PATENT REGIME IN INDIA

Introduction

In India the pharmaceutical sector is one of the fastest growing industries. The Indian pharmaceutical industry produces nearly 8% of the world’s drugs and is among the top 15 drug manufacturing countries in the world. It is the fifth largest manufacturer of bulk drugs. However, the structure of the Indian pharmaceutical industry is changing swiftly with the introduction of the Patents (Amendments) Act, 2005. This Act is in compliance with Trade-Related Aspects of Intellectual Property Rights (TRIPS) provisions of the World Trade Organisation (WTO). TRIPS is an instrument in terms of rules, regulations, and dispute settlement for trade between countries. It applies to industries where Intellectual Property (IP) plays a key role. It is a product of mind. It includes

- Literary, artistic and scientific works
- Inventions in all fields of human endeavor
- Scientific discoveries
- Industrial designs
- Trademarks, service marks, commercial names and designations

The current study deals with scientific discoveries in the field of pharmaceutical industry. The pharmaceutical products are provided protection for a minimum period of 20 years under TRIPS and this protection is known as a Patent Right. Protection of drugs through patents is important in pharmaceutical industry because financial investments are huge and risky.

Each country has its own Patent Act. The patent act that was in force in India before 2005 recognised the patenting of the processes of manufacture of drugs and not the drugs themselves. However on March 29, 2005 the Indian Parliament passed the Patents (Amendment) Act, 2005. The Act is in compliance with the TRIPS Agreement of WTO. The new Patent Act now recognises product patents instead of process patents. The transition was not immediate. India signed the TRIPS Agreement of WTO in 1995. But being a developing country was given a transition period of 10 years. Within these 10 years, the Indian Patent Act was to be made compliant to TRIPS Agreement. During these 10 years
various amendments were made in the Patent Act and finally a completely modified version as per TRIPS requirement was passed in March 2005. The current chapter is based on the impact of WTO Patents regime in India.

**World Trade Organisation**

WTO or World Trade Organisation was established on January 1, 1995 with headquarters located in Geneva, Switzerland. It has a membership of 150 countries, which account for over 97% of the world trade. WTO is the only international organisation dealing with global rules of trade between nations. Its main function is to ensure that the trade flows as smoothly and freely as possible. WTO has various agreements through which it tries to ensure that trade is fair and practical as far as possible. The agreements are the result of negotiations between the members. They relate to goods, services and intellectual property.

**WTO Agreement on TRIPS**

The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into existence on April 15, 1994. It introduced intellectual property rules into the multilateral trading system.

**What are intellectual property rights?**

*Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.*

Creators can be given the right to prevent others from using their inventions, designs or other creations — and to use that right to negotiate payment in return for others using them. These are “intellectual property rights”. They take a number of forms. For example books, paintings and films come under copyright; inventions can be patented; brand names and product logos can be registered as trademarks; and so on.
TRIPS Agreement on Patents

The TRIPS Agreement requires member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1). The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33).

Further the TRIPS Agreement provides certain flexibilities to its member countries that include:

1. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

2. Each member has the right to determine what constitutes national emergency or other circumstances of extreme urgency, during which patent rights may be temporarily suspended. Public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent national emergency or other circumstances of extreme urgency.

3. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge.

Implications of the TRIPS Agreement for the Indian Pharmaceutical Industry

1. Product patents to be allowed for all drugs from 2005.

As per the Agreement all member countries were expected to comply with the new provisions of TRIPS from 1st January, 1995 onwards. A transition period of 10 years from 1995-2005 was given to developing countries. India signed the TRIPS Agreement in 1996. With the signing of the agreement India agreed to make its IPR Laws TRIPS compliant from 1st January 2005. This means that post 2005 Indian firms cannot manufacture copies of patented products through a different process.
Only drugs which have been patented before 1995, or those that have completed their patent protection can now be manufactured freely.

2. **Patent holders can import products.**

This means patentee will be under no obligation to produce the patented product locally. The removal of import and tariff barriers as per the WTO requirements will further facilitate the patentee to avoid local production and to rely on imports from its own home country. Patent holding firms can manufacture drugs in their home country (Article 27.1) and sell in India.

