



## International Journal of Innovative Pharmaceutical Research

Journal homepage: [www.ijipr.com](http://www.ijipr.com)

### Pharmaceutical Patenting in India and its Observed Status: Overview

Sagar N Patil<sup>\*1</sup>, Rekha Sarikonda<sup>1</sup>, Amol Gaikwad<sup>2</sup>, Sneha Sahu<sup>1</sup> and Yashwanth Kumar D<sup>3</sup>

<sup>1</sup>Global Institute of Intellectual Property Rights, Bangalore-560002, India.

<sup>2</sup>Deputy Manager, Global IP & Strategic Planning, Wockhardt Ltd, Aurangabad-431001, India.

<sup>3</sup>Pacific University, Udaipur, Rajasthan-313024, India.

#### ABSTRACT

In today's knowledge driven economy intellectual property rights encourages the innovators and empowers them to collect full value of their invention, which induce country growth. The post-GATT period has brought a noticeable attention towards intellectual property rights protection and the pharmaceutical industry is attempting a parallel run with the state of affairs. The paper portrays the patent, the patentability and procedure of patenting as well as analyzes the trend in pharmaceutical intellectual property rights growth and its current status. The review and analysis is based on secondary data published. The statistics study reveals that the pharmaceutical patents (drug, chemical, bio-technology) contribute 28.51% in connection with overall patents granted in various fields by IPO, 1997-2010. Thus the present report mainly discuss about trends of pharmaceutical patents in Indian Patent Office.

**Keywords:** Intellectual property rights, GATT, Patent.

#### INTRODUCTION

##### Patent

Protecting one self's creation and services is done by IPR intellectual property rights are legal rights, which result from intellectual activity in the industrial, scientific, literary and artistic field. IP is divided into two industrial property and copy rights. Inventions related to process or products are eligible for grants of patent. Patents are the monopoly right granted by the central government to the applicant for a limited period (20 years) in lieu of full disclosure of invention. Patents are categorized into ordinary patents, patents of addition, convention application with priority date, national phase application (PCT). Inventions are patented by inventor (patentee) in individual country or one behalf of corporate or other entities through patent co-operation treaty (PCT). IP is essential for country's technological, economical and social development. This article reviews about structure of pharmaceutical patenting in India by identifying its process and dealing with pharmaceutical patent journey in India. These days numerous patents are granted for pharmaceuticals related to product formulation process steps and new chemical entities

(NCE's).

#### Indian Patent ACT

The patents act 1970, which come into force in 1972, has been amended thrice, 1999, in 2003 finally 2005 as in Table no 1. This act repealed old Indian patent design act 1911. The obligation an patent law in conformity with art.27. TRIPS forced amendment in Indian patent act which provided a mechanism for filing of patents applications related to pharmaceutical and agro-chemical products under a mailbox which could be only examined on or after 1 Jan 2005. Henceforth, effectively until 1 Jan 2005 india did not provide patent protection for pharmaceutical products.

#### Governing laws in india for IPR

##### Conditions of Patentability

The TRIPS agreement of the world trade organization lays down certain basic common features for grant of patents. The patent act 1970, defines an invention as a new product or process involving an inventive step and capable of industrial application [section 2(1) (j)]. These basic conditions of patentability are (Patent Agent Examination, 2010),

1. Novelty
2. Inventive step
3. Capable of industrial application.

**\*Corrospounding author**

**Sagar N Patil**

#### Non-Patentable Invention

Sections 3 and 4 of the patents act provide a list of inventions which are not considered patentable. These include inventions which are contrary to public health or morality or have the potential to cause harm to the public (Patent Agent Examination, 2010; Anonymous 2).

- a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
- b) an invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which cause serious prejudice to human, animal or plant life or health or to the environment;
- c) the mere discovery of a scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature;
- d) the mere discovery of new form of known substance which does not result in the enhancement of any known efficacy of that substance or the mere discovery of any new property or new use for the known substance or of the mere use of the known process, machine or apparatus unless such known process result in a new product or employs at least one of new reactant;
- e) a substance obtained by mere admixture resulting only in aggregation of the properties of the components thereof or a process for producing such substance;
- f) the mere arrangement, rearrangement or duplication of known devices each functioning independently of one another in a known way;
- g) a method of agriculture or horticulture;
- h) any process for medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any other process for similar treatment of animals to render them free of disease or increase their production or propagation of plants and animals;
- i) plants or animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production and propagation of plants and animals;
- j) a mathematical or business method or a computer programme *per se* or algorithms;
- k) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
- l) a mere scheme or rule or method of performing mental act or method of playing game;
- m) a presentation of information;
- n) topography of integrated circuits;
- o) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

#### **Patent Filing in India** (Patent Agent Examination, 2010)

- Who can file an application for patent?

