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IPR in Pharmaceuticals

Balancing Innovation & Access

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About TechSci Research

TechSci Research is a global market research and consulting services provider with offices in Canada, UK, and India. TechSci offers a large number of high quality research reports across a broad range of industries such as IT & Telecom, Water & Water Recycling, Consumer Goods and Retail, Automotive and Energy & Power. The industry reports are generated after in-depth primary research surveys with stakeholders of the respective industry coupled with exhaustive secondary research of relevant publications like company annual reports, government policy documents, and proprietary databases, which provide details of competitors, valuations, trends and forecasts. The company's proprietary forecasting models uses various analyses of both industry-specific and macroeconomic variables on a state-by-state basis to produce a unique 'bottom-up' model of country, regional and global industry prospects. Combined with TechSci's detailed analysis of company activity and industry trends, the result is a uniquely rich evaluation of the opportunities available in the market.

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D.S. Rawat
(Secretary General) ASSOCHAM

ACKNOWLEDGEMENT

It gives me immense pleasure that ASSOCHAM in association with Department of Pharmaceuticals, Government of India is organizing Conference on IPR in Pharmaceuticals: Balancing Innovation & Growth. It may be noted that the Indian patents (amendment) Act, 2005 introduced product patents in India and marked the beginning of a new patent regime aimed at protecting the intellectual property rights of patent holders. The amendment aimed to address issues like global competition, high innovation risks, short product cycle, need for rapid changes in technology, high investments in R&D, etc which are essential for changing trade environment in terms of production and marketing. However, it is obvious that the implementation of the IPR can be effective only if we have a good supportive structure for granting patent in shortest possible time.

I extend my heartiest thanks to all the stakeholders including Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, ICMR and others for lending their support to this Conference. I also thank our Knowledge Partner of this Conference "TechSci Research" for its wonderful efforts in putting up this report on the subject of IPR in Pharmaceuticals.

I also acknowledge the efforts put in by Sandeep Kochhar, Deputy Director and Head-ASSOCHAM Healthcare & Pharma Division and his team members Karanveer Singh, and Shagun Ahlawat for organizing this Conference.

I not only wish the Conference a great success but also assume that ASSOCHAM shall continue to organize such programs for larger public benefits with great degree of excellence.

(D.S.Rawat)
Secretary General
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1 Executive Summary

Indian pharmaceutical industry is a prominent industry in terms of production, consumption and exports of pharmaceutical products. Following the enforcement of Indian Patents (Amendment) Act, 2005, the country has been generating high revenues globally, and is currently the world's third largest pharmaceuticals market, in terms of volume sales. The Act has also encouraged innovator multinational companies to sell their products in India, without worrying about a low-priced copycat version, due to product patent protection. Further, with reduction in the approval time for set up of new pharmaceutical companies, the Indian pharmaceuticals market is expected to soar high over the next five years.

However, post implementation of product patents, several essential drugs have become inaccessible to the masses, due to affordability issues. In this respect, the existing regulations and policies need significant improvement to be really effective in achieving their objectives.

Policies framed and enforced by the government, to monitor anti-competitive practices and antitrust issues, should help prevent unfair competition while promoting healthy competition, wherein consumers are benefited. Further, healthy competition among pharmaceutical companies, aids in promoting R&D, since the companies would want to come up with new/ innovative/ niche products to create product differentiation and gain market share.

For approval of innovative drugs in the Indian market, both domestic and foreign players are complying with the regulatory requirements of the country, thereby generating huge revenues, while ensuring access to low-priced medicines,and promoting growth in the industry. Indian pharmaceutical companies are continuously improving their R&D capabilities and investing heavily on research in pharmaceuticals and biotech products, and investing more into generation of IPRs for the company.

2 Intellectual Property Rights

Intellectual Property Rights (IPR) are legal rights given to creators of intellectual goods & services in the fields of science, literature, arts and industrial designs. These rights protect creators by granting rights to monitor the use of their creations for a defined period of time. In addition to safeguarding the creativity of the creators, IPR fosters a country's economic growth, gives incentives for technological innovation, and captures investment that subsequently create job opportunities for citizens of a country.

Types of IPR:

- Patents
- Copyrights
- Trademarks
- Industrial Designs
- Trade Secrets
- Geographical Indications
- Layout Design for Integrated Circuits
- Protection of New Plant Variety

Patent: A patent is an exclusive right granted to the patent holder for an invention, which is a creative product or a process that offers a new method of doing something or provides a new technical solution to a problem. It provides protection to the invention, which means that the invention cannot be commercially produced, used or distributed without the consent of the patent owner. The protection is granted for a period of 20 years.

The Patents Act, 1970 contains the following sections, emphasized in context of screening of applications in pharmaceuticals and allied fields:

'Invention' relates to a new product, or a process with an inventive step, possessing an industrial application.

An 'inventive step' is an invention that has a technical advance as compared to the existing knowledge, or possessing an economic significance, or both, and which is non obvious to a person skilled in the art.

The product has to be capable of industrial application, i.e., the invention should be capable of being made and used in an industry.

3 Intellectual Property Rights: Pharmaceutical Industry

3.1 Why do we need IPR in Pharma?

One of the key drivers for commercial and economic growth in the pharmaceuticals industry is innovation. Intellectual Property (IP) Protection is of vital importance for innovative pharmaceutical companies, in order to continue to be able to fund their research and development (R&D) of new medicines.

IPR in pharma provides an impetus to local research and innovation, thus boosting economic activity in the pharmaceutical sector. Any national IPR policy pertaining to pharma sector needs to balance the interests of both foreign manufacturers as well as local innovators such as budding entrepreneurs and small and medium enterprises.

Role of Indian Patent Office in Pharmaceutical Patenting

Pharmaceutical patenting is essential to promote innovation and technological development in the country. Therefore, utmost check of quality, consistency and uniformity in examination and grant of patents, is the top most priority for the Indian Patent Office. To achieve this, the patent office introduces guidelines for examination in important areas such as traditional knowledge and biotechnology. Moreover, Indian Patent Office is continuously upgrading its internal resources by remodelling its internal work structure or its public interfaces, in order to be more effective. Indian Patents Office operations are closely related with Indian Judiciary System, wherein the courts help resolve the patent related disputes.

The Indian Patents Act, 1970

The Indian Patent Regime can broadly be categorised under the following three phases:

- Patents and Designs Act of 1911, which consisted of a product patent regime for drugs and medicines.
- Post 1972, the Patents and Design Act, 1911, was replaced by the Patents Act, 1970. Due to this, drug product patent protection was taken off and process patents came into action. During the time, India became one of the key manufacturers and suppliers of low cost yet high quality drugs.
- After TRIPS, process patents were once again replaced by product patents in India, with effect from 1 January 2005.

Removal of pharmaceutical product patent protection in 1972, resulted in the formation of an independent Indian pharmaceutical industry since the number of licensed drug manufacturers increased in a process patent IP framework.

In 1970, multinational companies accounted for 80-90% share in India pharmaceuticals market, which decreased through 2004, due to the abolition of product patents.

Indian pharmaceutical firms began to imitate and produce generic versions of patented drugs in other countries, supported by that country's well developed infrastructure and great process skills. This led to the introduction of copied brands of patented drugs at affordable prices in the Indian market.

Further, in case of process patents, the provisions related to compulsory license, license of rights, examination of patent within 3 years of filing date, and burden of proof in a patent infringement case reduced the scope of protection.

3.2 Impact of IPR on Indian Pharmaceutical Industry

The Patent Act, 1970, granted only process patent for drugs, which allowed even small and medium Indian companies to manufacture local versions of drugs produced abroad, and export these generic drugs. Any other company that was able to manufacture a drug, developed and patented by some other company, and use a new process for drug development to avoid the bulk of manufacturing costs, was able to produce and sell the copied version of the drug at low cost.

Drugs sold in the Indian market during this time were low cost owing to the low cost of product, compared to the costs involved in the manufacture of drugs. Manufacturing costs include wages of medical and scientific personnel involved in research, along with the costs involved in experimentation on animals and humans over a long duration before launch of a new drug.

Product patent, effective January 1, 2005, implies that Indian pharmaceutical companies cannot produce generic versions of a patented drug. Post the launch of product patents in Patents Amendment Act, 2005, India has an opportunity to take advantage of its large scientific manpower base and encourage the Indian pharmaceutical industry to emerge as an innovator of new drugs. In addition, the new ordinance allows faster processing of patent applications. As per the product patent framework, the duration for sending out requests for product patent examination has been reduced from 48 months to 36 months.

Another provision incorporated in the Indian Patent Amendment Act, 2005 is the availability of patent rights from the day of filing of the patent, and not from when the patent is published. This provision will buy the innovator some credibility in the pharmaceutical marketplace, increasing researchers' and investors' confidence in the innovation.

Patent Amendment Act, 2005 also entails that any pharmaceutical company holding patent for

a particular drug, may force the company manufacturing the generic version of the same drug, to cease its production while the product is under patent protection.

The Patent Act also acts upon an important parameter known as patent extension or evergreening of patent, which allows patent extension beyond the patent protection period on grounds of increased innovation in the product. In cases where the patent holder introduces a new application for the patented drug, the patent holder may not be granted a patent extension unless the new application enhances the therapeutic efficacy of the drug. The judgement to not grant a patent extension to Novartis for its blockbuster cancer drug, Glivec, in 2013, has been criticised by global pharmaceutical companies in the United States and EU, complaining lack of strong IPR laws in India.

However, India has showcased a mature way of dealing with the protection of intellectual property, as in some cases application for compulsory licensing has been rejected by the government. For example, in BDR Vs Bristol-Meyers Squibb's (BMS) case, the patent controller rejected BDR's application for compulsory licensing of the drug, Dasatinib.

With respect to patent filing, patent applications for any new drug invention made by any resident of India will have to be first filed in India, prior to filing anywhere else in the world.

Additionally, a patent application based oncollaborative research work done in India, has to be filed in India first. This includes Patent Cooperation Treaty (PCT) application as well.

Post Indian Patent Amendment Act 2005, IPR rewards innovative drug manufacturers by providing them temporary monopoly, thereby enabling them to charge higher prices for the drug manufactured, while it is still under patent protection.

