GUEST ARTICLE

PATENT LAW AND THE INDIAN POLICY SHIFT

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1. INTRODUCTION

Over the past two decades, India has substantially intensified the protection of Intellectual Property Rights (IPRs). This has although happened due to a number of concomitant factors, and the principal cause can be attributed to India's obligation under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).[2] IPRs are a bundle of exclusive private property rights granted for promoting the progress of science and useful arts. The theoretical underpinning suggests that IPRs act as incentives for innovation and thus benefits the society as a whole. Different categories of IP have different justifications based on theories of property propounded by Locke, Hegel, Kant, Bentham, etc.[3] In the case of patents, the primary utilitarian justification is disclosure of knowledge which would have otherwise remained secret.

However, the most fundamental core of IPRs is the right to exclude. This right is designed to create to convey market power to the inventor to inhibit static competition by others and thus they also impose a social monopoly cost on the society. However, free-market economists understand this relationship in terms of the ability of IPRs to create dynamic efficiency by contributing to innovation. IPRs although central to the concept of free markets come along with costs of excluding competition, which equally forms the edifice of free markets.

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[2] The WTO Agreement on Trade-Related Aspects on Intellectual Property Rights (1994) Available at: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

[3] William Fisher, Theories of intellectual Property, Harvard Law School, Available at: http://www.law.harvard.edu/faculty/tfisher/iptheory.html

Consequently, the optimal IPR policy would be the one that balances the interests of the technology producers' vis-à-vis the public interest in its use and consumption.[4]

IPRs involve categories of works which are assured protection through Patents, Copyrights, Trademarks, Geographical Indications, Industrial Designs, Layout Design Protection, Plant variety Protection and Trade Secrets. While the major debate in the policy shift has occurred in the area of Patents, there have also been significant changes in the law and policy of other forms of IP protection. In fact, certain forms of IPR's have been newly introduced complying with India's obligation under the TRIPS Agreement, viz., the protection of Geographical Indications, Layout Design Protection and Plant Variety Protection. The existing Patent, Industrial designs, Copyright and Trademark legislations were either drastically amended or reintroduced to comply fully with the TRIPS Agreement Mandate. In the last couple of decades, India has seen significant reforms in its IP policy in the wake of globalisation under the WTO. While policy shifts in other forms of IPR's have their implications on India's socio-economic growth, the changes in the patent scenario are worth examining in detail. It is mainly due to the impact created by the patent monopoly in India's ability to achieve economic transformation and social welfare that this policy shift will be gaining importance in the days to come.

2. THE INCREASING PRESSURE ON OPTIMAL PATENT POLICY

The non-monopoly origins of the patent system provide us with deep critical insights about the fact that the current understanding of the patent law and policy is partially flawed in its approach.[5] The patent system developed out of a vision for industrial development in certain parts of Europe. Patent policies aimed at technology transfer and internal competition accrued Industrial Revolution in Great Brittan in

[4] Correa Carlos, Managing the Provision for Knowledge: The Design of Intellectual Property Laws, UNDP (2002) Available at: http://web.undp.org/globalpublicgoods/globalization/toc.html

[5] Zorina Khan, History of Patents, (2002) available at: www.iprcommission.org/papers/word/study.../sp1a_**khan**_study.doc

early 19th century.[6] However, this was a period in which there was total flexibility in terms of designing patent policies in favour of territorial or national interests. The second half of 19th century saw international consensus in Patent protection through the Paris Convention of 1883.[7]

Even while there were certain minimum obligations, they were non-binding in nature and hence member countries substantially had the freedom to frame policies although with limited flexibilities. Paris Convention primarily did not require its member countries to give effect to the agreement unless they had a patent law in the territory. The Paris Convention essentially occurred through a process of general consensus which suggests that the member countries formally agreed to standards which were reflective of its internal patent policies. The 20th century saw the rise of United States and a few Asian countries which framed suitable patent policies based upon the then available flexibilities in the international patent norms. Thus, if the patent system has a history of delivering on the general socio-economic welfare and growth of certain countries, it can well be seen that the patent system fundamentally focused on its essential object. It was the sovereign countries ability to use those flexibilities that matured the patent system into a tool for socio-economic growth.

