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India's Pharmaceutical Industry in the WTO Regime: A SWOT Analysis

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Abstract

A SWOT analysis of the Indian Pharmaceutical Industry (IPI) in the WTO regime reveals that the much acclaimed IPI's expertise in process development skills were made possible by the amendments made to the Indian Patents Act 1970. This strength should be utilized maximum to benefit from opportunities that arise from vertical disintegration of research, clinical trails and manufacturing by the multinationals. The weakness however lies in the fact that such opportunities will be limited to a few firms in this sector. IPI faces threats in the form of competition from other Asian giants particularly China which has similar expertise in process development and reverse engineering. This paper argues that the IPI should adopt various strategies like producing off patented products, new patented products by acquiring compulsory licensing or cross licensing, collaborate with multinationals not only in R&D and manufacturing but also in marketing new patented products and improving the standards of production to widen the export market.

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1. INTRODUCTION

The debate on intellectual property protection in the pharmaceutical sector has assumed significant importance because of its socio economic relevance especially among the developing economies. Realising that WTO regime is a reality, at least some of the developing countries are looking for means to improve the competitive advantage of this industry within the WTO framework, since the future growth of the pharmaceutical industry will be governed not only by the domestic business environment but will be shaped by the changing global scenario. In the knowledge based pharmaceutical industry where the technology becomes obsolete fast, the process of innovation however is long and expensive. The constant need to upgrade the technology in this field is met by the resource rich western world and hence they demand higher standards of protection for their innovations and products uniformly than that is currently prevalent among their trading partners. Such variations in the intellectual property protection standards result in counterfeit products and affect the trade interests. The Trade Related Intellectual Property Rights System (TRIPS) Agreement was born to protect the interests of the industry, trade and services. Whereas the higher standards of protection is relatively advantageous for the developed economies which are ahead of the developing economies in terms of innovations and research and development (R&D), among the developing economies it is less advantageous for those where the domestic industry is not very strong to invest in R&D to pursue new product development or process development skills. Among the developing countries those, which have a relatively well-developed domestic industry, would benefit by assessing the various options and adopt appropriate strategies to operate in the WTO regime. WTO regime is a reality and with only two more years left for 2005 which marks the end of the transitional period meant for initiating reforms, it would be advantageous to assess the situation before the pharmaceutical industry of a country like India which has almost completed a full circle adopting product and process patent regimes.

This paper presents the various options and strategies that are available before the Indian Pharmaceutical Industry (IPI) by assessing the Strengths, Weaknesses, Opportunities and Threats (SWOT analysis) in the context of the TRIPS Agreement. In doing so, Section 2 provides the evolution of the pharmaceutical industry in India. Section 3 discusses the minimum standards that the developing countries should provide for in the TRIPS Agreement and the implications of the same for the IPI. This section also presents the various strategies that are available for the pharmaceutical industry in the WTO regime. The various sub-sections of Section 4 present a SWOT analysis and the possible strategies that emerge from the SWOT analysis are also discussed in this section. Section 5 presents the summary.

2. THE EVOLUTION OF THE INDIAN PHARMACEUTICAL INDUSTRY

In India, modern system of medicine is a twentieth century phenomena, though the traditional system of medicine has been in practice for many centuries. Therefore, in discussing the evolution of the Indian Pharmaceutical Industry (IPI), three points of time are very relevant. These are: 1900-1970, 1970-1990 and the decade of 90s. The period 1900-1970 signifies the dominance of the multinationals in this field that were basically importing the bulk drugs and formulations from abroad. Most of the domestic manufacturers were engaged in repacking the formulations produced by the multinationals and production was concentrated in the hands of the multinationals. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in 1892, which was followed by the establishment of Alembic Chemical works in 1907 and Bengal Immunity in 1919. At this point in time, the Patents Act of 1911 was in practice, which facilitated patenting all the known and possible processes of manufacturing the said drug besides patenting the drug itself. Hence, the indigenous firms were legally prevented from manufacturing most of the new drugs introduced by the TNCs during the life of the patent secured by the latter, i.e. 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. The domestic firms were also forbidden from processing a patented drug into formulations or importing it. However, the Second World War and the introduction of sulpha drugs and penicillin gave impetus to the pharmaceutical industry. The policy instruments of independent India emphasised on creating a strong public sector unit. In the pharmaceutical front, specific areas of production were defined for the public, private and the

domestic sector, though the performance of the multinationals allowed them some leeway in the production of drugs reserved for other sectors also. The setting up of the public sector units and the technical institutes meant for creating technical skills in the country contributed to the growth of the domestic industry. By 1952, a few drugs like tetanus anti-toxin, PAS and Indocblorhydroxyquinoline were produced in India from their basic stages (Narayana, PL, 1983: 39). However, the import content of the basic drugs was high due to which the prices of the pharmaceutical products of India were the highest in the world.

The second period of 1970-1990 is very significant for the IPI since, a few important changes that had implications on the growth of the IPI took place during this time. The Patent Act of 1911 was amended in 1970 that came into force in 1972. The 1970 Patent Act provides protection for the processes of manufacturing the drug for 7 years from the date of filing the application or 5 years from the date of the grant of the patent. Under this Act, only one process that was used in the actual manufacturing could be patented. This change brought a renaissance to the pharmaceutical industry of India. More units larger in size and capacity set up in the '70s and '80s started producing drugs, which were primarily imported till then. The technical institutes that were set up in the early '50s and 60s resulted in creating technical and engineering skills, which could easily adapt the technology developed elsewhere proved to be very advantageous for the industry. By 1972, over 100 essential drugs covering a wide spectrum of therapeutic groups like antibiotics, sulpha drugs, anti leprotic drugs, analgesics, antipyretics, vitamins, tranquillisers, photochemical and various other pharmaceutical chemicals were produced in India from basic stages (Narayana, 1983:42). As Table 1 reports, a significant increase in the production of bulk drugs and formulations is observed before and after the '70s.

In the early '70s, the government introduced the Monopolies and Restrictive Trade Practices Act and the Foreign Exchange Regulation Act, which aimed at reducing the concentration of economic power with few units and controlling the flight of foreign exchange from the country. Basically units, which were not bringing in any new technology were asked to reduce their foreign equity and renewal of their license was also subject to their bringing in new technology. This resulted in the dilution of the foreign equity, which is reported in Table 2. As a strategy to protect the domestic industry from competition, the FERA companies were also not permitted to produce a list of drugs, which were delicensed during the '80s.

In the '90s, several significant changes occurred in the pharmaceutical sector with the introduction of trade liberalisation measures. All those drugs, which were reserved for the production by the public sector, were delicened in two stages[1]. One immediate impact of this delicensing of the drugs was that production increased manifold as is evident from Table 1 besides increasing the competition among the domestic firms and from foreign companies in the '90s. The increased production had a positive impact on exports and on the balance of trade (Table 3**).** Of the exported drugs, formulations account for a higher percentage and in imports bulk drugs account for a larger share. Exports were also spread to develop and developing countries (Table 4). The government also increased the automatic approval limit for foreign direct investment in the pharmaceutical industry from 40 percent to 51 per cent. This was subsequently increased to 74 per cent in 1997. In 1994, Government of India signed the TRIPS Agreement (elaborated in Section 3).

