

India's IPR Policy: A Sector Wise Analysis

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Abstract—The new government's pro-investment stance and the "Make in India" initiative has improved India's image on the global stage, but in order to actually achieve the desired benefits in terms of increased foreign participation and long term investment, having an IPR structure conducive to fostering a business friendly environment is a prerequisite. Currently India's IPR regime lacks the trust factor internationally as evident from its low ease of doing business ranking (Rank 142 out of 189 countries, as per the ease of doing business ranking by the World Bank, 2015). This paper focuses on the objections raised by other countries against the current IPR policy of India. Countries such as the US have accused India of "piracy" for selling a cheaper version of the medicines sold by its pharmaceutical giants and infringement of patents in IT industry. IP specific issues under different sectors ranging from agriculture, biotechnology and pharmaceuticals have been explained. This paper aims to present a thorough analysis of the current IPR situation and seeks to determine the validity of the claims against India. Clarifying its anti-monopoly stance, settling the allegations of selling counterfeited and pirated products, in addition to promoting India as an attractive business destination by streamlining its IPR procedures, India needs to take a strategic approach to align its IP regime with the international standards without sacrificing its domestic needs.

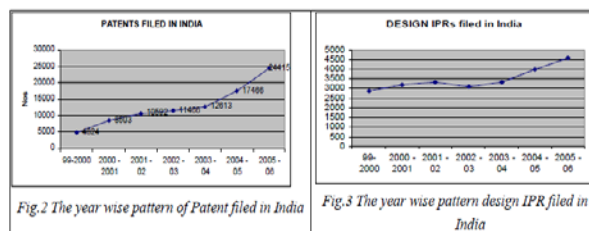
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1. DEFINITION

Intellectual property rights can be broadly defined as legal rights established over creative or inventive ideas. Such legal rights generally allow right holders to exclude unauthorized commercial use of their creation by any other third party. IPRs are the territorial rights which have a fixed term and can be renewed after a stipulated time as specified in the law by way of making payment toward official fees. Exceptionally, trade secrets have an infinite life but they don't have to be renewed. Apart from this, trade secrets have another nature of being assigned, gifted, sold and licensed like any other tangible property. Unlike other moveable and immovable properties, these rights can be separately held in many countries at the same time. IPR can be held only by legal entities i.e., who have the right to sell and purchase property. In the other way, any non-autonomous institution doesn't have rights to own intellectual property. These rights are protected by their respective sections and rules.

2. TIMELINE OF PATENTING IN INDIA

Patent policy in India has a long history dating back to pre-independence days. The two committees which were formed are The Patent Inquiry committee and Ayyangar committee which noted that foreign patentees were acquiring patents not "in the interests of the economy of the country granting the patent or with a view to manufacture there but with the object of protecting an export market from competition from rival manufacturers particularly those in other parts of the world". Thus India "is deprived of getting, in many cases, goods...at cheaper prices from alternative sources because of the patent protection granted in India [1]. The reports concluded that foreigners held 80-90% of the patents in India and were exploiting the system to achieve monopolistic control of the market [2]. The committees therefore suggested that a patent system that focused on access to resources at lower prices would be beneficial to India. The patents act of 1970 was based on the recommendations of these committees which focused on principle of national treatment to foreigners, search for novelty, inventions were made non patentable and granted patents for 14 years. It provided only for process patent and not product patent in food, chemicals and medicines. This contradicted with TRIPS which provided for both product and process patents in all fields of technology. Also the term of patents was 20 years under TRIPS. India became a member of Paris convention, patent cooperation treaty, Budapest treaty and finally complied with TRIPS in 2005. The most important amendments India brought in was to extent the term of patent to 20 years and debarring of ever greening of patents, a process by which patent holder extended the life of the patent with minor tinkering with the products. The legislation raised bar for what constitutes invention and what cannot be patented.