In accordance with section 6, the following persons may file an application for a patent;

1. Inventors

2. Assignee
3. Legal representative of any deceased person.
  - Where to apply?

Depending upon in whose jurisdiction, an Indian resident resides or has principle place of business can file an application for patent at the head office of IPO, governing that jurisdiction. A foreign national who is interested in filing an application for patent in India must have an address for service in India or principle place of business in India.

- Types of application?

1. Ordinary application: it is an application which is filed in IPO without claiming priority of any other application. It may be accompanied with provisional or complete specification.
2. Convention application: it is an application which is filed in IPO claiming priority of similar application filed in convention country. It must be accompanied with complete specification and must be filed within 12 months of single application in convention countries.
3. International patent application: the international patent application which is filed through Patent Cooperation Treaty is also referred as Patent Cooperation Treaty application. In accordance with Rule-19, the International Application should be filled either in English or Hindi in Indian Patent Office as receiving office.
4. Patent Cooperation Treaty National Phase Application : if an applicant has filed an International Patent Application designating India then the said International application can only be prosecuted in India. If it enters the national phase within 31 months from the date of filing or from date of priority, if any.

#### **Filing an Application for Patent Accompanied with Provisional / Complete Specification** (Patent Agent Examination, 2010)

An application for patent whether ordinary, conventional or an international patent application filed under Patent Cooperation Treaty must be filed in Form 1. The application for patent should be accompanied with either provisional or complete specification which is to be filed in Form 2.

1. Declaration as to inventor ship.
2. Statement and undertaking.
3. Proof of right to make an application.
4. The authorization of an agent.

For International Patent Application which enters national phase, following documents in addition are to be submitted

1. Form 6 and/or Form 13 are required.
2. Document evidencing a change of name of applicant if a change occurred after filing date and has not been reflected in notification from international bureau.

#### **Provisional Specification**

Specification which does not contain claims is regarded as provisional specification. It is filed in case

when the invention is not complete or it is at preliminary stage at the filing of application. However it should not be interpreted as rough draft of complete specification. In accordance with section 9-i the applicant is given 12 months' time to file complete specification pursuant to filing provisional specification. The fee for filing an application accompanied with provisional specification is Rs 4000 for legal entities and Rs 1000 for an individual.

### Complete Specification

The provisional application is deemed to be abandoned if complete specification is not filed within 12 months from date of filing provisional specification. It is a techno-legal document which completely describes invention and best mode of carrying out invention.

A complete specification includes following:

1. Title.
2. Field of invention.
3. State of art in the field.

4. Object of the mention.
5. Statement of invention.
6. Detailed description of the invention.
7. Claims.

### Time Limits (Patent System in India, 2011)

Every step in filing a patent is provided with certain time period, in the meantime the applicant has to provide and complete the specific procedure. The time limits of important procedure are shown in table no 3.

### Patent Granting

If the controller is satisfied than in accordance with Sec-43, he grants the patent else expeditiously as possible. On grant of patent the controller publishes the fact, that the patent has been granted in official gazette, and thus the controller enters the date on which patent was granted on the register of patent.

