"Patented Medicines vs. Right to Health"*

Harshavardhan Yadav **

Abstract

Health is one of the fundamental basic needs of all human being. The *right to life includes the right to health.* The Constitution as well as International Covenants and treaties relating to Human Rights recognize that the right to health would encompass a number of elements from prevention to cure to access to drugs. However, the introduction of product patent from 1st January 2005, gives a monopoly to the patent owner for the production of patented article during the term of the patent (20 years). Therefore, product patent protection for medicines and agro-chemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. Thus reduces accessibility and affordability of drugs consequentially denial of access to medicines to the poor across the India. In order to harmonize, the conflicting interests' judicious use of provisions like compulsory license and other measures such as Drug Subsidies, Price Control Mechanism, and Price Ceilings is required.

I. Introduction: -

No other legal subjects have been attracting so extensive social and academic concerns as intellectual property rights (IPRs) during the last two decades. We may have all noticed that IPRs not only receive increasing significance in trade-related practices, whether at the national level or international level, but also are closely involved with people's daily life for example people may use IPR-related products or processes every day, such as a patented medicine, a copyright-reserved book and more often, all kinds of trademark-contained merchandises, etc.

Thus, the current conventional wisdom is that the world's most successful nations are those best at producing, acquiring, developing and controlling Intellectual Property.[1] The

*This paper was presented and published in the **One Day National Seminar on Intellectual Property Rights and Patent Laws, IPRPL-2012** (25TH August 2012) Sponsored By JIS GROUP EDUCATIONAL and Organized By GREATER KOLKATA COLLEGE OF ENGINEERING & MANAGEMENT, BARUIPUR.

** B.A.LL.B (Hons.), Dr. Ram Manohar Lohia National Law University, Lucknow, (U.P.) and currently pursuing Doctor of Juridical Science (J.S.D.), National University of Study and Research in Law, Ranchi, (Jharkhand).

recognition that Intelltual Property in the form of literature, science, knowledge and its fair dissemination and access to knowledge has a broader role to play in the development of all individual as well as the fabric of society.[2] Intellectual property rights are recognized as human rights in the Universal Declaration of Human Rights, 1948[3], and in other international and regional human rights treaties and instruments. However, the relationship between intellectual property systems and human rights is complex and calls for a full understanding of the nature and purposes of the intellectual property system. It is suggested by some that conflicts may exist between the respect for and implementation of current intellectual property systems and other human rights, such as the rights to adequate health care, to education, to share in the benefits of scientific progress, and to participation in cultural life.[4]The recent appeal of the multinational drug major Novartis in the Supreme Court against denial of patent protection to its anti-cancer druge Glivec has established this conflict.

This paper attempts to analyze certain core issues such as ***whether the monopoly right conferred via Intellectual Property legislations transgresses the Right to health specially right to access the drug as enshrined under article 21of Constitution of India.*** **If yes, then the next inquiry is** ***how to resolve these conflicting interests.***

II. Product Patent[5] and Access to Drug:-

Health is one of the fundamental basic needs of all human being. The *right to life includes the right to health.*[6]In legal term as well the fundamental human right treaties[7] recognize that the right to health would encompass a number of elements from prevention to cure to access to drugs. Once Indira Gandhi said, "idea of a better world is one in which medical discoveries would be free from patent and there will be no profiteering from life and death ". However,

---

[1] Graham Dutfield & Uma Suthersanen *" Global Intellectual Property Law"* , 1st ed. , (2008), Edward Elgar Publishing Ltd., Pp 5.

[2] Anne Flanagan, & Maria Lilla Montagnani, *"Intellectual Property Law: Economic and Social Justice Perspectives"*, 1st ed., (2010), Edward Elgar Publishing Ltd., Pp x.

[3] Article 27.(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

[4] See "Human Rights and Intellectual Property: An Overview" available at http://www.wipo.int/tk/en/hr/ (last visited on 5 July, 2012).

[5] A "product patent" is a patent giving protection to a product as such, e.g. as an apparatus, a device or a chemical compound. If the patented product is a chemical compound, the patent is also called a "substance patent".

[6] State of Punjab v. Makinder Singh Chawla, AIR 1997 SC 1225

[7] 'The right to a variety of facilities and conditions necessary for the realization of the highest attainable standard of health' – ICESCR, General Comment 14 'The right to the attainable standard of health in international human rights law is a claim to asset of social arrangement – norms, institutions, laws and enabling environment that can best secure the enjoyment of this rights'- WHO

