AUTHORS

Dr. M.K. Gupta
Lecturer,
PG Dept, of Commerce
Government College,
Faridabad

Mehak
Lecturer in Finance,
DAV Institute of
Management,
Faridabad

Surviving the Patent Regime

The Effect on Pharma Industry

ABSTRACT

Even after the completion of one and a half year of Patent (Amendments) Act, 2005, there has been no effect on the pharmaceutical industry in India, as was being expected. The passage of the Act was supposed to have lead to a rise in the prices of drugs in the country. This was due to the fact that once the Indian companies stopped manufacturing patented drug molecules; there would be shortage of drugs/ substitutes of drugs available in the market. Patent holding firms will have a monopoly in the market and would charge prices of drugs according to their own considerations. However, prices of most of the medicines continue to remain the same. Even the availability of the medicines has not been affected by the enactment of the law. The paper below analyses the situation that prevails in the Indian pharmaceutical industry after the implementation of the Patent (Amendments) Act, 2005.

1. INTRODUCTION

One of the largest and most advanced among the developing countries. It has done tremendous progress in terms of scientific knowledge base creation and development of infrastructure required for production of world-class drugs. It has immense flexibility to move from one drug to another with the ability to respond quickly to new demands. Even after the completion of one and a half year of Patent (Amendments) Act, 2005, there has been no effect on pharmaceutical industry in India, as was being expected. The hype that surrounded the Patent Act has proved to be wrong. In the study that follows an overview of the situation of the Indian pharmaceutical industry has been done and an effort has been made to find out how far the patent Act has affected us.

2. IMPACT OF PRODUCT PATENTS ON INDIAN PHARMACEUTICAL INDUSTRY

The Patent (Amendments) Act, 2005 was passed on 29th March 2005. The Act has completed almost one and half year in the country. This means that more than a year has passed since the product patents have been introduced in the country. The passage of the Act was supposed to have lead to a rise in the prices of drugs in the country. This was due to the fact that once the Indian companies stopped manufacturing patented drug molecules; there would be shortage of drugs/ substitutes of drugs available in the market. Patent holding firms will have a monopoly in the market and would charge prices of drugs according to their own considerations. However, till date no effect of product patents has been observed in the market. A detailed analysis of the Indian pharmaceutical industry shows:

1. 97% of the drugs used in India are off patent. The government has a list of 354 drugs listed as 'Essential Medicines'. None of them is patented.

2. Drugs patented before 1995 do not come under TRIPS purview. This means that drugs that received patent protection before 1st January 1995 can still be produced through reverse engineering by Indian firms.

3. Till date only one company has succeeded in securing a patent in India. The

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Controller General of Patents granted the first product patent in pharmaceuticals to Roche India Pvt. Ltd, the Indian arm of Swiss drug maker F Hoffmann La Roche, on 1st March, 2006 for its biotech drug Pegasys (Pentaferon apha-2a). No other company will now be allowed to launch a generic version of the drug in India. The company had applied for the patent under the Mailbox facility for post-1995 inventions. Pegasys, a recombinant DNA technology drug, is one of the advanced drugs in the Interferon series of proteins, which has varied end uses, mainly for treatment of serious viral infections and consequent diseases like cancer. It has specific application in adults who have hepatitis C and signs of liver damage.

Many Indian companies like Hyderabad-based Shantha Biotechnics market interferon drugs in India. These companies, however, would not need to discontinue production and marketing. This is because, as per the patent rules, companies that had introduced the drug prior to January 2005 would not need to stop production, even if a patent is granted. Novartis is another multinational company that has applied for a patent for one of its drug – Gleevec. The drug is used for the treatment of cancer. A few Indian firms are making the same drug through reverse engineering. However till 30th September 2007 the case was pending with the Madras High Court.

4. Even prices of patented molecules are under the control of National Pharmaceutical Pricing Authority (NPPA) through Drug Price Control Order (DPCO), 1995. The authority has the power to

a. Control the prices of all drugs with a minimum turnover of Rs. 4 crore per annum. Drugs with even lesser turnover can also be kept under price control if there is a monopoly situation.

b. Fix ceiling prices for commonly marketed standard pack sizes of price controlled formulations and it is obligatory for all units in India to follow that price. The NPPA has divided the total pharmaceutical market into 11 segments -

(i) Analgesics and Antipyretics - Most of the popular drugs like analgin, aspirin and paracetamol are off patent. Yet DPCO coverage is high hence prices are low.

(ii) Antacids and Anti-ulcerants - This segment has a large number of new under patent molecules, due to ongoing R&D on developing more effective ways to combat acidity/ulcers. However DPCO coverage is high. The major drug is Ranitidine. But this drug has gone off patent in July, 97.

