



EFFECT OF PATENTS AMENDMENT ACTS ON PHARMACEUTICAL INDUSTRY

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ABSTRACT

Patent is an intellectual property right identifying with inventions and is a grant of exclusive right, for limited period, given by the Government to the patentee, in return of full revelation of this invention, for barring others, from making, utilizing, selling, bringing in the patented product or process delivering that product for those reasons. India originally amended Indian Patent Act (1970) in 1999 and again in 2002. On March 23, 2005, the Indian Parliament passed the Patent Amendment Act, 2005. It was the third and last amendment to the Indian Patent Act, 1970. The amended Patent Act fits in with prerequisites put forward by the World Trade Organization's (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS). Under the new product patent law, Indian drug creators can never again manufacture and market figured out variants of drugs patented by foreign drug makers. The main aim of this thesis is to define the patent amendments in 1970, 1999, 2002, and 2005 and identify the effects of these amendments on Pharmaceutical Sector.

1. INTRODUCTION

Every nation has its own Patent Act. The patent act that was in power in India before 2005 perceived the patenting of the procedures of manufacture of drugs and not simply the drugs Anyway on March 29, 2005 the Indian Parliament passed the Patents (Amendment) Act, 2005. The Act is in consistence with the TRIPS Agreement of WTO. The new Patent Act currently perceives item patents rather than process patents. The change was not prompt. India consented to the TRIPS Arrangement of WTO in 1995. Be that as it may, being a developing nation was given a progress time of 10 years. Inside these 10 years, the Indian Patent Act was to be made consistent to TRIPS Agreement. Amid these 10 years different corrections were made in the Patent Act lastly a totally altered form according to TRIPS prerequisite was passed in March 2005. The present section depends on the effect of WTO Patents administration in India.

Several Drug Price Control Orders and National Pharmaceutical Pricing Policies guarantee that the provisions of the patent laws in India are connected to the upside of public health and prosperity. De-licensing of the Indian pharmaceutical industry has given another wellspring of vitality to local manufacturers' producers who are currently allowed to make any drug appropriately allowed by the Drug Control Authorities.

2. PATENTS ACT

Patent is ground for the favour of the inventor conferring on him the right to use his invention to the exclusive of all others. It is granted for a period, (i.e.) for a settled time of five years where the item

or process identifies with food or medicine or for a time of 14 years in different cases. On the off chance that the investor can't utilize or work the innovation without anyone else, he can do child in relationship with other or allot it to other or he can grant licenses to other to work the creation for thought or for expenses which is called Royalty

The patent framework which has been in obscure since the start of the seventeenth century in England and in India from 1856 has enormously helped the industrial development. The chief of granting restricted protection to the innovator for a period in light of his uncovering the creation, and from that point discharging the development to public utilize has enhanced production of goods and services on mass scale.

3. PATENT AMENDING ACTS

▪ Indian Patent Act 1970

The Patent Bill was first presented in Parliament in 1967, however the Patent Act, 1970 came into power just in 1972. The Indian Patent Act 1970 which is in task in our nation does not allow item patents on medicines, agricultural items and atomic energy.

The Indian Patent Act 1970 came into power on twentieth April 1972. Under this Act item patents were not allowable and just process patents were granted in regard of developments related to drugs, medicines, foods and agrochemicals. This empowered indigenous drug industry to manufacture items patented in different nations by developing and utilizing an alternate procedure. This practice of creating a drug from an alternate procedure came to be known as figuring out. This was generally in charge of the country and the Indian drug industry accomplishing amazing all round advancement and development.

▪ Patent First Amendment Act 1999

Other than the EMR, India had two more points of reference to cross along the TRIPS hindrance to acquaint different changes with the IPA by January 1, 2000 and to present item patents by January 1, 2005. The Patent Second Amendment Bill of 1999 was presented in the Upper House on December 20, 1999 to cross the primary point of reference (and abstaining from running into the DSB in Geneva) and to revise the IPA to roll out improvements that were required quickly. The bill, in any case, was not passed by the Rajya Sabha and was referred to the Select Parliamentary Committee. The committee analyzed the bill and concluded that they expected to comprehend the issues promote before they could send their report.