3. **Twenty year term for all existing and future patents**

This means that drugs once patented will enjoy protection for a period of 20 years. During this period no Indian firm can manufacture a generic copy of the drug, unless the government declares a national emergency. However, TRIPS Agreement permits generic manufacturers to obtain market approval from the patent office during the patent term itself, so that immediately after the expiry of the patent term a generic copy can be manufactured.

**Study of Indian Patent Laws**

The concept of Intellectual Property started in India during the British rule when enactments like the Patent Act of 1856, 1859, 1872 and 1883 were introduced. However, since their introduction, they have been amended many times to bring them to their present status.

**History of IPR in India**

The first Indian Patent Act was enacted in 1856. The Act granted exclusive rights and privileges to the inventor. It was enacted without the previous sanction of the Queen of England, hence was repealed in 1857. It was replaced by another Act in 1859 and involved plugging of certain loopholes in the previous enactment. The Patents and Designs Protection Act of 1872 and 1883 further supplemented it. Then came the Designs Act V in 1888, which was again repealed by the Designs Act II of 1911. It adopted the provisions and structure of the Patents and Designs Act, 1907 of United Kingdom. After independence, a committee of
enquiry was appointed under the chairmanship of Justice Bakshi Tekchand to suggest the modifications and alterations needed in the Indian Patents and Designs Act 1911, so as to make it an effective instrument for technological self-reliance. The Act of 1911 prevailed till 1970 when the Indian Patent Act, 1970 was passed on 27th February 1970. It formed the basis of Patent Law in India and came into effect from 20th April 1972. During the period 1947 to 1970, the Act of 1911 provided a strong product patent regime. Most of the effective drugs were under the patent control of foreign companies and were not produced in India. The Foreign Direct Investment (FDI) in drug industry was minimal, just enough for marketing activities. The country was totally dependent on imports for bulk drugs and there was some production of formulations mainly by few national sector units. The drug prices were the highest in the world.

**Indian Patent Act 1970**

The Indian Patent Act 1970 came into force on 20th April 1972. Under this Act product patents were not allowable and only process patents were granted in respect of inventions related to drugs, medicines, foods and agrochemicals (Section 5). This enabled indigenous drug industry to manufacture products patented in other countries by developing and using a different process. This practice of producing a drug from a different process came to be known as reverse engineering. This was largely responsible for the nation and the Indian drug industry achieving excellent all-round progress and development. Developing its own technology and producing widest range of drugs enabled the country to become self-reliant & self-sufficient. The consumers got effective drugs at the cheapest prices in the world. Many of the drugs produced by the Indian manufacturers satisfied the most stringent quality standards of regulatory authorities even of advanced countries like America and European Union. Indian drugs being cost effective competed with established products of MNCs in international markets.

**Patents (Amendment) Act, 2005**

The Indian Parliament passed the ‘Patents (Amendment) Act, 2005’ on 29th March 2005. The Act received the President’s assent on 4th April 2005. The Amendments were third in
series after those made in 1999 and 2002, finally making it TRIPS compliant as per India’s
commitment under WTO. The passage of the Act was preceded by intense debates and
discussions. The Amended Act had to address to certain basic issues pertaining to the future
of the Indian pharmaceutical industry like future of the generic manufacturers and
compulsory licensing. Below is a detailed analysis of the major amendments in the new
Patent Law as amended in 2005 and the amendments made in it through the Patents
(Amendment) Rules. 2006.

1. **Scope of Patentability –** (u/s 2&3) – It is common in the pharmaceutical sector to file
patent applications for already known molecules, which are patented, by doing little
improvements over the original molecule. This extends the monopoly of the patent holder
after the expiry of the original patent. This process is referred to as evergreening. The
subsequent patent often extends the monopoly and blocks the entry of generic products. It
may be noted that patented products are expensive whereas the generic products are cheaper.
In the light of such process it was absolutely necessary for developing countries like India to
limit the scope of patentability only to new chemical entities to ensure the affordability and
availability of medicines. The obligation under TRIPS is to provide patent protection for
investors in pharmaceutical sector. However TRIPS Convention does not define what ought
to be patented or what is the scope of patentability. This implies that WTO members are free
to adopt their own definitions.

The Act introduces **three new definitions in Section 2- inventive step, new invention and
pharmaceutical substance.** The reason given for these definitions, are to limit the scope of
patentability.

