International Research Journal of Human Resource and Social Sciences
ISSN(O): (2349-4085) ISSN(P): (2394-4218)
Impact Factor 3.866 Volume 3, Issue 06, June 2016
Website- www.aarf.asia, **Email** : editoraarf@gmail.com

Patent regime and the right to health in India

Gazala Farooq Peer
PhD. candidate at the Centre for Law and Governance, JNU, New Delhi
Email: gazalapeer@gmail.com

Abstract

Under the domestic law as well as the international law and commitments developed over the years, the right to health has been established as one of the basic human rights. The expansion of the concept of the right to health as a human right has resulted in the right to access to medication becoming a substantive component of this right. However, under the patent regime a paradox of sorts is created where on the one hand the domestic law is trying to reduce the pricing of drugs through various measure but while complying with the international law and commitments the balance of interests has shifted in favour of the multinational corporations. In cases where countries have tried to reduce the pricing of drugs the pharmaceutical corporations have resorted to legal action. The TRIPS does not encompass the local socioeconomic realities of the developing countries. The TRIPS and the procedure to be followed under the TRIPS have caused a gross breach of fundamental rights and principles of justice and fairness in developing countries like India. The future of public health in India and realization of the right to health depends largely on the restoring of the delicate balance between the interests of the patentee and public at large.

Key words: patent, TRIPS, right to health, generic drugs, access to healthcare

INTRODUCTION

In India every day 30,000 people die of preventable infectious diseases due to lack of resources to purchase drugs[12].The issue of affordability got mass attention when in the developing countries people were unable to purchase effective therapies for HIV/AIDS. For example, in South Africa, where one out of eight persons is infected with HIV/AIDS, the yearly cost of patented retro-viral

[1] 1Oxfam, "Where is the Money?" Oxfam petition to the G8 meeting in Genoa, July 20,
[2] . legalservicesindia.com/article/.../trips-&-right-to-health-149-1.html. Retrieved on 2nd Dec, 2013.

therapies goes up to $12,000[3]. A study by the United Nations estimated that 150 mg of HIV drug, fluconazole costs $55 in countries where the drug is not patented as compared to $697 in Malaysia, $703 in Indonesia, and $817 in the Philippines, where it is[4]. Whenever these developing countries have tried to take measures to reduce the prices, the corporations who hold patentshave resorted to legal action[5].

Despite the International human rights instrument like ICESR (International Covenant on Economic, Social and Cultural Rights) and UDHR (Universal Declaration of Human Rights), recognizing theright to health as a human rightremains a distant dream.

Right to health: an international law obligation

The first healthcare legislation was enacted in the nineteenth century[6] in the backdrop of increase in trade and commerce that also resulted in transmission of diseases from one country to another. The nations, thus, wanted to regulate the trade and commerce taking the plea that right to health is a fundamental right and all the trade and commerce is subject to it[7]. Over the years, this concern for public health led to the incorporation of right to health in conventions and declarations at the international level. The first such law was laid down in the Constitution of the World Health Organization (WHO) [8].The Preamble to The Constitution of WHO defines health as „a state of complete physical, mental and social well being and not merely the absence of disease and infirmity[9]. The right to health does not refer exclusively to the right to health care but also a range of socioeconomic factors that promote condition of healthy life and other aspects of health care

[3] Judy Rein, International Governance through Trade Agreements: Patent Protection for Essential Medicines, 21 NwJ Ind L &Bus 379, 400 (2001). See also Frederick Abbott, The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis, 2001 Widener L Symposium J 71.

[4] United Nations, Report of the High Commissioner of the Human Rights Commission on Economic, Social and Cultural Rights, The *Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, UN* Doc E/CN.4/Sub.2/2001/13 at 14, para 44 (2001) ("UNCHR Report").

[5] Recently South Africa was the target of litigation initiated by a number of pharmaceutical manufacturers over South Africa's Medicines and Related Substances Control Act of 1997. The US government initiated an action against Brazil within the World Trade Organization ("WTO").

[6] H. Irina, Competition Law and Patents, Ed 1st, Published by Edward Elgar Publishing Ltd, 2008, p.70.

[7] Ibid.

[8] Text of the article "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without the distinction of race, religion, political belief, economic or social condition*." http:/www.who.int/rarebook/official_records/constitution.pdf. Retrieved on 1st Dec, 2013.

