“Media & Advocacy Plan for PhRMA in India”

SUBMITTED TO:-
DR. SANDEEP NARULA
DEAN, SCHOOL OF PHARMACEUTICAL MANAGEMENT

PRESENTED BY:-
PRAGATI ARORA
MBA-PM09

About PhRMA

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA is committed to advancing public policies in the United States and around the world that support innovative medical research, yield progress for patients today and provide hope for the treatments and cures of tomorrow.

Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

LITERATURE REVIEW

- Prakash et. al. in 2018 explained that Indian Pharmaceutical Market is dominated by the generic market and invention has a very little share in its expansion due to lack of proper multidisciplinary work between the preclinical and clinical scientists, deficient funding, heterogeneous interests of the involved sectors and lack of systematic training of workforce. Till now, the Indian Patent System is balancing the delicate balance between the interest of the patentee and Indian population. There are several stories regarding the product patent, off-patent products, and how the inventor company tries to save their inventions from generic marketing.

- Arvind Kasthuri in 2018 described that India has been trying desperately to live up to their identity as health subcenters, waiting to be transformed to shrines of health and wellness, a story which we will wait to see unfold. Studies on awareness are many and diverse, but lacunae in awareness appear to cut across the lifespan in our country; barriers to access in the financial, organizational, social, and cultural domains can limit the utilization of services, even in places where they are available; the public sector offers healthcare at low or no cost but is perceived as being unreliable, of indifferent quality and generally is not the first choice, unless one cannot afford private care and warning to Indian Healthcare to get ready to face a future which is full of possibility and uncertainty in equal measure**.**

- Shalini Arora and Rekha Chaturvedi(2016) explained that Compulsory Licensing of Pharmaceutical Patents in India. Section (3d) can be viewed as a parameter of patent eligibility for Pharmaceutical inventions. In order to raise the standard and quality of Pharmaceutical drugs the domestic pharmaceutical companies should be provided with more incentives and soft loans and the Government should make it lucrative and easy for them to go for R&D to develop new drugs and subsequent clinical trials

RESEARCH PROBLEM

- Why global biopharmaceutical firms hold back from investing in the country and what initiatives need to be taken to build an innovative biopharmaceutical industry in India?

- What are the main challenges with access & affordability for medicines in India?

- What advancements can be made in the public healthcare system?

OBJECTIVES

To develop and place articles in relevant channels for representing PhRMA in India:-

- The commitment and contribution of the global innovative bio-pharmaceutical organizations in the country
- Bringing change in perception of GOI towards establishing a strong world-class intellectual property (IP) systems that encourages and rewards medical innovation
- The current role of Government in improving availability and accessibility of medicines

RESEARCH METHODOLOGY

✓ **Study Type:** Descriptive study

✓ **Study Duration:** Three Months (4th February to 4th May)

