

# National Intellectual Property Rights Policy: An Analysis

Intellectual Property Rights (IPR) refer to rights provided to individuals or organizations pertaining to specific innovation or invention in products or processes for a certain period of time. They exist in the form of patents, trademarks, Geographical Indicators (GIs), copyrights, etc. IPR intends to spur and incentivize creativity and innovation and facilitate access to knowledge in order to achieve social and economic welfare.

In 1994, member countries of the World Trade Organization (WTO) signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which established the global standards for IPRs. India has the Patent's Act, 1970 under which the patent system operates in the country and the Indian Copyright Act, 1957. As a signatory to the TRIPS agreement, India introduced the Patent Amendment Act of 2005, which signaled a shift from process patents to product patents; to make the act TRIPS compliant. India has based its patent law on the twin principles of encouraging protection of IPR and safeguarding public interest through a "**pro-public health**" and "**pro-access**" stance.

However, in light of the recent patent judgments passed in notable cases such as the one surrounding Compulsory Licensing (CL) in *Bayer vs. NATCO*, or the decision to not grant patent protection to *Glivec* (a cancer drug manufactured by Novartis since it failed to meet the stipulated novelty requirements), there is an increased debate over the country's IPR policy and laws.

## India on the Global Innovation and IPR Scale



India is ranked **29<sup>th</sup>** out of 30 countries in the *International IP Index 2015*, released by the Global Intellectual Property Center of the US Chamber of Commerce. This ranking measures the overall IP environment in a country. China is ranked **19<sup>th</sup>** in the same list.



India ranks **76<sup>th</sup>** out of 143 countries (down from 66 in 2013) on the *Global Innovation Index 2014* published by Cornell University, INSEAD and World Intellectual Property Organization (WIPO). It is the lowest ranked among the BRICS nation, with China occupying the **29<sup>th</sup>** rank.

Recently, the USA raised concerns over the IPR regime in India and classified India on the '*priority watch list*' in a special 301 Report released by US Trade Representatives (USTR) in 2014.

Taking cognizance of these latest developments and rankings, the Government of India has adopted a pro-active approach towards drawing a roadmap for IPR in the country and coming out with a policy to improve investment climate in the country as well as promoting innovation and improving national competitiveness; India has even declared this decade as the '**Decade of Innovation**'.

It is in this context that this brief analyzes the setting up of the National IPR Think Tank, the draft IPR policy released by this think tank, and the potential impact on the pharmaceutical and Information Technology (IT) sector in the country. The penultimate section also compares India with some other major countries on important IPR issues.

## Setting up of the National IPR Think Tank (NITT)

On 22<sup>nd</sup> October 2014, the Department of Industrial Policy & Promotion (DIPP) set up a National IPR Think Tank (NITT) to draft an overarching IPR Policy and advise the government on IPR related issues. The NITT was set up to review the existing IPR policy, make recommendations to further strengthen and improve the same, make suggestions on increasing administrative efficiency as well as highlight best practices related to IPR around the globe.

Accordingly, the 6-member NITT chaired by Justice Prabha Sridevan submitted the first draft of the National IPR Policy on the 19<sup>th</sup> December. The draft policy touches upon various aspects of the IPR framework in the country and the need to create an innovation ecosystem while ensuring that the policy should work in the larger public interest. The highlights are mentioned below:

### Highlights of the National IPR Policy draft

- 1) Proposes the establishing of an **IP Promotion and Development Council (IPPDC)**, which would open IP Promotion and Development Units in all states in order to create a single window system for promotion, awareness and utilization of IP in the country.
- 2) Calls for the creation of a **Multi-Agency Task Force** to coordinate between different agencies and strengthen the enforcement mechanism so as to ensure better IPR protection.
- 3) Recommends designation of **specialized patent bench** in the Bombay, Calcutta, Delhi & Madras High Court for ensuring speedy disposal of patents cases; setting up branches of the Intellectual Property Appellate Board (IPAB) in the five regions, Ahmedabad, Bombay, Calcutta, Delhi & Madras, where Indian Patent Offices (IPOs) are functioning.
- 4) Stresses on the need to **augment the capacity and resources** at the disposal of IPOs to deal with the increasing number and complexity of IPR filings in the country in a *time-bound and effective manner*.
- 5) Suggests the enactment of a law to bring **utility models** under the IPR legal regime (to tap into the ingenuity of **local innovation**); introducing a first time patent fee waiver and developing a support system for Micro, Small and Medium Enterprises (MSMEs) to spur innovation.