[9] The Constitution of WHO (1945)

such as food, nutrition, housing and a healthy environment[10]. The right to access to medication is one of the important aspects of this right.[11] Therefore the parameters of Right to Health are:11

- Availability: public health, healthcare facilities and goods and services should be made available in a sufficient quantity at the national level.
- Accessibility: healthcare facilities and goods and services should be available to all without any discrimination.
- Acceptability: it means that such facilities as mentioned above must be respectful as per medical ethics and should be sensitive to cultural needs.
- Quality: facilities and goods and services must follow the given standards.

With the increasing emphasis on the right to health, the right has been recognized as an important human right in many national and international documents. At least 60 countries have incorporated the right to health in their national constitutions, or courts have laid down laws for the same[12].

The UDHR, acustomary international law principle binding on all nations irrespective of ratification, in its Article 25(1) says*: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, and housing and medical care and necessary social 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." "…Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection."*

Article 11(1) of International Covenant of Social and Cultural Rights says,

"The States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions. The States Parties will take appropriate steps to ensure the realization of this right, recognizing to this effect the essential importance of international co-operation based on free consent."

Article 12 International Covenant on Social and Cultural right is more comprehensive which states that:

[10] R. J. Dupuy (1979): international institute of human rights studies.
[11] Article 12(2) (c) and (d) of ICESR.
[11]*Supra* note 8, p. 78.
[12] *Supra* note, 8, p.72

"The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

The three aspects of health care enshrined in the international instruments on human rights are: The right to health as a basic human right; the aims at achieving health care needs specific groups of persons; and the prescription for the implementation of right to health[13]. The obligation to safeguard the right to health would mean that the state shall take the measures to stop the external interference, adopt legislation, and take administrative and judicial measures for providing adequate health care.

Right to health in India

The right to health was not incorporated in the Constitution of India as a fundamental right. In the recent times we have seen that the Supreme Court of India by giving a wide interpretation to right to life under Article 21 of the Constitution of India, has made right to health a fundamental right[14]. This major development can be safely credited to the public interest litigation movement in India[15]. In most of these judgments the Supreme Court of India while upholding the right to health, made the Directive Principles of state policy justifiable.[16] In an array of judgments the Supreme Court held that the substantive content of the right to life includes the right to live with human dignity

[13] Johanna Gibson, Intellectual Property: Medicine and Health, ASHGATE Publishing Ltd, Ed; 2009

[14] *Paramanand Katara v. Union of India.,* AIR 1989 SC 2039; Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996) 4 SCC 37; In India a Directive Principles of State Policy casting a duty upon the State to implement adequate healthcare measures has been expanded under Article 21 to include Right to Health: Paramanand Katara vs. Union of India (AIR 1989 SC 2039).

[15] The petitions and PILs range from PILs concerning workers health hazards to petitions filed by individual seeking rights of emergency medical care and HIV issues and to PILs for banning smoking in public spaces.

which includes the right to good health[16]. The Supreme Court in *Consumer Education and Research Centre v. Union of India*[17] for the first time expressly held that „[t]he right to health . . . is an integral part of right to life[18].“

In a significant case of *PaschimBangaKhetMazdoorSamity* case[19] the Supreme Court addressed the issue of sufficiency and accessibility of emergency medical treatment. The Court in this case rejecting the argument of recourse scarcity held that social rights are enforceable[21]. Further it was held that Article 21 of the Constitution casts an obligation on the state to ensure medical facilities and it is the duty of the state to preserve life.[20]In addition to recognizing the right to emergency services, the court also addressed the importance of providing preventive medical services. The court has observed that a healthy body is a prerequisite for attainment of all other rights.[21]

[16] Article 47 (state shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties); Article 38 (social order to promote the welfare of the people);Article 39(e) (health of workers, men, women and children must be protected from abuse); Article 41 (right

[16] Vincent Parikulangara v. Union Of India 1987 (2) SCC 165, Paschim Banga Khet Mazdoor Samity and Others v. State of West Bengal , Murli Deora v. Union of India & Ors.(2001)8 SCC 765, Consumer Education and Research Centre v. Union of India (1995)3 SCC 42, M.C. Mehta v. Union of India and Ors., (1999)6 SCC 9, „X“ v. Hospital „Z“ (2003) 1 SCC 500, Parmanand Katra v. Union of India,(1989)4 SCC 286.

