ANALYSIS OF PRODUCT PATENTS IN PHARMACEUTICALS FOR MAILBOX APPLICATIONS GRANTED BY INDIAN PATENT OFFICE DURING 2005-06 TO 2009-10

A thesis submitted towards partial fulfillment of

5 year BS-MS dual degree programme

by

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CERTIFICATE

This is to certify that this dissertation entitled "**Analysis of product patents in pharmaceuticals for mailbox applications granted by Indian Patent Office during 2005-06 to 2009-10**" towards the partial fulfillment of the BS-MS dual degree programme at the Indian Institute of Science Education and Research, Pune represents original research carried out by **Dharmraj Robins Chourasia** at URDIP (CSIR Unit of Research Development of Information Products),Pune under the supervision of Dr. A.A. Natu, Faculty, IISER Pune and Dr. Raj Hirwani, Head, URDIP during the academic year 2011-2012.

Institutional Supervisor

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Date:
Place: Pune

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CANDIDATE'S DECLARATION

I hereby declare that the matter embodied in the report entitled "**Analysis of product patents in pharmaceuticals for mailbox applications granted by Indian Patent Office during 2005-06 to 2009-10**" are the results of the investigations carried out by me at the Department of Chemistry, URDIP(CSIR Unit of Research Development of Information Products) Pune, under the supervision of Dr. A.A. Natu and Dr. Raj Hirwani and submitted towards the partial fulfillment of the 5 year BS-MS dual degree programme at the Indian Institute of Science Education and Research, Pune.

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Dharmraj Robins Chourasia

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Abstract:-

This project deals with the analysis of the granted mailbox patent applications in India. The applications which were specifically related to the pharmaceutical product patents and filed during the period from Jan 1995- Dec 2004 are considered as the mail box applications. Prior to signing GENERAL AGREEMENT ON TRADE AND TARRIFS (GATT) agreements we had only process patents for pharmaceuticals, food and agro products. As a part of GATT agreement which was signed in December 1994, India was given 10 years to change its patent law. A pipeline protection of 10 years (1995-2005) was introduced under which a product patent application for pharmaceutical can be filed but it will not be examined till 2005 (mail box) Therefore it will be interesting to analyze the mail box patents in view of its impact on the pharmaceutical industry. The project includes the introduction to Patents and the nomenclature used in the Patents Act, 1970. It will also include a focused review on various milestones which are passed during the filing of Patents in India.

The analysis involved the classification and bucketing of 2371 mailbox pharmaceutical patents granted by Indian Patent Office. The study will also highlight the most proliferic assignees their technology focus, therapeutic areas for the mail box applications related to the pharma industry.

CHAPTER 1

INTELLECTUAL PROPERTY REGIME IN INDIA:-

Intellectual property means the property developed from the idea of human mind. The era of Intellectual property brought an industrial, economical and cultural development in the society. This led to another form of property right for the owners of intellectual properties. The property right pertaining to such intangible assets is called Intellectual property rights (IPR). [1]

The Intellectual property is an asset and, as such, it can be bought, sold, mortgaged, licensed, exchanged or gratuitously given away like any other form of the property. Obtaining a legal right over the property, the creator of the Intellectual property seeks to ensure that he has the exclusive right over it. In such case, the property can be put to use by others only with his consent. Also, ownership of Intellectual Property Right is a legal recognition and reward you receive for your intellectual efforts. Globally, such properties are a good source of national wealth and mark of an economic leadership. [1]

Simultaneously, this idea of protecting intellectual property led to the evolution of Intellectual Property system in India. Since then Intellectual Property Rights regime is in a state of rapid and continuous evolution in India.

The building blocks of Intellectual property regime in India are those identified by the TRIPS governed by the WTO. They are

- PATENTS,
- COPYRIGHTS,
- TRADEMARKS,
- INDUSTRIAL DESIGNS,
- GEOGRAPHICAL INDICATORS,
- TRADE SECRETS,
- INTEGRATED CIRCUITS.

At present the following legislations on Intellectual Property Rights are in force in India–

1. THE PATENTS ACT, 1970 as amended by The Patents (Amendments) Act (2005) along with The Patents (Amendments) Rules 2005 [Effective from 5-5-2006]
2. THE DESIGNS ACT, 2000 along with The design Rules, 2001
3. THE TRADE MARKS ACT, 1999 along with The Trade Marks Rules, 2002
4. THE GEOGRAPHICAL INDICATIONS OF GOODS (Registration And Protection) Act, 1999 and The Geographical Indications of Goods (Registration And Protection), Rules 2002
5. THE COPYRIGHTACT, 1957 as amended in 1999. [2]

And, India is a member of the following International Organizations and Treaties in respect of Patents:

a) World Trade Organization (WTO) with effect from 01-01 -1995.

b) Convention establishing World Intellectual Property Organization, (WIPO).

c) Paris Convention for the protection of Industrial Property with effect from Dec.7, 1998.

d) Patent Co-operation Treaty (PCT) with effect from Dec.7, 1998.

e) Budapest Treaty with effect from 17th December, 2001. [2]

A. PATENTS

Introduction:

Patent is an exclusive right granted by the government to the applicant for his invention of which should be new, non-obvious, useful and patentable as per the patentability criteria in the national law. Patent is a monopoly right of inventors. This is the right to exclude others from making, using or selling his invention. The owner has to enforce his rights by suing in case of an infringement of his rights [3].

A patent offers technical solution to a technical problem. A patent enunciates a contract between an inventor / applicant and the Government and gives the territorial right in the country where it is granted.

A patent may be granted for a product, or a process. In the case of a product, the patent is in the end product. In the case of a process, the patent does not lie in the end product but only in the process of production.

Patentability criteria:

In order to get patent for an invention, the invention has to be patentable. In India, as per Patents (Amendment) Act, 2005, the definition of invention is given as-

a) A new product or process involving an inventive step and capable of an industrial application.
b) An invention must consist of Patentable Subject Matter ; and
c) It should not fall under section 3 of The Patents Act [4].

So, normally in order for a subject matter to be patentable it should fulfill three conditions they are

i. Novelty:

An invention is considered to be new, if it does not form a part of the state of the art, i.e., for an invention to be new (novel), it should not be anticipated by prior knowledge in public domain either by way of prior publication anywhere in

the world or by prior use in India or by prior claim in India on the date of filing of patent application or priority date.

ii. Inventive step(Non-obviousness):

For the grant of patent, an invention must be something that represents significant and essential improvement over Prior Art i.e. it should not be obvious to the person skilled in the art.

iii. Industrial Applicability:

An invention must have some practical application. "Industrial applicability" in relation to an invention means that the invention should be capable of being made or used in an industry [3].

Invention not patentable (Under Section 3 of The Patents Act):

The Act under Section 3 defines non patentable inventions. [2] These are:

a) An invention which is frivolous or which claims anything obvious contrary to well established natural laws.
b) An invention the primary or intended use or commercial exploitation of which would be contrary pubic order or morality or which causes 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 an abstract theory or discovery of ant living thing or non living substances occurring in nature.
d) The mere discovery of any new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process result in a new product or employment of one new reactant.
e) A substance obtained by a mere admixture resulting only on the aggregation of the properties of the components there of or a process for producing such substance.

f) The mere arrangement or 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 the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human being or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
i) Plant and animal in whole or any part thereof other than micro organisms but including seeds , varieties and species and essentially biological processes for production or propagation of plants and animals.
j) A mathematical or business method or a computer for per se or algorithms.
k) A literary, dramatic, musical or artistic work or any other aesthetic creation what so ever including cinematographic works and television productions.
l) A mere scheme or rule or method performing mental act or method of playing game.
m) A presentation of information.
n) Topography 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.