(iii) Antibiotics - The earlier generation drug groups such as Penicillin, (e.g. Amoxycillin) and macrolides (e.g. Erythromycin) have mostly gone off patent. Newer generation groups like Quinolones (e.g. Ciprofloxacin) and Cephalosporins (e.g. Ceftriaxone) are still under patent. DPCO mostly covers the major latest drugs. However Cephalosporins will be soon off patent by 2010 and they have a high export potential.

(iv) Antituberculosis - All popular drugs are off patent. DPCO continues to cover the major drug Rifampicin. Export opportunities may grow manifold if the spread of AIDS leads to large-scale resurgence of TB in Developed nations.

(v) Antiparasitic and Antifungal - Most of the popular drugs used in India are off patent. DPCO coverage is low. Under DPCO'95 some drugs have been excluded but no new addition has been made. Presence of a large number of firms in this segment keeps the price low.

(vi) Cardiac Therapy - Most of the popular drugs used in India are off patent. DPCO coverage is also low. The leading players are mostly Indian companies. With increasing level of urbanization in India, heart trouble is

on the rise. Also, cardiac therapy is a long-term therapy, providing a good market to the Indian companies.

(vii) Corticosteroids - All drugs popularly used in India are off patent. Though some major drugs were excluded under DPCO'95, it still covers the major drugs Betamethasone and Dexamethasone.

(viii) NSAIDS, Anti-rheumatic - All drugs popularly used in India are off patent. DPCO coverage is high due to the inclusion of the major drug Ibuprofen under price control. A large global market for NSAIDS makes Ibuprofen the top pharmaceutical product exported from India. But, the presence of a large number of firms in the industry keeps prices low.

(ix) Respiratory System - Patent coverage is very low. Also, as DPCO has most popular anti-cough drugs, there have been price hikes and high sales growth.

(x) Vitamins - They are mostly used in case of deficiencies in India. Globally, the trend is to take them as tonic. So, if such a trend develops in India, the domestic market is expected to be huge. All drugs are off patent. But DPCO coverage is high hence prices are low.

(xi) Other Therapeutic Segments - This covers segments like anti-anaemic, anti-diabetic, anti-emetic, anti-histamine, anti-malarial, CNS, psychiatry therapy, gynaecologicals, nutrients and mineral supplements. The major group is psychiatric group. DPCO coverage is high in all segments.

All major drugs (approx 97%) used in India are off patent. Hardly 3%of the drugs are under patent. Applications for those 3% molecules are lying with the Patent Office. Within a span of 1.5 years only one molecule has received a product patent. And for that molecule also, the company has not yet raised the prices. Further, DPCO coverage is high on major patented drugs. Medicines patented before 1995 can still be manufactured. Applications for molecules patented after 1995, are still lying in the mailbox. The Patent Office is examining those applications. The study shows that molecules that are now under development shall take atleast 2-3 years to get a patent.

It appears that the Patent Law has still not reached at the grass root levels in the Indian pharmaceutical industry. The actual effect of product patents will be visible by 2008-09 when newly developed patented molecules reach India.

3. PRIMARY DATA SURVEY

A survey was done from various groups of people in Faridabad, Gurgaon (Haryana), Delhi and Noida (Uttar Pradesh) to find out what they felt about the Patent Act, 2005, The groups of people comprised of employees of pharmaceutical companies, private medical practitioners, doctors working in various hospitals and nursing homes, chemists, pharmaceutical distributors and wholesalers, people who were taking medicines i.e. patients of various diseases like cardiac, blood pressure, brain stroke, cancer etc and the general public at large.

These groups of people were asked various questions related to the amended patent Act of 2005, its after-effects according to their knowledge and awareness about the pharmaceutical industry etc. The survey was done on the basis of personal interview and through questionnaire drafted separately for separate groups of people. Further the tabulated result shows the figures calculated in percentages and are not absolute figures. Following is a detailed analysis of the survey. Tabulated result of the survey of the various categories of people has been shown accordingly.

Table1
Details of sample selected for primary data

S. No.	Category	No. of Respondents
1.	Private Medical Practitioners	104
2.	Doctors Employed in Hospitals	94
3.	Patients taking medication for a period of 1-5 years	106
4.	Patients taking medication for more than 5 years	128
5.	Chemists	58
6.	Pharmaceutical Distributors	53
7.	Company Employees	112
8.	General Public	227
	Total	**882**

(Based on primary data)

Category – Company employees, Employed Doctors, Private Medical Practitioners, Chemists and Pharmaceutical Distributors

1-The new patent law is appropriate for India

The respondents were asked whether they were satisfied with the finally Amended Patent Act or not. Further they were also asked whether they would like to suggest any changes in the final draft or how would they like to see this law being implemented. To this the respondents gave a mixed reply. 36.36% of the company employees, 35% of doctors and private medical practitioners (approx), 29% of chemists and 39% of pharmaceutical distributors gave a positive reply. Approximately 40% of respondents in all groups gave a negative reply i.e. they felt that the Indian pharmaceutical industry is going to suffer due to the introduction of patent regime.

