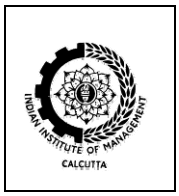

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Trends in Pharmaceutical Patenting in India

by

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Trends in Pharmaceutical Patenting In India

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ABSTRACT

This paper aims to look at the significant shifts in pharmaceutical patenting in India before and after the Third Amendment in the Indian Patents Act (1970) in 2005, to conform to the TRIPS agreement of the WTO. Data on patents granted, including application details and abstract of the invention, published in the weekly Indian Patent Office Journal have been considered. The paper provides a comparative analysis of granted patents, before and after the Third Amendment, primarily in respect of therapeutic inventions relating to certain chronic human ailments. The issues of product and process patenting, conventional and traditional drugs, and extent of protection claimed by applicants are analyzed. The paper also aims to see the changes, if any, in the composition and diversity of applicants before and after the Third Amendment. Other issues that are covered include comparison of patents filed by foreign and Indian applicants, companies and individuals, processing time for applications and firm preferences with regard to location of filing of patents.

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I Introduction

Indian industry has had to face two particularly daunting challenges in the nineties. A protected market has given way to a liberalized environment where it faces competition from imported products. Indian industry has also had to cope with rapid technological developments and innovation occurring in both product and process technologies. The nineties also saw India's accession to the World Trade Organization (WTO) that necessitated changes in another aspect of the nation's industrial environment, IPR regulations. One sector of industry that has been most affected by changes in patenting regulations has been the Indian pharmaceutical industry. Until the Third Amendment to the Indian Patents Act of 1970, India granted only process patents for pharmaceutical products, unlike the countries that followed the Paris Convention for the Protection of Industrial Property that granted product patents. The length of process patent protection was also significantly less than that granted by Convention Countries. India's acceptance of the Trade Related Aspects of Intellectual Property Rights marked a significant shift in India's position with regard to Intellectual Property Rights (IPR) protection. It also provided opportunities for firms who could now try to secure product patent rights for new drugs that they developed. This paper aims to look at the significant changes in patenting for pharmaceutical products, if any, in India before and after the Third Amendment in the Indian Patents Act (1970) in 2005, to conform to the TRIPS agreement of the WTO

II Review of Literature

Patenting behaviour of firms reveals not just trends in technological development, but also their intentions with regard to target markets. Though most studies of patenting and patent policy have used them to study the relationship between technological development and

economic growth (Penrose, 1951, Taylor and Silberstron, 1973), or in order to assess the research and innovation process in a national and international context (Bosworth, 1984, Schiffel and Kitti, 1978), some studies have analyzed it from the perspective of company policy for assessing the level of technology development in a particular sector, taking patent statistics as a technolgy indicator (Aston et al, 1989, Mogee, 1991, Liu, 1997). Patent analysis has also served as a basis for analyzing a firm's policy with regard to research, development and exploitation of foreign markets (Shipman, 1967, Abraham and Moitra, 2001, Abraham and Moitra, 2005).

The issue of pharmaceutical patents has been a topic of intense scrutiny and debate worldwide since large pharmaceutical firms have always considered product patents to be critical in erecting entry barriers to competitors. Chaudhuri (2005) has analyzed the implications for developing countries of changes in their patent regulations as a consequence of the TRIPS agreement. Love (2004) finds that patent system provides incentives for only those drugs/ innovations, which have markets. The companies generally invest in R&D in the proven therapeutic areas i.e. "Me-too drugs", thereby promoting incremental innovation. Thus, the patent system provides inadequate rewards for new molecules or the riskier first-in-class products. Chaudhuri (2008) has considered the issue of whether pharmaceutical patents are really necessary to encourage innovation in developing countries. Breke and Stromm (2009) also point out that the patent system reduces the incentive to invest in R&D by over investing in advertising or marketing activities, thereby reducing the probability of new product development by a potential entrant, and hence adversely affecting innovation. Generous patent system (and drug prices) tends to stimulate marketing rather than R&D incentives. In terms of patenting

behaviour of Indian firms Mazumdar and Meenakshi (2009) finds that the vertically integrated Indian Pharmaceutical firms that produce both bulk drug and formulation demonstrate greater technological innovation and efficiency. Most large firms are found efficient, and these experienced technological innovation longer. Although R&D and efficiency are not strongly correlated, firms that made R&D investments benefited from technological innovation.

This paper provides a comparative analysis of shifts in patenting in India in the area of pharmaceutical patents for a six month period (July to December) in 2002 and 2007. The two periods were chosen since they preceded and followed the Third Amendment to the Indian Patents Act (2005). The idea was to examine the significant shifts, if any, in pharmaceutical patenting in India before and after the amendment to the Indian Patents Act to conform to the TRIPS agreement of the WTO.

III Hypotheses

This study aimed to test the following hypotheses:

1. Indian applicants have filed for and been granted more process patents than the foreign applicants in 2007 compared to foreign applicants who preferred to file for product patents

2. New patentees have emerged since changes in Indian patenting regulations to allow for product patents.

3. **(a)** There have been significant changes in the types of diseases covered by disclosures in the patents granted in 2007 vis-à-vis 2002.

   (b) Of the diseases targeted, patent applications claiming at least one of the therapeutic uses as Cardio-Hypertension (4) is the most prominent targeted disease both in 2002 and 2007.

4. Indian firms claiming process patents have a tendency to designate a lesser number of therapeutic uses for the process than foreign firms since Indian firms develop process patents only to secure the market for treating specific diseases that have been already developed by an existing product patented (patented abroad) drug. The possibility of an Indian firm having developed a new molecule before 2005 is very low.

5. Product Patent applicants have greater tendency to claim/ disclose wide ranging therapeutic/ disease uses (more than 1)

6. Companies originating in OECD countries (or having OECD country Priority) have tendency to claim for likely and potential therapeutic uses in greater number of diseases than the rest.

7. Indian Individuals show disposition for patents relating to Ayurvedic/ herbal compositions/ medicines.

8. Patents frequently claim/ disclose therapeutic uses in following diseases together

    Cancer and AIDS (1, 2)

    Bone and Immune-related (10, 11)

    Neurological and Psycho (7, 8)

    Cancer and Skin (1, 13)

    Cardio and Renal (4, 5)

    Diabetes and Renal (14, 5)

    Cardio and Diabetes (4, 14)

    Diabetes and Obesity (14, 15)

    Cardio and Obesity (4, 15)

    Diabetes and Eye (12, 15)

    Neurological and Immune-related (8, 11)

Gastro and Cardio (3, 4)

Gastro and Psycho (3, 7)

Gastro and Neurological (3, 8)

Immune-related and cancer (1, 11)

Immune-related and AIDS (2, 11)

Immune-related and Cardio (4, 11)

Immune-related and Renal (5, 11)

Immune-related and Diabetes (11, 14)

Immune-related and Eye (11, 12)

Immune-related and Skin (11, 13)

Cardio and Respiratory (4, 9)

Neurological and Respiratory (8, 9)

Immune-related and Respiratory (9, 11)

9. Individuals are claiming only few of the 15 therapeutic/ disease uses (AIDS, cancer, diabetes, cardio).

10. The US and other OECD applicants exhibit a much greater variety i.e. low patent density relative to Indian and other foreign applicants.

11. (a) There is no significant change in the patent applications processing time for grant at the Indian Patent Office despite the legislation to this effect.

(b) There is a difference in the time taken for procession of foreign applications and Indian applications in 2002 and 2007.

12. There is a shift in terms of location of filing of patents after Indian began to accept product patent applications and this is borne out by changes in filing patterns of patents granted between 2002 and 2007

12. Product Patent regime has encouraged companies from developed world and bigger domestic players to seek 'product' patents.

III Description of Data

1. 15 diseases have been looked at (leaving aside acute ailments and infections):

Disease	**No.**	**Freq. of occurrence of Diseases**	
		(2007)	**(2002)**
Cancer	1	160	9
AIDS	2	59	2
Gastro	3	138	4
Cardio-Hypertension	4	227	18
Renal	5	82	5
Sexual	6	31	1
Psycho	7	120	3
Neurological	8	197	4
Respiratory	9	110	1
Bone	10	135	3
Immune-related	11	90	1
Eye	12	79	1
Skin	13	110	2
Diabetes	14	123	6
Obesity	15	43	1

2. **2002-03**

Total filing:	11466 (Indian: 2693; PCT: 7049)
Total patents granted:	1379
Total chemical/ Drug patents-:	399/ 312

2007-08:

Total filing:	35218 (Indian: 6040; PCT: 23891)
Total patents granted:	15261
Total Chemical/ Drug patents:	6375/ 4267, Biotech- 314

Source: ***Annual Report, Office of the Controller General Patents, Designs and Trade Marks (CGPDTM), Intellectual Property Office, India, 2002-03*** **and** ***2007-08.***

The FY is from April to March. As the data pertains to the six-month period (July-December), the number of patents in a half-year would be roughly half the number cited above.

3. We have collected data pertaining to granted patents only. Many of the filed applications are not followed by 'Request for examination', which means the applicants are not interested in pursuing such applications. Moreover, granted patents are for 'inventions', whereas many filed applications do not qualify as 'inventions'. Hence, granted patents are better indicative of 'inventions' capable of being worked in any nation.

* Around 275 legal entities have single patents in the 2007 data (six-month period). There are 454 Product Patents in this period.

Data Collection

The subject matter of this study required the pertinent Indian patent data to be collected from the time-periods prior to and post Indian Patent (Amendment) Act 2005. Thus, we selected six-month period from July to December of 2002-03 and 2007-08 annual years.