In order to prevent the dominance of monopolistic power in the Indian pharmaceutical industry, the government may grant compulsory license to generic drug manufacturers, in an effort to control the prices of costlier drugs to make them affordable and accessible for the public. Also, the government can intervene through price regulation measures and make the innovator drug accessible and affordable to general masses.

For instance, in 2001, Indian drug manufacturer Cipla, supplied anti-retroviral drugs to treat HIV, to some African countries at lesser price in comparison to the price charged by multinational companies (MNCs). Cipla cut down the drug price by as much as 98%, i.e., from approximately USD10,000 per year to USD140 per year for an initial three-drug combination.

In India, majority of expenditure on medicines is incurred out of pocket, and provision of medical insurance schemes is not yet popular in India, and

so grant of a product patent may not be beneficial to the general public, who might end up paying premium prices for drugs.

The confusion among the drug manufacturers with regard to the scope of product patent is not there anymore because the definition of novelty is much clearer. A new form of a known drug, which does not result in enhancement of the efficiency of the substance is not patentable. The new form of the drug is only patentable only if it results in enhancement of the known efficacy of the drug. This patent act amendment has prompted drug manufacturers to focus on innovation that is beneficial to the consumers. Due to the introduction of product patent in India, copying of other pharmaceutical company's product has decreased and the prices of innovator products have gone up. Consequently, treatment has become unaffordable for AIDS, heart & diabetic patients and those affected with mental ailments belonging to the low income and even middle income group, as new drug inventions would get product patents and the patent holders would charge premium price to recover its product research and development costs.

Product patent has its pros and cons in the Indian pharmaceutical sector. Before product patent protection, Indian pharmaceutical companies were able to introduce new medicines in the market and export them abroad within a short span of time and at relatively affordable costs. Additionally, there was stiff competition among domestic pharmaceutical companies, since in the absence of product patents, companies introduced similar products in the market.

The reintroduction of product patents in 2005, took away the freedom of pharmaceutical companies to produce generic versions of innovator's drugs while the drug is under patent protection.

Post the introduction of product patents in India, there have been many instances which indicate the growing control of multinational companies in Indian pharmaceuticals market. Acquisition of Piramal Healthcare's generic medicine unit by US-based Abbott Laboratories in 2010, for a price of USD3.7 billion, and buyout of Hyderabad-based Shantha Biotech by France's Sanofi Aventis in 2009, for USD700 million, are examples of increasing power of foreign MNCs in Indian pharmaceuticals market.

3.3 IPR Pharma Policy and Regulatory Landscape in India

TRIPS- A New Regime:

On 1 January 1995, General Agreement on Tariffs and Trade (GATT) negotiations introduced the New Intellectual Property Right (IPR) regime under Trade Related Aspects of Intellectual Property Rights (TRIPS). This amendment required developing countries like India to amend their existing IPR policies, and adopt policies similar to those in developed regions such as the US, Europe, etc.

A few main provisions related to Patents in TRIPS are as follows:

- Patents shall be granted for any invention, whether a product or process, in all fields of technology, including pharmaceuticals, on account that the inventions meet the standard criteria for patentability, which are novelty, inventive step, and industrial applicability.
- The permitted duration of protection must expire no later than 20 years from the date of filing the patent application.
- The patent owner has the right to prevent unauthorized use of patented process.

TRIPS agreement allows a few exceptions to be made by the member country, in case where exceptions do not affect normal exploitation of the patent. One of the examples is the Bolar provision, in which generic drug manufacturers of patented products, are allowed to use the patented invention without authorization of the patent owner, even prior to the expiry of the patent duration. This is done for research purposes, so that generic producers can obtain regulatory approval from public health authorities for the marketing of the generic version of the drug as soon as the patent expires.

TRIPS agreement allows members to authorize use of patents by third parties, without the approval of the patent owner. For instance, in case of a compulsory license or for public noncommercial purposes by the government.

The Central Drug Standards and Control Organization (CDSCO):

It is the main regulatory body that holds the responsibility of ensuring the patent approval, and production and marketing of quality drugs in India at affordable prices. The organization works under the Ministry of Health and Family Welfare, and provides standards and measures for analysing the safety, efficacy and quality of drugs, cosmetics, diagnostics, and devices in India. CDSCO holds the responsibility of regulating the market approval of new drugs and clinical trials standards, supervising drug imports, and authorizing licenses to manufacture cosmetics and pharmaceutical drugs.

The National Pharmaceutical Pricing Authority (NPPA):

It was formed in 1997 under the Department of Chemicals and Petrochemicals, and is responsible for fixing or revising the prices of bulk drugs and formulations at certain intervals of time. It is also involved in timely updating of the list of drugs under price control format, on the basis of inclusion and exclusion of drugs in Indian pharmaceutical industry, as per the established guidelines. NPPA updates data on production, exports, imports and market share of pharmaceutical firms; and keeps a check on the availability of medicines in the country. It also provides information to the Parliament, on issues related to drug pricing. Along with the Department of Chemicals and Petrochemicals,

NPPA also undertakes policy, planning, and development and regulatory activities related to chemicals, petrochemicals and pharmaceuticals industries.

Other ministries such as Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry, and the Ministry of Science and Technology also play a role in the regulation process. The process for acquiring marketing approval for any new drug is managed by the coordination of different departments, along with the Drugs Controller General of India (DCGI), in situations when the application is for a biological drug or one based on recombinant DNA technology.

Department of Industrial Policy and Promotion, and the Directorate General of Foreign Trade:

Both these government organizations address issues related to industrial policies such as patent regulation, exports of drugs, etc., and are supported by the Ministry of Commerce and Industry, and the Ministry of Chemicals and Fertilizers.

Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Department of Science and Technology (DST) and the Department of Environment, Ministry of Environment and Forests: These organizations possess the right to regulate licensing and quality control issues related to drugs. The drug controllers of the state hold the authorization to provide licenses for the manufacture of approved drugs and analyse quality control, as per the Central Drug Standards Control Organization (CDSCO). The Ministry of Health and Family Welfare broadly analyses pharmaceutical issues within the larger context of public health.

National IPR Policy:

In October 2014, the Department of Industrial Policy and Promotion (DIPP) formed a six member Think Tank headed by Justice (Retd.) Prabha Sridevan to draft the National IPR Policy of India. This was done to solve issues, seek suggestions and comments from stakeholders on following areas:

- IP Awareness and Promotion
- Creation of IP
- Legal and Legislative Framework
- IP Administration and Management
- Commercialization of IP
- Enforcement and Adjudication
- Human Capital Development

This policy was constituted in India to promote knowledge, regarding how effective protection of IP rights, aids in making optimal use of the innovative and creative skills of people in India.

Regulatory framework for pharmaceutical sector in India was enacted/ revised after the TRIPS Agreement, fully complies with TRIPS Agreement, and hence provides a stable and effective legal framework for protection and promotion of IP

across various domains. This is clarified through an action taken by the Indian Patent Office (IPO), which rejected a key patent claim on Hepatitis C drug Sovaldi (sofosbuvir) manufactured by Gilead Sciences Inc.

Gilead's Sciences Inc., patent application was opposed by Hyderabad based Natco Pharma in 2014, on the grounds that Gilead's new drug molecule with little modification does not meet the criteria of novelty and significantly enhanced therapeutic efficacy, when compared with the original compound. Hence, Sovaldi failed to comply with legal requirements of Indian Patents Act, 2005 and Gilead's patent application was rejected, thereby reinforcing that India's patent regime for pharmaceuticals sector is robust and on track.

Additionally, Sovaldi (sofosbuvir) costs USD84,000 for 12 weeks therapy internationally. However, Gilead, was aware about the robustness of Indian Patents Act, and has planned to sell this drug in India at a price of USD900 for 12 weeks of treatment.

With effective implementation of IP regime in Indian pharma sector, many generic equivalents of Sovaldi would arise. As a result, the price of the drug formulation would further decline, despite prior licensing agreements of Gilead in India, thus providing a huge relief to a large number of patients suffering from Hepatitis C in the country.

3.4 IPR Pharma Policy and Regulatory Landscape Comparison India Vs. US Vs. Europe

Table 1: Comparative Analysis of IPR Landscape: India Vs. US Vs. Europe

Policy	India	US	Europe
Compulsory License (CL)	Used in the country as per section 84 of Patents Act, 1970.	CL is not supported, Presence of big pharmaceutical companies selling costly innovative drugs that are relatively affordable to the US patients.	Spread of many corporate giants, hence huge base for innovator drugs. Therefore, No CL required.
Evergreening Patent	Evergreening granted as per section 3(d) of the IP Act, and requires significant enhancement of the existing drug for awarding a patent.	Allows Evergreening of patents, thus allowing pharmaceutical companies to establish a monopoly over the patented drug.	Grants patents and allows evergreening of patents, thereby allowing monopoly in the European pharmaceutical sector.
Data Exclusivity	Does not exist in India.	5 years for new pharmaceutical entities, 3 years for new indications under pharmaceutical drugs.	8 Years (+ 2 years market exclusivity, + 1 year for new indication).
Pricing and Reimbursement	Lacks effective implementation of reimbursement schemes. Generic manufacturers are able to undercut the prices set by patentees to make the drug affordable to all. Drugs in India are price controlled with several low cost generic versions available for domestic and international market.	Drugs in the US are reimbursed based on weighted average prices and prices are bid competitively. The generics are priced after due consideration of the number of competitors for the brand equivalent.	EU lacks a harmonised system for pricing and reimbursement of pharmaceutical products and each EU member state holds different schemes and policies for reimbursement.

Source: TechSci Research

Pharmaceuticals industry presents a strong case for patents because of its capital-intensive nature and huge implications, thereby demanding better understanding of the current guidelines in the areas of patent policy.

When it comes to comparison between IPR Pharma Policy in India, the US and Europe, all three regions protect innovation through their own set of laws and regulations.

The Indian patent system has been criticised by foreign multinational companies for its grant of compulsory license to a generic drug manufacturer. Grant of compulsory license in India is beneficial to its low income class population, since it allows low-cost versions of a high-priced drug to be sold in the market, hence making the drug easily accessible to the general public. On the other hand, the US and Europe are against the adoption of compulsory licensing policy, since the manufacture of an innovative drug involves significant investments, and issue of compulsory license does not seem justified for the innovator drug company. At the same time, compulsory licensing acts as a barrier against subsequent improvements/ innovations in drugs. Along the same lines, evergreening of patents is allowed in the US and Europe, which means extension of the patent period for a particular drug with significant changes.

