

Patenting trends in Indian pharmaceutical industry

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Although patent filing is increasing worldwide, it does not follow a uniform growth trend. China and South Korea have seen a substantial growth in patent filing as compared to developed nations. Regarding India, the growth is minimal. The trend reveals that more patents in India are filed for formulations, dosage forms, combination drugs and mode of delivery. New drug discovery has moved away from chemical entities to biological moieties. India, though known for its significant contribution to pharmaceutical industry by way of generic drugs is yet to make a meaningful presence in the patent scenario.

Keywords: Patents; Pharmaceutical industry; Patent filing

Introduction

India is a leading producer of generic medicines and caters to most developing nations by providing lower priced drug formulations. The Indian pharmaceutical industry is also one of the leading filers of Abbreviated New Drug Applications (ANDA) in the USA and further supplies finished formulations to the European region. However, it is generally observed that the Indian patent scenario is not robust and see a lower number of patent applications from the industry despite the tremendous growth in terms of market presence. The present study is an attempt to highlight the patent filing trends in India, with respect to pharmaceutical patents and assess the available opportunities to intensifying research and generate a larger patent portfolio.

A global R&D funding forecast study¹ has reported a growth in R&D funding. An increase in R&D investment was observed in Asia, particularly China, while an unchanged investment in R&D spending in North America indicated a period of stability, security and healthy competition across industrial sectors. According to Unnikrishnan², India adopted the patent regime in pharmaceutical sector to comply with the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005. This change in patentable subject matter although resulted

in more prominence to foreign drug makers especially in the new and innovative medicine space, the market is nevertheless dominated by local companies who have gained strength as generic drug manufacturers.

A report published by Indian Brand Equity Foundation (IBEF)³ states that the Indian pharmaceutical industry accounts for about 2.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms.

The statistical data published by WIPO⁴ disclose that the number of patent applications filed in India has witnessed a steady growth and has plateaued in the recent past. Pharmaceutical patents are ranked second with respect to the volume of applications but is still a fraction of pharmaceutical patents filed worldwide.

A study of the patenting trends in pharmaceuticals is important as the industry is focused on manufacturing life-saving drugs which are often patent protected, providing the innovator an opportunity to commercially exploit their research products without any competitor product during the life-time of the patent. The Indian companies though, are leaders in the generic drug industry, wherein they enter the market after the life time of a patent, but it still provides them an opportunity to exploit the

market by adding certain unique features to the drug product and exercise monopoly over that particular feature. An economical process for making a new drug formulation, change in dosage regimen and new form of drug delivery are all examples of patents that bestows commercial advantage to a patent holder ever after the expiry of the innovator patent.

Objective of the study

To understand the patent filing trends in India with reference to pharmaceutical industry.

Methodology

Patent applications and publication data worldwide in pharmaceutical science was reviewed to understand the recent trends in terms of growth and implication of international treaties such as TRIPS and related changes in national laws to be compliant with TRIPS. The trends were examined from the data for a two-decade period (1997-2016). The period coincided with that of India signing the Patent Co-operation Treaty (PCT) and TRIPS agreement coming into effect. The patent landscape in India with reference to change in Patent Act that allowed product patents in pharmaceuticals in 2005 was studied to understand the growth and pattern of patent applications.

The Indian patent database was accessed at the Indian Patent Office website to understand the Indian scenario while WIPO (World Intellectual Property Organization) website was accessed to determine worldwide trends in filing of patent applications. Additionally, Thomson Innovation (now known as Derwent Innovation) was used to map and analyse the trends observed in patent filing in various countries across the world and the different sub-areas in pharmaceutical industry.

Analysis

Patent filings worldwide have grown substantially since the early 1990s. A number of new chemical entities to treat a new wave of disease conditions were developed during the 1980s to mid-1990s. Most of these product patents have since expired and a range biological drugs are now being developed and patented. With a large amount of work having been conducted in the last three to four decades, there is a general perception that new chemical entities are less likely to be discovered or patented and focus has shifted to biological entities and formulations.

International scenario

As per trends observed, pharmaceutical patents that topped the filings and grant across the world earlier has shown a decline while computer technology and electrical machinery accounted for maximum number of patent applications filed in the last decade. These two fields have shown substantial growth in the recent past. Other industries that have observed a rapid rise in patent filings are food chemistry, automobiles and telecommunications industry. Pharmaceutical industry however, is still among the top five industries that witnesses large research activity and patent applications. USA, China and Europe account for more than half the pharmaceutical patents filed worldwide in 2015 as depicted in Figure 1.

