markets. However, they are for products targeted at developing country markets and not for diseases where 99 per cent or more of the burden is on low and middle-income countries. Also, there are differences in the diseases pattern prevalent in the developed and developing countries. For instance, the percentage of mortality in developing countries in infectious and parasitic diseases, circulatory diseases and cancer is 43, 24.5 and 9.5 per cent respectively. The corresponding figures for the developed countries are 1.2, 45.6, and 21 per cent respectively (Report on Pharmaceutical Research and Development Committee, (PRDC) 1999). Therefore, anticancer research and cardiovascular diseases have been the main focus of research of the pharmaceutical firms of the West. There were 1,422 anti cancer projects in development by the world wide pharmaceutical industry in May 1999. In contrast, pneumonia, diarrhoea and tuberculosis that account for 18 per cent of the global disease burden are subject of less than 0.2 per cent of global medical research and third world diseases such as malaria, chagas disease, tetanus, and lymphatic filariasis have so far not attracted the developed countries' attention.

The patenting activity by the Indian inventors in the US and Europe and other primary data of study suggest that `any discovery research is and would be on global diseases and on products for the worldwide market. But Indian firms are allocating a `non-negligible portion of their R&D budgets to tropical diseases research and LDC products and that the fraction of this going towards the discovery of new products, rather than development may well are increasing' (Lanjouw, 2000, P.20).

The number of patents filed and granted also indicates the level of inventive activity and the R&D capabilities of a country. The developing countries' R&D declined to about 4 per cent in 1990 from nearly 6 per cent in 1980 despite the steady increase of R&D outlays in Asian countries particularly in South Korea and Taiwan. This negligible R&D also reflects in the number of patents filed by them. 95 per cent of the 16,50,800 patents granted in the US between 1977 and 1996 were conferred upon applications from 10 industrialised countries. The developing countries accounted for less than 2 per cent of the total number of patents (Correa 2000). Table 4 presents the number of patents filed by Indians and others in the patent office of India. Invariably the number of patents filed and granted by others is higher than those of Indians. Interestingly, there is a huge gap between the number of applications filed by Indians and the actual number of patents. Implicitly a large number of applications are turned down because such inventions already exist or the inventions lack non-obviousness or industrial applicability. It suggests that the companies with inventing ability should keep themselves updated of the developments taking place elsewhere and try to make their

inventions distinct from others. This suggests the important role that will be played by information technology in searching for evidence and prior art.

Patent applications by industry during 1995-2000 indicate that pharmaceuticals rank the highest with 396 applications followed by chemicals (337) and electronics ranks the least with 23 applications (IPR, Vol.6, No.9, 2000). Table 5 gives the number of patents filed by some of the Indian pharmaceutical companies with the Indian patent office. Though many of them could be for the processes developed, yet it indicates that the impending WTO regime has stimulated the R&D activity and importantly filing of patent applications also.

In view of the importance of the R&D in a knowledge-based industry like pharmaceutical sector, there needs to be a close relationship between the industry and the academic institutes. One of the reasons for the western world's dominance in R&D is due to the strong research collaboration that exists between the universities and the industry where the research lead provided by the university is taken up for further research by the industry both to explore new areas as well as to work on the existing knowledge available in the public domain. This is very much essential for a country like India, which is opening up now, so that further research is done on areas that are most essential for the welfare of the people. The following example of Merck will be useful in this context. Merck is a US based pharmaceutical company and has a very high in-house R&D expertise. `Between 1972 and 1974, two scientists Michael S Brown and Joseph L Goldstein of the University of Texas identified the key steps in the production of Cholesterol, work for which they were awarded Nobel Prize in 1985. Their findings motivated Merck's scientists to launch research on cell culture assays for cholesterol inhibitors as early as 1975. In 1978, Merck isolated Lovastatin the Mevacor compound from a microorganism of the soil. Mevacors NDA was approved for marketing in August 1987. The product reached $260 million sales in 1988, the first full year of marketing and it reached $ 1 billion sales in 1991. As soon as Brown and Goldstein's discovery was made, it was publicly available. Yet Merck was the only company that effectively exploited their findings (Gamberdalla, 1995). This is a very heuristic illustration. There could be several such findings that may be effectively explored. In India also such strong association between the academic institutes and industry needs to be established. Academic institutes can serve the role of research boutiques where basic research or further research based on knowledge that is available in the public sources may be undertaken and industry can proceed with further development or commercialisation of the compound identified by the university. Since 1995, there has been a steady improvement in the patents filed by the academic institutions in India, which is presented in Table 6. Until recently, the culture of protecting the inventive work through patenting was almost non-existent in the academic institutions as most teachers felt that the knowledge should be shared freely through publications and seminars. This was no different than the thinking prevailed in the R&D institutions. After India became a member of the WTO, a new thinking has started taking routes in universities and academic institutions regarding patents (Intellectual Property Rights, Vol. 5. No.8, 1999) and these institutions have started filing patent applications.

