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RESEARCH ARTICLE

INNOVATION IN PHARMA SECTOR: THE IMPACT OF IPR (PRODUCT PATENT) IN INDIAN SCENARIO: AN OVERVIEW

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ABSTRACT

The Indian Pharmaceutical Industries underwent phenomenal change after 1 January 2005, when international patent laws were implemented. India's domestic pharmaceutical companies have experienced a significant increase in R and D spending to be competitive in the world market. Although the Indian pharmaceutical market is very small and does not have enough funding for drug discovery programs, India has well-educated scientists, a well-established computer industry, and technological know-how for the manufacture of bulk drugs and formulations. This article discusses various challenges of India's pharmaceutical industry and how it could tie to the American Pharmaceutical industry. Recent globalization and the development of the information superhighway have brought the countries of the world closer. From a business perspective, the world is one market place. The American pharmaceutical industry has played a pioneering role in the development of the drug industry through in-depth, timely, and useful research and bulk manufacturing of drug products. Although the US pharmaceutical industry is enjoying the leadership position, it can no longer be content to focus only on the US, Japanese, and European markets.

INTRODUCTION

Intellectual property refers to the exclusive rights granted by the State over creations of the human mind, in particular, inventions, literary and artistic works, distinctive signs and designs used in commerce. Intellectual property is divided into two main categories: industrial property rights, which include patents, utility models, trademarks, industrial designs, trade secrets, new varieties of plants and geographical indications; copyright and related rights, which relates to literary and artistic works.

What are Patents?

A patent is an exclusive right granted by the State for an invention that is new, involves an inventive step (or is non-obvious) and is capable of industrial application (or useful). It provides its owner the exclusive right to prevent others from making, using, offering for sale, selling or importing the patented invention without the owner's permission. A patent is a powerful business tool for companies to gain exclusivity in the market over a new product or process and develop a strong market position and/or earn additional profits through licensing.

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A patent is granted by the national or regional patent office. It is valid for a limited period of time, generally for 20 years from the filing date (or priority date) of the patent application, provided the renewal (or maintenance) fees are paid to keep the patent in force. In some countries, a longer period of protection may be obtained for pharmaceutical products to compensate for the loss of effective period of protection due to delays in obtaining marketing approval from the relevant public health regulatory bodies. In return for the exclusive rights granted by a patent, the inventor is required to disclose his invention to the public in the patent application with sufficient detail to enable a person skilled in the relevant technology to practice the claimed invention. Patents, and in many countries patent applications, are disclosed to the public through publication in an official journal or gazette. In the field of pharmaceuticals, great importance is attached to the protection of undisclosed test data, which is required to be submitted for obtaining marketing approval of new drugs. Authorities in charge of marketing approval for new drugs are thus required to protect such data against unfair commercial use by competitors. Further, authorities should protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure the protection of such data against unfair commercial use. The duration of data exclusivity varies from country to country but is often of 10 years.

What can be patented?

In most countries, patents may be obtained for product and process in any field of technology, including pharmaceuticals, provided that they comply with certain requirements. In patent law, an invention is generally defined as a solution to a technical problem. An invention may relate to the creation of an entirely new product or process, or may simply be a functional improvement to a product or process that provides a unique solution to a technical problem. To be eligible for patent protection, an invention must meet several criteria, which may differ slightly from country to country. On the whole, however, most countries worldwide use the same (or similar) criteria for patentability, namely that

- It is new (novelty requirement);
- The invention consists of patentable subject matter;
- It involves an inventive step or be non-obvious (inventive step or non-obviousness requirement);
- It is capable of industrial application or useful (industrial applicability or utility requirement); and
- It is disclosed in the patent application in a clear and complete manner (disclosure requirement).

Key issue: Process patent protection Vs Product patent protection

A key legal requirement of the TRIPS (Trade Related Intellectual Property rights) agreement is for all WTO (World Trade Organization) members to replace process patent with product patent in all fields including pharmaceuticals. Why does the process patent and product patent debate attract considerable attention in the world of pharmaceuticals? Historically, product patent was excluded in most developed countries. In France, product patent protection was prohibited under the law of 5 July 1844. Since then, French legislation has evolved and limited product patent was allowed on 2 January 1966.In Germany, product patent was explicitly excluded under the law of 25 May 1877 and was introduced as late as 4 September 1967.In Switzerland, product patent for pharmaceuticals was explicitly prohibited by the constitution for a long time and was introduced only in 1977.In Italy, pharmaceutical patents were prohibited until 1978. In Spain, product patent was introduced in 1986 as a consequence of the country's accession to the European Economic Community (EEC) and the law was effective from 1992. Likewise, product patent was traditionally excluded in developing countries. Nearly fifty developing countries did not grant patent protection for drugs when the Uruguay Round began in 1986 (Lanjouw *et al*.1998)[1]. The rationale behind this was to allow local pharmaceutical companies to produce patented drugs by using new processes. Countries may therefore pursue a self-sufficiency policy for the pharmaceutical industry to ensure an adequate supply of medicines at affordable prices to cover the broadest spectrum of diseases. Technically, a chemical compound (a pharmaceutical product) can be obtained through different processes and methods. From a legal perspective, product patent protection would prevent all other processes and methods from producing the same chemical product. In contrast, under process patent protection, a second producer can produce it provided that an alternative method is used to make the same chemical product. Economically, a process patent regime promotes a more competitive environment, compared to the monopoly regime created through a product patent. The key lies in the fact that the impact of downstream innovation associated with these two forms of patent protection is substantially different. A process patent would reward the downstream innovator without preventing further innovation while a product patent can prevent further innovation. This issue is particularly important in the area of pharmaceuticals. An inter-industry survey shows that patents are most important to protect innovation within pharmaceutical industries. Only five of 130 industries surveyed rated product patents as a method to prevent duplication higher than six (on a seven-point scale) and pharmaceutical industries were one of the five. The explanation for this lies in the unique characteristics of molecules and compounds and the fact that they are extremely easy to copy once discovered (Nogues et. al. 1993) [26]. In short, a product patent regime increases the patent protection standard significantly comparing to a process patent regime.

Indian Patent System and Indian Pharma Industry

The Indian Patents Act 1970

This legislation implemented in 1972 made pharmaceutical product innovations, as well protection. It allowed innovations patented elsewhere to be freely copied and marketed in India. Therefore foreign firms did not find patenting in India worthwhile. This act further restricted import as those for food and agrochemicals, unpatentable in India thus greatly weakening IPR of finished formulations, imposed high tariff rates and introduced strict price control regulation with the 1970 Drugs Price Control Order. This gave a boost to the Indian pharmaceutical industry.

India beyond 2004

In granting patents, there is a trade-off between the costs incurred by the country granting the patent due to monopoly pricing and the gains accruing to it due to encouragement to innovative efforts.The Indian Pharmaceutical Sector has come a long way, being almost non-existing during 1970, to a prominent provider of health care products; meeting almost 95% of Country's Pharmaceutical needs. Currently the Indian Pharma Industry is valued at approximately $8.0 billion. Indian Pharmaceutical Industry has over 20,000 units; around 260 constitute the organized sector, while others exist in the small scale sector.

