

Patents and Right to Health

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Abstract: *The paper analysis the impact of patent law on the right to health. the new patent regime has seriously affected the development of the pharmaceutical sector. The manufacture of drugs has been the key concern in according the right to health. Earlier the generic medicine used to take care of the rising prices of the drugs and it was easy for the poor common man to procure the drugs. However the grant of product patent is likely to affect the affording of medicine which will in affect hamper the right to health. Therefore the paper analyses the inter relationship of the same.*

Keywords: right to health, patent and medicine, patent system, price rise, compulsory license

1. Introduction

Health is the supreme concern of every human being because a healthy mind lives in a healthy body. The right to health is associated with access to health care and the building of hospitals. This is correct, but the right to health extends further and includes a wide range of factors that can help in leading a healthy dignified life. [1]

The sound health depends upon many extraneous factors including environment, the physical fitness of a person, healthy food, but principally it is attained by the perfect intake of the nutrients and the access to the medicines which boosts the normal functioning of the vital organs of the body. If a diseased body is not provided with the appropriate level of nutrients or the access to the medicines, then the optimum level of health cannot be maintained leading to the denial of the right to health which disturbs the functioning of the body and the immunization system gets weakened and the body becomes diseased [2].

2. Right to Health

There are several provisions in International documents regarding health issues. Universal Declaration of Human Rights (UDHR) provides that everyone has the right to a standard of living adequate for the health and well being of himself and his family, including food, clothing, housing and medical care and necessary services and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. [3] The International Convent on Economic, Social and Cultural rights (ICESCR) covers a wide spectrum of rights, [4] namely, right to work, [5] right to just and favorable conditions of work [6], right to social security [7], right to adequate standard of living [8], right to health [9], and right of everyone to enjoy cultural life, benefits of scientific progress and protection of scientific, literary or artistic production [10]. State parties have an obligation to take progressive measures for the realization of the right set forth in the ICESCR [11]. The State parties to the ICESCR recognizes right of everyone to enjoyment of the highest attainable standard of physical and mental health [12]. Health is a fundamental human right indispensable for the exercise of other human rights. [13]

The Indian Constitution through judicial craftsmanship ensures the right to health and access to the medicines is a necessary corollary to the right to life and personal liberty [14]. The right to health is ensured in India through various statutory enactments, e.g., Maternity Benefit Act, 1961; Narcotic Drugs and Psychotropic Substance ct, 1985; Prevention of Food Adulteration Act, 1954; The Pharmacy Act, 1948; The Transplantation of Human Organs Act, 1994; Mental Health Act, 1987; Biological Diversity Act, 2002; The Epidemic Diseases Act, 1987; The Dangerous Drugs Act, 1930; Drugs and Cosmetics Act, 1940; The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954; Drugs Control Order Act, 1950; Medical Termination of Pregnancy Act, 1971; and National Food Security Act, 2013, etc.

In *Consumer Education and Research Centre v. Union of India* [15], the Supreme Court held that the right to health, medical aid to protect the health and vigour is a fundamental right under Article 21 read with Articles 39 (e), 41, 43, 48 A to make the life meaningful and purposeful with dignity of person. Facilities for medical care and health against sickness ensure stable manpower for economic development and would generate devotion to duty and dedication to give the worker's best physically as well as mentally in production of goods or services.

In *Parmananda Katara v. Union of India* [16], it has been held that it is the professional obligation of all doctors, whether government or private, to extend medical aid to the injured immediately to preserve life without waiting for legal formalities to be complied with by the police under Cr.P.C. Everyone concerned will also keep in mind that a man in the medical profession should not be unnecessarily harassed for purposes of interrogation or for any other formalities and should not be dragged during investigations at the police station and it should be avoided.

The Supreme Court laid down the scope and ambit of these provisions in following words [17]:

In a welfare state it is the obligation of the State to ensure the creation and the sustaining of condition congenial to good health [18]. Maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of mankind. Attending to health therefore is of high priority – perhaps the one at the top [19].

In *P. B. Khet Mazdoor Samity v. State of West Bengal* [20], the Supreme Court opined that providing adequate medical facilities for the people is an essential part of the obligations undertaken by the government in a welfare state. Failure on the part of the government hospital to provide timely medical treatment to a person in need of such treatment, results in violation of his right to life guaranteed under Article 21. In *State of Punjab v. Mohinder Singh Chawla* [21], the Apex Court opined that the employee was entitled to reimbursement of charges paid by him in the treatment of the ailment from the State. In *CESC Ltd. v. Subash Chandra Bose* [22], the Supreme Court relied on international instruments and concluded that right to health is a fundamental right. In *Devinder Singh Shergil v. State of Punjab* [23], the respondent State was directed to pay Rs. 22,000 as per AIIMS rates for surgery and Rs. 73,000/- for expenditure incurred on medicines.

3. Health and Medicine

It has been rightly observed that contribution of medicines to health is undisputedly important, thus, the access to drugs is an essential part of the right to health. Health services are needed to deliver medicines to people who are sick—as much as to prevent illness. But the existence of health services without the ability to deliver medicines simply leads to the denial of these services [24].