Besides patenting the innovations, sound licensing practices are essential to enhance the utility of research done by universities. For instance, University of California at Sanfransisco and Stanford University jointly hold a patent that covers the technique for combining genetic materials. Rights for this patent were not sold exclusively but were available to any one for a reasonable fee. This patent brought the universities more than $100 million in licensing revenues over the years and has been widely credited with the emergence of the

biotechnology industry. On the other hand assigning the rights to one company might have slowed the evolution and commercialisation of biotechnology (Zilberman et al, 2000). Therefore, a strong collaboration with research institutes and the industry could reduce the research cost in the industry like the expenditure in screening and synthesising the chemicals and the university could provide the research lead. Gamberdalla (1995) observes that university research had a positive and significant effect on corporate patents and industry R&D and geographical proximity increases the strength of the effect of university research on corporate patents. The contribution of university research is greater if the industry and university scientists can interact more easily.

2.3 Patents, Foreign Direct Investment and Technology Transfer

One of the expected outcomes of strengthening the IPR is the increase in foreign direct investment (FDI) in R&D, direct manufacturing or joint ventures. However, the impact of stronger patents on FDI remains inconclusive from the available evidence since IPR is only one of the factors in attracting FDI. FDI flows depend on skills availability, technology status, R&D capacity, enterprise level competence and institutional and other supporting technological infrastructure (UNCTAD, 1996; Correa, 2000). Highlighting the FDI flows to countries with allegedly low levels of IPR protection, Correa (2000) observes that the perceived inadequacies of intellectual property protection did not hinder FDI inflows in global terms. Thus FDI increased substantially in Brazil since 1970 until the debt crisis exploded in 1985, while in Thailand FDI boomed during the eighties. In contrast developing countries that had adopted stronger protection have not received significant FDI inflows. He further observes that FDI in the pharmaceutical industry outpaced FDI in most other sectors in Brazil after patent protection for medicines was abolished in that country. In Italy after the introduction of process patent protection in 1978, FDI increased. Hence, it appears that patent production does not have significant impact on FDI. After the abolition of protection on pharmaceuticals in Korea, though no new subsidiary was set up, in the existing companies, foreign capital had increased and the pharmaceutical industry accounted for 23 per cent of total foreign capital. Foreign investment did increase because, FDI was not allowed in formulations. So the only way to enter the country was to collaborate with a local firm (Kirim, 1985). In the case of India after the adoption of process patents in the pharmaceutical sector, the number of foreign collaborations increased from 183 in 1970 to 1041 in 1985 (Mehrotra, 1989) perhaps because of the fact they were catering to a larger market.

Kumar (2001) argues that in developing countries like India, focus of the FDI policy should be to maximise its contribution to the country's development rather than on merely increasing the magnitude of inflows. In other words, attracting FDI in specific sectors is more important than aiming at increasing the FDI per se and that alone is not going to improve investments in R&D. Multinational enterprises (MNEs) have so far come to India primarily for exploiting her large domestic market and their contribution to India's exports is negligible. During the stronger patent regime before the '70s, and after that also, the market share of the MNEs in vitamins and other nutrients was more than 90 per cent while in the case of anti T B drugs it was only 18 per cent (Sen Gupta, 1996). In contrast, MNEs account for nearly 40 per cent of China's manufactured exports.

Several studies quoted by Dunning (1992) point out that US affiliates in Canada consistently spent less on technology creating activities than did their indigenous counterparts. Other Canadian studies have found that foreign ownership is either not significantly or is negatively

correlated to R&D performance. He also observes that the R&D intensity of foreign controlled firms in the Canadian pharmaceutical industry was less than that of their locally controlled counterparts.