Indian Pharmaceutical Industry Post 2005: Innovation before Imitation

Indian patent act 1970, primarily focused on process patent. This proved to be a boon to Indian manufacturers. By doing modification in the manufacturing procedure of a product, they were able to market the drug substance as well as drug product even before the expiration of patent. A scientific word to describe this approach is reverse engineering, and Indians, in course of time, became masters at this. This helped to establish the foundation of a strong and highly compatible domestic pharmaceutical market. Due to rigid price control, the drugs were marketed at a comparatively low price. With largest number of US FDA(United States Food & Drug Administration) approved manufacturing facilities outside United States, India became the source of quality product at

affordable price. As a result it is now a source of low costs drugs to entire world including the largest and most regulated market of USA.

Objective of the Study

The review work will try to reflect on following issues:

- What kind of measures or policies is required to make India a potentially strong global Pharma hub?
- What various R&D and business strategies have been adopted by Indian Pharma Industries to sustain business after the issuance of Patent Ordinance in 2005?
- How did new patent regime promote new business avenues and new initiatives taking into consideration the current business scenario?
- What have been the effects of various R&D and Business models on Indian Pharma Industry, which were adopted in response to Patent Ordinance?
- What was the status of Mergers & Acquisitions before and after 2005?
- To know the impact of Mergers & Acquisitions models adopted in the current market situation as far as Indian Pharma industry's role is considered and what kind of benefits it offers to the global Indian Pharma Industry?
- To know whether MNC's or national companies are aiming at the Mergers & Acquisitions and what kind of opportunities will they avail in times to come?
- Status of Generic Market in India after 2005 and the strategies of Indian Generic Players.
- Evaluate the impact of Patent Ordinance on Indian Generic market and its future.
- The impact of new patent regime on controlled prices of drugs.

Literature Review

This section aims to provide an overview concerning the implications of higher standard of patent protection in developing countries like India. As one of the basic justifications of a patent regime is to foster dynamic innovation as compensation to static losses by granting temporary monopoly rights, the literature review focuses on two dimensions of patent protection: (a) static effects; and (b) dynamic effects.

Static effects of patent protection

There is a level of consensus among economists that developing countries will suffer a loss in welfare in the short run with reinforcement of IPRs. Earlier work (Chin et. al. 1988) [5] suggested that even if IPRs enhance global efficiency for substantial innovations, developing countries would incur important losses and world welfare losses may emerge. Consumers in the developed countries may also suffer from an increase in global prices and other productive inefficiencies if patent protection becomes global. Nogues *et al*. (1993) [26] presented an analytical framework to assess the social losses incurred by the introduction of patent protection for pharmaceuticals. They stress on that the social costs of introducing patent protection depend very much on the pre-patent structure of the pharmaceutical market. This was because patents sustain monopoly prices and if the pre-patent market situation is characterized by competition, the introduction of patents will entail higher social losses than if that situation is characterized by monopolistic behavior (Refer Table 1).

Table 1. Effect of patent protection on the pharmaceutical industry in three representative countries

Country	Int. Patent Law Applicable year	Impact on Country
South Korea	1986	Local firm market share increased from 87.3% (1986) to 89.2% (1990).Local firms have 75%of patent applications. Now an exporter of modern pharmaceutical technology.
Mexico	1991	Tripling of investment by research-based Pharmaceutical companies. Competitiveness of domestic industry enhanced by technology transfer.
China	1993	17% annual growth rate for the pharmaceutical market. Number of joint venture increased

The static loss is particularly relevant to small countries that rely heavily on technology inflows and lag considerably behind the product cycle. These small economies will find it increasingly difficult to access newly patented inventions if other access or commercialization incentives are not implemented. The negative impact of stronger patent protection has been confirmed by several empirical studies. Simulating the introduction of patent protection for pharmaceuticals by assuming different market structures and different demand price elasticities, some studies found non-negligible price increases and welfare losses in southern countries (Maskus *et al*. 1994) highlighted the importance of available, close and off-patented therapeutic substitute drugs that can restrain prices and limit potential welfare losses. With the introduction of patent protection, affordability and availability should be two major aspects to be considered when assessing static effects. Currently, while price, which affects affordability, is perceived as the dominant source of the static effect in the literature, little attention has been given to availability. One recent case study illustrated the static impact of patents on drugs (Subbaram *et al*. 2004). In 2001, for the purpose of monitoring medicine prices and improving access to essential drugs, the World Health Organization (WHO) and Health Action International (HAI) developed a standardized methodology for surveying the availability, affordability and components of medicine prices in developing and transitional countries. Data concerning 14 chronic disease medicines were collected in 30 surveys that covered India between 2001 and 2005.

To enable international comparison, the price data was expressed as Median price ratios (MPR) rather than actual prices, with an international comparison between prices and international reference prices (WHO and HAI 2005). In the public sector of survey sites, the median of the MPR for patented brands (six core medicines) was four times higher than the international reference prices. About 50 per cent of the patented brand medicines were in the range of 1.71-7.28 times higher than international reference prices. India has been able to maintain low drug prices, which are among the lowest in the world. For instance, a comparison between a US patented drug and the equivalent Indian drug shows that the US drug price is

40 times higher than that of the generic drug found in India known as Omeprazole. A price comparison of certain blockbuster drugs between US and India is illustrated in Table 2.

Table 2. Blockbuster drugs price comparison of certain drugs in USA and India

Brandname /Company	Generic name	Dosage Per tablet	US price (US$)	Indian price (US$ equiv.)
Prilosec/Astra Merck	Omeprazole	20 mg	3.76	0.09
Prozac/ Eli Lilly	Fluoxetine	10 mg	2.28	0.63
Zocor/ Merck	Simvastatin	10 mg	2.07	0.21
Zantac/ Glaxo-Wellcome	Ranitidine	150 mg	1.72	0.02

Source: Chaturvedi and Chataway (2006)

Dynamic effects of patent protection

Contrary to the above consensus regarding negative static effects, the assessments of the dynamic effects of strong patent protection are less categorical. Some theoretical analyses assumed a positive relationship between the strength of patent protection and the rate of innovation. To cite a few examples, according to Diwan and Rodrick (1991) [8], an increase in patent protection unambiguously promotes innovation. Diwan *et al*.(1991)[8] showed that if developing countries have a need for innovations that differ from that of developed nations, strong intellectual property protection may be desirable. Hamied *et al*.(1993)[15] asserted that IPRs have a positive effect on the health conditions of people in developing countries. Drugs are not available for many diseases that affect developing countries because of weak incentives to manufacture these drugs. Governments of developing countries must negotiate with pharmaceutical firms to obtain these drugs, and stronger IPR protection increases the probability of successful agreements. Weaker IPR protection increases the chances of the drug being copied after it has been introduced, leading to a lower present day value of the drug and lower incentive for drug innovation. In contrast to the above optimistic views, a number of other studies suggested that there was a significant probability that stronger IPR protection may slow down technological progress in the long run. Chin *et al*. (1990)[5],Deardorff *et al*.(1992)[7] and Helpman *et al*.(1993)[16] suggested that mechanistically transferring innovations from the developed world to developing countries is problematic. The spur to domestic innovation was modest in these settings. Siebeck *et al*.(1990)[33] suggested that firms still find it profitable to maintain current technologies, to devote fewer resources to or delay investment in development activities and opt to wait longer before marketing a new product or technology (Refer Fig. 1).