The delicensing of the drugs and the policy of the government to allow sub-contracting or loan licensing[2] system resulted in an uneven growth of the domestic pharmaceutical industry. Though there are no official statistics that tells the exact volume of production by the loan licensees, according to the industry sources, about 70 percent of the production in the pharmaceutical sector is contributed by loan licensees. As of 2000, it is estimated that the total number of units engaged in the production of pharmaceutical units is 24, 000 (including that of loan licensees). Out of which 1.25 per cent or 300 belong to the organised sector and 23, 700 belong to the small and medium sector (GITCO, 2000). It is estimated that out of this 300 units only a few units will have the R&D facilities that is recognised by the Department of Science and Technology (DST), while most others have sophisticated quality control laboratories, some of which even

1. 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).

2. Loan licensing refers to the system of getting the product produced in a unit or units other than the parent unit. The parent unit provides the materials and sets the quality standards. This system enables the parent unit to cut down some of the establishment costs and for the loan licensee it covers the overhead charges and saves the trouble of marketing.

match the international standards[3]. Most of the firms are engaged in the production of finished formulations that are in the off patent segment. Lack of adequate funds for modernisation, increased competition from the private sector and high cost of production resulted in the decline of the public sector in the '90s. With the decline in the public sector, the investment in R&D also declined from this sector (Table 5). This Table also reports that R&D, as percentage of sales turnover was hardly 2 per cent, which indicates that the percapita R&D expenditure by the firm is extremely low. Direct employment provided by the organised industry and the small-scale sector is estimated at 2,90,000 and 1,70,000 respectively in 1999. The indirect employment created in the ancillary industry and in distribution trade is estimated to be 24,00,000 (PERD, 2000). 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 USA, Japan, Europe and China in terms of volume of production.

The above paragraph in nutshell highlights the heterogeneous nature of the pharmaceutical firms where a handful of firms are engaged in R&D. Thus, we have a small percentage of manufacturers who have the capacity to invest in R&D, while majority of the firms are engaged in the production of off patent drugs and are functioning as contract manufacturers. A cursory glance over the growth of the IPI presented in Tables 1 &3 demonstrates that much of the capacities in the IPI have taken place after the amendment to the Patent Act was made in 1970. In the following section, the broad implications of the TRIPS Agreement for the IPI are presented.

3. IMPLICATIONS OF THE TRIPS AGREEMENT

Prior to the TRIPS Agreement, the intellectual property rights concerning the trade (that included patents, utility models, trade marks and industrial designs) were governed by the Paris Convention of 1883, which was revised up to 1967. The Paris Convention was fairly liberal and left the subject matter of patent, terms of patent and the duration of protection to be decided by the concerned national governments. Thus maximum divergence was observed in the case of

3. The Department of Science and Technology (DST) lays down certain conditions to be qualified for a DST recognized R&D unit. Those, which do not satisfy these conditions, may be classified under quality control laboratories. Hence, there could be under estimation of the investment made in R&D.

the pharmaceutical sector (Lalitha, 2001) where some countries protected the end product while many countries protected only the process of manufacturing and some chose to protect neither.

With the increase in trade and scientific innovations, trade in counterfeit products started increasing, affecting the trade interests of the developed countries. In 1984, Section 301 of the US Trade Act of 1974 was amended which gave the President of the US, the power to impose trade sanctions on those countries where inadequate intellectual property protection to the goods of the US origin prevailed. Brazil, Argentina and Korea were the worst hit with 100 per cent duty imposed on their products that were exported to the US. India also bore the brunt of the situation. This lead to seven years of negotiation (1986 to 1993) between the developed and the developing countries regarding the subject matter and the type of protection not only for industrial products but also for agriculture and trade and services. Thus the Uruguay Round of Agreement on Trade Related Intellectual Property Rights with a much-enhanced scope was born. In the Uruguay Round, the scope of the TRIPS Agreement was widened to cover patents, copyrights and related rights, geographical indicators, industrial designs and protection of undisclosed information. The World Trade Organisation (WTO) was set up in 1995, which replaces the earlier General Agreement on Tariff and Trade. WTO is the implementing authority of the TRIPS Agreement.

The minimum standards mentioned in the TRIPS Agreement that have immense implications for the developing countries are:

(a) Patents shall be granted for any inventions, whether products or processes, provided they are new, involve an inventive step and are capable of industrial application.

(b) Patents shall be granted in all fields of technology. No discrimination is allowed with respect to the place of the invention, or based on whether the products are locally produced or imported.

(c) Diagnostic, therapeutic and surgical methods of treatment for humans or animals, as well as plants and animals and essentially biological processes for the production thereof can be excluded from patents by the member countries.

(d) Patents, an effective Sui Generis regime or a combination of both, shall protect plant varieties.

(e) Exclusive rights conferred in the case of product and process patents are defined, subject to the principle of exhaustion in the case of imports. Inventions shall be disclosed in a manner, which is sufficiently clear and complete for a skilled person in the art to carry out the invention. Indication of the best mode of carrying out the invention, as well as information concerning corresponding patent applications and grants may be required.

(f) National laws can define limited exceptions to the exclusive rights.

(g) Member countries can determine the grounds to allow conditions for granting compulsory licenses without the authorization of the patent-holder besides those that have already been set forth.

(h) Revocation/forfeiture is subject to judicial review.

(i) The term of protection shall be at least 20 years from the date of application.

(j) Reversal of the burden of proof in civil proceedings relating to infringement of process patents is to be established in certain cases.

Source: Correa, (2000).

In simple terms, the implications of these standards for India and similar developing countries particularly in the pharmaceutical sector are that: patents will be granted both for products and processes for all the inventions in all fields of technology, which includes the pharmaceutical sector (where only the process of manufacturing a drug was protected under the Patent Act of 1970); 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 unauthorised 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.

India as a signatory to the TRIPS Agreement will have to amend the existing patent laws to provide for product patents in the pharmaceutical sector. In all areas, other than the food, drugs and chemicals the standards of protection in India is on par with the other countries. In order to implement the policy changes, India has been allowed a transition period that will end on January 2005. Already Patent law amendment[4] has been made in 1999 to accept the product patents applications from 1995 and to provide exclusive marketing rights (EMR) in India for a period of five years or till the grant of the patent (whichever is shorter) for products of other WTO member countries.

The exclusive marketing rights allows the patent holder who has obtained the marketing rights in another member country to sell his products in India for five years or till the patent rights are sanctioned whichever is earlier. So even if the Indian patent office takes time to process a particular application, if a said product has been sanctioned patent or marketing rights in another WTO member country, then that product can be sold in India till the time of grant and will enjoy the status of a patented product.

