Patent (third) Amendment Bill: Way out for India.
(With special reference to Pharmaceutical Industry)

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ABSTRACT

The pharamceutical industry has been growing at a good pace. The global output of Indian industry ranks 4th in terms of volume and 13th in terms of value. It is one of the globally competitive industries with a strong R & D base, with exports accounting for nearly 32% of total revenue & 90% of the exports contribute generic products. Together they sell medicines worth Rs. 2,00,000 crore every year in the country and export drugs worth Rs. 9,000 crores with no protection for product patent there was scope for all of them to survive as long as it uses unpatented process. In the process India had become the most competitive pharmaceuticals market in the world. However after thriving for decades on process patent, the industry is now facing a huge challenge in the form of Product Patent, being brought up in Patent (third) amendment bill, beginning 2005. This paper seeks to identify the impact of the patent (third) amendment bill on Pharmaceutical industry. It also proposes solutions to common problems that may arise because of the amendment.

INTRODUCTION

The right to life and health is a fundamental right guaranteed to every person living in India and is non-negotiable. There should be an environment that will ensure sustained accessibility and affordability of medicines and treatment for every individual in India, including access to affordable Anti-Retroviral Therapy for persons lving with HIV/AIDS. The Indian Pharmaceutical Industry has come a long way from its modest beginning in 1970 to become a prominent maker of healthcare products, meeting almost 95% of country's healthcare needs. Now, the industry is steeping into a new zone by accepting the challenges of TRIPS agreement.

BACKGROUND OF PHARMACEUTICAL INDUSTRY

The pharmaceutical Industry, globally is characterized by two categories - innovators and generic (generics are unbranded copies of off-patent drugs). In countries where patent protection rules are regorous, 70 to 75% of the market is dominated by innovators and remaining are controlled by generic players. The pharmaceutical indsutry has been growing at a good pace. The industry's revenue have manifold from Rs. 4 bn in 1970-71 to Rs. 290 bn by 2002-2003 registering a compounded annual growth rate of 12.7%. As per the estimates of FICCI, in fiscal 2003 the domestic pharma market was valued at approximately $6bn. The global output of Indian industry ranks 4th in terms of volume and 13th in terms of value. It is one of the globally competitive industries with a strong R & D base, with exports accounting for nearly 32% of total revenue & 90% of the exports contribute generic products. Since 1970 from a market share of 30%, today the domestic pharma companies control over 70% of market and are growing on an average of 20% per year. The industry is highly fragmented with about 10,000 manufacturing units (300 are in organized sector); it employs about 5 lakh people and provide another 2.5 million jobs in the pre & post production. The top ten companies account for more than one-third of the market. As per FICCI estimates, the industry's turnover is expected to touch $25 bn by 2010.

World's Top 10 Blockbuster Drugs and their Patent Status

World's Top 10 Brands in 2003	Year Approved	Patent Expiry	Whether Present in India
Lipitor (cardio-vascular)	1996	2017	Yes
Zocor (cardio-vascular)	1991	2009	Yes
Zyprexa	2003	2017	Yes
Norvasc	-----	Off Patent	Yes
Eprex/Procrit	1999	2013	Yes
Prevacid (anti-ulcerant)	1995	2010	Yes
Nexium	2001	2020	Yes
Plavix	1997	2019	Yes
Seretide	2000	2010	Yes
Zoloft	1991	2012	Yes

Source: Analyst, Feb 2005 issue

At the moment, there are no fewer than 20,000 pharmaceutical companies operating in India. Together they sell medicines worth Rs. 2,00,000 crore every year in the country and export drugs worth Rs. 9,000 crore. For four years, Indian pharma majors like Ranbaxy and Dr. Reddy's Laboratories (DRL) had enjoyed a dream run in the US. By using their low-cost manufacturing and product development skills, these and others like Cipla, Wockhardt, Sun and Lupin had cornered a 4 percent share of the $16-billion US generics market. They had developed a reputation as the lowest-cost manufacturers in a market with the world's highest drug prices. But now, for the first time shock waves are sent through the stock market and the industry. Ranbaxy Laboratories announced an 8 percent drop in quarterly sales to Rs. 470 crore and net profit plunged 93 percent to Rs. 4 crore compared to Rs. 59.20 crore in the same quarter the year before. The stock market reacted by knocking some 5 percent off DRL's stock.

With no protection for product patent there was scope for all of them to survive as long as it uses unpatented process. In the process India had become the most competitive pharmaceuticals market in the world. However after thriving for decades on process patent, the industry is now facing a huge challenge in the form of Product Patent, being brought up in Patent (third) amendment bill, beginning 2005.