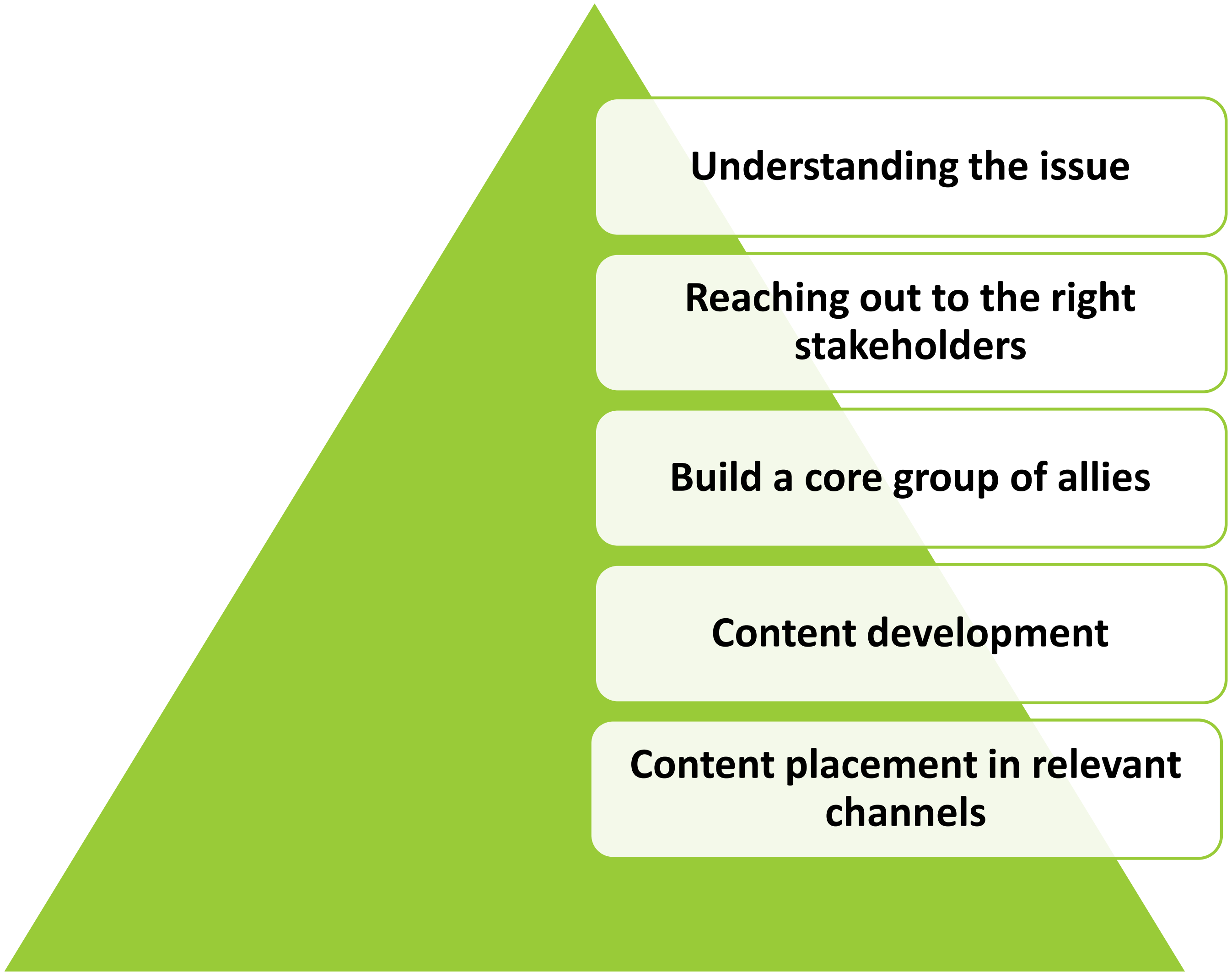
✓ **Data Collection method:** Secondary research

✓ **Source of Secondary data:**

Secondary research**,** we refer a broad array of industry sources for our secondary research, which typically include; however, not limited to:

- Indian Pharmaceutical Scenario to Scientific and technical writings for IP framework & regulations and related preemptions
- Authentic new articles on healthcare infrastructure of India, current market trends, clinical trials, Innovative research & technology in biopharmaceutical companies and its products in India, other related releases for market evaluation

COMMUNICATION APPROACH



PROPOSED PLAN OF ACTION

Track 1 – Media Outreach and narrative build up

Track 2 - Broad-Based KOL Engagement

Track 3 – Build Media Allies
Track 4 – Research & Content - Broad Base Communication agenda around other relevant indices and reports

Key Indices/Events & Conferences

- GIPC- IP Index launch
- Global Innovation Index
- Global Competitiveness Report

NEW VOICES IDENTIFIED

Dr. Neelam Mohan- Paediatric Gastroenterology & Hepatology- Medanta The Medicity

Prof. Nilanjan Banik, Bennett University, India

Anoop Misra, Director Department of Diabetes & Metabolic Disease, Fortis Hospital

Prof. Deepak Gaur
Jawaharlal Nehru University

Ms. Malathi Lakshmikumaran, Director, Lakshmikumaran & Sridharan attorneys

Ms. Malathi Lakshmikumaran, Director, Lakshmikumaran & Sridharan attorneys

Shantanu Srivastava, Associate Director, CUTS International

Chirag Trivedi, President, ISCR

Quarter Plan (April-June 2019)