The data was collected from the Indian Patent Journal (previously Gazette), which is a weekly publication of the Indian Patent Office.

Patent Journal/ Gazette: It is to be noted that prior to the Indian Patent (Amendment) Act 2005, there were no provisions of prior publication and pre-grant opposition in the Indian Patents Act. Hence, prior to 2005, only the granted patents were published in the said gazette or journal. Later, in the wake of the amendment, the publication is done twice. Once, within the eighteen months prescribed time period of filing of a patent application; and again after the patent has been granted (relevant sections being Sections 11 and 25 of the said Act). However, the collected data for the purposes of this study belongs to the granted patent published data only.

Priority Information: The 2002-03 published granted patent data did not show the priority country data (in the case of patent applications filed under the Patent Cooperation Treaty or the 'Convention' applications). Therefore, the nationality and address of the applicant has been considered as 'Country of Origin' for the applicants (both ordinary and conventional) for the purposes of analysis. However, in the 2007-08 data, other than the 'Country of Origin' information, the 'Country of Priority' information, i.e. country of first filing for the same patent application, has also been considered as such information was available in the 2007 Patent Journal publication.

Applicant: In respect of the published granted patents pertaining to the July-December 2007 Patent Journals data, Applicant, Title and Priority information are collected from the Indian Patent digital database and www.india.bigpatents.org. The digitization of the Indian Patent data started in 2002-03 and has been carried out as an activity of 'Modernization Projects' under the Five-year plan of the Govt. of India. As such, the applications have not

been digitized on a strict chronological basis. Hence, the applicant of any patent application (including both pre-grant and post-grant stages) may be the original applicant or an assignee thereafter. This is also to note that such 'assignments' can happen anytime during the life of any patent.

In case of Joint Applicants or Joint Venture Companies[1] (JVs), only the first applicant or more frequently occurring (or 'dominant') JV partner has been considered. Examples of such Applicants are JVs of Merck, Pharmacia etc. An exception is made in the case of Sanofi-Aventis and Sanofi-Synthebalo companies, since both JVs have filed similar number of patents i.e. 8 and 7 respectively, which are highest among all such Joint Applicants or JVs i.e. neither of the two partners could be considered 'dominant'.

Therapeutic Uses or Diseases: For the purposes of this study, we have considered only those patents, which were 'meant' for treatment of chronic ailments of humans. Therefore, we discounted the 'acute' or 'short-term' infections (bacterial, viral, protozoa or parasitic), multivitamins and antioxidants and other such supplements (unless specified for certain ailments), acute generalized pain, surgical and fracture treatments, dental and hair treatments, injuries of general nature pertaining to muscles, ligaments or bones etc. Then, based on the frequency of occurrence of the therapeutic uses of the inventions, as observed in the said 2002 and 2007 Patent publication data, the diseases were limited to 15 categories. No discrimination is made between 'new molecules' and 'new derivatives of known molecules'; since the granted Indian patents are assumed to comply with the requirements under sections 2(1)(j) and 3(d) of the Act. Similarly, novel intermediates of known drugs or compositions, and/ or their manufacturing processes, have also been

[1] Joint Ventures, here, refer to all legal entities that include two or more partner companies

included for the purposes of this study. Furthermore, both modern (including biotechnology inventions) and traditional medicines have been considered.

Invention: A thorough search and intensive study of all the published granted patents, pertaining to IPC classes 'C' and 'A' (chemical and biotechnology fields), in July-December 2002 and July-December 2007 Patent Journals (Gazettes) has been carried out. The purpose of such an exhaustive search was two-fold:

1. To find if any product has been claimed in the specification, since post Indian Patent (amendment) Act 2005 India also adopted the 'Product Patent' regime.
2. To ascertain the potential therapeutic applicability of the patent(s) against the diseases or ailments.

The complete specifications of such granted patents, which include full disclosure of any invention and claims, are not available in the said Journal (hard copy or digitized). Further, the foreign priority application data (in case of Conventional and National Phase/ PCT Applications) were also not available consistently for many of the priority applications such as, Japanese, Chinese, German, Austrian etc, the following strategy was adopted to achieve the aforementioned objectives:

(a) The Conventional and National Phase/ PCT Applications (July-December 2007 data): The foreign Priority application or other 'corresponding' applications for the same invention (also defined under section 8 of the Indian Patents Act, and PCT) were retrieved through the Internet sites (www.wipo.org, ep.espacenet.com, www.jpo.go.jp, patft.uspto.gov, www.freepatentsonline.com, www.cipo.ic.gc.ca, www.freshpatents.com etc). Since, an Indian application and other corresponding foreign applications

have the same priority i.e. these pertain to the same or substantially same invention; they theoretically can be assumed to contain the same disclosure and claims of invention. Hence, examination of any such corresponding foreign application specification discloses the requisite details (1 & 2). However, as the national Patent laws and Patent Office practices differ for individual National Patent offices, there may be some differences among the corresponding application specifications. Further, some corresponding application specifications may have undergone 'voluntary amendments' in due course of time, leading to minor differences in the disclosure of invention and claims.

(b) Applications (July-December 2002 data): The priority application data is not available with these applications' published data. However, as only process patents for already known products have been applied for (and thereby granted); name of the compound or product is found available in the 'Abstract' details of these applications published data has been used as the reference data The details of such known compound or product name is was sourced from Drug Indexes company information.

(c) Ordinary Applications (July-December 2007 data): As such applications are originally filed in India, these may or may not have been filed abroad. Therefore, those ordinary applications, which have also been filed abroad, have been searched as above (a). Whereas, those ordinary applications, which have not been filed abroad, information was 'deduced' from the available 'Abstract' details as above (b).

The following points should also be noted about the data

(i) The foreign corresponding application or ordinary specifications that have been examined pertain to the pre-grant stage of such application i.e. only the 'filed' (not granted) specifications of such granted patent applications are considered.

(ii) Patents – Product or Process: If the foreign corresponding application or ordinary application specifications claim at least one 'product' (including intermediate product(s), byproduct(s) or 'gene', 'cell', 'protein' etc.), such patent application is considered as a 'product' patent application. If the application specification is not available, for instance, in case of ordinary applications, Abstract data is relied upon. However, the granted specification may or may not contain any or all of such 'product' claims.

(iii) Applicability: The disclosure of the invention (in the specification) may indicate one or more diseases for which an invention may be useful. Such disclosure, if cited as prior publication, is sufficient to prevent future applicants from claiming such 'uses'. Hence, all 'potential' uses of an invention, as disclosed, are considered for this study. However, only the defined diseases (15 categories) have been indicated. If the application specification is not available, for instance, in case of ordinary applications, Abstract data is relied upon.

Distribution of Product/Process Patents

Our first hypothesis was that Indian applicants have filed for and been granted more process patents than the foreign applicants in 2007 compared to foreign applicants who preferred to file for product

patents A comparative analysis of patent applications reveals that Indian applicants have filed for and been granted more process patents than the foreign applicants in 2007. It is to be noted here that pre-2005 applications for product patents were filed in the mailbox facility that was implemented by the government in 1999 (Raju, 2004) as per the provisions of the Patents (Amendment) Act of 1999. The percentage of distribution of foreign/Indian applicants for process/product patents) is shown in **Table 1**

Table 1: Distribution of Foreign/ Indian applicants for Process/Product Patents

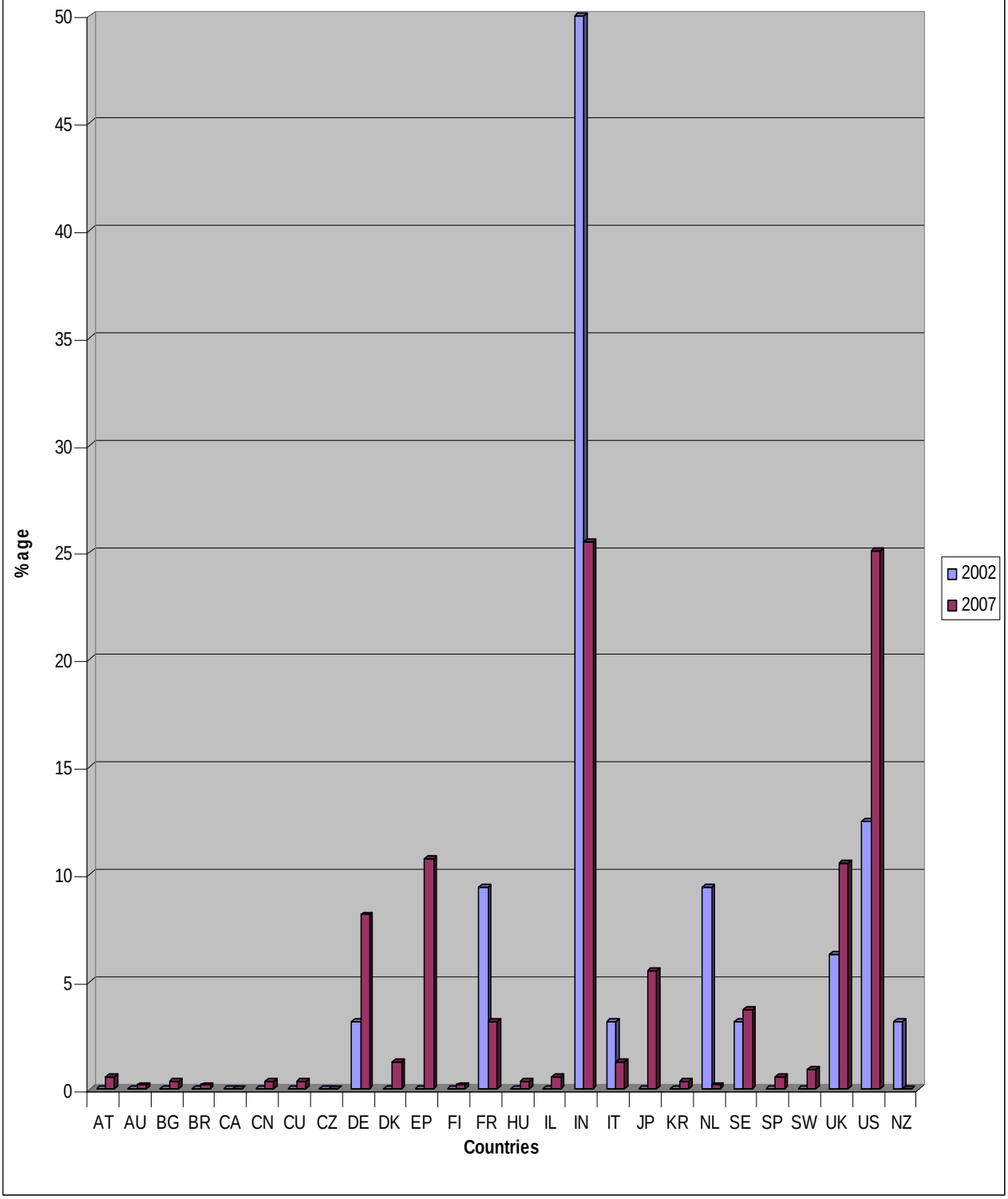
Nationality **Patent Type**	**Indian Cos. Patents** **No. (%age)**	**Foreign Cos. Patents** **No. (%age)**
Product	87 (61.37%)	367 (91.75%)
Process	55 (38.73%)	33 (8.25%)