Non patentable inventions relating to atomic energy (Under Section 4 of The Patents Act): [2]

> *" no patent shall be granted in respect of an invention relating to atomic energy falling within subsection (1) According to section 20 of the Atomic Energy Act,1962(33 of 1962)".*

According to section 20 (1) Atomic Energy Act, as for the commencement of the act,

No patent shall be granted for the invention when in the opinion of central government are useful for or related to the production, control, use or disposal of atomic energy or prospecting mining extraction , production , physical and chemical treatment

fabrication , enrichment , canning, or use of any prescribed substance or radioactive substance or insuring of safety in atomic energy operation.

Term of Patents:.

Once a patent is granted, certain monopolistic rights are conferred upon the patentee, as an incentive for disclosing his invention to the public. These monopoly rights, generally for a period of 20 years, are *assignable* thus enabling the patentee to *license* invention thereby maximizing his profit. [4]

Mailbox applications:

They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period — Article 70.8. This is sometimes called the "mailbox" provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty ("newness").

And if the government allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it had to — subject to certain conditions — provide the patent applicant an exclusive marketing right for the product for five years, or until a decision on a product patent was taken, whichever was shorter. [5]

When the 1999 amendment was passed by the Indian Parliament, the mailbox provision was introduced with retrospective effect from 1st January 1995. The provision was introduced as Section 5(2) of the (amended) Indian Patents Act. The mailbox provision came to an end on 31st December, 2004 and the final amendment of the Indian Patents Act in 2005 provided for product patents in pharmaceuticals. [6]

B. COPYRIGHTS

Copyright is protection that covers published and unpublished literary, scientific and artistic work. Copyright relates to the exclusive right to do or authorize to do a certain acts in relation to original Literary, dramatic or musical work, artistic creations (paintings, photographs, work of architecture, artistic craftsmanship), Cinematographic films, Sound Recording, Software programmed etc, provided such works are fixed in a tangible or material form. [7]

Unauthorized copying or reproduction of the author's work amounts to infringement. But, a fair dealing with the work for private uses i.e. study, research, review, criticism etc, without an intention of commercial gain is not infringement. Copyright subsists for a term of the lifetime of the authors plus 60 years in case of a literary, dramatic, musical or artistic work. In the case of joint authorship, the term is calculated from the death of the last living author.

C. TRADEMARKS

A trademark is a visual symbol in the form of word, name, logo, label etc, as applied to an article of commerce, with a view to indicate origin of manufacture or service or vendor in that respect and enable customers to distinguish the product of one manufacture from the goods of the other.[8]

Section 25 of the Act, states the tenure of trademarks as follows:

> *"The registration of a trade mark, after the commencement of this Act, shall be for a period of ten years, but may be renewed from time to time in accordance with the provisions of this section.."* [8]

D. INDUSTRIAL DESIGN

Design means only the features of shape, configuration, pattern, ornament, composition of color or line or a combination thereof. It must be applied to any article, whether two dimensional or three dimensional or in both forms, by any industrial

process or means, which in the finished article appeal to and are judged solely by the eye. A registered Design remains in force for a maximum period of 15 years. [9]

E. GEOGRAPHICAL INDICATION

Geographical Indications are similar to trademarks in that they function as source indicators. However, the key distinction lies in the fact that while a trademark identifies a good or service as originating from a particular producer, a geographical indication identifies not the producer of the good concerned, but the geographical region from where the product originates. [10]

The registration of a geographical indication is valid for a period of 10 years and can be renewed successively for further period of 10 years each. A registered geographical indication cannot be assigned, transmitted, mortgaged, pledged or licensed.

F. TRADE SECRETS

Trade Secret means a formula, pattern and any instrument design which is kept confidential and through which any business or trade can edge over its rival and can enjoy economic gain. Trade secrets can be anything from a chemical compound, manufacturing process, design or preserving materials or even a list of consumers or clients. Trade secrets offer protection for an indefinite time period.

G. INTEGRATED CIRCUITS

Integrated circuits are essentially semi conductor chips. These contain transistors, resistors, capacitors and their interconnections, fabricated in a tiny, single piece of semiconductor material. The protection of the layout design of the circuit is referred as the protection of Integrated circuits. The layout designs of integrated circuits are creations of human mind which makes them a part of intellectual property. [11]

The registration of a layout-design shall be only for a period of ten years counted from the date of filing an application for registration or from the date of first commercial exploitation anywhere in India or in any country whichever is earlier.

GENERAL TERMS:-

1) Application Number is assigned to each patent application depending on Patent Cooperation Treaty, National Phase or Domestic filling.
2) Date of Publication is the date on which the patent application is published in the patent journal.
3) Date of Application is the date on which the patent application is filled at the Patent Office.
4) Patent No. is number assigned to each patent application after it has been granted.
5) Date of Patent grant is date when the patent application is granted and gets assigned with a patent number.
6) Priority date is the date of first filling of application in any member country of Treaties.
7) Priority Information gives the details about the country and application no. which is claimed for prior art search.
8) Applicant is a body responsible for filling of patent application.
9) Types of applicant mean the nature of the body based on different criteria.
10) Applicant or Assignee country means the country it belongs or is headquartered.
11) Inventors are people related to invention and can be different from applicant.
12) Title is the name given to a patent and it broadly covers the nature of invention.
13) Abstract is a brief short note of the invention.
14) Description is the complete disclosure of the invention.
15) Category of patents is used to classify patents depending on products.
16) Technology focus is used to classify patents depending on the research area.
17) Specific compounds are compounds that the patents focus on.
18) Class of compounds is the code defined by DERWENT and is called as Derwent Class Code.

CHAPTER 3

RESEARCH METHODOLOGY

The main objective of the study was to get an overview on the patents granted for the applications during the period from 1995-2004 wherein the analysis was focused on the patents related to the pharmaceutical sector.

The list of the pharmaceutical patents as granted by the India Patent Office from 2005 till date was downloaded from the Indian Patent Office website. These patents were filtered to shortlist the patent applications filed between 1st, January, 1995 to 31st, December, 2004.These patents were the mail box applications.

There were 3488 pharmaceutical patents granted by the Indian Patent Office till date amongst which 2371 were the mailbox patent applications.

The full text/bibliographic details for these mailbox applications were then downloaded from the Derwent Innovation Index/ Indian Patent Information Retrieval System online database. The list was then compiled and considered for further analysis.

CHAPTER 4

RESULTS AND DISCUSSIONS:

The search resulted in a dataset of 2371 granted patents. These patents were analyzed based on the technologies used by different companies/organizations to treat various diseases.

The spreadsheet embedded below gives the detailed classification for the records. The patent filings have been analyzed and categorized as given below based on the full texts (if available) and Derwent Abstracts.

- Type of patents
- Therapeutic Area
- Chemical Classification
- Specific compounds claimed

The analysis was further considered to get an overview on the following trends:

- Technology Analysis – Therapeutic area, chemical class of drugs etc
- Year wise filing activity
- Number of patents granted per year.
- Assignee Analysis
- Assignee Focus
- Assignee Country Analysis

Robins IISER EXCEL LIST.xlsx

I. Analysis based on the types of Mailbox Applications

Out of a total of 2371 granted patents from the mailbox applications 645 were filed as PCT applications, 1001 entered into India during the National Phase entry while 725 were filed as national filings (others). The number of National Phase being highest clearly shows the importance of Indian market globally. Further, Table 1(b) and Graph 1(B) predict that Indian Patent Office Mumbai had a completely reverse trend from the other Indian Patent Office's.

