



PHARMA DEVELOPMENT AND LAW: ARE THEY PARALLEL?

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ABSTRACT

Intellectual Property (IP) is subject to limitations and the government can impede with the monopoly rights of the IP owners by issuing compulsory licenses, granting licenses of right and daunting with limits on the ground of public health and morality. In the pursuit called competition and development, it is forgotten that an iota of difference does matter. A general perception or what everyone considers as the seeming definition that poverty is a condition where people's basic needs for food, clothing, and shelter are not being met. But many across the globe have no access to indispensable drugs. One basic reason is of course again poverty, where, in many developing countries, consumers do not have enough purchasing power. Other important factors are inadequate national health, infrastructures and financing systems. The prices of medicines also play a vital role as many people in developing countries have to pay for their own medicines and there are no general health insurance systems. This paper addresses the concerns of patent law in pharma industry growth and its implications in developing countries.

KEY WORDS: Intellectual Property; Patents; Pharma; Medicine; Rights; Law.



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INTRODUCTION

Property rights have become a major concern in today's world so as to gratify the right in rem and right in personam. Opulence and property rights are inextricably associated. The importance of having well-defined and strongly protected property rights is now extensively acknowledged among economists and policymakers. A personal property system gives persons the elite right to employ their possessions as they see able-bodied. That authority over what is theirs, leads property employers to take complete version of all the benefits and costs of employing those possessions in a meticulous manner. The procedure of evaluating costs and benefits builds what economists call efficient outcomes. That decodes into higher standards of an existence for all. It is only in the last few decades, however, that economists have acknowledged the significance of property rights. Throughout much of the history of modern economics, the subject was given short confession. Even Stalwart supporters of the market economy polished over the subject. Not unexpectedly, much terrible development policies resulted from that disregard. Even if policymakers in developed countries and international institutions now recognize the critical role played by a system of private property in economic development, they are limited in what they can do to help developing countries evolve such a system. The point gets more crucial in terms of intangible property. In context with IP, there is growing recognition that patents and IPR cannot be regulated under a universal standard. Different socio-economic conditions and levels of development require different intellectual property systems. The patent system may entail considerable short-term costs for developing countries, mainly due to administrative costs and problems, with higher prices for medicines and key technological inputs, while long-term benefits seem uncertain and costly to achieve in many nations, particularly for the poorest countries. Moreover, higher standards of patent protection are unlikely to have a positive effect on local innovation, except in those few countries (and sectors) that have reached a certain level of technological development and have the capacity to finance substantial research and development. Higher standards of IPR protection were implemented in the developed countries only when a threshold level of technological advancement was achieved. For instance, pharmaceutical products were excluded from patent protection in Germany till 1968, in Switzerland till 1977, in Italy till 1978, in Spain and Portugal till 1992, and in Finland till 1995.¹ In countries with a longer history of pharmaceutical product patents, such as Canada, France and the UK, compulsory licensing provisions were quite liberal. India's pharmaceuticals sector is yet another example of benefiting from a more relaxed patent regime.² All these factors should be considered when harmonization and higher standards of IPR are thrust upon developing countries.

Property

The concept of property was understood in different styles and contexts³ – as theft, robbery, murder, slavery; a bundle of sticklike rights as a thing or a collection of things that one owns as a security and liberty; a social relationship power; a myth. It is also viewed as the exploiter of poor; it protects the poor⁴; a natural right an artificial creation of state; a principal hope for preventing ecological disaster in the world's rainforests.⁵⁻⁶ According to Blacks' Law Dictionary, 1979, legally property is in rem as opposed to in personam. However, it has been understood and construed, according to time and need. Now the role of property rights has been acknowledged by economists in determining the allocation of resources and distribution of output in shaping the incentive structures for successful economic performance of the economy. There are various theories of property based on political, economic and social ideologies like the Natural Law Theory, Meta-physical Theory, Historical Theory, Positive Theory, Psychological Theory and Sociological Theory.⁷ Property can be classified as tangible and intangible. Tangible are those which can be seen and touched, whereas intangible are those which cannot be touched or seen but whose benefit is experienced or enjoyed. Eventually what is important here is not to classify them, instead to appreciate its economic value.