## Analysis of the National IPR Policy draft

The IPR Policy recognizes the importance of a comprehensive, vibrant and balanced IP regime in the country as a means to attaining social and economic welfare and to create an innovation ecosystem in the introduction and vision of the draft. However, it does not follow up on this when talking about the specifics. As a result, while steps aimed at increasing awareness of IPRs are indeed most welcome, the draft is almost completely silent on the principle of **knowledge sharing and knowledge access**. While recognizing the fact that benefits of the IP laws are primarily enjoyed by foreign IP holders, it doesn't talk about measures to increase the number of domestic patent filings which is currently about **20%** of the total patent filings in the country.

The policy draft seeks to draw a correlation between a strong IP protection framework and increased foreign investment in manufacturing in the country under the 'Make in India' program; however it does not present any *empirical evidence* supporting the same or raise a point over whether IP protection in itself guarantees more foreign investment. On the contrary, it is extremely hard to provide any empirical evidence. In the US, while the number of patents has increased from 59,715 patents in 1983 to 244,341 in 2010, annual growth in the total factor productivity reduced from 1.2% in 1970-79 to below 1% in 2000-09 and the annual expenditure on R&D has oscillated in a band of 2.5% of the GDP for over three decades.

The policy makes a mention of enacting a law bringing utility model laws under the ambit of the IPR legal regime. Utility model refers to certain *modifications or improvisations* that result in increasing the usefulness of the product or process. Currently, utility models or 'petty patents' are not recognized in India. However, they are a part of IPR frameworks in over 100 countries including US, Japan, China and Korea. Granting utility models for a limited time frame is a step that is expected to provide a boost to MSMEs that account for 8% of the GDP and 40% of India's exports. At the same time, we would like to raise a word of caution that there is a need for strict safeguards around utility models so as to prevent inferior quality of innovation or development of a monopoly in some sectors.

## Impact of the Policy on Pharmaceutical and Information Technology Industry in India



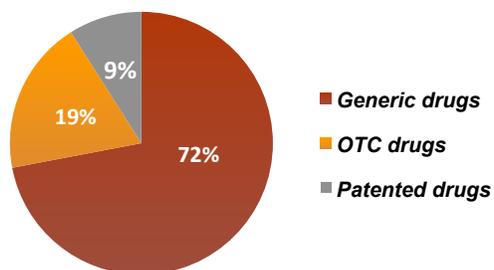
### Pharmaceutical Industry

India is one of the world's largest exporters of pharmaceutical products and is often referred to as the '*Pharmacy of the World*' as it supplies low cost life-saving medicines to the developing nations; the UNICEF's Supply Annual Report 2012 recognized it as the largest supplier of generic medicines. Furthermore, the availability of generic medicines has improved access to quality medication at low-cost for millions of Indians.

*\*Source for data: IBEF, DoP, Planning Commission*

#### Pharmaceutical Industry in India at a Glance

72% of the revenue generated comes from generic drugs.



India's pharmaceutical exports stood at USD **14.84** billion in 2013-14. *Hyderabad accounts for 20% of all pharma exports.*

The Indian pharma sector is estimated at USD **49** billion by 2020. Produce nearly **20%** of the world's generic drugs in terms of volume.

#### Pharma Vision 2020

Gol wishes to make India a hub for *drug discovery & pharmaceutical innovation.*

Create **5 million jobs** in the pharma sector.