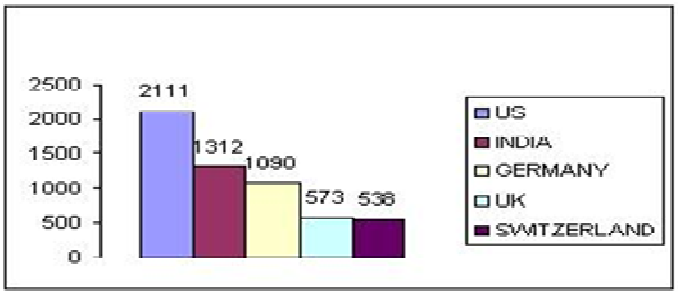

Fig. 1. India 2nd Globally (Investment in R&D) (Rs in Crores)

Therefore, extending patent protection to developing countries should not represent a strong stimulus to increase research and development activities; the technology gap separating rich and poor countries may eventually be wider. The preceding review reveals that the link between strong IPRs and the social welfare impact on pharmaceuticals in developing countries has not been well established. While it was less contentious that patent protection leads to static inefficiency, the dynamic benefits associated with stronger patent protection seem uncertain. Specifically, some weaknesses can be identified in the existing studies. First, studies on the impact of patents on prices and innovative activity focused almost exclusively on developed economies (Gambardella *et al*.1995). Second, empirical evidence regarding the impact of the TRIPS Agreement is rather limited. As most developing countries were required to implement the TRIPS in 2005, the actual impact is hard to assess given the limited period of TRIPS implementation. Third, existing studies generally do not differentiate patenting by foreign entities from that by domestic entities in a given country. The amount of research and development investment and the number of patents (filling and granted) by nationals are two key indicators to assess the dynamic effects of the patent protection. Though not perfect, these two indicators illustrate to a certain extent the level of inventive activity and the innovative capabilities of a country in a specific sector. First, in terms of research and development investment, little evidence is found that incentives intended under a higher standard of patent protection after the 1993 Patent Law Amendment have contributed to stimulate domestic research and development activities. (Refer Fig. 2.)

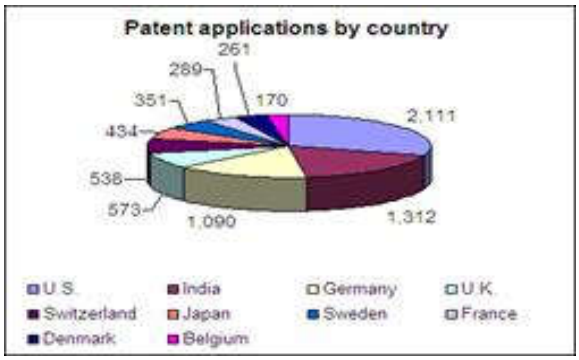

Fig. 2. Globally Patent applications

In terms of the patent applications, patents filed in India are mainly from domestic Indian firms. Two Indian entities, the Council of Scientific and Industrial Research and Ranbaxy, were in the top ten of the World Intellectual Property Organization's list in 2002. Patent applications by industry during 1995-2000 indicated that pharmaceutical companies ranked highest with 396 applications. India filed 392 Abbreviated New Drug Applications (ANDA) in 2002. India's share of ANDA filings has been rising consistently and stood at around 23 per cent in 2003. Indian domestic pharmaceutical industries spent on an average only 0.5 per cent to 3.0 per cent of their turnover on research and development (The Centre for Management of IP in Health R&D 2005). The total amount of research and development expenditure for pharmaceuticals was even less than that of a single major Western multinational counterpart. Moreover, rather than undertaking fundamental research work, most of this research and development was oriented towards marketing and commercialization.

Consequently, about 97 per cent of about 3,000 pharmaceuticals produced generic drug versions of foreign brands. As the TRIPs Agreement was forcible to prevent Indian firms from producing patented drug in 2005, Indian firms accelerated the pace to build up their capacity to innovate. From 2003 to 2004, pharmaceutical industries in India spent approximately 13.2 billion Rupees on research and development; representing 3.6 per cent of their turnover. Ahuja *et al*.(2005) [28] suggest that from about 2 per cent of total sales around three to four years ago, the average research and development expenditure of the leading research-based domestic firms in India had gone up to around 5-6 per cent in by 2004. Among these companies, Ranbaxy, Dr Reddy's, Cipla, Wockhardt, Torrent, Sun, Lupin and Nicholas Piramal are prominent examples. Ranbaxy is among the top 100 pharmaceutical companies in the world and the 15th fastest growing company. It kept a dedicated research facility in Gurgaon staffed with over 1,100 scientists. It spent US $ 75 million on research and development in 2004; a 43 per cent increase over its 2003 expenditure. Dr. Reddy's research and development expenditure increased from 7 per cent in 2002-03 to 10 per cent in 2003-04 and was slated to increase further in the future. The research and development expenditure has been rising and the trend is particularly strong among leading Indian companies, e.g., Ranbaxy, Dr Reddy's, and Cipla. (Refer Table 3).

Table 3. Sales of major domestic companies in India

Rank*	Company Name (Domestic Pharmaceutical Companies	Gross Sales in Rs Million*	Gross Sales in US $ millions*
1	Ranbaxy#	17,459	356.3
2	Cipla	10,475	213.8
3	Dr. Reddy's Lab	9841	200.8
4	Nicholas Piramal	5667	115.7
5	Wockardt Ltd	5583	113.9
6	Lupin Labs	5437	110.9
7	Cadila Healthcare Ltd	5087	103.8
8	Sun Pharma	4764	97.2
9	Alembic Ltd	4738	96.7
10	Morepan	4297	87.7

-Filed data, Ranbaxy existence was reported.

The Growth Scenario of Indian Pharmaceutical Industries

India's US$ 3.1 billion pharmaceutical industry is growing at the rate of 14 percent per year. It is one of the largest and most advanced among the developing countries. Over 20,000 registered pharmaceutical manufacturers exist in the country. The domestic pharmaceuticals industry output is expected to exceed Rs260 billion in the financial year 2002, which accounts for merely 1.3% of the global pharmaceutical sector. Of this, bulk drugs will account for Rs 54 bn (21%) and formulations, the remaining Rs 210 bn (79%). In financial year 2001, imports were Rs 20 bn while exports were Rs87 bn (Refer to Fig. 3).