In the case of India, total FDI flow has been stagnating, due to various forms of regulatory framework and the government control over production that was prevalent for a long time. These regulations have been relaxed as part of the liberalisation measures and currently 100 per cent foreign equity is allowed in the pharmaceutical industry. Table 7 provides information on the total FDI and FDI in the pharma industry. Vast differences are observed between the amount approved and the actual inflow, which suggests that a large number of proposed investments do not materialise and perhaps wither away due to the bottlenecks encountered at the time of implementation. In pharmaceutical industry till 1999 it has been less than 0.50 per cent. However, with the measures towards adopting stronger patents and increasing the FDI limit in the pharmaceutical industry from 74 per cent to 100 per cent should attract more FDI over a period of time. The FDI approved in pharmaceutical sector accounted for Rs.1614.6 though the actual inflow could be much lower than this.

Patents and Technology Transfer

To qualify for the patent, an invention should be novel, non-obvious and capable of industrial application. As per this, the applicant reveals the content of the patent in the patent application, which is in the public domain. However, such disclosure could undermine the competitive advantage of the invention encouraging the innovator to protect the invention as a trade secret rather than with a patent. For as detailed earlier in the case of Viagra, it is possible to get access to patent information from the patent office of any of the countries and develop a new product based on the information obtained in the patent application form thanks to the rapid development of information technology. A sizeable level of technology currently available is due to `spill overs' or developing an alternative process that is very close to the existing one. This is the reason why the actual technology in a patent is often kept as a trade secret (Correa, 2000; Mehrotra 1989) and which leads to entering in to a separate licensing agreement with the innovator for the transfer of that technology.

The high cost of development and rapid obsolescence may prevent the transfer of technology and the patent holder may prefer direct exploitation or import of products than transferring the technology or know-how. Fear of competition also dissuades the transfer of technology or demands a high royalty for the transfer, but huge royalties may have a negative impact on the expenditure on R&D. In the case of India, though in the pre'70s era, the technology transfer by the big TNCs did not support the indigenous technological abilities, yet in the post '70s, a large number of small and medium size firms have also been transferring their drug technologies to India, thus encouraging an atmosphere of competition in technology transfer (Mehrotra, 1989). But India has encountered difficulties in getting access to technology for a component known as HFC 134 A, which is considered the best available replacement for certain chlorofluorocarbons. Patents and trade secrets cover this technology, and the companies that possess them are unwilling to transfer it without majority control over the ownership of the Indian company (Correa, 2000).

The presence of multinationals did not lead to large-scale technology transfer. Between 1965-1982, top 10 multinationals introduced technology for production of only 9 bulk drugs, while 4 public sector companies introduced technology for 51 bulk drugs and the top Indian private sector companies for 36 drugs. Even in drugs that were open for MNCs, they were not

particularly keen to introduce technology in essential drugs (Mehrotra, 1989). In the pharmaceutical industry technological self-reliance can be obtained if bulk drugs are indigenously produced from their basic stage. There has been a notable increase in the manufacturing of bulk drugs from the basic stage onwards which increased from Rs. 240 crores in 1980-81 to Rs. 3148 crores in 1998-99. Besides improvements has also been achieved in new drug delivery systems, basic research and development.

While the available evidence on product patents impact on R&D is inconclusive, one of the minimum standards mentioned in the TRIPS agreement is that import of a patented product in a host country will be treated as equivalent to producing the same in the host country. Intellectuals strongly oppose this since by allowing such a provision developing countries will not benefit by way of R&D or technology transfer and it will also lead to exploitation of the consumers and therefore recommend working of the patent in the host country. This fear is more valid in countries where the domestic industry is not strong or where the major part of the consumption is met by imports alone. In such circumstances the `working requirement' will not achieve anything since, unless the patent holder cooperates, transfer of technology will not take place. In such cases, compulsory license will be a useful instrument, which is elaborated, in the following pages.

3. FLEXIBILITY IN THE TRIPS AGREEMENT

In the foregoing session, the probable impact of product patents on some of the important aspects like prices, R&D, foreign direct investment and technology inflow was highlighted. Stronger patents because of the exclusive rights effectively rules out competition and ensures the monopoly power of the patent holder throughout the period of protection. The scepticism regarding the access by the developing countries to important breakthroughs in medicine made by the developed countries however linger on. Hence it is feared that it will have adverse effects on trade and may impede the transfer of technology and know-how. Article 7 of the Agreement states the objectives of the IPR as `the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations'. As per this, flexibility to define the national laws within the TRIPS framework is available under the clauses of compulsory licensing, exceptions to exclusive rights and the principle of exhaustion, which are discussed below.