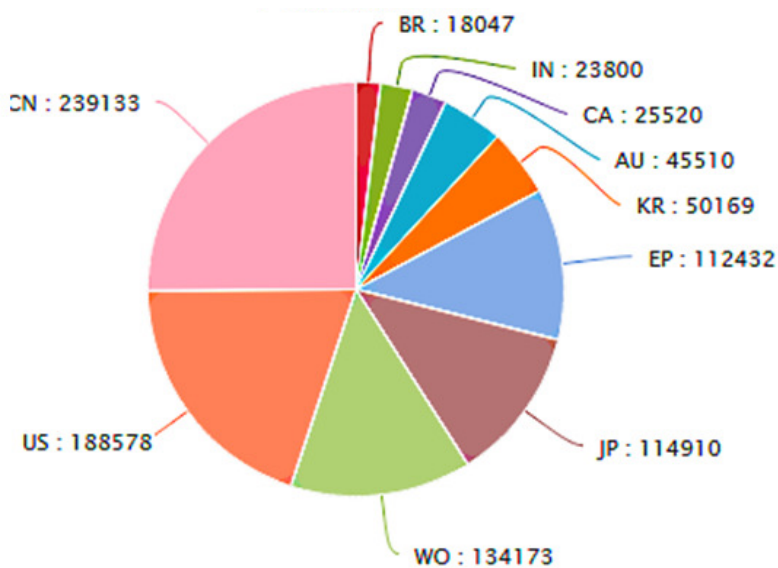
Global patent trends

The quantum of patent applications filed over the last few years disclose that although the number of patents filed worldwide grew in numbers, the rate of growth has declined. The developed countries are growing slower than some of the developing nations.

The trend was similarly observed in the pharmaceutical industry. A slower growth has been observed in the last decade partly due to the costs involved in patent filing, maintenance and world economic scenario. The dearth of new blockbuster drugs too has contributed to this trend.

A recent report on R&D expenditure endorses the view that research expenditure worldwide has reduced in some parts while it has increased in other parts of the world. Over the last several decades, global pharmaceutical companies based in the western world have led in research expenditure worldwide but in the last decade or so, a downward shift has been observed. Various factors such as worldwide economic slowdown, strengthening of regulatory laws and entry of generic players have contributed to this reduction. Other factors that have influenced the research investments are consumer resistance to high priced drugs and lack of a strong pipeline of new drugs¹. The new drug pipeline has been found to be vastly reduced for synthetic chemical molecules and the focus has shifted to biological molecules which show therapeutic effects.

The patents filed disclose a focus on smaller projects and quick results. Process improvements, newer and improved products form a significant part



Country code	Country
BR	Brazil
IN	India
CA	Canada
AU	Australia
KR	S Korea
EP	Europe
JP	Japan
WO	PCT
US	USA
CN	China

Fig. 1—Worldwide pharmaceutical patent filing trend (2010-15)

Source: *Worldwide Innovation Filing Trends 1995-2015; Aug 2015*, Gridlogics, Published Online, PP.6 (<https://patseer.com/2015/08/worldwide-innovation-filing-trends-1995-2015/>)

Table 1—Share of total global R&D spending

Region /Country	2014	2015	2016
North America	29.1%	28.5%	28.4%
U.S.A.	26.9%	26.4%	26.4%
Asia	40.2%	41.2%	41.8%
China	19.1%	19.8%	20.4%
Europe	21.5%	21.3%	21.0%
South America	2.8%	2.6%	2.6%

(Source: 2016 Global R&D Forecast Funding, 2016)

of the patent landscape. The goal is to achieve a commercial gain in as small time frame as possible.

The worldwide research expenditure trend is shown in Table 1.

Patent filing and publication

To understand the filing phenomena, a search was conducted in Thomson Innovation database using WIPO's International Patent Classification (IPC) in the area of pharmaceuticals using the classification code

A61K (PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES) that encompasses the pharmaceutical industry. Other smaller sections in the classification code in related areas were not included to avoid ambiguity of data as there could be overlap of other technology areas as well. Table 2 reveals the filing and publication trend in the last two decades.

Patent applications were filed largely by multinational companies who have a relatively greater R&D spend. Figure 2 depicts the list of top ten companies.