**Inventive step** According to definition u/s 2(j)(a) an invention satisfies the criteria of
inventive step if it is ‘a feature of an invention that involves technical advance as compared
to the existing knowledge or having economic significance or both that makes an invention
not obvious to the person skilled in the art.’

Hence, to meet the inventive step criteria the patentee will either have to show that the
invention includes a technical advance or has economic significance, or both.

**New invention** According to definition u/s 2(l), ‘Any new invention or technology which
has not been anticipated by publication in any document or used in the country or elsewhere
in the world before the date of filing of patent application with complete specification’. For
the purpose of the Act the definition of the patent has been retained the same as earlier.

**Patent** as defined in Section 2(j), is ‘a patent granted under this Act’.

**Pharmaceutical substances** The Act defines pharmaceutical substances u/s 2(ta) as, ‘any new entry involving one or more inventive steps.’

On this front the Act is positive for the Indian industry. For the purpose of this Act, ‘salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixture of isomers, complexes, combination of other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.’

This means that pharmaceutical companies cannot extend the life of their patented drug simply by changing the chemical structure of the drug.

**Immunity to on going generic producers** - This was one of the most important issues that the Act had to address. It is regarding the future of the generic producers in India who are currently producing pharmaceuticals, the product patent applications of which are in the ‘mailbox’. These producers will have to stop operations in India when patent rights are granted to such pharmaceutical products under the new patent regime. The government has tried to protect the rights of generic producers in India in Section 11(A) third provision wherein it is provided that “the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investments and were producing and marketing the concerned product before January 1, 2005 and “which continue to manufacture the products covered by the patents on the date of grant of patent....” In addition to this it is provided that “no infringement proceedings shall be instituted against these enterprises.” In simple terms it means that Indian companies have got as good as compulsory licenses for the new molecules that will be patented in the new patent regime in India. Domestic companies can continue to make patented items after paying reasonable royalty to patent holders, if they had been manufacturing prior to January 1, 2005, i.e., no action can be taken against such companies.

**Pre Grant Opposition** – Pre Grant Opposition is a provision whereby third parties can oppose the grant of patent to the inventor by the patent office. The Act provides 11 grounds
on which the pre grant opposition can be made (Section 25(1)). Not only this, the Act also provides for a provision whereby third parties can oppose a patent even after it has been granted u/s 117(A). This is known as post grant opposition. Thus India provides for both pre grant and post grant opposition in its patent legislation. The time frame for filing opposition proceedings is 6 months.

Compulsory Licenses – The effective and efficient issuance of compulsory licenses by the government of India is must to curb the abuse of patent rights by the patentee. The TRIPS Council allows developing countries to adopt effective compulsory licensing mechanisms which include straightforward, transparent and fast procedures that do not suspend the execution of the license for commercial as well as for non-commercial use by the government, including production for export. In this regard the government has made certain amendments in the Act. The Act quickens the time limit for response from the patent holder under section 84 (6). This is where the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period. The Controller can now interpret ‘reasonable period’ to mean a period not ordinarily exceeding six months.

With respect to exporting drugs to a country which makes a request for a generic drug, the Act gives the option to the requesting country to simply give notification to the exporting country or to issue a compulsory license itself before making the request, u/s 92(A). As a result exports from India to countries having insufficient manufacturing capacity can take place even in the absence of a compulsory license in the importing country.

Impact of Patents (Amendment) Act, 2005

The impact of the new Act on India has been studied in two steps

1. On the basis of primary data survey
2. On the basis of secondary data survey
Primary Data Result

A survey has been done from various groups of people to find out what they felt about the Patents (Amendment) Act of 2005 and its after-effects. The main aim of the survey is to know the impact of Patents (Amendment) Act, 2005 on

a. Patients (Table 5.1)

b. Indian pharmaceutical industry (Table 5.2)

Table 5.1

Impact of Patents (Amendment) Act, 2005 on patients
(Figures in percentages)

<table>
<thead>
<tr>
<th>Response</th>
<th>Employed Doctors and Private Medical Practitioners</th>
<th>Patients</th>
<th>Chemists and Pharmaceutical Distributors</th>
<th>Company Employees</th>
<th>General Public</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Respondents opinion whether prices of drugs has increased or not</td>
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Respondents opinion whether there is a decrease in availability of medicines or not