There were a total of 542 patents granted in the six-month period of 2007 of which 88 were for process patent applications and 454 were for product patent applications. Of the 88 process patents, 55 were by Indian applicants and only 33 were by foreign firms. However, Both Indian and Foreign Cos. sought more product patents. Thus we see that while the percentage of product patent applications by Indian firms is smaller that for foreign applicants the share is still substantial.

New Patentees

The second hypothesis that we tested was that new patentees have emerged since changes in Indian patenting regulations to allow for product patents. **Table 2-A** and **Table 2-B** show the percentage of patents that have been granted country wise and company wise respectively in the six-month periods under consideration in 2002 and 2007.

Table 2-A: Patent Grants (%) Country-wise



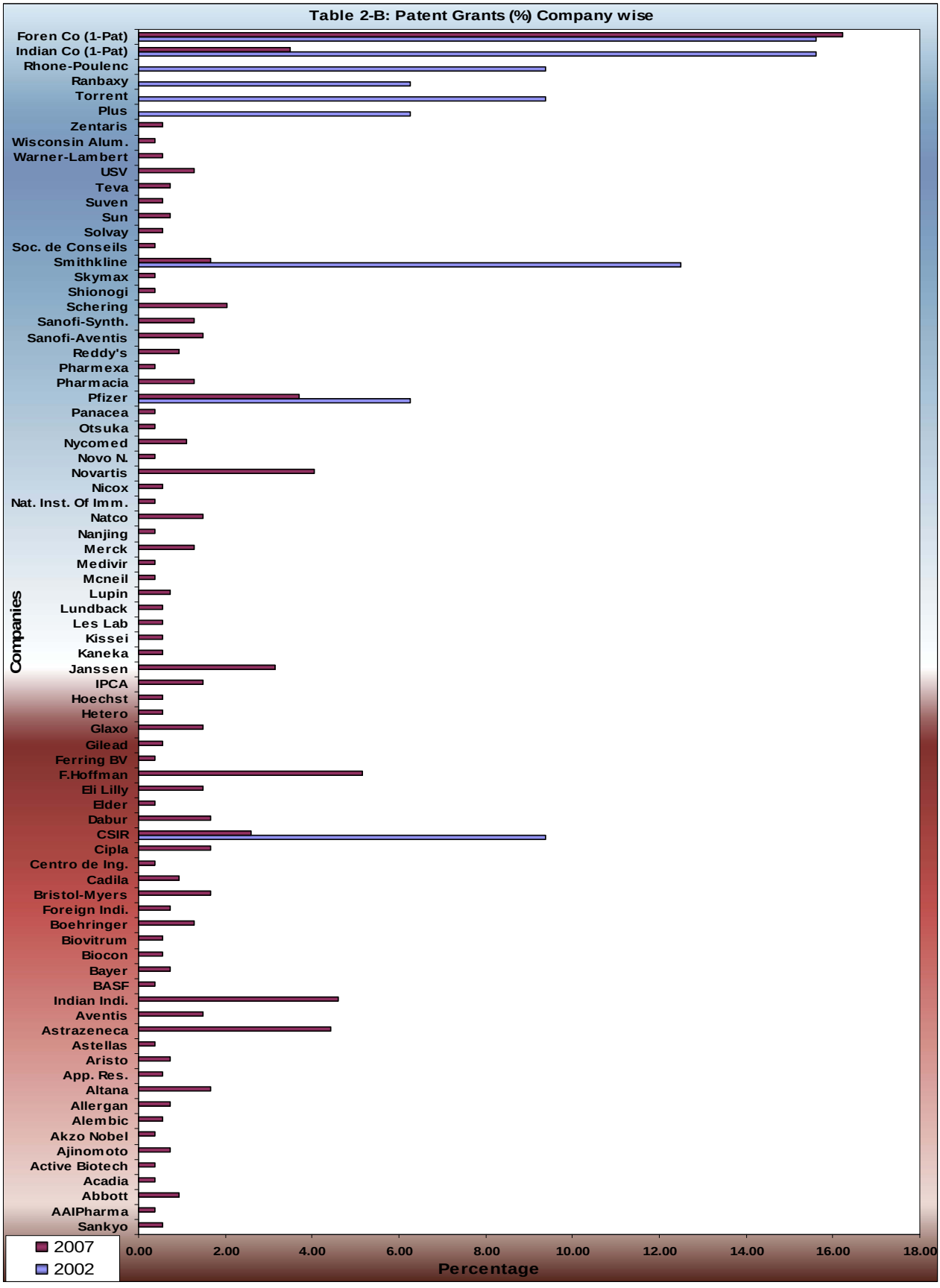


Table 2-B: Patent Grants (%) Company wise
Companies
Foren Co (1-Pat)
Indian Co (1-Pat)
Rhone-Poulenc
Ranbaxy
Torrent
Plus
Zentaris
Wisconsin Alum.
Warner-Lambert
USV
Teva
Suven
Sun
Solvay
Soc. de Conseils
Smithkline
Skymax
Shionogi
Schering
Sanofi-Synth.
Sanofi-Aventis
Reddy's
Pharmexa
Pharmacia
Pfizer
Panacea
Otsuka
Nycomed
Novo N.
Novartis
Nicox
Nat. Inst. Of Imm.
Natco
Nanjing
Merck
Medivir
Mcneil
Lupin
Lundback
Les Lab
Kissei
Kaneka
Janssen
IPCA
Hoechst
Hetero
Glaxo
Gilead
Ferring BV
F.Hoffman
Eli Lilly
Elder
Dabur
CSIR
Cipla
Centro de Ing.
Cadila
Bristol-Myers
Foreign Indi.
Boehringer
Biovitrum
Biocon
Bayer
BASF
Indian Indi.
Aventis
Astrazeneca
Astellas
Aristo
App. Res.
Altana
Allergan
Alembic
Akzo Nobel
Ajinomoto
Active Biotech
Acadia
Abbott
AAIPharma
Sankyo
2007
2002
0.00
2.00
4.00
6.00
8.00
10.00
12.00
14.00
16.00
18.00
Percentage

In 2002, only 8 country firms/individuals were granted patents. By 2007, the number had risen to 23. However, India and the US remain the two most prominent countries of origin in respect of the patent grants. In 2002, only 10 entities (including ordinary/ foreign individuals as separate groups) received 2 or more patents, and 10 companies received single patents; while in 2007, 74 entities (including ordinary/ foreign individuals as separate groups) received 2 or more patents, and 107 companies received single patents. F. Hoffmann has emerged as the company with maximum patents in 2007 replacing Smithkline Beecham, which has much less patents in the same period but accounted for maximum number of patents in the corresponding 2002 period.

Diseases Targeted

We sought to examine two aspects of the diseases covered in the third hypothesis. The first, that there have been significant changes in the types of diseases covered by disclosures in the patents granted in 2007 vis-à-vis 2002 is proven from the study **(Table 4 & Table 5)**. In this regard, we find that:

(a) Diseases related to Neurological, Respiratory, Ortho/ Bone, Skin and Immune disorders have shown max increase in such order (descending); while diseases like Cancer, HIV/ AIDS, Sexual, Diabetes and Obesity have shown increase less than 10%.

(b) Of all the grants, patent applications claim at least one of the therapeutic uses as Cardio-related or Hypertension as the most prominent or targeted disease, both in the 2002 and 2007 periods. However, as a percentage of total grants per year, Cardio-related or Hypertension and Renal disorders have shown decrease.