A compulsory licensing (CL) system is incorporated in the patents, whereby a person other than the patentee or the government is authorized to produce a patented product. Even under the Paris convention, the provision for CL was there, where a CL cannot be granted before the expiration of four years from the date of filing the application or three years from the date of grant of the patent whichever is longer. But this provision was hardly utilised by the industry because even before the end of the third year of the grant, the process was known. The TRIPS agreement does provide certain grounds (though not limited to them) for a country to exercise the CL option.

The link between IPR and high domestic prices provided the main justifications for weakening the level of protection for drugs by means of comprehensive compulsory licensing practices (Brago in Siebeck et al, 1990). Greece and Yugoslavia have also evolved compulsory licenses. Canada is one of the countries, which frequently adopted CL to check the price of the patented drugs. In Canada, CL of products to local firms is encouraged,

though the innovating firms view compulsory licensing and renewable patents as restrictions on their rights.

CL in the US has more often been used to restrict the anti competitive practices and as a remedy in more than 100 antitrust case settlements. The use of CL[5] is allowed under specific grounds and contains detailed conditions under which a CL can be granted. Like for instance, the CL could be issued under the grounds for (a) refusal to deal by the patent holder, (b) emergency and extreme urgency, (c) anticompetitive practices, (d) non-commercial use, and (e) dependent patents. The TRIPS Agreement does not limit the members right to issue CL only on these grounds. For example, the German patent law has provided that CL could be issued in the interest of public while the Brazilian patent law allows for CL in cases of insufficient working (this is under debate). Though the US is against any country using the CL and the drug cartel of the US is against the issuance of the compulsory licensing, yet `ironically under the US law, the US's own patent legislation is far more liberal than that which it is trying to impose on developing countries. Under the US law, if the government wants to use a patent, it can do so without the need for a CL and without negotiating with the patent holder. The patent holder can ask for compensation but has no other rights. In addition, the Bayh Dole Act gives the government wide ranging powers to issue CL' (Scrip's Year Book, 2000, Vol.1: 165). In fact, in the US, many compulsory licenses have also been granted in order to remedy anti-competitive practices. In some cases, the licenses have been granted royalty free. `CL has been used as a remedy in more than 100 antitrust case settlements, including cases involving Meprobamate, the antibiotics Tetracycline and Griseofulvin, synthetic steroids and most recently, several basic biotechnology patents owned by Ciba-Geigy and Sandoz, which merged to form Novartis. Statistical analysis of the most important compulsory licensing decrees found that the settlements had no discernible negative effect on the subject companies' subsequent research and development expenditures, although they probably did lead to greater secrecy in lieu of patenting' (quoted in Correa, 2000:91).

Article 40.2 of the TRIPS agreement spells out that `nothing in this Agreement shall prevent Members from specifying in their national legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A member may adopt, consistently with the other provisions of this Agreement appropriate measures to prevent or control such practices which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing in the light of the relevant laws and regulations of that member' (GATT Agreements). In China, `any entity which is qualified to exploit the invention or utility model has made requests for authorisation from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and such efforts have not been successful within a reasonable period of time, the patent office may, upon the application of that entity, grant a compulsory license to exploit the patent for invention of utility model' (as quoted in Keayla, 1994b: 196).

Some of the developing countries have argued that working of the patent should not include importation and thus have put forth the case for compulsory licensing of a patented product in the event of `non-working' in the host country. Watal (2001) however argues that `it is not clear what developing countries hope to achieve by using this condition of local manufacture. It clearly helps domestic industry in getting access to the technology but would this force the

[5] This paragraph draws largely from Correa (2000)

pace of transfer of technology? By itself, `working' requirements are not likely to encourage the transfer of technology, as right holders are not likely to cooperate in giving the required know-how. Where such cooperation is not required, local licenses can be obtained by making `refusal to deal' or `public interest' a ground for compulsory licenses, without confronting the non-discrimination clause in Article 27.1. Similarly if the problem is lower prices i.e., to force the use of local labour and materials, thus enabling the manufacturer to offer the patented invention at lower prices, it can also be tackled directly by making the sale of patented inventions on unreasonable terms a ground for compulsory licenses. If `working' were the only ground for compulsory licenses, by `working' the patent within three years from its grant, and selling the resultant product at unreasonably high prices for the entire patent term, the right holder saves himself from compulsory licensing' (P 318-319).