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<tr>
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<td>18</td>
<td>14</td>
<td>29</td>
<td>34</td>
<td>27</td>
</tr>
</tbody>
</table>

(Source: Field Investigation)
Graph 5.1
Impact of Patents (Amendment) Act, 2005 on patients
(Figures in percentages)
Respondents opinion whether prices of drugs has increased or not

Category wise response

<table>
<thead>
<tr>
<th>Category</th>
<th>Yes</th>
<th>No</th>
<th>Can't Say</th>
</tr>
</thead>
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<td>Chemists and...</td>
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</tr>
<tr>
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<td>49</td>
<td>39</td>
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</tbody>
</table>

Average Response

- Yes: 11%
- Can't Say: 26%
- No: 63%
Graph 5.2
Impact of Patents (Amendment) Act, 2005 on patients
(Figures in percentages)
Respondents opinion whether there is a decrease in availability of medicines or not

Category wise response

Average Response
Impact of Patents (Amendment) Act, 2005 on patients

The respondents have been asked two main questions whether

a. the Patents (Amendment) Act of 2005 has lead to an increase in the prices of drugs
b. the Patents (Amendment) Act of 2005 has lead to a decrease in the availability of medicines

The above two question have been asked because when the Patents (Amendment) Act of 2005 came into force there was a fear that since Indian firms shall not be allowed to reverse engineer patented drug molecules, the drugs shall be sold in the country by the innovator companies only. This would eliminate all competition in the market and lead to an increase in the prices of medicines.

Impact on prices of medicines

During the primary data survey it has been found that majority of respondents did not face any extreme rise in prices of drugs. The results have been shown in Table 5.1 (Graph 5.1). The people who are mostly affected by rise in the prices of drugs are the patients. Only 13% of the patients said that there has been an increase in the prices of drugs since 2005. Similarly, only 12% of the respondents in the general public category have said that there is an increase in the prices of drugs. 68% of the chemists and pharmaceutical distributors and 69% of doctors and private medical practitioners believe that the majority of drugs they are selling or prescribing have remained at almost the same price. However, they said that there has been some price rise in medicines as a result of implementation of VAT. 70% of the company employees said that there is no increase in the prices of medicines of their companies. Some of the respondents even cited examples of orders by the Ministry of Drugs and Chemicals to some of the drug multinationals to lower the prices of their drugs in Indian market.

Impact on availability of medicines

In case of availability of medicines the majority of respondents said that they did not face any problem regarding the availability of medicines. The results have been shown in Table 5.1 (Graph 5.2). The doctors and registered medical practitioners said that the common diseases which spread like epidemic (malaria, tuberculosis, typhoid, cholera, flu, influenza etc) can be very easily treated with drugs already available in the market;
all of which are off patent. Diseases like polio are being eliminated with free vaccines from the government. Only 6% of the patients and 5% of the general public said that there has been a decrease in the availability of medicines. 80% of the patients and 68% of the general public said that the non-availability of medicines has never created a problem for them. They said that with time, the number of chemist shops has in-fact increased. In certain areas of Delhi, Gurgaon and Faridabad where the local municipal corporations have been carrying out sealing drives in residential areas, the respondents said that only the medical facilities like chemist shops and nursing homes have some amount of exemption. Some of the respondents even cited names of some chemist shops that provide 24-hour service.

**Impact of Patents (Amendment) Act, 2005 on Indian pharmaceutical industry**

At this level the respondents have been asked the following two main questions whether

i. the Act is harmful for Indian firms

ii. the Act has triggered more mergers and acquisitions

| Table 5.2 |

**Impact of Patents (Amendment) Act, 2005 on Indian pharmaceutical industry**

*(Figures in percentages)*

<table>
<thead>
<tr>
<th>Response</th>
<th>Employed Doctors and Private Medical Practitioners</th>
<th>Patients</th>
<th>Chemists and Pharmaceutical Distributors</th>
<th>Company Employees</th>
<th>General Public</th>
</tr>
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<tr>
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<td>8</td>
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</table>

Respondents opinion whether Patent Act is harmful for Indian firms or not

<table>
<thead>
<tr>
<th>Response</th>
<th>Employed Doctors and Private Medical Practitioners</th>
<th>Patients</th>
<th>Chemists and Pharmaceutical Distributors</th>
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<th>General Public</th>
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<td>15</td>
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</tbody>
</table>