Table 4: Changes in Types of Diseases Targeted by Patent Applicants

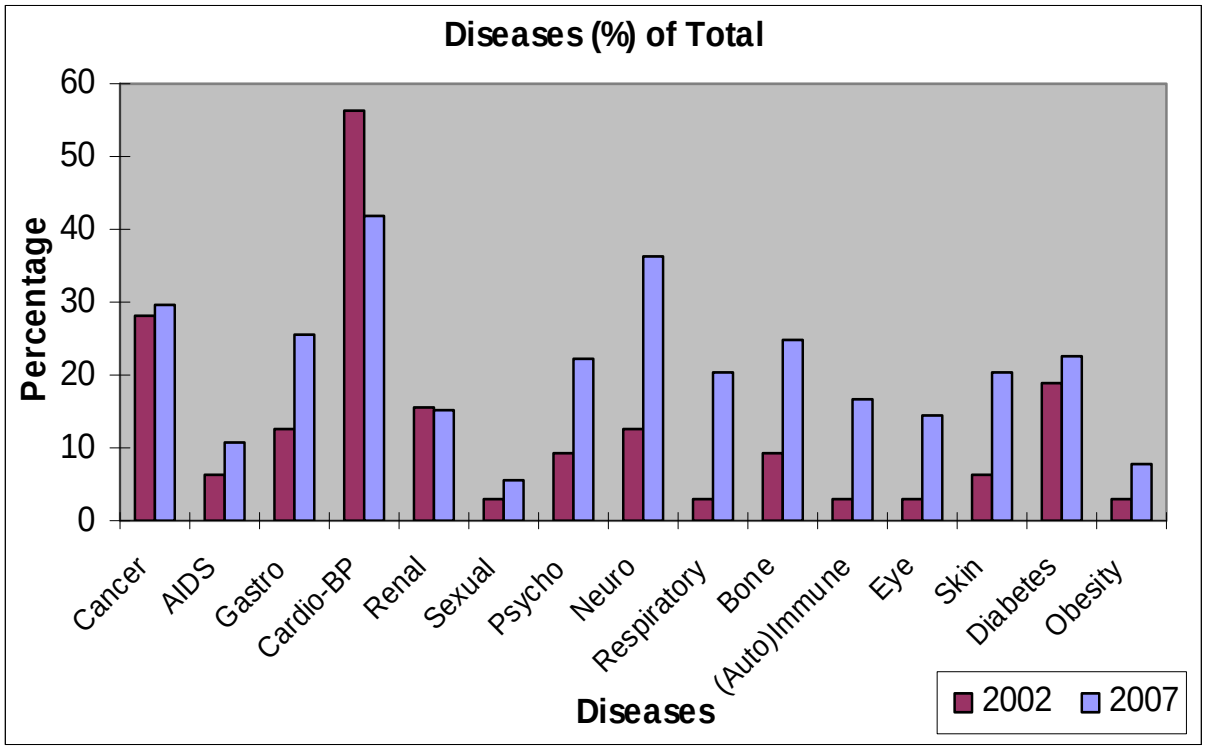
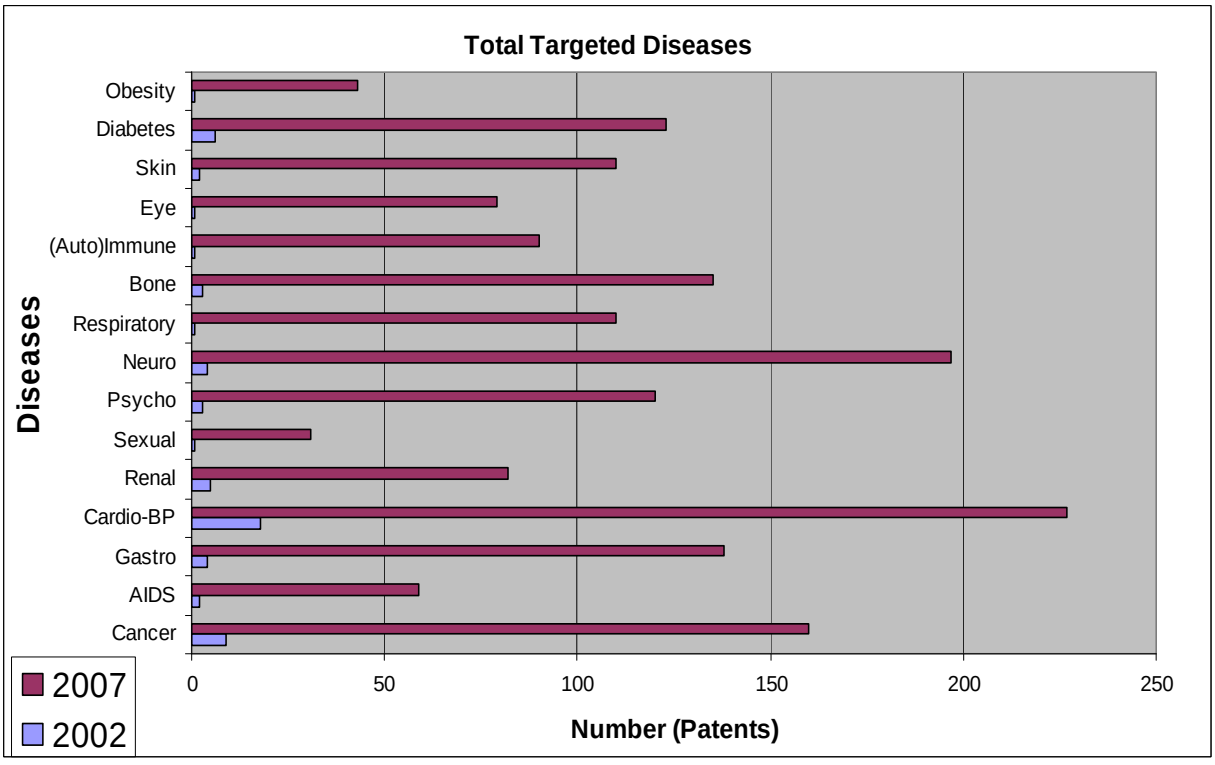


Table 5: Diseases Targeted by Number of Patents 2002-2007



Diseases Targeted in Process Patents

The fourth and fifth hypothesis that was tested was that Indian firms claiming process patents have a tendency to designate a lesser number of therapeutic uses for the process than foreign firms. This hypothesis was developed to check whether Indian firms develop process patents only to secure the market for treating specific diseases that have been already developed by an existing product patented (abroad) drug. It was also hypothesized that that the possibility of an Indian firm having developed a new molecule before 2005 is very low.

An analysis of data shows that while the hypothesis is indeed supported by the data, the difference is not that very significant. 80 percent of Indian process patent applications covered only one disease, as compared to 63.6% for foreign firms. However, 2 Indian process patents covered 5-6 diseases, while only one foreign process patent claimed against four diseases. The number of diseases targeted, and the percentage distribution is shown in **Table 6** and **Table 7**.

Table 6: Number of Patents Targeted Per Disease

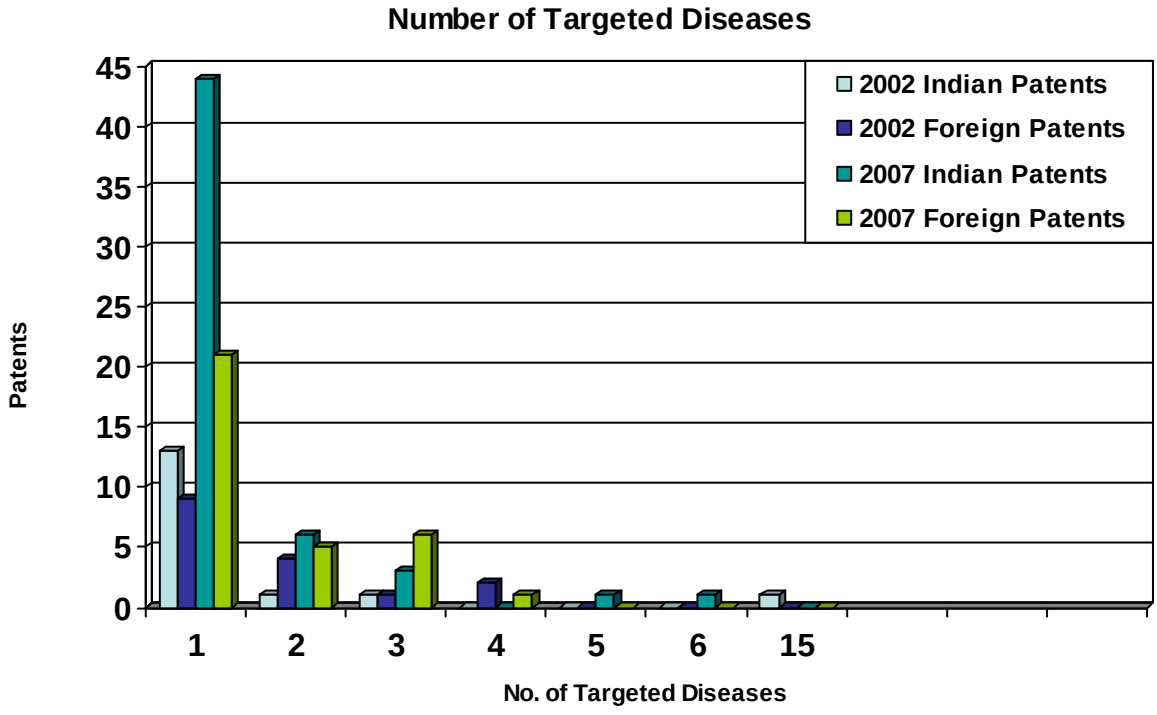
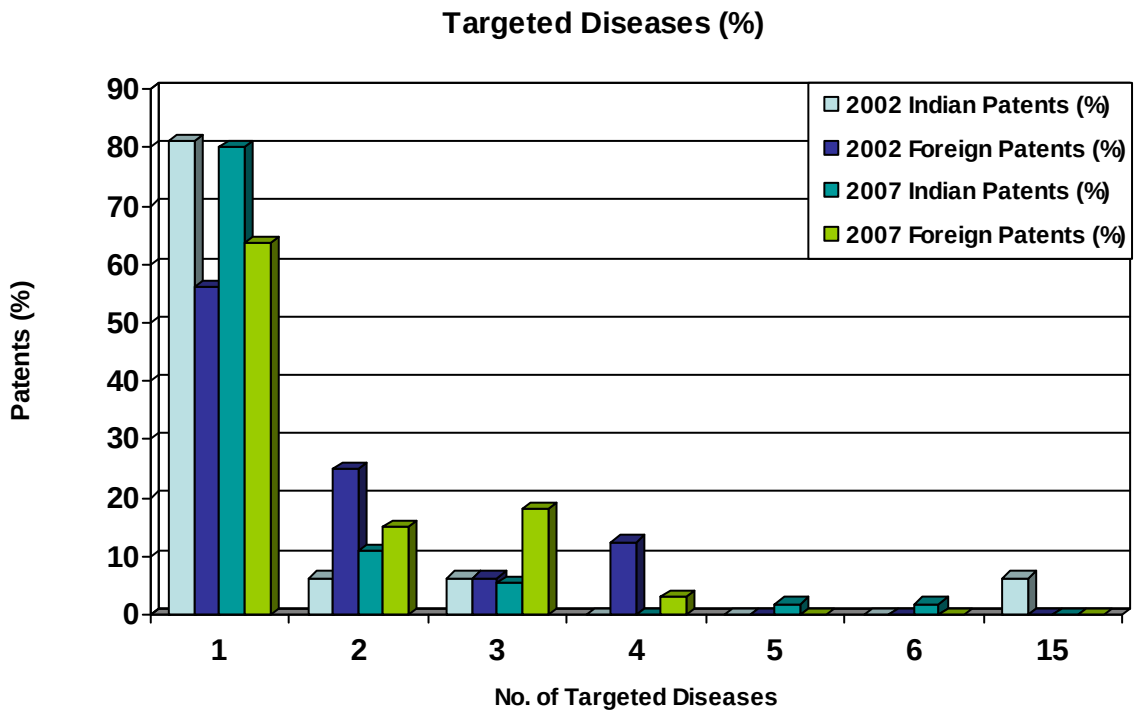