Article 30 allows limited exception to patent rights. It states that `members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Accordingly, the following types of exceptions may be provided: `acts done privately and on a non-commercial scale or for a non-commercial purpose; use of the invention for research or teaching purposes; experimentation on the invention to test or improve on it; preparation of medicines under individual prescriptions; experiments made for the purpose of seeking regulatory approval for marketing of a product after the expiration of a patent; use of the invention by a third party that had used it before the date of application of the patent and importation of patented product that has been marketed in another country with the consent of the patent owner' (Correa, 2000:75). Another exception known as Bolar exception also permits the pre-market testing of generic products during the patent term, so that they can be marketed immediately upon expiration of the patent.

The other important aspect that is gaining attention is the parallel trade. Objectively, the patent owner looses his rights once the product is on the market or when the patent owner has sold his innovations. This principle is known as the principle of exhaustion of rights or commonly known as parallel trade. TRIPS leaves the decision on rights of national or international exhaustion to national laws. The US adopts a national exhaustion principle whereby the patent owner will have no control over the product once it is placed in the domestic market. But he can exercise his rights outside the US market regarding the price and quantity of the product. The European Union applies the regional exhaustion principle whereby the rights are exhausted within the EU region. International exhaustion gives no right to the patent owner once he has sold his product. The international exhaustion is consistent with the objective of TRIPS agreement mentioned in Article 7. The advantage of international exhaustion is that developing countries such as India can scout for cost advantages of the patented product. Both national and international exhaustion has its own merits and demerits. For instance while the international exhaustion disallows the exclusive rights of the patent owner globally and thus can gain access to the patented product, but an unscrupulous patent owner/manufacturer can restrict the supply of the product that is exported. In those cases exercising the compulsory license option can lead to getting the

patented product in required quantity. Besides, using the international exhaustion, lot of `grey' goods could also be traded.

All these provisions suggest that patented product can be manufactured, traded and used for experimental purposes, within the provisions of the TRIPS Agreement. The national laws will have to clearly define the cases in which such provisions could be used to benefit the people and the industry.

3.1: Steps Initiated by the Government of India

Through the first amendment to the Patent Act made in 1999, the Government of India (GOI) has facilitated the `Mail Box' system and the Exclusive Marketing Rights for products patented elsewhere. The mailbox has initiated the process of accepting the patent applications from January 1, 1995, which will be processed in 2005. The EMR has so far not attracted many applications.

The Doha[6] declaration has made it clear that each member has the right to grant CL and the freedom to determine the grounds upon which such licences would be granted. This is however subject to certain conditions like: authorisation of such use will have to be considered on its individual merits; the proposed user will have to make efforts over a reasonable period of time to get a voluntary license on reasonable commercial terms (except in cases of national emergencies); legal validity of the CL decision and the remuneration will be subject to judicial or other independent review and the CL can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.

In the amended Patent Act of India Sections 82 to 94 in Chapter XVI deal with CL. These sections provide details of: general principles applicable to working of patented inventions; grounds for grant of CL; matters to be taken into account by the controller of patents while considering applications for CL; procedures for dealing with CL applications; general purposes for granting CL and terms and conditions of CL. Under Section 87, when the controller is satisfied that the application for the grant of a CL or the revocation of the patent after the grant of CL has a prima facie merit, the applicant will have to serve copies of the application to the patentee and to advertise the application in the official gazette. The patentee or any other person may oppose the grant of the CL within the period specified by the controller, who can also extend the time. Thereafter the controller will decide on the case after hearing both sides. Any decision by the controller to grant a patent can be contested. Under Section 117 A, an appeal can be made to the Appellate Board. The applicant will be able to use the CL only if and after the Appellate Board turns down such appeals. The problem with the amended provisions is that the entire process is excessively legalistic and provides the patentees the opportunity to manipulate by litigation. The huge expenses involved in fighting the large pharmaceutical companies holding the patents may dissuade the non-patentees from applying for licenses in the first place. Chaudhuri suggests that there is enough justification to carry out further amendments to simplify the general provisions of CL in the Act to enlarge its use, such as listing the medicines eligible for CL in public health crises (inclusion of such drugs can not be a ground for opposition and appeal). For any drug in the public health list, the controller may immediately after receiving an application grant the CL, fixing a royalty rate using the royalty guidelines.

[6] Arguments in this and the following paragraph are drawn from Chaudhuri (2002).