Issue	Story	Messenger	Target Publications
COMPETITIVENESS	**Innovation is required to meet the challenges of a growing disease burden** An innovative pharma industry needs a robust and predictable IP environment. Innovators need the assurance that research will be rewarded	Prof. Deepak Gaur, Jawaharlal Nehru University (JNU)	Mint, The Hindu Business Line, First Post
	Innovation: A critical tool for enhancing competitiveness Innovation is being increasingly acknowledged as a critical tool for enhancing competitiveness, tackling societal challenges, and driving economic growth and development. The move from a resource led to an innovation led economy can help nations in accomplishing the twin goals of sustainable and inclusive development	Prof. Chirantan Chatterjee, IIM, Ahemedabad	The Hindu Business Line, The Economic Times, BBC, Business Standard

INTELLECTUAL PROPERTY	**Section 3(d) prevents evergreening of drug patents/ Narrow patentability criteria and Section 3(d) remain a concern** India's IP regime, including Section 3(d) requiring biopharmaceutical inventions to show enhanced efficacy, continues to affect its investment environment as it does not provide patent protection for incremental innovation	**Dr. Ratna Devi, chief executive officer, DakshamAHealth, and founding member, Indian Alliance of Patient Groups**	**First Post, The Hindu Business Line, The Better Indian**
	Creation of IP- a massive opportunity Intellectual Property (IP) is the bedrock on which the development of new treatments and cures are built. IP is critical for improving healthcare indicators of the nation. A strong IP framework will deliver tremendous benefit to India, including increased investment in clinical research, high-paying and skilled jobs, transfer of medical knowledge and early access to the new medicines	Ms. Malathi Lakshmikumaran, Director, Lakshmikumaran & Sridharan attorneys	Mint, ET Healthworld or First Post
	Medicine: Price control The government is increasingly relying on price controls on medicines and medical devices to rein in the rising cost of healthcare in the country. Though this is well-intended, it may have several unintended consequences such as discouraging investment and R&D spending	Dr. Amir Ullah Khan, Indian Economist, Director, Aequitas Research	Newsminute, Quint, The Indian Express, The Hindu Business Line

INNOVATION	**Reward Innovation** The bright promise of an innovative biopharmaceutical industry in India will only be fulfilled if we work together to build, sustain and grow a scientific, economic and policy ecosystem that promotes and rewards medical innovation	**Prof. N.K Ganguly, Former Director General, ICMR**	**Scroll, The Hindu Business Line, The Indian Express**
	Leading the path of favorable innovation policies Much needed respite for the global research based pharmaceutical companies as the Indian govt. had announced the removal of price caps on innovative, patented drugs for the first five years of commercialization. While we are on the right track, a lot more needs to be done	Dr. Chaitanya Koduri, US Pharmacopeia	The Hindu Business Line, Business World, Scroll
	Move up the value chain by enabling innovation and new drug discovery Are patients' needs and aspirations really met? What can be done to cover the gaps? - Role of science and innovation in increasing access and filling the gaps	Dr. Ratna Devi, chief executive officer, DakshamAHealth, and founding member, Indian Alliance of Patient	BBC, The New Indian Express, Mint

Article Pitched and Coverage Appeared

Headline: Stir The IPR Pot for Innovation

Publication: The Economic Times

Page: The Edit Page

Edition: National

Date: 08 April 2019

Coverage Link:
https://economictimes.indiatimes.com/blogs/et-com
stir-the-ipr-pot-for-innovation/

Stir the IPR pot for innovation

April 8, 2019, 12:04 AM IST Economic Times in ET Commentary | Edit Page, India | ET

By Ranjana Smetacek

Last month, the US Chamber of Commerce's Global Innovation Policy Centre (GIPC) released its 7th annual International Intellectual Property (IP) Index, which assesses the IP climate in 50 world economies. India moved from 44th rank in 2018 to 36th in 2019. But, looking at the scores across the eight categories assessed, India comes in well below the average score of the top five economies, and scores considerably lower than the Asia average.

India's national IP Rights Policy (IPR) was created in 2016. One of its stated objectives was 'to guide and enable all creators and inventors to realise the potential for generating, protecting and utilising IP which would contribute to wealth creation, employment generation and business development'. It also aimed to 'foster predictability, clarity and transparency in the entire IP regime in order to provide a secure and stable climate for stimulating inventions and creations'.