Table 7: Percentage of Patents Targeted Per Disease



Claims by Country of Origin

The sixth hypothesis that we tested was that companies originating in OECD countries (or having OECD country Priority) have tendency to claim for likely and potential therapeutic uses in greater number of diseases than the rest. In the 2007 period, the applicants originating from the US, Switzerland, Germany, Sweden, France, UK, Nederland and Spain (all OECD countries) tend to claim more than one disease use per application intended for product patent grant. Whereas, applicants originating from non-OECD nations, such as, India, China, Cuba, Brazil etc. tend to more often claim single disease use per application intended for product patent grant. Further, applicants originating from India are also claiming large number of process patents **(Table 8)**. However, in the 2002 period, the applicants generally claim against single disease use in the process patents **(Table 9)**.

Table 8: Patent Claims (Uses of Drugs against Diseases) 2007

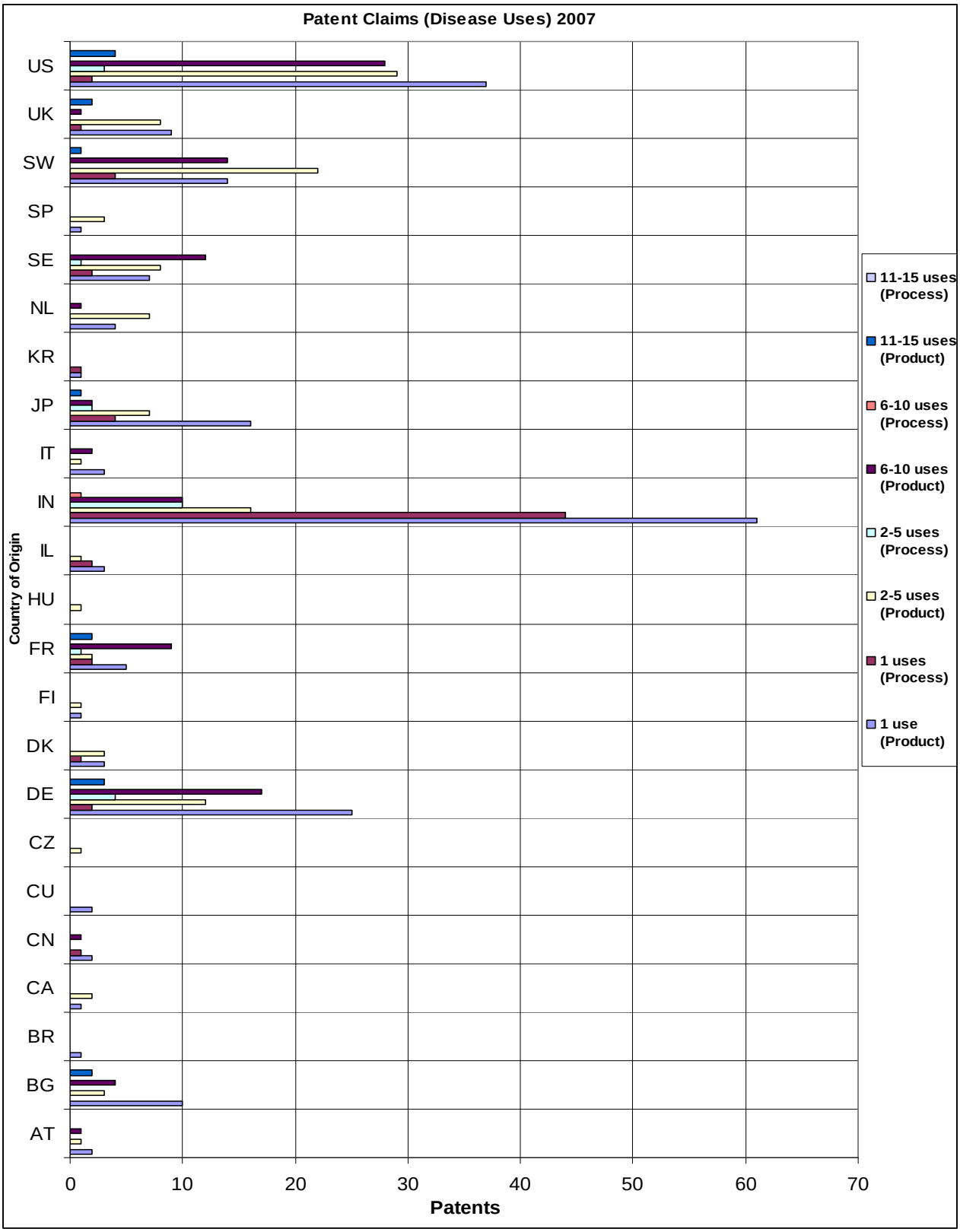
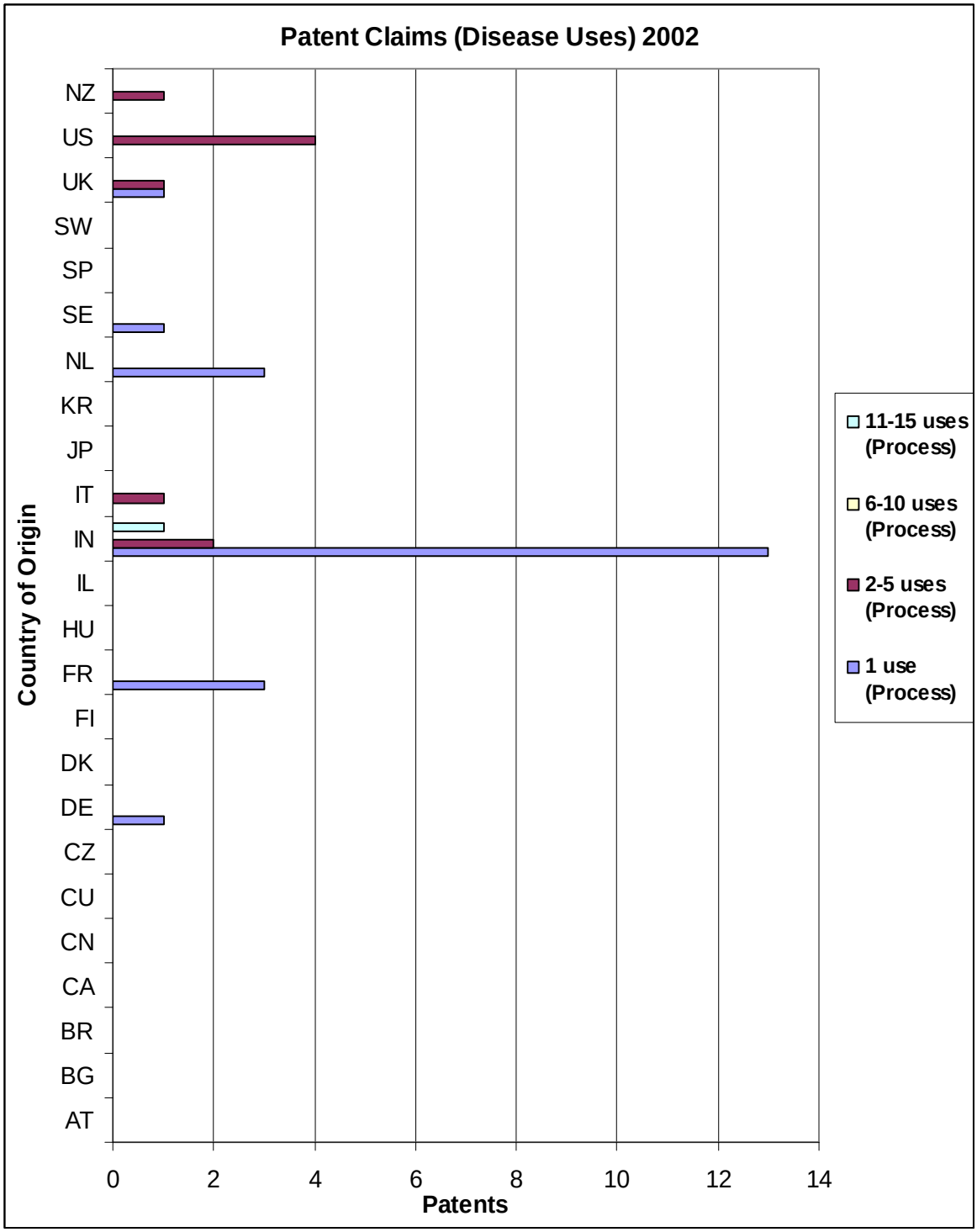
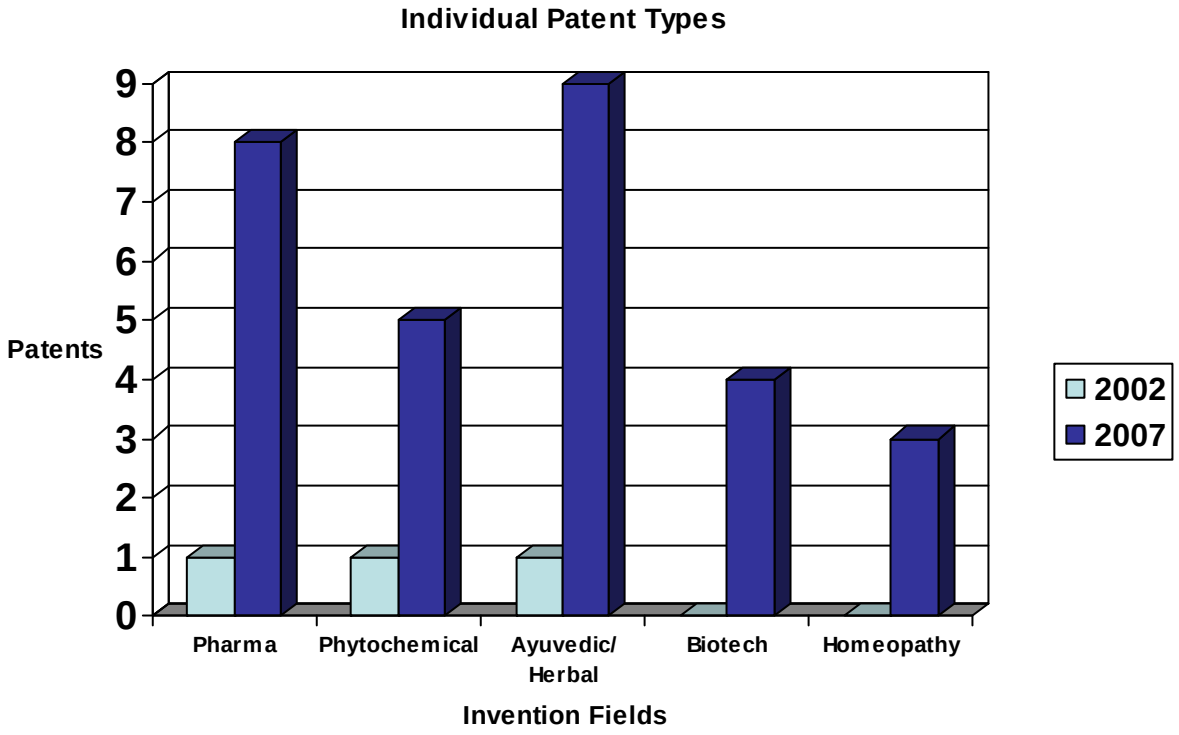