Source: WIPO report "Impact of IPR on economic growth"

3. MAJOR CONTROVERSIES RELATING TO IPR IN DIFFERENT SECTORS

3.1. Pharmaceuticals

The patent system that India established was clearly against the IP regime promoted by US. The US terms India's activities of finding an alternative cheaper method or alternative as "piracy". The pharmaceutical industry in US has supported this claim time again. Phrma, the association that represents US based pharmaceutical company's points out, "Based on the refusal of the Government to provide pharmaceutical patent protection, India has become a haven for bulk pharmaceutical manufacturers who pirate the intellectual property of the world's research-based pharmaceutical industry" [3].

Indian supreme court has time and again ruled that introduction of patenting of pharmaceutical product would inhibit the availability of medicines for the population of India and developing countries more generally. Novartis, Swiss pharmaceutical giant filed a suit against Cipla, Indian pharma giant for selling its affordable version of respiratory drug Onbrez. Cipla sold it for Rs. 130 for 10 pills whereas Novartis sold it at five times the cost at Rs.677. Not only this Novartis was accused of importing a negligible quantity of drug for only 8000 patients whereas the demand was much higher as 1.5 cr patients suffer from lung and respiratory disease in India. In 2012, India revoked three patents on grounds that included lack of novelty/inventive step and "repetitive patents" on the same drug. These were for Pfizer's cancer drug Sutent, Roche Holding's Hepatitis C drug Pegasys and Merck's asthma treatment aerosol suspension formulation. The intellectual property appellate board in 2013 upheld the grant of compulsory license to Hyderabad based Natco Pharma limited to produce and market Nexavar, patented cancer drug of multinational pharma major Bayer Corporation which sold Nexavar at Rs.2.8 lakh for a pack of 120 tablets. Whereas the generic version produced by Natco for the same drug costed Rs. 8800 only.

3.2. Agriculture

Agriculture sector goods and services can be protected through different types of IPR such as patents, plant breeders rights, trademarks, geographical indications and trade secrets. Indian patents act 1970 could be applied mainly for agricultural tools and machinery or the process for development of agricultural chemicals. However methods in agriculture or horticulture, life forms of other microorganisms like plant varieties, strain/breed of animals, fish or birds as well as products derived from biochemical process, treatment of plants and animals to render them free from disease or increase their economic value does not constitute patentable subject matter.

Given the importance of agriculture in Indian economy, there has been extensive public debate in implementing TRIPS related to agriculture sector. These relate to institution of plant

breeders rights, patent for biotechnological inventions and geographical indications. The trips proposals seen as patenting of life itself, raising ethical as well as socio economic questions [4]. An association of farmers in Karnataka attacked US multinational seed company, Cargill seeds in 1993, expressing concern over food security if seeds were patented.

Another area of IPR related to agriculture sector that has raised the issue recently is geographical indications. GI tags have been granted to Darjeeling tea, Assam muga silk, Banaras brocades etc. But the same has not been away from controversies. Basmati rice growers in Pakistan reportedly have moved to GI dispute tribunal against granting basmati GI tag to India, since most of the basmati producing areas are in Pakistan. In this case most Indians believe that India should have a strong law on geographical indications so that Indian names are not patented and misused for economic gain in India's export market.

3.3. Biotechnology

Though the inventions filed in biotechnology were mostly of foreign origin but there has been considerable increase in Indian applications as well. As in other jurisdictions, in India too, the claim must be new, non-obvious, and industrially applicable and requires sufficient disclosures. When the existence of a new compound is discovered in nature, one cannot patent it because the form it exists in is not available in nature. Further to translate it into a patentable subject, the discovered component must be substantially changed through human interventions into a form which does not occur in nature or employed in a process resulting in technical advancement or is of economic significance. Some patentable inventions are gene sequences, modified microorganisms, living entities of artificial origin etc. But some non-patentable subjects are new use or new property of known substance, discovery of living things or non-living substances in nature, any invention which is harmful to human etc. Major controversies relating to biotechnology patenting relates to claim being cancelled on the grounds of lack of clarity on distinguishing features, insufficient disclosure etc. Not only this, environmental concerns have been raised regarding biotechnology patented products.