India has certainly made progress on the seven objectives laid down in the National IPR Policy across patents, trademarks, copyrights and designs. It has acted to increase public awareness, commissioned technology and innovation support centres, and instituted training programmes in some states. But much is left to be done: strengthening the legislative framework to respect IP; improving the enforcement and adjudicatory mechanisms that deal with infringements; supporting the generation and commercialisation of innovation; developing human capital to bolster capacity for research and skillbuilding. We need to recognise IP as avalue creator for India, and build the country's capability for innovation through IP creation, protection, and commercialisation.

Coverage Snapshots

PhRMA
RESEARCH • PROGRESS • HOPE

THE TIMES OF INDIA

Don't grow complacent with India's improved Ease of Doing Business ranking: Plenty of red tape still ties us up

Ranjana Smetacek

We have recently been basking in the knowledge that India has fared well in the World Bank's latest Ease of Doing Business (EODB) report. For the second year running, our country was recognised among the best performing nations when it came to reforms in the business environment. This year India moved 23 places up the rankings chart, from 100 to 77. Previously rated the worst-performing Brics economy, India has now become the median economy among Brics and the best in South Asia.

The greatest improvements have been recorded in 'dealing with construction permits' where the country jumped 129 places to reach 52, and 'trading across borders' where India has moved 66 places to reach 80. However, India slipped in the categories of 'paying taxes' (despite the implementation of the Goods and Services Tax) and 'resolving insolvency' (despite the adoption of the Insolvency and Bankruptcy Code).

It is important that we do not grow complacent with these improved rankings. We must see instead the extent of the red tape that we still need to do away with.

The scope of this EODB index is limited after all and, by the World Bank's own admission, the indicators are not designed to portray the entire macroeconomic scenario of any country or reflect its growth prospects. While this report is a recognition of the positive steps India has taken, our performance here can only be a function of the parameters laid down by the World Bank. This result cannot be extrapolated as an overall improvement in EODB, on the other important parameters.

In this scenario, it is important for the government to tread carefully and ensure that rash policy decisions are not taken

Policy and regulation remain important factors that must be assessed while measuring the actual EODB. The proposal of retrospective tax was not so long ago and the resultant economic uncertainty should not be forgotten. We also need to deal with the foreign investment reporting format recently instituted by the Reserve Bank of India.

This new reporting system is completely contrary to ease of compliance and has served to make foreign investment reporting more confusing and challenging. Similarly, the draft e-commerce policy released last year elicited extensive criticism from across industry.

We should pay heed to several other aspects of our business environment, some of which have been making global news. We can only be attractive to innovative industries if we have in place a robust and predictable system for intellectual property protection. We should introspect about consistently being rated poorly in Transparency International's Corruption Perceptions Index.

We should be troubled by our position in the Crony Capitalism Index (yes, there is such a thing) and the widespread perception that success in Indian business is predicated upon close and unethical relationships with government officials. We should be concerned with our falling rating in the Press Freedom Index which sees our media independence as compromised.

We should worry about the anxiety that has loomed most recently, stemming from air pollution in India's capital city and the resultant health effects on its hapless residents. Finally, there is no denying the real and widespread apprehension that has resulted from the steady rise of populist right-wing sentiment across India and which has drawn rebuke from international human rights organisations.

It is understandable that our policy makers would cite the EODB index as a barometer for how easy it is to conduct business in our country and an indicator of (the lack of) red tape, cost burden and overall entrepreneurial mobility. Of course, a good rank is expected to translate into a better chance of securing foreign investment and the government expects an even better ranking next year, as the reforms' benefits are more fully realised.

But we must address numerous challenges in order to sustain any meaningful economic growth while also ensuring job creation. In this scenario, it is important for the government to tread carefully and ensure that rash policy decisions are not taken. It is important to look holistically, objectively and with a critical eye at every aspect of our economy to assess what else we need to do.