Figure 1

NET PROFIT MARGIN (*in percent*) OFTOP FIVE PHARMA COMPANIES

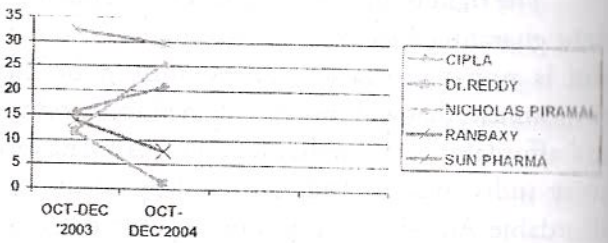
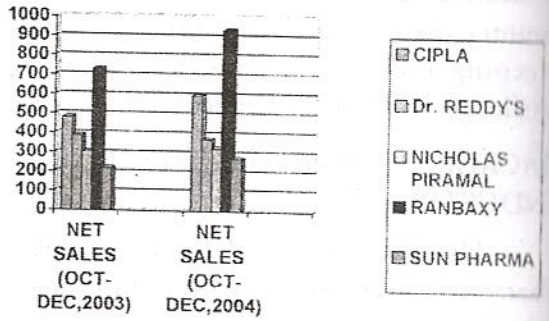


Figure2

NET SALES (*in Rs. Crore*) OF TOP FIVE PHARMA COMPANIES



THE THIRD PATENT AMENDMENT BILL

The patent (third) amendment bill, is a bill which will pave the way for a new patent law. As India is a member of World Trade Organisation, it had to fulfill the obligation under the TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement. The main aim of new Bill is to further amend IPA (1970), not only make the law.

The Indian Patent Act 1970 that came into effect from 1972 provided the pharma industry with only 5-7 years of process patent protection, which gave the domestic industry a huge opportunity to produce generics. In brief, it meant that domestic companies could copy drugs patented abroad as long as the processes used were different. Last year more than 60,000 generic brands in 60 therapeutic areas were available in India accounting for 1% of value and 8% of volume of world pharma markte.t Under the Indian Patent Act, the grant of compulsory license is available only for those drugs that ar e patended under the act. Compulsory licensing is not provided for drugs patented elsewhere. But, under the 1994 WTO's TRIPS Agreement, India committed to adopt product patent for food, drugs, chemicals and embedded software. The salient objectives of the Patent (third) amendment bill are to introduce product patent regime for all invention, to delete the provisions relating to EMRs (exclusive Marketing Right) and to introduce provision of grant of Compulsory Licenses to supply drugs to countries which have no manufacturing capacities to meet their acute public health problems and to strengthen issues relating to public health. In other words, any drug or medicine patented after 1995 can no longer by cloned by Indian companies. This Bill will increase the prices of new medicines for:

* Cancer
* H.I.V.
* Diabetes
* Common Diseases

Even today medicines reach less than 40% of the population. A patent system that encourages monopolies could price new drugs out of the reach of most consumers.

INTRODUCTION OF PRODUCT PATENT

PATENT: A patent is a limited monopoly given to individuals/corporations for a limited number of years for technological inventions/ innovations by preventing others from using the patented technology. It is granted at the request of individuals/corporations by the Patent Office in respective countries. Hence, the patent right is available within the territory of the granting countries. Patents are granted as an incentive for innovation. At the same time Patent laws all over the world have safeguards to prevent the abuse of the monopoly granted to the Patent holder.

Process patent does not prevent others from making the product per se but prevents other from using the patented process as well as using, offering for sale, selling or importing the product obtained from the patented process. On the other hand, **product patent** prohibits others from making, using, offering for sale, selling or importing the patented product.

Indian Scenario

In the Indian Patent Act 1970, food medicines and drugs including substances obtained by chemical processes were granted only process and not product patent. As a result, more than one person was allowed to make the same drug provided they use different process to make their version of the product (if the process is protected by patent). Further, till 2002, the term of patents for pharmaceutical inventions was only seven years. These two factors enabled competition in the market by permittin more than one producer to produce the same drug. This resulted in the phenominal growth of pharmaceutical industry in India and increased availability and accessibility of drugs. As a result drugs are available in India at world's lowest price. However with the latest

amendment whatever falls within the purview of definition of 'invention' will be patentable in India. The amendment to the Act in 2002 defines invention as "A new product or process involving inventive steps & capable of Industrial application".

