## Intellectual Property Rights galloping India the Success way: Study of Innovation and Competitiveness in the Indian Context

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## Abstract

The twenty-first century will be the century of knowledge, indeed the century of the intellect. Over the past 30 years, a number of major developments and transformations have taken

place in Indian markets. The choices available to Indian consumers have gone up drastically, be it the number of cars that people can choose from, the number of hospitals they have access to, or even the phones they use to connect to others or the Internet.

A nation's ability to translate knowledge into wealth and social good through innovations and delivering on competitiveness will determine its future. Innovation and competitiveness are linked at a national level as reflected by the strong correlation between the scores of countries on the Global Innovation Index and the Global Competitiveness. Thus innovations hold the key to the creation as well as processing of knowledge

In looking at the needs for India's next stage of growth, both industry and policymakers are focusing on strategies for fostering capacity for innovation. The link between innovation and competitiveness can be clearly demonstrated at a national level, and at a subnational level there is also a growing need for understanding the dynamics of innovation and to take requisite steps accordingly.

Addressing these competitiveness concerns will require acknowledging that innovation and intellectual property (IP) protection are linked, as today's invention is tomorrow's innovation. A stable intellectual property rights (IPR) regime is the foundation of a globally competitive nation, drawing in investments, specifically from FDI. Ultimately, India will do well in the long term if it enables a robust IP ecosystem and protects the IP of its own companies. It will also provide a stable framework for multinational companies wanting to enter India. Yet there are some critical impediments, which have hampered prospects for broader acceptance of IPR norms, and if addressed may enable greater economic cooperation between countries.

This research paper will look at the broad contours of India's current IPR regime and offers an assessment of the current situation as well as scenarios for continued advancement. It begins by looking at the overarching laws and protections afforded to specific types of IP in India. Then the present scenario has been examined, both theoretically as well as through data and analysis, to provide a quick assessment of India's present IPR regime. The next section looks at the case study of fostering innovation in India's pharmaceutical sector. Finally, this essay puts forth solutions for removing bottlenecks and helping India create a more robust and stable IPR regime.

## Introduction

In looking at the needs for India's next stage of growth, both industry and policymakers are focusing on strategies for fostering capacity for innovation. The link between innovation and competitiveness can be clearly demonstrated at a national level, and at a subnational level there is also a growing need for understanding the dynamics of innovation and to take requisite steps accordingly. With this in mind, a stable IPR regime is the foundation of a globally competitive nation, drawing in investments, specifically from FDI. Ultimately, India will do well in the long term if it enables a robust IP ecosystem and protects the IP of its own companies. It will also provide a stable framework for multinational companies wanting to enter India. Yet there are some critical impediments, which have hampered prospects

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Over the past 30 years, a number of major developments and transformations have taken place in Indian markets. The choices available to Indian consumers have gone up drastically, be it the number of cars that people can choose from, the number of hospitals they have access to, or even the phones they use to connect to others or the Internet. All this is a result of market oriented policy reforms that India undertook in the early 1990s, which enabled the telecom, automobile, and retail banking revolutions.

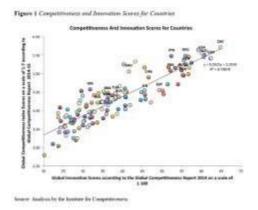
Innovation and competitiveness are linked at a national level as reflected by the strong correlation between the scores of countries on the Global Innovation Index and the Global Competitiveness Index (highlighted by Figure 1). At a subnational level there is also a growing need for understanding the dynamics of innovation and to take requisite steps accordingly. This idea starts with understanding that India's innovation is a varied reality and not a singular one, with Indian states growing at varying rates.

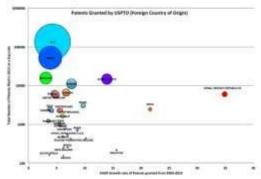
Yet despite these goals, the Global Competitiveness Report 2014–15 of the World Economic Forum shows India has dropped eleven places and is currently ranked 71 on a list of 144 countries considered for the study.1 Similarly, on the 2014 Global Innovation Index copublished by the World Intellectual Property Organization (WIPO), Cornell University, and Institut Européen d'Administration des Affaires shows that India is ranked 76th out of a total of 143 countries. In both of these rankings, India is placed somewhere in the middle, demonstrating the state of competitiveness and innovation in the country.

Addressing these competitiveness concerns will require acknowledging that innovation and intellectual property (IP) protection are linked, as today's invention is tomorrow's innovation. A stable intellectual property rights (IPR) regime is the foundation of a globally competitive nation, drawing in investments, specifically from FDI.<sup>3</sup> With this in mind, it is appropriate to acknowledge that the patent ecosystem in India has undergone a change since liberalization in order to cater to growing pressure from foreign countries and domestic companies wanting to export to markets where specific IP standards are required. Accordingly, India embraced the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the General Agreement on Tariffs and Trade (GATT), later renamed the World Trade Organization in 1994. This enabled India's IP system and companies to align themselves with global IP standards and supported an increasing move toward harmonization of its IPR regime to global standards. This has aided companies from countries abroad to have a level playing field against companies in India, competing against each other in a range of industries where patents are crucial to gain competitive advantage over peers.

## The IPR System in India

India's IPR system is underscored by a number of policies, laws, and international agreements that shape protections for domestic rights holders as well as how the country views its global obligations. The origins of India's





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Figure 2 Parents Granted by USPTO



Note: Data: Competitivesso: a balls could be and for sheat/ying user, for finitenag a competitive and macrotive seconomy. Searce SIG 2014 Sectory for Competitivesess, Judia

IPR system date back to British colonial rule, when as a colony the state enacted various rules and enforcement mechanisms pertaining to IP rights. Post-independence, India retained elements of these structures while updating some guiding regulations and other bureaucratic structures. As India moved toward liberalization, privatization, and globalization in the 1990s and later, Indian policymakers made further adjustments to keep up with growing needs of domestic and international stakeholders. As a result, today the statutory foundation of India's IPR regime is composed of a patchwork of key laws, governing bodies, and international agreements. These structures are further detailed below.