*(Source: Field Investigation)*
Graph 5.3
Impact of Patents (Amendment) Act, 2005 on Indian pharmaceutical industry
(Figures in percentages)

Respondents opinion whether Patent Act is harmful for Indian firms or not

**Category wise Response**

<table>
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<th>Yes</th>
<th>No</th>
<th>Can't say</th>
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<tr>
<td>Employed Doctors and Private Medical Practitioners</td>
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<tr>
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</table>

**Average Response**

- Yes: 23.2%
- No: 14.6%
- Can’t say: 62.2%
Graph 5.4
Impact of Patents (Amendment) Act, 2005 on Indian pharmaceutical industry
(Figures in percentages)
Respondents opinion whether the Patent Act has triggered more M&As or not

Category Wise Response

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<tr>
<th>Category</th>
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<tr>
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</table>

Average Response

- Yes: 21.8%
- No: 14.2%
- Can't say: 64%
Impact on Indian firms

The results have been shown in Table 5.2 (Graph 5.3). Majority of respondents in all categories, 58% of the company employees, 73% of doctors and private medical practitioners and 73% of chemists and pharmaceutical distributors said that the law has not harmed the Indian firms. The respondents said that the Indian firms had already prepared themselves for the year 2005. They said that moreover the government has introduced the provision of pre grant opposition as well as post grant opposition. This has given a lot of security to the Indian firms. This has also insured that multinational companies do not get fake patents. They cited the case of ‘Gleevec’ of Novartis pending in the Andhra Pradesh High Court. They said that cases like these will ensure that Indian firms do not suffer. Moreover they said that the majority of drugs being produced and consumed in India are off-patent hence are beyond the purview of the Patent Act. Only 2% of the company employees, 12% of doctors and private medical practitioners and 19% of chemists and pharmaceutical distributors said that the law is not in the interest of the country. They said that the impact of the law shall be visible only 5-7 years after its enactment when multinational companies will start bringing patented molecules in the country and Indian firms shall not be able to produce them.

Impact on mergers and acquisitions

The results have been shown in Table 5.2 (Graph 5.4). 65% of the doctors, 70% of chemists and pharmaceutical distributors and 64% of the company employees said that the new law has triggered a wave of mergers and acquisitions in the Indian pharmaceutical industry. They said that Indian companies are now trying to acquire companies in foreign countries that have patented drugs so that they can get them patented in India. This is helping them to retain their market shares. The company employees said that M&As are the best suited technique for Indian companies because discovery and development of NCEs takes time.

All the respondents have been asked if they would like to give suggestions for any changes in the law. The respondents cited the following main issues

✓ The government authorities should keep a strict watch on the drugs being patented and the prices being charged for them.
The process of patenting a drug should be made as much transparent as is possible and should be free from corruption and red tapeism.

The government should grant subsidies on patented drugs that are beyond the reach of common man.

If we look at the above suggestions carefully, we find that the amended Patent Law that is now in force is taking care of all these requirements. This can be said because

1. The definition of a patent is very conclusive and incorporates all possible requirements that can be provided. We have already studied this in the clause of “Scope for Patentability” u/s 2 and 3.

2. The Patent office provides complete information on patents being granted. It issues its monthly journal that provides all the latest updates to the general public. This journal can be had directly from the Patent Office or through post. For a common man to understand the Patent Act the Patent Office has issued a Draft Manual, where the law has been translated and interpreted, section-wise, in simple language. This Draft Manual is also available online.

3. All major drugs that are essential have been put by the government under Essential Supplies Maintenance Act (ESMA). The government can control the prices of such drugs any time it feels that their procurement is a problem for the general public.

Hence we can say that the government has tried to safeguard the interests of the common man.

Secondary Data Result

Impact on prices, availability of drugs and Indian companies

A detailed analysis of the Indian pharmaceutical industry shows:

3. 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.

4. 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.
5. A total of 9 NCEs have come in the Indian market. There are no related drug molecules already being sold in the market that have chemical properties similar to these 9 drugs. Hence a comparison of price rise cannot be made.

