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EQUITY DIMENTIONS OF PHARMACEUTICAL PATENT PROTECTION IN INDIA

AUTHOR - DR. ARCHANA K, ASSISTANT PROFESSOR OF LAW, KARNATAKA STATE LAW UNIVERSITY, NAVANAGAR, HUBBALLI

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ABSTRACT

'Human health or Intellectual Property Rights protection?' is one of the highly debated issues of the world in the last few decades. While health is a fundamental human right indispensable for the exercise of other human rights, protection of intellectual property rights is considered as the essential booster for the innovators to invent. Starting from the *Universal Declaration of Human Rights, 1948*, number of International Covenants, Treaties relating to human rights recognize right to health is a basic human right. However, study reports indicate that despite progress made in the last few decades, millions of the people in the developing countries, including India do not have access to medicines. With the advent of Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Patent regime of many countries, including India has changed from process patenting to product patenting and resulted in denial of access to essential medicines to the poor segments of the society. it is argued that the changes incorporated to the patent system of India directly impacted the right to health of the people of India. In this background, this paper attempts to analyze the provisions of Patent law on pharma Patent in India to examine whether right to health and patent rights, specifically, the pharmaceutical patentees rights are adequately balanced in India.

Keywords: Intellectual Property Right, Pharma Patent, Right to health, TRIPS Agreement

INTRODUCTION

With the advent of Trade Related Aspects of Intellectual Property Rights (TRIPS), the intellectual property (IP) regimes, especially Patent Laws have changed in India. While TRIPS agreement is meant to harmonize IP protection across the member countries of WTO so as to maintain minimum level of protection to the inventions in all the member countries, the Agreement undermined the significance of basic human right to health. India being a signatory to TRIPs, amended its Patent law to adopt the minimum standards of protection stipulated and one of the major changes was shifting from process patenting to product patenting of pharmaceutical drugs. This drastic change resulted in sudden increase in the price of patented medicines and the constitutionally guaranteed right to health of people of India was at stake.

Under the Constitution of India, health is recognised as a fundamental right through various judicial pronouncements and hence, access to medicines is essential component of right to health. A monopolistic patent granted for new medicines is seems to be an issue, because of the conflict between financial gains of the companies and the right to access the medicines by the public. Although there is no direct denial of access to the patented medicines, it is deemed to be restricted due to the high prices of the medicines. In this background, this paper attempts to analyze the provisions of Patent law on pharma Patent in India to examine whether right to health and patent rights, specifically, the pharmaceutical

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patentees rights are adequately balanced in India.

Patent and Public Health

Patent provides right to the patent holder to exclude others from an unauthorised access of the patented product or process. The pharmaceutical industry is also one such industry, where new pharma drugs are invented which help in saving the lives of millions of people, who are suffering from various kinds of diseases. Inventing a medicine requires intensive research, and financial investment as these experiments are highly expensive and unpredictable. Hence, protecting such lifesaving inventions by granting exclusive monopoly rights through 'Patenting' act as incentive for innovation. In order to promote further invention for the advancement of science and technology new inventions are essential, which can ensure the right to health of public in a better manner. However, a major challenge posed at international and domestic level is to maintain a balance between public health and patent protection.

While right to health is considered as a basic human right worldwide and as fundamental right in India, even after development in healthcare technologies, billions of people do not have access to basic medicines or health care facilities in the world. According to the World Health Organisation "over 13 million people die each year from infectious and Parasitic Diseases and half of them are reported from developing countries".[1258] One of the major reasons which impede the people to have access to medicines is their exorbitant prices, and patent protection granted over the medicines is the major reason for such high prices.

Right to Health in India

The Preamble of WHO states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic and social condition".[1259] Therefore, in India, right to health is given the status of fundamental right under the aegis of Article 21 of the Constitution along with other provisions of Fundamental rights by the judiciary. The Supreme Court, while interpreting Article 21 of the Constitution ruled that the expression 'life' does not connote mere animal existence, but includes, *inter alia,* the opportunities to eliminate sickness and physical disability.[1260]

In *Vincent Panikurlangara v. Union of India and Others*,[1261] the Supreme Court of India addressed critical issues surrounding the regulation of pharmaceutical drugs in India. It emphasized the State's obligation to enhance regulatory mechanisms, improve drug quality standards, and prioritize indigenous drug production. In addition to that, the Court in *Unnikrishnan, J.P. v. State of Andhra Pradesh*,[1262] held that the maintenance and improvement of public health is the duty of the State to fulfil its constitutional obligations cast on it under Article 21 of the Constitution. In *Consumer Education and Research Centre v. Union of India*,[1263] the Supreme Court explicitly held that the right to health and medical care is a fundamental right under Article 21 of the Constitution and this right to health and medical care, to protect health and vigour are some of the integral factors of a meaningful right to life. In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*,[1264] while widening the scope of Article 21 and observing the responsibility of the government to provide medical aid to every person in the country held that the primary duty of the government is to secure the welfare of the people, which includes adequate medical facilities for the people. Hence, this obligation on

[1258] World Health Organization. Communicable Disease Prevention, Control and Eradication, available at, http://www.who.int/countries/eth/areas/cds/en/ last cited on 1/2/2026.