Importantly, patents have played a key role in changing national and global innovation landscape. The IPR trends during 2003-13, the approved rate of designs (87.38%) and trademarks registrations (65.54%) were significantly higher than the granted patents (22.06%) in India. Though, the patents (63.26%) have generated huge revenues than the designs, trademarks and GIs over last decade.Total number of patent grantsoverthe last 10 years was 69,745 out of which 21.71% were granted to Indians and 78.29% wereto foreign applicants. Maharashtra, Delhi and Southern states are leading in filing patents. Streams like chemical and mechanical engineering have produced highest number of patents whereas bio-technology and foods field were at the low preference.

### TYPES of Protected IP and Their Coverage by Indian Law

Under Indian law, there are six discernible major categories of innovations that are eligible for IP protections.

**Patents.**<sup>4</sup> Patents are a set of exclusive rights that are granted to an inventor for making, selling, or using an invention. Three core pieces of legislation—the Patents Act of 1970, Patent Rules of 2003, and Patent Amendment of 2005—form the basis of patent law in India.

The Patents Act has provisions with respect to compulsory licensing, the government's rights to fix prices for patentable goods, and use of some patents for the government only. The Patent Amendment also allows petitioners to file applications through electronic media (though the paper copy should be filed within one month).

Of note, over the course of several decades, India's patent law has taken a range of different approaches to the question of "process patents"-that is, whether processes (in contrast with products/molecules/chemical compounds) may be patented. The 1970 law granted process patents, and under its provisions, patents for chemicals, medicines, and drugs were initially granted for a period of fourteen years. This situation changed with the enacting of the Patent Amendment Act of 2002 and Patent Rules, which extended the patent term for a period of twenty years (as well as adding several other provisions related to fees and other questions). Yet with the Patent Amendment of 2005, process patents were completely abolished. This amendment has specific implications for chemical and pharmaceutical industries in particular, which will be discussed later.

**Trademarks.** Trademarks are recognizable signs, designs, or expressions that identify the goods and services of a producer as being distinct from another. In India, the Trademark Act of 1999 was a redrafted version of the Trademark and Merchandise Marks Act of 1958 that extended trademarks to services as well. Coverage for trademarks in India is ten years from the date the application is first made, while a 2010 amendment to the act enabled stakeholders to take advantage of provisions in the Madrid Protocol, a treaty that protects trademarks in multiple countries through the filing of one application with a single office.<sup>5</sup>

<sup>4</sup>Intellectual Property India, "The Patents Act, 1970," http://ipindia.nic.in/ipr/patent/patent\_Act\_1970\_28012013\_book.pdf.

This section also draws from N.K. Acharaya, Textbook of Intellectual Property Rights, 7th ed. (Hyderabad: Asia Law House, 2014). <sup>5</sup>"Madrid Protocol Takes Effect in India," World Intellectual Property Review, August 7, 2003, http://www.worldipreview.com/news /madrid-protocol-takes-effect-in-india.

**Copyrights.** Copyrights are a form of intellectual property that grants the creator of an original work exclusive rights for distribution for a limited period of time. The first copyright act came to India in 1914, which was modeled on the British Act of 1911. After independence, India's copyright regulations underwent thorough revisions, ultimately resulting in the Indian Copyright Act of 1957, which included (among other provisions) an extension of copyright protections to cover 50 years of protection. Since then, the act has been amended five times (most recently in 2012), with amendments covering further extensions of the copyright period, updates to reflect the digital environment, and coverage for other media forms, including radio diffusion, cinematographic film, and others.

**Geographic indicators.** A geographic indicator highlights a place of origin for a product and for the purpose of IP may be closely linked to the perceived value of the good. Examples of geographic indicators include Darjeeling tea, Banarasi Saree in India and Havana, and Champagne internationally. India's Geographic Indications of Goods (Registration & Protection) Act is relatively new, as it first passed in 1999 and was made in fulfillment of obligations under GATT, to which India is a signatory. The purpose is to exclude unauthorized persons from misusing geographic indicators and protecting consumers against deception from passing off goods not related to any geographic area. The registration of such indicators is valid for a period of ten years and can be renewed for further periods of ten years successively.

**Industrial Designs.** Indian law also safeguards IP protections for industrial designs based on the unique look or feel of an invention, such as its pattern, shape, or texture. For the purpose of registration, design-related IP protections can be conferred on fourteen classes of goods. Once registered the period of design is fifteen years with renewals at every five-year period. After fifteen years the design becomes open and public property.

<sup>6</sup> Additionally, within the field of design the Semiconductor Integrated Circuits Layout Design Act and Rules of 2000 seeks specific protections for semiconductors. This act gives an owner an exclusive right to create layout design for a period of ten years. The act enables the owner to commercially exploit their creation and, in the cases of infringement, seek relief under its provisions.

<sup>7</sup>**Agriculture.** Under Indian law, IPR related to innovation in crops and planting are covered by the Protection of Plant Varieties and Farmers' Rights Act of 2001. This act seeks to provide for the "establishment of an effective system for protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants." The duration of protection of registered varieties is different for types of crops. For trees and vines, the protection is eighteen years, while for other crops it is fifteen years. Similarly, for extant varieties, protection is fifteen years from the date of notification.

#### DOMESTIC Governance and Management of IPR

To execute and enforce the statutory guidelines above, India has a patchwork bureaucracy, which, as of this writing, is being updated under the guidance of a new national IP think tank. As such, the governance and management of IPR in India still currently falls under various offices that cut across different parts of the national government.

As can be seen in Figure 4 and Table 1, IP protection is the responsibility of a number of departments, including the Department of Education, the Department of Information Technology, the Department of Agriculture and Cooperation, and the Department of Industrial Policy and Promotion, among others. While several of these departments can be found within the Ministry of Commerce and Industry, other departments are housed in ministries from different parts of the national government.