4. FUTURE SCENARIO OF THE INDIAN PHARMACEUTICAL INDUSTRY

The above discussion highlights that the impact of IPR will largely depend on the developmental status of the economy such as the availability of technical manpower and infrastructure, capacity of the domestic industry, and so on. A country with a strong domestic industry such as India is in a relatively advantageous position than a country where domestic industry does not have much presence and depends on multinationals. It is true that the impending WTO regime has stimulated the R&D investment in India. Some of the big units have started strengthening their R&D and have also filed number of applications for patents. There is some evidence available regarding the mergers and amalgamations to pool the human and financial resources (CMIE, 2000) to strengthen the R&D in new product development. These firms will definitely benefit by the stronger protection. Some of the R&D and manufacturing facilities set up in these firms meet the international standards, and they have already been approached by multinationals for conducting research and undertaking manufacturing on their behalf. Besides the R&D investment in traditional chemical based screening, some of the R&D firms are looking for breakthroughs in biotechnology research. With TRIPS allowing the patenting of the living organisms, research in biotechnology is the latest buzzword in the Western pharmaceutical industry. Significant breakthroughs have already been made in the area of stem cells and cloning which have potential cure for some of the dreaded diseases like cancer, Parkinson disease, Alzheimer's and nervous disorders. Cloned animals have been patented and are being used for research purposes. The human genome project or the sequencing of DNA, which has already spent about $3 billion, will be highly beneficial for the pharmaceutical companies to identify the toxicity of the new drugs on different population or in knowing the reasons for prevalence of certain diseases in specific regions or communities.

In contrast to this, in India biotech research is concentrated in the areas of vaccines, diagnostics, molecular and cellular biology, cell culture, fermentation and hybridoma technology. Lalitha (2001) observes that some of the research based pharmaceutical firms have ventured into biotech research since the late '90s. Recombinant vaccines (for typhoid, rabies and hepatitis B), HIV 1&2 diagnostic test kit and gene probe test for TB are some of the important areas where research is being currently carried out. It is also observed that though simple diagnostic kits, were the first to arrive in the biotech market elsewhere, in India only a handful of companies are engaged in the production of TB diagnostic kit. Nevertheless, a few companies have developed technology in enzyme immobilization used for conversion in the synthesis of semi-synthetic penicillin like ampicilin and amoxcyline. In the case of DNA or r-DNA research, research is at a basic level, for two reasons. India does not recognize patenting living organisms and because of the moral and ethical issues concerning the human stem cells and embryonic research, R&D firms tread cautiously in this area. As part of trade liberalization though most of the drugs were delicensed yet, bulk drugs produced by the use of re-combinant DNA technology and bulk drugs requiring in vivo use of nucleic acid as the active principles and formulations based on use of specific cell or tissue targeted formulations shall continue to remain under compulsory licensing (Government of India, 2000). Also a committee set up under the Department of Biotechnology scrutinizes each research application concerning embryos and only embryos discarded in the fertility clinics can be utilized for research purposes. This area being highly research and resource intensive currently very few firms are engaged in this research.

Pharmaceutical outsourcing is increasing world over and it is expected that contract research and manufacturing would reach $6.4 and 22.5 billion respectively in 2001 (Scrip's Year Book, 2000). These figures could increase still more with the vertical disintegration of activities by the multinationals as they review their core competencies. Henceforth, R&D could take place in one country, manufacturing in another and marketing rights could be given to a totally different country. Domestic units with state of art facilities, infrastructure and manpower that matches the product profile of the multinationals would derive the maximum benefits. These units could flag off the foreign direct investment in manufacturing and R&D. This segment that has been able to export its products to both developed and developing countries (Table 3) can widen the market further in the universal patent regime provided the manufacturing practices and the quality standards match the standards at the export destination. While the medium and big units can adopt any of the or combination of strategies that were mentioned above, at present the future of the thousands of small units is not very clear. Under normal circumstances, units that are producing the generic drugs should not get affected because these drugs are not patent protected. But it is likely that, they may face competition from large producers who may compete on larger volume and lower cost of production. Evidence from Jordan indicate that the local industry had to suffer in terms of investment and production and a number of small local firms had to close their operations (Correa, 2000).

In order to increase the global prospects of the pharmaceutical industry in the post 2005 period, the Central Government has fixed the deadline of December 2003, to comply with the Good Manufacturing Practices set by World Health Organisation. Since this is mandatory for all the units, it means incurring expenditures that could range from Rs. 15 lakhs to 1 crore per unit. In some cases, it would involve shifting to new premises altogether. A few units might exit from business because of this. As contract manufacturers it is essential that both the parent unit and the loan licensee meet these requirements in cases where the production is meant for exports. While these standards improve the quality on par with international standards, it will also act as potential entry barriers for new firms to enter (Lalitha, 2002b).