A further analysis of the patent filings during the two decades reveal a growth in number of filings despite any significant drug discovery. Although the drug pipeline was shrinking, the industry focussed on extending the patent life of marketed products by way of new dosages, new salts with improved efficacy and polymorphs along with new biological entities. An upsurge in combination patents has been observed, wherein drugs providing synergy were combined to yield improved results. The generic pharmaceutical companies made a substantial contribution to the increase in number of patents filed and published.

It has been observed that patent applications initially increased towards the turn of the last century as disclosed in Figure 3. The scenario however changed in the last decade when the number of patent filings reduced indicating a slowdown despite the number of filings increasing from Asian countries such as China and S Korea, while more patents were published and granted.

Table 2—Patents published under A61K

Period	Number of patents filed	Number of patents published
1997-2006	2,101,208	1,752,941
2007-2016	1,961,218	2,596,673

Pharmaceutical industry in India

India changed its Patent Act in 1971 to exclude product patents in pharmaceutical and food sectors. This was primarily incorporated to provide a boost to domestic industries and safeguard health and food needs of the population at large. However, when India signed the TRIPS agreement, this had to change.

The agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organisation (WTO) that sets down minimum standards for intellectual property (IP) regulation and came into force on 1st January 1995. This introduced intellectual property law into the international trading system for the first time. In 2001, a further meeting was held in Doha, to address the concerns of developing countries and provide certain safeguards to protect national interests including compulsory licensing.

The member countries were provided adequate time to amend their local laws. The developing countries including India were allowed to implement the regulation by January 1, 2005, thus providing a period of additional ten years. It was agreed that although TRIPS agreement provides scope for its members to implement the provisions and achieve a balance to cater to matters of national interests such as public health, epidemics etc. members could not

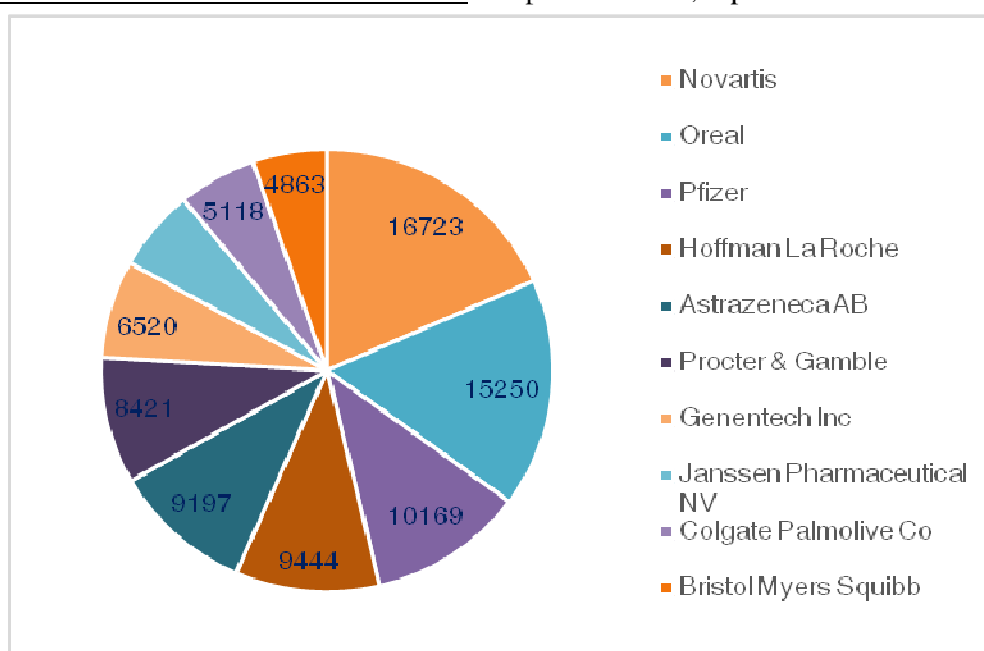


Fig. 2—Top ten global patent applicants (1997-2016)