4. CONCERNS WITH INDIA'S IPR POLICY

The issue of IPR was once again raised when India was ranked last for two years in intellectual property right index out of 30 countries by US chamber of commerce. Also on april 30'2015, US had brought out special 301 report, annual review of state of global intellectual property right protection and enforcement, in which it listed India in "priority watch list country" requiring close scrutiny for their alleged weakness in diverse areas including pharma, IT and publishing . It expressed concerns over issuance of single compulsory license by India. Section 3(d) of Indian patents act 1970, does not allow patent to be granted to inventions involving new forms

of known substance unless it differs significantly with properties related to efficacy.

India's IP Regime has been continuously questioned by the developed countries, especially the US for its alleged non-compliance with the TRIPS regulations. The office of US Trade Representatives recently came out with their Report 301, an annual report prepared under the Section 301 as amended of the Trade Act of 1974. This Report identifies the barriers to trade suffered by US companies and products, due to the Intellectual Property laws in foreign countries. It also seeks to identify and classify such countries where US persons are not provided "fair and equitable" market access and an effective protection of the Intellectual Property rights.

In the 301 Report, 2015, India has again been placed on the "Priority Watch List" indicating India is a country with "serious deficiencies in intellectual property rights" requiring immediate attention of the USTR. This is one step below the worst category of "Priority Foreign Countries" that deny fair and equitable market access and protection of intellectual property rights to US companies. The USTR continues to criticize India's pro-access IP policies and suggest measures that will help improve the abysmal state of IP regime in India, but will actually only help the pharmaceutical giants, especially of the US.

Following are some of the allegations put forth by the USTR against India's IP regime and the reasons why they are invalid or right away illogical:

1. India and China are leading suppliers of counterfeit pharmaceuticals shipped all over the world.
 - A product will be considered counterfeited if it infringes a trademark. This infringement is motivated by excessive prices charged, especially for medicines. The real concern here should be the medicines sold that are unregistered, substandard or unsafe, which is not really an issue of IPR.
2. By means of domestic preference procurement, local content/ investment requirements, and other means, India is unlawfully incentivizing domestic companies and discriminating against the foreign companies. Also, India imposes unfair tariffs on medicines, medical devices in addition to allowing compulsory licensing for products in certain cases if they aren't manufactured in India.
 - In the interest of the developing countries to develop to progress in terms of technological advancements, WTO TRIPS allows the governments of developing nations to encourage domestic production through governmental measures instead of allowing large MNCs with IP rights to exploit the countries by providing them a complete access. Such discretionary powers to curtail monopoly pricing are enjoyed by other governments as well, such as the US Department of Defence. Compulsory licensing by governments encourages domestic production and promotes competition and thus, limits the monopoly pricing of imports.
3. US raise several concerns over the condition of the environment of getting and enforcing patents in India in biopharmaceutical sector, green technologies.
 - Despite investment in the modification of the patent offices in India and the fact that the majority of patents issued in India belong to the US, it still has been leveling accusations against the country.
4. US is concerned that the Section 3(d) of India's Patent Act limits the patentability of potentially innovations that could be beneficial, in addition to those that enjoy patents in multiple other regions.
 - Section 3(d) of the Patent Act actually limits the patenting of new uses of medicines or new forms till they give an evidence of significant curative benefits. It, in effect, restricts the granting of weak patents that will serve the only purpose of enhance monopoly profits. Thus, instead of eliminating or loosening this Section, it must be effectively implemented and strengthened.
5. The US also suggested India to improve its patent opposition mechanisms.
 - The decisions of the patent opposition are evidence-based and informed, made as per the reference of the WTO TRIPS agreement and assisted by the involvement of knowledgeable generic companies and other patent filers. Dozens of unworthy pharma patent applications have been successfully eliminated over the past 10 years.
6. The United States is apprehensive of the application of the Compulsory Licensing Law by India, and is thus monitoring its application.
 - While the US has issued multiple government use licenses itself on hundreds of patents, it is accusing India of over-exploiting the Compulsory Licensing route, when India has, thus far issued only 1 Compulsory License and that too in full compliance with the national law, the TRIPS agreement and the Doha Declaration on TRIPS agreement and Public Welfare.