The strength of the Indian pharmaceutical industry is in reverse engineering. Such units by utilising the provisions under compulsory licensing, exceptions to exclusive rights and the Bolar exception should aim at producing the generic version of the patented product and those that are nearing patent expiry. Such firms should also be engaged in research leading to new drug delivery mechanisms and in identifying new uses of existing drugs. In this context, it is also essential to protect the innovations that have been introduced by the technology spillovers. Evenson (in Siebeck et.al 1990) and Watal (1997) suggest that in order to develop domestic innovations, developing countries require utility models or petty patents. These petty patents can be available for a shorter period of time for process innovations made over an existing product. The TRIPS agreement leaves members to introduce such legislation, as there are no specific rules on this subject. Such patents will encourage the small firms.

One of the concerns regarding product patents is the access to patented products. Some of the provisions within the TRIPS agreement mentioned in the above paragraphs, clearly indicates that price controls could be imposed on the patented products. However, exemptions from price controls has been suggested by the government for the products that are produced domestically using the domestic R&D and resources and are patented in India. Such exemptions will keep the prices high and make access to the drugs difficult. It appears that `who patents the product' matters more for the government than what is patented. In the

recently concluded Doha meeting, a separate declaration on the TRIPS agreement has clarified that members have the right to grant compulsory licence in the area of pharmaceuticals and that they have the freedom to determine the ground upon which such licenses are granted (Economic Times, 21 November, 2001) which can have a considerable impact on the availability as well as on their prices. However, the amendments made by the Government of India, make the procedures very cumbersome which needs to be revised in the third amendment to the Patents Act. While parallel trade in pharmaceutical may facilitate access to medicine, yet compulsory licence will be the only course of option to facilitate flow of technology and R&D. Scherer and Watal (2001) suggest that tax concessions should be provided to the pharmaceutical manufacturers to encourage them to donate the high technology drugs to the less developed and developing countries which is a viable option.

A majority of the population does not have access to the essential medicines (most of which are off patent) either in the government or private health care systems because they are not within their capacity to reach. Now that the percentage of drugs under price control has been reduced drastically it is essential to keep the prices of the essential drugs under check, especially those concerning the common diseases.

Currently only a handful of pharmaceutical firms in India invest in R&D which needs to be improved. The Pharmaceutical Research and Development Committee (1999) has suggested that a mandatory collection and contribution of 1 per cent of MRP of all formulations sold within the country to a fund called pharmaceutical R&D support fund for attracting R&D towards high cost-low-return areas and be administered by the Drug Development Promotion Foundation. The domestic universities and other academic institutions can play the role of research boutiques or contract research organisations (CRO), which can supply the technical know-how and manpower. Units that already have such facilities can also function as a CRO for other firms.

In the post TRIPS era, the government will have to probe in to factors that contribute to the widening gap between the proposed FDI and the actual FDI and rectify these bottlenecks. Similarly the difference between the number of patents filed and the patents granted calls for a detailed analysis to figure out where the Indian firms are lacking.

Governments at various levels should take active part in disseminating knowledge about the IPRs and the possible strategies that can be adopted by the industry. This will remove some of the impediments. Lessons should be drawn from the Chinese experiences where systematic efforts were taken to educate the bureaucrats, policy makers and the industry about the WTO and product patents in the pharmaceutical industry. India will have to strengthen the patent examination process and speed up the processing procedures. This will help in checking the products that may enter the country utilising the import monopoly route provided by the EMR. Besides a strong institutional and judicial framework will have to be set up for monitoring the prices, to prevent infringement and trade dress cases of patented products respectively.

As far as India's pharmaceutical industry is concerned, various options are possible in the WTO regime. These are to: (a) manufacture off patented generic drugs, (b) produce patented drugs under compulsory licensing or cross licensing, (c) invest in R&D to engage in new product development, (d) produce patented and other drugs on contract basis, (e) explore the possibilities of new drug delivery mechanisms and alternative use of existing drugs, and (f) collaborate with multinationals to engage in R&D, clinical trials, product development or

marketing the patented product on a contract basis and so on. Besides these strategies, India's strength lies in process development skills. This expertise utilised within the WTO framework with emphasis on quality standards will provide India a competitive advantage over other Asian countries.