Table 9: Patent Claims (Uses of Drugs against Diseases) 2002



Individual filings in Ayurvedic/ Herbal Compositions

The seventh hypothesis was that Indian Individuals show disposition for patents relating to Ayurvedic/ herbal compositions/ medicines. Of the 3 patents granted to Indian individual applicants in 2002 one each belongs to pharmaceutical, ayurvedic and phytochemical (naturally occurring substances) categories. Of the 29 patents granted in 2007, 8 belong to pharmaceutical, 9 to ayurvedic/ herbal, 4 to bio-tech, 3 to homeopathic and 5 belong to phytochemical (naturally occurring substances) categories. Again, only 6 are process patents (all Indian, and 3 of these 6 are pharmaceutical), while the remaining 23 are for product patents. 27.6% are from non-synthetic pharmaceutical, and around 55% are from traditional medicine areas (including homeopathy). **Table 10** shows the distribution of patents filed by applicants for different types of diseases hereunder.



Diseases Correlations

The eighth hypothesis that we tested was with regard to disease combinations for which applications had been filed. The hypothesis was that patents frequently claim/ disclose therapeutic uses in following diseases together:

Cancer and AIDS (1, 2)

Bone and Immune-related (10, 11)

Neurological and Psycho-related (7, 8)

Cancer and Skin (1, 13)

Cardio and Renal (4, 5)

Diabetes and Renal (14, 5)

Cardio and Diabetes (4, 14)

Diabetes and Obesity (14, 15)

Cardio and Obesity (4, 15)

Diabetes and Eye (12, 15)

Immune-related and Neurological (8, 11)

Gastro and Cardio (3, 4)

Gastro and Psycho (3, 7)

Gastro and Neurological (3, 8)

Immune-related and cancer (1, 11)

Immune-related e and AIDS (2, 11)

Immune-related and Cardio (4, 11)

Immune-related and Renal (5, 11)

Immune-related and Diabetes (11, 14)

Immune-related and Eye (11, 12)

Immune-related and Skin (11, 13)

Cardio and Respiratory (4, 9)

Neurological and Respiratory (8, 9)

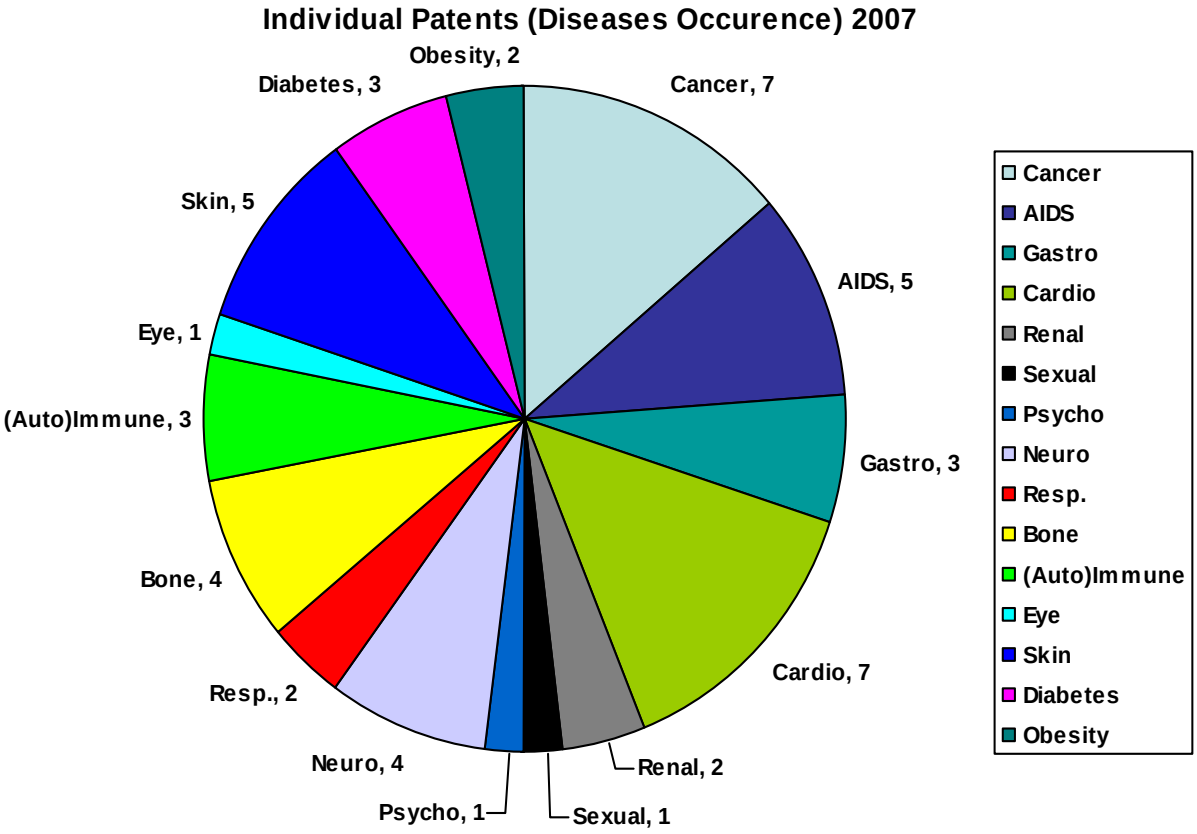
Immune-related and Respiratory (9, 11)

Here the major correlation that was observed in terms of patent claims was between neurological disorders related claims and those for treating psychiatric ailments. No other significant correlation is observed from an analysis of the data.