However, the TRIPS Agreement was a watershed where the individual countries were left with little or no policy options due to the limited nature of flexibilities. The binding nature of obligations came out as fetters on countries willingness to bypass the international norms thereby allowing it to frame policies in national interests. Moreover, the TRIPS Agreement owes its origin to certain vested corporate interest which lacks sound sense of balance in allowing countries to move on the growth path. It is in this context that we attribute the TRIPS Agreement for disallowing countries to frame optimal patent policies in the light of its socio-economic objectives. Such pressure is quite visible when we examine the recent policy shifts in the Indian scenario. Further, the attempts for international substantive patent law

[6] *Ibid.*

[7] The Paris Convention on Protection of Industrial Property (1883)

harmonization and the mounting pressures created by FTA's (Free Trade Agreements) are testimonial to this syndrome. The EU-India free trade agreement had initially contained provisions on data exclusivity and patent term extensions and patent-linkage being put at the negotiating table.[8] However, good sense prevailed over the Indian government and the PMO in 2010 issued a statement that India will not negotiate TRIPS-plus commitment that goes beyond domestic laws. Bilateral investment treaties are another contentious area which can have implications on domestic patent law and policy. BITs have harsher provisions on expropriation which require full compensation for any act of direct or indirect expropriation including due exercise of regulatory power. Some commentators are of the opinion that India's 83 BITs (72 in force) are way TRIPS –plus and hence India has to tread a cautious path especially in the light of India having issued a compulsory licence on Bayer's drug Sorafenib (Nexavar).[9]

3. INDIA'S PATENT POLICY PRE-REFORMS ERA

Although India saw its first Patent Legislation in 1856, the essential policy focus gained momentum only after independence. Two expert committees were established in independent India to study the functional implications of the then prevailing Patents and Designs Act 1911 and to provide suggestions on the type of a patent system that India should implement. The Patent Enquiry Committee (1948-50) reported that, "the Indian patent system has failed in its main purpose, namely to stimulate inventions among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country, so as to secure the benefits thereof to the largest section of the public." The second committee, known as the Justice Ayyangar Committee (1957-59), 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".[10]

[8] EU- India FTA Negotiations

[9] Prabhash Ranjan, Compulsory Licences and BITs, Indian Express (2013)

[10] Report on the Revision of Patent Laws, Ayyangar Report (1959)

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. The committees therefore suggested that a patent system that focused on access to resources at lower prices would be beneficial to India.[11]

The Patent Act of 1970, the current legislation on patents in India, was based on the recommendations of these committees. The committees suggested abolition of the then existing product patent system for substances intended for use or capable of being used as food or as medicine or drug. Thus with the introduction of the Patent Act in 1970, India provided only process patents in case of pharmaceutical and chemical innovations. This conscious policy choice was made in light of abuse of the patent system by foreign patent holders. Even the term of protection for process patents in case of pharmaceuticals was limited to a maximum of seven years. The general term of protection was also limited to fourteen years. Compulsory licensing was a mechanism through which the abuse of patent rights was sought to be remedied. However in such cases certain criterion was set before any compulsory license could be issued. The patent law also provided for license of rights in case of certain areas where it was felt that everyone should have the right to use the patent straight away without having to listen to patent holders excuses.