- ✓ Patentable Inventions
- ✓ Exclusions from patentability
- ✓ Term and Date
- ✓ Application Requirements
- ✓ Compulsory Licensing
- ✓ Right to import & parallel import
- ✓ Bolar Provisions

▪ **Patents (Amendment) Act 2002**

The second amendment of the Patent Act 1970 was directed in 2002. It incorporates changes in the extent of patentable inventions, grant of new rights, augmentations of the term of protection, provision for inversion of burden of proof in instances of process patent infringement, and conditions for CL (Act No. 38 of 2002). An amendment to the Patents Act, 1970, in particular, the Patents (Amendment) Act, 2002 has been advised in the Gazette of India on 25.6.2002. Changes have been realized in the regime of CL for a non-working patent. Under this Act, a CL would now be able to be granted regardless of whether the patented invention isn't working in India. Different justification for issuing a CL incorporate – national crisis, public non-business utilize which may emerge or is required as the case might incorporate public wellbeing emergency identifying with AIDS, HIV, TB, Malaria or different pestilences. Along these lines, this Act can be named as noteworthy advance which specifically demonstrated India's unfaltering increase to TRIPS regime.

▪ **New Indian Patent (Amendment) Act 2005**

On 23 March 2005 the Patent (Amendment) Bill 2005 was passed by the RajyaSabha . (Upper House) There has been next to no public discussion around the Bill to decide the effects of the amendments that have been made. A few amendments have been made to the Ordinance (the new Patent Bill 2005). Be that as it may, a large number of these neglect to address the serious concerns of the issues identifying with access to medicines.

From the content that has been made accessible, the following gives investigate of the key issues of the new law which were voted on and the potential effect:

- a. Expansion of the Scope of Patentability
- b. Inventive Step
- c. Interpretation of the word - Pharmaceutical substance
- d. Inventions not patentable
- e. Immunity to ongoing generic production
- f. Pre-grant Opposition
- g. Publication
- h. Compulsory Licensing
- i. Discretionary powers of the patent office
- j. Quick Examination

4. PATENT ACTS AND PHARMACEUTICAL INDUSTRY

Protection of intellectual property rights in India keeps on being reinforced further. The year 1999 saw the thought and entry of real enactment as to protection of intellectual property rights in congruity with worldwide practices and in consistence with India's commitments under TRIPS. The Government of India has taken a few measures to streamline and fortify the intellectual property organization framework in the nation. Tasks identifying with the modernization of patent data administrations and trademarks vault have been executed with assistance from WIPO. The

Government of India is actualizing a task for modernization of patent workplaces at an expense of Rs.756 million joining a few parts, for example, human asset development, enrolling extra inspectors, infrastructure support and fortifying by method for computerization and re-engineering work practices, and disposal of excess of patent applications. An amendment to the Patent Rules was advised on June 2, 1999 to disentangle the procedural viewpoints. The ramifications of TRIPS for the pharmaceutical area are that: patents will be granted both for items and processes for every one of the developments in all fields of innovation; the patent term will be twenty years from the date of the application (contrasted with seven years under the 1970 Act), or, in other words all the part to all part nations and along these lines precludes every one of the distinctions in the protection terms won in various nations.

5. EFFECT OF PATENTS ON THE PHARMACEUTICAL SECTOR

• Effects of Product Patents and Prices of Medicines

The discussion on effect of item patents on the pharmaceutical business in India has focused on the issues of cost of the patented item and their availability. The positive affiliation is seen between more grounded protection and costs of the drugs, additionally the costs declined with the expiry of patent. The reception of process patents alongside the domestic controls that confined the job of Pharmaceutical Industry of India has achieved a place of close independence in definitions. After long involvement of having a negative parity of trade in pharmaceutical items, India began getting a charge out of positive parity of trade from the late 1980s. Underway volume India represents 8% of world's pharmaceutical production and is the fifth biggest in the world.