A key figure in these structures is the Controller General of Patents Designs and Trademarks (CGPDTM), whose office falls under the Department of Industrial Policy and Promotion at the Ministry of Commerce and Industry. This office is a critical element of India's IP structure, as it is responsible for managing the broadest spectrum of IP types. As highlighted in Figure 4, the CGPDTM has various

<sup>6</sup>Ministry of Law, Justice and Company Affairs (India), The Semiconductor Integrated Circuits Layout-Design Act, 2000, Act of Parliament no. 37 of 2000, no. DL-33004/2000 (New Delhi, September 4, 2000), http://sicldr.gov.in/Resources/SICLDRA1.pdf. <sup>7</sup>Ministry of Law, Justice and Company Affairs (India), The Protection of Plant Varieties and Farmers' Rights Act, 2001, Act of Parliament no. 53 of 2001, no. DL-33004/2000 (New Delhi, October 30, 2001), http://agricoop.nic.in/PPV&FR%20Act,%202001.pdf. registries under it, namely trademark and geographic indicator registries. The trademark registry is located at five regional centers, and the geographic indicators registry is located at Chennai. Similarly the CGPDTM has four regional patent offices under it, located at the four metropolitan centers, namely Mumbai, Chennai, Delhi, and Kolkata. The patent information system at Nagpur also reports to the CGPDTM. In addition to the above registries and offices, there is also a national institute for IP management under the CGPDTM.

### Figure 4 Office Structure of CGPDTM



Source: Controller General of Patents, Designs and Trademarks (India), Annual Report 2012–2013 (New Delhi,2013), http://ipindia.gov.in/cgpdtm/Annual Report\_English\_2012\_2013.pdf.

LEGISLAtion	Department	Agency/ Body		
Detents Act 1070 (amonded in 1000, 2002	Department of Industrial			
Patents Act, 1970 (amended in 1999, 2002	Department of Industrial	Controller General of Patents,		
and 2005)	Policy & Promotion	Designs and Trademarks (CGPDTM)		
	Department of Industrial	Controller General of Patents,		
Designs Act, 2000				
	Policy & Promotion	Designs and Trademarks (CGPDTM)		
	Toney a Tromotion			
	Department of Industrial	Controller General of Patents,		
Trade Marks Act, 1999 (amended in 2010)				
	Policy & Promotion	Designs and Trademarks (CGPDTM)		
Geographical Indications of Goods	Department of Industrial	Controller General of Patents,		
Geographical indications of Goods	Department of Industrial	Controller General of Patents,		
(Registration & Protection) Act, 1999	Policy & Promotion	Designs and Trademarks (CGPDTM)		
Copyright is protected through Copyright	Department of Higher			
		Copyright Office		
Act, 1957, as amended in 2012	Education			
	Education			
Layout of transistors and other circuitry				
elements is protected through The Semi-	Department of Information	Semiconductor Integrated Circuits		
conductor Integrated Circuits Layout-	Technology	Layout Design Registry		
Design Act, 2000				
Design Act, 2000				
New varieties of plants are protected				
	Department of Agriculture	Plant Varieties and Farmers' Rights		
through the Protection of Plant Varieties and				
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Farmers' Rights Act, 2001				
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#### International Protections for IPR: TRIPS

Finally, the third pillar of India's IPR regime is defined as its obligations under international frameworks. On this front, perhaps the most pressing and important agreement for understanding India's engagement in the international IPR system is its response to TRIPS. India's position with respect to TRIPS began with being defensive about the country's obligations and its IPR developments, slowly changed to moderation, and finally changed to being aggressive with respect to some specific dimensions.

<sup>8</sup>Initially, India held a more defensive view of the international IPR regime. In the 1970s, it passed through a phase of "know-why" oriented technological learning, when the country focused technological development on building up process capabilities through reverse engineering. This phase was possible because India's 1970 Patent Act allowed for this view of "know-why" development coupled with emerging IPR culture, such as by allowing process.

<sup>9</sup>patents on chemical substances. Internationally, this put the country at odds with the suggested requirements of TRIPS after 1994 when the agreement came into force. Ultimately, India saw a proliferation of its "process" industry during the initial years from the 1970s onwards, while at the international level pharmaceutical companies already wanted a more stringent IPR regime. India's pharmaceutical industry initially was strongly opposed to the idea of product patents and led the push for defense against TRIPS.

<sup>10</sup>During the 1990s, the pharmaceutical industry's business interests in India became sharply divided, with some multinational corporations wanting to export to overseas markets, utilizing India's largely cheap labor. These corporations came out strongly in support of the TRIPS Agreement. A large number still did not feel that they had adequately caught up with the rest of the pack and wanted the process patent regime to be extended.

India accordingly signed the TRIPS Agreement in 1994. Mentioned in the GATT treaty was also that member countries conform to their national legislations on IPR and to the conventions and suggestions contained in the treaty. The declaration recognizes members' "right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." It also grants each member the "right to determine what constitutes a national emergency or other circumstances of extreme urgency" in implementing TRIPS.

### Analysis

The acts and legislations of India at present are increasingly coming in contact with international conventions, and in the years ahead further harmonization with the international system is expected. The IP system is in a state of transition, and a look at its facts and figures offers insights into the functioning of the system under the boundaries of these key legislations and treaties.

### Trends in IP Activity<sup>11</sup>

The functioning of the IP ecosystem in India can be gauged effectively from the trends in IP activity. The section looks at four kinds of IP that fall under the CGPDTM. These statistics reflect trends pertaining to various IP activities as reported by different offices/registries. What follows are some of the trends that have been observed in the IP filings and grants of the CGPDTM over the past few years.

#### **Paten**Ts

The total number of patent applications filed rose from 2,613 in 2003–4 to 43,674 in 2012–13. Though these figures are far smaller than commensurate figures for China and the United States (whose total patent applications were 825,136 and 571,612, respectively, in 2013). India's patent office is eighth overall in patent filings in 2013 according to the WIPO, ahead of patent filings in offices of Canada and Brazil with filings of 34,741

<sup>&</sup>lt;sup>8</sup>A "know why" capability is in contrast with a "know how" capability. A know-why capability is based on understanding the process and reverse engineering, while a "know-how capability is based on increasing the production efficiency.

<sup>&</sup>lt;sup>9</sup>A process patent is in contrast with a product patent. A process patent is granted for a manufacturing process that is different from the original process, while a product patent is granted for only a product that is different from the original product.

<sup>&</sup>lt;sup>10</sup>"Declaration on TRIPs Agreement and Public Health," World Trade Organization, November 20, 2001, http://www.wto.org/english/ thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.htm.