Even the patent law criterion was left undefined which ultimately placed judiciary on the upper hand for determining the standards of patentability. Interestingly the Indian judiciary consciously followed a stricter approach in the light of the enshrined policy object of the patent system. In effect, the patent system prior to the economic reforms and TRIPS obligations was conservative in its approach. This accrued immense benefits to the Indian pharmaceutical industry which has today become the largest generic drug producer in the world. Paradoxically, the provision for product patents failed to stimulate innovations in other areas of technology even before the advent of TRIPS. Thus, the Indian technology industry can traditionally be understood as not essentially based on the patent framework. Several other factors including a closed license regime were also responsible

[11] *Ibid.*

for a lack of innovation and enterprise in different areas of technology in India.

4. INDIA'S PATENT POLICY POST-REFORM ERA

The reforms invoked in the early 1990 have changed the whole policy and legal outlook underlying the Patent regime in India. Although such reforms have been initiated in the light of TRIPS Agreement under the WTO, it appears that there are few more reasons than what meets the eye. Although India as a developing country initially argued against the inclusion of IPR's under the WTO framework, the current policy seems to suggest a different approach. A couple of major factors have influenced the current patent policy namely:

The changing alliances in the industry: Certain sections of the Indian industry are working on patent based business models, which presuppose Indian investments in R&D. What could also be seen is a spate of mergers and acquisitions by foreign firms in India and Indian firms across the globe. The increasing consolidation in the Indian industry has changed the equations of optimal patent policy needed to achieve socio-economic goals.

IP as a tool for attracting FDI: The current policy of industrial development based on foreign capital is believed to presuppose stronger IPRs. It is viewed that investments occur only when there is strong IP policy in favour of protecting foreign capital investments. Thus, even while there exist certain policy space in the international IP regime, it is the willingness of national governments to use those spaces that make the real difference. Thus from a low protection patent regime India has seen a significant shift upward.

The following were the major changes made to the Patents Act, 1970 since the post-reform era:

- Increase in the Patent term for 20 years for both products as well as processes.
- Provision of exclusive marketing rights in case of mailbox applications during the transitional period from 1995-2005.

- Specific definition of patent law thresholds which was earlier left to judicial interpretations.
- Abolition of licensing of rights.
- Narrower compulsory licensing provisions without proper time framework.
- Reversal of burden of proof in case of process patents.
- Patents for new subject matter including micro-organisms.

5. IMPLICATIONS OF THE POLICY SHIFT

One of the major criticisms of the current Indian patent policy is the allowance of product patents for drugs and chemicals, which it would have preferred to avoid, but for the TRIPS mandate.[12] Although certain sections of the Indian industry have matured into global firms, the vast majority of the industry is still based on foreign technology absorption and minimal R&D investments.[13]

However, the current policy also envisages certain stop gap arrangements for existing generic production[14] and also measures which could exclude minor improvement over of new chemical entities innovation.[15] However, such interpretation is left to the domain of judiciary which possesses a tremendous possibility of bypassing the public interest policy and stronger interpretation of private property rights in information.[16] This has put the whole issue of access and affordability of patented drugs and the consequent drying up of generic sources.

The economic significance test introduced into the inventive step criterion has also invited equal criticism.[17] While the patent system was traditionally designed for innovations worth protecting, it has slowly

[12] Article 27.1 of TRIPS

[13] Sudip Chaudhuri, The WTO and Indian Pharmaceutical Industry, Oxford University Press, (2005)

[14] Section 11(A)(7)

[15] Section 3(d)

[16] The Indian judiciary has shown tremendous inclination to align with the public interest goals of patent policy. See the discussion in later section.

[17] Section 2(1) (ja)

shifted its stance in favour of investments worth protecting. This has economic implications inasmuch as economic feasibility, even without improvements in technology may still be protected under the patents regime. The current definitions on patent law thresholds introduced, even while there exists sufficient flexibility under TRIPS, represents a significant shift from the traditional notions of patentability. The guideline issued by the Indian Patent Office however tend to adopt a cautious approach.[18]