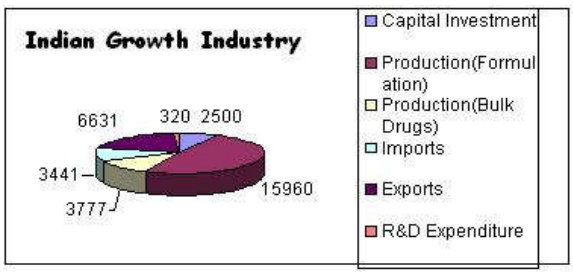

Fig. 3. Indian Pharma Industry Growth

With transition into the new regime many Indian companies are mobilizing a large pie their resources in their R&D budget. A large number of pharmaceutical corporation have set up research facilities of global standard and have initiated research program for New Drug Delivery Systems and Drug Discovery Program. The Pharmaceutical Research and Development Committee (1999), has suggested that a mandatory collection and contribution of 1 per cent MRP of all formulations sold within the country to a fund called Drug Development Promotion Foundation. Government of India encouraged the R&D in pharmaceutical companies by extending 10 year tax holiday to this sector. Besides, planning commission has earmarked $34 million towards drug industry R&D promotion fund for the tenth plan. The focus under the R&D effort is to encourage development of new molecules. A provision of Rs. 150 crore has been made under the Pharmaceutical Research & Development Support Fund. A Drug Development Promotion Board under the Department of Science & Technology has also been set up for the utilization of this fund (Refer Table-IV)

Table 4. Sales of major foreign multinational companies in India

Rank*	Company Name	Gross Sales in Rs Million*	Gross Sales in US $ millions*
1	Glaxo-Wellcome	9346	190.7
2	Hoechst-Marion-Roussel	5505	112.3
3	Novartis India Ltd.	4384	89.5
4	Knoll Pharma	3333	68.0
5	Pfizer	3272	66.8
6	SmithKline Beecham Pharm. India	3195	65.27
7	E Merck India Ltd.	3134	64.0
8	Wyeth Lederle Ltd	2947	60.1
9	Rhone-Poulenc India Ltd.	2629	53.7
10	German Remedies Ltd	2307	47.1

Currency exchange rate: 1 US $ ~Rs 49 or Rs 1 million ~$ 0.0204082million
*Rankings and gross sales values will change accordingly with time.

The Indian pharmaceutical market; Value of Production

India's pharmaceutical market may not be impressive by international standards, but considering the total Indian economy, it is one of the major economic sectors in India. According to the Indian Drug Manufacturers' Association (IDMA) annual publication, the estimated value of production of bulk drugs and formulations in India during 2000–2001 was approximately Rs 22,187 crores (~$ 4.5 billion) out of which Rs. 4344 crores is for bulk drugs and Rs. 17,843 crores for the formulations (currency conversion rate used is Rs 49 ~ US $ 1.00 or Rs. 1 crores~ $ 0.204082 millions). Table-V summarizes the value of production of bulk drugs and formulations during the past decade. The bulk drug production increased by nearly 20% every year, whereas the value of formulations increased at an average rate of 15% per year. Table V clearly indicates the rapid growth of the pharmaceutical sector in the Indian market.

Major players in the pharmaceutical industry in India

Two types of companies exist in the Indian pharmaceutical sector: companies of Indian origin (domestic) and foreign MNCs (Refer to Table no-VI). The rankings of the major players based on their sales figures. Glaxo-SmithKline, Cipla, Dr. Reddy's Laboratories, and Ranbaxy are the top four companies in terms of gross sales. Other companies' sales

values are very similar, and the rankings can change with time. The top MNCs with a presence in India are Glaxo-SmithKline, Hoechst Marion Roussel, Knoll Pharma, and Pfizer. Approximately 20,000 pharmaceutical units exist in India. Ranbaxy, the leading domestic company, reported sales of Rs.1745.9crores ($ 356.3 million, assuming that $ 1.00 ~ Rs 49) during 2000. Glenmark Pharmaceuticals, Cadila Healthcare, Ajanta Pharma, and Elder Pharmaceuticals are among other upcoming companies.India currently holds U.S. $ 6 billion of the $ 550 billion global pharmaceutical industry but its share is increasing at 10 % a year. When compared to 7 % annual growth for the world markets overall, this speaks of a very promising scenario.

DISCUSSION

Recently, India enacted changes in its patent laws that will have significant impact on the pharmaceutical industry. These changes were intended to bring Indian patent law in accordance with requirements under World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights or TRIPS. This introduced product patent in the industry. The product patent regimen post 2005 has its own challenges and rewards. India is a member/signatory to-TRIPS (1995), Paris Convention (1998), Convention on Bio-diversity (1994), Budapest Treaty (2001), Berne Convention, Universal Convention for Copyright (1952) and many others.

Table 4. Value of production of bulk drugs and formulations in India during the past decade

Year	Bulk Drugs			Formulations		
	Value Rs. in Crores	Value $ Millions**	% Growth	Value Rs. in Crores	Value $ Millions**	% Growth
1991–92	900	183.7	24.0	4800	979.6	25.0
1992–93	1150	234.7	27.8	6000	1224.5	25.0
1993–94	1320	269.4	14.8	6900	1408.2	15.0
1994–95	1518	309.8	15.0	7935	1619.4	15.0
1995–96	1822	371.8	20.0	9125	1862.2	15.0
1996–97	2186	446.1	19.9	10494	2141.6	15.0
1997–98	2623	535.3	20.0	12068	2462.9	15.0
1998–99	3148	642.5	20.0	13878	2832.3	15.0
1999-00*	3777	770.8	16.7	15860	3236.7	12.5
2000-01*	4344	886.5	15.0	17843	3641.5	12.5

Estimated.**Currency exchange rate: Rs 49 ~ US $ 1.00 or Rs 1 crore ~$ 0.204082 million

Table 6. Top 10 Pharmaceuticals in India (On the basis of Revenue)

Rank	Company	Revenue2004 (Rs Crore)	Revenue 2004 (USD millions)
1	Ranbaxy Laboratories[#]	4,461	1,026
2	Dr.Reddy's Laboratories	1,933	444
3	Cipla	1,842	423
4	Nicolas Piramal India	1,387	319
5	Aurobindo Pharma	1,260	290
6	Glaxo-SmithKline	1,228	282
7	Lupin Laboratories	1,180	271
8	Sun Pharmaceutical Industries	1,110	255
9	Cadila Healthcare	1,091	251
10	Wockhardt	980	225

Old File, as Ranbaxy existence was reported that time

Some of the significant changes in the Indian economy in recent years are:

- Indian GDP growth was 6.9% in 2004–2005 with the expectation of clocking an annual growth at 5.5% between 2006 and 2020;
- Consumer spending in India grew at an average rate of 11.5% per annum, with a consumer confidence index of 72% in 2005, compared with 63.5% in 2004 as per MasterCard's international survey;
- Growth of the global pharmaceutical market in 2004 was 7%, and turnover was US $ 518 billion; the Indian pharmaceutical industry grew at 6.4% in 2004 with a compound annual growth rate (CAGR) of 8.7% during the period 2000–2004. It may be noted that price-led growth has been negative, indicating growing pressure on the industry.
- In 1996 six of the top ten firms in the industry are Indian firms. By 1991, domestic firms accounted for 7 per cent of the bulk drugs production and 80 per cent of formulations produced in the country (Lanjouw *et al*.1998).