• Effect of Weak Protection Regime

One of the significant focal points of the all inclusive framework is that, it would encourage access to new medical items. While welfare misfortune because of conceivable cost increment in the post WTO regime is high helped in the vast majority of the examinations, the welfare misfortune due non presentation of new patented drugs in India because of the feeble protection regime isn't talked about enough. In this specific circumstance, one of the benefits of the item patents is that the more grounded patents will give access to the most recent innovations in the drugs, which the developed world won't shy far from presenting in India.

• Effects of Product Patents and Research and Development

One of the upsides of the all inclusive patent regime is that private venture capital firms wind up eager to put resources into innovation based new businesses; specialized information streams all the more quickly from university laboratories to the commercial center and nearby firms end up ready to dedicate generous assets to web look. The higher expense of the R&D turns out to be a powerful passage hindrance for new firms and subsequently just firms with substantial stream of assets end up in charge of industrial inventive activity. In developing nations, just couple of firms has refined R&D facilities and other advantage primarily from the overflows of the resultant R&D. In any case, with the end goal to proceed onward to the higher echelon, firms need to put resources into R&D.

For example, cost of developing one new drug in the US expanded from \$54 million of every 1970 to \$231 million of every 1990. Late investigations demonstrate that 1 out of 5000 mixes combined amid applied research in the long run achieves the market. Despite the fact that worldwide investment in the R and D has been expanding quickly, R &D endeavors require a bit much outcome in new items and developments.

- **Effects of Patents, Foreign Direct Investment and Technology Transfer**

One of the normal results of fortifying the IPR is the expansion in remote direct investment (FDI) in R&D, coordinate manufacturing or joint ventures. Notwithstanding, the effect of more grounded patents on FDI stays uncertain from the accessible proof since IPR is just a single of the factors in attracting FDI streams rely upon skills availability, technology status, R&D limit, endeavor level ability and institutional and other supporting mechanical infrastructure.

- **Effect of Patents (Amendment) Act 2005**

The effect of the new Act on India has been considered in two steps

- On the basis of primary data survey
- On the basis of secondary data survey

A. Primary Data Result

An overview has been done from different gatherings of people to discover what they felt about the Patents (Amendment) Act of 2005 and its delayed consequences. The fundamental point of the review is to know the effect of Patents (Amendment) Act, 2005 on

- a. Patients
- b. Indian pharmaceutical industry

Table 1 Respondents opinion whether prices of drugs has increased or not

Response	Employed Doctors and private medical practitioners	Patients	Chemists and pharmaceutical distributors	Company employees
Yes	15	18	15	17
No	65	60	60	50
Can't Say	20	22	25	33

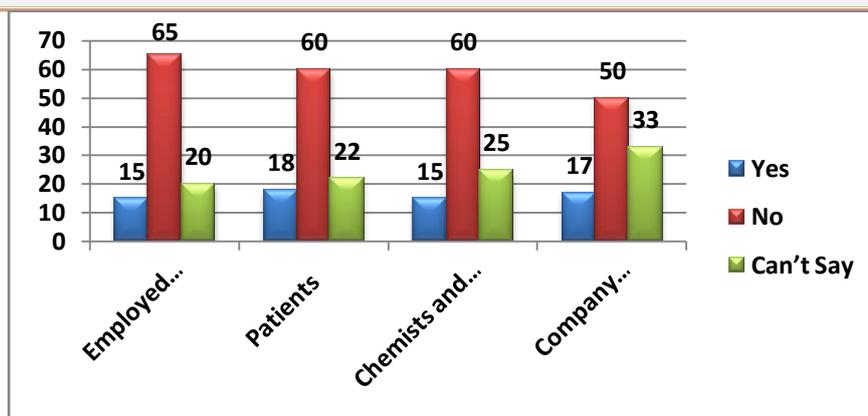


Figure 1 Respondents opinion whether prices of drugs has increased or not

➤ **Effect of Patents (Amendment) Act, 2005 on patients**

The respondents have been made two primary inquiries whether

- a. the Patents (Amendment) Act of 2005 has prompt an expansion in the prices of drugs
- b. the Patents (Amendment) Act of 2005 has prompt a decline in the accessibility of medicines

The over two inquiry have been asked on the grounds that when the Patents (Amendment) Act of 2005 came into power there was a dread that since Indian firms will not be permitted to figure out patented drug atoms, the drugs will be sold in the nation by the pioneer organizations as it were. This would wipe out all opposition in the market and prompt an expansion in the prices of medicines.