World wide, no conclusive evidence is available from the experience of other countries on the impact of product patents since, many countries adopted product patents in the mid '80s or in the '90s, and hence there are varied opinions about the probable impact of the product patents on the pharmaceutical industry and on the general public. Within India, based on the experience of the 1911 Patent Act and the development achieved after the adoption of the 1970 Patent Act, mixed reaction prevail within the industry about the product patents in the WTO regime. One segment of the industry is strictly against the product patent system since the monopoly status to a few will restrict the competition and adversely affect the growth of the industry. In R&D and new product development the MNC's dominance will invariably increase since less than 1 per cent of the IPI invests in R&D. Further, the long protection period will restrict the technology development in the industry. Also the monopoly status will lead to increasing the prices of the products by manifold. The increased competition from domestic and multinationals will lead to the exit of firms especially in the small-scale sector affecting the employment. In contrast, the other segment of the industry views that product patents will help in bringing new investment, technology, R&D and

4. In May 2002, the bill concerning the product patents was passed in the Upper House of the Parliament.

new medicines. Besides, there is a section of the academicians and intellectuals who forewarn that product patents will make the Indian industry depend on the multinationals and because of the monopoly impact on the prices, drugs will be inaccessible to majority of the population. Nevertheless, there is also an emerging argument that TRIPS do allow some level of flexibility and a right mix of the TRIPS along with the existing policy guidelines will be favourable for the host country (Watal, 2001, Cullet, 2001).

With this background, in the following paragraphs, the various options that are available to the pharmaceutical industry in the new patent regime are discussed. These options/strategies are not mutually exclusive and a unit may be exercising more than one option or combination of strategies depending on its capacities and resources.

3.1 R&D and New Product Development

In the WTO regime, units that invest in R&D and patent their innovations are in an absolute advantageous position over others. Invariably, western firms with a higher rate of innovations will be in a better position to introduce their products in all the WTO member countries without the fear of their products being duplicated. The long protection period also ensures that such firms will benefit by way of royalties, licensing fees, technology transfer fee and the advantage of being a monopoly to reap the benefits of large investments made in R&D.

Besides the investment in R&D, the direction of these investments is also important. Currently, research interests in the West are in developing new drug delivery systems (NDDS) of the existing and new medicines and biotech products. NDDS is the process of modifying the delivery of the drug once it is consumed. In the traditional delivery systems, this aspect was not given adequate care with the effect the impact of the drug increases rapidly on taking the drug and declines rapidly within a brief period of time. This leads to longer use of the drug and adverse side effects of the drugs to humans. The NDDS addresses this issue of the sustained release of the drug in the body for effective diffusion of the drug in controlling the disease. For instance, research is going on in making the insulin available in the form of a spray than as a shot.

With the TRIPS allowing the patenting of living organisms, research in biotechnology and gene therapy is the latest buzzword for the pharmaceutical industry of the West. 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. Besides these emerging areas, anticancer research and cardiovascular diseases have been the main focus of research of the pharmaceutical firms. Leading pharmaceutical companies of the West are engaged in research that concerns breast cancer, followed by prostate cancer, melanoma, ovarian cancer and leukaemia. There were 1,422 anti cancer projects in development by the world wide pharmaceutical industry in May 1999. However, the third world diseases such as malaria, chagas disease, tetanus, and lymphatic filariasis have so far not attracted the developed countries' attention.

There are different options available for firms engaged in new product development. Besides the lucrative option of benefiting by the first mover advantage, products that are the results of subsequent research on the patented product can be cross-licensed. If the subsequent product by itself becomes a standalone product, then the firm has the option to develop it further or selling it to some other firm to save the costs in clinical trials. For firms, which have already invested in the R&D, the WTO regime opens out more opportunities to enter into collaboration with other manufacturers for R&D, technology and manufacture or for marketing. Firms in developing countries can also obtain exclusive marketing rights for the patented product in other countries. The uniform patents also facilitate protection in other countries simultaneously. Hence, even if some countries have reservations in patenting living organisms, such patents can be sought elsewhere. The other option, which is common in the West and is also emerging in the developing countries including India, is the option of mergers or amalgamations which will give the advantage of pooling the financial resources and gaining strength in R&D besides avoiding duplication of research.

3.2 Contract Research or Manufacture

Globally there is a trend towards outsourcing or contracting research or manufacturing especially by the firms in the developed countries as these firms review their core competencies and seek to cut their in-house fixed costs. Such disintegration of research and manufacturing has increased the amount spent on contract research and manufacturing from $4.8 billion to $ 6.4 billion (Table 6), and $19.4 billion to $ 22.5 billion respectively (Scrips Year Book). As vertical disintegration of the process of drug manufacturing takes place, research and development on a molecule could take place in one country, clinical trails in another and the final manufacturing or parts of that in a third country while the rights to market could be given to a different country altogether. Such disintegration which reduces the cost of the total drug development though offers tremendous scope for contract research and manufacturing in the developing economies, yet depends on factors such as the host country's business policy and environment, infrastructure and skills available, location of R&D, and the quantum of foreign direct investment set aside for contract research or manufacturing.

In the Western countries, contract research organisations (CROs) are engaged in the preliminary investigations on a molecule and once the potential of the molecule is identified, they are sold to pharmaceutical companies, which develop it into a commercial product. A significant advantage for these CROs is that they are backed by sound venture capital finance schemes, which support such research activities. Therefore, one of the options for IPI would be to develop capacities that will serve as a CRO and efforts in pooling the research done in college of pharmacies, academic institutions and universities, besides research directions may also be evolved to suit the prevailing needs of the industry and society.

It is true that all R&D efforts do not and may not necessarily result in new products and innovations. Generally firms tend to be secretive about the R&D direction and details, which leads to duplication of research. As a result, many new products that were introduced in the US were also not innovative in nature and hence were not eligible for patenting (Lanjouw, 1998 and Lu and Comanor, 1998). Considering the risks involved in the new product development and the high attrition rates in various research stages and clinical trials it may be advantageous for firms to utilise its resources to work as a contract researcher or

contract manufacturer either for a domestic firm or for a multinational. Such contract manufacturing activities can be undertaken only if the line of research or chosen drug is closest to a firm's research or process or manufacturing capabilities. More importantly in order to become a contract researcher or a contract manufacturer, it is essential that the units have the right type of infrastructure and facilities and meet certain international standards set for research or manufacturing practices.

3.3 Patented Products and Compulsory Licensing

Recent interpretations of the various articles of the TRIPS Agreement (Watal, 2001, Cullet, 2001) suggest that flexibility is available within the framework of the TRIPS Agreement for the developing countries to have access to the patented products. Article 30 of the TRIPS Agreement 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 bonafide 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). The 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 option to get access to the patented product is through the issuance of compulsory licenses (CL). CL is the authorisation issued by the government permitting a third party to make, use or sell a patented invention without the patent owners consent. Circumstances of national emergency or extreme urgency, unsuccessful negotiations to get license for the patented product could be some of the reasons for exercising this option, though the user must pay adequate remuneration to the patent holder. Countries like the US, UK and

Canada have utilised this option very frequently. Particularly, the US has issued CL to restrict the violations of anti trust laws. The tranquilliser meprobamate, synthetic steroids, the antibiotic griseofulvin, cytokine biopharmaceutical patents owned by Novartis and Chiron, and the 9-AC cancer drug patent rights assembled under the merger of Pharmacia AB with Upjohn are all examples of utilising the CL. These options can be best exercised by firms, which have (a) expertise in process development, (b) adequate infrastructure and (c) expertise to develop technologies without the help of the patent holder to produce the licensed drug. If such capacities are not present in the domestic firms then the CL will be useful only to import. Use of CL or Bolar exception however calls for compensating the patent holder through royalties, the percentage of which could be fixed mutually or legally.