They said that the Indian population that comprised of a large number of below poverty line population could not afford to pay for patented drugs. According to them the actual low-income group citizens of India who could not even afford their meals properly were just not in a position to pay for expensive patented drugs. However they said that the impact of patent regime would be felt only after the drugs start getting patented. This will take a minimum of 3-4 years as most of the drugs in the Indian market being commonly used are off patent.

Category – Patients and General Public

The two categories- patients and the general public were asked a separate set of questions. The questions asked were a little more general, based on their knowledge and awareness about the pharmaceutical industry.

1-Source of information on patent act and the Government's initiative to create awareness

The respondents were asked about their source of information on the patents act and whether they were satisfied with the government's efforts to create awareness on the issue. Towards this approximately 40% - 50% of the respondents replied that they had no information about the Patent Act. The percentage was more in the patient category of the remaining respondents approximately 12-15% of those interviewed said that T.V. (television) was their source of information on Patent Act.

Approximately 12% of the patients attributed newspaper as their source of information. The percentage was higher amongst the general public category i.e. 30%. Radio was the main source of information for approximately 2% of the patients whereas friends and social gatherings accounted for 3% of the patients and 12.5% of the general public.

Table 2

Statement - The new Patent Law is appropriate for India ***(Figures in percentages)***

Company Employees		
Yes	**No**	**Can't say**
36.36	27.27	36.37

(Based on primary data)

Table 3

(Figures in percentages)

Employed Doctors			Private Medical Practitioners		
Yes	**No**	**Can't Say**	**Yes**	**No**	**Can't Say**
37.2	39.1	23.7	26	40	34

(Based on primary data)

Table 4

(Figures in percentages)

Chemists			Pharmaceutical Distributors		
Yes	**No**	**Can't Say**	**Yes**	**No**	**Can't Say**
32	38	30	29	43	28

(Based on primary data)

Table 5

Statement - Source of information on Patent Act

Patients Percentage of Respondents Accepting as Yes / No / Can't Say									
Taking medication for more than 5 years					Taking medication for the past 1-5years				
T.V.	**N.P.[1]**	**Radio**	**Others**	**N.I.[2]**	**T.V.**	**N.P.**	**Radio**	**Others**	**N.I.**
21	18.5	5.5	12.5	42.5	21	18.5	5.5	12.5	42.5

(Based on primary data)

Table 6

General Public Percentage of Respondents Accepting as Yes / No / Can't Say

T.V.	N.P.[1]	Radio	Others	N.I.[2]
15	30	2.5	12.5	40

N.P. – Newspaper [2]N.I. – No Information on Patent Act *(Based on primary data)*

Table 7

Any visible changes in the following after 2005

Patients Percentage of Respondents Accepting as Yes / No / Can't Say						
Statement	**Taking medicines for more than 5 yea**			**Taking medicines for 1-5 years**		
	Yes	**No**	**Can't say**	**Yes**	**No**	**Can't say**
Increased price of drugs	62.5	12.5	25	58.16	28.63	13.21
Difficulty in availability of medicines	17.5	65	17.5	16.43	69.64	13.93

(Based on primary data)

Table 8
General Public

Percentage of Respondents Accepting as Yes / No / Can't Say			
Statement	**Yes**	**No**	**Can't say**
Increased price of drugs	49	12.0	39.0
Difficulty in availability of medicines	15	57.5	27.5

(Based on primary data)

2-Changes after the enactment of patent law in 2005

As far as the prices of medicines are concerned majority of respondents approximately 60% of the patients and 49% of the respondents in general public category said that the prices of medicines have increased. But what is important is that the respondents cited the implementation of VAT (Value Added Tax) as the main reason for price increase. When asked about the quantum of **price rise**, the respondents said that, on an average the prices of medicines that they had been using had increased by about 5-10%. They did not complain of any price rise beyond 15%. Hence, the rise in prices was mainly attributed and being seen as the genuine inflation which had been affecting other commodities also.

As regards the availability of medicines was concerned, majority of respondents approximately 68% in the patient category and 57% is the general public category gave a negative reply. They said that with time, the number of chemist shops had in-fact increase. In certain areas of Delhi and Faridabad where the local municipal corporations had been carrying out sealing drives, the respondents said that only the medical facilities like chemist shops and nursing homes had some amount of exemption. Hence, as far as the availability of medicines was concerned the respondents said that they faced no problem. Some of the respondents even cited names of some chemist shops that had 24-hour service.

4. CONCLUSION

The study highlights situation that prevails after the enactment of the Patent Act. This way, it can well be concluded that the Patent Act has neither affected the price of medicines nor their availability. Further it can also be concluded that the real effect of the patent Act will be visible only by 2009-2010 when newly discovered patented drug molecules enter the Indian market.

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