From table (2) and graph (C), it is observed that during the period of ten years Indian Patent Office Chennai had maximum no. of granted patent applications filing.

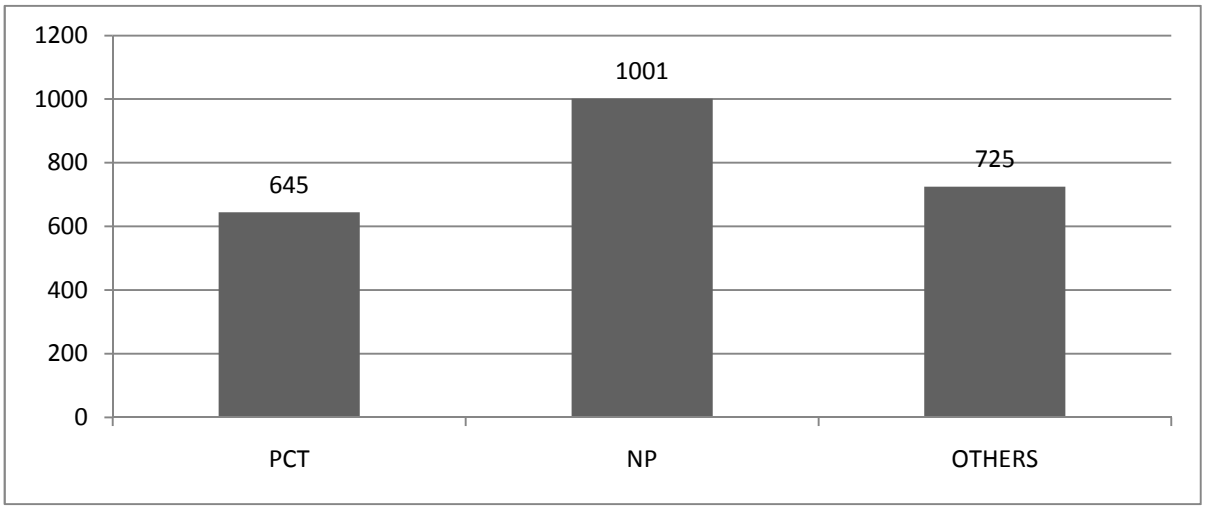
1. *Table for Types of application and Number of applications*

   a. For India

Patent Cooperation Treaty (PCT)	645
National Phase (NP)	1001
OTHERS(Domestic Filing)	725