3.4 Production of Drugs Using the Process Capabilities

For firms, which are not able to get the CL for some reasons, the option would be to develop a product much around the original invention. Also since, most innovations are developed on the earlier innovations, firms that can reverse engineer the patented product can cross license the product that is subsequently `developed'. Strategically these firms are better placed since at the end of the patent term, they can enter the market with their generic version. This option is best suited for firms, which have already developed technical capacities to reverse engineer a product. Such firms have an important role in inducing competition and reducing the price. Though such `inventions' do require investment in R&D to adapt the technology, yet the investments are not huge like in the case of the first innovator. Some of the countries like India, China, Brazil and Korea have developed such capabilities. However, this processing skills or reverse engineering cannot be exercised on patents obtained after 2005, except in the case of CL or other exceptions. In countries like India and China, reverse engineering has been carried by a few firms, which have the resources to invest in technology and manpower. However, products that were patented before 1995 can still be produced through reverse engineering and such products can be sold in markets where they are not protected. As an alternative, firms will have to keep tab of products where the patent protection will be expiring soon.

Skills in process development could also be used in developing new drug delivery mechanisms which has larger potentials and are very much required to combat diseases like the tuberculosis, where the long duration of the treatment

and the side effects of the drugs force the vulnerable patients to discontinue the treatment which results in increasing the incidence of the disease.

3.5 Production of Off Patented Products

For firms with inadequate resources to venture in to new drug development, the safe option would be to produce drugs that are off patent or to produce the essential drugs, which are specified for developing countries and are much in demand. Most of the drugs are short in supply, but the technology to produce such drugs however is already available among the producers. Given the fact that many of the developing countries do not have adequate production facilities, production of essential and off patent drugs by units with standard production facilities will open up a wider generic market. Adopting this strategy will ensure that the production, peoples' access to medicine and employment in the industry are not unduly affected in the WTO regime.

It emerges from the options above that a firm with resources to invest in R&D can engage either in new product development or in new drug delivery systems. Such firms may also be engaged in process development of patented drugs though CL or other options or finding the alternative use of existing drugs. Firms, which do not have such resources to go for new product development or NDDS, can function as contract researcher or manufacturer. For firms operating with limited resources, the generic market is a safe option. The various options mentioned above lead us to a SWOT analysis, which is presented in the following paragraphs.

4. STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS OF THE INDIAN PHARMACEUTICAL INDUSTRY

4.1 Strengths of the Pharmaceutical Industry of India

The large volume of production capacities is one of the basic advantages of the Indian industry contributed by the big and small producers, resulting in close competition and relatively low prices of the drugs compared to other countries, much due to the Patent Act of 1970. Though a sizeable percentage is engaged in the production of formulations, yet the production capabilities in the research-intensive bulk drugs are also increasing (Table 1). Even in the early '80s the Indian industry (both public and private) introduced technology to produce 79

bulk drugs, whereas the multinationals introduced technology to produce 38 bulk drugs only (Mehrotra, 1989). Importantly, besides producing drugs that are off patent, the domestic industry has also developed expertise in process capabilities to produce drugs that are still on patents.

Process Development Skills As evident from Table 7, some of the patented drugs have been introduced in India within a period of five or six years when the patent protection on those products was effective elsewhere. In the case of Ranitidine and Ciprofloxacin there were 30 and 51 producers in the year 1996 when the patent protection was still effective and these firms were also exporting to countries where this drug has not been patent protected. The most successful strategy so far adopted by the IPI is to develop the indigenous version around the original product, which becomes a close substitute to the patented product. Once a close substitute to the patented product arrives in the market many producers follow the suit resulting in reduction in the price, which happened in the case of amoxycilin and ranitidine. Another interesting case of utilisation of the weaker patent regime is the case of `viagra' (sildenafil citrate) introduced by Pfizer. A patent for this drug was granted by the US patent office to Pfizer in 1993. Thanks to the advances made in information technology due to which the US patent records and industry literature are readily available, the Indian firms could produce the indigenous version of the product within weeks for a fraction of costs, what apparently took Pfizer 13 years and million of dollars in R&D to perfect. Currently six brands of sildenafil citrate are sold in India with a suffix GRA. Besides the process patent regime, the other advantage that worked in favour of the industry in this product was that out of the 30 raw materials used in this drug, 26 are available locally. Because of these reasons, Pfizer is not going to `introduce' this product in India, though it might sue the Indian companies for copyright violations and using their trade dress. Such tremendous expertise demonstrated by the Indian firms also proved to restrain the MNCs from introducing their products in India (Lanjouw 1998, Basant, 2000) for the fear of facing competition from counterfeit products.

The capacity to develop new products through process developments is also evident from the fact that during the last quarter of October-December 2001 alone, pharmaceutical companies in India launched 330 new products (Times of India, March 13, 2002). Table 8 presents the list of companies, which have filed more than 10 patent applications in the last five years. A sizeable percentage of them could be for the processes developed. A single firm viz. Dr. Reddy's

Laboratories alone has filed 40 and 12 process patents applications in the US in the area of diabetics and cancers. Such evidences clearly indicate that process development skills are higher than the product development skills for the Indian firms.

Lower Prices of Drugs Watal's (1997) study demonstrates that because of the large number of producers with expertise in process capabilities, new products did not have the `first mover advantage' or enjoyed it only for a limited period of time. Therefore, price reduces after the entry of competition. Besides the competition, the relatively lower prices of cost of production, materials and skilled labour compared to other countries have resulted in the lower prices of the drugs, which is an obvious advantage for the Indian firms. It has been feared that this advantage would be lost with the adoption of product patents (Keayla 1994, Sengupta 1998, Agrawal and Saibaba, 2001). It may be recalled that in the recent case of supplying anti-AIDS drugs to South Africa, the price quoted by the Indian firm was the lowest at $350 per year per person compared to the $1679 quoted by the multinationals. The price advantage of the IPI would provide an edge over the others in exploring the export markets.

Some of the Indian firms are strengthening their production capacities to enter the world generic market in the WTO regime. For instance, Dr. Reddy's Laboratories has signed an agreement to acquire the UK based BMS laboratories and Meridian Health Care Ltd, a wholly owned subsidiary of BMS Labs. BMS is manufacturing and marketing generic drugs in the UK. This acquisition will pave way for Dr. Reddys entry in the Rs. 6070 crore UK generic markets.

Already, Indian pharmaceutical firms have entered the global market. As shown in Tables 3&4, the exports are increasing and importantly, exports have their share in the NAFTA, EC and OECD countries also, which indicates that a certain percentage of the Indian drug products already meet the international quality standards. With the Drug Controller General of India making the `Good Manufacturing Practices' mandatory for all the units by December 2003, there will be more units, which will be able to meet the international standards of quality and widen their export market in the developed countries.