6. Drug Prices in India are controlled by the National Pharmaceutical Pricing Authority (NPPA) through the Drugs (Prices Control) Order (DPCO), 1995. DPCO has been issued by the Government of India under Section 3 of the Essential Commodities Act, 1955. NPPA 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:
   
   - Analgesics and Antipyretics
   - Antacids and Anti-ulcerants
   - Antibiotics
   - Antituberculosis
   - Anti-parasitic and Antifungal
   - Cardiac therapy
   - Corticosteroids
   - NSAIDS, Anti-rheumatic
   - Respiratory System
   - Vitamins
   - Other therapeutic segments

   - 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.

   - 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 went off patent in July, 97.
✓ **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.

✓ **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.

✓ **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.

✓ **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 urbanisation in India, heart trouble is on the rise. Also, cardiac therapy is a long-term therapy, providing a good market to the Indian companies.

✓ **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 like Betamethasone and Dexamethasone.

✓ **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.

✓ **Respiratory System:** Patent coverage is very low. Also, as DPCO covers most popular anti-cough drugs, there have been lesser price hikes,

✓ **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.
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.

Impact on mergers and acquisitions
The Patents (Amendment) Act has definitely lead to more mergers and acquisitions in the Indian pharmaceutical industry. Indian companies are now adopting this route to remain more competitive in the industry. Table 1.8 given in chapter 1 of the study shows that 61.4% of the Indian pharmaceutical industry is covered by the top 10 firms in the country. The point to be noted here is that all 10 firms belong to India. Similarly Table 1.9 given in the same chapter shows that these 10 companies have done a total of 40 merger and acquisition deals in the past 9 years. Out of these 40 deals 30 deals are in foreign countries. The Indian pharmaceutical companies are acquiring foreign firms in order to increase their market share. We already know that drug prices in India are some of the lowest in the world. Hence acquiring already established companies in foreign countries is providing them with ready markets for selling cheap drugs. The immediate increase in capturing foreign markets is the result of fear of losing their market shares in India. In foreign markets Indian companies are selling not only their own drugs but also the patented drugs of acquired companies. This proposition is proving to be very successful also. Table 4.26 and Table 4.27 given in chapter 4 of the study show how foreign markets are proving to be more successful for Indian companies than the domestic (Indian) market.

Apart from increase in market shares mergers and acquisitions are also helping Indian firms to gain R&D strength. Table 4.20 given in chapter 4 of the study shows how poor are Indian companies in the R&D of NCEs. This is because R&D of new molecules requires a huge amount of money. All the 9 NCEs that have been patented in India since 2005 belong to foreign companies. It is a matter of common understanding that no company shall provide its prospective research compounds to any other company. Indian firms have realised the importance of R&D in the new patent regime. That is why they have started acquiring foreign companies that have prospective research compounds. Table 1.9 given in chapter 1
of the study shows that Indian companies made 13 M&A deals with an objective of gaining R&D strength. Already we know that the cost of doing R&D of new molecules in India is very low as compared to foreign markets (Table 2.2 given in chapter 2 of the study). Hence the emphasis of Indian companies is now to acquire research compounds from foreign companies and bring out new NCEs.

Findings

1. During the primary data survey certain issues came forward. Majority of respondents from company employees’ category, pharmaceutical distributors, chemists, doctors and registered medical practitioners were all very optimistic about the Patents (Amendment) Act, 2005. Very few of them complained that the new Act has resulted in an increase in the prices of drugs or lead to a shortage of drugs or harmed the Indian pharmaceutical industry. The patients and the general public interviewed were also of the opinion that they have not observed any steep rise in the prices of drugs or faced any shortage of medicines. On the contrary, a vast majority of the respondents reported that it has definitely made the Indian pharmaceutical firms more competitive than before. This shows that the government has succeeded in its efforts of bringing the TRIPS compliant Patent Law in India and also getting it implemented in public interest.

2. Majority of drugs being used in India are off-patent. A lot of drugs being sold in India are the ones that got patent protection before 1995 and hence do not come under TRIPS purview. A total of 9 new molecules have entered the Indian market. Hence there is no immediate health crisis in India as was being presumed before the enactment of the Patent (Amendments) Act, 2005. Moreover, apart from the above mentioned issues, the government has kept the whole pharmaceutical industry in the country under its control through NPPA and DPCO.