Materialization of Property Rights

The primary purpose of property rights and their accomplishment is that they purge destructive competition for control of economic resources. Well defined and well protected property rights, reinstates competition by violence with competition by peaceful means.⁸ A report by the World Bank (1997), *The State in a Changing World*, accentuates not only the need to have sheltered property rights, but also the need to pay attention to the surfacing nature of property rights for the advancement of third world countries. To prevent the tragedy of commons property rights are required.⁹ For example, a plot of land is used by number of people to graze their cattle, and as the number of cattle increases or the number of people using such land for grazing their cattle increases, the land will become barren and unsuitable for grazing. Hence the natural rights and the economic incentive theory justify the concept of protection of Intellectual Property Rights (IPRs) similar to that of any other property protection, therefore, not making the value of such IP (Intellectual Property) bleak, where any state imposes law for exclusive rights.

The rights and need of IP, an emerging economy

IP has been recognized as vital factor for trade between countries. IP theft has become the epidemic of Multi National Corporations (MNCs) in many of the developing economies across the world.¹⁰ There is no exact definition of IP because it is a basket of different rights and is as diverse as human ingenuity. IPR's are an artifact of industrialization and modernization, designed to protect and reward individual ingenuity and innovation reflected in new ideas or inventions.¹¹ IP is not supreme, where no private person can take pleasure in an

exclusive right with respect to IP without the control and regulation by the government under the sovereign doctrine of *eminent domain*. IP is subject to limitations and the government can impede with the monopoly rights of the IP owners by issuing compulsory licenses, granting licenses of right and daunting with limits on the ground of public health and morality.⁷ As universally understood by all it is a property created as a result of intellectual creative effort or commercial status and goodwill. According to World Intellectual Property Organization (WIPO), IP refers to creations of the mind like inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. It is basically in the form of intangible, territorial and statutory law provisions. They are Copyright, Trademarks, Patents, Industrial Design, Integrated Circuits, Undisclosed Information / Trade secrets and Geographic Indicators (GIs). IP is divided into two sections (WIPO) namely Industrial property and Copyright. The rights of IP are governed and protected in various countries by The Patents Act 1970; The Copyright Act 1957; The Trademarks Act 1999; The Designs Act 2000; The Geographical Indication of Good's Act 1999. The Indian Contract Act 1956, The Biological Diversity Act 2002, The Environmental Protection Act 1986, The Forest Act 1980, provides protection for Bio Resources in Traditional Knowledge (TK) indirectly. Industrial properties are inventions providing a way out to technical tribulations where industrial designs are artistic and visual creations determining the characteristics of industrial products. It includes inventions (patents), trademarks, industrial designs, and geographical indications of source, service marks, commercial names and designations and the protection of unfair competition. Copyright includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs. Generally, it is the manifestation of the author's ideas that is protected rather than the ideas themselves. An example of an idea published in the form of an article where reproduction of the same is forbidden without the approval of the author. The innovations and creative expressions of indigenous and local communities are also considered as IP and because they are traditional they may not be entirely protected by present IP structures. Access to, and equitable benefit-sharing in, genetic resources also raise IP questions. Normative and capacity-building programs are underway at WIPO to develop unprejudiced and suitable legal and practical responses to these issues (WIPO) Patents are exclusive rights given to the creator for invention. According to United States Patent and Trademark Office (USPTO), a patent is an intellectual property right granted by the Government of the United States of America (USA) to an inventor to exclude others from making, using, offering for sale, or selling the invention anywhere in the USA or importing the invention into the USA for a limited time in exchange for public revelation of the invention when the patent is granted. According to

Haley (2000) patenting propensity indicates that either there is trust in the country's IP protection or a larger reliance on maintaining secrecy as long as possible and less faith in their country's IP protection, where the former has greater or more susceptibility to patent and the latter has lesser susceptibility to patent. The USA government grants three types of patents namely utility patents, design patents and plant patents. Where utility patents are granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any improvement thereof to the existing ones. Design patents are granted to anyone who invents a new, original and ornamental design for an article of manufacture. Plant patents are granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant. On the contrary, The Patents Act, 1970 in India does not give any utility patents, hence not encouraging discoveries as an intellectual property which actually demonstrates the quality of the IP protected. Patents are of only one type in India. It is granted only for inventions and where TK not under public domain is also not considered as an invention. The patent is granted for a period of twenty years.