4.2 Weaknesses

Low Level of R&D It should be admitted that the process patents which enabled the Indian firms to produce a `new' product without much investment in R&D has brought in a sense of complacency about their performance (Lalitha, 2001) among the pharmaceutical firms. Many pharmaceutical firms in India rely completely on the spill over benefit of the R&D undertaken by few units in the industry. In India, prior to the '90s, the government R&D was much higher than the private R&D (Bowander, 1998). But due to poor linkages between research laboratories and industry, utilisation of such research and research infrastructure facilities have remained at low level. This scenario changed in the '90s. 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. Further, of the 161 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). Obviously, the percapita R&D expenditure suggests that much of the investment is perhaps going towards reverse engineering rather than towards new product development. Despite the small number of units engaged in R&D, the real R&D expenditures in the pharmaceutical sector increased at a higher rate during the '90s than during the '80s. For instance, R&D, which increased at the rate of 7.6, 8.2 per cent during 1974-80 and 1980-86, declined to zero in 1986-91. Though this improved to 14 per cent during 1991-95, making the overall growth rate during 1974-95 at 7.2 per cent, yet the R&D to sales ratio of the pharmaceutical industry was stagnating around 1.37 per cent during 1991-1994 (Basant, 2000). This low investment in R&D is reflected in the lower number of patents filed by and granted for the residents compared to the non-residents in India (Table 9). As far as the Patent Cooperation Treaty (PCT facilitates patenting in several countries with single application) India is nowhere near Korea or even China. (PCT applications by Korean individuals and companies have increased from a mere 84 in 1992 to 1573 in 2000. According to the World Intellectual Property Organisations PCT statistics, Korea accounts for 46.1 per cent of the PCT applications filed in the Asian region with over 700 applications and India has filed about 168 PCT applications). The huge cost involved in patenting and subsequent fees to make the patent protection effective during the protection term and the huge fees involved in PCT even after the subsidy provided for developing country members also may subdue the firms' enthusiasm

to file patents and rather make it advantageous to sell the invention to other firms for further development.

Lack of popularity of the contract research organisations is one of the reasons for the low R&D in India. In India, though a small number of firms are specifically undertaking research on contract basis, the concept of contract research organisation has not yet become popular due to (a) the fear of the competitor gaining knowledge about the strategies of the said firm and (b) lack of funds from sources other than the parent firm to support new ideas in research.

Stagnant Foreign Direct Investment

The introduction of the MRTP Act and the FERA reduced the level of foreign direct investment (FDI) in the pharmaceutical sector in the '80s. However, with the adoption of trade liberalisation measures, the limit for automatic approval of FDI was first raised from 40 to 51 per cent and subsequently to 74 per cent and in 2001 it was raised to 100 per cent. However, in spite of measures like increasing the ceiling limit for FDI, decontrolling of the drugs, opening up the sector for competition and significant measures that indicate the adoption of WTO regime etc, the FDI has not increased substantially, though in the earlier years these measures had a role in improving the FDI (Table 10). Table 10 also indicates that there is a vast difference between the FDI approved and the actual inflow. Most of the indicators mentioned in this Table have declined in the year 1998. In the year 2000, the FDI approved stands at Rs. 1614.6 crores, which could perhaps be the industry's response to the delicensing of the five bulk drugs, increasing the FDI limit and the amendment in the patent law to provide for the mailbox and the EMR, but the general decline in the FDI could be due to the recession that had set in worldwide. Table 11 reports that there has been a decline in the FDI investment in the developing countries since 1997 and the percentage of India's share had also declined from 2 per cent in 1995 to 1.2 per cent in 1999. In the case of pharmaceuticals, wide fluctuations are observed in the approved FDI and therefore actual inflow could also be different. However, the relatively small improvements in the number of foreign collaborations over the initial years and the decline from 1995 (Table 11) perhaps indicate that the foreign investors are currently interested in consolidating their position rather than going for collaborations. There was also some evidence of firms trying to consolidate their position by going for mergers and acquisitions. Out of the total 252 mergers and 145 acquisitions between 1991-97, pharmaceuticals accounted

for 5.2 and 8.3 per cent respectively. Yet the ones that increase technology or the so-called green field investments were few (Basant, 2000).

Lack of Initiatives in New Product Development

The low level of R&D obviously shows that new product development is obviously not the interest of the pharma majors of India, though some are taking efforts to step up investment in this direction. In the emerging field of biotechnology, industry's interest is in the field of molecular and cellular biology, tissue culture etc. A survey of Indian patents in bio-technology during 1972-1988 carried out for the department of biotech and subsequently updated till 1991 showed that patenting in biotechnology is foreign dominated with nearly 75 per cent of the patents owned by foreigners. The trend continues to be the same a decade later. Predominantly, patents related to the pharmaceutical sector cover processes for the preparation of antibiotics, vitamins, enzymes, antibodies and vaccines.

Besides the number of vaccines that are available, the number of biotech products in the market is very less. 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. The effort, which may have industrial applicability, is nowhere near commercialization. One reason for the slow pace of research in this field is while the process of invention in the BT field is difficult and a long drawn process, copying such techniques is relatively easy. Hence, in the absence of product patents companies have been reluctant to commercialize their products (Lanjouw, 2000).

Insufficient Institutional Infrastructure

Currently, processing of patent applications in the Indian patent office (IPO) takes a minimum of four to five years. Industry sources point out that the lack of technical manpower at the IPOs create hassles in the filing of the application itself and this could lead to further delay at the stage of collecting evidence on prior art to establish the novelty of the product. Delays in processing the patent

applications could be to India's disadvantage especially in the context of the fact that no other country but for India and Argentina have accepted to provide `Exclusive Marketing Rights' for products patented elsewhere. While the TRIPS Agreement is silent on the scope and effects of EMRs, it specifies the conditions under which EMR can be granted that are mentioned below.

(a) A patent application has been filed in a WTO member country (host country) after the entry into force of the TRIPS Agreement (i.e. 1 January 1995);

(b) A patent application has been filed for and granted in another WTO member after the afore stated date;

(c) Marketing approval has been obtained for such a product in the said other WTO member and

(d) Marketing approval has been obtained in the host country. (Watal, 2001, P119).

If these conditions are met, then a patentee will have to be granted EMR for a period of five years or till the patent is granted or rejected whichever is shorter. Since India has accepted to provide for EMRs, it implies that if the processing of an application takes longer time, till then a product can make use of the monopoly marketing rights. In the case of Argentina, the Argentine patent office confirmed EMR on a US company, and later it was found that the patent application of the said product 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). It is possible many products can gain entry in the country using this route. Therefore, it is essential that our patent processing system should be equipped with the necessary manpower and infrastructure to expedite the processing.

The other weakness is that lack of understanding of the various clauses under the TRIPS Agreement among the industry members. First and foremost it has to be recognised that the TRIPS agreement is not against measures taken to protect the interests of the common public. In fact, Article 8 of the TRIPS agreement permits WTO members to take appropriate measures consistent with the other provisions of TRIPS to enhance public or national interest including measures to prevent abuse or resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology. Implicitly, the

national governments can suitably introduce changes in their laws which will check anti competitive practices that prevent access to medicines by public, or technology transfer, unwarranted price increases etc. Secondly, industry circles argue that treating the imports as equivalent to domestic production will lead to exploitation of the consumers and restrict the competition. 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. Watal (2001) argues that 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). These arguments make it clear that it requires complete understanding and proper interpretation of the different clauses of the TRIPS agreement to utilise the flexibility available. In this context, India unlike China has not considered the utility patents that are granted for small innovations for a limited period of time. Given the process capabilities of India, utility patents will serve by increasing the resources and boost the innovation capacity of the small and medium firms, which cannot go for patents.