3. The Patent (Amendments) Act has lead to a steep rise in the merger and acquisition activity in the Indian pharmaceutical industry. Indian companies are using the option of M&As to survive in the patent regime. M&As are helping Indian firms
   - To explore foreign markets as Indian companies fear losing their market share in India to patented drugs.
4. There are certain issues regarding the Patents (Amendment) Act, 2005 that need to be addressed. They are as follows:

a. Section 2(1)(ja) of the Act says that "inventive step" means 'a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art'.

Hence, to meet the inventive step criteria the patentee will either have to show that the invention includes a technical advance or has economic significance, or both. In other words, the requirement of technical advancement is compromised and diluted by the fact that a patent could be simply granted on economic significance alone. Proving economic significance is not difficult for big pharmaceutical companies. Hence, whenever a drug is about to reach its patent expiry all that a firm needs to do is to bring an advanced version of the already patented drug and simply prove its economic significance over the already patented drug and retain its monopoly. Therefore, economic significance alone should not determine the inventive step of patentable innovation. Thus, the definition dilutes the requirements of an inventive step and broadens the existing provision to the benefit of the patent holders.

b. Section 11(A) of the Act makes use of the terms 'significant investment' and 'reasonable royalty'. However the terms are neither explained nor defined. The question of significant investment poses a threat of potential infringement suits and litigation as the patent holder may challenge the meaning of significant investment in order to extract a royalty payment. With respect to 'reasonable royalty' it creates the problem of excessive demands from the patent holder and litigation. Furthermore Section 90 provides that the remuneration would take into consideration the perspective of the patentee which includes the expenditure incurred by the patentee for making and developing the invention and for obtaining and keeping the patent in
force. It may be argued that these considerations for determining the royalty and other remuneration would enhance the already superior bargaining position of the patentee and fail to uphold the public interest.

c. The Act allows public to oppose a patent application by filing a pre-grant opposition within six months from the date of its publication or any time before the grant of patent, whichever is later (rule 7, Patents (Amendment) Rules, 2006). Thus, for an application published, say, on January 1, 2009, though the six month deadline will expire on June 30, 2009 under the current provision, the patent office cannot shut the door on pre-grant opposition applications filed after this date. Suppose during the 6 months time the patent office receives one application for pre-grant opposition. Under the current rules if all the proceedings take place within their due time and the controller of patents gives his decision within 1 month the likely date of patent grant shall be July 31, 2009 (rule 11, Patents (Amendment) Rules, 2006). The office can continue to entertain opposition applications till that date. If the Patent office receives an opposition representation, say, on July 30, 2009, the patent office cannot refuse. This process could go on as long as the applications for pre-grant oppositions are filed till the grant of patent. However the patent tenure for the party applying for the patent starts from the day of filing of the patent. Hence this provision of entertaining applications till the date patent is granted makes the process very delaying.

d. The Patent Office has put on its website a ‘Draft Manual of Patent Practice and Procedure’ issued by the Patent office of India in 2008. The Manual is intended to provide detailed information to the public and users of patent system on the practices and procedures followed by Patent Office for processing of patent applications. The Manual incorporates provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 and the Patents Rules, 2003 as amended by the Patents (Amendment) Rules, 2006. However, the Preface of the Manual states “The Manual does not constitute rule making and hence does not have the force and effect of a law. Statements made in the Manual are not in themselves an authority for any action by an officer of the Patent Office”. If this is true then the relevance of putting a manual on its website cannot be understood.
Suggestions

a. The provision in Section 2(1) (ja) should have required the applicant to comply with both the requirements of an inventive step, i.e., technical advance over the existing knowledge and economic significance. The text in the Act should be as follows- "inventive step" means ‘a feature of an invention that involves technical advance as compared to the existing knowledge and having economic significance and that makes the invention not obvious to a person skilled in the art’.

b. The Act should be amended to include the definition of the two terms and these should also be explained numerically. This means the government should set a limit to maximum royalty that a patent holder can charge. The accepted norm, in European countries, is 4-5% of the drug sales. A higher royalty will increase the price of generic drugs and may reduce the accessibility and affordability of medicines. Similarly the term 'significant investment' should also be tied in figures to remove any ambiguity in the law.