A. *Graph for Number of different types of applications filed in India*

X =Types of applications filed in India; Y = number of applications



b. For each Indian Patent Office

DELPCT	65
DELNP	192
DEL	224

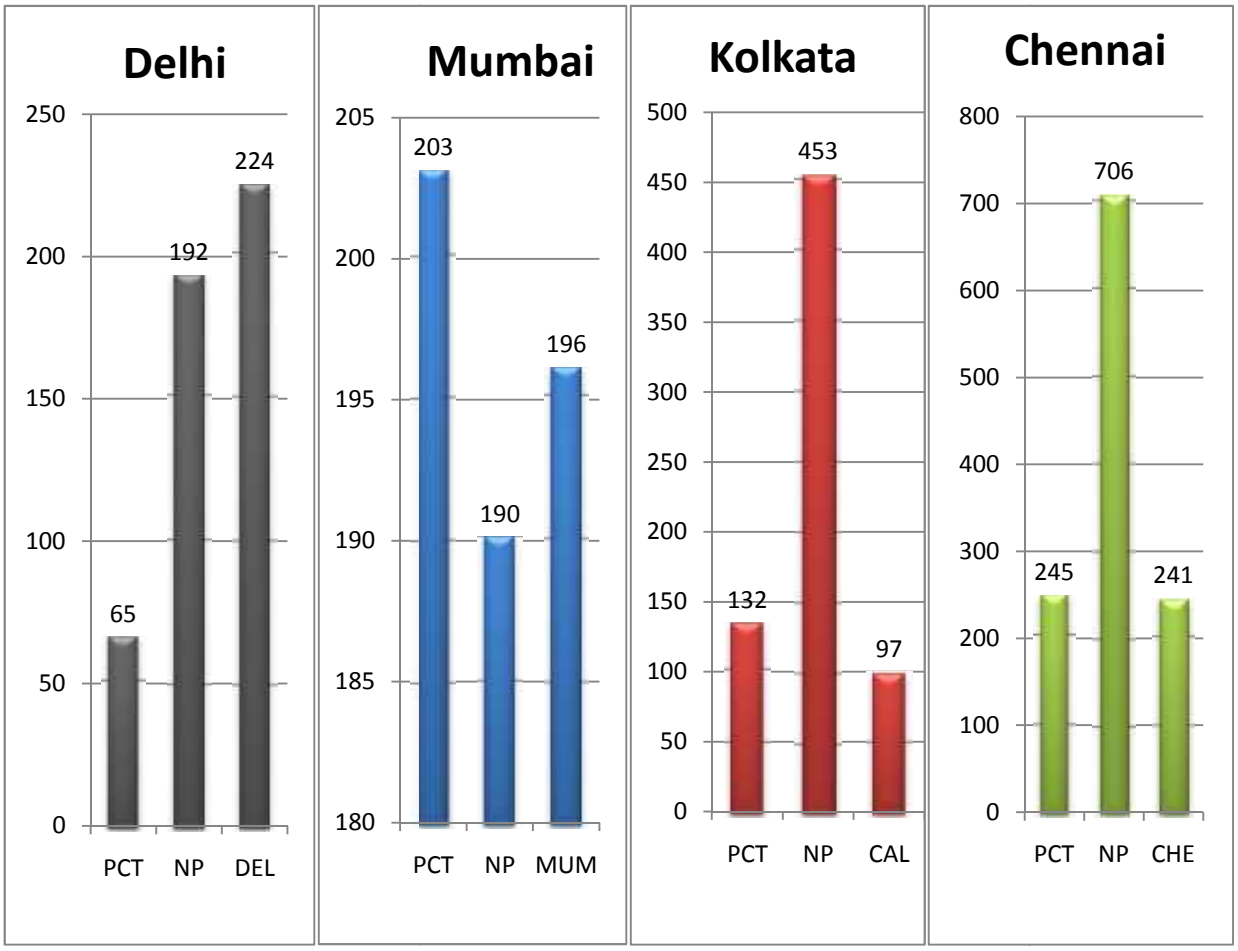
MUMPCT	203
MUMNP	111
MUM/BOM	178

KOLPCT	132
KOLNP	271
KOL/CAL	91

CHEPCT	245
CHENP	427
CHE/MAS	232

B. *Graph for Number of different types of applications filed at Indian Patent Offices*

X = types of applications in different IPO; Y = number of applications

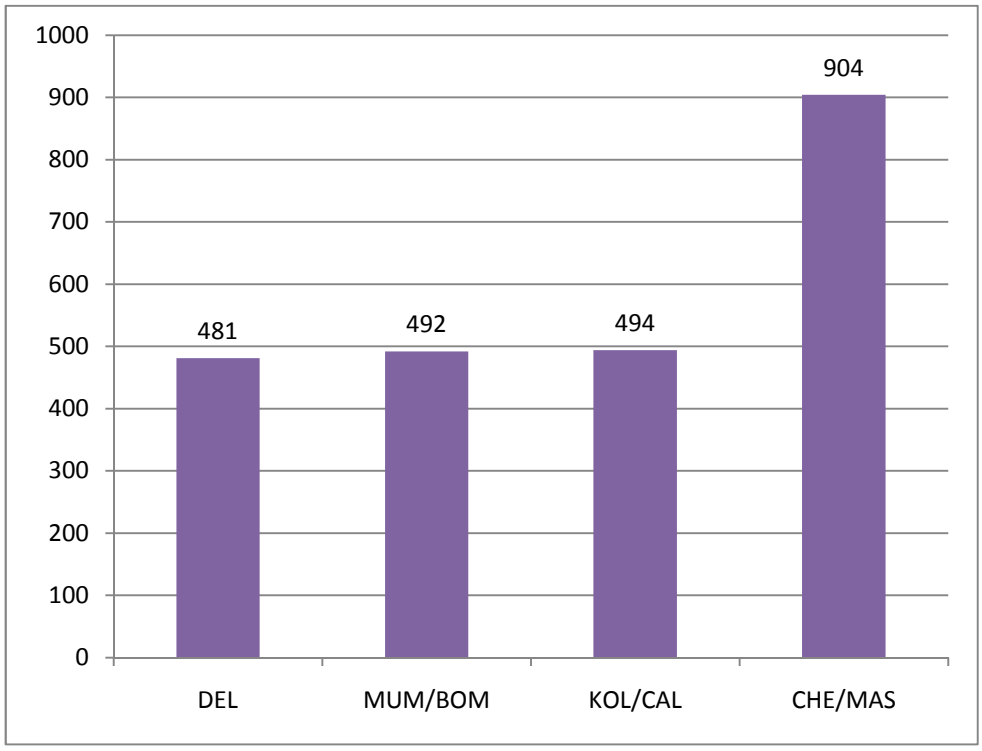


2. *Table for Indian Patent Office and. Number of applications filed*

DELHI IPO	481
MUMBAI IPO	492
KOLKATA IPO	494
CHENNAI IPO	904

C. *Graph for Number of filings at each Indian Patent Office*

X = different Indian Patent Office in India; Y = number of applications filed



II. Date of Filing:

The date of filing was considered to get an overview on the Year wise filing activity of the pharmaceutical mail box granted patent applications and is depicted in figure 4 below:

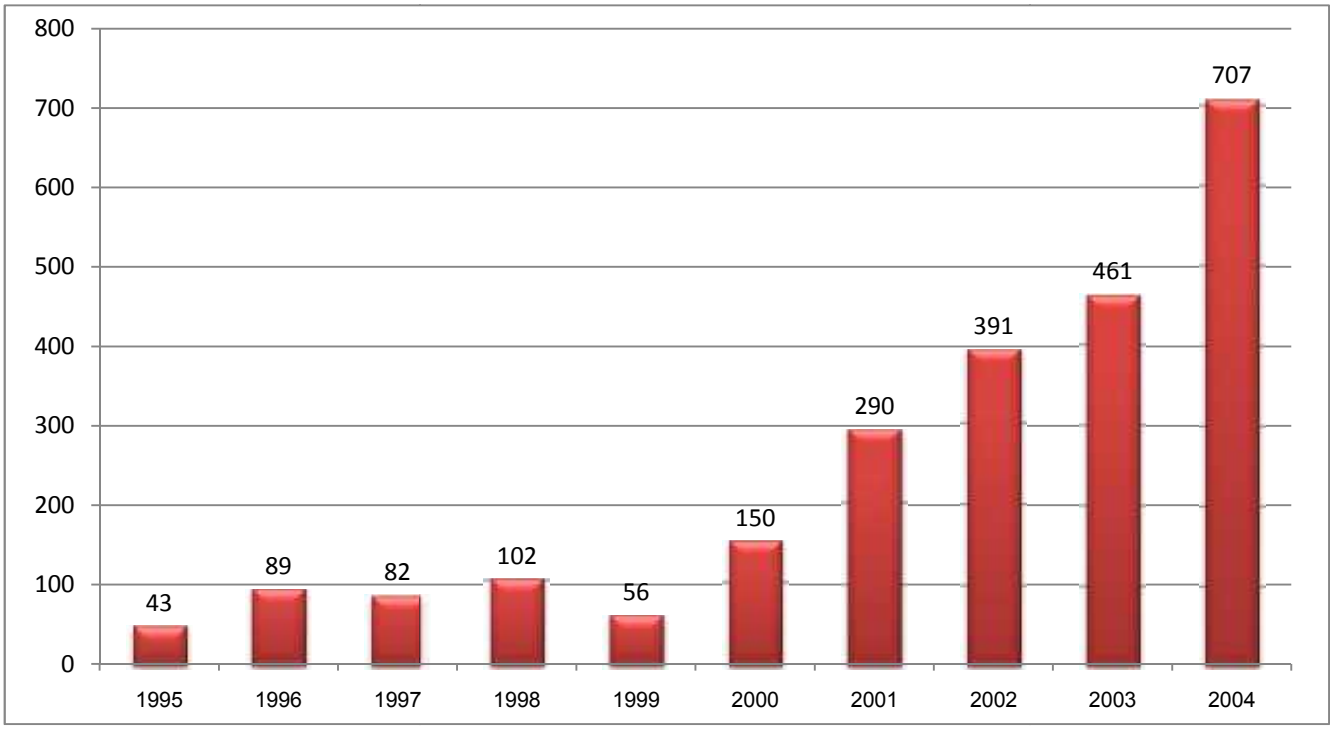
Figure 4 highlights that 2004 took a huge jump to 707 numbers of filling and was the highest of all ten years. It can be observed that the number of filing increased every year as the timeline of mailbox was ending.

3. *Table for Number of filings each year*

1995	43
1996	89
1997	82
1998	102
1999	56
2000	150
2001	290
2002	391
2003	461
2004	707