➤ **Effect on prices of medicines**

Amid the essential information review it has been discovered that dominant part of respondents did not confront any outrageous ascent in prices of drugs. The outcomes have been appeared in Table 1. The people who are for the most part influenced by ascending in the prices of drugs are the patients. Just 18% of the patients said that there has been an expansion in the prices of drugs since 2005. Essentially, just 15% of the respondents in the general public class have said that there is an expansion in the prices of drugs. 60% of the scientific experts and pharmaceutical distributors and 65% of specialists and private medical practitioners trust that the larger parts of drugs they are selling or prescribing have stayed at nearly a similar price.

Table 2 Respondents opinion whether there is a decrease in availability of medicines or not

Response	Employed Doctors and private medical practitioners	Patients	Chemists and pharmaceutical distributors	Company employees
Yes	12	10	5	8
No	69	72	65	67
Can't Say	19	18	30	25

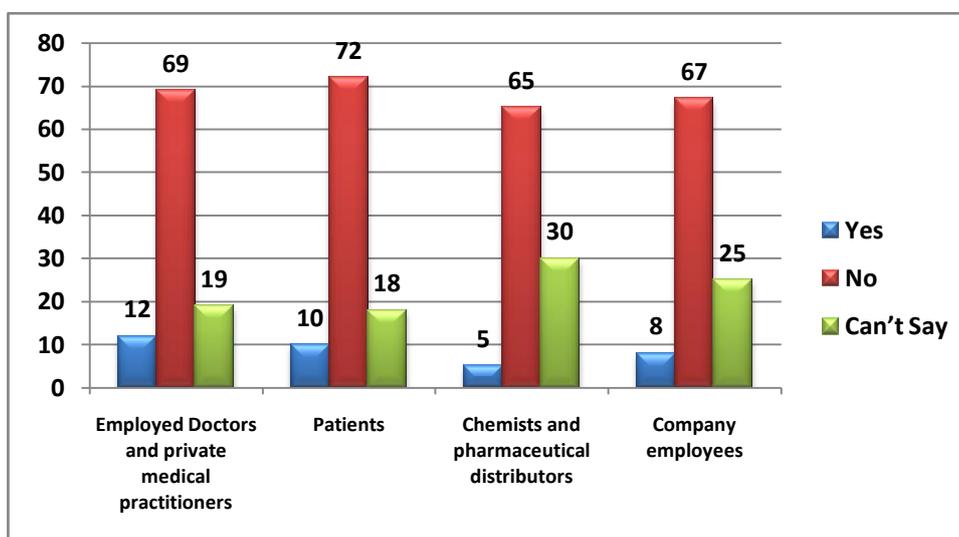


Figure 2 Respondents opinion whether there is a decrease in availability of medicines or not

➤ **Effect on availability of medicines**

If there should arise an occurrence of accessibility of medicines the dominant part of respondents said that they didn't confront any issue with respect to the accessibility of medicines. The outcomes have been appeared in Table 2. The doctors and registered medical practitioners said that the normal diseases which spread like plague (malaria, tuberculosis, typhoid, cholera, influenza, flu and so on) can be effectively treated with drugs officially accessible in the market; which are all off patent. Diseases like polio are being wiped out with free immunizations from the government. Just 10% of the patients and 8% of the company employees said that there has been a decline in the accessibility of medicines. 72% of the patients and 67% of the company employees said that the non-accessibility of medicines has never made an issue for them.