**Table.1 India patent Act 1970 and Amendments (Anonymous 1)**

The Patent Act, 1970	Patents Act 1970 effective 20 April 1972 Patents (Amendment) Act 1999 effective 1 January 1995 Patents (Amendment) Act 2002 effective 20 May 2003 Patents (Amendment) Act 2005 effective 1 January 2005 Patents Rules 1972 effective 20 April 1972 Patents (Amendment) Rules 2003 effective 20 May 2003 Patents (Amendment) Rules 2005 Patents (Amendment) Rules 2006 effective 5 May 2006
----------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

**Table.2 Patent offices in India**

Patent Office	Territorial Jurisdiction
Mumbai	The states of Gujarat, Maharashtra, Madhya Pradesh, Goa, Chhattisgarh, Union Territories of Daman and Diu and Dadar and agar Haveli.
Delhi	The states of Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttaranchal, National capital territory of Delhi and Union territory of Chandigarh.
Chennai	The states of Andhra Pradesh, Karnataka, Kerala, Tamil Nadu and Union territories of Pondicherry and Lakshadweep
Kolkata (Head office)	Rest of India

**Table.3 Important time limits**

Activity	Timeline (months)	Extension (months)
Provisional to Complete specification	12	NIL
Submission of proof of right to apply	6	Till grant accept with PET U/R 137
Statement registration, foreign filing U/S 8	6	DO
Request for examination under Sec 11(b)	48 from date of priority	NIL
Compliance of objection after FER	12	NIL
Notice of opposition after notification	12	
Restoration of lapsed patents	18	NIL
Renewal fees	Ending of preceding year	6

**Table.4 Patents granted by IPO during 1997-2010 (All Fields) (Rau BS et al., 2012)**

Year	Chemical	Drug	Food	Electrical	Mechanical	General	Bio-technology	Computer/electronics	Other fields	Total
Grand total	13632	6164	1402	5351	14901	5346	2158	4909	6931	63597
Overall percent based on grand total	21.43	9.69	2.20	8.41	23.43	8.41	3.39	7.72	10.90	100

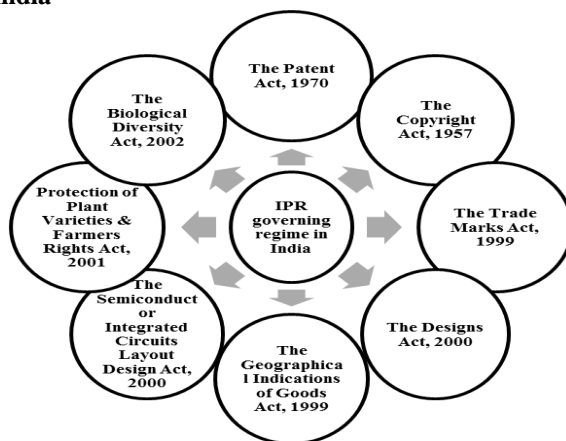
**Table.5 Patent filing trends during 1996-2010**

YEAR	NUMBER OF PATENTS
2006	68289
2007	69207
2008	68649
2009	66981
2010	63992

**Table.6 Pharmaceutical's PCT Applications**

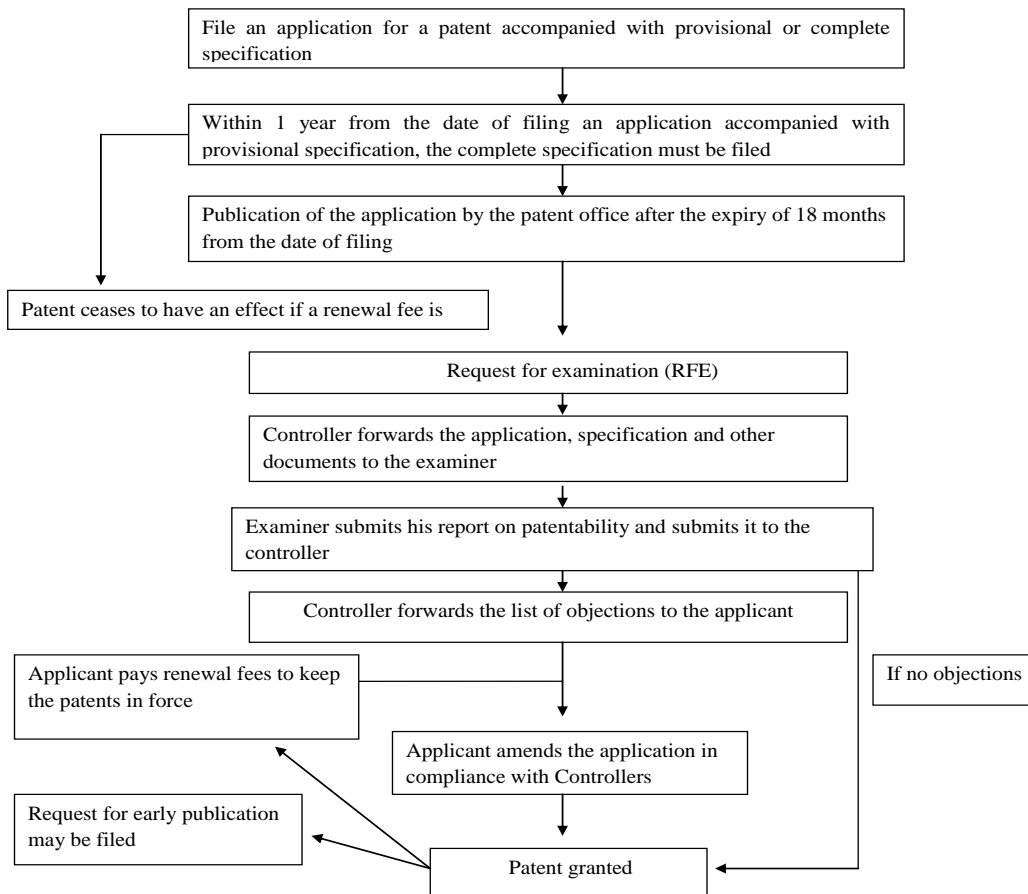
YEAR	INDIA	EUROPE	USA
2010	145	2253	3302
2011	143	2270	3221