A medicine is panacea for a fatal disease. Therefore their availability and affordability is *sine qua non* for sound health of people. The emergence of treatable pandemics, the resilience of others, place unparalleled importance on access to drugs as part of the right to health. In such situations, the role of the medical professionals and pharmaceutical industry become significantly important. There is need to provide proper medication of a particular quantity and quality so that the right to health can be sustained and the medicine should be economically accessible, easily available and of good quality in the market. The greatest tragedy, however, is that, while there has been a globalization of medical research, and a globalization of knowledge about medicine, there has not been significant globalization in the availability of medicines.

4. Patent System

Historically, the granting of a patent was a reward, bestowed by the state, to an inventor in return for making the invention available to the public. [25] A patent can be defined as a monopoly right granted to person who has invented new and useful product or a significant improvement of an existing product or the process for making the product [26]. It covers a wide range of rights, e.g., the right to manufacture, advertise, distribute, sell, assign, and license for the new product or process [27] for a defined period of 20 years [28].

Patents are only granted after applicant satisfies the requirements of registration which imposes a number of limits and safeguards [29] on the types of inventions that are patented, the scope of monopoly granted and the nature of information that is disclosed in the patent [30]. Henry Grabowski [31] in his article has written that “The patent system has played a critical role in incentivizing R & D

investments for global disease like AIDS, Cardiovascular illness, and cancer. At the same time, relatively little public or privately supported R & D investment is currently directed to disease specific to developing countries such as malaria, tuberculosis, etc., even though these diseases currently afflict millions of individuals.

5. Patents and Medicine

The right to life and health is a fundamental right guaranteed to every person living in India and is non negotiable. But in new patent regime, product patent protection for medicines and agrochemicals 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. Unfortunately, monopoly pricing of existing drugs causes static problems of insufficient market access for patients. When the Uruguay Round of Trade Negotiations for the General Agreement on Tariffs and Trade (GATT) was launched, more than fifty countries did not confer patent protection on pharmaceuticals, including some developed countries. Some regarded this absence of protection as necessary to promote access to drugs at competitive prices; others criticized it as unfairly depriving inventors of the benefits generated by their contributions [32].

The access to medicine has been seriously affected by new patent regime. Before the enforcement of TRIPS agreement, the countries were providing the process patents in case of pharmaceuticals, and thus the companies were in a position to come out with generic version of the drugs making easy availability and cheap drugs to the patients. However with the adherence to the TRIPS agreement the product patent needs to be granted making it difficult to come out with the generic version of the drugs except in cases the medicine is off patent. Supporters of new patent regime say that patent is not the only factor for the inaccessibility to medicine; there are several other factors. In fact, a feature of a patent protection is that it spurs research, so that constantly alternatives keep appearing in the market and often the alternatives are better ones.

6. Conclusions and Suggestions

Health is one of the basic fundamental needs of all human beings. Fundamental human treaties recognize the right to enjoyment of the highest attainable standards of physical and mental health. Health policies encompass a number of elements from prevention to cure and access to drugs. The maintenance of health has, in fact, become incidental to the manufacture, prescription and sale of drugs. The promotion of approved drugs for unrestricted use by pharmaceutical companies and physicians has led to drug-resistant disease microorganisms. There has been a consequent resurgence of TB, malaria and other illnesses, which the allopathic system had earlier boasted of having eliminated.

Price Rise

It is generally believed that the patent system will lead to spurt in the prices of the drugs. Drug Prices [33] become a key issue in countries that have not been able to set up the

basic physical and human infrastructure of the health system. In the field of human health the grant of product patent to pharmaceuticals inevitably leads to a great escalation in the price of life saving drugs. [34]

Access to medicine and the price of drugs depends on a wide variety of factors, including the cost of research and development, production, distribution and marketing. In developing countries, prices are an important factor while in developed countries pharmaceuticals are largely publicly funded, through reimbursement and insurance. Thus, in developing countries prices have direct implication for access to medicines. [35]

The fear [36] that prices of medicine will spiral is unfounded and there shall be no price hike due to new patent regime. In the first place 97 % of all drugs manufactured in India are off patent and so it will remain unaffected. These cover all the life saving drugs as well as medicines of daily use for common ailments. In the patented drug also, in most cases, there are always alternatives available, and thus, price control is inherently built in. The access to essential drugs is notified by the WHO and is regulated one. Furthermore the price factor can be taken care of, if the short- run and long-run objectives are separated. [37]

Easy Licensing and Compulsory License

The licenses and compulsory licensing generally leads to the competition in the market which can also keep a check on the price-rise of the medicine. The pharmaceutical companies should help out the developing companies by issuing licensing with easy terms and conditions in relation to access to essential medicines. Therefore, the companies should be ready to supply the medicine by reducing their profit margin in order to avoid the resort to compulsory licensing and the competition on account of it. In addressing the concerns of developing countries and health issues, the WTO decision of DOHA Declaration allows member countries to import generics from other countries under compulsory licenses if the member country was unable to manufacture drugs within their home country and was suffering from a serious health crisis [38]. The Doha Declaration does not modify TRIPS but restates that member states are allowed to fully use the exceptions provided in the treaty to foster public health goals [39].

