

## National Intellectual Property Rights Policy 2016: An Analysis

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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 along with 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, India's reputation with regards to recognizing and enforcing IPRs has been far from satisfactory. India was ranked 29<sup>th</sup> out of 30 countries in the **International IP Index 2015** released by the **Global Intellectual Property Chamber of the US Chamber of Commerce**. The United States also raised concerns over the IPR regime of the country when it placed India on the ‘**priority watch list**’ in a report released by the US Trade Representatives (USTR) in 2014. Further, the judiciary too has been skeptical in recognizing IPRs, especially those concerning pharmaceuticals. This was highlighted by the Supreme Court refusing to grant patent protection to Gilvec, a cancer drug manufactured by Novartis.

In light of such developments, the Government adopted an assertive approach to draw a roadmap for IPRs in the country. The National Intellectual Property Rights Policy was enacted to improve investment climate, promote innovation and facilitate commercial exploitation of IPs. The Policy is in sync with India's declaration of the present decade as the ‘**Decade of Innovation**’.

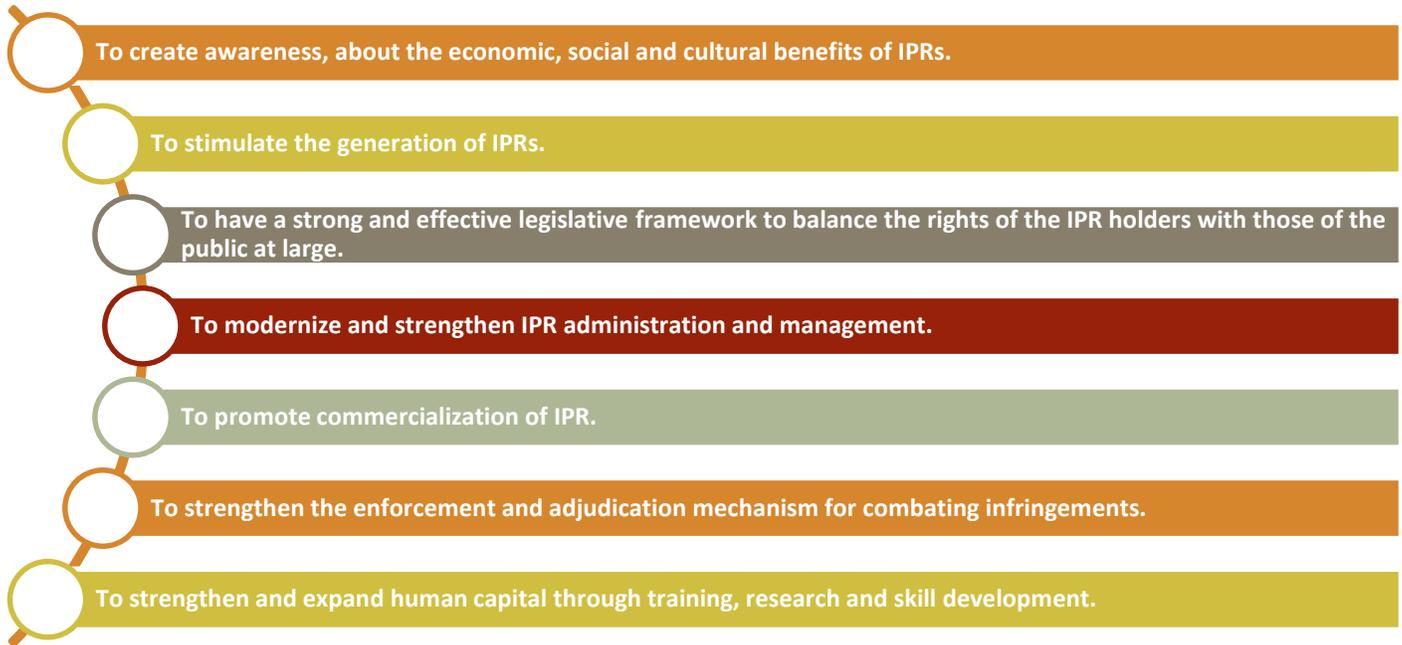
In this context the brief analyzes the Policy with regards to its potential impact on innovation and the overall economy, with a special focus on the Pharmaceutical and Information Technology sectors.

### National Intellectual Property Rights Policy

The Policy was adopted by the Union Cabinet on May 12<sup>th</sup>, 2016. It recognizes India's well established TRIPS compliant legislative framework to safeguard IPRs, and seeks to balance her developmental concerns by utilizing the flexibilities provided in the international regime.

The Policy especially focuses on generating awareness about IPRs, and highlighting the importance of IPRs as a marketable financial asset and an economic tool.

The objectives are mentioned below:



## Features of the National IPR Policy

The Policy recognizes the importance of innovation and creativity in the growth and development of a knowledge economy. It equates innovation with generation of IPs. The twin focus of the policy is enabling commercialization of IPs through awareness generation; and easing administrative bottlenecks by easing procedures. **Copyrights, presently administered by the Ministry of Human Resources, are sought to be brought within the purview of the Department of Industrial Policy and Promotion (DIPP) to make them uniform with the other IPs.**

In order to boost commercialization and value for IPs, the policy proposes a study to examine the feasibility of an IPR exchange. Such dedicated IP exchange could facilitate investment in IP driven industries by bringing together investors and IP owners/users. **The policy also urges the Government to explore the possibility of expedited examination of patent applications to promote manufacturing in India.** The Policy also takes note of the rural and marginalized economy. It states that providing financial support to the less empowered group of IP owners or creators, such as farmers, weavers, artisans, craftsmen etc., through rural banks or co-operative banks, should be a priority.