Table 1
Balance of Trade in Pharmaceutical Sector

(Rs. Crores)

Year	Exports of Drugs	Imports of Drugs	Balance of Trade
1960-61	1.55	17.60	-16.05
1965-66	3.80	13.80	-10.00
1970-71	8.46	24.27	-15.81
1973-74	37.33	34.16	3.17
1980-81	76.18	112.81	-36.63
1987-88	289.99	349.44	-59.75
1988-89	467.6	446.91	20.69
1989-90	856.8	652.12	204.68
1990-91	1254.6	604.0	650.6
1991-92	1489.5	807.38	682.12
1992-93	1541.5	1137.4	404.1
1993-94	1991.7	1440.0	551.7
1994-95	2465.3	1537.0	928.3
1995-96	3443.2	1867.0	1576.0
1996-97	4340.0	1039.2	3300.8
1997-98	5353.0	1447.1	3906.0
1998-99	6153.0	1446.8	4706.2
1999-00	6631.0	1502.0	5129.0

Sources: Pillai and Shah, 1988, Chaudhury, 1999, and 39th IDMA Annual Publication 2001.

Table 2

Investment in R&D by Public and Private Sector

(Rs. In lakhs)

Year	Public Sector	Private Sector
1972-73*	586.00	
1981-82*	2900.0	
1983-84*	4000.0	
1994-95	578.13 (0.89)	16002.68 (0.41)
1995-96	484.33 (1.07)	19388.69 (0.40)
1996-97	517.33 (1.42)	20238.13 (0.35)
1997-98*	22000	
1998-99*	26000	
1999-00*	32000 (2.0)	

Note: * break ups for public and private sector are not available. Figures within brackets indicate the percentage of R&D in sales turnover.

Source: Mehrotra (1989), Indian Pharmaceutical Industry an Overview; IDMA (2001), and Handbook of Industrial Policy and Statistics 2000, P 505

Table 3: Exports of Pharmaceutical Products from India*

Country	1995-96	1999-00
Total Exports	34432	66310
USA	4238	6718
Russia	3036	4932
Hong Kong	1919	3562
Germany	3418	3252
Nigeria	1199	2577
UK	1142	2568
Singapore	868	2452
Netherlands	1436	2192
Iran	634	1796
Brazil	170	1627
Italy	721	1514
Vietnam	885	1413
China	361	1371
Spain	765	1287
Srilanka	825	1242
* Total Exports to top 15 countries	21617	38503

Source: 39th IDMA Annual Publication, 2001

Table 4

Number of patents filed and granted to Residents and Non-Residents

	Applications for patents filed			Patents Granted		
Year	Residents	Non-residents	Total	Residents	Non residents	Total
1994	1588	3212	4800	448	1287	1735
1995	1545	5021	6566	415	1198	1613

1996	1660	6632	8292	359	661	1020
1997			10155			

Notes: Break ups are not available for the year 1997
Source: World Intellectual Property Organisation, Industrial Statistics, 1997

Table 5
Patent Applications by Units with R&D

Recognized R&D Units	Number of Applications
Panacea Biotec Ltd	95
Ranbaxy Laboratories Ltd	51
Lupin Laboratories Ltd	28
Cipla Ltd	26
Sun Pharmaceutical Industries Ltd	20
Tablets (India) Ltd	18
Hoechst Marion Roussel Ltd	17
Ajanta Pharma Ltd	15
Dr. Reddys Research Laboratories	14
Natural Remedies Private Ltd	13
Natco Pharma Ltd	12
Kopran Ltd	11

Source: Intellectual Property Rights, (IPR) Vol. 6. No.9, September 2000.

Table 6
Patent Applications Filed by Academic Institutions

Year	Universities and Others	IIT and IISc	School	Total
1995	4	31		35
1996	11	18		29
1997	23	15		38
1998	15	34	1	50
Total	53	98	1	152

Source: Intellectual Property Rights (IPR) Vol.5, No.8, August 1999.

Table 7
Foreign Direct Investment in India

(Rs. Crores)

Year	Amount Approved	Actual Inflow	FDI Approved in Pharma	% of Pharma FDI to total approvals
1991	534	351		
1992	3888	675		
1993	8859	1787	29.9	0.34
1994	14187	3289	163.0	1.15
1995	32072	6820	185.8	0.58
1996	30147	10389	118.2	0.33
1997	54891	16425	182.9	0.33
1998	30814	13340	91.1	0.30
1999	28367	16868	79.8	0.28
2000	37043	12763	1614.6	4.36
Total	246802	82707	2465.3	1.00

Source: Handbook of Industrial Policy and Statistics, 2000, Foreign Trade and Balance of Payments, CMIE, July 2001.

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