Investment and Market

Investment in the health sector of developing countries remain very low by any standard, and patents system further complicates the access to medicines for the needy people of those countries. Availability of medicine demand for investment and market size, e.g., a large market and high demand for a product might lead to considerable revenue for the company even at a lower price. Therefore the change in the mindset of the people manufacturing medicines can address the problem effectively by lowering the prices.

Differential Treatment

The TRIPS agreement makes it obligatory for every country to amend and adopt their patent regime in tune with the TRIPS agreement, however, three types of countries have been identified, and i.e., developed, developing and least developed country (LDC). Since the gap in the economic

capacity and technological capacity is too wide, therefore, there is a need for the differential treatment under the TRIPS agreement.

Analysis of Expenditure

The expenditure incurred by a drug company on the infrastructure, research and development, advertisement and concession and commissions to the market forces determine the price of the drug. Generally, the companies inflate their financial statement which ultimately leads to the higher price for the drug. Therefore, the regulatory bodies should be created which can look to the financial statements and analyze them in a reasonable manner to carve out the perfect cost of the drug with due regards to the profit content for the company.

References

- [1] World Health Organization, "The Right to Health", Office of the United Nations High commissioner for Human Rights, United Nations, Geneva, June 2008
- [2] *Consumer Education and Research Centre v Union of India*, (1995) 3 SCC 42.
- [3] Article 25 (1) of Universal Declaration Of Human Rights, 1948; see also Jeniffer H. Lee and Ritu Sadana , "Improving Equity in Health by Addressing Social Determinants", The Commission on Social Determinants of Health Knowledge Networks, World Health Organization, 2011
- [4] M. K. Sinha, "Basic Documents on International Human rights and Refugee", pp. 111-121, Manak Publications, New Delhi, 2000
- [5] Article 6 of the ICESCR
- [6] Id., Article 7
- [7] Id., Article 8
- [8] Id., Article 11
- [9] Id., Article 12
- [10] Id., Article 15; See also, Article 27, UDHR, 1948; Article 13(1), American Declaration on Rights and Duties of Man, 1948
- [11] Id., Article 2 (1)
- [12] Id., Article 12 (1)
- [13] General Comment 14, The Right to the Highest Attainable Standard of Health, 11 August 2000 available at <http://www.unhchr.ch>, visited on 3-11-2016.
- [14] Article 21 of the Indian Constitution.
- [15] AIR 1995 SC 922
- [16] AIR 1989 SC 2039
- [17] *Vincent Panikurlangara v. Union of India*, AIR 1987 SC 990
- [18] Id. at 994
- [19] Id. at 995
- [20] AIR 1996 SC 2426
- [21] AIR 1997 SC 1225
- [22] AIR 1992 SC 573
- [23] 1998 (8) SCC 552
- [24] Deegan Cook, Chandrasekharan S, Angrist M, The Dangers of Diagnostic Monopolies, p. 405-406, Nature, 2009
- [25] L. Garrett, The Coming Plague: Newly Emerging Diseases in a World Out of Balance, London, Penguin, 1995, p 480.

- [26] Section 2, Indian Patent Act, 1970; see also E. Ernest Goldstein, *Cases and Materials on Patent, Trademark and Copyright Law*, pp. 1-3, Brooklyn The foundation Press, Inc. 1959
- [27] Section 48 of Indian Patent Act, 1970
- [28] Id., Section 53
- [29] Id., Sections 3- 5
- [30] Sections 6 – 43 of Indian Patent Act, 1970; See also, Feroz Ali Khader, *The Law of Patents- with a special focus on pharmaceuticals in India*, p. 37, Lexis Nexis, Butterworths Wadhwa, Nagpur, 2009
- [31] Henry Grabowsky, “ Patents, Innovation And Access to New Pharmaceuticals” *Journal of International Economic Law* (2003) 849-857
- [32] Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, pp 10-14, CUP, 2003; See also, N.S. Sreenivasulu, “Intellectual Property Rights”, *Regal Publication, New Delhi; JILI, Vol. 51:3, 2007*
- [33] J. Rovira, “ The Pricing of Pharmaceuticals In Law Income Countries”; *European Journal of Health Economics*, 2002, p 223-224.
- [34] Gupta, J.L.,” Intellectual Property Rights Need For A Liberal Approach” *JILI*, Vol. 47 No. 4, 2005, p 502-507.
- [35] TRIPS, “ Intellectual Property Right And Access to Medicine,” available at www.who.org.
- [36] Kamalnath, “ Pharma and IT To Benefit,” *Yojana*, March 2005, 49-51.
- [37] Maskus Keith E & Carsten Fink, “ Intellectual Property and Development,” Copublication of the World Bank and Oxford University Press, Washington, 2005, p 215.
- [38] https://www.wto.org/english/news_e/news15_e/trip_24feb15_e.htm visited on 02-02-2018
- [39] Anderson Angela J., “ Global Pharmaceutical Patent Law in Developing Countries- Amending RIPS to promote Access for All, Berkeley electronic Press (Bepress), 2006.