EXCLUSIVE MARKETING RIGHTS

The holder of EMRs, granted in respect of products covered by product patent application, will continue to enjoy their exclusivity till the patent is granted or rejected. To avoid delays in the examination of such product patent applications for grant of patent, the ordinance requires those applications to be examined immediately.

COMPULSORY LICENSE

It is one of the most controversial provisions of patent legislation. Compulsory licensing means a situation where a government allows an agent to produce a patented product without the consent of original patent owner. Such authorization is provided under Article 31 of TRIPS. Chapter XVI of the Act deals with provision of Compulsory License in India. The recent ordinance has added a new provision, section 92A, which allows the grant of compulsory License to manufacture and export a patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems, provided a compulsory license has been granted in that country.

Due to existence of compulsory license provisions, MNCs will be forced to work their inventions in India in case they obtain an Indian Patent. In the event, for a period of more than 3 years if the patented inventions is not worked in India; the patent will be open for compulsory license. Thus Indian industry as a whole is likely to benefit.

India's Situation as WTO member

There are several reasons why India's situation is unique among WTO Members:

a. In the period of the GATT Uruguay Round negotiations, India alredy maintained a vibrant generic pharmaceuticals sector and was the country most likely to be affected by a change in the global pharmaceutical patent regime.

b. India employed a skilled negotiating team that bargained hard to secure the viability of its domestic pharmaceutical industry. The terms of the deal struck in Articles 65 and 70 of the TRIPS Agreement were India's response to pressures from the United States, Europe and Japan and their pharmaceutical industry constituency.

c. Among significant developing country producers of pharmaceuticals, India alone has taken full advantage of the TRIPS transition arrangements. And thus has encouraged the development of its generic pharmaceuticals sector, which is a principal supplier of low cost pharmaceuticals not only to its domestic market, but also to the rest of the developing world.

d. The Indian pharmaceutical producers demonstrated to the world that medicines to treat HIV-AIDS could be produced and sold at a fraction of the price being charged by the major Pharma companies, and opened the door to the possibility of comprehensive treatment of those infected with HIV.

PROBLEMS:

After the introduction of product patent protection only the patent holder or any authorized person through license can produce the patented drug during the lifetime of the patent. As a result, there would be only one manufacturer producing and distributing the patented product. (Most of the Patents are hold by American Pharmaceutical companies) Introduction of product patents means that drug companies in the normal course come out with generic will not be able to do so until the expiry of 20 years of patented life. Further, the implementation of product patents cover all drugs patented on or after 1 January 1995. Hence, the

product patent regime reduces the access to many new drugs and compromises the right to health.

Indian companies have to compete with the MNC, who until now faced unfair competition, as their Indian counterparts produced their products at a fraction of the original cost and in lesser time. For instance, to develop and clinically test a new drug, it costs around $500-600mn for MNCs, while the Indian companies could manufacture the same drug for just $15-20mn. The impact of product patent in India will not be visible immediately. However, the product patent will reduce the access to new medicines. The companies which have new patented products will be able to launch new drugs in the market and those that do not patented products will have to either continue with their old products or spend on R & D activities to introduce new products.

As a result the product patent gives a monopoly to the patent owner for the production of patented article during the term of the patent (20 years). Therefore product patent protection for medicines and agro-chemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. The introduction of product patent thus reduces accessibility and affordability of drugs. The impact of monopoly on access to medicines is already felt in India. The Controller of Patents has granted an Exclusive Marketing Right (EMR) to Novartis AG, for the drug called Gleevec used for the treatment of patients suffering from Chronic Myeloid Leukaemia (CML), a life threatening form of cancer. EMR is granted as a transitional arrangement before providing product patent protection.

Monopoly drugs

Company	Brand/category	Price per unit
Novartis capsule	Gleevec/anti-cancer	846 per
Aventis	Vaxigrip/Influenza Vaccine	650 per vial
Aventis	Avaxim 160/ Hepatitis A Vaccine	1360 per vial
Astra	Meronem/ Anti-bacterial	2245 per vial
Fulford	Caelyx/Anti-cancer	43000 per vial
Aventis	Okavax/chicken pox vaccine	1412 per vial

Source: Fortune India, Feb 28, 2005 issue

Comparision of drug prices (In Rupees)