from 1st January 2005, drug product patent protection has been reintroduced in India to comply with the requirement under the Trade-related Aspects of Intellectual Property Rights (TRIPS) of the General Agreement on Tariffs and Trade/ World Trade Organization (WTO).[8] The product patent prohibits others from making, using, offering for sale, selling or importing the patented product. As a result, the product patent gives a monopoly to the patent owner for the production of patented article during the term of the patent (20 years). Therefore, product patent protection for medicines and agro-chemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. The introduction of product patent thus reduces accessibility and affordability of drugs and the consequent denial of access to medicines to the poor across the globe. On the other hand, the pharmaceutical industry claims that high prices explained by the massive expenditure on R&D; however, the truth is that drugs they actually research have little relevance to real medical needs. Moreover, the kinds of profits that big pharmaceutical MNCs generate are an indication of profiteering and not just legitimate profit making. Further, it has also led to a situation where medicines required to treat diseases that predominantly occur among the poor not well researched. Instead, drugs that used for "lifestyle" diseases like impotence, baldness, obesity, etc are highly researched.

Thus after a above discussion we can conclude that to some extent there is a tussle between the monopoly right conferred via Intellectual Property legislations and the Right to health specially right to access the drug.

Harmonization of Conflicting Interest:-

The second issues assume the significance as to how to resolve or to harmonize the conflicting interest of both the patent holder and public at large. The interest of the patent holder looked after by granting him the product patent on his invention. At the same time ensuring that, the patented drugs would be available at affordable price to ensure the interest of the public. Thus, balance need to created and conducive environment for the pharmaceutical firms to operate without hassles on one hand and access to affordable life saving drugs to the common populace on the other.

It is noteworthy to point out that the WTO Doha Declaration on TRIPS Agreement and Public Health (2001), in which, inter alia, observed that countries have the sovereign right to

[8] Sudip Chaudhuri, " Multinationals and Monopolies: Pharmaceutical Industry in India after TRIPS" , Economic & Political Weekly (March 24, 2012) , Sameeksh Trust Publication , Vol XLVII No. 12. Pp. 46-54.

enact laws that safeguard domestic interests. It recognized the gravity of public health problems in developing countries and clearly provided that the member countries had the right to protect public health and to promote access to medicines for all. The declaration focuses mainly on questions related to the implementation of patents, such as compulsory licensing. *Compulsory licensing* has used as a tool to regulate the exclusive rights conferred by patents. Further, especially for developing countries a wide consensus that domestic laws, while being TRIPS compliant, need to make full use of "flexibilities" available in the TRIPS agreement. Indian Patent Act, 1970 strategically exploited TRIPS' flexibilities to the hilt. It introduced higher standards for pharmaceutical patentability[9], a very potent opposition mechanism where any member of the public could effectively oppose a patent grant and some of the widest compulsory licensing norms that the world has ever known.[10] The order awarding a compulsory license to Nactco, a Hyderabad based Pharmaceuticals Company for manufacture of the anti-cancer drug Nexavar by Controller General of Patent is a positive and interesting turn. Before issuing the compulsory license The Controller General of Patent concluded that in physical sense Bayer[11] was not working the patent and not meeting the condition that the **public's "reasonable requirements"** with respect to the patented invention were being satisfied.[12]

Other initiatives that the Government needs to take in order to strike the balance between the conflicting interests are as follow:-

- ***Drug Subsidies:*** This can be a major step, which the government can take to keep the prices of drugs within the reach of the pockets of the public. Subsidies should granted in cases of drugs, in the same manner as they are granted in LPG, petrol, Kerosene oil, sugar and other essential commodities.

- ***Price Control Mechanism:*** The government should also introduce a price control system for stringent monitoring of prices of drugs not mentioned in the 'Essential Drugs List'. This is to ensure that the prices of 'other drugs' do not increase which would drill a hole in public pocket. Nearly 75% of the retail pharma market is currently outside price control and the government should constitute a panel that

[9] Section 3 (d) of the Patents (Amendment) Act, 2005 prevent the ever-greening of patent monopolies on medicines.
[10] V. Venkatesan, *" The current patent system is deeply flawed"*, Frontline (may 4, 2012) . Pp. 26-31.
[11] Bayer is a Multinational Medical Giant which invented and selling the anti-cancer drug Nexavar.
[12] C.P. Chandrasekhar, "A big step forward" Frontline (May 4, 2012) . Pp. 10-12.

would monitor changes in price of unscheduled drug (control free). If the panel is convinced that rate at, which the price of a particular unscheduled drug has raised without a valid reason or due to unfair trade then it can ask the government to control and bring the price within the reasonable limits.

- ***Price Ceilings:*** The National Pharmaceutical Pricing Authority can also perform an additional task of putting a ceiling on the maximum price of a particular product. These should also include fixing a higher ceiling for the generic drugs and a lower one for branded drugs. This will also put pressure on the large companies to exit from generic business. The ceiling on the prices will ensure that the maximum price of a particular drug is well within the reach of the masses. Few things, which can be taken into account while fixing the ceiling would be the amount spent in research and development, the cost involved in production of the invention plus the subsequent marketing of the product.