7. US is looking at India for enhancing its enforcement measures including border enforcement.
- India shouldn't be compelled to employ scarce government resources for public enforcement of what essentially constitute private rights, especially when India's border enforcement measures are fully TRIPS compliant.

The interest of the country and its citizens in access to green technologies, medicines, agricultural techniques and materials can only be served if the country doesn't cater to the monopoly interests. Thus, in order to strengthen its right to health stance, India must soon clarify its anti-monopoly stance.

5. CONCLUSION AND SUGGESTIONS

The dual role played by intellectual property rights- first, as temporary monopolies granted to innovators, and second, as a tool to ensure the social, scientific, cultural progress and innovation, makes its protection extremely crucial for a developing country like India. The question on the relationship between IP rights given to innovators and the promotion of innovation in the society has been deliberated upon for years in economics, politics and law. Temporary monopolies result in increasing prices, dis-allocating resources and a net loss in welfare. Also, it is widely accepted that innovation is incidental and cumulative, thus requires access to pre-existing literature. Therefore, an excessive IP protectionist policy ends up hurting the very objectives it is supposed to ensure. Existing empirical research doesn't uphold the hypothesized relationship between the granting of IP rights and innovation and productivity. Bessen and Meurer, found in their empirical work in Patent Failure (2008), that increased patenting, led to a decline in social welfare. Also, the literature that does show that there exists a relationship between stronger patent regimes and innovation, maintains that it doesn't hold true for developing economies.

Thus, it can be deduced that a system centred around maximization of intellectual property would impair true sharing of knowledge and true advancement in technology, arts and culture. Therefore, the IP policy must be developed with a cautious and nuanced approach towards intellectual property, bearing in mind India's state as an emerging economy and its international position. In addition, it must be acknowledged that there is no positive societal result in the mere creation of intellectual property. India's IP policies are in line with TRIPS and it should continue to utilize the flexibilities available in TRIPS and other international treaties for taking care of its national priorities. India should also be cautious in participating in such bilateral and plurilateral agreements that will increase its IPR responsibilities more than the existing level.

It also must be noted, however, that greater IPR protection is necessary for India to be able to participate in global R&D in a manner that is at par with its level of technological sophistication. For India to be able to transform itself from being the "pharmacy of the world" to a leader in innovation in the pharmaceutical industry, Indian industry needs to collaborate with the world leaders in the pharmaceutical research. This is possible only if India's IPR is able to convince the developed nations with the sophistication of the legal framework in the country regarding the protection of intellectual property. This has to be done while maintaining the primacy of developing a policy that is informed by the principles of fairness and equity, balancing protection of intellectual property along with limitations and user rights such as those that promote access to medicines, governmental work, cultural rights and ensure freedom of expression, research and innovation.

The existing empirical literature shows that the effectiveness of patents and protectionist policies varies from industry to industry. Considering the economic background and socio economic inequalities in India, having stringent patenting rules in sectors like pharmaceuticals, agriculture can prove to be extremely detrimental for the masses. Whereas, in order to promote growth and innovation, patenting of softwares and technological process and products is a welcome step.

Creativity and Innovation are the forces which drive growth, development and progress in the knowledge economy. We conclude with the words of Debabrata Saha, the Deputy Permanent Representative of India to the United Nations, while speaking on the introduction of the Development Agenda at the World Intellectual Property Organization- "Intellectual property rights have to be viewed not as a self contained and distinct domain, but rather as an effective policy instrument for wide ranging socio-economic and technological development. The primary objective of this instrument is to maximize public welfare."

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