Such patent policies in the US and Europe result in monopoly that eventually harms consumers as they are liable to pay high prices for patented drugs.

India is a developing country and its IPR regime is also different from developed regions such as the US and Europe.

US and Europe have supported the New IPR regime under TRIPS, because of technological advancements and developments. Hence, India has become a country open to new technological and scientific system. Also, the US and Europe manufacturers are more into research and development and hence, witness a rise in the expenditure incurred on R&D, but earn comparatively less revenue due to compulsory licensing and lack of evergreening of patents in India.

Hence, if IPR protection in India is stronger, foreign pharmaceutical companies could be reassured regarding patent protection, recovering their costs, thereby encouraging them to innovate further.

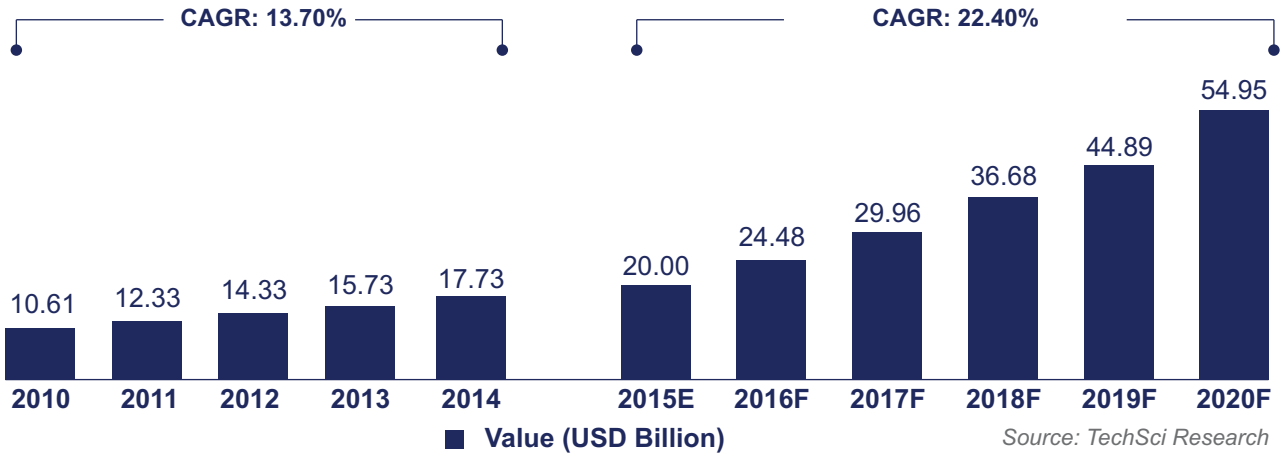
4 India Pharmaceutical Industry Market Outlook, 2020

4.1 Market Size and Forecast

Indian pharmaceutical sector has witnessed significant changes over last few years. From being mainly a generic manufacturer to providing complex drug formulations to foreign pharmaceutical markets, the sector has grown significantly. Indian pharmaceuticals market stood at approximately USD17.73 billion in 2014. The launch of Make in India campaign in 2014, is anticipated to further accelerate domestic manufacturing of pharmaceuticals. Moreover, growth in healthcare insurance industry in India is also expected to complement the growth of pharmaceuticals market in the country.

With a projected turnover of approximately USD54.95 billion in 2020, India is expected to be one of the top countries in the world by 2020, in terms of pharmaceutical production.

Figure 1: India Pharmaceuticals Market, By Value, 2010-2020F (USD Billion)



Source: TechSci Research

Growth Drivers for Indian Pharmaceutical Industry

Alternating disease profile and favorable demographics

Socio-economic changes and increasing urbanization in India, along with rising sedentary lifestyle are a few key factors driving India pharmaceuticals market. People in the country are increasingly suffering from lifestyle related diseases including obesity, diabetes, cardiac diseases, etc. The number of people in India suffering from these diseases is expected to double over the next five years, which is expected to drive the demand for quality, yet affordable treatment, in the country.

Active Involvement of Multinational Pharmaceutical Companies

Over the last few years, foreign pharmaceutical companies have entered the Indian pharmaceuticals market through major acquisitions, launches of new medicinal products, etc. For example, in July 2015, India's Torrent Pharma acquired Zyg Pharma Ltd., in order to launch new pharmaceutical products. Moreover, these foreign firms are adopting differential pricing in India, to deal with the issue of affordability in the country and strengthen their presence in the market. Multinational companies are launching patent-protected drugs in the Indian market at price points lower than those in developed markets. For instance, drugs like Diovan by Novartis, Januvia by Merck, Sharp & Dohme, and Galvus by Novartis, are being sold at 20% lesser price in India compared to their respective global prices. Additionally, the introduction of pricing and reimbursement schemes in India may benefit the pharma industry by increasing sales/profitability, since such schemes would improve the access of costlier medicines to common man.

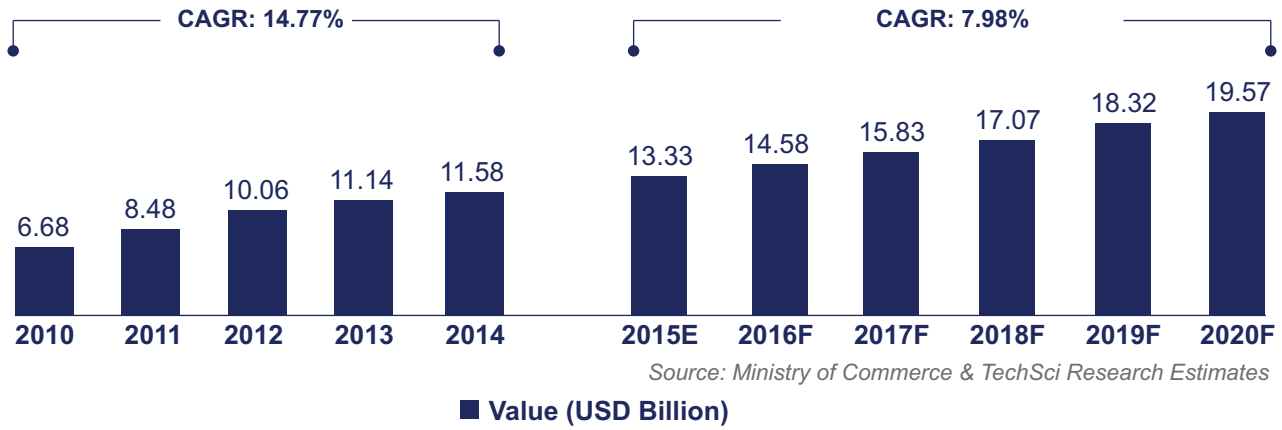
High Exports to Developed as well as Emerging Markets

Exports of pharmaceuticals are another major factor contributing to the growth of Indian pharma industry, with the US being the main export market for generic drugs. Besides developed countries, Indian pharma companies have established significant presence in a few fast-growing markets as well, including Russia, South Africa, Brazil, Mexico, and South-East Asia. These markets offer strong growth prospects for Indian drug manufacturers, in respect of providing generic versions to markets with high spending on healthcare, along with the added advantage of easier regulatory pathway.

Growing Mergers in Emerging Markets

Partnerships between Indian pharmaceutical companies and multinational companies of the emerging markets is increasing. Such ventures benefit the Indian companies from R&D and manufacturing point of view, while helping MNCs in establishing extensive marketing and distribution footprint in emerging markets.

Figure 2: India Exports of Pharmaceutical Products, By Value, 2010-2020F (USD Billion)



Source: Ministry of Commerce & TechSci Research Estimates

4.2 Exports and Forecast

Exports of pharmaceutical products from India grew at a CAGR of 14.77%,in value terms, during 2010-2014. Major export destinations for Indian pharmaceutical products are the US, South Africa and Russia. In 2010, India exported USD6.68 billion worth of pharmaceutical products, which included high exports of generic drugs, followed by active pharmaceutical formulations and traditional medicines. Strong domestic manufacturing base in India has helped with the development of a large number of generic drugs that are much cheaper when compared their branded versions. These generic versions of drugs arein high demand in countries with large diseased population, absence of drug manufacturing capacities, and low income price-sensitive markets.

In order to boost pharmaceutical exports, the Ministry of Commerce, in 2015, announced its plans to set up an inter-departmental committee, to look into export-related issues and awareness programmes in emerging markets like Africa.

Exports of pharmaceutical products are projected to grow at a CAGR of 7.98%, in value terms, during 2015-2020. Lower growth during 2015-2020, is anticipated on account of the regulatory scenario in top export markets of the US, Russia and Africa, where regulatory approvals are being delayed. In addition, consolidation of pharmacy players in North America has resulted in the presence of leading players that hold better bargaining power. Major instances are the acquisition of US distributor Celesio by US pharmacy McKesson's in 2014, and formation of a joint venture between the US wholesale distributor, Cardinal Health, and CVS Caremark in 2013. Consolidation of pharmacy players is leading to an increase in pricing

pressures for generic companies existing in the US market, which is expected to result in a decline in the year-on-year growth of pharmaceutical exports from India over the next five years.

Further, a steep decline in currency in emerging markets like Africa, Russia, Ukraine and Venezuela, is expected to add woes to drug manufacturing companies that supply pharmaceutical drugs to that region, and are unable to generate high revenues on account of selling their drugs at a low priced currency.

Country Analysis:

US: India is the largest supplier of medicine to the US, and pharmaceutical exports from India to the US rose from USD3.44 billion in 2013 to USD3.76 billion in 2014.