[17] (1995)3 SCC 42

[18] This case was concerning the occupational health hazards faced by workers in the asbestos industry

[19] Paschim Banga Khet Mazdoor Samity and Others v. State of West Bengal., 1996(4) SCC 37, supra note 22.

[21]The court held that, "… *But at the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. The Court recognized that substantial expenditure was needed to ensure that medical facilities were adequate. However, it held that a state could not avoid this constitutional obligation on account of financial constraints. Whatever is necessary for this purpose has to be done. In the context of the constitutional obligation to provide free legal aid to a poor accused this Court has held that the State cannot avoid its constitutional obligation in that regard on account of financial constraints. The said observations would applywith equal, if not greater, force in the matter of discharge of constitutional obligation of the State to provide medical aid to preserve human life."*

[20] This was held following a previous case concerning emergency medical treatment in Paramanand *Katara v Union of India*. The case concerned the availability of emergency medical treatment for a seriously injured man at a local hospital. The hospital doctors refused to provide the emergency aid and referred him to another hospital 20 km away. The injured man died en route to the other hospital. The Court required the state to remove legal impediments imposed on doctors and hospitals for providing emergency medical aid.

[21]

2

3

„Social Rights and the Indian Constitution“, 2004 (2) Law, Social Justice & Global Development Journal (LGD) http://www.go.warwick.ac.uk/ elj/lgd/2004_2/kothari. Retrieved on 02-Dec-2013.

to public assistance in certain cases, including sickness and disability); and Article 48A (the state‟s duty to protect the environment).

As mentioned above the right to health has emerged out of a range of different petitions and public interest litigation.[22]Thus the scope of the right has got broadened encompassing many different aspects of health[25].

Securing right to health: A paradox

THE INDIAN Patent Act of 1970 was enacted on the policy considerations put forward by the Ayyangar committee report.The report was drafted keeping in mind the socioeconomic conditions of the India population. Purpose of the Act was to remove monopoly of multi national corporations and local firms. This development helped in generating processes for making new drugs. Local generic production of pharmaceuticals also increased and foreign pharmaceutical companies reduced the number of patents.By 1991, Indian companies produced 70% of the drugs for the national market. The desirable price reduction was supported by the drug control policy. This kind of protection was not only justified but also desirable for the Indian conditions[23]. Thus, the Indian Patent Act, 1970 helped in improving many health indicators[24].

As India is a member of WTO it has a commitment to comply with the provision of theTRIPS(TradeRelated Aspects of Intellectual Property Rights) that came into force in 1995. One of the significant provisions of the TRIPS agreement was that patents be kept available in a mail box.Under the TRIPS agreement India was provided a window of 10 years.Despite that the drugs which were patented from 1995 could not be produced generically for the reason that the provisions for the mail box were given a retrospective effect[25]/[26].In addition to that one of the

[22] The petitions and PILs range from PILs concerning workers health hazards to petitions filed by individual seeking rights of emergency medical care and HIV issues and to PILs for banning smoking in public spaces [25]This recognition established a framework for addressing health concerns within the rubric of public interest litigation and in a series of subsequent cases, the Court held that it is the obligation of the state not only to provide emergency medical services but also to ensure the creation of conditions necessary for good health, including provisions for basic curative and preventive health services and the assurance of healthy living and working conditions.

[23] The antacid drug Ranitidine can be found in the West as the patented drug Zantac, but in India it is produced generically. The drug is 26 times more expensive in the UK than in India, and 56 times more expensive in the United States. The antibiotic ciprofloxacin is also produced generically in India, and it is up to 15 times cheaper than in the UK and the United States.

[24] UNDP, Human Development Index, 2003, op cit. "In 1970 the child mortality rate was 137.2 deaths per thousand births, and in the year 2001 it had fallen to 67/1000. The average life expectancy in 1970 was 49.4 years and by the year 2001 it had increased to 63.3"

[25] Indian companies like Cipla can no more produced the generic version of drugs in violation of TRIPS provisions have been filed by the foreign pharmaceutical companies against Indian companies for infringing the patent law. Moreover, the Indian manufactured drugs are also seized.Recently, a number of cases See Roche vs. Cipla: In this case Cipla produced a generic version of patented drug "Tarceva", though the matter is still pending in the Apex Court, the chances is that Cipla may have to compensate Roche.