Quality Standards

While the uniform patent regime opens up the trade opportunities for the Indian firms yet, sustaining the same will entirely depend on the quality of the products that are being exported. Yet adoption of certain international quality standards will be necessary sans which registration will not be available on such products in developed countries. Though, the quality of the products will have to be improved not only for the sake of the global market but also in the interests of the domestic consumers. Whereas the companies with larger turnovers and research facilities have already adhered to the good laboratory practices and good manufacturing practices set by the World Health Organisation, yet the level of adherence at the small-scale units level which are large in number is low and

causes concern because as a contract manufacturer they play an important role in the production. Therefore lack of standards at the small units level could affect the export opportunities of the parent units too. Adherence to these quality standards will cost anything between Rs.30 lakhs to Rs. 1 crore for a small-scale unit and in certain cases, it may necessitate setting up operations in new premises altogether. Units which cannot incur these expenditures and upgrade their standards will have to exit from business. In the case of ciprofloxain an antibiotic that was discussed much during the anthrax scare it came to light that though there are more than 70 firms engaged in the production of the said drug in India, yet only two firms had the chance to export to US since only these two met the necessary quality standards of the US.

4.3 Opportunities

Emerging Biotech Research

Biotech research in India is an emerging field. Unlike the West where stem cells, cloning and genome dominate the research scenario, 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 carried out. A firm based in Gujarat has also successfully commercialized an anti-leprosy vaccine. However, the following evidences indicate that biotechnology based research and drug development will soon become popular. Reliance Life Sciences in Mumbai and the National Institute of Biological sciences in Bangalore are the two research organisations identified in India by the US National Institute of Health to receive state funding from the US for doing stem cell research and they will also supply embryonic stem cells for researchers in the US. Reliance Life Sciences has also obtained a provisional US patent in the area of embryonic stem cells recently. The patent application covers a novel method of isolation of inner cell mass (IPR, September 2001).

The Pune based Ruby Hall Clinic and the Dutch Biotech major Mesibo have signed a Memorandum of Understanding to do research on stem cells extracted from the umbilical cord blood. This will provide cost effective treatment in

Talassemia, which occurs in India. Besides this, it is also expected to have cure for Alzheimer's disease and Parkinson's disease. The stem cells taken from the umbilical cord blood were used in two surgeries on patients suffering from Parkinson's disease and thalassemia disease. The Ahmedabad based Pharmaceutical Education for Research and Development (PERD) has opened a biotech unit to provide research facilities for small and medium units, which do not have such facilities.

Further, the research in biotechnology is also opening up new opportunities in `biometrics' where raw clinical data are transmitted to India to be evaluated by teams of specialists. India's advantage has been that it has vast pool of medical professionals who have clear advantage in terms of language over their counterparts in some of the neighbouring nations. Indian software professionals are also helping the biotech field by developing softwares needed to understand the medical secrets of the human genome (Jesse, 2001). The other important area where information technology could play a significant role for IPI is in e-commerce, which will widen the generic market.

Collaboration Between Industry and Academia

At present, the industry -university collaboration is at its nascent stage in India. Though in some regions common research facilities do exist, yet the knowledge about such facilities is not widely spread and limited to a few big firms who in any case do not utilise them (Lalitha, 2001). In the Western countries, close collaboration exists between the industry and academic institutes, where the academic institutes serve the role of research boutiques. However, the proposed WTO regime has also stimulated the research institutes to file patent applications. Between 1995 and 1998, academic institutions have filed 152 applications. Of this, the various IITs and Indian Institute of Science have filed 98 applications (IPR, 1999). Therefore, an effective collaboration between the industry and the academia will ensure that available research talents are well utilised benefiting both. The research done by the CSIR, college of pharmacies and the universities are also the existing sources of avenues for collaboration.

Process Development Skills

The Indian pharmaceutical industry should make the most of the advancements made in the information technology to scout for manufacturing and research

alliances world over to take advantage of the outsourcing of research and manufacturing that is taking place because of vertical disintegration of these activities in major pharma firms globally.

The expertise in process development should be fully made use of by utilising the flexibility that is available under the TRIPS framework such as the CL on some of the new drugs and delivery systems that are being researched. Very recently researchers have finished sequencing the malaria parasite `plasmodium falciparum' (Maher, 2002). This project started in 1996 at the Institute for Genomic Research (TIGR) in Rockville, MD is expected to publish its findings in summer 2002. Malaria afflicts 300-500 million people and kills 1-3 million, the incidence of which occurs mostly in the developing countries. Malaria also allows fatal genetic illnesses such as sickle cell anaemia to thrive in the gene pool. Hence a vaccine developed for this disease would be a boon for the developing countries where the prevalence of this disease is more. Among the biotech products that are being developed a few firms undertake development of vaccines. The Indian firms should explore such cases, which are ideal for the issue of CL.

Access to Wider Market

A substantial percentage of the turnover of the Indian companies is spent in strengthening the marketing network which may be useful in going for a marketing collaboration with other firms especially in products where the domestic producers do not have the comparative advantage of producing the drug locally. For instance, Nicholas Piramal is talking with Chisei Pharmacy to bring in `curosur' a biotech drug that can be used for the survival of the premature babies. It is also entering into co-licensing and marketing deal with Roche Pharmaceutical of the US to introduce a biotech cancer drug `peg interferon' (Times of India, March 13, P.11). Another pharma major Ranbaxy has obtained exclusive marketing rights from a US firm to sell a cardiovascular drug in several Asian countries including China, South Africa and non-exclusive rights in Mexico. Since the delivery profile of this drug cannot be easily infringed, the firm is sure of not having generic competition in these countries.

With the universal patent regime in place by 2005, a wider export market in generics is open for the Indian producers. The example of a pharma major of India acquiring UK based firm that was cited in the earlier paragraphs also

supports this. This route of acquiring a unit abroad to facilitate entry in that market however will be limited to a few firms only and others will have to utilise the direct exploratory route. Presently, African countries import pharmaceutical products in bulk quantities relatively at high prices compared to India from the developed countries. The incidence of AIDS is also high in these countries and the estimated market potential for pharmaceutical production in Africa is to the tune of US$ 30 billion and that for health care services approximately US $15 billion (Manthan, September, 2001). Already, the domestic firms either directly or through the merchandise route export pharmaceutical products to neighbouring countries, South Africa, parts of Europe and the USA (Lanjouw 1998, Lalitha 2001). Though the process development skills and lower production costs provide an edge over other countries for the IPI, yet strengthening the standards of production would help India to cater more to the developed countries markets.