c. India has the provision for both pre-grant and post grant opposition. Hence in case a patent is by chance granted on frivolous ground an applicant can file an application against the grant of patent even after it has been granted. Hence the current provision of receiving applications for pre-grant opposition till the date a patent is granted should be amended. The patent office should entertain only those applications for pre-grant opposition that are received within the first 6 months only. Any person who wants to oppose the patent should apply under the provision for post-grant opposition (Section 25(2)).

d. The Draft Manual has been put up by the Patent Office on its website and hence the office can in no case deny its responsibility over it. If the Manual is not the final end for both the patent officers and the general public then it should be taken off the website; or the office should make it authentic enough for everybody to rely on it. Otherwise in this format the Manual is nothing more than confusion for both the public and the patent officers.
Conclusion

The study is based on the TRIPS Agreement of WTO. The Agreement gives the discoverer of a creation an exclusive right over his/her creation for a certain period of time. This right is known as patent. The study further deals with the enactment of the Patents (Amendment) Act, 2005 in India. India had to bring this law as it is a member of the WTO. The law applies to all fields of sciences art and craft and geographical designs. Here in this chapter the law has been studied only in context with the Indian pharmaceutical industry. Before the law came into force a lot apprehensions were there in the market regarding the harmful effects of the Act on the industry and the common man. However, the study shows that the government has been successful in implementing the law to the benefit of the pharmaceutical industry and the common man. The primary data survey shows that the various interest groups have till now, not faced any problems as a result of the Act. This was further verified using the secondary data wherein it was found that the government has put a lot of checks in place like the NPPA and DPCO so that the country does not suffer in any way.
References

1 http://www.indiaonpi.com/keystat.htm

2 Certain comments were expressed by the Union Minister for Chemicals and Fertilizers during the discussion for Draft National Pharmaceutical Policy in cabinet meeting. The issue related to raising price control width of drugs. October 31, 2006. DD News telecast.

3 In 1997, Novartis a pharmaceutical company based in Switzerland filed a patent application in the Chennai (Madras) Patent Controller’s office for a cancer drug Gleevec (Glivec). In 2003, the company was granted Exclusive Marketing Rights (EMR) for marketing Gleevec in the Indian market. On the basis of the EMR, Novartis obtained orders preventing some of the generic manufacturers from generic equivalents of Gleevec. Novartis was selling Gleevec at USD 2666 per patient per month. Generic companies were selling their generic versions at USD 177 to 266 per patient per month. In 2005, the generic companies filed a pre-grant opposition against Novartis’ patent application for Gleevec, claiming that Novartis’ alleged “invention” lacked novelty, was obvious to a person skilled in the art, and that it was merely a “new form” of a “known substance” that did not enhance the substance’s efficacy, and was thus not patentable under section 3(d) of the Patents Act. These arguments were based on the fact that Novartis had already been granted a patent in 1993 for the active molecule - imatinib mesylate, used in Gleevec, and that the present application only concerned a specific crystalline form of the salt form of that compound. And thus the various forms of imatinib mesylate must be considered the “same substance” under section 3(d) of the Patents Act. In January 2006, the Patent Controller in Chennai, in a landmark decision, refused to grant Novartis a patent, agreeing with the contentions of the generic companies that the subject application lacked novelty, was obvious, and was unpattentable under section 3(d) of the Act. The patent rejection meant that generic companies could manufacture and market their drug, both in India and abroad, who make available the generic imatinib mesylate priced at less than one-tenth the price that Novartis was charging (USD 166 to 266 instead of 2666 per person per month).

4 www.expresspharmaonline.com

5 Details of list of patented drugs taken from the Indian Patent Office (Refer A-6 in Annexures for the complete list)

6 National Pharmaceutical Pricing Authority, 3rd/5th Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India – 110001. The data has been drawn through the following reports

   a. The National Pharmaceutical Pricing Authority has fixed / revised the prices in respect of 285 formulation packs vide notifications / orders dated 12.03.2009.
   b. Notified price of Scheduled Bulk Drugs (As on 15.5.2008)
   c. Ceiling Prices of Scheduled Formulations (As on 15.5.2008)
d. Maximum Retail Price (Including Excise Duty* And Local Taxes) Fixed Under Para 10(B) Of DPCO, 1995 (Updated to 15.2.2008)
e. Data was also taken online from the official website of the authority @ nppa.nic.in