[26] Dr. Reddy"s consignment of drugs to Brazil by Dutch custom on the charge of patent infringement

major concern is the non-uniform system of compulsory licensing. It is a system which allows manufacture of patented drugs by domestic companies only through a license issued by the Government.The major concerns on the compulsory licensing system are:

1. There is no fixed time frame within the procedure of issuing of compulsory license. This allows for prolonged legal wrangling and delay.
2. The apprehension of delay on account of the absence of a royalty cap, i.e. a cap on the maximum amount of royalty which a patentee has to pay after getting the license.
3. Article 31 (b) of the TRIPS says that "such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time". Thisprovision on many instances has been used to prevent issuance of compulsory license[27].
4. The provisions of TRIPS do not allow an application for compulsory license to be filed before three years from the date of granting of the patent. This period is called "lock in" period.
5. The definition of „invention" in the context of a developing countries like India has many loopholes[28] resulting in frivolous applications.
6. Section 85 of the Patent Act provides for revocation of patents in case the patent is not used. The section says that *the compulsory license will be revoked if the patentee does not work out the patent within two years*. The problem is that there is no provision which can provide that the license can be issued to some other enterprise in the public interest.

[27] Article 31(b) of the TRIPS agreement says: "such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time" In the case of the EC versus Canada, article 27.1 was used as one of the justification for attempting to prevent a country from issuing compulsory licenses that dealt specifically with pharmaceuticals (WT/DS/114/R).

[28] In the Indian law inventive step has been defined as a feature of an invention that "involves technical advances as compared to the existing knowledge or having economic significance or both." It has been argued that inventive step really should apply only to technical advance as it defines the innovative content in an invention. Thus the incorporation of "economic significance" can dilute the criteria for what is an invention - viz., a trivial invention with little technical advance but of economic value would become patentable by this definition. It is to be seen how this clause will be interpreted while Patents are being granted. However, this is one amendment that should be actively considered in the act (deletion of a reference to economic significance, or the replacement of "or having economic significance" with "and having economic significance").
In the section in the Indian law defining what is not patentable (Section 3.d.) the following is mentioned: "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy". While this tightens the definition and is designed to prevent "ever greening" of Patents (i.e. extending Patent periods by making small changes in the original molecules or by finding new uses for the same) the phrase "unless they differ significantly in properties with regard to efficacy" has caused some concern. It has been argued that this phrase can be arbitrarily interpreted to allow for some degree of ever-greening as what constitutes a significant different in efficacy is subjective.

7. Clause 27.2, 7 and 8 of TRIPS provide a countervailing clause to disputes that are in consideration of publicgood.

The present patent system therefore affects healthcare by reducing access to the pharmaceutical products, restricting the access to products and processes which are necessary for innovations and improvements.

The WTO (World Trade Organization) ministerial conference of 2005 on TRIPS and the Right to Health raised concerns and stressed the need that TRIPS has to address the issues at international as well as national level. It stressed that TRIPS agreement should not prevent the member nations from taking steps to protect public health in their respective states. The WTO conference also aimed at stressing that TRIPS should be interpreted in such a manner as to be supportive to the member states in their concerns to address public health issues. The conflict presented by TRIPS and patent regime was made clear in the Doha Declaration[32]. The Doha declaration stressed an urgent requirement for promoting access tomedicines. It further asserts that countries should take measures if they consider it important to protect public health. The Doha debates is said to be a step forward towards achieving the health standards[33].Each member would have the right to grant compulsory licenses, and freedom to determine the grounds upon which such licenses would be granted and what constitutes a national emergency, or a matter of extreme urgency.[34]Avoiding the monopoly of the Drugs industry and guaranteeing the protection of Developing Country‟s wellbeing. However, Doha Declaration is not obligatory on the Members, thus raising grave doubts about its realization.

conclusion

India has an international commitments on both the fronts; securing right to health and complying with the international agreements on trade. The paradoxical situation emerges when these commitments are conflicting with each other. Article 15 of ICSER[35] on the one hand protects the interest of the authors and scientists but on the other hand it refers that the scientists should work for the benefit of the public. Similarly, Article 8 of TRIPS allows for measures to be

[32]*See* Declaration on TRIPS and Public Health, adopted by the WTO Ministerial Conference, Doha, Nov. 2001, WT/MIN(01)/DEC/2