<sup>&</sup>lt;sup>11</sup>This section draws heavily from various rounds of annual reports from the Indian Controller General of Patents, Design and Trademarks, Department of Industrial Policy and Promotion, Ministry of Industry and Commerce, all of which are accessible at http://ipindia.gov.in/main\_text1.htm.

and 30,884 applications, respectively. The WIPO data included applications by foreign companies through the Patent Cooperation Treaty route as well as by Indian institutions, individuals, and companies. The patent grants have likewise increased from 2,469 to 4,126 during the commensurate period. These grants are also miniscule when compared with international patent offices.

<sup>12</sup>At a subnational level, Maharashtra reported the maximum number of filings, which has remained unchanged in the years 2007–8 and 2012–13. Delhi and Karnataka are other subnational regions doing well on patent filings. Also, it is worth noting that the states that have a higher GDP tend to have higher patent filings. This trend is indicated by an  $R^2$  value of 0.76. One needs to look at the patent innovation in India according to the state categorizations, as this helps one understand the dynamics of innovation in a much better manner.

<sup>13</sup>While looking at the international filings, it is interesting to note that the maximum filings occur through the Patent Cooperation Treaty (PCT) route that is roughly 85% of all the applications made by nonresidents in 2012–13. The United States reported the maximum number of PCT filings in India, and the top three countries for both 2007–8 and 2012–13 were the same, with the United States, Germany, and Japan accounting for more than 50% of patent filings in India.

## Trademarks

The various registries of trademarks have reported an increase in the number of trademarks filed from 92,251 to more than double at 194,216. The registered section however shows a haphazard pattern with registrations moving up and down in a random manner, suggesting limited insights from an analysis of this raw data. **DESIGN** 

Designs have also seen an increasing trend from 2003–4 to 2012–13. The number of designs filed has increased from 3,357 to more than twice that number at 8,337. The designs granted have also increased significantly from 2,547 in 2003–4 to 7,252 in 2012–13.

## **Geographical Indicators**

Geographical Indicators have registered an incoherent pattern over the past few years since the act came into being in 1999 and the GI registry was established. Over the past five years, 132 indicators have been registered.

Year	Patents	Designs	Trademarks	GIR	PIS/IPTI	Total
2003-2004	16,53,66,982	53,01,165	27,06,75,959	45,000	0	44,13,89,106
2004-2005	40,72,54,457	64,59,282	37,94,85,262	1,10,000	0	79,33,09,001
2005-2006	93,64,28,079	75,60,563	49,75,09,410	2,18,090	1,02,911	144,18,19,053
2006-2007	1,06,34,17,330	1,00,80,300	55,79,28,069	3,47,370	1,56,338	163, 19, 29, 407
2007-2008	1,30,24,08,136	1,00,23,450	63,00,36,633	4,18,960	2,78,542	194,31,65,721
2008-2009	1,56,14,63,824	1,23,66,048	69,15,02,297	4,63,360	5,05,510	226,63,01,039
2009-2010	1,42,61,73,541	91,45,030	71,61,25,436	4,89,440	5,98,954	215,25,32,401
2010-2011	1,58,78,10,509	1,06,26,985	86,15,00,000	2,75,706	5,39,585	246,07,52,785
2011-2012	1,64,40,23,224	1,26,11,650	1,03,53,00,000	48,08,265	6,43,000	269,73,86,139
2012-2013	1,70,47,84,657	1,29,32,740	1,10,45,00,000	8,77,750	1,45,712	282,32,40,859
Total	1179,91,30,739	9,71,07,213	674,45,63,066	80,53,941	29,70,552	1865,18,25,511

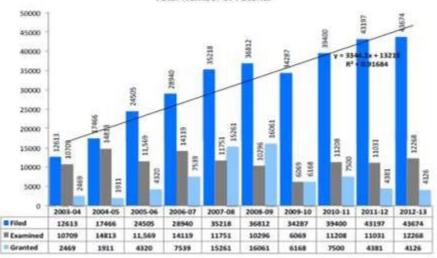
COMPARISON of the revenue generated for	the LASt 10 years
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Source: Annual Reports of IPR

<sup>12</sup>An R2 value is a measure of goodness of fit of a linear regression. The value R2 is a fraction between 0.0 and 1.0 and has no units. An R2 value of 0.0 means that knowing X does not help one predict Y. There is no linear relationship between X and Y, and the best-fit line is a horizontal line going through the mean of all Y values. When R2 equals 1.0, all points lie exactly on a straight line with no scatter. An R2 value of 0.73 is strong enough to predict a correlation between X and Y.

<sup>13</sup>To know more about the PCT route, see "The PCT Applicant's Guide,"WIPO,http://www.wipo.int/pct/guide/en/gdvol2/pdf/gdvol2.pdf.

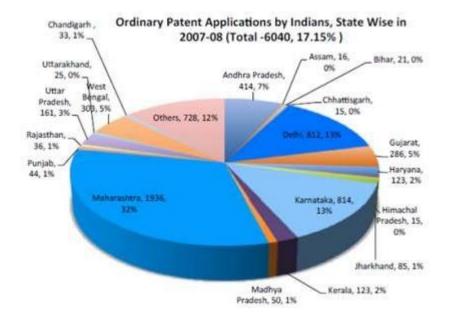




**Total Number of Patents** 

Source: Annual reports (various rounds), CGDPTM.





Source: Annual reports (various rounds), CGDPTM.

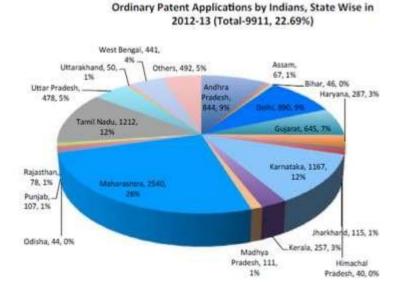
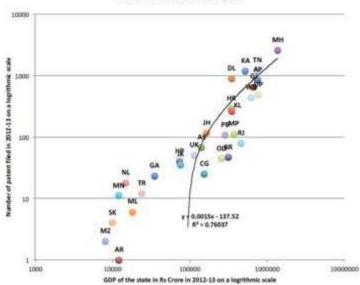


Figure 7 Ordinary Patent Applications by Indians, State Wise in 2012-13.