India fulfilled the WTO Commitment and our Patent's (Amendment) Act 2005 has become TRIPS Compliant since 1st Jan 2005. India thus joined the countries having industrialized free market economies. The trend of patent filing in our country has tremendously increased, Economic Times of Jan 7, 2009 has reported that "a total of 35,218 patent applications were filed, 6040 from domestic and 29,178 from foreign applicants in the last fiscal". Though innovations and strengthening of the Patent System is important for Industrial Growth, it is equally important to take necessary steps to safeguard the sanctity of our Patent System and prevent filing and grant of frivolous unpatentable subject matters, which is being addressed. All this has generated an interest in Indian Industry and market and India is now becoming inundated with interest from multinational companies looking to invest in its burgeoning pharmaceutical industry, considering the advantages of the Indian market viz. solid legal framework & strong financial markets; committed to free market economy & globalization; large middle-class market with huge growth potential and huge cost advantage. The new patent regime has led many multinational pharmaceutical companies to look at India as an attractive destination not only for R&D but also for

contract manufacturing, conduct of clinical trials, generic drug research and co-marketing alliances. The focus of the Indian Pharma Companies is also shifting from process improvisation to drug discovery and R&D. Indian companies are setting up their own R&D setups and are also collaborating with the research laboratories like CDRI, IICT etc. The Indian Pharmaceutical Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian Pharma Industry is estimated to be worth $ 4.5 billion, growing at about 8 to 9 percent annually. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. There are about 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce the complete range of pharmaceutical formulations, i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e., chemicals having therapeutic value and used for production of pharmaceutical formulations.

The Statement of Problem

The first round of trade negotiations took place while the Preparatory Committee was still working on drafting the Charter because the participants were anxious to begin the process of trade liberalization as soon as possible. Their results were incorporated into the General Agreement (GATT), which was signed in 1947. The GATT completed 8 rounds of multilateral trade negotiations (MTNs). The Uruguay Round (the 8th round) first multilateral agreement dedicated to the sector. It was a significant first step towards order, fair competition and a less distorted sector,(Understanding The WTO: The Agreements) Concluded with the signing of the Final Act on April 15,1994, in Marrakesh , and produced the World Trade Agreement (WTO) and its annexes As of January 2000, all developed and developing countries who are members of the World Trade Organization (WTO)were obligated to have domestic laws and enforcement mechanisms that comply with the international standards set forth under the Agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPs), is the most comprehensive multilateral agreement on intellectual property.

The agreement covers five broad issues

- How basic principles of the trading system and other international intellectual property agreements should be applied
- How to give adequate protection to intellectual property rights
- How countries should enforce those rights adequately in their own territories
- How to settle disputes on intellectual property between members of the WTO
- Special transitional arrangements during the period when the new system is being introduced. Intellectual property: protection and enforcement

During post independence and pre 1970, the cost of the drug in India was very high with low availability and high import dependency. Export initiative was very less and R&D activities were practically non-existence due to lack of patent protection. During this period 80% of the ownership and 90% of the market share was with MNC's.

Period Between 1970 to 1995

Government taken two important steps

- Introduced 'DPCO' to protect the Consumers against high price
- Indian Patent Act 1970 to 'Process Patent'- patenting the process use to make the particular drug formulation but not the product patent (patenting the process itself)

Effects

- India did not provide product patents in pharmaceutical and agricultural chemicals allowed local pharmaceutical companies to replicate drugs by adopting a different manufacturing process (reverse engineer products). These reforms made new drug available cheaply and promoted import substitution by encouraging the local firms to make copies of the drugs by developing their own process followed by bulk drug production.
- The share of pharmaceuticals in national exports has increased from 0.55 per cent in 1970-71 to over 4 per cent by the 1999/00.
- India's share in world exports of pharmaceuticals has risen by 2.5 times over the 1970 to 1998 period making India, the second largest exporter of pharmaceuticals after China among developing countries by exporting products to country like Russia, Africa , China , and South America .
- Furthermore Indian companies were free to ship reverse engineered drugs to patent recognizing countries on or after the day of expiry. Such a liberal patent environment benefited Indian firms at the expense of MNC's; causing some MNC's to opt for minimal presence in India. As a result, foreign ownership in Indian drug industry decreases to 39% in 1993 as compared to 80% in 1970 before the introduction of this act.
- The characteristics of patenting between 1978 and 1996 are reviewed, based primarily on applications published by European patent office. Numbers of pharmaceutical applications have increased steadily, and there are now approximately 6000 published each year, or 10% of total.

Period Between 1995 to 2005

- Exclusive Marketing Rights- This new provision has been incorporated in the Patents Act, 1970 as amended by The Patents (Amendment) Act, 1999 with effect from 1st January, 1995. EMR will be valid for a period of five years or till the date of grant of the patent or date

of rejection of the application for the grant of patent whichever is earlier.

- It is now possible to make an application for patent claiming for a substance itself intended for use or capable of being used as Medicine or Drug, excepting the intermediate for the preparation of drug.
- India joined the Paris Convention and the Patent Cooperation Treaty in 1999.
- India has a ten years transition to provide product patents viz. till the end of 2004. It is by now widely recognized that the abolition of product patents in chemicals and pharmaceuticals has facilitated the development of local technological capability in chemicals and pharmaceutical industry by enabling the domestic firms in their process innovative activity.

Patent amendment act 2005

- Provision related to black box application- if filled before 1Jan. 2005 under the transition provision of TRIPS, any manufacturer who has made significant investment for the manufacturer of product and has produced and marketed the product before 1 Jan. 2005 will able to continue the production after 1jan. 2005 without infringing the patent.
- Parallel import, grey imports, ”Exhaustion” of rights- parallel or grey market imports are not imports of counterfeit products or illegal copies these are the products sold by a patent holder in one country is exported by a buyer to another country where the price for the same patented drug is higher. This effectively reduces the profits of the patent holder as the phenomenon of parallel import usually reduces the price of the product in the country to which it is exported.
- Compulsory licenses- such licenses can be granted for manufacture and export to "any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided that compulsory license has been granted by such country." Only it limits the amount they can export when the drug is made under compulsory licenses. All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import to various countries.
- Herbal preparations-Those having medicinal values can be patented under the new amended law.
- In the period between 1995-2005 and thereafter, status quo has been seen with respect to cost of the drug and it is expected to continue that way till 2007. But after 2007 particularly after 2010 as MNC’s and research based companies start launching their patented molecules, the cost of drug is going to increase.
- 7. The availability of drugs in antibiotic segment & other agents for topical infection may not be affected but the availability of life style drugs will be affected as most of the MNC’s are engaged in new drug development in this area only but imports will remain constant.