The writer is former Director General of Organisation of Pharmaceutical Producers of India

THE ECONOMIC TIMES

INTELLECTUAL PROPERTY RIGHTS

Stir the IPR Pot for Innovation

Ranjana Smetacek

Last month, the US Chamber of Commerce's Global Innovation Policy Centre (GIPC) released its 7th annual International Intellectual Property (IP) Index, which assesses the IP climate in 50 world economies. India moved from 44th rank in 2018 to 36th in 2019. But, looking at the scores across the eight categories assessed, India comes in well below the average score of the top five economies, and scores considerably lower than the Asia average.

India's national IP Rights Policy (IPR) was created in 2016. One of its stated objectives was 'to guide and enable all creators and inventors to realise the potential for generating, protecting and utilising IP which would contribute to wealth creation, employment generation and business development'. It also aimed to 'foster predictability, clarity and transparency in the entire IP regime in order to provide a secure and stable climate for stimulating inventions and creations'.

India has certainly made progress on the seven objectives laid down in the National IPR Policy across patents, trademarks, copyrights and designs. It has acted to increase public awareness, commissioned technology and innovation support centres, and instituted training programmes in some states. But much is left to be done: strengthening the legislative framework to respect IP; improving the enforcement and adjudicatory mechanisms that deal with infringements; supporting the generation and commercialisation of innovation; developing human capital to bolster capacity for research and skill-building. We need to recognise IP as a value creator for India, and build the country's capability for innovation through IP creation, protection, and commercialisation.

In healthcare, for instance, to develop and deliver new treatments to patients, innovator companies must be able to rely upon predictable and enforceable IP rights.

FILE PHOTO

Ideas of India

Regretfully, GoI's initial momentum has not continued to translate into any meaningful change in policy or practice. The pharma industry's concerns range from weak patent enforcement, an unpredictable environment, and the threat of compulsory licensing, to non-transparent market access policies, high tariffs and taxes, and an unpredictable environment for clinical research.

India's patent examination backlog is another problem, where patents being examined currently were filed six to eight years ago. Such backlogs postpone clinical trial activity and ultimately the introduction of new medicines.

The inability to pay out-of-pocket and the lack of insurance cover will hopefully be addressed to a great extent by the Ayushman Bharat initiative. The National Health Protection Scheme (NHPS) proposes to extend health insurance cover to 40% of the population that's most in need. State governments could work with the pharma industry on optimising drug procurement and distribution to address healthcare access challenges. Increased access to medicines can go hand-in-hand with pro-innovation policies for the benefit of patients.

India's IP system needs to be thoughtfully assessed, and legal flexibilities used judiciously for humanitarian non-commercial use in treating diseases that are epidemic or communicable, with compulsory licensing being invoked only as a rare exception in rare circumstances. Not only would strong IPR make India more attractive to innovators, but a robust IP framework would also deliver increased investment in clinical research, high-paying and skilled jobs, transfer of medical knowledge and early access to new medicines.

The writer is former director general, Organisation of Pharmaceutical Producers of India (OPPI)

Headline: “Countering the Diabetes Burden with Innovation: Dr. Vishwanath Mohan”

Publication: The Economic Times

Page: The Edit Page

Edition: National

Date: 04 May 2019

Coverage Link:

https://health.economictimes.indiatimes.com/news/industry/countering-the-diabetes-burden-with-innovation-dr-vishwanath-mohan/69169940

Dr. Vishwanath Mohan
Chairman & Chief Diabetologist,
Dr.Mohan's Diabetes Specialities Centre

As the diabetes capital of the world, India currently has about 72 million people with the disease and the number is expected to rise to a whopping 134 million by 2045. The prevalence is not just growing among the older generation but is now hitting the younger generation as well. According to a report by Indian Council of Medical Research, data in its diabetes registry show that one in every four people under 25 with diabetes in India has adult-onset type-2 diabetes, unlike before when type-2 diabetes was seen only in older adults or those with obesity.

These statistics are not only worrying from a healthcare perspective, but also from an economic standpoint. What happens when the most productive section of society is affected by a lifestyle disease like type-2 diabetes, where poor diet and lack of exercise contribute to the onset of disease? Patients with diabetes are at risk for long-term complications (damage to the cardiovascular system, kidneys, eyes, nerves, blood vessels, and feet). The economy suffers, as people with diabetes have, on an average, two times higher healthcare costs than the ones living without the disease. This not only threatens the productivity level of our workforce but also means a significant loss of national income.