Source: Annual reports (various rounds), CGDPTM.

Figure 8 Patent and GDP Data for States (2012-13)



Patent and GDP Data for States

Source: Annual reports (various rounds), CGDPTM; and Ministry of Statistics and Programme Implementation.

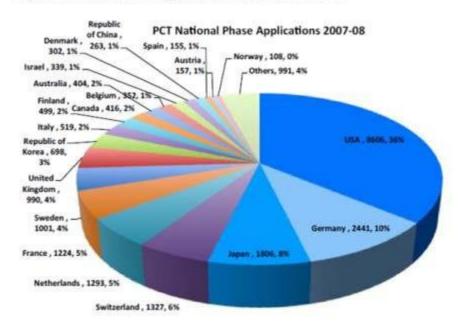


Figure 9 PCT National Phase Applications, Country Wise in 2007-08

Source: Annual reports (various rounds), CGDPTM.

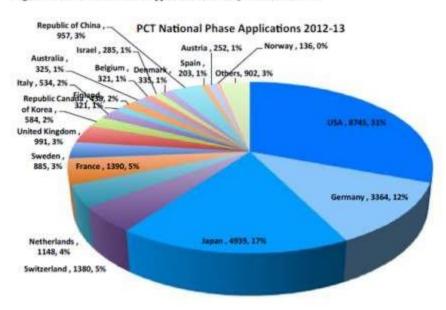


Figure 10 PCT National Phase Applications, Country Wise in 2012-13

Source: Annual reports (various rounds), CGDPTM.

### Analysis

All these trends demonstrate that the present IPR regime, especially after India became a signatory to TRIPS, has strengthened compared with the past and is bound to strengthen moving ahead in light of greater harmonization between IPR regimes across the world. IPR in years to come might see an increasing national participation that will auger well for the IPR ecosystem to develop to its full potential in India. This trend will also be important from a future competitiveness point of view. Countries that have had stronger IPR regimes have tended to develop more than countries with an absence of robust IPR protections.

## Case Study: Fostering Innovation in India's Pharmaceutical Sector<sup>14</sup>

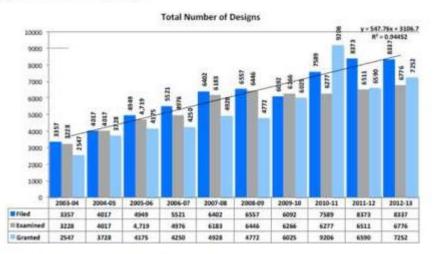
While the preceding sections looked at India's IP protections from the vantage point of individual types of



Figure 11 Total Number of Trademarks

Source: Annual reports (various rounds), CGDPTM.





Source: Annual reports (various rounds), CGDPTM.

IP, it is helpful to view India's IPR regime in the context of a particular industry, to see how a stronger regime might have larger impacts on India's macro economy. With this in mind, the sector that could witness a lot of changes with the emergence of an IPR regime in India is the pharmaceutical sector. In this sector, patents are crucial for gaining competitive advantage, and India's promotion of IP protections is of critical importance to this sector's health and continued development.

The pharmaceutical industry in India at present is highly fragmented and clustered and faces stiff competition. The industry is clustered in the western states of Gujarat and Maharashtra and also in the southern belt of Andhra Pradesh and Tamil Nadu. It is highly fragmented and had over 10,000 pharmaceutical manufacturing units in 2007. At a high level, a typical global pharmaceutical company has a value chain that consists of three core steps where value is added to a product: (1) drug discovery and development, (2) clinical trials, and (3) manufacturing. Most Indian companies are not really entering the market

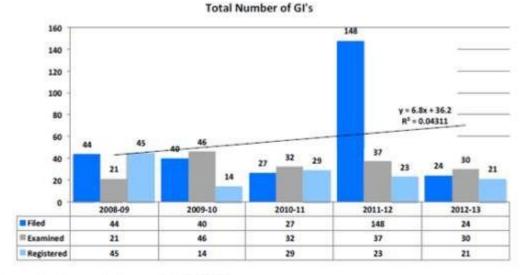


Figure 13 Total Number of Geographic Indications

#### Source: Annual reports (various rounds), CGDPTM.

for drug discovery and development at this point and prefer to copy from existing drug concepts. They go in after this for equivalence testing at the clinical trial stage and f inally go in for manufacturing active pharmaceuticals, which are then added to formulations to yield final pharmaceutical drugs.

Additionally, the overall focus of Indian companies is still on operations and marketing without looking at the technology development that is a strategic imperative for most multinationals. This focus arose from the 1970's process patent regime. Over time it also led to a mindset termed "jugaad innovation."<sup>15</sup> Jugaad is a Hindi word that literally means "makeshift" and roughly translates as "overcoming harsh constraints by improvising an effective solution

#### Geographical Indicators

Geographical Indicators have registered an incoherent pattern over the past few years since the act came into being in 1999 and the GI registry was established. Over the past five years, 132 indicators have been registered.

<sup>14</sup>This section draws heavily from the pioneering work of Professor Michael E. Porter of Harvard Business School. http://kkozak.wz.cz/ Porter.pdf; and Vivek Wadhwaand et al., "The Globalization of Innovation: Pharmaceuticals: Can India and China Cure the Global Pharmaceutical Market," Kauffman, June 2008; For a detailed analysis, see appendix 1 and 2 for recent developments and conceptual frameworks as applied to the pharmaceutical industry in India.

<sup>15</sup>For more on Jugaad Innovation, see http://jugaadinnovation.com.

### Analysis

All these trends demonstrate that the present IPR regime, especially after India became a signatory to TRIPS, has strengthened compared with the past and is bound to strengthen moving ahead in light of greater harmonization between IPR regimes across the world. IPR in years to come might see an increasing national participation that will auger well for the IPR ecosystem to develop to its full potential in India. This trend will also be important from a future competitiveness point of view. Countries that have had stronger IPR regimes have tended to develop more than countries with an absence of robust IPR protections.