Within the domestic market, the rural market remains largely unexplored and the drugs is in short supply (Phadke, 1998). The reach to this market has to be through the government health care system. Most of the state governments favour policies and practices favouring the SSI sector, hence producing the essential drugs for the government health care system is an appropriate strategy for the SSI sector, especially when they operate with limited overheads and resources. Further, in the domestic market, though a large capacity has been created in the formulations sector, yet it is reported that concentration is found more in the antibiotics, vitamins and analgesics and antiseptics. As compared to this production of anti TB drugs, antimalarial, CNS stimulants or antileprotics are less than the actual demand [5] (Lalitha, 2001, IDMA, 2001[6]). This area needs to be strengthened.

The differences in the diseases pattern also indicate a different market for Indian firms. To elaborate, 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

5. This is based on a study done on pharmaceutical industry in Gujarat.

6. These production, supply data were obtained from the annul publication of IDMA and pertain to selected companies of the organized sector. Another point to be noted is that these data do not take into account the substantial production that originates in the small-scale industries.

and Development Committee, (PRDC) 1999). Further, 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. Implicitly, the developed countries will not be addressing the medicinal needs of the developing countries. Incidentally, the development of vaccine for Malaria which is under different stages of clinical trials are currently carried out not by multinationals but by WHO, with its relatively well-developed domestic industry, India can cater to these markets. In view of this, it is essential that the available research funds be focussed on these tropical diseases.

Access to New Medicines

In the domestic market, product patents facilitate access to the latest patented medicines, which under the process patents were not introduced for the fear of competition from counterfeit products and the resultant lower prices on their products. The universal patent regime rules out the differences and hence a patented product can be introduced in all the markets and a discriminatory price structure will also evolve to make inroads in the developing country markets.

Foreign Direct Investment and Technology

Besides the access to medicines, the product patents is expected to facilitate flow of technology and foreign direct investment since due protection will be available in the host country. Lack of adequate protection has been cited as one of the reasons that restrict the flow of technology and investment particularly in the pharmaceutical sector by the developed countries (Mansfield, 1995). However, in this aspect, India will have to compete with China, Argentina, Brazil and similar other countries which also have a fairly developed domestic market and will be competing to garner a share in the available FDI. Procedural simplifications at the various government departments will largely facilitate such investment deals.

4.4 Threats

While the TRIPS open up several advantages and opportunities before the pharmaceutical industries, yet there do exist certain threats, which are mentioned below.

Prices One expected outcome, which has been vociferously pointed out in the context of the product patents in the pharma industry is the price of the medicines. In the absence of the health cover for majority of the population, prices of the drugs in the WTO regime is an issue of concern. It is feared that the low purchasing power of the common people in India and other developing countries will restrict their access to the new inventions (Agrawal and Saibaba, 2001). However, experience in Jordan show that prices of the patented products did increase (Correa, 2000), yet there are also evidences from India itself that the level of pre patent market competition also acts to check the prices (Watal, 1996). Scherer and Watal (2001) argue that the discriminatory pricing strategy usually adopted by the MNCs and corporate tax incentives on medicines donated by the pharmaceutical companies will provide access to patented drugs in the WTO regime. Though patents will not have any impact on the off patent drugs and those which are already existing in the market, yet the price controls will have to play a significant role in this segment to ensure that such price controls are adhered to by the companies.

More than 70 per cent of the small-scale units in the pharmaceutical industry operate as contract manufacturers either for the domestic companies or for the subsidiaries of the multinationals (Lalitha, 2001) which help in controlling the overheads and thereby the prices of the products. In the WTO regime, small-scale units dependent entirely on the production contracts is likely to be affected if the parent company decides to (a) cater to the export market alone or (b) discontinue the existing line of production. Further to meet the export requirements, it is essential that both the parent company and the contract manufacturers meet these standards. While some units may be able to invest in these standards, others who are not able to will have to exit from business, because the GMP certificates will be compulsory to get the license and to continue operation. Hence, the cost of production and thereby the prices of the existing products might increase in the post WTO regime even in the off patent segment. Further, the universal patent regime will result in small manufacturers facing severe competition from domestic firms and multinationals, on the basis of production volume and cost. Very small firms with inadequate funds and market can be affected the most, while the large firms will have to divert a larger amount towards promotional expenditure to sustain their brand in the market.

Competition Globalisation of the markets will lead to dumping of the products in different countries. It might adversely affect the production and employment if the

domestic industry is vulnerable. Already, the pharmaceutical industry of India faces threats to its business from the neighbouring China. China is able to produce larger volume of many of the intermediates and bulk drugs and has been selling at a much lower rate than that is prevailing in India. This has particularly affected the bulk drug producers in the SSI segment. Business sources point out that because of dumping, some of the bulk drug units have closed down their business in Gujarat, Andhra Pradesh and Karnataka (Lalitha. 2001).

Foreign Direct Investment It is expected that the universal patent regime will facilitate FDI in both R&D and manufacturing facilities, though conclusive evidence do not emerge either in favour or against this argument. The decision to locate the R&D activities by a multinational enterprise (MNE) could depend on various factors like the host country's policy on FDI, availability of human resources and physical infrastructure market size, and the level of IPR protection. The severity of the US regulatory bodies has also been a strong factor in encouraging US firms to set up R&D and manufacturing facilities elsewhere (OECD, 1985, Kumar 1996). The comparative advantage of lower cost of establishing R&D facilities in LDCs however, does not however weigh in favour of locating such facilities in LDCs (Lanjouw, 1998). Because, 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). An insignificant relationship between patent protection and location of R&D activity emerges in the analysis of Kumar (1996 and 2001). He argues that if the overseas R&D is directed to local adaptations and supports local production of MNE and not necessarily in new product development, then IPR will not have much influence on the decision to locate R&D by an MNE. Even in the weaker patent regime of India, MNEs such as Ciba, Hoechst, ICI, Uniliver, Cadbury and Astra had set up their R&D. However, in the late '90s, MNCs like Ciba Geigy, Boots, Hoechst and Rhone Poulenc have closed down their R&D facilities in India. Some have started the process of winding up their bulk drug manufacturing operations anticipating change in the patent laws (Sen Gupta, 1998). It should be recognised that FDI provides only necessary conditions and are effective only in the presence of responsive local entrepreneurship that is willing to complement imported knowledge with extensive in house technological effort on absorption, adaptation, continuous updating and eventually on innovation (Kumar, 2001).

Technology Transfer A patent excludes others from the sale, use and manufacture of the patented item. However, once an application is filed in the patent office it becomes a public document and anybody with the technical skill can understand and undertake to produce similar product. Hence, the main technology involved in developing the drug is often kept as a trade secret and separate agreements or arrangements will have to be made to facilitate actual transfer of technology. Hence, it is unlikely that the mere adoption of product patents alone will result in increasing the technical know-how or foreign direct investment in the host country, though it will facilitate the process. But the advantage of developing a new process around the existing technology within a short period will be lost for the IPI.

Exclusive Marketing Rights Developing countries like India in order to avoid abuse of EMRs, 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. P.97). It is alleged by the industry sources that the imported drugs are granted approval without adequate examination and import regulation is limited to specific categories of biological drugs. Hence, to prevent spurious drugs entering the country using EMR route it is essential that such drugs undergo thorough examination and are introduced only after they are certified suitable to the Indian environment and the consumers. Similar is the case of clinical trials. Tougher clinical trials rules and regulations regarding clinical trials in the West and the lax in the effective administration of the same in India resulted in conducting clinical trials of a cancer drug on patients in a research institute in the southern part of Kerala. Hence, care needs to be exercised in allowing FDI.