In the process patent regimen pharmaceutical industries in India were involved in manufacturing largely the generic molecules and were complacent on the work for new chemical entities (NCE). Even the sense of urgency was missing in their approach to explore a new market. Also, pharmaceutical industry did not receive a significant input of foreign direct investment. Pharmaceutical multinationals maintained a low key presence in Indian market due to absence of product patent and rigid price control. But with the advent of TRIPS and India complying with it, a change in approach by pharmaceutical industry was seen. To cope up with the regulations of Amendments in the revised patent act, pharmaceutical industry have altered its development and marketing strategies. New strategies have been adopted not only for the survival but also for continuing the trend or dominance that the Indian pharmaceutical industries have been showing in past three decade. Pharmaceutical multinationals have maintained a low key presence in Indian market due to absence of product patents and rigid price controls. Pharmaceutical industry did not receive significant foreign direct investment (FDI). From August 1991 to December 1998 this industry accounted for a meager 0.44% of the total FDI. Introduction of product patent will see multinationals strengthening their presence in the country. The second largest population in the world, a growing economy and rising income levels makes Indian market difficult to ignore. For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. With rich scientific talent and research capability, Indian pharmaceutical industry is all set to take great leap forward in the Intellectual Property Protection regime. With efficient use of its pool of scientific and technical personnel, India has vast opportunities in both export and outsourcing and has the potential to become a global hub in the area of R&D. The patent ordinance also provides adequate safeguards to protect the interest of the domestic industry and the citizen from any increase in prices of drugs. The impact of the new regulations will not deter the Indian pharmaceutical industry but will reshape its landscape. The new amendments will encourage the strategy of replacing the imitation attitude with innovative ideology.

Impact on Pharmaceutical Industry

Impacts on Social Policy: The GATT-TRIPs rules prohibit member countries from discriminating, in granting patents, "as to the place of invention" and the "field of technology." These criteria will constrain Countries in their use of IPRs as tools for development.

Collabration: Many companies are collaborating in joint R&D and product and process development to synergise their knowledge-base and effectively exploit available human resources and infra-structure. Recently,Orchid Chemicals Pfizer International, Glaxo as well as critical Ranbaxy’s. Cipla formed a partnership with Avesthagen, a biotechnology company based in Bangalore, to develop biopharmaceuticals and targeted therapies.

Institutions: The technological capabilities of Indian companies and institutions have attracted leading MNCs to start R&D joint ventures, commission contract research and set up R&D centers. India’s string synthetic skills, business instincts, & fiercely cost competitive domestic market add up to a terrific advantages for global bulk market. Indian companies are setting up research centers and conducting trials

to counter disease that are specific to Indian subcontinent. Prices and quality of drugs are to become internationally competitive. Analysis of the Indian Pharmaceutical Industry; with emphasis on opportunities in 2005.

Current global pharmaceutical market

The current pharmaceutical market is worth more than $317 billion. The major contributing regions are the United States, Japan, and Europe. GlaxoSmithKline, Pfizer, and Merck are the top three companies in the pharmaceutical market, with annual sales of $23.5, 22.6, and 20.2 billion, respectively. Pfizer has the largest R&D budget, which is hovering at $4.4 billion. Most of the major US pharmaceutical companies showed double-digit growth in 1999 .Drug prices vary from country to country. Citizens of developing countries cannot afford expensive medicines that are under patent. Multinational companies (MNCs) must either choose to sell a product at a low price in these countries or face the challenge of piracy or parallel trade. Types of diseases in Third World countries may vary from those in developed nations. However, because of the lack of sizable profits from distributing pharmaceutical products in Third World countries, MNCs are reluctant to conduct research to develop new drug molecules to treat these diseases.

India's preparation for 2005

After the signing of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Trade Agreement in Marrakech, Morocco, in April 1994, WTO was created.WTO is an institution rather than an agreement such as GATT. It sets rules governing trade between its 132 member countries. It has allowed member countries until 1 January 2005 to make necessary adjustments before they are required to abide by WTO rules. Three major conventions exist to protect patents and intellectual property rights: the Paris Convention, which includes the United States and 100 other countries; the Inter American Convention, which includes the United States and Latin American nations; and the Madrid Arrangement, which includes 26 European nations (8). The World Intellectual Property Organization (WIPO), a part of the United Nations, is responsible for promoting the protection of intellectual property as well as administering various multilateral treaties. Despite all the treaties and rules, policing patent infringement and piracy has become a monumental task. Each country is required to take measures to address these problems. The secondary outcome of these efforts could be to develop technology and promote patenting in every country, which will automatically help protect international patents. Likewise, India is making efforts to develop modern technology in the pharmaceutical industry. The key task is to promote R&D that is on par with the technology in other advanced countries. After 2005, the globally harmonized patent system would prohibit the production and marketing of patent-protected new drugs. Indian officials want to ensure that Indian people do not suffer in terms of high costs of medicines after 2005. The goal is to prevent the American, European, and Japanese pharmaceutical monopolies from exploiting the Indian population. Basic needs for the development of the pharmaceutical sector are funds, infrastructure, R&D management, and human resources. The Indian government and the IPI have been focusing their efforts so that these necessities are ready for 1 January 2005.

Efforts by the Indian government

The Indian government is encouraging private and public sectors as well as foreign investors to increase investments in pharmaceutical R&D. Some positive steps taken by the Indian government in recent years include

- Recognition of the pharmaceutical industry as a knowledge-based industry
- Reduction in interest rates for export financing
- Additional tax deductions for R&D expenses
- Reduction in the price control of pharmaceuticals.

As an example, the import duty surcharge of 3.5% on vaccines and life-savings drugs has been removed. A 10% surcharge on custom duty has also been scuttled. Small-scale industry exemptions have led to the proliferation of small formulation manufacturers and low-cost drug manufactures. DPCO came into existence in 1970 and thereafter was revised in 1979, 1987, and 1995. DPCO controls the domestic prices of major bulk drugs and their formulations

Efforts by the Indian pharmaceutical industry

The IPI, seeking to take full advantage of benefits offered by the government, has been allocating money to R&D. Its focal points are drug discovery, development of drug delivery systems, biotechnology, and bioinformatics. Companies are reevaluating their strengths and emphasizing product segments that are profitable to the company. Many companies are trimming their portfolios to focus on particular therapeutic segments. Pharmaceutical marketing is also changing rapidly, and pharmaceutical companies are making elaborate marketing efforts.Companies such as Sun Pharma, Nicholas Piramal, and Dr.Reddy's Laboratories have opted for brand/company acquisition to increase therapeutic reach and market penetration. Such specialization would make the entry of MNCs difficult. Some theorize that companies with a strong marketing force would be attractive for possible take-over. Many pharmaceutical companies are entering into marketing arrangements such as Hoechst Marion's agreement with Nicholas Piramal and Ranbaxy's pact with Cipla, Glaxo, and Hoechst Marion. Recent mergers and acquisitions include Nicholas Piramal's acquisition of Roche Products, a company mainly involved in diagnostic products and Zydus Cadila's acquisition of German Remedies in India. Sanofi Synthelabo, the second largest pharmaceutical company in France, will buy out Ahmedabad-based Torrent Pharmaceuticals. Very recently, Dr. Reddy's Laboratories signed a definitive agreement to acquire 100% of Meridian Healthcare and BMS Laboratories, whose primary business is manufacturing and marketing generic pharmaceuticals in the United Kingdom.