[1259] *Ibid.*
[1260] *Francis Coralie Mullin v. The Administrator, Union Territory Of Delhi and Others*, 1981 AIR 746
[1261] AIR 1987 SC 990
[1262] AIR 1993 SC 2178.
[1263] AIR 1995 SC 922.
[1264] AIR 1996 SC 2426.

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the government can be discharged only by providing medical care to the persons seeking to avail of those facilities. Hence, right to health and the associated health policy in India is based on the idea of providing affordable health care facility to all citizens of a country.

TRIPS AGREEMENT AND PHARMA PATENTING

The establishment of the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have led to a tremendous paradigm shift in IPR regime of the world. The objectives and principles of TRIPS Agreement was to contribute to the promotion of the mutual advantage of producers and users in regards to technology.[1265] It also emphasises that protection should consider public health and public interest to prevent the abuse of IP rights by the holders and restrain trade.[1266] Therefore, protection of public health was one of the major concerns when the TRIPS Agreement was being negotiated. As a result, the Agreement contains flexible provisions, that could be utilised to alleviate the negative impact of pharmaceutical patents on access to medicines. The flexible provisions include,

i. exclusion of patents for those inventions which have adverse impact on public health,[1267]

ii. diagnostic, therapeutic, and surgical methods for treating humans or animals,[1268]

iii. Compulsory licensing in view of public health and access to medicine, in case of national emergency or situation of extreme urgency,[1269] Public, Non-commercial Use of Patents by the Government, when the right holders refuse to voluntary license on reasonable terms, in cases of Anti-competitive practices,[1270] and in case of dependent patents[1271] and for the supply of the medicines to domestic market, when authorised by the member country.[1272]

iv. Bolar Exemption[1273] or limited exceptions to the exclusive rights conferred by a patent for early working, which permits the use of an invention for the purpose of obtaining approval of a generic product before the expiry of the patent or for research or experimental use of an invention; and

v. Parallel Importation, where products are purchased legally in one country and imported into another country without the approval of the patent owner and authorised distributors.

While these flexibilities are mentioned in TRIPS Agreement, the right to make use of these flexibilities was being challenged, legally and politically, by multinational pharmaceutical companies and governments of developed countries.[1274] In addition to that, many of the member countries of TRIPS contended that, the provisions of TRIPS is affecting the basic right to health of the people. Hence this major challenge concerning patent and public health was discussed at length in the Doha Declaration on TRIPS agreement and Public Health in 2001, pursuant to which efforts were made to balance the grant of patent to pharmaceutical companies in relation to the public health needs.

Three primary concerns about the public health issues arose due to TRIPS Agreement was addressed by the Doha Declaration. Paragraph 4 of the Declaration, confirms the right of the member nations to interpret the agreement with the aim of improving public health crises and asserted the compatibility of the Agreement with public health. Further, the Declaration clarifies that the nations have

[1265] Article 7 of the TRIPS Agreement, 1994.
[1266] *Ibid.*, Article 8.
[1267] *Ibid.*, Article 27.2.
[1268] *Ibid.*, Article 27.3(a).
[1269] *Ibid.*, Article 31(b).
[1270] *Ibid.*, Article 31(k)).
[1271] *Ibid.*, Article 31(l)).
[1272] *Ibid.*, Article 31(f))
[1273] *Ibid.*, Article 30
[1274] In 2000, 39 drug companies challenged the validity of the legislation that used the TRIPS flexibilities made by the South African Government.

autonomy to enact their own legislation without influence from external actors. In addition to that, Paragraph 5 affirms the rights of members to grant compulsory licenses and the right of WTO members to adopt their own policies with respect to exhaustion of rights, or parallel importation rights, and compulsory licensing was allowed only to the extent of supplying the medicines to the domestic market of the authorizing country. Lastly, Paragraph 6 addresses the difficulties faced by countries that are incapable of manufacturing pharmaceutical products and permits the member countries to manufacture and export medicines through compulsory licensing to the developing or least developed countries.