5. SUMMARY

The above discussions is summarised in a matrix below.

STRENGTHS	OPPORTUNITIES	WEAKNESSES	THREATS
I Process development capabilities →	1. Produce patented drugs through compulsory/ cross licensing 2. Produce generic drugs of those nearing patent expiry 3. Produce off patented drugs 4. Contract manufacturing of patented products 5. New drug delivery mechanisms 6. Concentrate on developing drugs specific to third world diseases	7. Capacity is limited to a few units with R&D, Good laboratory practices and Good manufacturing practices; hence only a few units will benefit 8. Has not provided for utility patents to benefit from the process development skills	
II Lower cost of production →	1. FDI in manufacturing 2. Wider export markets especially in generic products 3. Contract manufacturing and research	1.Quality standards and GMP will have to be strengthened	1.Tough competition from China, Korea and Brazil.
	Universal patent regime may facilitate more investments	**III.** Low level of domestic and FDI in R&D ←	
	Strengthen availability of venture capital funds for such efforts to function as a contract research organisation	**IV** Low level of interaction between industry and academia ←	
		V Lack of technical manpower to process patent applications →	1.Longer time to process the applications and reduction in the patent protection period 2.Exploitation through EMRs.

To conclude, the SWOT analysis brings out that the major strength of the industry is in process development nurtured by the Patent Act of 1970, which has helped the industry to grow and has also benefited the consumers. On the basis of this built up capacity, in the WTO regime also, India could benefit by MNCs strategies such as the outsourcing of R&D, production and marketing provided the local firms' current research interests, manufacturing capacity, technical and scientific manpower and the product profile matches the MNCs interests. Towards that goal, strengthening the laboratory and manufacturing practices will improve the competitive advantage for India over others from the Asian region. Simultaneously efforts should also be geared towards improving the domestic R&D and increasing the FDI in R&D. Care needs to be exercised in processing the FDI cases so that such investments do not result in increasing the FDI per se but contributes to improving technology. Most importantly, the IPI needs to assure the common public that in the process of globalisation and in the pursuit of new drug discovery, people's access to medicines and the interests of the consumers will not be adversely affected.

Table 1: Value of Production of Bulk Drugs and Formulations

(Rs.in Crores)

Year	Bulk Drugs	Formulations
1950-51	2	8
1965-66	18	150
1975-76	113	544
1980-81	240	3148
1991-92	900	4800
1992-93	1150	6000
1993-94	1320	6900
1994-95	1518	7935
1995-96	1822	9125
1996-97	2186	10494
1997-98	2623	12068
1998-99	3148	13848
1999-00	3777	15860
2000-01*	4344	17843

* Estimated

Source: 39th IDMA Annual Publication 2001, IDMA Bulletin XXXII (2001), World Bank Technical Paper no. 392

Table 2: Ownership Pattern of Foreign Companies

Share of Foreign Equity (%)	Number of Companies in 1976-77	Number of Companies in 1981-82
Above 74	20	5
50-74	11	14
40-50	13	16
26-40	14	10
Below 26	6	3
Total	64	48

Source: Pillai and Shah (1988), P. 19.

Table 3: 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, Chaudhry, 1999, and 39th IDMA Annual Publication 2001.

Table 4: Share of Drugs and Pharmaceuticals in India's Export Trade

Bloc/ Year	94-95	95-96	96-97	97-98	98-99	99-00	00-01
ASEAN	3.54	3.25	4.26	4.76	8.11	7.42	5.79
CIS	11.70	9.19	13.7	12.45	8.2	14.13	13.92
EU	2.95	3.06	3.45	3.94	3.56	3.30	3.06
LAIA	6.35	10.82	10.79	13.58	9.09	8.36	9.11
NAFTA	1.93	2.53	2.42	2.62	2.78	2.37	2.83
OECD	2.32	2.61	2.83	3.29	3.30	2.97	3.06
OPEC	2.80	2.87	2.86	3.11	3.19	3.97	3.41

Note : Figures are percentages to total
Source: Calculated from Foreign Trade and Balance of Payments, CMIE, July 2001

Table 5: 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 6: Pharmaceutical and Biotech Expenditure on Contract Services

(Billion $)

Particulars	1999	2001
Contract research	4.8	6.4
Contract manufacturing	19.4	22.5
Contract manufacturing (US Only)	0.3	0.5

Source: Scrip's Year Book 2000, Vol.1, Industry and Companies, p.153.

Table 7: Introduction of On-Patent Drugs

Drug name	Year of Global introduction	Year of Indian marketing approval or Introduction in India	Introduction Lag (Years)	Year of European Patent Expiry
Cefuroxime sodium	1978	1988	10	1994
Cefaclor	1979	1991	12	1994
Netimicin	1980	1988	8	1994
Aciclovir	1981	1988	7	1995
Ranitidine	1981	1985	4	1997
Captopril	1980	1985	5	1997
Norfloxacin	1984	1988	4	1998
Ketoconazole	1981	1988	7	1998
Famotidine	1984	1989	5	1999
Ceflazidime	1983	1988	5	2000
Ciprofloxacin	1986	1989	3	2001
Ofloxacin		1990		2001
Roxithromycin		1992		2001

Source: Lanjouw, 1998

Table 8: 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 9: Number of Patents Filed and Granted to Residents and Non-Residents in India

	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 10: Foreign Direct Investment in India

(Rs. Crores)

Year	No. Approvals	Amount Approved	Actual Inflow	% of Inflows To approvals	FDI Approved in Pharma	% To Total approvals
1991	289	534	351	65.73		
1992	692	3888	675	19.36		
1993	785	8859	1787	20.17	29.9	0.34
1994	1062	14187	3289	23.18	163.0	1.15
1995	1355	32072	6820	21.26	185.8	0.58
1996	1559	30147	10389	28.74	118.2	0.33
1997	1665	54891	16425	29.92	182.9	0.33
1998	1191	30814	13340	43.29	91.1	0.30
1999	1726	28367	16868	59.46	79.8	0.28
2000	1194	37043	12763	53.41	1614.6	4.36
Total	11518	246802	82707	33.51	2465.3	1.00

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

Table 11: Foreign Direct Investment and Collaborations

Year	No of collaborations	FDI in India Rs. In crores	FDI to all developing countries US $Mn	FDI to India as % to all developing countries	No of collaborations in Pharma
1991	632	351	35494	0.2	4 (0.63)
1992	1522	675	47130	0.6	24 (1.58)
1993	1474	1787	66574	0.8	34 (2.30)
1994	1852	3289	90036	1.1	48 (2.59)
1995	2336	6820	106990	2.0	50 (2.14)
1996	2303	10389	131451	1.8	45 (1.96)
1997	2325	16425	172571	2.1	56 (2.40)
1998	1786	13340	176764	1.5	46 (2.57)
1999	2224	16868	185408	1.2	44 (1.98)
2000		12763	178004		

Sources: CMIE, Foreign Trade and Balance of Payments, August 2001, Report on Currency and Finance, 2000-01

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