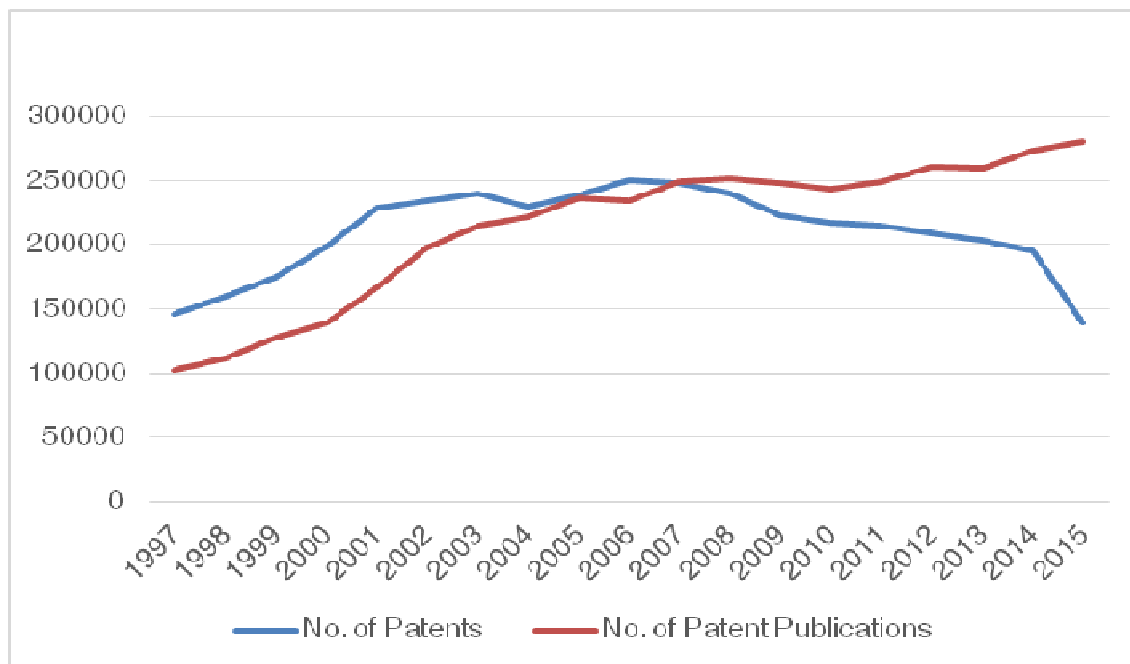


Fig. 3—Patents filed and granted worldwide - 1997-2015

discriminate between different fields of technology in their patent regime.

India implemented the agreement, excluding certain types of chemical entities such as polymorphs and salts and combination of drugs from patentability. The exclusions were made keeping in mind the cost and access to healthcare in the country and prevent large pharmaceutical companies from making drugs inaccessible to the general population who do not have the financial strength to meet their health care needs. It is important to note the absence of a government funded comprehensive health care facility in the country.

The implementation of the agreement, led to a large spike in patent filings only to stabilize in the last 3-4 years. Although, the exclusion of second use and polymorphs and salts did result in the industry voicing its concern, this did not in any way hamper the filing of new applications.

Indian pharmaceutical patents

Indian pharmaceutical industry is the third largest in the world consisting largely of generic pharmaceutical companies. The companies or individuals who create or develop new molecules or biological entities for treating medical conditions are known as innovator companies while those that enter

the market with improved process or modified dosage regimens once the product patent has expired are known as generic manufacturers. The advantage of generic drug is its competitive pricing generally attributed to lower investments in the development phase. A generic pharmaceutical product goes through an abridged approval process in most countries and hence is developed at a lower cost to the company.

The Rs. 1,50,000 crore worth pharmaceuticals industry is currently one of the most robust sectors in the country² catering to both domestic and most of the world markets. Although India's adoption of product patent regime in 2005 for the pharmaceutical industry in order to be compliant with WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has given relatively more prominence to foreign drug companies in new and innovative drug development, the market is still largely controlled by local companies with their proven capabilities in generic drugs.

The pharmaceutical industry in India has grown from USD 6 billion in 2005 to USD 30 billion in 2015 and is expected to go up to USD 55 billion by 2020³. The cost of production in India is significantly lower than that in USA and Europe which bestows India with a significant advantage. The generic industry in India is the largest component in the sector and

accounts for about 70% of the products. Indian companies export the generic drugs to several developing nations across Eastern Europe, Africa, Latin America and Asia. They also market and sell their products in regulate economies such as North America and Western Europe.

According to a recent report, patented drugs form only 9% of drug revenues generated in India³. However, the focus on process patents is considerably high among generic manufacturers and so are the investments in intellectual property (specifically patents).

Patent filing and publication

According to WIPO Statistics Database, pharmaceutical patents are the second largest subject matter protected in the patent applications filed in India⁴ as depicted is Figure 4.