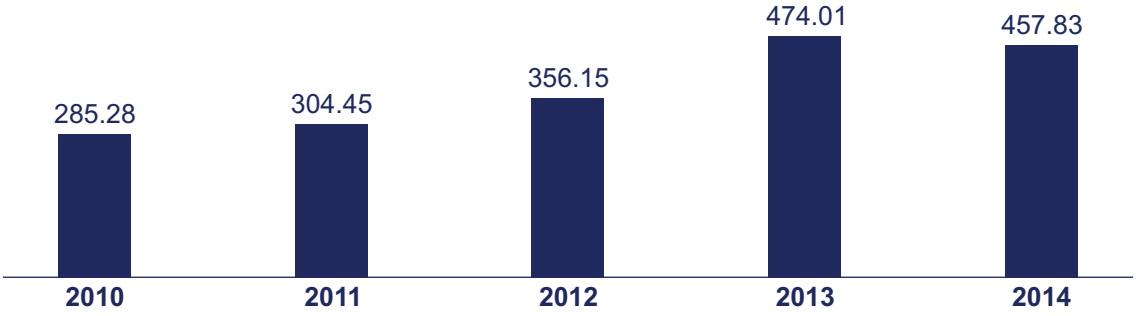
Table 2: India Exports of Pharmaceutical Products to the US, By Value, 2010-2014 (USD Billion)

Year	Export Value (USD Billion)	Year-on-Year Growth Rate
2010	1.83	–
2011	2.53	38%
2012	3.09	22%
2013	3.44	11%
2014	3.76	9%

Source: Ministry of Commerce

Pharmaceutical exports to the US are rising due to the increasing demand for high quality generic drugs in the market. However, the growth rate for exports of pharmaceutical products from India to the US is declining, due to increasing US Food and Drug Administration (FDA) scrutiny on the quality of pharma products coming from drug manufacturing plants located in India. In order to boost the growth rate of exports to the US, Indian companies will need to leverage their compliance to US FDA regulations.

Figure 3: India Exports of Pharmaceutical Products to South Africa, By Value, 2010-2014 (USD Million)



Source: Ministry of Commerce

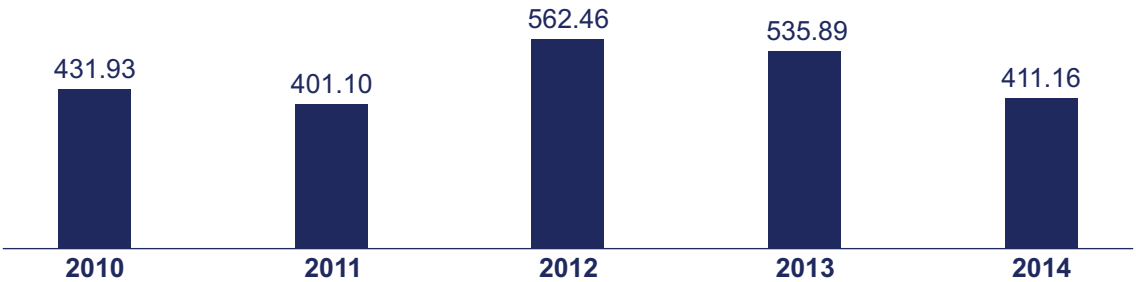
South Africa: South Africa is facing rising health concerns due to high prevalence of diseases. There exists a huge demand & supply gap for pharmaceutical products in the country. South Africa, being an under developed nation, the demand for affordable yet quality drugs is high. However, the exports of pharmaceutical products to Africa are being affected owing to the following barriers:

- Port delays and prolonged custom valuation.
- Testing and certification requirements may lead to rejection of products at ports, and the cost of returning consignments to India is huge.
- Registration process for any generic pharmaceutical drug is time consuming. In addition, obtaining regulatory approvals for any new generic drug could take as long as 3-5 years.

Further, the reach of Indian pharmaceutical companies, to doctors, hospitals, distributors in Africa is low, which also restrains exports of pharmaceutical products from India to Africa.

Russia: India exports antibiotics, hepatitis vaccines, medication for intestinal infections and anti-mycotics, to the Russian pharmaceuticals market. Prescription medicines account for the largest share in the total pharmaceuticals exported from India to Russia.

Figure 4: India Exports of Pharmaceutical Products to Russia, By Value, 2010-2014 (USD Million)

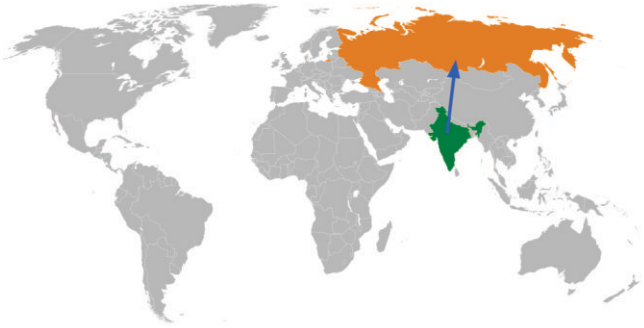


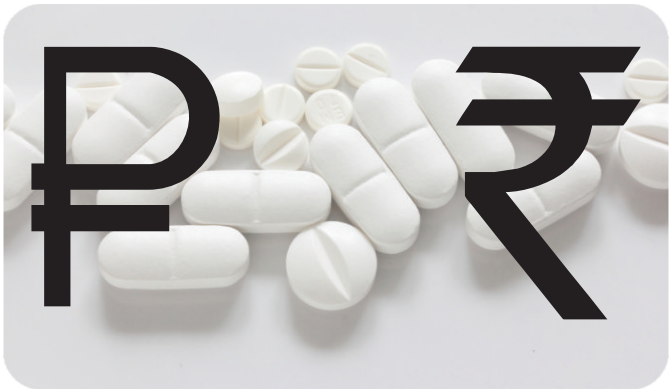
Source: Ministry of Commerce

The exchange rate crisis in the country is affecting the pharmaceuticals market in Russia. For example: Dr. Reddy's pharma revenues in Russia dropped 9% in dollar terms despite a rise of 30% in Rubles. Hence, stabilization of the currency is of utmost importance in generating revenues through exports.

In addition, many Indian companies are operating through the Pharmaceutical Benefits Program (PBP) and hospital tenders, for supplying vital and essential drugs, for which prices are then regulated by the Russian government.

However, some positive factors are expected to drive pharmaceutical exports to Russia. Indian pharmaceutical manufacturers are awaiting amendments to Law No. 61-FZ "On Circulation of Medicines" that will allow Indian companies to register new drugs and enter the Russian market, effective July 1, 2015. Such amendments will simplify the registration process for certain pharmaceutical products including reference drugs, essential drugs, etc. Also, the Russian government plans to modify the existing procedure for the examination of applications, to determine whether a pharmaceutical preparation can be considered an orphan drug. Since orphan drugs treat rare diseases, it is difficult to conduct clinical trials for such drugs and obtain registration in Russia. However, with the incorporation of amendments to Law No. 61-FZ, effective July 1, 2015, Russian authorities will begin accepting clinical trials conducted outside Russia. This amendment provides an edge to India to move on to becoming a base for conducting clinical trials, creating opportunities for Russia drug manufactures to file for more patents in India for any innovator drug.





4.3 Estimated Loss to Global Pharmaceutical Industry

Total Sales at Risk are estimated using the sales of the patented products that are due for expiry. The sales of patented product, one year prior to its expiry, are taken into account while calculating total sales at risk.

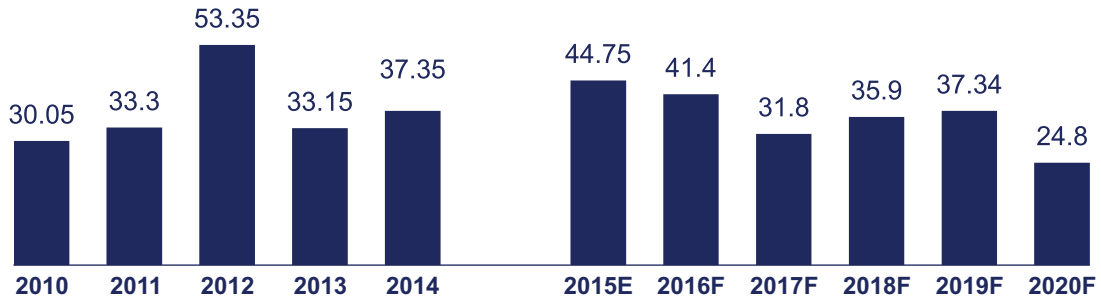
Sales Loss: Loss or drop in sales due to the expiry of patents, on account of drop in the selling price of the drug due to the launch of low-cost generic versions of the original drug.

Table 3: List of Key Drug Patents Expired Globally, 2014

Drug	Company
Copaxone	Teva Pharmaceutical Industries
Celebrex	Pfizer
Symbicort Turbuhaler	AstraZeneca
OxyContin	Purdue Pharma
Exforge	Novartis
Baraclude	Bristol-Myers Squibb
Epogen	Amgen
Valcyte	Roche
Risperdal Consta	Johnson & Johnson
Evista	Eli Lilly

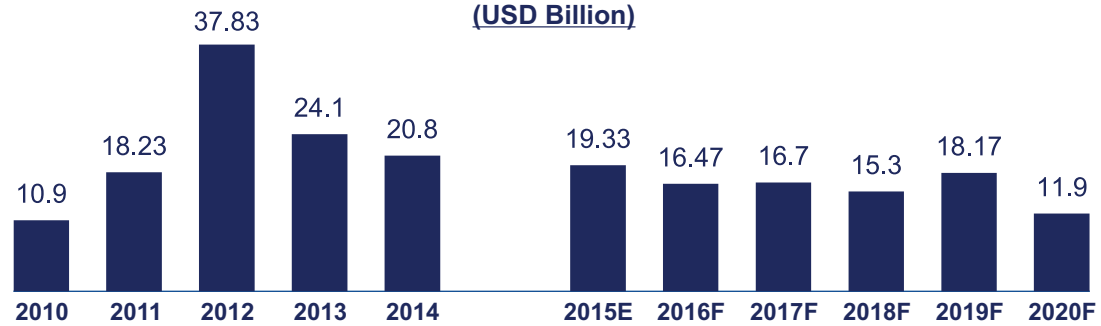
Source: TechSci Research

Figure 5: Global Pharmaceutical Sales at Risk, By Value, 2010-2020F (USD Billion)



Source: TechSci Research Estimates

Figure 6: Sales Loss to Global Pharmaceutical Industry, By Value, 2010-2020F (USD Billion)



Source: TechSci Research Estimates

4.3.1. Estimated Loss to US Pharmaceutical Industry due to lack of IPR

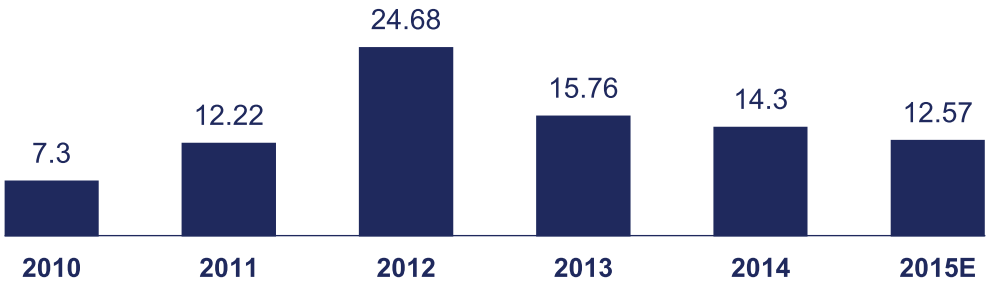
Of the top 10 drug manufacturing companies globally, 6 are located in the US. Due to the low number of patent expirations in 2014, there was less invasion of generic drug manufacturers in the US. The patent expiry of many innovator drugs post 2015 in the US will boost demand for generic versions of these off-patent drugs. Also, it is expected that the import of generic drugs from developing countries such as India, China etc. will witness robust increase in coming years.