In order to expedite the adjudication of disputes, and ensure enforcement of IPR, **the Policy suggests the setting up of dedicated commercial courts to deal with IP related matters.** It also suggests that the possibility of resolving IP disputes through Alternative Dispute Resolution Mechanism should be explored.

Strengthening of enforcement mechanism is yet another focus point of the Policy. This could be achieved by enhancing co-ordination among various agencies of the government as well as non-government players (such as

the private sector and NGOs); and by encouraging application of technology based solutions in the enforcement of IPRs.

Various other measures proposed by the policy include criminalization of unauthorized copying of movies, encouraging Corporate Social Responsibility (CSR) funds into open innovation and expanding capacity building in IPR through training, teaching, research and skill building.

However, the Policy seeks to promote IP as an end in itself rather than placing it within the larger context of the innovation ecosystem. It suggests that publicly funded research institutions must convert their discoveries into IP assets, by linking career progression of the researchers in such institutions with the generation of IPs. This could impede the free flow of information in the long run.

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



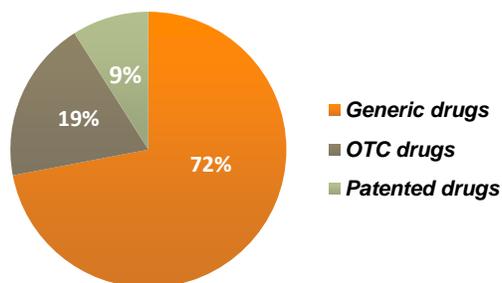
### Pharmaceutical Industry

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.

*\*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 15.5 billion in 2014-15. *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 availability of generic medicines has improved access to quality medication at low-cost for millions of poor people from all over the world. The Policy acknowledges the importance of this economically essential and socially relevant generic drug industry and suggests that strong measures be taken against attempts of counterfeiting generic drugs.

The Patents Amendment Act of 2005 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, Gleevec 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 although the policy highlights the need for integrating the aspects surrounding public interest into the law, it falls short of suggesting any concrete measure to do the same. Furthermore, while the document seeks to draw a correlation between strong IP protection and a viable economic ecosystem, it is worth highlighting that the Parliamentary Standing Committee on Commerce had in its *110th Report on FDI 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. In light of the same, the Policy doesn't propose to dilute the existing legal framework with regards to compulsory licensing and anti-evergreening.



### **Information Technology Industry**

India has a very strong and well-renowned information technology and business process outsourcing sector with exports touching **USD 82 billion**<sup>1</sup> in 2014-15. 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 favoured open standards and the Department of IT had finalized its Policy on Open Standards for e-Governance in 2010.

The policy mentions that the proposed IPR regime would benefit the Digital India initiative of the GoI as the slogan of "Creative India; Innovative India" is to be interlinked with the future IPR roadmap. It has talked extensively on

<sup>1</sup> Data Source: Reserve Bank of India (RBI)

the need to curb piracy and has suggested stronger enforcement to ensure the same. Further, it has emphasized the promotion of **Free and Open Source Software** along with adoption of open standards.<sup>2</sup>

## 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, Telengana, Uttarakhand and West Bengal are yet to set up a SInC in their respective states.** 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	TRIPS
	<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-Measures for Compulsory Licensing of Patent Implementation-were introduced in 2012 replacing the order measures of 2003 & 2008.	Strongly oppose it due to excessive lobbying of corporate giants (like pharmaceutical companies).	Article 31 provides negative conditions on grant of compulsory licenses. It is to be granted only when negotiations for voluntary license with the patent holder, on reasonable terms, fail. Further, even when such license is granted, the patent holder has to receive payment.
<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	

<sup>2</sup> Open Source Software is one that can be modified and shared by anyone as it's "source code" remains open. Such software is different from a "Proprietary Software" or "Closed Software" whose source code is the property of its original authors, the only ones legally entitled to copy or modify it.

			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.	As a pro-business measure, TRIPS seeks to promote grant of patents and restrict issuance of compulsory licenses.
<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 discovery and hence does not warrant the awarding of a patent.	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.	Does not specifically deal with the issue, however Article 27 lays down that patents should be granted for all inventions, either products or processes, in all fields of technology without discrimination.
<b>Precedence</b>	Yes. In the case of Novartis v/s Union of India. Indian supreme	-	Have granted to almost all companies.	

	<p>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.</p>			
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## 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 National IPR Policy is a significant step in that direction.

The 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 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. The policy suggests some measures in this regard, such as expanding the ambit of the Traditional Knowledge Digital Library (TKDL) to also include fields other than Ayurveda, Yoga, Unani and Siddha; and a generic suggestion to promote India's rich traditional knowledge, something more specific would have been more impactful.

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. The Policy does mention that the Union should work closely with the state governments for curbing IP offences, and to include them in the broad consultation process, it falls short of suggesting anything concrete for a more active involvement of the states in the proposed IPR roadmap. 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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