At this level the respondents have been asked the accompanying two primary inquiries whether

- i. the Act is unsafe for Indian firms
- ii. the Act has triggered more mergers and acquisitions

Table3 Respondents opinion whether Patent Act is harmful for Indian firms or not

Response	Employed Doctors and private medical practitioners	Patients	Chemists and pharmaceutical distributors	Company employees	General Public
Yes	15	35	20	3	12
No	69	40	70	55	59
Can't Say	16	25	10	42	29

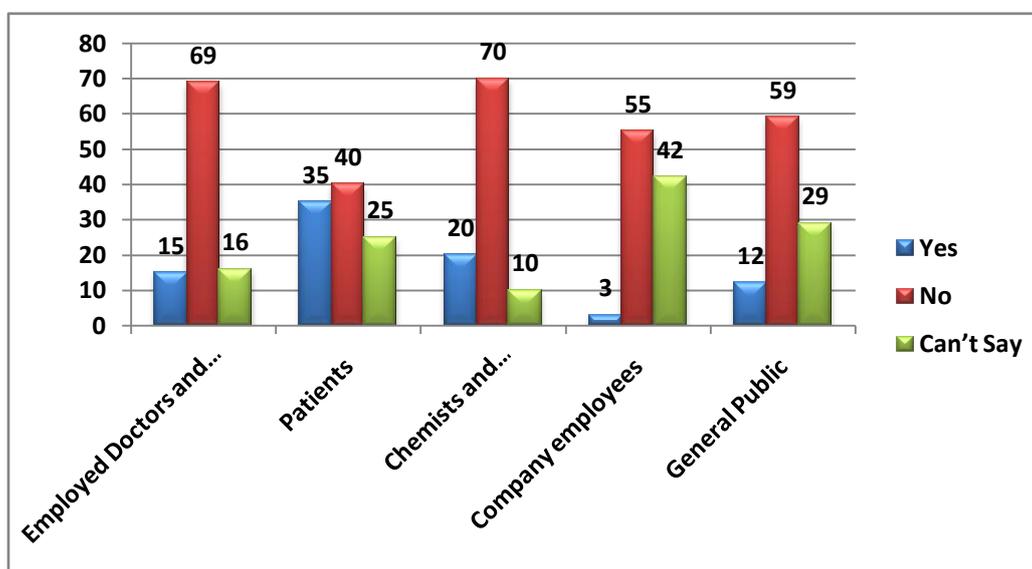


Figure3 Respondents opinion whether Patent Act is harmful for Indian firms or not

➤ **Effect on Indian firms**

The outcomes have been appeared in Table 3. Larger part of respondents in all classifications 55% of the company employees 69% of doctors and private medical practitioners and 70% of chemists and pharmaceutical distributors said that the law has not hurt the Indian firms. This has given a great deal of security to the Indian firms. This has likewise safeguarded that multinational organizations don't get take patents. Just 3% of the company employees 15% of doctors and private medical practitioners and 20% of chemists and pharmaceutical distributors said that the law isn't in light of a legitimate concern for the nation. They said that the effect of the law will be unmistakable just 5-7 years after its enactment when multinational organizations will begin getting patented atoms the nation and Indian firms will not have the capacity to deliver them.

Table 4 Respondents opinion whether the Patent Act has triggered more M&AS or not

Response	Employed Doctors and private medical practitioners	Patients	Chemists and pharmaceutical distributors	Company employees	General Public
Yes	67	65	68	65	55
No	18	15	16	10	15
Can't Say	15	20	16	25	30