Table 4: US Partial List of Key Drug Patent Expirations, 2014

Drug	Patentee	Indication
Namenda	Forest laboratories Inc	Alzheimer Diseases
Kaletra	Abott Laboratories	HIV Infections
Celebrex	Pfizer Inc	Colorectal Neoplasms
Relenza	GlaxoSmithkline plc	H1N1 Influenza
Velcada	Johnson & Johnson	Matle-Cell Lymphoma
Nexium	AstraZeneca PLC	Gastroesophogal Reflux

Source: TechSci Research

Figure 7: Sales Loss to US Pharmaceutical Industry, By Value, 2010-2015 (USD Billion)



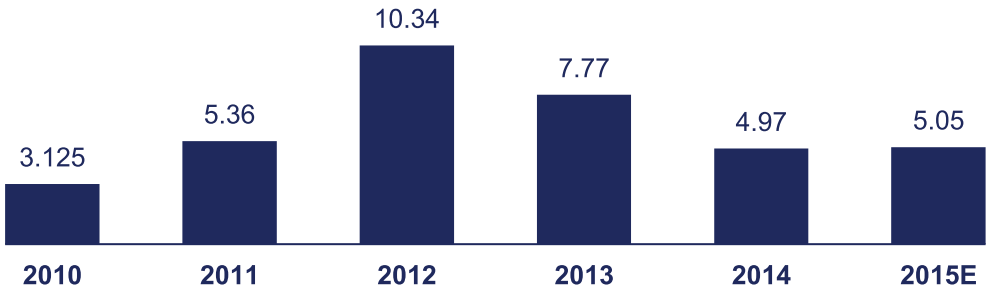
Source: TechSci Research Estimates

Table 5: US Partial List of Key Drug Patent Expirations, 2015 Onwards

Drug	Patentee	Indication
Abilify	Bristol-Meyers Squibb Co	Catalepsy
Zyvox	Pfizer Inc	Bacterial Infections
Glivec	Novartis AG	Acute lymphocytic leukemia
Sandostatin	Novartis AG	Islet cell Adenoma
Crestor	AstraZanca PLC	Hypertriglyceridemia
Cialis	Eli Lily & Co	Impotence
Revlimid	Celgene Corp	Myelophthisic Anemia
Alimta	Eli Lily & Co	Mesothelioma
Reyataz	Bristol Meyers Squibb Co	HIV Infections
Concerta	Johnson & Johnson	Hyperkinesis
Lyrica	Pfizer Inc	Diabetic Nephropathies

Source: TechSci Research

Figure 8: Sales Loss to Europe Pharmaceutical Industry, By Value, 2010-2015 (USD Billion)



Source: TechSci Research Estimates

4.3.2. Estimated Loss to Europe Pharmaceutical Industry Due to Lack of IPR

European industry invests approximately USD1.12 billion in research and development of each new medicinal product entering the European pharmaceuticals market. However, the region is becoming increasingly dependent on a high percentage of imported generic medicines.

European pharmaceutical industry particularly benefits from increasing number of supplementary private insurance schemes, and the rising standard of living, which are enabling patients to pay for medicines out-of-pocket. The lower utilization of generic medicines in European countries results in less saving on account of consumption of generic medicines.

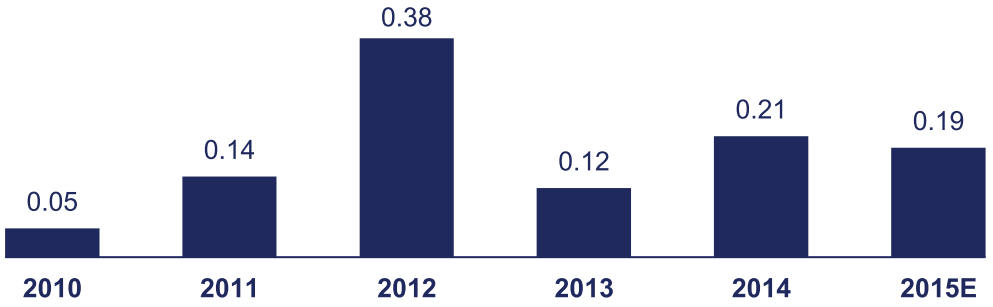
The introduction of the Bolar provision in Europe in 2004, has enabled European manufacturers to develop generic medicines within Europe prior to patent expiry, thereby contributing to the growth of European pharmaceutical industry.

Table 6: Europe Partial List of Key Drug Patent Expirations, 2015 Onwards

Drug	Patent Expiry Year
Olmesartan medoxomil	2017
Oesltamivir	2016
Pegfilgrastim	2017

Source: TechSci Research

Figure 9: Sales Loss to Indian Pharmaceutical Industry, By Value, 2010-2015 (USD Billion)



Source: TechSci Research Estimates

4.3.3. Estimated Loss to Indian Pharmaceutical Industry Due to Lack of IPR

The introduction of product patents on January 1, 2005 in the Indian patent regime, has created opportunities for multinational pharmaceutical companies for both contract manufacturing and high research and development, specifically, for conducting clinical trials.

Upon patent expiration of any patented drug manufactured by a foreign pharmaceutical giant, India benefits by launching the generic version of the drug, which is low priced compared to the branded innovator drug, and affordable to the general population of the country. This proves advantageous for the Indian pharmaceuticals market.

Table 7: Indian Partial List of Key Pharmaceutical Formulation Patent Expirations, 2015 Onwards

Pharmaceutical Formulation	Patentee	Patent Expiry Year
A Triazolo [4,5-d]pyrimidine compound of formula (ii)	AstraZenca AB	2018
A modified release pharmaceutical composition of bicalutamide	Panacea Biotech Limited	2026
Immune Stimulating And Controlling Composition Comprising Bacterial Chromosomal DNA Fragments And Non-Toxic Lipopolysaccharides	Eyegenic Inc.	2022
A Composition For Treatment Of Diabetes	Ayurvedic Life International LLC	2023
Methoxy Phosphonate Nucleotide Prodrug	Gilead Sciences, Inc	2020

Source: TechSci Research

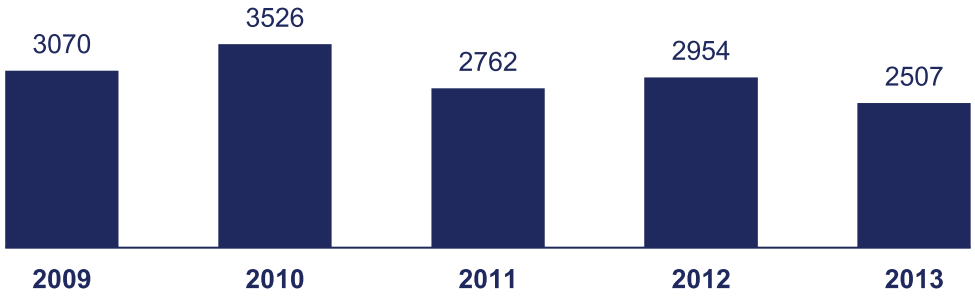
5 Current Status of Pharma Patents in India

Patent filing refers to the process of applying for a patent in the Indian Patent Office. Patent filing is required for the thorough examination of a product (in this case a pharmaceutical product), and checking its compliance with the Indian Patent Amendment Act, 2005. Patent filing in any country is a measure of the expansion of science and technology in that particular country.

Patent filing in India decreased at a CAGR of 4.94% during 2009-2013. However, of the total 42,951 patent applications filed in India in 2013, 10,941 were filed by Indian applicants, compared to the 9,911 applications filed in 2012. Hence, the domestic patent filing system has witnessed an increasing trend in patent filing over the last couple of years. In addition, introduction of quality system in Indian Patent Office, that involves adoption of patent manual, patent office procedures and various other guidelines associated with quality examination led to an increase in patent filings in India. A change in the patent application examining process has resulted in an increase in the number of drug patents filed, along with increased collaborations between innovator companies and generic drug manufacturers. Hetero Research Foundation was ranked among the top 10 Indian patent applicants in terms of applications filed in scientific and R&D domain, holding 17 pharma patents in 2013.

Therefore, Indian government is expected to continue revising the guidelines for examination of applications, to facilitate strong Intellectual Property Rights (IPR) for pharmaceuticals. An example is the change in section 3(d) guidelines of the Indian Patent Act across different provisions of the patent law, which does not allow incremental innovation to be patented. Such changes in the

Figure 10: India Drug Patents Filed, By Volume, 2009-2013 (Number of Patents)



Source: IP India

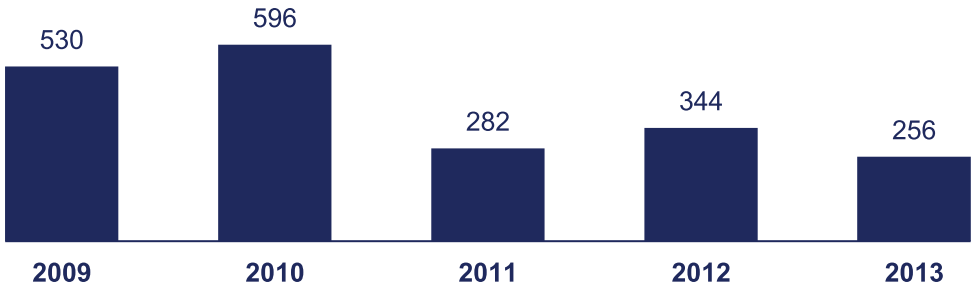
guidelines will bring clarity and uniformity in various provisions of the Indian patent law.