PHARMA PATENTING IN INDIA

India adopted patenting laws to recognise new and useful inventions made during British period. However, patenting of medicine has undergone drastic changes over the period and the growth of pharma patenting provisions can be classified into Before and Post TRIPs Agreement Developments.

i. Before The TRIPS Agreement

Patent rights were introduced in India for the first time in 1856 by the British Government and Later replace the earlier patent legislation with the Patents and Designs Act, 1911. It had a product patent regime for all inventions including pharmaceutical inventions. After independence, the new Patents Act, 1970 was enacted which excluded product patenting of pharmaceutical drugs. This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry.

The Act had the objective to guarantee low-cost drugs to the people of India and hence, introduced process patenting for pharmaceutical inventions, which was limited to methods of manufacture of medicines. Additionally, the term of protection for such process patenting was for a period of seven years from the date of filing or five years from the date of sealing the patent, whichever is less. Further, the Act had provisions for compulsory licensing by the government, i.e., to interfere in the exclusive monopoly rights given to the patentee, if the reasonable requirements of the public with respect to the patented invention have not been met or that the patented invention is not available to the public at a reasonable price.[1275]

The Patent Act of 1970 was a boon to Indian pharma companies to reverse engineer and copy the patented drugs of other countries without obtaining assignment or licences, and they could offer a large number of cheaper generic versions legally in India at a cheaper price. All these provisions of Patent Law was aiming to ensure accessibility of medicines to all and to ensure right to health of the people.

ii. Post TRIPs Agreement Developments in India

After India became signatory to TRIPS Agreement, the Patent legislation of the Country was amended thrice to comply with the TRIPS requirements. Product patenting for medicine with the extended term of protection for 20 years is one among the other significant change brought under the Patent(Amendment) Act, 2005. Besides that, the amended Act restricts the reverse engineering options of domestic firms and introduced standards of patentability, and many other provisions to prevent abuse of pharma patenting. Major changes made under the Act include,

1. Standards of patentability

The Act gives a detailed list of inventions, which cannot be considered for patenting. Among the others, Clause 3(d) states that the discovery of a variant of an existing substance or process that does not enhance efficacy significantly is not patentable. The clause attempts to discourage frivolous inventions by stating that new use of the known substance or new properties or form of known substance

[1275] Section 84 of The Patents Act 1970.

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without enhanced efficacy cannot be patented. This clause aims to prevent evergreening of patents. Evergreening refers to the practice of making slight modifications to the original patent and seeking patent protection for this slightly modified product. It is prevalent practice used by Pharmaceutical companies to maintain their profit by maintaining their monopoly but does provide any proportionate benefits to the public in general. The purpose behind evergreening is economic benefits for the company and mostly doesn't involve any significant therapeutic advantage to the patients. The Hon'ble Supreme Court in the case of *Novartis v. Union of India & Ors*,[1276] clarified the position of evergreening in India, where, Novartis application was rejected as an attempt towards "evergreening".

Besides that, Clause 3(p) states that traditional knowledge or mere aggregation of traditional knowledge cannot be patented. It directly prevents biopiracy and protects the indigenous knowledge of tribal communities from patenting and also ensures protection to traditional methods of Ayurveda, siddha, Unani forms of medications.

2. Government Use of Patents

To prevent 'denial of access to medicines' the Act permits the Government to use patented inventions. The Act stipulates that, in case of patent in respect of any medicine or drug, the government has the power to make use of such patented product or for its distribution in any dispensary, hospital or any medical institution.[1277] Such act of Government use cannot be challenged as infringement of patent rights by the patentee.

Besides that, Section 100 empowers the Central Government to use patented inventions for governmental purposes, i.e., the government, or authorized individuals, can use, make, and sell inventions for governmental objective of public welfare and Section 102 empowers the central government to acquire an invention if it is necessary to do so in the public interest by publishing a notification to that effect in the Official Gazette. Although such use is subjected to the condition of paying royalty to the inventor or patentee, to ensure public health any patented pharma drug or equipment can be used or acquired by the government.

3. Compulsory Licensing

Compulsory licensing is known to be a process of granting the license to the third person by governmental institutions in order to use the patent. It limits the power and control of the patentee over the pharmaceutical drug. The act recognises the power of the government to interfere and grant compulsory licences on various grounds.