The fusing position for Indian IPR system

Regarding the patent law and bilateral ties with the USA, the viability for Indian patent office to consent to Hyderabad based Natco Pharma to make a generic version of German pharmaceutical company Bayer's cancer drug Nexavar? Let's consider the case where HIV drugs which were patented by the USA, lost its case on appeal when the generic version of the same was supplied to African HIV patients.¹² Right to health is a constitutional right across many countries. Life saving drugs should not be patented. Health cannot be challenged in terms of business with the life of humans. Article 8 of TRIPS also emphasizes to give protection to public health and public interest.¹³ As defined by WHO (1948), health is 'a state of complete physical, mental and social well being and not merely the absence of disease or infirmity'. The developments in pharmaceutical industry provoked the USA government with concentrated pressure on bringing about a change in Indian patent law, which is superfluous. Certain recent incidents that can be tinted are the Natco Pharma has been permitted to produce a generic version of Bayer's cancer drug Nexavar by the Indian patent office in 2012, in the process Bayer lost its appeal in the Supreme Court. On the similar lines Novartis was also not granted patent by the Supreme Court in 2013, for the cancer drug Glivec, though Novartis holds patent for Glivec in various countries including USA. Pfizer, of the USA, also struggles with patent disputes in India.¹⁴ Emphasizing the attention towards pharma industry and the makers' influence legislators, regulatory agencies or other instruments group have the sturdiest representations to the USA government against India's IPR regime, asserting that the IP law of India is not compliant with WTO's TRIPs. While examining the Indian Patent Law, the magnitude is observed in regard to two issues, one, Section 3(d) on similar lines with Section 22 of the

Intellectual Property Code of the Philippines and second, Section 84 of the Indian Patent Law. Under Section 3(d), new forms of existing medicines cannot be patented unless they improve therapeutic efficacy, hence India rejected a patent for Glivec.¹⁵ Section 84 allows issuing a compulsory license to meet the reasonable requirements of the public at a reasonably affordable price. A compulsory license can also be granted under Section 92 of the Act in case of a national emergency. Natco Pharma got a compulsory license, the first ever in India, for generic Nexavar under Section 84. Multinational drug makers sense that the Section 84 narrows the criteria for patentability and undermines incentives for innovation. It can be well thought-out that Section 84 endeavours is to ensure a larger segment of the population in India be able to afford health care, as shored up by the TRIPs and WTO. It is more viable that, in India Glivec be sold for Rs. 14 lakhs than \$ 92,000 in the USA and the generic Veenat for Rs 1 lakh per patient a year.¹⁶ It is also emphasized that inequality in health care is highly deplorable by relating it to business.¹⁷ The economic value of plants or living organisms for pharmaceutical purposes is gargantuan and benefiting not only to the pharmaceutical industries engaged in Research and Development (R & D) but to the host country and indigenous community also, who gain from ownership of the biological resources and expect adequate compensation for resource use, especially after the CBD in 1992. The Convention unambiguously ascertains the control and sovereignty of local agency over the biological resources and its diversity.¹⁸ Many incidents of biopiracy by the US in the name of patent have already been observed. With improvement in molecular biology and accessibility of sophisticated diagnostic tools for screening, it has become pretty valuable for pharmaceutical firms to conduct research through bioprospecting.¹⁹ Today, less than 50,000 patent applications are filed every year in India, bestowing more significance to patent, whereas the USA diminishes the significance by granting patent even for petty things in the category named utility patents and the utility model will not work in the pharma sector as drug innovations are generally not small-company innovations and for the reason that the potential for abuse is very high²⁰. In high-technology laboratories, extracts from biological

specimens go through rapid and precise screening procedures that agree for the isolation of chemicals displaying an exclusively targeted activity. In 1980, not an iota of the USA pharmaceutical industry budget was spent on research on higher plants, but now, it is estimated that more than 200 companies and research organizations across the world are screening plant and animal components for medicinal purposes. The USA must reach the WTO's dispute settlement body as a replacement of appealing bilaterally with the embedded threat of retreating trade benefits and not negotiating IPR as part of trade agreements with other countries and blocs such as the European Union, direct technical deliberations amidst the IPR policy are being held only with the USA. Discovery of several life-saving drugs together with anti-neoplastic drugs, e.g. vinblastine, taxol, topotecan and etoposide in the recent past has renewed the interest of pharmaceutical industries in bioprospecting. The combination of high quality services at low cost is also making India a final target for health tourism.²¹