## Case Study: Fostering Innovation in India's Pharmaceutical Sector<sup>14</sup>

While the preceding sections looked at India's IP protections from the vantage point of individual types of IP, it is helpful to view India's IPR regime in the context of a particular industry, to see how a stronger regime might have larger impacts on India's macro economy. With this in mind, the sector that could witness a lot of changes with the emergence of an IPR regime in India is the pharmaceutical sector. In this sector, patents are crucial for gaining competitive advantage, and India's promotion of IP protections is of critical importance to this sector's health and continued development.

The pharmaceutical industry in India at present is highly fragmented and clustered and faces stiff competition. The industry is clustered in the western states of Gujarat and Maharashtra and also in the southern belt of Andhra Pradesh and Tamil Nadu. It is highly fragmented and had over 10,000 pharmaceutical manufacturing units in 2007.

At a high level, a typical global pharmaceutical company has a value chain that consists of three core steps where value is added to a product: (1) drug discovery and development, (2) clinical trials, and (3) manufacturing. Most Indian companies are not really entering the market for drug discovery and development at this point and prefer to copy from existing drug concepts. They go in after this for equivalence testing at the clinical trial stage and f inally go in for manufacturing active pharmaceuticals, which are then added to formulations to yield final pharmaceutical drugs.

<sup>15</sup>Additionally, the overall focus of Indian companies is still on operations and marketing without looking at the technology development that is a strategic imperative for most multinationals. This focus arose from the 1970's process patent regime. Over time it also led to a mindset termed "jugaad innovation." Jugaad is a Hindi word that literally means "makeshift" and roughly translates as "overcoming harsh constraints by improvising an effective solutionusing limited resources."

<sup>16</sup> It is a temporary substitute and not formally an actual innovation that is generally looked upon as a systematic and process-driven activity. Jugaad as a mindset has caused shortcuts to emerge, which have resulted in poor patenting rates in India. This mindset is in contrast to the general value chain for most global pharmaceutical companies.

However, a number of Indian companies also increasingly see the value of this drug discovery route in trying to move up the value chain. In addition, a lot of strategic alliances have emerged between Indian companies and their global counterparts. Indian drugs are also under a price control regime and face regulatory issues, with the recent acquisition of Ranbaxy by Sun Pharma coming under investigation by the Competition Commission of India. The acquisition is now complete.<sup>17</sup>

<sup>18</sup>This is a step in the right direction that was taken to promote competition and not let the consumer suffer due to acquisition. However, the Indian pharmaceutical industry still is mostly operative at the low end of the value chain, with generic drugs accounting for a

<sup>&</sup>lt;sup>16</sup>Navi Radjou, Jaideep Prabhu, and Simone Ahuja, "A Q&A with Navi Radjou, Jaideep Prabhu and Simone Ahuja, Authors of Jugaad Innovation," Jugaad Innovation, http://jugaadinnovation.com/about-the-authors/qa-with-authors/.

<sup>&</sup>lt;sup>17</sup>The National Pharmaceutical Pricing Authority is the nodal agency for controlling prices of certain essential drugs; the Ranbaxy site now redirects to Sun Pharma. For more on this, see http://www.ranbaxy.com/sun-pharma-to-acquire-ranbaxy-in-a-us4billion-landmark-transaction/.

<sup>&</sup>lt;sup>18</sup>The main problem in the acquisition was that the merger was causing monopolization in certain product molecule markets. The Competition Commission of India (CCI) intervened, and where the market share was very high following the merger, the CCI insisted on divesting that product from the entity.

considerable portion of the revenues for players in the Indian market.

Ultimately, the industry structure will be altered significantly with a stringent IPR regime. There will be an incentive to invest in R&D. The scale of operations may also increase with better prospects for exports from larger companies. This will also enable Indian companies in the pharmaceutical domain to move up in the value chain and have better realizations and greater investment in R&D. The companies could move toward a differentiated pricing regime with different prices as per the paying ability of consumers in Indian and foreign markets.

## Impediments to Future Growth of the IPR Regime and Future Steps

Ultimately, in both pharmaceuticals and its wider industries, India will do well in the long term if it enables a robust IP ecosystem and protects the IP of its own companies. Yet there are critical impediments that have hampered prospects for broader acceptance of IPR norms and that if addressed may enable greater economic cooperation between countries. Some of these impediments are tangible while others appear to be intangible.

The tangible factors are as follows:

General environment of protection and enforcement with respect to IPR

Concerns raised in the U.S. Trade Representative's Special 301 Report during its various rounds since 1989, due to which India is on a priority watch list since 1994

The U.S. Chamber of Commerce's GIPC's Index, which ranked India last among the 25 counties considered for the index in 2014 and second-worst after Thailand in 2015

Growing piracy, particularly over the Internet with respect to various IP rights and copyright law

<sup>19</sup>The cost of registration of IP, which at times are quite high, leading a number of IPR regimes to go for a utility model

Low digitization of patent records and lack of human resources in IP offices

A large backlog of cases pertaining to IPR that has resulted in a delayed process of redressing grievances

<sup>20</sup>No special court for IPR

<sup>21</sup>Lack of protection for trade secrets

The intangible aspects of IPR that are impediments to a full-scale adoption of the current IPR regime are as follows: Sociocultural and other historical factors Access to medicines for poor people

Regarding these two intangible factors, although India's association with the patent regime has been longstanding, neither corporations nor the common people have really latched on to the idea. Since most people in a country like India are poor, access to medicines will become increasingly difficult if the IPR regime is established as it is in United States. The industry is also largely informal, fragmented, and at the bottom end of the value chain, where imitation is rampant. Expecting the industry to change overnight is not pragmatic. The fact that most medicines are generics in India does not mean that India does not upgrade the IP system to foster innovation, at least for the top 35 players in the pharmaceutical sector. At the present stage of development of the industry and economy, India should aim for strengthening IP protection while at the same time granting greater autonomy to the National Pharmaceutical Pricing Authority and other regulators for a more innovative, yet at the same time a highly regulated, industry.

Addressing these issues will require a policy direction that will enable India's IPR regime to follow global standards while at the same time realizing the innovation potential

<sup>&</sup>lt;sup>19</sup>"Protecting Innovation by Utility Models," WIPO, http://www.wipo.int/sme/en/ip\_business/utility\_models/utility\_models.htm. <sup>20</sup>Unlike some other Asian countries (most notably Malaysia and Taiwan), India does not have a special court for settlement of IPR-related disputes. There is in existence the Intellectual Property Appellate Board, but this board has its own set of issues with respect to functioning and understaffing.