Firstly, 'if the reasonable requirements of the public with respect to the patented invention have not been satisfied' or 'the patented invention is not available to the public at a reasonable price' or the patented invention is not worked in India', the Government can permit any interested and competent pharma drug producer to replicate patented product and process after the expiry of three years from the date of issuance of a patent.[1278] the Controller of Patents issued the first compulsory license to Natco Pharma for Bayer's drug Nexaver, after being convinced that it had fulfilled all the necessary conditions present under section 84 of the Act, and later, this order was upheld by the Supreme Court.[1279]

The Act, provides the Government the power to issue compulsory licences in case of any national emergency or extreme urgency or for public non- commercial use, and in such circumstance the Government can waive off the time period of 3 years given under section 84, and issue compulsory licenses.[1280] Proviso to the section clarifies the application by mentioning the spread of epidemic diseases should be treated as emergency and primacy to the protection of public interest should be

[1276] AIR 2013 SC 1311.
[1277] Section 47(4) of The Patent Act, 1970.
[1278] *Ibid.*, Section 84.
[1279] *Bayer Corporation v. Union of India*, 2014 SCC OnLine Bom 1056.
[1280] Section 92 of The Patent Act, 1970.

given. the Act also provides compulsory licensing provisions to protect the human rights of the least developed countries, and permits the controller of patents to issue compulsory license for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems.[1281]

4. Bolar Provision and Parallel Importation

Besides these provisions, the Act also incorporated the Bolar provision and parallel importation requirements of TRIPS Agreement. The Act allows early workings of a patented invention for the purposes of obtaining regulatory approval for the invention.[1282] Thereby it enables generic drug manufacturers to get marketing approval for their products before the expiration of the patent. It is intended to promote timely access to affordable medicines.

Further, the practice of legally acquiring the patented good from a foreign country and selling the goods in the domestic market or vice versa at a slightly lower prices is also considered legal[1283] under the Act and the section states that it will not be considered as infringement, if there is importation of patented products by a person who has legally acquired it from a person who is "*duly authorised under law*" to produce, distribute and sell.

PHARMA PATENTING AND RIGHT TO ACCESS TO MEDICINES IN INDIA

Despite all these provisions under the Indian Patent Act, there are several challenges posed to secure right to health of the public in India. Although Patent law and policy has a notable connection with the promotion of pharmaceutical drugs and equipment, which is essential for ensuring right to health and access to essential medicines, India has not yet ensured right to access medicines at a reasonable price to all. the challenges posed by the pharma patenting after the TRIPS agreement are many.

Although India is ranked as the 4th biggest pharma industry, number of researches and inventions made in the pharma sector is very limited. Till India adopted product patenting, many of the pharma companies are investing in preparing generic medicines. Even after two decades after the TRIPS Agreement, majority of the patented lifesaving drugs are owned by foreign or multinational pharma companies. These pharma companies charge high prices for their patented medicines. in a developing country like India,generic competition plays a crucial role in reducing drug prices and increasing access to affordable medicines. Due to the present product patenting policy of India, these patented drugs block generic competition and impede access to more affordable options for patients.

To control and monitor the drug prices in India, the Government established the National Pharmaceutical Pricing Authority (NPPA). The Drug Pricing Control Order, 2013 (DPCO) issued a decade ago by NPPA is the main regulatory system in controlling the prices of medicines and to ensure that these medicines are available at a reasonable price to the general public. Unfortunately, DPCO observes the prices of only those medicines that was mentioned in the National List of Essential Medicines (NLEM). The pharmaceutical companies add additional chemical components, which does not enhance the efficacy of such medicines, to avoid pricing by DPCO. This results in rise in the price of essential drugs can restrict access to life-saving treatments and contribute to health inequalities.

To curb the evil of non-affordable prices or inadequate supply, only remedy available under the Act is to obtain compulsory licence. However, this licencing requires observing some preliminaries such as, issuance of Compulsory licence is permitted only after three years after sealing of patents, negotiate for voluntary licences by the interested pharma companies

[1281] *Ibid*, Section 92 A.
[1282] *Ibid*, Section 107A (a).
[1283] Ibid., Section107A(b).

with the patent holder, Convincing the controller of patents that, such compulsory licensing is necessary in the public interest, etc. these procedural and implementational lacuna is posing challenges to the right to access medicines in India.

Conclusion

To conclude, patents and public health are two sides of the same coin. Although the Patent Act of India has several provisions to curb the abuse of patents, especially pharmaceutical patents, right to pharmaceutical patents and the right to health is not well balanced. The very basic essence of the fundamental right to health is the right to have access to medicine. In order to cater to the this inherent right of an individual and overall health care, there is a need to make changes to the compulsory licence requirements of the Act. In case of life saving drugs, the tedious and time consuming process of issuing compulsory licences needs to be waived off. Further, the Government should be empowered to revoke the patents of pharmaceutical companies in cases of excessive pricing. In addition to that, NPPA has to check whether essential drugs are available at a reasonable price in India and update the Drug Pricing Control Order which is aimed at balancing the interests of the public at large as well as the innovators.