The proposed guidelines also lay emphasis on words such as "invention" and "inventive step", and elaborate on how these words need to be interpreted during examination of applications seeking patent protection on pharmaceuticals. Clarity on the guidelines and provisions of the Indian Patent Act would help innovative drug manufacturers to understand the eligibility of their innovation for patent protection.

With the introduction of uniform evaluation standards, it would be easier and convenient for pharma companies to apply for patents in India.

In 2005, when India amended its patent law and began granting product patents, only three pharmaceutical patents were granted. As patent approvals started increasing, patent challenges and litigation cases also started to pile up, thereby affecting the number of drug patents filed and granted in India. The number of drug patents granted in India decreased from 344 in 2012 to 256 in 2013.

Figure 11: India Drug Patents Granted, By Volume, 2009-2013 (Number of Patents)



Source: IP India

The Controller General of Patents, Designs and trademarks issued draft guidelines in 2014, with an aim to help examiners and controllers of the patent office to consistently achieve uniform standards while examining and granting patents. It is essential that the new guidelines complement the existing norms and procedures. The explanation of guidelines on certain provisions of patent law, relating to the grant of pharma patents, will enforce a standard procedure for evaluating and judging complex patent applications.

Due to the intricacies and implications involved in case of patent examinations of drugs and formulations, the Indian government is expected to formulate separate guidelines for pharma products.

Many domestic pharmaceutical companies such as Natco, Cipla and Glenmark dealt with multinationals including Novartis, Merck and others over patent infringement cases. In some cases, domestic generic drug manufacturers also approached the government and the regulatory authorities to issue compulsory license against patented medicines.

Case Studies

Case 1: Novartis Vs Union of India & Others

Product	Glivec
Plaintiff	Novartis AG
Defendant	Union Of India and Others
Year of Filing	1998
Year of Rejection	2013

In 1998, as per the TRIPS agreement of the World Trade Organization, Novartis filed a patent application for beta crystalline form of 'Imatinib Mesylate' in Glivec, which is an antileukemia drug. The patent filing was processed only in 2005, once the Patent Amendment Act, 2005 in India allowed for protection of product patents.

The patent application of Novartis was rejected by the Assistant Controller of Patents and Designs on the ground that the drug failed to meet the requirement of novelty and nonobviousness as per the Indian Patents Act, 1970.

Novartis then approached Madras High Court in 2006, but before the court could intervene in the case, it was transferred to Intellectual Property Appellate Board, which deviated from the decision given by the Assistant Controller of Patents and Designs, and stated that Novartis met the requirements of novelty and non-obviousness as per the Indian Patents Act. However, the Intellectual Property Appellate Board rejected the patent application on grounds that the drug was only a discovery of a new form of the original substance, which did not enhance the known efficacy of that substance, and Novartis could not present any proof indicating the significant efficacy of the drug. Failure to meet the requirements as per the Indian Patents Act, 1970, led to the rejection of patent application by the board.

Unsatisfied with the decision of the appellate board, Novartis filed an appeal in the Madras High Court stating that the requirement as per the Section 3(d) of the Act related to "enhanced efficacy" was unjustified. In 2007, the Madras High Court said the objective of the Section 3(d) was to prevent privileges obtained through intellectual monopoly, or evergreening of patents by companies, and stated that Novartis had the right to approach a court of law over the Appellate Board.

Eventually, in 2009, Novartis appealed directly to the Supreme Court with stress on their chief contentions, which included:

That Novartis had met the criteria of novelty; the beta crystalline form of the compound had enhanced efficacy over other variants of the same compound such as Imatinib or Imatinib mesylate, and hence all requirements of the section 3(d) of the Indian Patents Act, 1970 stood fulfilled.

That adequate research was done to selectively produce the beta crystalline form of Imatinib mesylate and it was worthy of being granted patent rights.

The contentions made by the Additional Solicitor General of India were:

Owing to the publications related to beta crystalline form of the compound in the 'Cancer Research and Nature' in 1996, and various other disclosures in Zimmerman patents and those by US Food and Drug Administration, the form is neither novel nor non-obvious.

Additionally, the efficacy requirement as stated in section 3(d) of the Act should be interpreted on lines of therapeutic efficacy and not merely physical efficacy.

Post scrutinising the contentions of the parties, the Supreme Court of India stated that Novartis failed to meet the requirement of novelty and that it failed to qualify the test of invention owing to various publications and disclosures already made about the beta crystalline form of Imatinib mesylate. Further, after interpreting the efficacy of the drug, the court held that physical efficacy of Imatinib mesylate in beta crystalline form is enhanced in comparison to other forms, but there was no substantive and conclusive evidence to prove that beta crystalline form of Imatinib mesylate will produce an enhanced or superior therapeutic efficacy.

Hence, Novartis failed to meet the requirements under Section 3(d) of the Indian Patent Act, owing to which the Supreme Court of India, confirmed the rejection of the patent application filed by Novartis for Glivec before the Indian Patent Office, in 2013.

Case 2: Bayer Vs Natco

Product	Nexavar
Plaintiff	Natco Pharma
Defendant	Bayer AG
Year of Filing	2008
Year of Rejection	2013

Germany based Bayer Corporation invented a drug called Sorafenib, that has been in use for the treatment of advanced stage liver and kidney cancer since 1990s. The company first filed the patent for the drug in 1999 in the US Patent and Trademark Office, and filed a PCT International Application in 2000. Post examinations under the provisions of Patent Act, 1970, the company was granted patent in 2008 in India. The company also received the regulatory approval for importing and marketing its drug under the brand name Nexavar.

Natco Pharma Limited, an Indian generic drug manufacturer, developed the method to manufacture Sorafenib, and was granted a license to manufacture and market the drug in tablet form in 2011.

The cost of the therapy through this drug is INR2,80,428 per month and INR 33,65,136 per year.

Natco Pharma Limited filed for a compulsory license in 2011 under Section 84(1) of the Patents Act, 1970. The company approached Bayer Corporation with a request for voluntary license, to manufacture and sell the drug at a proposed selling price of INR8,800 for one month treatment as compared to INR2,80,428 per month charged by Bayer Corporation. Natco Pharma raised the following issues against Bayer Corporation:

The reasonable requirement of affordable medicines for public have not been met. As per the statement given by Bayer Corporation, Bayer assumed that 80% of the patients suffering from liver and kidney cancer require Sorafenib. This means that demand for the drug is directly linked to the number of patients.

Table 8: Supply and Demand for Sorafenib in India, By Volume, 2008-2010 (Units)

Disease	Total Patients	Demand for 80% of Patients	Bottles Per Month (required)	Bottles Imported in 2008	Bottles Imported in 2009	Bottles Imported in 2010
Liver Cancer	20,000	16,000	16,000	Nil	~200	Unknown
Kidney Cancer	89,000	7,120	7,120			

Source: IP India

Bayer imports and sells the drug in India, and has not been involved in the manufacture of the drug in the country to make full use of the invention. Also, the drug is overpriced and not accessible to most of the people. Only limited stock of the drug is available; it is available in metro cities- Delhi, Mumbai, Chennai and Kolkata.

Bayer Corporation received the FDA approval for the drug in 2005, and launched the same in 2006 globally. However, despite filing an application for drug launch in 2006 globally, the company clearly neglected India, and did not launch the drug in India until 2009.

Natco Pharma requested for the grant of compulsory license and was granted the same by the General Controller of Patents in March, 2012.

Following were the terms and conditions acceptable to Natco as per the provisions in section 90 of the Indian Patent Act, 1970.

a) The right to manufacture and sell Sorafenib will be restricted to the Indian territory.

b) The drug will be manufactured only to meet the demand for patients suffering from renal and hepatic cancer.

c) Natco Pharma shall pay 6% of the product sales as royalty to Bayer Corporation.

d) The initial selling price of the drug will be INR 74 per tablet, which will cost INR8,800 for a pack of 120 tablets for a month's treatment.

e) Natco will provide the drug free of cost to at least 600 needy patients per year.

Case 3: F. Hoffmann-La Roche Ltd. Vs Cipla Ltd.

Product	Tarceva
Plaintiff	Roche Ltd.
Defendant	Cipla Limited
Year of Filing	2007
Year of Rejection	2009

Roche Ltd. and F. Hoffmann jointly own a patent with Pfizer Products Inc., for a small drug molecule called Erlotinib, also known as Human Epidermal Growth Factor Type-1/Epidermal Growth Factor Receptor (Her/Egfr) inhibitor. Erlotinib is used to kill certain cancer cells, while affecting less of normal human cells.

In accordance with the Indian Patent Act, 1970, La Roche Ltd., F. Hoffmann and Pfizer Products Inc., entered into Development Collaboration and Licensing Agreement, in 2001. This collaboration benefited La Roche Ltd., by giving it a license to use, sell, and offer Erlotinib for sale, which was marketed as Tarceva.

The Central Drug Standard Control Organisation, Directorate General of Health Services, Central Government had registered Tarceva in 2005, in the name of La Roche Ltd.

various quinazolin derivatives are already being sold in India for treating different types of cancer. Hence, Ernotinib is not patentable under Indian Patents Act, 1970.

La Roche Ltd., has been actively involved in the manufacture, marketing and sale of Tarceva in India, since 2006.

F. Hoffman along with Pfizer Products, Inc., was granted patent for Erlotinib in India in July 2007, by the Controller General of Patents, Trademarks and Designs, New Delhi.

In 2007, Cipla Limited, which has a registered office in Mumbai, planned to launch a generic version of the drug Ernotinib in India, and export the same to various other countries. In 2008, La Roche Ltd., got acquainted with the plans of Cipla Limited, to infringe La Roche Ltd.'s rights, La Roche Ltd., filed a complaint against Cipla Limited, seeking permanent injunction and damages.