Benefits to India from modernizing the IPI

At a World Intellectual Property Organization (WIPO) conference in 1999, Dr. P.V.Venugopal summarized the possible benefits to India of modernizing the IPI. This section discusses some of these benefits.

Social: The development of the IPI would create new jobs, but mainly it would provide access both to modern technology in the field of medicines and to medicines developed indigenously. As a result, it will be able to provide new drug formulations and improved healthcare treatments to Indian patients. In particular, new medicines would be available to treat diabetes, cardiovascular diseases, cancer, and psychological disorders. But even during the drug discovery and development phases, significant funds would be invested in local communities. As a result of changes in the culture and in the social environment, new types of diseases are invading India. India must have a concrete plan to protect itself from these diseases, and the development of the pharmaceutical sector is the first step.

Economic: The development of the pharmaceutical industry would help the Indian economy produce more national wealth. Foreign investment would increase, and Indian companies would have the opportunity to collaborate with many companies from around the world. Indirectly, developing the pharmaceutical industry would also help other industries. The related employment opportunities in various fields are no less important. If good jobs were available locally, citizens would not feel the economic pressure to migrate to the United States, Europe, or Japan. Development of clinical trial centers would provide funding from private pharmaceutical industries to local hospitals. In return, a staff of nurses and doctors would be maintained, which would benefit local communities.

Political: Economic growth will bring political stability to India. It will improve international credibility and create a visionary rather than a reactionary political regime. The poverty level in India stands at 27%, which is very high compared with China's 5% level, for example. Making medicines affordable to all Indian citizens is a noble goal, but one must strive for a fair distribution of low-priced medicines to the masses and high priced modern medicines to wealthier people. The economic development that would result from growth in the pharmaceutical and computer sectors could trigger development of other sectors and indirectly lower the poverty level. India can then achieve macro economic growth through education, infrastructure development, improved sanitation, and enhanced public health. In a political sense, these developments will forge a win–win situation for Indian citizens and politicians. Changing disease patterns must be understood, and policies must be prioritized for the treatment of diseases. A committee of representative physicians from various internal states, government officials, and key executives from various pharmaceutical companies could likely muster the clout required to meet the health requirements of Indian citizens as well as promote the country's pharmaceutical industry.

Opportunities: India is the largest democracy in the world, with a majority of its citizens fluent in English. Its GDP is $447 billion. India's GDP grew at an average rate of 5.5% between1990 to 1997. During the current five-year plan, it is expected to grow at 6.4%, and in the next five-year plan it is projected to be 9%. The Indian government's policies are open to foreign investments, and the country is developing the necessary infrastructure for economic growth .India's huge middle class approximately 250 million people have a vigorous buying capacity. On average, however, per capita annual expenditure on pharmaceutical products is just $3.00, a negligible amount when compared with the amounts spent in Japan ($412) and in the United States ($191). An increase of only two dollars in per capita expenditure on pharmaceutical products would provide a tremendous marketing opportunity to pharmaceutical companies in India. Countries such as China, Indonesia, Pakistan, and Bangladesh also have low per capita expenditure, and importing medicines from India could help develop their drug markets. Development of the pharmaceutical sector would not only help decrease unemployment in India, but it would also help secondary industries flourish. This economic growth helps increase buying power, which in turn will make India an attractive market for US pharmaceutical giants. Currently, Indian companies are not abiding by patent laws. MNCs have nearly two and a half years to analyze data and take steps to position themselves in the Indian pharmaceutical market. Indian pharmaceutical companies have zero or negligible drug discovery programs. Drug molecules from an Indian company may not be licensed. The Indian government has not been open to foreign investments in the past three decades. However, now Indian authorities claim to provide a more predictable and healthy environment for businesses. Culture and business practices in India are very different than those of the western world. Thus, a strategic alliance with an Indian counterpart in which the partners' strengths complement each other would be advantageous. Many US companies are strong in technological knowledge. An Indian counterpart could provide the additional knowledge of local industry, government, banking, and marketing.

A domestic company could provide local information at a faster rate, and a US company would more easily become acquainted with local norms and customs. Political turmoil, which is a possibility in any country, can affect industrial sectors, but a strong coalition with a local company would help alert the partner of potential political turmoil. The expenditure per patient for a clinical trial in India is much less compared with that in the United States. The cost of drug development depends on the type of therapeutic segment, previous knowledge gained from a similar program, and complications that arise during the clinical study. Thus, it is difficult to pinpoint the exact cost of drug development in India, but it is much less than that in the United States. India has plenty of doctors and hospitals. Outside companies may find it fruitful to establish an alliance with an Indian company that has its own clinical trial setup. For example, if a drug must be developed to treat a tropical disease, India could be an ideal place for conducting clinical trials. India has the dubious distinction of being home to the largest number of people with diabetes. With a poor healthcare infrastructure, it is logical to assume that many more people remain undiagnosed. The occurrence of diabetes may lead to other health problems, mainly cardiovascular diseases. This reality provides numerous opportunities for pharmaceutical companies to market medicines to treat these illnesses. Several modern medicines are available in the United States to treat diabetes and related diseases, and manufacturing them in India could cost considerably less because of India's lower labor cost. Formulations production could be contracted out to local companies; thus, drugs could be sold at an affordable cost to Indian citizens. In addition, in drug discovery programs few drugs are brought forward for further development even though

the backup compounds are good. Licensing these drugs to Indian companies for further development is a possible alternative to letting a new drug go by the wayside. The cost of drug development could be reduced, and the drug development program could succeed. Recently, companies such as Ranbaxy and Dr.Reddy's Laboratories are manufacturing generic drugs in India and selling them on the US market. India's several ancient drug/medical systems (e.g.,ayurvedic and homeopathic) may lead to the discovery of many valuable drug molecules that could be developed as modern formulations. American companies have an opportunity to establish alliances with Indian companies that specialize in these medicines. If they are found to be advantageous treatments, they could be brought to the US market, and the US population could also benefit. Skinner discusses sales models for pharmaceuticals and proposes new paradigm for sales and marketing. A model refers to as the customer (new millennium) model, requires marketing personnel to ask two questions: What is best for customers and their development? And how do these values affect marketing plans and sales objectives?

We seek rewards by providing authenticity and relevance. This fact means that when an American pharmaceutical company plans to penetrate the Indian market, it must first clarify the needs of Indian physicians and customers. The new pharmaceutical products must be developed according to the needs of the Indian population. An alliance with an Indian company that has strong marketing skills would help respond to these needs .Many Indian companies export drugs to Russia and to Middle Eastern, Asian and African countries .Honing this type of alliance would also provide US companies with access to these markets. WTO actions promote spreading the cost of R&D to a larger base and increasing the availability of drugs to a larger population. These actions would reduce the cost of drugs in the United States. Only two companies in India Dr. Reddy's Laboratories and Ranbaxy have sizable drug discovery programs. Dr. Reddy's Laboratories has licensed preclinical to Phase III compounds to Nordisk and Novartis. This move has given Novartis an opportunity to work with one of India's premier pharmaceutical companies. More and more alliances and mergers are expected between the US giants and domestic pharmaceutical companies in India.