D. *Graph for Number of applications filed each year*

X = year; Y = number of applications filed



III. Date of Patent Grant

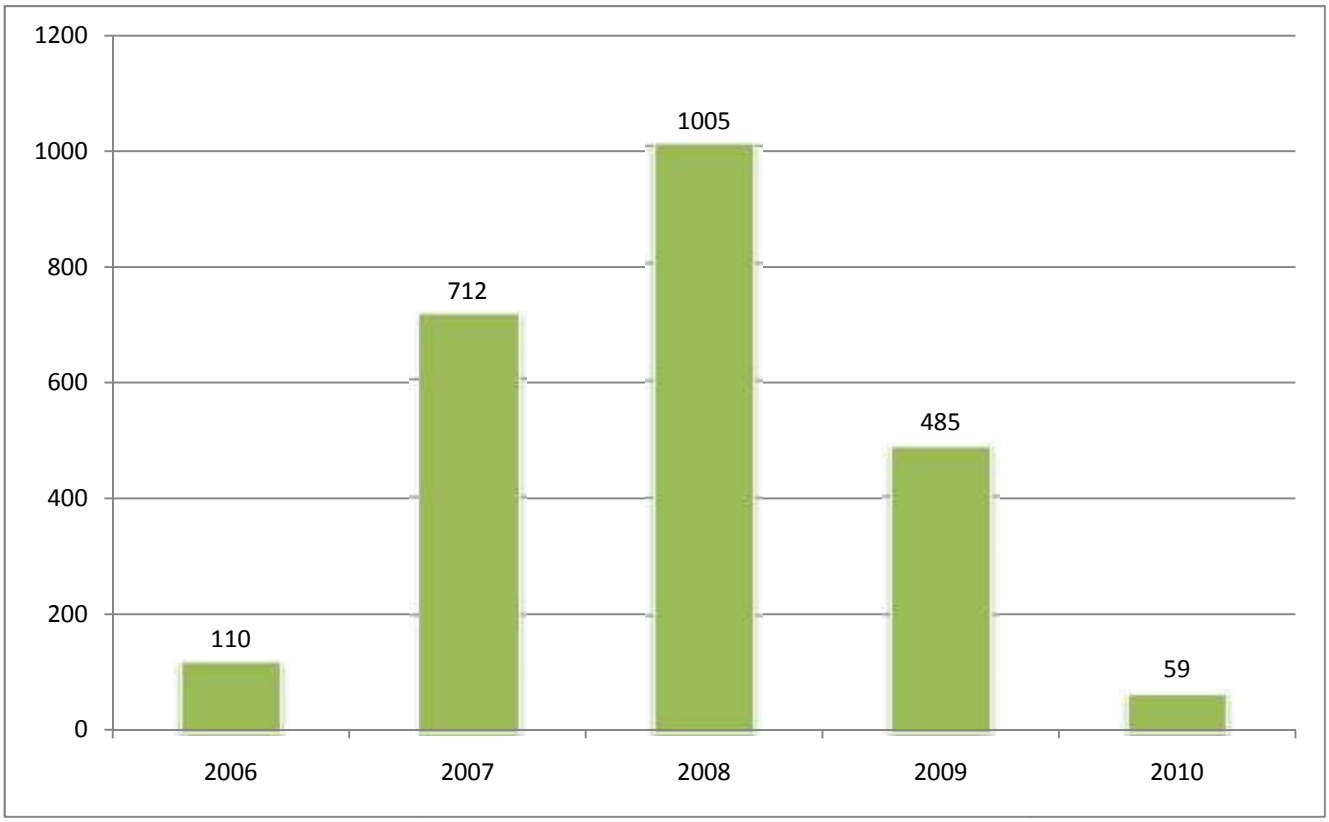
The date of granted was considered to get an overview on the number of patents granted which depicts that Indian Patent Office granted maximum number of patents (1005) in 2008 followed by 2007(712).

4. *Table for Number of Patents granted each year*

2006	110
2007	712
2008	1005
2009	485
2010	59

E. *Graph for number of patents granted each year*

X = year; Y = number of patents granted



IV. Patent Number

Indian Patent Office has granted around 40,000 patents till date. But the analysis of mailbox patent applications granted depicted the first patent to be 196774. Therefore for analysis the range was considered from patent number 195000 to 240000. The class width was selected 5000 patents for analysis. Only 4 patents

were found between 195000 and 200000, and it was very less compared to the other ranges.

Table (6) gives the data, showing the contribution pharma patents were always less 10% of all patents. The contribution of pharma patents decreased to only 319 patents in the last 10000 patents granted.

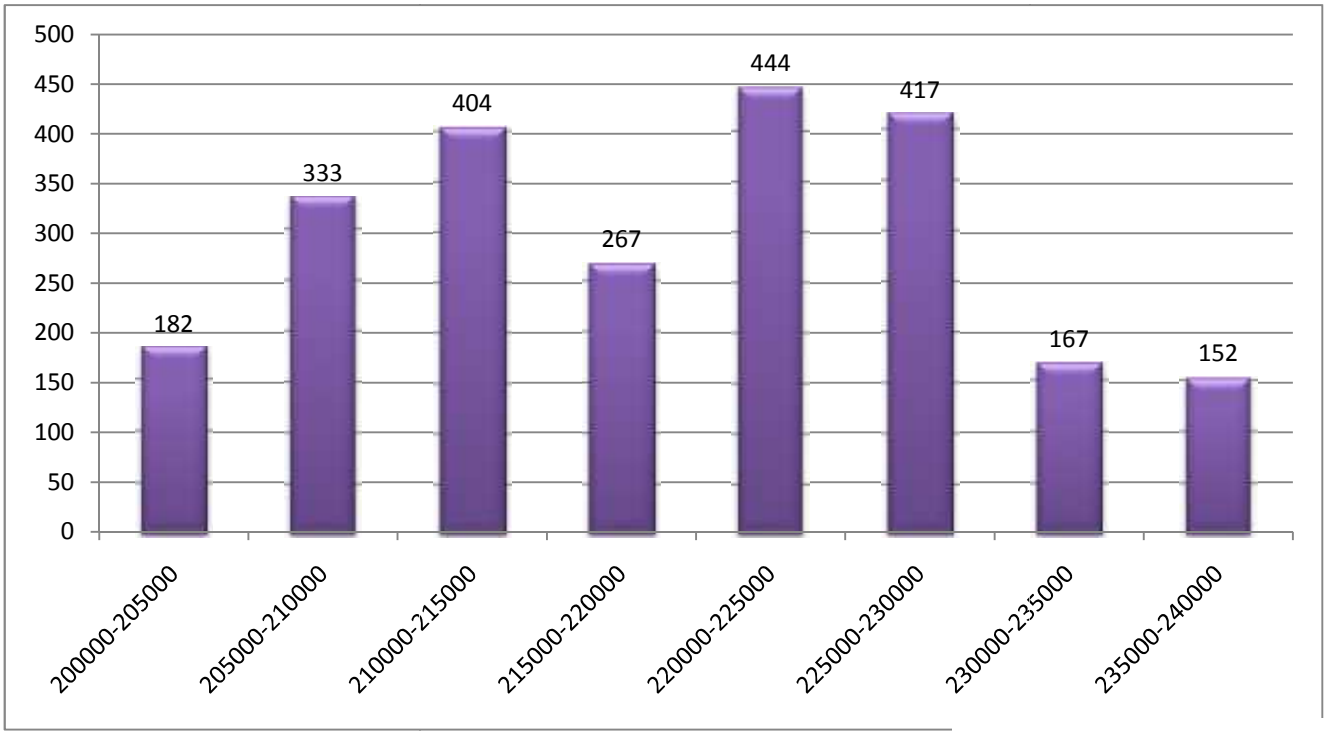
5. *Table for Number of pharmaceutical patents granted / 5000 patents granted in India*

200000-205000	182
205000-210000	333
210000-215000	404
215000-220000	267
220000-225000	444
225000-230000	417
230000-235000	167
235000-240000	152

F. *Graph for number of pharmaceutical patents granted per 5000 patents in India*

Y = number of pharmaceutical patents granted

X = range of patent number granted in India (class width=5000)



V. Priority Information

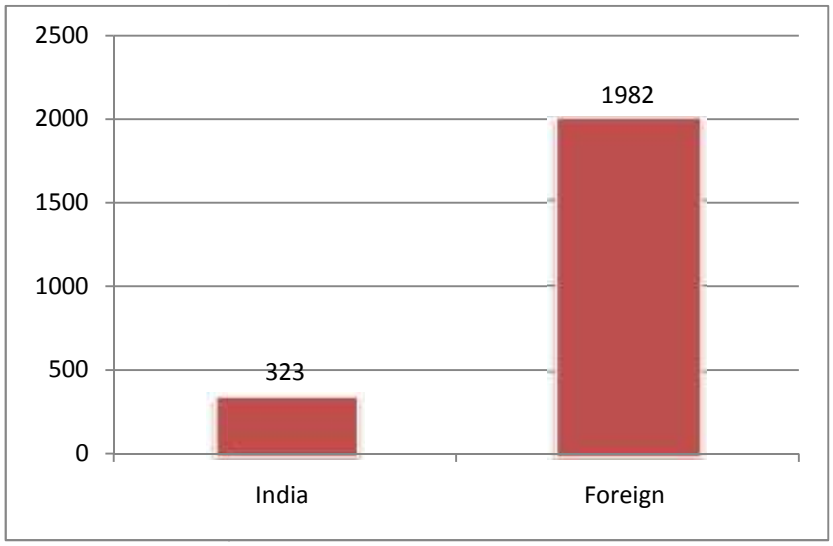
In the table (8) shown below, it states that on the basis of priorities claimed, foreign countries lead India with a very wide margin of difference..