[33] Doha Declaration on the TRIPS Agreement and Public Health, WORLD TRADE ORGANIZATION WT/MIN(01)/DEC/W/2 (14 November 2001 (01-577 MINISTERIAL CONFERENCE Fourth Session Doha, 9 - 14 November 2001

[34] European Commission, 2001, p. 6

[35] 1. The States Parties to the present Covenant recognize the right of everyone:
(a) To take part in cultural life;
(b) To enjoy the benefits of scientific progress and its applications;
(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

taken that are necessary to protect public health, promote public interest and further technological development. Patent protection excludes the patenting of inventions that might be contrary to public order or morality including the protection of humans, animal or plant life, or health. [29]

The Indian Patent Act provides for the safeguards for domestic manufactures of drugs that produce generic drugs with reduced pricing. The Act made access to healthcare easy for a large segment of the population. At the same time the Act also guaranteed the rights of manufacturers, thus striking a balance. In addition, the jurisprudence that emerged from the Supreme Court of India supported the delicate balance between the local manufacturers and the public interest.

With the coming in force of the TRIPS the balance of interests has shifted in favour of the MNCs. The TRIPS does not encompass the local socioeconomic realities of the developing countries. The TRIPS and the procedure to be followed under the TRIPS has caused a gross breach of fundamental rights and principles of justice and fairness in developing countries like India. The future of public health in India and realization of the right to health depends largely on the restoring of the delicate balance between the interests of the patentee and public at large.

Bibliography

1. Haracoglou Irina. Competition Law and Patents. Ed 1st. Published by Edward Elgar Publishing Ltd. 2008.
2. Johanna Gibson. Intellectual Property, Medicine and Health. ashgate Publishing Ltd. Ed; 2009.
3. Hart N. The social and economic environment and human health. In: Detels R, Holland WW,McEwen J, Omenn GS, eds. *Oxford textbook of public health.* 3rd edn. Vol 1. Oxford: Oxford University Press, 1997. 95–123.
4. Porter D. Public health and centralization: the Victorian British State. In: Detels R, Holland WW, McEwen J, Omenn GS, eds. *Oxford textbook of public health.* 3rd edn. Vol 1. Oxford: Oxford University Press, 1997. 19–34

reports

[29] Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

1. Oxfam. “Where is the Money?” Oxfam petition to the G8 meeting in Genoa. July 20, 2001.
2. Oxfam. “Oxfam International Report: Debt Relief Still Failing the Poor”. July 19, 2001.
3. UNDP, Human Development Index, 2003.
4. The Constitution of WHO (1945)
5. United Nations, Report of the High Commissioner of the Human Rights Commission on Economic, Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. UN Doc E/CN.4/Sub.2/2001/13 at 14.
6. Declaration on TRIPS and Public Health. Adopted by the WTO Ministerial Conference. Doha. Nov. 2001. WT/MIN (01)/DEC/2.
7. Doha Declaration on the TRIPS Agreement and Public Health. WORLD TRADE ORGANIZATION WT/MIN (01)/DEC/W/2 (14 November 2001 (01-577 MINISTERIAL CONFERENCE Fourth Session Doha.

Journals

1. Social Rights and the Indian Constitution. 2004 (2), Law, Social Justice & Global Development Journal.
2. Areas of Concern Related to Public Health in Indian Patents Act.
3. Judy Rein. International Governance through Trade Agreements: Patent Protection for Essential Medicines. 21 NWJ Ind L &Bus 379. 400 (2001).
4. Frederick Abbott. The TRIPS-Legality of Measures Taken to Address Public Health Crises: a Synopsis. 2001 Widener L Symposium J 71.
5. Mamdani M. The myth of population control: family caste and class in an Indian village. New York: Monthly Review Press, 1972.

Cases referred

1. ParamanandKatara v. Union of India. AIR 1989 SC 2039
2. PaschimBangaKhetMazdoorSamity v. State of West Bengal (1996) 4 SCC 37
3. Vincent Parikulangara v. Union of India 1987 (2) SCC 165.
4. MurliDeora v. Union of India &Ors. (2001)8 SCC 765.
5. Consumer Education and Research Centre v. Union of India (1995)3 SCC 42.
6. M.C. Mehta v. Union of India and Ors. (1999)6 SCC 9.
7. „X“ v. Hospital „Z“ (2003) 1 SCC 500.