**Fig.1 IPR governing regimen in India**

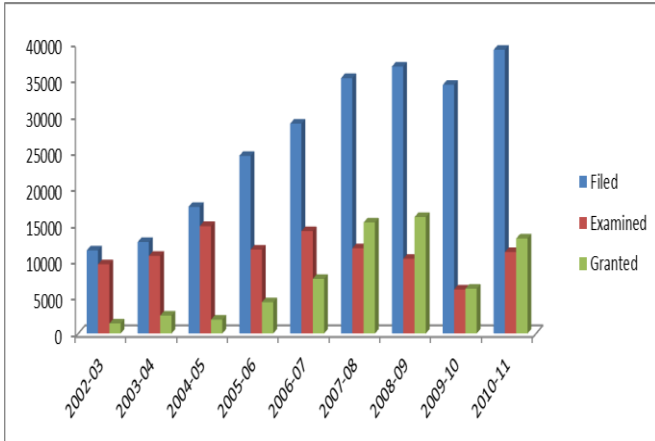


**Fig.2 Stepwise procedures for obtaining patents**

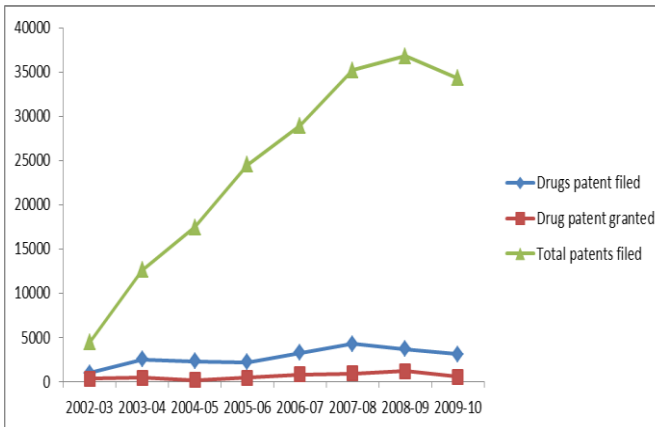
Steps for prosecuting patent application in India



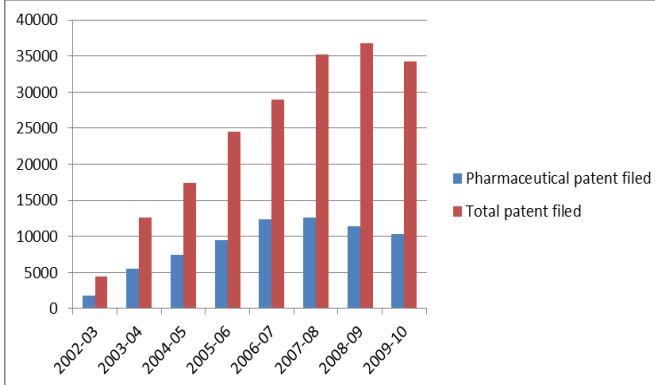
**Fig.3 Performance of Indian patent office**