Patenting by Individuals

The ninth hypothesis was that individuals are claiming only few of the 15 therapeutic/ disease uses (AIDS, Cancer, Diabetes and Cardio-related/ Hypertension). This hypothesis is not supported by the data. In fact there is great diversity in diseases for which individuals claim patents. In 2002, Indian individuals were granted patents with diabetes as the targeted disease (process patent). In 2007, Cancer and Cardio are the most targeted diseases, followed by AIDS and Skin-disorders. Neurological and Bone-related disorders also occur (all are predominantly product patents). Diabetes, however, has average occurrence, though more as Process patents. In 2007, only 4 were foreign (3 German and 1 US) with all product patents. For these, Cancer followed by Immune-disorders, were targeted diseases. In 2002, 2 patents claim only one disease per patent and the third claims all 15 disease uses. In 2007, 20 patents claim only one disease per patent, 8 patents claim 2-5 disease uses per patent and only 1 patent claims 6-10 diseases (Observation). These observations are summed up as pie-chart in **Table 11**.

Table 11: Patenting by Individuals

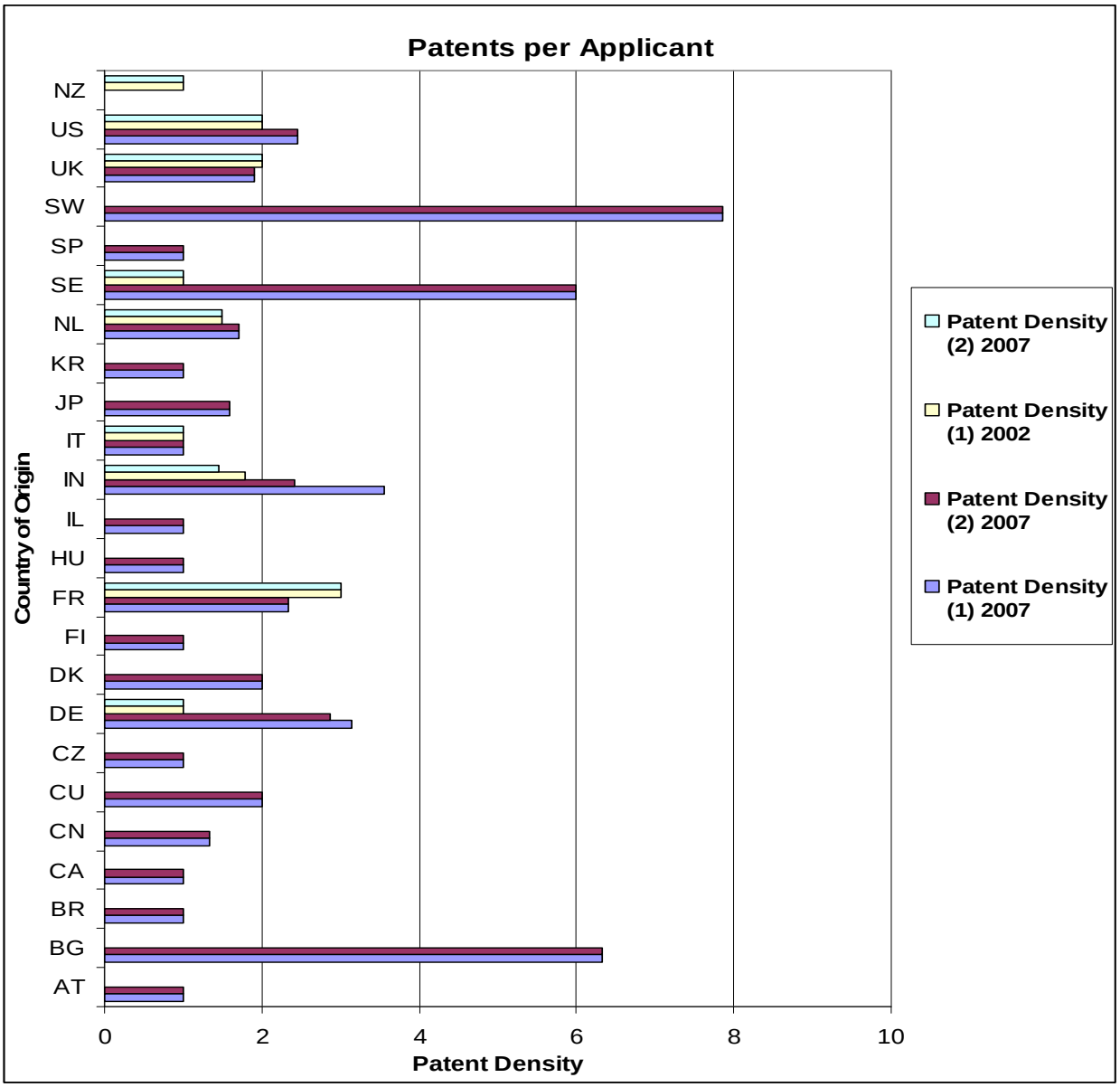


Patent Density

The tenth hypothesis was related to patent density (ratio of total number of patents to total number of applicants per country). The hypothesis was that US applicants exhibit lower patent density, followed by Indian applicants, than other foreign applicants, who exhibit much higher patent density. In 2007, Switzerland shows the highest patent density (55) followed by Belgium (19) and Sweden. Other countries seem to show much lower patent density along with the US. The Patents per Applicant by country of Origin distribution is depicted in **Table 12.**

Note: Patent Density (1) considers individuals as a single entity, while Patent Density (2) considers individuals as separate entities for purposes of calculation.

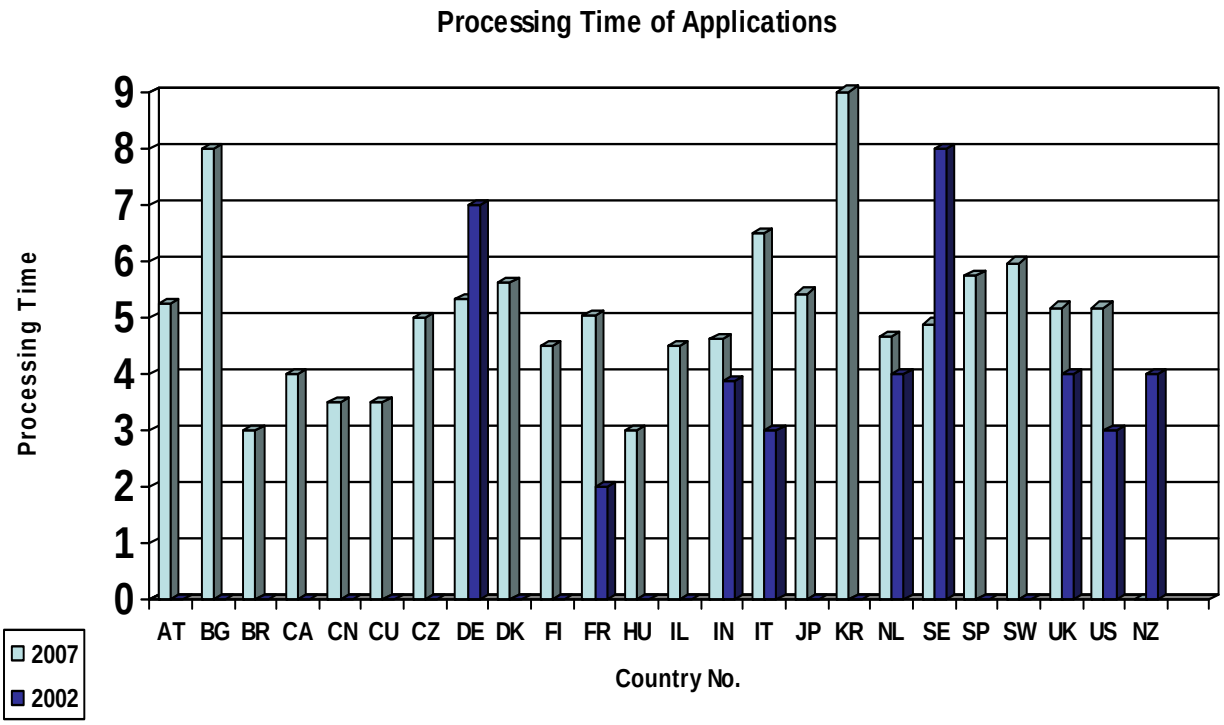
Table 12: Patents per Applicant by Country of Origin



Processing time for Patents

The eleventh hypothesis that was tested was that there is no significant change in the patent applications processing time for grant at the Indian Patent Office despite the legislation to this effect and that there is a difference in the time taken for procession of foreign applications and Indian applications in 2002 and 2007.