The Patents Amendment Act of 2005 also improved the legal framework surrounding patents in the pharmaceutical domain by allowing for product patents. However, the same act provides for measures to protect the interests of the public and ensure that the act is not exploited to create an economic monopoly for a product. Section 3(d), prevents the '*evergreening*' of patents i.e. prolonging the life of the patent by making minor modifications that do not necessarily improve the therapeutic efficacy of the original patented product. It also allows for Compulsory Licensing of drugs to ensure availability of affordable medicines to the public under Section 84.

However, the judgments passed by the judiciary allowing Compulsory Licensing of the drug Nexavar by NATCO under Section 84 in the *Bayer vs NATCO* case, or the decision to not grant a patent extension to Novartis for its blockbuster cancer drug, Glivec under Section 3(d) has invited criticism from global pharmaceutical companies, the United States and EU which complain of a lax IPR law in the country.

In our viewpoint, this criticism is unwarranted as India has a robust IPR law and has time and again showcased a great level of maturity when it comes to dealing with protection of intellectual property. Moreover, the Doha Declaration emphasizes the importance of implementing and interpreting the TRIPS Agreement in a way that supports public health. Moreover, the application for CL has been rejected on various occasions; most recently, in the *BDR vs Bristol- Meyers*

*Squibb's (BMS) where the controller rejected BDR's application for CL of **Dasatinib**. Therefore, it is unfortunate that the policy draft is silent on the need for integrating the aspects surrounding public interest into the law and doesn't suggest any concrete measure to do the same. Furthermore, while the document seeks to draw a correlation between strong IP protection and increased foreign investment, it is worth highlighting that the Parliamentary Standing Committee on Commerce had in its *110th Report on FDI (foreign direct investment) in Pharmaceutical Sector* observed that 100% FDI in the sector **hadn't resulted in increased employment opportunity, technology transfer to domestic companies or a substantial increase in R&D spending**.*

In essence, any dilution in the existing legal framework in the country could adversely impact the domestic pharmaceutical industry; in particular the extremely strong and fast growing generics segment. The maximum impact would be felt in the states of Telengana, Andhra Pradesh, Himachal Pradesh, Punjab, Gujarat, Madhya Pradesh and Maharashtra, which have existing pharma clusters. In particular, Hyderabad, accounting for 20% of all exports would be affected if manufacturing of generic drugs takes a hit. Now, domestic manufacturers occupy 77% of the sector in the country, and with patented drugs worth around \$170 billion expected to go off by 2015, there will be a huge surge in generic products and would provide an opportunity for Indian companies to grow further. In such a circumstance, it is imperative that the policy seeks to protect the interests of domestic manufacturers and ensure access to affordable healthcare for millions of people in India and around the globe.



### Information Technology Industry

India has a very strong and well-renowned information technology and business process outsourcing sector with exports touching **USD 85 billion** in 2013-14. As far as IPR surrounding IT sector is concerned, the Patents Act, 1970 provides for exclusion of a computer programme *per se* other than its technical application to industry or a combination with hardware under *Section 3(k)*. However, about **64%** of software used in India is pirated, which is a huge cause of concern for software companies. Moreover, India *does not grant pure software patents* and instead protects software under the Copyright Act. As a matter of fact, the government has favored open standards and the Department of IT had finalized its Policy on Open Standards for e-Governance in 2010.

The policy draft does mention the point that the policy would benefit the Digital India initiative of the GoI as it would allow for utilization of IPs in e-commerce and other IT based startups. It has talked extensively on the need to curb piracy and has suggested stronger enforcement to ensure the same. However, it would have been useful had it mentioned alternatives to the IPR regime in the IT sector such as the need for *free/open-source software* or the need to adopt open standards

## Role of States in protecting IPR and promoting innovation

States are an important and integral part of the India growth story and it is in this respect that they are expected to play a proactive role in supporting the national IPR regime and encouraging innovation through an institutional set-up. The National Innovation Council (NInC) has facilitated the setting up of State Innovation Councils (SInCs) to supplement its efforts to drive the innovation agenda. Accordingly, 31 SInCs have been set up in the country. **Notably, Andhra Pradesh and Telengana are yet to set up a SInC in the state**. Furthermore, states such as Gujarat have taken the lead in creating an IP friendly environment; Gujarat has done so by launching the State Innovation Portal as well as the Centre on IPR under the aegis of Gujarat Council of Science & Technology (GUJCOST) at the Gujarat National Law University. Some states have also created IP cells in the police department under the Economic Offences Wing. Therefore, it is important for the states to actively engage in creating the right environment for IPR through concerted measures.