Table 3—Patent Applications filed under A61K in India

Period	Number of Patents filed	Number of Patents published
1997-2006	34,132	12,835
2007-2016	55,135	77,657

A classification code based search was carried out in Thomson Innovation database to understand the trend in patent applications filed in India. The International Patent Classification (IPC) code published by WIPO was used and the code A61K that encompasses the pharmaceutical industry was chosen to understand the trends. Table 3 shows the filing trends in the last two decades.

An analysis of patent applicants in the last two decades highlight the fact that it is dominated by multinationals with few Indian companies among the top applicants. However, more Indian applicants are appearing on the list in the last decade indicating that more Indian companies are focusing on research and its protection by way of patents.

The patent filing data shows an upward trend during the period 1997-2006 and displaying a distinct jump about 2005 when India enacted the law that allowed product patents.

However, post the initial spike in filing, the patent filing trend has stabilized in the last 3-4 years and a growth though predicted is not expected to be large but steady in nature.

A visual map of technologies or claims of the patents filed in India during the last decade from 2007 was created using the Themescape tool available in Thomson Innovation (Fig. 7). It is interesting to note

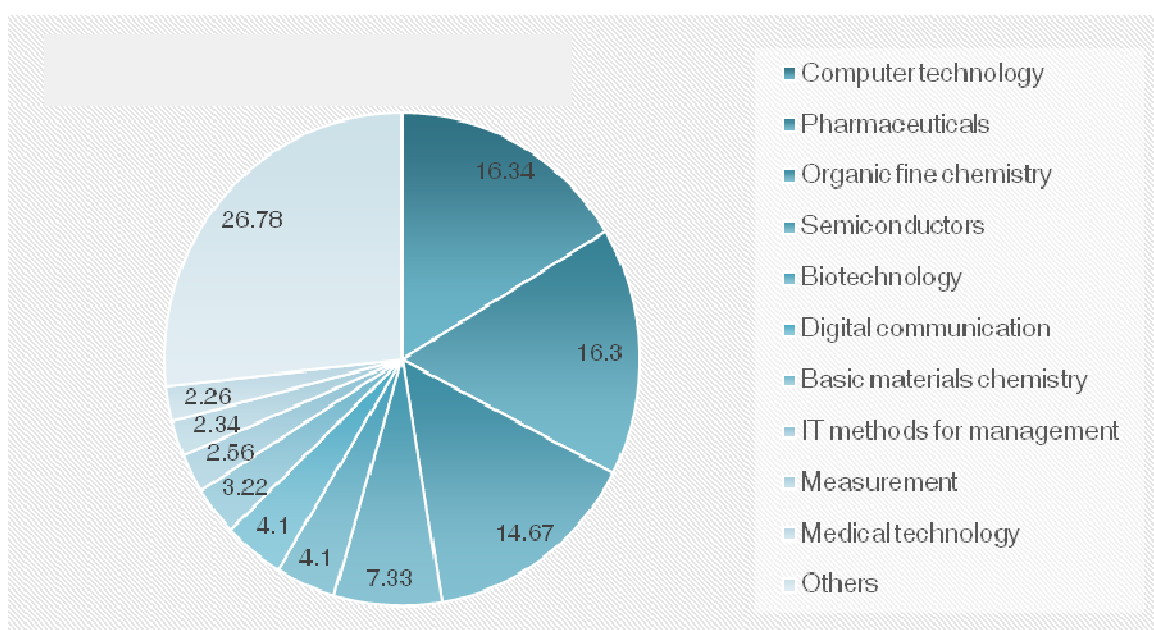


Fig. 4—Patent filing trends in India based on technology
(Source: Statistical country profiles-India: WIPO statistics database, 2016)