Table 13: Processing time for Patents



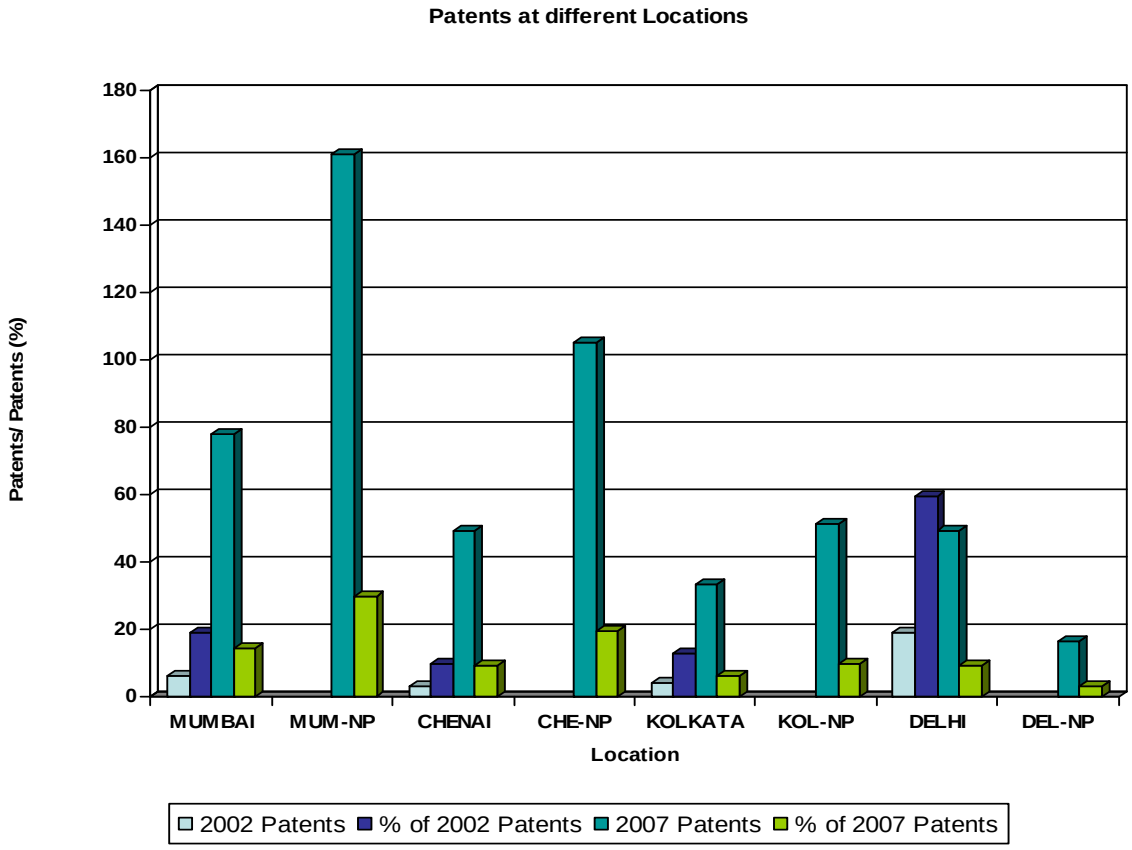
An analysis of the data reveals that rather than a decrease there is actually an increase in the average number of years taken for grant of patents between 2002 and 2007. This increase is, in part, due to the large increase in the number of applications filed on a year-on-year basis since 2005. However, one interesting aspects of the date is that even though the number of Indian applications have considerably increased, the increase in time taken for grant for Indian applications is less than that for countries like the US and the UK. Only applications from Germany and Sweden show decrease in time taken for the grant of patents in the said period.

Location of Filing

The twelfth hypothesis was that there is a shift in terms of location of filing of patents after Indian began to accept product patent applications and this is borne out by changes in filing patterns of patents granted between 2002 and 2007. There is a clear shift in grant pattern in 2007 in favour of

Mumbai followed by Chennai (Kolkata is stable, while Delhi is declining). This is primarily due to an increase in national phase applications at Mumbai and Chennai.

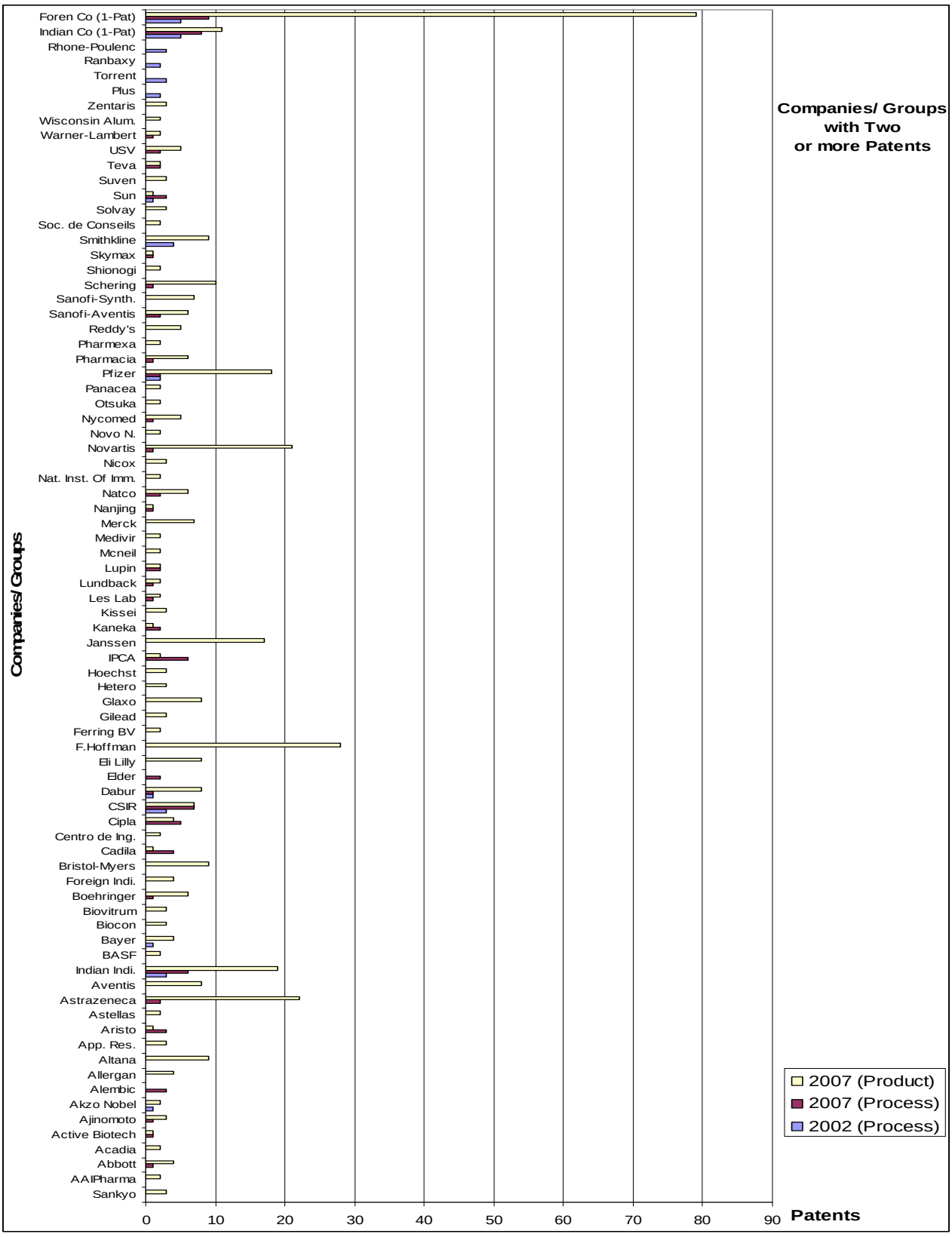
Table 14: Location of Filing of Patents



Product Patenting by Firms

The final hypothesis was that the product patent regime has encouraged companies from developed world and bigger domestic players to seek product patents. This is proven by the data. Of the 86 new foreign firms that filed for patents in India, 90% file for product patents. And of the 18 new Indian companies 60% have filed for product patents. SmithKline the largest applicant in 2002 is relegated to 8th position in 2007. The top 3 patentees of 2007 did not file in 2002. Of the Top Six firms/organizations, by the number of patents, only Pfizer and CSIR are common in both 2002 and 2007. The trends have been shown in **Table 15**.

Table 15: Patent Filing by Firms



Conclusion

Analysis of patent data has always been considered to be an important method of assessing aspects of technological change, research and innovation. This paper provides a comparative analysis of shifts in pharmaceutical patenting in India by examining granted patents for two six-month periods (July to December) in 2002 and 2007.

We find that both Indian and Foreign Companies sought more product patents. Of the total granted patents in both the periods, Indian applicants were more numerous. Although, the percentage of product patents by Indian firms after the Third Amendment is smaller than that for foreign applicants, the share is still substantial. Further, new patentees have emerged since changes in Indian patenting regulations allowed for product patents.

Among all the therapeutic uses, cardio or hypertension related disorders are the most prominent diseases that the patents claim to target in both the periods. However, there have been significant changes in the types of diseases covered by disclosures in the patents granted in 2007 vis-à-vis 2002. For instance, Neurological, Respiratory, Ortho/ Bone, Skin and Immune related disorders have shown significant increase, whereas Cardio and Renal related disorders have shown some decrease percentage wise in this period. It is also found that to some extent Indian firms claiming process patents have a tendency to designate a lesser number of therapeutic uses than foreign firms.

Companies originating in OECD countries (or having OECD country Priority) have tendency to claim for likely and potential therapeutic uses in greater number of diseases than the rest. Another interesting finding indicates that Indian Individuals show disposition for product patents relating to traditional (Ayurvedic/ herbal etc.) medicines. Further, in respect of 'Patent density' (patents per applicant per country of origin), US applicants exhibit lower patent density, followed by Indian applicants while other foreign applicants exhibit much higher patent density. Regarding patent application processing time, there is actually an increase in the average number of years taken for

grant of patents between 2002 and 2007. However, the increase in time taken for grant of Indian applications is less than that for countries like the US and the UK. Further, there is a shift in terms of location of R&D after Indian began to accept product patent applications and this is borne out by changes in filing patterns of patents granted between 2002 and 2007.

There are some aspects of the data that merit further study. Many applications for product patents claim new patents for what are essentially derivatives of existing products. Further analysis of these applications and of the firms that file such applications could reveal differences between the patenting strategies of Indian and foreign firms. The changes of location of filing of patent applications also needs to be studied in greater detail. Differences in filing of Indian applications, filing of 'national phase' applications by foreign firms doing R&D outside India and filing of 'national phase' applications by foreign firms doing R&D in India could reveal shifts in location of pharmaceutical R&D within India.

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