## Comparative Analysis of the Issues surrounding IPR

	INDIA	CHINA	US/EU
<b>ISSUES</b>			
<b>COMPULSORY LICENSING (CL)</b>			
<b>Position</b>	Section 84 of Patents Act 1970 deals with it. Use it for the greater benefit of the public in certain areas like Health.	New Measures- <i>Measures for Compulsory Licensing of Patent Implementation</i> - were introduced in 2012 replacing the order measures of 2003 & 2008.	Strongly oppose it due to excessive lobbying of corporate giants (like pharmaceutical companies).
<b>Precedence</b>	Granted its first CL in a pharmaceutical case (Bayer v/s Union of India).	Never granted to anyone in the past.	Have granted to some companies during their initial years of IP legislations but now doesn't grant.
<b>Arguments</b>	Legitimate as per the TRIPS clauses	-----	Violation of the treaties; it is against the spirit of innovation and scientific discovery. The companies would not invest in R&D and there will be no incentive to manufacture new drugs.
<b>Impact</b>	Might have an impact on foreign investment in manufacturing of drugs in the country.  Access to cheap drugs to the Indian public.	Due to a more pro-business policy, current five-year plan (2010-15) and unwillingness of government to impact trade with developed countries, China might not take this route; Emerging as a key negotiation tool with drug companies for government.	As major drug discoverers and manufacturers are here so these countries are reluctant to engage in trade with those opting for CL route by imposing various sanctions.
<b>EVERGREENING</b>			
<b>Position and Arguments</b>	Section 3 (d) of IP act deals with it. Justifies on the grounds of significant improvement over the previous product. Merely changing the basic formula/composition or minor modifications cannot contribute to a significant	Have granted patents to the companies even with minor modifications or slight improvement in the original product composition.	Grants patents and allows evergreening of patents thereby allowing for companies to establish a monopoly over the patented product.

discovery and hence does not warrant the awarding of a patent.

### Precedence

Yes. In the case of Novartis v/s Union of India. Indian supreme court revoked the patent awarded to Glivec, on the basis of therapeutic efficacy. As a result, the generic companies can continue to manufacture the generic version of the drug.

Have granted to almost all companies.

### Conclusion

Intellectual property rights (IPRs) will become an important pillar in India's future growth story. By providing an impetus to local research and innovation, IPR could provide a boost to economic activity in all sectors of the economy. But equally importantly, a national IPR regime needs to balance the interests of foreign manufacturers and innovators with those of indigenous innovators – particularly budding entrepreneurs and small and medium enterprises. It further needs to ensure that the interests of the weakest and most deprived sections are not jeopardized – especially in social sectors like health. These conflicting pulls and pressures can be managed only through a stable and predictable IPR policy. The NITT draft document is a significant step in that direction.

The draft policy does seek to balance the goals of economic growth and social justice, and makes important recommendations towards the same, as noted in this brief. However, there are some areas where the draft document could have made more comprehensive recommendations. In particular, it would be important to ensure that India's rich repository of traditional knowledge – particularly in areas like medicine – is offered the same level of intellectual property protection as other products and processes. It is equally important for state governments to play the role of constructive partners in creating and maintaining a robust, equitable and predictable IPR regime. They need to do this by establishing State level Innovation Councils and strengthen them through financial and other support. They also need to organize awareness drives to sensitize their people about the importance of IPR. In this, higher education institutions will need to play a pivotal role.

Overall, this policy document is a significant, though not entirely adequate, step forward towards evolving a holistic, just and fair IPR policy regime.

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