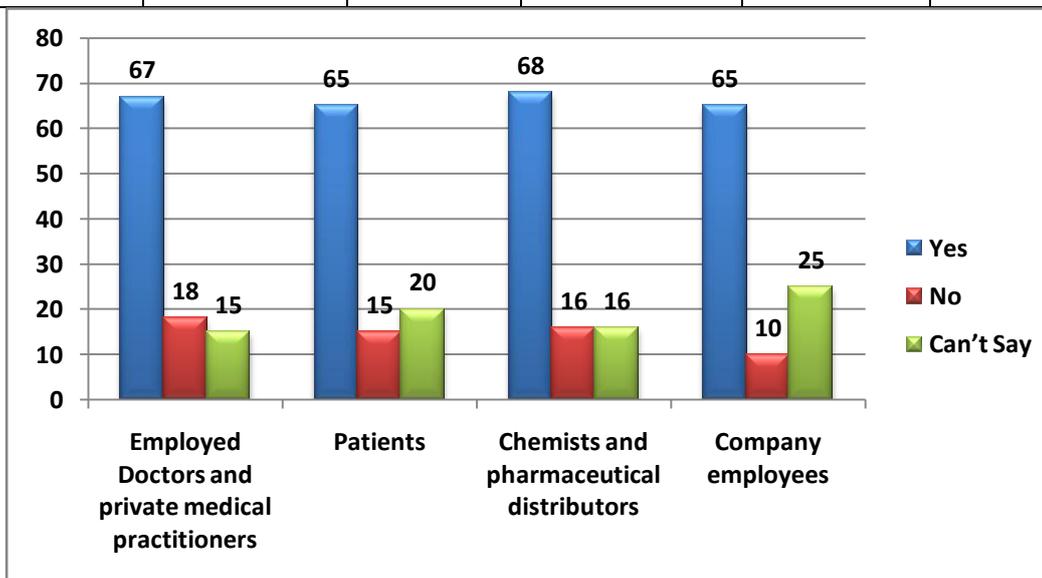


Figure 4 Respondents opinion whether the Patent Act has triggered more M&AS or not

➤ **Effect on mergers and acquisitions**

The outcomes have been appeared in Table 4 67% of the doctors, 68% of chemists and pharmaceutical distributors and 65% of the company employees said that the new law has set off a rush of mergers and acquisitions in the Indian pharmaceutical industry. They said that Indian organizations are currently endeavoring to procure organizations in remote nations that have patented drugs so they can get them patented in India. This is helping them to hold their pieces of the pie. The company employees said that M&As are the most appropriate strategy for Indian organizations since revelation and development of NCEs requires significant investment.

B. Secondary Data Result

➤ **Effect on prices, availability of drugs and Indian companies**

A definite investigation of the Indian pharmaceutical industry appears:

- ❖ 97% of the drugs utilized in India are off patent. The government has a rundown of 354 drugs recorded as 'Basic Medicines'. None of them is patented.
- ❖ Drugs patented before 1995 don't go under TRIPS domain. This implies drugs that got patent protection before first January 1995, can in any case be created through figuring out by Indian firms.
- ❖ An aggregate of 9 NCEs have come in the Indian market. There are no related drug particles as of now being sold in the market that have chemical properties like these drugs. Subsequently an examination of price rise can't be made'.
- ❖ 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 ability to 6

➤ **Effect on mergers and acquisitions**

The Patents (Amendment) Act has certainly led to more mergers and acquisitions in the Indian pharmaceutical industry. Indian organizations are currently embracing this course to stay more focused in the business. The Indian pharmaceutical organizations are obtaining outside firms with the end goal to expand their piece of the overall industry. We definitely realize that drug prices in India are a portion of the most reduced in the world. Consequently procuring officially settled organizations in outside nations is furnishing them with prepared markets for selling cheap drugs. The quick increment in catching remote markets is the consequence of dread of losing their pieces of the pie in India. In remote markets Indian organizations are selling their own drugs as well as the patented drugs of acquired organizations. This suggestion is turned out to be extremely successful too.

6. CONCLUSION

The significant changes presented in the Indian Patent Act that were required to meet India's commitments to worldwide agreements and settlements. The new Patents Act (Patents Amendment Act 2005) has made a solid patent framework in India. Generally speaking the present Act has expanded the extent of patenting and gives stringent protections to the patentee. The new Act would assume a noteworthy job in making an innovation driven market.

The pharmaceutical area would confront the maximum effect. On one hand more up to date drugs would enter the market, and then hand drug prices are relied upon to ascend as generic drugs for drugs patented post 1995 would need to be pulled back. A patented drug gives the firm holding the said patent on it an imposing business model and along these lines it can request a high price for the drug. It would be troublesome for Indian firms to control the market.

The real changes made in the Indian Patent Act would have noteworthy effect. The market would progressively move toward becoming technology driven. Indian firms would need to contend in the

new situation. The new Act gives little degree to firms to encroach upon items that are secured by patents.

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