Complications

Accepting the international patent laws does not mean that the patent rights would be fully enforced. IDMA's stance on the patent law changes are

- To comply with specific minimum requirements and only in cases in which it is suitable
- To transfer and disseminate technology as much as possible
- To accept new developments that are conducive to the economic and social welfare of India's citizens. The Indian drug industry must be protected to serve the health of its billion people.
- Not to rush into reforms and if needed, request extensions and complete the reforms in stages
- To make use of loopholes in trade-related intellectual property rights using ingenuity and imagination.

This stance makes it clear that the IPI will try to make use of loopholes as much as possible. The reasons may be legitimate. it is question of one's point of view. The policy seems aimed at providing standard drugs to the masses rather than making modern, expensive drugs available to a few privileged people. However, once the Indian government experiences the benefits of fully honoring the international patent laws, the situation might change. The IPI was expecting a weighted tax benefit on overseas expenses for the pharmaceutical industries such as those for clinical trials, regulatory approvals, patent filing, and litigations. The IPI also expected incentives for R&D. The 2002 budget, which disappointed everyone, may have a hidden message in it. The finance minister of India announced a scheme, called *Janaraksha,* to improve access to healthcare for rural communities, indicating that the government wants to focus on the health of poor people by providing them adequate healthcare facilities. Thus, US companies are expected to establish operations such as clinical trial facilities in India. US pharmaceutical companies invest significant amounts of money to develop new types of formulations and drug delivery systems. For poor countries like India, the cost of drugs is a much more important factor than are fancy drug delivery systems. Local authorities are reluctant to grant approval for such formulations, which they consider to be marketing gimmicks.

A recent report showed that once-a-day formulations are not successful in India patients question the effectiveness of the medicine if only one tablet is administered per day. Such an initial setback can be wiped out by first conducting suitable clinical trials in India to prove the point and then educating patients .Without doubt, India has a parallel economy, so it may be difficult to completely abolish reverse engineering and piracy of drugs. Transparent policies are essential to attract long-term investments. Healthcare reforms in India are inevitable in the current era, and they will ensure a sufficient supply of drugs, controlled prices, and the development of new products. Nevertheless, widespread corruption and a deeply integrated system of bribery make every transaction complicated and expensive. It is very difficult for US companies to apply FDA rules to a manufacturing site in India. The process would require extensive planning, financial investment, training, and a major shift in peoples' attitude. Apart from this, FDA must inspect these sites for GMP compliance. Considering the approvals backlog in the United States and the practical difficulties in conducting inspections in a foreign country, planning of such inspections would be very cumbersome. Local private inspectors could ascertain compliance according to FDA guidance; however, noguarantee exists that the Indian FDA will agree to all the changes. Reciprocity would be needed in terms of these agreements and would undoubtedly lead to long negotiations. The Indian FDA may not approve the current paradigm of the drug development process in the United States. When it comes to GMP and GLP issues, the attitude of top management is the key parameter and thus, the US parent company would be required to provide extensive training to top management and change the culture in the Indian subsidiary. The American pharmaceutical industry has experienced a major influx of Asian Indians, and many of them have reached high levels. In a decade, if the IPI truly flourishes according to expectations, a reverse brain drain from the United States could occur. Its effects may be experienced in the pharmaceutical schools (e.g., teaching assistants) and industry (e.g., scientist level jobs), but no change is expected in the near future.

Business dealings with an Indian company

India's present problems are not solely economic but also are the result of political, psychological, and cultural attitudes. With Indian people migrating back from the United States, few things would change. Among its middle class are numerous college graduates, 40% of whom have degrees in science and engineering. Political, legal, and cultural factors are very critical when dealing with Indian counterparts and the government. The most important point is, don't attempt revolution, but try evolution. With the experience of British rule in its history, Indians are sensitive about foreign people and companies trying to take over. The Indian people and government must first trust foreign companies and their motives. A US company may not want to "invent" new diseases (e.g. male erectile dysfunction) and propose medicines to the Indian people. Indians take significantly less medicines and may not accept a radical change in their medicine cabinets.

Concludatory Comments

Significant amendments in Indian intellectual property rights (IPR) since 1994 continue to Impact the business dynamics in the Indian drug, pharmaceutical and healthcare industries. With pharmaceuticals being a knowledge-driven sector, competitive positions, among other Considerations, are decided on the ability of companies to continually innovate and rapidly diffuse proprietary innovations into the marketplace under a protective and enforceable national canopy provided by IPR. This synopsis tried to present the growth and future of the Indian pharmaceutical industry from such a perspective.Many countries started honoring patent laws from 1 January2005, and India is among the countries that affected. With the second-largest population in the world, a highly educated population that is fluent in English, and well-developed buying power, India has great potential for industrial growth .Its current GDP growth is approximately 6.2%. The annual per capita expenditure for pharmaceuticals is merely $3 compared with $191 in the United States. India has a strong infrastructure for pharmaceutical business environment. The IPI may not be a direct threat to the US pharmaceutical companies, but the Indian pharmaceutical market has important potential that the American pharmaceutical industry may want to explore. Cultural differences may prompt American companies to enter this market with caution; thus, it may be advisable for US companies to acquire suitable Indian companies for easy penetration of the Indian market.

The following facts are noteworthy to gauge the impact of the introduction of pharmaceutical patents in India:

- Consistent growth rate of the Indian economy Rising income levels
- Increasing penetration of insurance on all fronts, especially after allowing entry of private players.
- For the 60% of the "poor" in India, who currently do not have access to pharmaceuticals, price rise and demand sensitivity due to patent introduction is irrelevant. Thus only a small part of the market will be affected by the new regime.

India is governed by a government which relies more on populist politics for survival and this would ensure that the best interests of the population is kept in mind without buckling too much under international pressures. The proposed research plan tries to reflect that a higher standard of patent protection could generate welfare losses for pharmaceutical industries in developing countries. India has been suffering from both static and dynamic losses, with higher drug prices, lower drug availability and underdeveloped domestic innovation capacity. The comparison is made on two grounds: first, contrasting legal systems in terms of patent protection in India, i.e., product patent and process patent in India; second, a similar pre-product patent market structure in the domestic pharmaceutical industry in India. As sufficient flexibilities exist within and beyond the TRIPS Agreement, the governments of developing countries should design socially optimal patent regimes by striking a balance between dynamic gains and static losses.

Possible Solution to the Product patent issue

The most practicable solution to the problem which at the same time allows for TRIPs compliance would be granting of dual licenses. This would mean that the patent would be partly product patent and after a reasonable time being given to the inventor to make a reasonably large profit it would be converted to a process patent whereby the patented drug can be manufactured by competing manufacturers using an alternative process. This would solve the problem of excessive hike in prices and would render the drugs more accessible to the millions suffering. Collaboration with the MNCs on various fronts such as research and development, manufacturing and marketing will help Indian Pharma companies make profitable breakthroughs.

"If people don't get a fair return in innovation, they won't invest in finding new cures for disease this will be disastrous for patients**".**

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