6. *Table for Priority Information.*

India	*323*
Foreign	*1982*

G. *Graph for number of different types of priority*

X = Types of priority; Y = number of priority



VI. Types of Applicant

Table (9), gives the data for various types of applicant of which number of Private companies was maximum. Various bodies of Government of India also took an active participation but the number was very less. There were many individuals who also filed and were mostly of Indian origin.

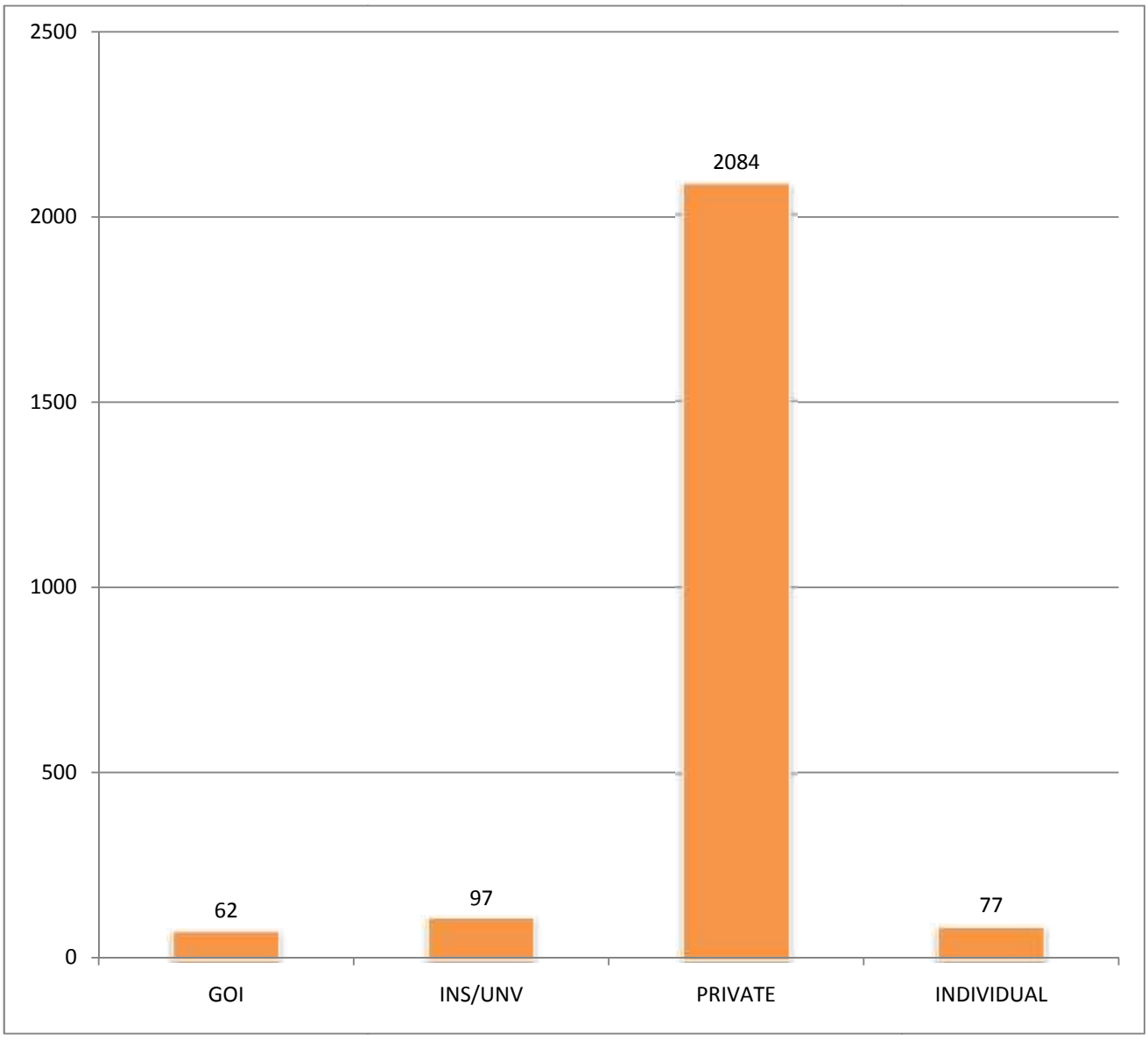
Research Organization under the Government of India refers to organizations like CSIR (Council of Scientific and Industrial Research), Department of Bio-Technology etc. Institute or University refers to colleges, academic institution etc. Private applicants refer to companies either public or private. Individual refers to applicants in the name of some natural person.

7. *Table for No. of different Types of applicant*

Research Organization under the GOI	62
INSTITUTE/UNVERSITY	97
PRIVATE	2084
INDIVIDUAL	77

H. *Graph for number applications filed by various types of applicants*

X = various types of applicant; Y = number applications filed



VII. Assignee analysis:

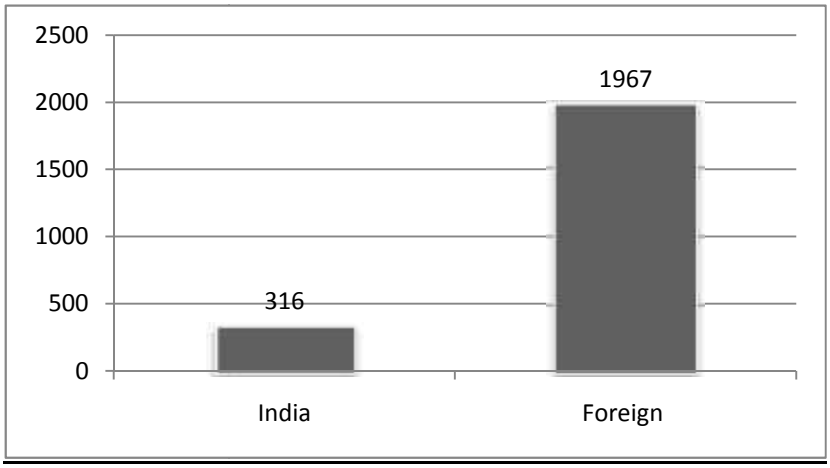
In the following table number 14; data-wise, the number of applications filed from assignee countries, has been shown. In this regard, the total number of applications available is 2283. And India accounts for nearly 13.8% of that total number. The rest is covered up by foreign countries.