<sup>&</sup>lt;sup>21</sup>The current law does not adequately protect trade secrets in India. There is a concern with respect to matters not falling under the contract law, as in the case of protection of trade secrets.

of various Indian states. The first public draft of the national IP policy seeks to clear the air on a lot of issues pertaining to the Indian IPR regime and is a step in the right direction. Future steps could help improve the acceptability of a more robust IPR regime and include the following policies.

<sup>22</sup>**Improvement in prESENT IPR regime.** This may take place with removal of prejudices and focus on scientific temper in people and providing an ease of filing patents. The draft IP policy is a step in the right direction that seeks to establish a "dynamic, vibrant and balanced intellectual property system in India." It will also involve having more Indians file different forms of IP like patents, etc. The utility model that is envisaged will also greatly benefit micro, small, and medium sector enterprises.

**ESTABLISHMENT OF SPECIAL IP COURTS with trained human resources.** Although an Intellectual Property Appellate Board (IPAB) is present in India, its functioning should be improved. The draft policy talks about increasing the powers of the IPAB and opening regional branches. It is imperative to have professional IP courts with trained lawyers and judges for effective understanding and enforcement of IP laws. This may be based on the model of other Asian countries like Malaysia and Taiwan, which could help improve the functioning of courts on IPR.

<sup>23</sup>**More rESEARCH on linkages between a better IPR regime and greater innovation.** This may be undertaken as research that calls for IPR regimes and their impact. Figure 1 in this report tries to do just that. This point requires a greater research focus on finding linkages between greater IP protection and greater innovation.

<sup>24</sup>**Protection of trade secrets.** Currently there is no separate legislation that regulates the protection of trade

secrets in India, though there is the draft Innovation Act of 2008 that seeks to protect the same. According to the WIPO, trade-secret protection is particularly important for small and medium-sized enterprises, as protection is indefinite. This legislation for protection of secrets would broaden the scope of the current IPR regime.

State level policy for improving innovation. At present there are very few present policies aimed at bettering IP and innovation potential in states. Such regimes could augur well for an improvement in investments under these regimes.

<sup>25</sup>Dispute resolution through bilateral talks and international treatles. Governments of several countries working together have a prominent role to play in resolving disputes. Recently, India and the United States have led the way in this regard by establishing "an annual high-level Intellectual Property (IP) Working Group with appropriate decision making and technical level meetings as a part of the trade policy forum." Similarly, India could look at treaties like the Hague Treaty on Industrial Designs to strengthen its IPR regime.

All these steps could help India not only attain competitiveness from the current viewpoint but also maintain sustainable competitive advantage over a longer t ime f rame and enhance i ts future competitiveness.

## Conclusions

The broad level contours of IP policy are now visible in the form of the national IP policy. India now needs to improve the IPR regime both from the side of the legislation and also from the side of enforcement of laws. This

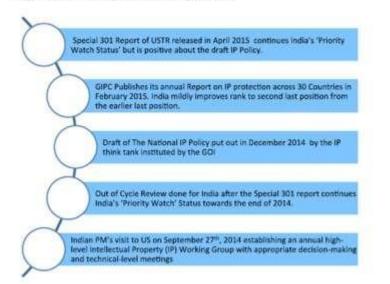
<sup>22</sup>IPR Think Tank (India), "National IPR Policy," December 19, 2014, http://dipp.nic.in/English/Schemes/Intellectual\_Property\_Rights/ IPR\_Policy\_24December2014.pdf.

<sup>23</sup>According to Stiglitz et al., there is no clear link between a stronger IPR regime and great innovation. This is also a concern that the American IPR regime—the positive example of IPR protection that served as the basis for encouraging other countries to sign the TRIPS agreement—seems to be too focused on rent seeking ,which may not be appropriate for developing countries. While it may be true that IPR regimes and innovations may not be connected empirically, what must be also observed is the incentive structure and how it gets distorted in the absence of adequate protection. Also, if IPR regimes are existent not only due to links with innovation but also a means of ensuring future R&D and inventions that act as the basis for innovations. Also, regimes elsewhere are bettering—a case in point is China a country with world's largest population and a per capita GDP roughly thrice of India, strengthening its IPR regime substantially. For more on this, see Giovanni Dosia and Joseph Stiglitz, "The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction," Laboratory of Economics and Management Working Paper Series, no. 2013/23, 2013.

<sup>24</sup>Tariq Ahmad, "Protection of Trade Secrets: India," Library of Congress, August 2013, http://www.loc.gov/law/help/tradesecrets/india.php.
<sup>25</sup> "DIPP Statement on Bilateral Mechanism for Discussing IPR Issues," Press Information Bureau, Government of India, October 3, 2014, http://dipp.nic.in/English/News/India\_US\_IPR\_04October2014.pdf.

improvement will help in the creation of a better environment for improving the overall innovation in the country. The need also exists to start looking at and understanding the IPR regimes abroad and, more importantly, bringing in the requisite changes, such as better digitization, in the present regime. For this, Indian states as well as industry will have to play a proactive role in asking the central government for a better IP protection regime so that there is greater innovation at the state level, which contributes toward the future competitiveness of India. Particular industries' performance, namely the pharmaceutical industry, will depend on the kind of IPR regime prevalent in India. It is important, however, that the likely impacts of introducing various measures are taken into account before framing and implementing IP policy.





Source Media reports and authors' own analysis.

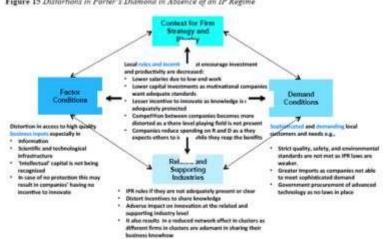


Figure 15 Distortions in Porter's Diamond in Absence of an IP Regime

Source: M.E. Porter, The Competitive Advantage of Nations (New York: Free Press, 1990); and authors' own work.