Cipla Limited alleged that the drug approval was applied for in May 2007, and was granted in October 2007. Additionally, it had received an approval from Government of Goa to manufacture Ernotinib in different pack sizes. Further, Cipla Limited has been marketing and selling the drug under the brand name 'Erlocip' since December 2007.

Cipla Limited also filed for revocation of patent granted to La Roche Ltd., stating that Roche's patented product lacks inventive step in terms that Ernotinib is a Quinazolin derivative and various quinazolin derivatives are already being sold in India for treating different types of cancer. Hence, Ernotinib is not patentable under Indian Patents Act, 1970.

In addition, La Roche Ltd. sold the capsule at INR4,800 per tablet, whereas Cipla Limited sold it at INR1,600 per tablet. Hence, in the interest of public health, the drug should be made available at affordable prices.

After due consideration, the Delhi High Court concluded that there was no infringement of the legal rights of La Roche Ltd., by Cipla Limited. Additionally, the court held that Cipla Limited was unable to provide enough evidence to establish grounds for revocation of patent of La Roche Ltd., and case was dismissed in 2009.

Case 4: Merck Sharp & Dohme Corporation Vs Glenmark Pharmaceuticals Ltd.

Product	Sitagliptin
Plaintiff	Merck Sharp & Dohme Corporation
Defendant	Glenmark Pharmaceuticals Ltd.
Year of Filing	2007
Year of Dismissal	2013

Merck Sharp & Dohme Corporation (MSD) invented Sitagliptin, and was granted patent for the drug molecule in India in 2007. Sitagliptin controls Type-2 Diabetes Mellitus. The drug was sold in India under the brands Januvia and Janumet, after receiving marketing approval in India in 2008.

The company had also granted license to Sun Pharmaceutical Industries Limited in India, to sell Sitagliptin under the brand Ístavel and Sitagliptin-Metformin combination drug under the brand Istamet.

In the interest of the Indian public, MSD priced Januvia at INR 43 per tablet, which is roughly 1/5th of the price at which the drug is sold in the US.

Glenmark Pharmaceuticals Ltd., was granted a US patent for the process for manufacturing Sitagliptin in 2012, and was alleged by MSD to have knowledge of patented Siptagliptin and its pharmaceutically acceptable salts Sitagliptin Phosphate Monohydrate. MSD claimed that Glenmark used the active ingredient Sitagliptin molecule, which is infringing MSD's Indian patent rights. In addition, it also stated that Sitagliptin and any of its acceptable salts are covered by its patent claims. On account of this, making, using or offering for sale, importing into India by Glenmark under the brand Zita and Sitagliptin Phosphate Monohydrate and Zitamet, infringes the suit patent and all its claims.

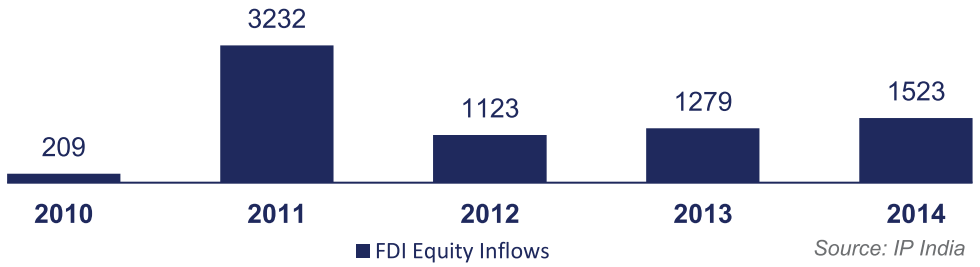
In 2013, the regulatory authorities ruled stating that Glenmark would be allowed to sell the products that are already in the market, and shall not further sell or distribute Zita and Zitamet in the Indian market.

6 Investment Landscape – Government and PPP

The Indian Government has been very active in boosting growth and investment in Indian pharmaceutical industry. It allows 100 per cent FDI (Foreign Direct Investment) under automatic route (without prior permission) in the pharmaceuticals sector. FDI favourably impacts the Indian pharma industry by providing access to more capital/funds for investing in R&D, which in turn, leads to creation of more IPR.

The act of protecting one's innovation through a patent has initiated investments from many multinational pharmaceutical companies in India. These MNCs are looking at India for its strength in contract manufacturing and as an attractive base for research and development (R&D), particularly for conducting clinical trials and other services.

Figure 12: India FDI Equity Inflows for Drugs and Pharmaceuticals, By Value, 2010-2014 (USD Million)



Source: IP India

The Department of Industrial Policy and Promotion (DIPP) data suggests that the drugs and pharmaceuticals sector in India has attracted FDI worth USD1,523 million during April 2014-March 2015.

Additionally, industrial licenses are not essential in India for most of the pharmaceutical products. Hence, drug manufacturers are free to develop any drug upon approval by the Drug Control Authority.

Indian and foreign pharmaceutical companies are progressing with rising patented drug launches in India. The Indian Patent Office granted 2008 patents between 2010 and 2013.

- The Department of Pharmaceuticals has drafted Pharma Vision 2020 document, with an aim to establish India as a leading county for end-to-end drug manufacturing and innovation. This initiative by the government aims at providing support to Indian pharmaceutical sector through state of - the - art infrastructure, internationally

competitive scientific research personnel for pharmaceutical R&D, and funding for research in the public and private sectors.

- Indian government is also preparing for a huge multi-billion dollar investment with 50 per cent public funding through its public private partnership (PPP) model, in order to enhance India's innovation capability. The aim is to push India into top five pharmaceutical innovation hubs by 2020, and establish global presence by launching one 1 out of every 5-10 drugs discovered in India at global level by 2020.

- The Government has been actively undertaking policy initiatives for growth of the pharmaceutical industry. One such initiative is tax-breaks in the pharmaceutical sector. There is also a weighted tax deduction at a rate of 150% for the research and development expenditure incurred. Steps to streamline methods for development of a new drug molecule, or clinical research, etc., have also been considered. Indian Government also launched two schemes including New Millennium Indian Technology Leadership Initiative in 2003, and the Drugs and Pharmaceuticals Research Programme in 1994-95, specially targeted at pharmaceutical research.

- The Central Drug Standard Control Organisation (CDSCO), which falls under the scope of the Ministry of Health and Family Welfare, is the main pharma regulatory body in India. The Drug Controller General of India (DCGI) presides over the CDSCO at both the central and state levels.

- Sun Pharmaceuticals acquired Ranbaxy Laboratories in 2015, in order to achieve full compliance with regulatory framework for drug manufacturing in India, meet expectations of Indian regulatory authorities, and increase R&D for launch of innovative products, thereby generating high revenues across India. Post-acquisition, Sun Pharmaceuticals now plans to invest USD300 million in R&D.

7 Competition: Investment Intense

India is home to approximately 8,000 small and medium enterprises (SME), which collectively account for around 70% of the total pharma companies in India. These SMEs are attracting investments in the Indian pharmaceutical industry, in the fields of contract research and manufacturing services, clinical research, etc., which would drive them to render a significant role in the transition of global pharmaceutical industry, wherein a number of blockbuster drugs are expected to go off patent in the coming years.

The Indian government has been supporting SMEs through several incentives including the development of pharmaceutical drug manufacturing SME clusters in various parts of the country such as Maharashtra, Pune, Vadodra, Ankleshwar, Aurangabad, Indore, etc. In 2010, Department of Pharmaceuticals (DoP), proposed a plan organize Cluster Development Proforma for Pharma Sector (CDP-PS) for enhancing the quality, productivity & innovative skills of SMEs in the pharmaceutical industry in India.

In 2013, Indian government had announced its plans to set aside USD74.9 million worth of funds for small and medium players in the pharmaceutical sector, to help SMEs upgrade their drug manufacturing facilities and boost drug production in India. Moreover, the Indian government plans to provide loans to these SMEs via certain banks to upgrade their drug manufacturing technology and quality.

Further, the Indian government has approved set up of six pharmaceutical parks in the country in 2015, with an estimated investment of USD26.9 million, which will promote domestic pharmaceutical manufacturing.

8 India IPR Pharmaceuticals Vision 2020

The Indian Government has been undertaking efforts to foster organised growth of the Indian pharmaceutical industry. In order to become a global leader in end-to-end manufacturing of drugs, the government launched Pharma Vision 2020. This initiative is aimed at reducing the approval time for launch of new pharmaceutical facilities, and as a result boost investments. In addition, efficient mechanisms such as the Drug (Prices Control) Orders and the National Pharmaceutical Pricing Authority (NPPA) have been implemented to counter the issues of affordability and availability of medicines.

This Vision entails the following missions:

- To make India a large global supplier of quality medicines at affordable prices.
- Prepare human resources for pharmaceutical industry and drug based R&D.
- Encourage Public - Private Partnership for the development of Indian pharmaceutical industry.
- Boost Pharma Brand India through international collaborations.
- Foster eco-friendly sustainable development of pharmaceutical industry.
- Promote availability, accessibility and affordability of drugs.

The Vision aims at bringing regulatory standards at par with the developed countries.

Further, all possible assistance needs to be provided to small-scale pharmaceutical manufacturers to promote compliance with standard manufacturing practices.

Pharmaceuticals Export Promotion Council of India, sponsored by the Ministry of Commerce, is working on imparting Intellectual Property Rights (IPR) knowledge to drug manufacturers. The Government is also supporting the pharmaceutical industry by providing guidelines on relevant documentation for product registration and subsequent exports.

9 Recommendations

Data Protection

Innovation is essential to the growth of Indian pharmaceutical industry. Bringing medicines to the market does not merely depend on manufacturing of the drug, but also on research and development, along with clinical trials to ensure quality, safety, and efficacy of the drug.

Manufacturers have to bear substantial costs in order to ensure that their innovation meets regulatory requirements, and this involves generating data through time and money consuming clinical evaluation. It is estimated that clinical evaluation can account for up to 40% of an innovator company's R&D costs. Thus, data protection is significant in order to prevent unfair commercial use of an innovator's research, and to strike a balance between the innovator's cost of bringing the drug to the market and a generic manufacturer's cost to enter the market.