8. *Table for Assignee country*

India	*316*
Foreign	*1967*

I. *Graph for number of applications from different assignee country*

X = Type of Assignee country; Y = number of applications



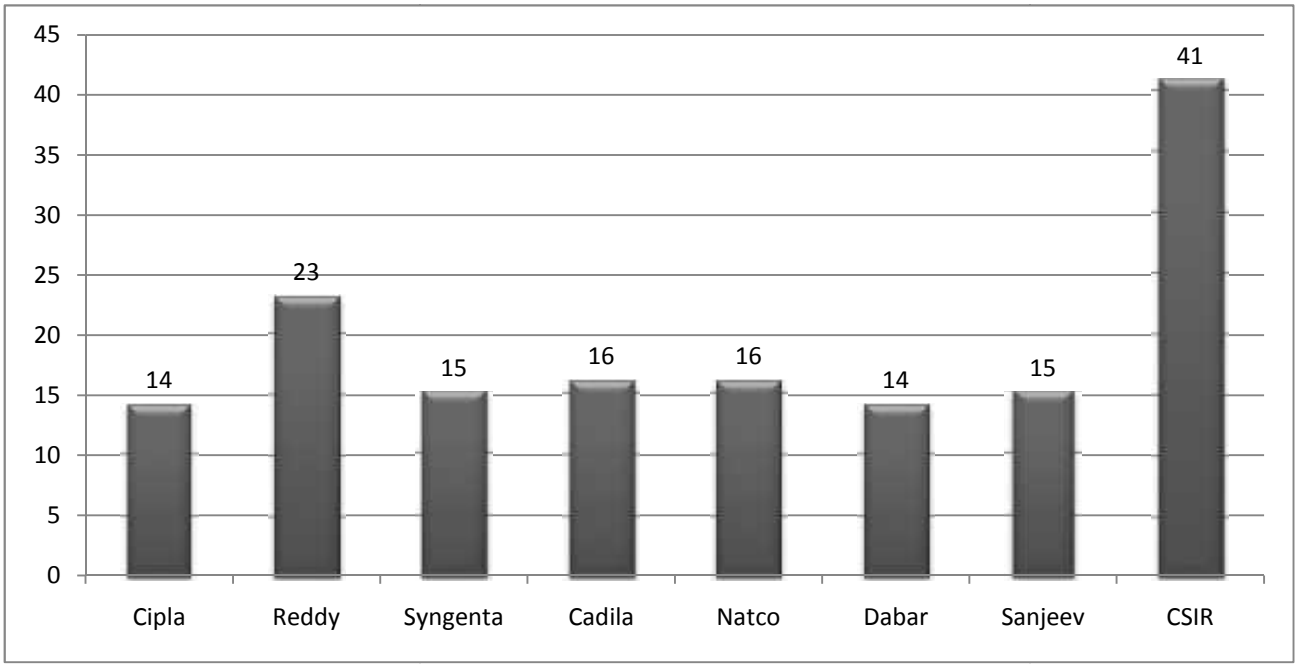
Further analysis of Indian applicant/ assignee resulted in a dataset of table (9). The table (9) depicts that CSIR was the leader among national applicants/Assignee with 41 patents.

9. *Table for number of patents of top national applicants:*

Cipla	14
Reddy	23
Syngenta	15
Cadila	16
Natco	16
Dabur	14
Sanjeev	15
CSIR	41

J. *Graph for number of patents of top national applicants:*

X = major companies; Y = number of applications



VIII. Category of patents:

Pharmaceutical patents can be mainly categorized into following categories:

- New Chemical Entity(NCE)
- Composition/Formulation
- Vaccines
- Method of Treatment
- Bio-Technology/Gene
- Delivery Systems
- Diagnosis
- Process

For our analysis the main categories found were NCE and Composition. Patents of other categories have been categorized as others for analysis.

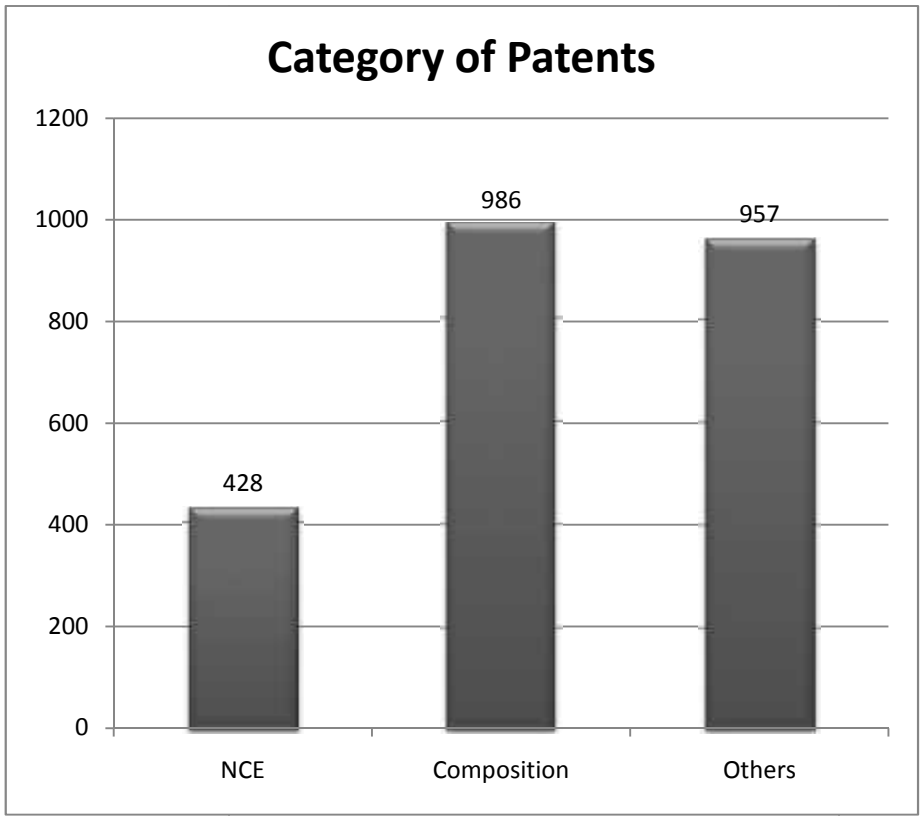
In this category the main focus was on NCE patents, Composition patents and others. NCE patents were 428 which is less than half of composition (986) and others (957). Mostly the area of filling was for composition patents.