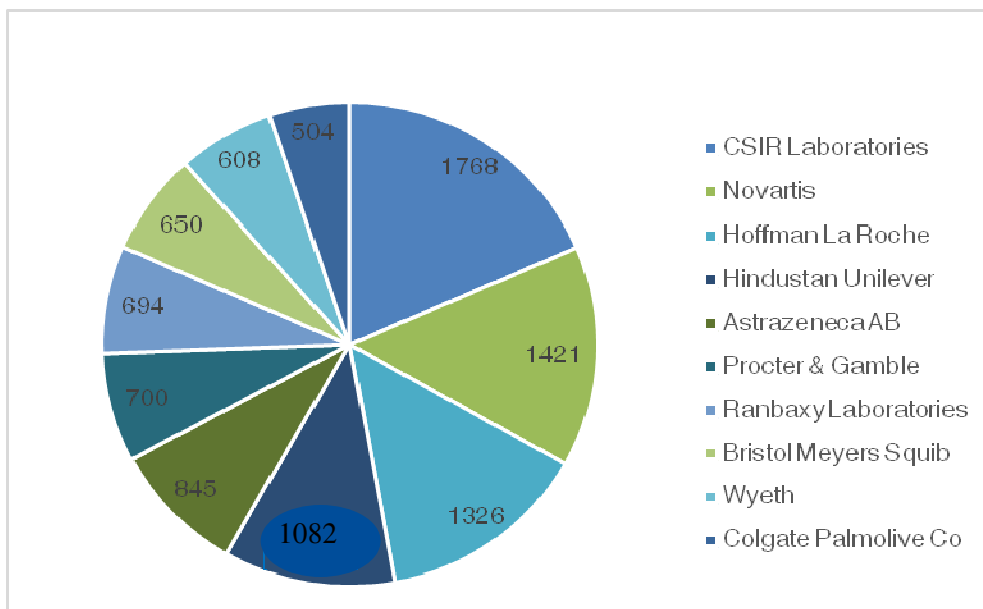


Fig. 5—Top ten patent applicants - India (1997-2016)
 Source: Thomson Innovation
 (currently Derwent Innovation: <http://www.derwentinnovation.com>)

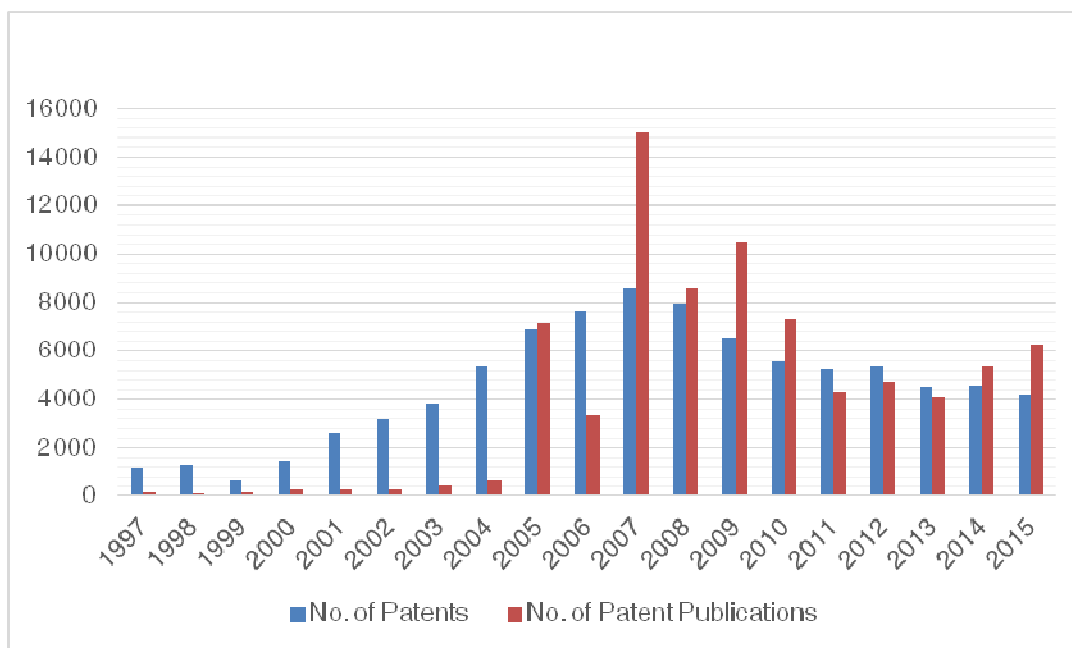


Fig. 6—Patents filed and published in India 1997-2015
 (Source: Thomson Innovation)

that most patents covered were filed to protect applications, formulations and devices. This reaffirms the finding that there is limited new drugs or chemical entities in the pipeline. The patent landscape also revealed the nature of the Indian industry that focused on short term gains via new and improved processes,

new formulations and dosage regimens rather than new molecules. It is significant that certain classes of drugs targeting certain disease conditions are of significant interest to the industry and resulted in more research and hence more number of patents.