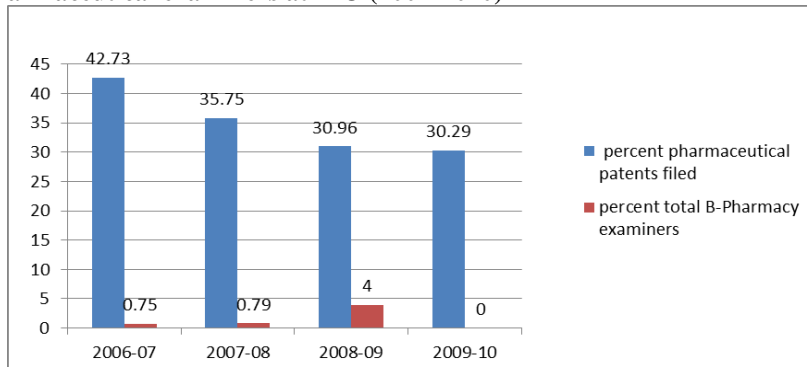
**Fig.5 Statistics of Patent: Drug patent Vs Total Patent filed**



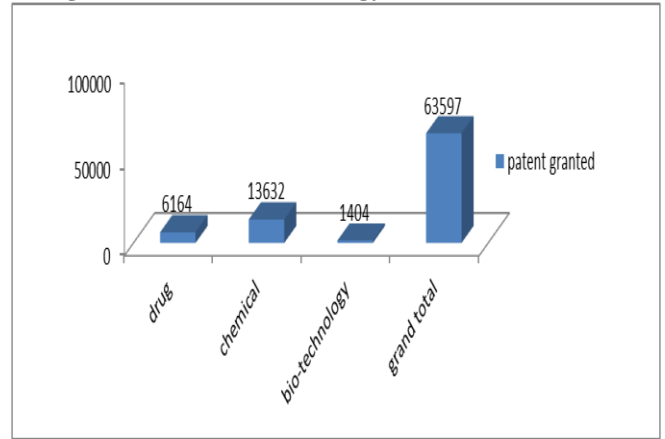
**Fig.7 Pharmaceutical (Drug, Chemical, Bio-technology) Patent Vs Total Patent filed**



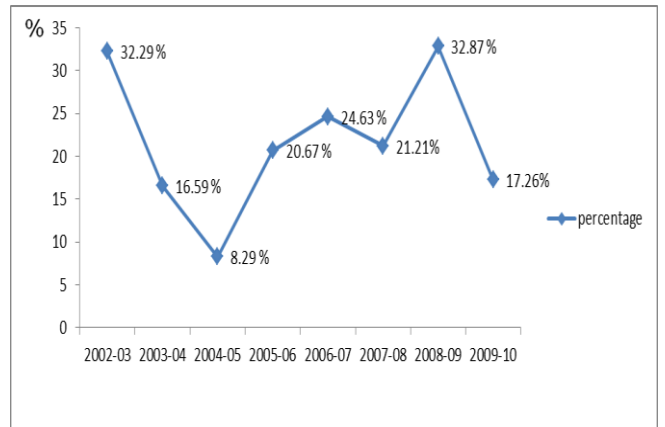
**Fig.9 Assessment of Pharmaceutical examiners at IPO (2007-2010)**



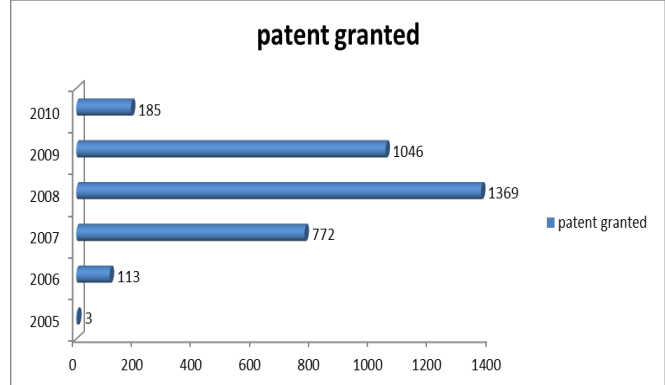
**Fig.4 Patent Granted at Indian Patent Office 1997-2010, (Drug, Chemical, Bio-technology)**