10. *Table for category of patents*

NCE	428
COMPOSITION	986
OTHERS	957

K. *Graph for number of patents of different categories*

X = different category of patents; Y = number of patents



IX. Technology focus:

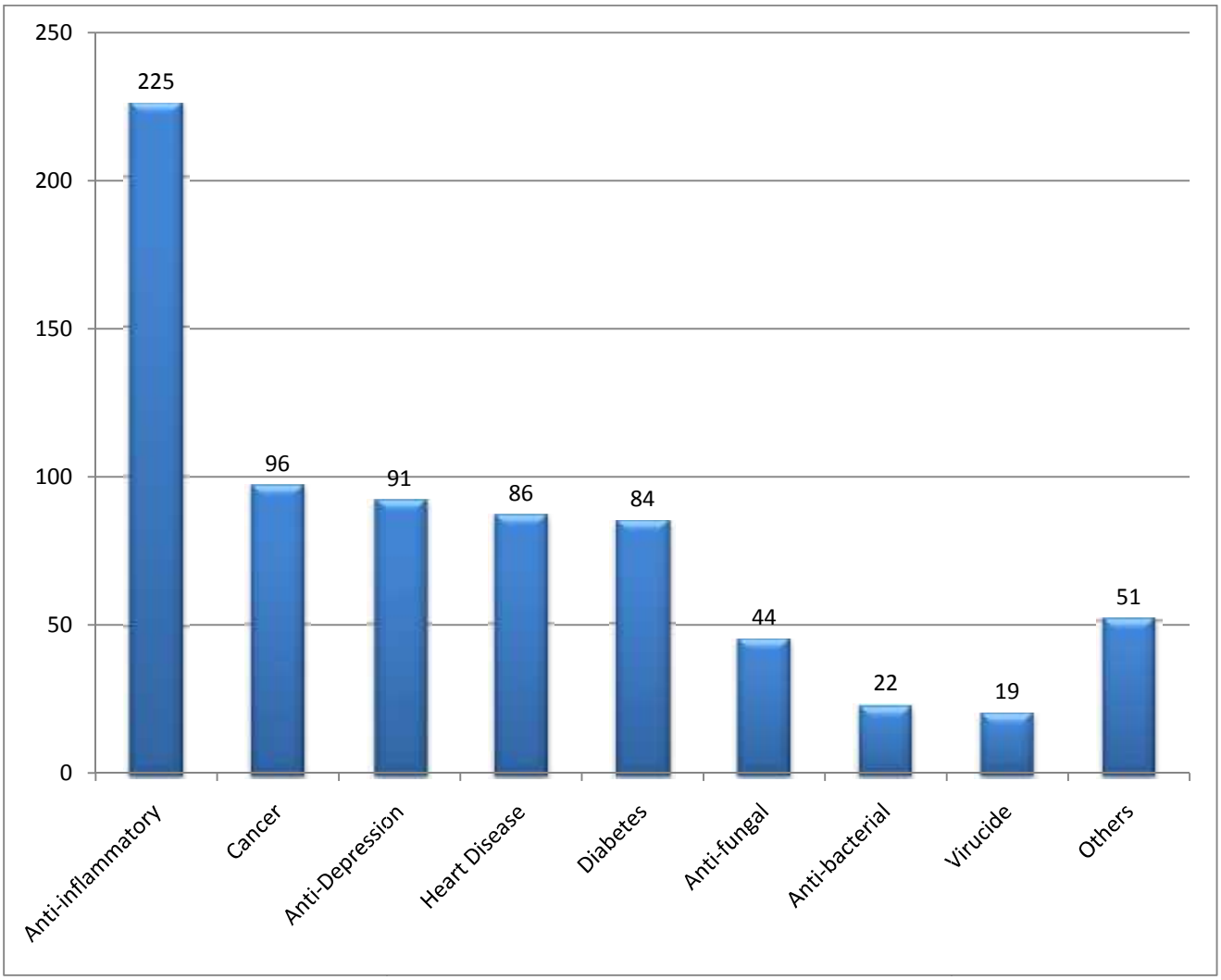
In the following extracted data of table number 15, the number of applications filed in context of technology focused portions i.e. therapeutic areas of different diseases has been illustrated. The data analysis gives an idea that maximum numbers of applications (i.e. 225) were filed for anti-inflammatory arena. Cancer and anti-depression follows, then, with the number of applications as 96 and 91, respectively. This shows that anti-inflammatory arena seeks a nice market among the therapeutic areas, as it accounts for about 31% of the total number of applications made.

11. *Table for Technology Focus(therapeutic area):*

Anti-inflammatory	225
Cancer	96
Anti-Depression	91
Heart Disease	86
Diabetes	84
Amide Derivative	58
Anti-fungal	44
Anti-bacterial	22
Virucide	19
Others	51

L. *Graph for Technology Focus(therapeutic area):*

X = therapeutic area; Y = number of Patents



X. Specific Compounds:

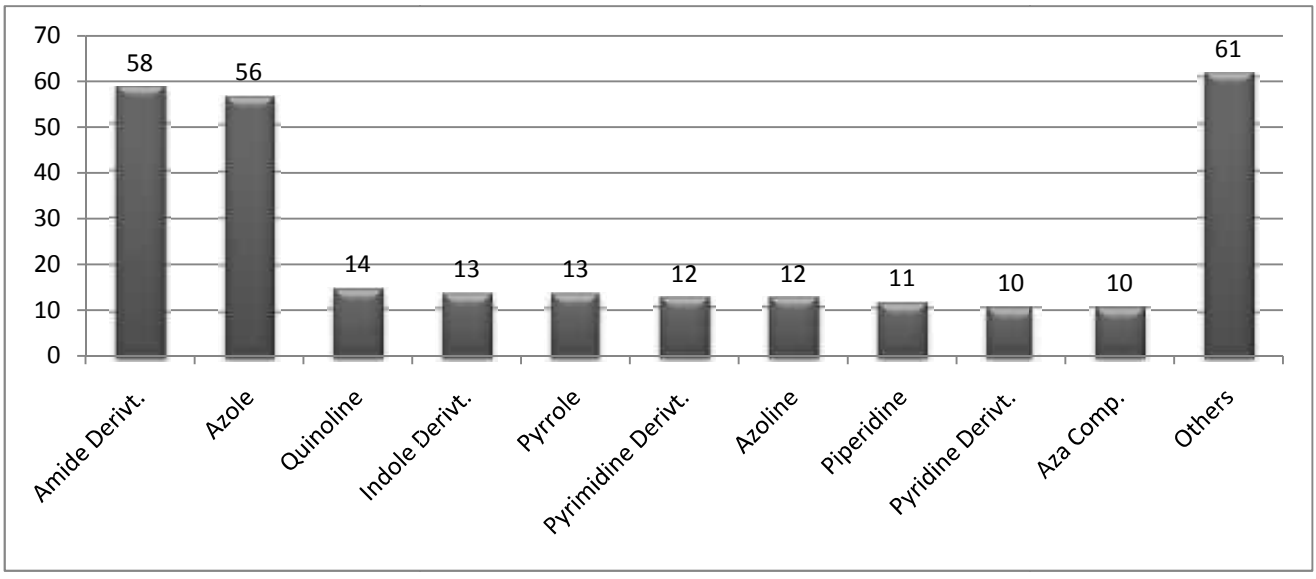
Numbers of some major specific compounds interpreted from patents are listed in table (14). The data predicts that amide derivatives were highest in number. Also it can be seen that nitrogen containing compounds have taken the lead in pharmaceutical patents.

12. *Table for number of applications with different major specific compounds:*

Amide derivative	58
Azole derivative	56
Quinoline	14
Indole Derivative	13
Pyrrole	13
Pyrimidine derivative	12
Azoline	12
piperidine	11
Pyridine derivative	10
Aza	10
others	61

M. *Graph for different major specific compounds:*

X = specific compounds; Y = number of patents



CHAPTER 5

CONCLUSION:

The number of granted mailbox patent applications in our database was 2371. All efforts have been made to complete the database. However, in a number of patent found most of the fields were empty. Using the information available like the name of the inventor, title, etc some patents was found using the Indian Patent Office website and Derwent Innovations index online database. But this search result was still unable to provide complete information. The huge number of cases where data was missing or incomplete due to time constraints still leaves a further scope of work. The following table was prepared for missing or uncompleted data:

Application no.	*All available*
Date of publication	*1*
Date of filing	*All available*
Date of patent grant	*All available*
Patent no.	*1*
Date of priority	*60*
Priority Information	*66*
Applicant	*1*
Type of applicants	*51*
Assignee country	*88*
Inventors	*45*
Title	*All available*
Abstract	*1210*
Description	*2285*
Category of patents	*All available*
Technology focus	*1561*
Specific compounds	*1959*
Class of compounds	*311*

The scientific part of the work was also interesting. The category of Technology Focus gives a very broad and brief discussion on major area of research. Further, It was predicted from specific compounds that most of the nitrogen containing compounds were of great importance. Among these amide derivatives was the leader. Due to constraints, I would like to end the discussion by asking a single question. *Can we do the analysis of property of specific compounds?*

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