Drugs, dosage	India	Pakistan	United States
Zidovudine (anti viral)100 mg	77	313.47	895.90
Atenolo (Cardiovascular) 50 mg	7.50	71.82	753.94
Boposide (anti- cancer) 100 mg, injection	190	554.69	6,210.30
Cirprofloxacin 500 mg (anti-infectives)	29	423.86	2,352.35
Rantidine (anti-ulcerants) 150 mg	6.02	74.09	863.59
Conversion rate of exchange considered US dollar- Rs 45.50, Pakistani rupee- Rs. 0.84			
Sources for prices: US prices- Red Book 2002, Pakistan - Pharmaguide, june 2002-03 India-IDR November/December 2003			

IMPLICATONS

The patenting of drugs will certainly have significant long-term implications on domestic industry. The new patent regime will open a new

chapter in the process of globalisation when almost the entire world will be governed by uniform set of rules as far as the vital health care industry is concerned. The Indian Pharmaceutical companies will have to focus on new drug research themselves. In short-term, no significant changes are expected. Vast majority of products (97%) available in India are already out of teh gamut of patents. There are about 5,500 application in black box at patents office, which will take the couple of years to clear and through clarity in this issue.

In long-term, MNCs will augment their presence in India, MNCs will also try to capitalize on low labour cost.

The new law prohibits many manufacturers from "making, using, offering for sale or importing the patented product", unless the patent holder is paid patent fees. As a result it is believed that the customers will be charged heavily by manufacturers in order to compensate for heavy patent fee. According to the reports by researchers, life saving drugs will cost 10 to 20 times more than their current prices. For instance, the generic version of Gleeve, an essential drug to treat cancer, currently cost Rs. 9,000 to Rs. 12,000 per month. In post patent era it will cost as much as 1.20 lakh. Another example is anti-retrovial drugs for treatment of AIDS. They currently cost Rs. 7,000 for one year course and post patent the cost will be around Rs. 2 lakh. According to activist, there are 40 million people living with HIV (5 million living in India) in the world. Of these, at least 6 million people are in immediate need for treatment. However nly 4.40 lakh peope with HIV in developing countries have access to anti-retrovial treatment and this access has been facilitated by the competition from an Indian generic drug, leading to sharp reduction in the cost of medicineby as much as 98 percent. For instance Cipla laboratories see anti-retrovial drug for treatment of AIDS at prive of $140 per patient per year as against the price of $12,000 being chargedby MNCs. Statistic suggest that most of the HIV patients belong to lower strata of society. In fact, not even 1% of them can afford such high prices. This means that these patients will be left without any alternative. Along with Indian customers, other customers of developing countries who export the Indian drug will be effected by high prices. According to WHO India is fourth largest producer of Pharmaceuticals and 66.7% of its exports are to developing countries. However assurance can be given to pharma community and consumers since 97% ofdrugs are off patent and 3% drugs which can be patented, there are methods and various alternatives that the government can use to ensure their availability at affordable price. There are also provisions that the patents can be revoked in public interest in cases such as national emergency or shortage of drugs. It is also argued that prices are greatly determined by market competitive situation. Prices of existing products will remain stable. Prices of patented products launched in India will possibly be high having parity with international prices, though the number such products will be few.

Another area of concern for the domestic industry is the "everngreening" of products. "Evergreening" is the term used when patent owners attempt to extend the patent monopoly by seeking a new patent that updates the first one before its expiry. According to IPA (Indian Pharmaceutical Alliance), big pharma players use this concept to keep modified versions of their patented drugs in the market, even after the original drug goes off patent. The IPA says that domestic industry can capture one-third of global generic trade of exports worth Rs. 90,000 crore by 2010, provided India's new TRIPS compliant Patent Act keeps evergreening.

However, it is also argued that Prices are greatly determined by market competitive situation. Prices of existing products remain stable. Prices of patented product launched in India will possibly be high having parity will international prices, though the number of such products will be few.

MAJOR ISSUES

- A major concern due to product patenting is the rise in the prices of drugs to our consumers. With the effect of product patent Indian people's accessibility to newer drugs will be

restricted only to rich of the country.