**Fig.6 Percentage of Drug Patent granted with respect to Drug Patent filed (2002-2010)**

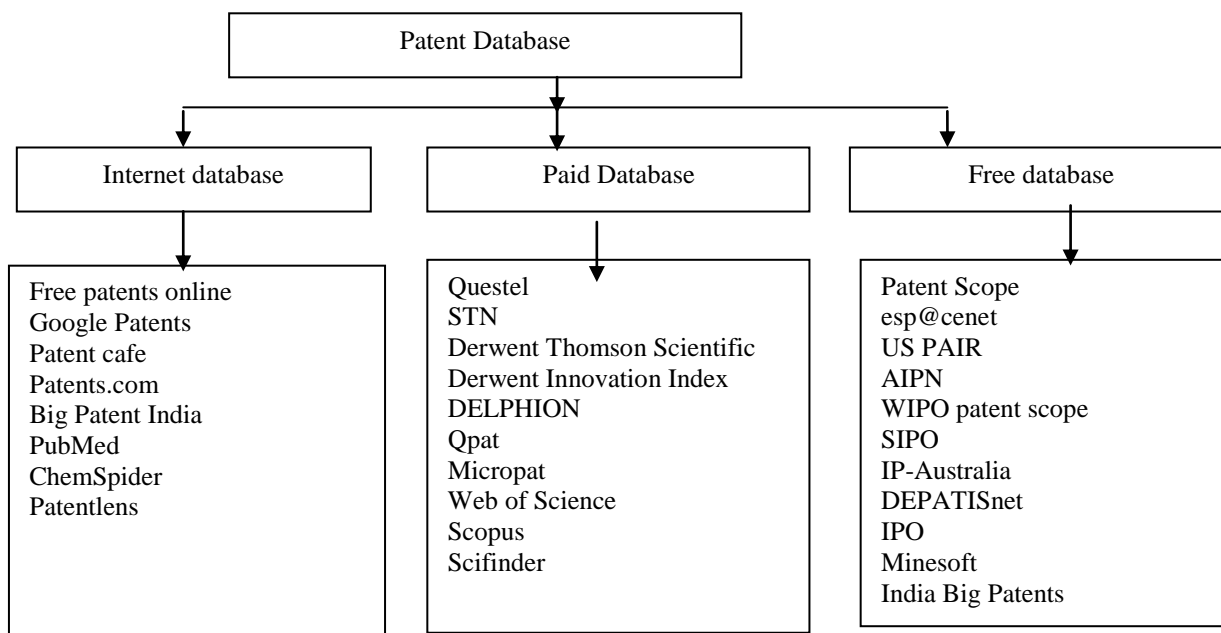


**Fig.8 Pharma Product Patents granted in India (2005-2010)**



## SEARCH DATABASE

Lack of information of patent database was hindrance in previous years. Nowadays there are several databases available to gain patent information.



### Procedure for Obtaining a Patent

#### Indian Patent Office Performance Statistic (Anonymous 3)

During term of 2002-2010, Fig no 3 indicates the applications filed, examined and granted relating to all fields of patents on year by year basis. Performance of IPO can be clearly studied by fig no which indicates the demarcation between patents filed and granted.

From the data of Table.4, we can put side by side the chemical, drug and bio-technology opposite of total patents granted. It can be seen that among the total patents granted, the pharmaceutical patent (Drug, Chemical, Bio-technology) constitute of 34.51%.

### Statistics of Patent

#### A. Drug Patent Vs Total Patent Filed (2002-2010) (Anonymous 3)

Among the total Patents filed in different years as depicted in Fig no 5, the Drug Patents summed 22266 which was about 11.46 % of total Patent filed in those years.

Same during the term of 2002-2010, by assisting the Fig no 5, the percentage of Drug Patent granted with respect to Drug Patent filed can be extracted which is revealed in Fig no 6. The patents granted are observed much less than the patent filed. The Drug Patent granted has been observed to gain gradual increase in post-TRIPS period except in case of 2009-10(17.26%).