# Appendix 1: Additional RecentDevelopments in IP Issues in India

Several changes have been seen in India's IPR regime since the formation of the new national government in May 2014. The first of these was Prime Minister Modi's five-day visit to the United States that started on September 27, 2014, after which the Prime Minister's Office of India and the White House on September 30 issued a joint statement. The statement mentioned the need to "establish an annual high-level Intellectual Property (IP) Working Group with appropriate decision-making and te<sup>chn</sup>ical-level meetings as part of the Trade Policy Forum."<sup>26</sup>

Next, the United States conducted an out-of-cycle review of India's IPR regime. The review had proposed a deadline for submission of written comments by the public by October 30, 2014, and had set a deadline for submission of written comments by foreign governments by November 7, 2014. Meanwhile, in another significant step the Department of Industrial Policy and Promotion (DIPP) on October 22 constituted an IPR think tank (comprising one chairperson and five other members) to draft the National Intellectual Property Rights Policy and to advice DIPP on IPR issues. The think tank submitted the draft legislation to DIPP and put this up on its website on December 19, 2014.

Also, the U.S. Chamber of Commerce's Global Intellectual Property Center in February 2015 released its annual report on IP, which placed India as a country having the second-weakest IP environment out of the 30 countries considered for making the international index. The index ranked countries on 30 parameters, with countries assigned one point for each parameter. India scored a dismal 7.23, just ahead of Thailand (7.10).

This Index was followed by the USTR's Special 301 Report, which came out in April 2015. The report placed India again on the Priority Watch List in 2015 and further encouraged progress on IPR issues. The report was also positive about the draft IP policy and the progress made so far. Considering the changes that are underway, India is indeed on the cusp of a major IP revolution of sorts that may change the dynamics of IP protection and enforcement, thus leading to greater innovation.

## National Intellectual Property Rights Policy - 2016

On 12 May 2016, the Indian government approved its first ever National Intellectual Property Rights (IPR) Policy. This National Policy was drafted by an independent IPR Think Tank that consisted of six members, chaired by Justice (retired) Prabha Sridevan.

The main focus of this policy is related to the slogan **'Creative India, Innovative India'**, which subsequently is aligned to different government initiatives and missions in recent times that include **'Make in India'**, **'Atal Innovation MISSION'**, **'Start-Up India'**, and 'Stand-Up India' promoting creativity, innovation and entrepreneurship in the country.

The guiding principles of the policy are explicitly elaborated in its Vision and Mission statements. The stated VISION of this policy is: 'An India where creativity and innovation are stimulated by Intellectual Property for the benefit of all; an India where intellectual property promotes advancement in science and technology,ARTS and culture, traditional knowledge and biodiversity rESOURCES; an India where knowledge is the main driver of development, and knowledge owned is transformed into knowledge SHAREd'.

While, the stated MISSION of the policy is: 'Stimulate a dynamic, vibrant and balanced intellectual property rights system in India to: (a) foster creativity and innovation and thereby, promote entrepreneurship and enhance socio-Economic and cultural development, and (b) focus on enhancing ACCESS to healthcare, food SECURITY and environmental protection, among other SECTORS of vital SOCIAL, economic and technological importance.

The scope of the policy encompasses all legislations related to intellectual property protection for the **inventors, creators, DESIGNERS and entrepreneurs** in the country, namely, the

- Patents Act, 1970;
- Trade Marks Act, 1999;
- Designs Act, 2000;
- Geographical Indications of Goods (Registration and Protection) Act, 1999;

- Copyright Act, 1957;
- Semiconductor Integrated Circuits Layout-Design (SICLD) Act, 2000;
- Protection of Plant Varieties and Farmers' Rights Act, 2001; and
- Biological Diversity Act, 2002.

The policy provides the guided principles of administration of eight aforesaid National Acts. The policy also proposes administration of related IPR Acts from a single line ministry, i.e. **Department of Industrial Policy and Promotion (DIPP)** under the Ministry of Commerce and Industry. Thus, IP resources under the Copyright Act and the SICLD Act are brought to DIPP respectively from the **MINIStry of Human Resource Development (MHRD)** and the **Department of Electronics and Information Technology (DeitY)**. Henceforth, DIPP will administer, admit applications, and maintain the respective registry for patents, trademarks, industrial designs, copyrights, SICLD, and geographical indications of goods.

The ministries, namely, the MINIstry of Agriculture and Farmers Welfare, and the MINIstry of Environment, Forest and Climate Change continue to administer the IP resources under the Biological Diversity Act and Protection of Plant Varieties and Farmers' Rights Act. The policy then emphasizes on safeguarding traditional knowledge (TK), genetic resources (GR), traditional cultural expressions (TCE) and folklores, which are essential for maintaining cultural diversity and unique identity of the country and the regions. Here, the policy suggests widening the scope of the existing Traditional Knowledge Digital Library (TKDL) by including different IP resources beyond the Indian systems of medicine.

The IPR policy also recognizes the interests of poor patients in developing countries as identified from its text: 'the contribution of the Indian pharmaceutical sector in enabling access to affordable medicines globally and its transformation to being the pharmacy of the world'. India is also a signatory to the recently adopted United Nations' Sustainable Development Goals (SDGs). One of the targets of SDG 3 (Good Health and Well-Being) emphasizes on easy and equitable access to medicines and vaccines. TheTarget states, '3.B Support the research and development of vaccines and medicines for the communicable and non communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use fully the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all'.

The majority of critics of this IPR Policy are apprehensive on weak provisions of affordable medicines and seeds in the IPR policy document3. Thus, the IP administrators in the country should recognize this provision in SDGs and India's commitments. DIPP should broaden its resources for safeguarding the interests of the poor patients.

The policy also emphasizes on operational strategies in strengthening IP incubation and facilitation centres in different creative and innovative organizations for improving their institutional IP portfolios at par with the global standards. The Atal Innovation Mission also has similar operational objectives. Thus, the IP awareness and capacity development in the industries, MSMEs (micro, small and medium enterprises), startups, R&D institutions, science and technology institutions, universities and colleges are given priority for the early foundation of a holistic and conducive innovation ecosystem in the country. While building strong IP-led cultures in the country, India's economic growth and technological progress would make a significant impact in other areas of human development, such as poverty alleviation and zero hunger.