It is recommended that data protection be introduced as an Intellectual Property Right in India, to benefit and drive the growth of pharmaceutical research and innovation. Such a policy would help India take advantage of its large pool of scientists, and attract foreign companies to invest in the country.

Strong Process and Response

Timeframe Manufacturers in the Indian pharmaceutical industry seek to achieve reduction in the timelines set for reviewing and responding to IPR filings.

Although, the Indian patent office is targeting at uniformity in patent application examinations, IPR standards will improve only when applications are processed and responded to, faster than they are being handled currently.

It is recommended that IPR for pharmaceuticals in India, be taken completely online to make the process more systematic and convenient for the industry. Digitization would strengthen online processing and maintenance of information database. Although, this would also require allocation of more personnel for patent examinations and training sessions to be organized as part of the resource development module, efficient management of IPR filings will help build a stronger IPR framework in India.

TechSci Research's Offerings

Market Exploration

- Market Landscaping
- Need Gap/Pain Point Analysis

Market Potential

- Market Size Estimation
- Market Forecasting

Product Development

- New Product Testing
- Price Sensitivity
- Market Segmentation

Positioning & Communication

- Pre & Post Communication /Advertising Effectiveness
- Event/ Promotion Effectiveness

Market Response

- Customer Satisfaction/ Tracking
- Usage& Attitude
- Brand Perception/ Tracking
- Consumer Behavior studies

Market Exploration

- Competitive Intelligence
- Competitors Profiling
- Competitive Benchmarking

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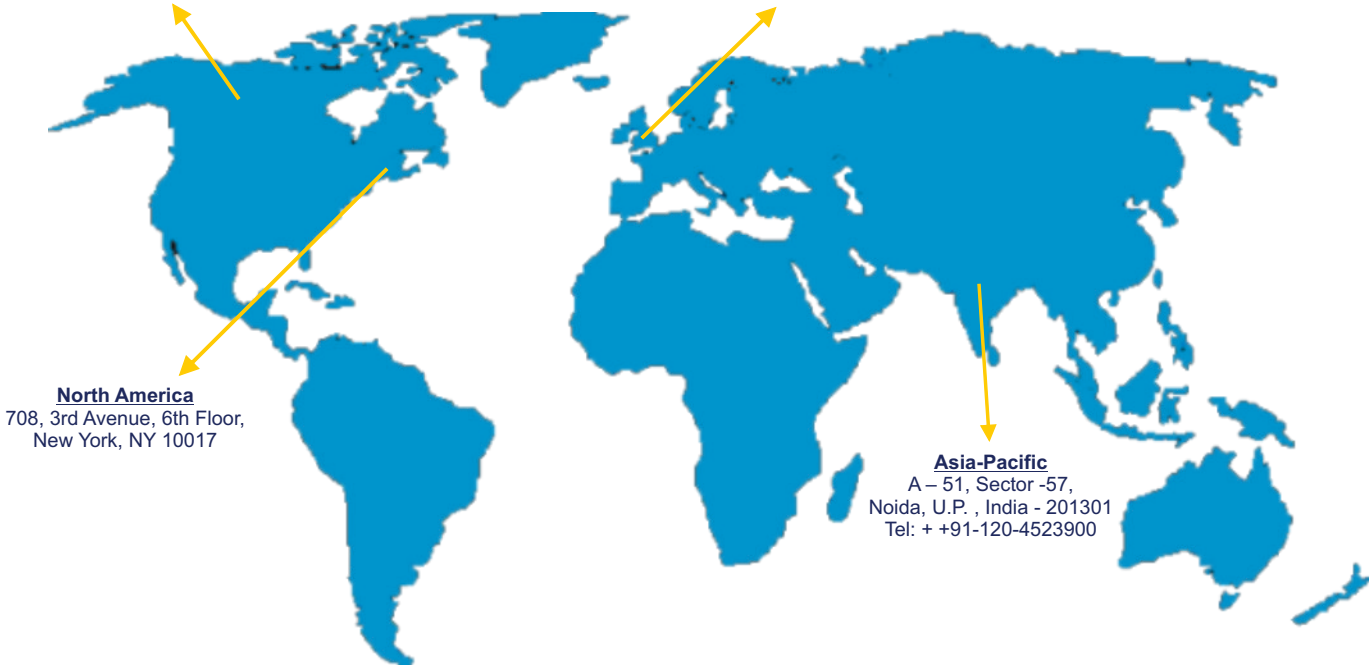

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ASSOCHAM: THE KNOWLEDGE ARCHITECT OF CORPORATE INDIA

EVOLUTION OF VALUE CREATOR

ASSOCHAM initiated its endeavour of value creation for Indian industry in 1920. Having in its fold more than 400 Chambers and Trade Associations, and serving more than 4,50,000 members from all over India. It has witnessed upswings as well as upheavals of Indian Economy, and contributed significantly by playing a catalytic role in shaping up the Trade, Commerce and Industrial environment of the country.

Today, ASSOCHAM has emerged as the fountainhead of Knowledge for Indian industry, which is all set to redefine the dynamics of growth and development in the technology driven cyber age of 'Knowledge Based Economy'. ASSOCHAM is seen as a forceful, proactive, forward looking institution equipping itself to meet the aspirations of corporate India in the new world of business. ASSOCHAM is working towards creating a conducive environment of India business to compete globally.

ASSOCHAM derives its strength from its Promoter Chambers and other Industry/Regional Chambers/Associations spread all over the country.

VISION

Empower Indian enterprise by inculcating knowledge that will be the catalyst of growth in the barrierless technology driven global market and help them upscale, align and emerge as formidable player in respective business segments.

MISSION

As a representative organ of Corporate India, ASSOCHAM articulates the genuine, legitimate needs and interests of its members. Its mission is to impact the policy and legislative environment so as to foster balanced economic, industrial and social development. We believe education, IT, BT, Health, Corporate Social responsibility and environment to be the critical success factors.

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ASSOCHAM represents the interests of more than 4,50,000 direct and indirect members across the country. Through its heterogeneous membership, ASSOCHAM combines the entrepreneurial spirit and business acumen of owners with management skills and expertise of professionals to set itself apart as a Chamber with a difference.

Currently, ASSOCHAM has more than 100 National Councils covering the entire gamut of economic activities in India. It has been especially acknowledged as a significant voice of Indian industry in the field of Corporate Social Responsibility, Environment & Safety, HR & Labour Affairs, Corporate Governance, Information Technology, Biotechnology, Telecom, Banking & Finance, Company Law, Corporate Finance, Economic and International Affairs, Mergers & Acquisitions, Tourism, Civil Aviation, Infrastructure, Energy & Power, Education, Legal Reforms, Real Estate and Rural Development, Competency Building & Skill Development to mention a few.

INSIGHT INTO 'NEW BUSINESS MODELS'

ASSOCHAM has been a significant contributory factor in the emergence of new-age Indian Corporates,characterized by a new mindset and global ambition for dominating the international business. The Chamber has addressed itself to the key areas like India as Investment Destination, Achieving International Competitiveness, Promoting International Trade, Corporate Strategies for Enhancing Stakeholders Value, Government Policies in sustaining India's Development, Infrastructure Development for enhancing India's Competitiveness, Building Indian MNCs, Role of Financial Sector the Catalyst for India's Transformation. ASSOCHAM derives its strengths from the following Promoter Chambers: Bombay Chamber of Commerce & Industry, Mumbai; Cochin Chambers of Commerce & Industry, Cochin: Indian Merchant's Chamber, Mumbai; The Madras Chamber of Commerce andIndustry, Chennai; PHD Chamber of Commerce and Industry, New Delhi.

Together, we can make a significant difference to the burden that our nation carries and bring in a bright, new tomorrow for our nation.

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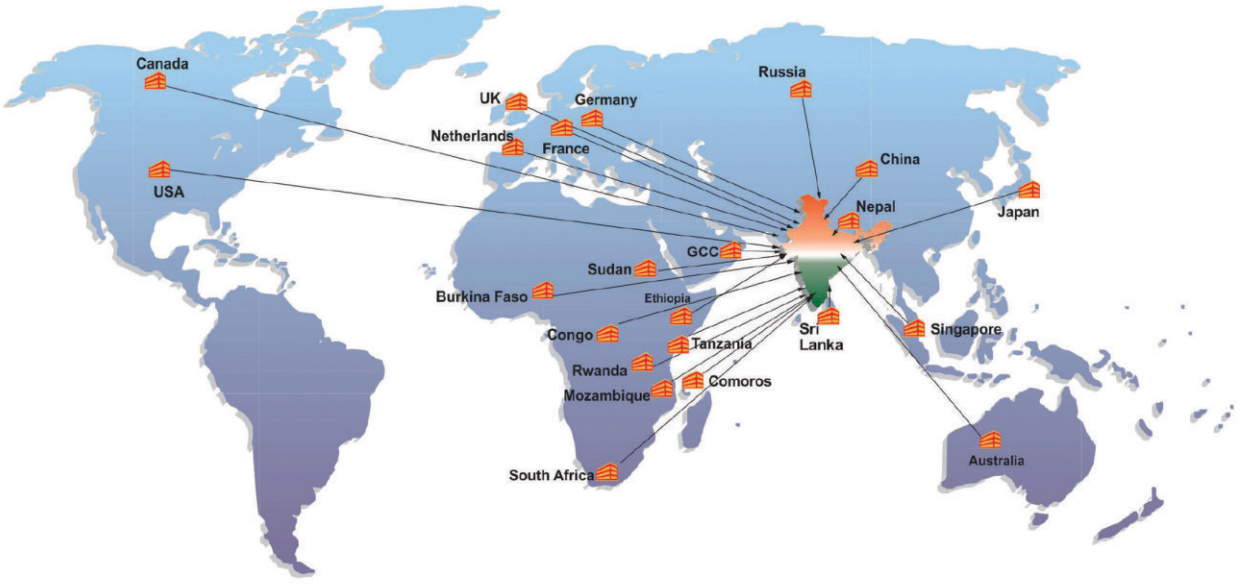
ASSOCHAM OVERSEAS OFFICES



The pictorial presentation of the world map does not purport to be the political and geographical maps of the world and India and is not drawn to scale. This is only indicative.

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