#### B. Pharmaceutical (Drug, Chemical, Bio-technology) Patent Vs Total Patent filed

From the graph it is observed, there is 9 folds increase total number of patents filed whereas pharmaceutical patents is only able to increase 4 folds in number.

#### C. Stastics of Pharma Product Patents granted in India (post-TRIPS period) (Rau BS et al., 2012)

Fig.8, suggest India's commencement of grant of Pharma product patent. Literature revels a total of 3488 Pharma Product Patents were granted all through the year 2005-2010.the post-TRIPS period has shown positive effect on pharmaceutical product patent, yet a down slope is observed after year 2008 which is to be noticed.

#### D. Assessment of Pharmaceutical Patents filed in connection with B-Pharmacy examiners at IPO (Rastogi T, 2010)

The Fig.9 brings to light that there has been always a deficiency in the number of the B-Pharmacy examiners at the IPO, which may have an impact on the Pharmaceutical patents granted. The Fig no.9 shows the comparison of the B-Pharmacy examiners with respect to the pharmaceutical patents filed.

#### E. Patent filing trends in Pharmaceuticals

Table.5 suggest that the patent filing in pharmaceuticals have faced 1.6% loss in 2010 when compared to 2009. It's not only because of the presence of newer technologies to treat diseases but also may be due to the advancement in those technologies which are taking place at a higher velocity.

#### F. Assessment between US, India and EP filings in Pharmaceutical Sector

Table.6 suggests that India is a lot behind in filing PCT applications as well. Also the important study we can compare is the number of patents filed by the countries in their national offices.

With the help of data from different sources it was found that found that the total number of patent filed in India for a period of 2006-10 was around 18000 patents but when we see the same data for the same years

in Europe and USA, we bring into being out that the number of patent applications filed in Europe and USA are 700004 and around 11874 respectively. This illustrates us that the total number of patent filed in the pharma sector by India lacks behind the other two offices with a great margin.

### CONCLUSION

In the pharmaceutical sector we notice that the patent filings have lessened in last few years worldwide. But when we check for the same in India we find out that in unkindness of decrease in patent filing in pharmaceutical sector, in year there was an increase in this drift in India. Also it can be concluded that there is a strong need required to give emphasis on Pharmaceutical patenting in India. Further two things can be pointed out. One, may be shifting of interest for bio-technology patenting among pharmaceutical and bio-tech innovators which can be said because only 11.46% of Drug patents were filed from 2002-10 in connection with total patent

filed during same period. Two, a large difference of pharmaceutical patent in comparison with all other field patents at IPO. The postulation is based on, among the 63597 (2002-10) total patent granted the Drug patent comprised of only 9.69% patent granted. Also the post-TRIPS showed a percent increase in Drugs patent filed which showed a tint of declination from 32.87% AS ON 2008-09 TO 17.26% in 2009-10. Whereas 1369 product patents were granted in 2008, showing effect of post-TRIPS period which is positive for Pharmaceutical sector in India. Most imperative impact irrespective of the fluctuation in pharmaceutical patent filed and granted, there has been noticeable lack of patent examiners (B-Pharmacy) at IPO. Furthermore India's lacking in patent filing India has to conquer their old policy and get into the field of IPR and file more patents in spite of publishing papers in the journals and produce a monetary value for their research. In addition the decision by the Supreme Court on the case of Novartis, GLEEVEC has brought a diversified focus on Patent system in India.

### REFERENCES

- Anonymous 1. [www.mirandah.com](http://www.mirandah.com)
- Anonymous 2. India Patent activity in domestic patent office, Sujit Bhattacharya.
- Anonymous 3. [www.ipindia.nic.in](http://www.ipindia.nic.in) (Annual Reports)
- Patent Agent Examination. Sheetal Chopra, Akash Taneja, 2010, Lexis-Nexis Publication.
- Patent System in India. Jyotiverma, Intellectual Property India 20 Dec 2011, [www.ipindia.nic.in](http://www.ipindia.nic.in)
- Rastogi T. IP audit: Way to a healthy organization, *Journal of Intellectual Property Rights*. 2010;15(4):302-309.
- Rau BS, Nair GC, Appaji PV. Current status Of Pharmaceutical Patenting in India. 2012;44(07):13-25.