CONCLUSION

India's IP laws are vigorous, and it does not need trifling the policy which provides ample credence to public interest while granting IPRs. India is a party to the WTO, and if any country has an issue with India's IP laws, then it should raise it at the WTO. It is recommended that perchance, time for the USA to examine its patent law. Why should India give in to the political advocacy groups, attempting to influence legislators, regulatory agencies or other instruments of government, as it is also a well known fact that anything under the sun is patentable according to the USA law?

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Conflict of interest

The author declares no conflict of interest.

REFERENCES

1. Eqbal B. Intellectual Property is a Privilege, not a Human Right, InfochangeTrade and Development; 2008 [updated 2015 December 15; cited 2016 March 8]. Available from: <http://infochangeindia.org/trade-a-development/intellectual-property-rights/intellectual-property-rights-are-a-privilege-not-a-human-right.html>
2. Addis M, Morrow P. Your Rights: The Liberty Guide to Human Rights. Pluto Press, London. 2005.
3. Reed OL. What Is "Property"? American Business Law Journal. 2004; 41: 459-501.
4. Bethell T. The Noblest Triumph: Property and Prosperity through the Ages, St. Martin's Press. 1998; 202.
5. Cairncross F. Costing the Earth, Harvard Business School Press, Boston. 1992; 142.
6. Hoskins L, Eiras AI. Property Rights; the Key to Economic Growth, in 2002 Index to Economic Freedom. 37- 45.
7. Reddy GB. Intellectual Property Rights and the Law, Gogia Law Agency. 2009.
8. Alchian AA. "Some Economics of Property Rights," *Il Politico*, the Collected Works of Armen A Alchian, Liberty Fund. 2006; 816-829.
9. Hardin G. The Tragedy of the Commons. *Science*. 1968; 162: 1243-1248.
10. Haley TG. Intellectual Property Rights and Foreign Direct Investment in Emerging Markets. *Marketing Intelligence and Planning*. 2000; 18: 273 - 280.
11. Shiva V. *Patents, Myths and Reality India*: Penguin. 2001.
12. Reichman JH. Compulsory licensing of patented pharmaceutical inventions: evaluating the options. *J Law Med. Ethics*. 2009; 37: 247-263.
13. Tiwari R, Tiwari G, Rai AK and Srivastawa B. Management of Intellectual property rights in India: An updated Review. *Journal of Natural Science, Biology and Medicine*. 2011; 2: 2-12.
14. Madhur H. Compulsory Licensing under Section 92A: Issues and Concerns. *Journal of Intellectual Property rights*. 2008; 13: 464-472.
15. Gabble R, Kohler JC. To patent or not to patent? The case of Novartis' cancer drug Glivec in India. *Globalization and Health*. 2014; 10:3.
16. Abboud. The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts. *Blood*. 2013; 121 (22): 4439-4442.
17. Bosanquet N, Sikora K. The economics of Cancer care in the UK. *The Lancet Oncology*. 2004; 5(9): 568-574.
18. Kumar P, Tarui, N. Identifying the contribution of indigenous knowledge in bioprospecting for effective conservation strategy. In: *Bridging Scales and Epistemologies Conference*, Alexandria, Egypt, March. 2004; 17-20.
19. RAFI Communique Bioprospecting/Biopiracy and indigenous people. 2006; 1-13. <http://www.latinsynargy.org/bioprospecting.html>.
20. Usha S, Annadurai The socio-economic development of India with respect to benefits from commercial exploration of Traditional Medicine and its protection. *International Journal of Pharma and Bioscience*. 2012; 3(1): 499-508
21. Ray S. Development of a Framework towards Successful Implementation of E-Governance Initiatives in Health Sector in India. *International Journal of Health Care Quality Assurance*. 2007; 20 (6): 64.