The subject matter of patents has also been expanded in the wake of TRIPS to include micro-organisms. Thus, a clear policy of excluding DNA patents and patents on essential sequence tags (EST's) seems to haunt the existing patentability standards in India. This is particularly after the seminal decision of the US Supreme Court in Myriad Genetics case in 2013.[19] Unfortunately, the recently issued biotechnology guidelines by the Indian patent office lack definitive clarity on this issue. Certain innovations in the areas of biotechnology form tools for innovations since the innovations in this arena are both sequential and complementary. Thus, the whole question of rapid innovation in this area is under debate due to anti-common effects in the biotech inventions.[20]

The compulsory licensing provisions have also invited criticisms due to lack of time frame which could frustrate the purpose behind ensuring competition principles within the Patent scheme. Before the advent of the product patent regime in case of drugs and chemicals the existence of the time frame was not a sensitive issue but the position has altered

[18] See, Manual of Patent Practice and Procedure, IPO Guidelines (2010) http://www.ipindia.nic.in/ipr/patent/manual/HTML%20AND%20PDF/Manual%20of%20Patent%20Office%20Practice%20and%20Procedure%20-%20pdf/Manual%20of%20Patent%20Office%20Practice%20and%20Procedure.pdf

[19] Association of Molecular Pathology (2013)

[20] Rebecca Eisenberg and Micheal Heller, Tragedy of the Anticommons: Anticommons in the Bio-medical Industry, Science http://www.sciencemag.org/content/280/5364/698.full

without ensuring significant protection against abuse of patent monopoly.

6. JUDICIARY THE SAVING GRACE:

There are at least two notable instances where the Indian judiciary has interpreted patent provisions to balance it with concerns of access to medicines. In Novartis v. Union of India, the Supreme Court interpreted Section 3(d) to require "enhanced therapeutic efficacy." [21] This criteria leads to differentiation was introduced by the Indian parliament in 2005 to prevent ever-greening of pharmaceutical patents.[22] Thus by requiring inventors to show how derivatives to new chemical entities lead to some kind of therapeutic efficacy for patients, Section 3(d) and the Novartis decision of the Supreme Court has raised many contentious issues. Recently, United States Trade Representative has threatened India to list as a Section 301 "priority foreign country" for alleged violations of US intellectual property abroad. The USTR claims that Section 3(d) of India's patent law unfairly discriminated between different categories of pharmaceutical inventions.[23]

India also issued a compulsory licence on Bayer's anticancer drug Nexavar in 2012. In an application made by an Indian generic company NATCO, the Controller General of patents issued the compulsory licence on all three grounds available under the Indian law. The Controller General made a finding that Bayer did not cater to a large section of the India public (Bayer was estimated to cater only to 2% of the patient population) and that Bayer's price for Neaxaver was not affordable by a larger section of the public (Rs. 2,80,000/- per patient per month) and that Bayer did not locally work the invention in India (Bayer imported all quantities of Nexavar into India).[24] This

[21] Novartis v. Union of India (2013)
[22] Section 3(d) Parliamentary Debates
[23] USTR Section 301 Report (2014)
[24] Natco Compulsory Licence (2012)

finding was confirmed by the Intellectual Property Appellate Board in 2013[25] and in July 2014, the high court has also confirmed the compulsory licence.[26] It may be noted that compulsory licence is an important flexibility granted under the TRIPS Agreement Article 31. However, the USTR report has raised objections owing to one of the grounds i.e. local working.[27]

7. CONCLUSION:

The policy shift in favour of stronger IPRs need not necessarily bring in larger investments. There is always a possibility of the patent holder exploiting the market through importation right thus putting the patent-investment link into question. What is expected out of a patent regime must be clearly understood in the light of socio-economic objects from a developing country's perspective. If socio-economic equity is a Constitutional goal, it goes without saying that IP policy must be designed and implemented based on competition factors rather than being totally carried away by economic arguments in favour of certain sections of the industry.

[25] Bayer v. Union of India (2013)
[26] Bayer v. Union of India (2014)
[27] USTR Section 301 Report (2014)