RESULTS

- ✓ India has been issued compulsory license since 2001, which allows them to produce a patented product or process without the consent of innovator of that product. Compulsory licensing is also retained despite US demands for this to be watered down.

- ✓ Moreover, there is no change in revised section (3d) amendments of Indian Patent Act 2016 which prevents evergreening of drug patents. Moreover, a lack of a strong IPR regime and drug price control also delay innovation

- ✓ Compulsory licenses are used more as a barrier for innovations, often failing to reduce price of medicines, the intention with which it is included in the TRIPS Agreement. Basis the NSSO survey pointing out 82% of urban population and 86% of the rural population are still not covered under any health insurance scheme (private or public) and millions are pushed into poverty every year to meet their medical expenses.

- ✓ India is the second largest pharmaceutical market in Asia estimated at US$ 5.40 billion and is growing by more than 13% annually. The country needs to upgrade its drug pricing policies so as to meet timely USFDA approval of orphan drugs, rare diseases and other lifesaving drugs, which in turn encourages innovation.

- ✓ The two most challenging areas of Healthcare is- Procurement & supply chain. India ranks high in the list of countries with highest Out-of-Pocket (OOP) expenditure on health in the South-East Asia region.

- ✓ Government spending on healthcare system including medicines, diagnostics and hospitals is only a meager 1.5% of GDP in India as compared to developing countries in Latin America which average about 7.5% of GDP. In fact, India, being the generic production hub, availability of essential generic medicines is very poor in public sector facilities because of lack of equipment, factors facilities and poor distribution model, which are the primary source of free medicines for a majority of India’s low-income population

RECOMMENDATIONS

- ✓ Assessment and Implementation of patent environment, high tariffs and taxes on medicines, and unpredictable environment for clinical research is important to attract US companies to tap on Indian market

- ✓ An innovative pharma industry needs a robust and predictable IP environment. Innovators need the assurance that research will be rewarded. A strong IP framework will deliver tremendous benefit to India, including increased investment in clinical research, high-paying and skilled jobs, transfer of medical knowledge and early access to the new medicines.

- ✓ The country needs to understand and accept the patent regime 2005 that encourages the innovation and discovery of new drugs by investing more in R&D

- ✓ The Government needs to spend more on public healthcare and would have to tighten its regulations regarding quality healthcare. Central and state governments should be in sync about innovations in funding mechanisms and increase the health insurance coverage

- ✓ The Government must focus on encouraging private spending and their participation as the part of CSR in improving healthcare

- ✓ Political parties seem not serious about Healthcare promises. In Modicare, mostly targeted beneficiaries live in Rural areas, so providing proper facilities is more challenging. Recently, Arun Jaitley announced of the settlement of 24 new Government collleges & Hospitals and aslo proposed that health budget for FY 2018-19 will be increased by 2% to 546 billion.

ARTICLES UNDERWAY-

- Countering the Diabetes Burden with Innovation
- Time to Fight the Cancer Battle with Stronger IP Laws/The Dire Need for Robust IP Framework/Treat Cancer with Policies That Matter
- Rising economic burden due to diabetes in India
- Policy Intervention is the New Medicine

REFERENCES

Ajay Prakash, Phulen Sarma, Subodh Kumar, and Bikash Medhi (2018). Intellectual property rights and Indian pharmaceutical industry: Present scenario. *Indian Journal of Pharmacology*. 50(2): 57–60, doi: 10.4103/ijp.IJP_320_18

Arvind Kasthuri (2018). Challenges to Healthcare in India - The Five A's. *Indian Journal of Community Medicine*. 43(3): 141–143, doi: 10.4103/ijcm.IJCM_194_18

S Ravindra Bhat (2018). Innovation and intellectual property rights law—an overview of the Indian law. *IIMB Management Review*. Volume 30, Issue1, Pages 51-61

Prabhat Kuamr Saha, Aditi Mukherjee(2019). Compulsory Licensing of Pharmaceutical Patents in India. *Economic & Political Weekly*. Vol. 54, Issue no. 5, ISSN (Print) - 0012-9976 | ISSN