- As per the guidelines, a product patent is granted for 20 years and process patent for another 20 yeaqrs. At present new drugs are made available within at 4-6 years period.
- As evident from the prices of drugs in India and other countries like Pakistan, and U.S.A. where product patents are in force, prices of drugs will go up by 5 to 10 times.
- Inadequate infrastructure in terms of granting of patents and functioning of patent offices in India, increased cost of administering and enforcing the patent system are other major issues to be pondered upon.
- It might result in local production being replaced by imports and hence loss of employment and self-sufficiency.
- Drugs worth about Rs. 3,000 crore, representing about 15% of domestic pharmaceutical market, is estimated to come under patent protection (Business Standard, 29th December, 2004).
- There would be complex patent-related litigations as the patent offices starts examining and granting patents after the rules are notified.
- Today Indian companies are the largest suppliers of low cost drugs to developing countries. For example, an estimated 60% of drugs to treat HIV-AIDS come from India. The new law will make this impossible, thereby threatening the live of hundreds of thousands- not only in India, but across the globe.
- Indian companies may not get royalties, which the MNCs may demand in respect of their patent molecules. Indian companies which are currently manufacturing certain molecules will be required to cease their activities once the patents are granted in respect of the same molecule (application for which were pending in the black box).
- Since MNCs are now assured of protection of their IP in India, they will be willing to transfer technology to Indian players.

In order to survive in the post patent regime, large Indian companies have to find the way out to face the challenges thrown by the Patent (third) amendment bill.

SUGGESTIONS-

- **Export by a Licensee:** The TRIPS agreement allows exports by manufacturers who produce through a compulsory license. Unfortunately the Indian Act does not explicity provide for this. This is of particular importance in the case of pharmaceuticals where Indian licensee can export drugs to the developing country markets at relatively lower prices, to the mutual benefit of both.
- **Contract Manufacturing outsourcing:** Low-cost and superior knowledge base are likely to act in India's favor and most MNCs will be propelled to set up R & D facilities in India. MNCs can transfer their technology to Indian manufacturers and get the drug manufactured in India. It is estimated that contract manufacturing market for global companies in India will touch $900mn ny 2010.
- **Global Research Hubs:** Research and development activities are thriving in India and most Indian companies can serve as research hubs for multinational players, considering the cost -effectiveness and presence of skilled human resource and fast developing infrastructure. India is already seeing an inflow of funds from both local investors and multinational organizations.
- **Clinical trials:** The large patient pool and low-cost investigators too will play a major role in this regard. These centers can move towards conducting clinical trials. Once clinical trial centers are set up in India according to international standards, the approval of Indian drugs will speed up.
- **Pre-grant opposition:** Pre-grant opposition is an instrument by which Patent applications

can be challenged-and a strong provision would help in limiting the numbers of Patents granted. The mail box that has been opened since 1995, and recognized in 1999 in our legislation, should not be an invitation to indiscriminate recognition. India must permit pre-grant opposition so that spurious applications with doubtful antecedents can be rigorously scrutinized.

- **Royalty Amount:** Following the lead of other countries, the royalty should not be more than four per cent. It cannot ve overlooked that such a royalty would inure to the monopolist patent holder without investing a rupee.
- **Patentability:** The first step in this direction would be to deny usage and dosage patents. Contrary to popular perception, there are many patents on a single drug mainly on their usage and dosage forms. Such multiple patents on a single drug will extend the monopoly beyond the expiry of original patent. A study shows that out of 1035 new drugs approved by the US regulatory authority during 1989-2000 only 35% contains a new chemical entity. However, the bill proposes to provide patents to new use of known medicines.
- **Revamp of the Compulsory Licensing:** Another step would be a total revamp of the compulsory licensing system. Thepresent compulsory license regime in the Patents Act is loade with cumbersome procedural formalities with no fixed time line. Fulfillment of these formalities itself delays the granting of compulsory licensing unreasonably and reduces the compulsory license to an ineffective mechanism to check monopoly.
- **Improving Infrastructure Facility:** Inadequate infrastructure in terms of granting of patents and functioning of patent office in India are a major cause for concern. If proper steps not taken, it may act as a major hindrance for the smooth functioning of the product patent regime.

CONCLUSION

It is a difficult to predict with certainly the impact of the January 1, 2005, TRIPS transition on the Indian generic pharmaceuticals sector because there are a substantial number of unknowns. The impact of this transition will become evident in the year to come. In the meantime, the Indian pharmaceutical industry must gear up to face the challenges. Due to existence of product patent regime and factor such as availability of skilled manpower at lower cost, India has the potential of emerging as a major exporter of new pharmaceuticals. Sooner or later the Indian pharmaceutical companies will have to transform into knowledge based organizations capable of producing researach-based medicine at prices affordable to the Indian people. MNCs may increase their focus on India by creating subsidiaries or entering into collaborations or licensing arrangement with Indian companies. At the moment, the choice of MNCs has been to establish fully-owned R&D subsidiaries in India. It would seem to be in the best interests of India and its people, as well as individuals througout the developing world in need of medicines, to manage this transition in a way that aviods severe disruption to the supply of important medicines.

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