ACCESS TO MEDICINES AS AN ELEMENT OF RIGHT TO HEALTH: WITH SPECIAL REFERENCE TO PHARMACEUTICAL PATENTS IN INDIA

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Abstract

The controversy between patent protection on one hand, and its relation to the accessibility and affordability of drugs on the other, is more critical than any other branch of Intellectual Property in the contemporary global debate. The TRIPS Agreement has made it obligatory for all member states to provide patent protection for pharmaceutical products and processes. The introduction of product patents in Indian pharmaceutical regime viewed as an international healthcare tragedy by millions suffering globally from life threatening diseases as a large number of them were getting benefitted from low cost drugs manufactured by the Indian generic drug manufacturing sector. This paper critically analyses the existing situations prevalent in India with respect to access to medicine. The author has dealt with the aspect of access to medicine as a human right and to what extent the medicines are "available, affordable and acceptable." This paper explores the present Indian legal system protecting the right to health by enabling the access to medicines. Lastly, the author has elaborated "the challenges with respect to the access to medicines in India" and subsequently, the author has given the suggestions to address the issue.

Key words

Pharmaceutical Patents, Access to Medicines, and Right to Health.

I. INTRODUCTION

"One third of the world's population still lacks access to essential drugs while in the poorest parts of Africa and Asia, over fifty percent of the population does not have regular access to the most vital essential drugs."

-M. Scholtz[1]

The foundation of human existence is not only ruled by science but also by 'law' as it plays a principal role in designing the social order. All the aspects of human existence are channelized through the portals of law. According to Kelson, "the Constitution as a grundnorm lies at the apex of the pyramid through which each law obtains its

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[1]M. Scholtz, *International Trade Agreements and Public Health: WHO's Role,* Conference on Increasing Access to Essential Drugs in a Globalized Economy Amsterdam (Nov., 1999).

significance."[2] As per D.D. Basu; "Constitution of India envisages a society wherein equality and justice have been engraved in the moral and legal attributes of the people."[3] Socio-economic rights are enshrined in the Indian Constitution and enjoy the same significance as is enjoyed by the civil and political rights.[4]

Access to medicines has always been a critical issue and it became exceptionally disputable after the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was finalized in 1995. There is a list of causes that contributes to the lack of accessibility to essential medicines. Especially, the single most material cause is the exceptionally high prices of drugs, which puts some of the most essential medicines entirely out of the reach of substantial population living in the developing countries.

The introduction of product patents in Indian pharmaceutical regime viewed as an international healthcare tragedy by millions suffering globally from life threatening diseases as a large number of them were getting benefitted from low cost drugs manufactured by the Indian generic drug manufacturing sector.[5] The introduction of patent to pharmaceutical sector, apart from addressing private interest, established the concern for public interest in the form of health care concern. However, it could not achieve the desired outcome as it caused rising in the existing prices of drugs. The fourth ministerial conference, held in 2001 in Doha, Qatar adopted a declaration with respect to the public health related aspect of TRIPS. The declaration spelled out the stand of the agreement and empowered nations to take necessary measures for the protection of public health. This was a principal milestone in the evolution of the access to public health as it essentially put the right to health above the concerns of the protection of individual property.

Winnie Byanyima[6] opined that, "the access to medicines is not just a poor country problem. The high price of drugs is crippling healthcare systems across the world. Millions of people are suffering and dying because the medicines they need are too expensive." Health is a basic human right, necessary for the enjoyment of many other rights, particularly the right to development and inevitable for living a life with dignity. The attainment of the right to health is also a primary goal of State's policies and programs, regardless of its economic, social, cultural, religious or political background. The deprivation of medicines causes immense and avoidable suffering such as ill health, pain, fear, loss of dignity and life.[7] Improving access to existing medicines could save millions of lives each year.

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[2]Hans Kelson, *The Pure Theory of Law and Analytical Jurisprudence* 55(1) *Harvard Law Review,* 44-70 (1941).

[3]Durga Das Basu, *Indian Constitutional Law,* 445 (Kamal Law House, Kolkata, 2011).

[4]Uday Shankar and Saurabh Bindal, *Socio-Economic Rights in India and Financial Crisis,* Paper Presented at University of Leipzig, Germany (2011).

[5]Janice Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation", 68 U. *PITT. L. REV.* 495 (2007).

[6]Executive Director of Oxfam and a member of the High-Level Panel on Access to Medicines, UN.

[7]The Montreal Statement on the Human Right to Essential Medicines (2005); Marks, S. (ed.), *Health and Human Rights: Basic International Documents,* Harvard: HUP (2006).

II. PHARMACEUTICAL PATENTS IN INDIA AFFECTING THE ACCESS TO MEDICINES

In 1957, the Government of India delegated Justice N. RajagopalaAyyangar Committee[8] to look into the matter of amendment of the Patent Law and provide recommendations to the government regarding the same. After two unsuccessful amendments in 1965 and 1967, the Patent Act was passed in 1970 and the greater part of the provisions of the 1970 Act were brought into effect on 20th of April 1972 with publication of the Patent Rules, 1972.

By 1970, foreign pharmaceuticals dominated almost 70% of the residential market and charged among the most elevated drugs costs in the world. Because of developing general public health concerns, the Indian government passed the Patent Act, 1970, which in a single killer blow disposed of all product patents on drugs.[9] Section 5 of the Act banned pharmaceuticals from acquiring product patents on their drugs, implying that pharmaceuticals could look for just process patent that are for the most part simple for other organizations to design around.[10] India evolved a standout amongst the most powerful generic pharmaceutical businesses in the world, and national Indian firms caught an extensive swath of the domestic market share of the overall industry some time ago held by outside firms.[11] However, in 1995, India joined the World Trade Organization (WTO), reinforcing its stature as a dependable and trustworthy trade partner in the international economy. As a result, India needed to amend its Patent Act, 1970 in 1999, 2002 and 2005.[12]

Since the passing of Patent Act, 1970 to the year 1995, India didn't recognize product patents for pharmaceuticals.[13] Due to this advantageous situation, Indian pharmaceutical industry was able to churn out innumerable generic drugs, demonstrating India as one of the principal generic drug manufacturers in the world.[14] India's domestic pharmaceutical industry, which was non-existent at a time, has transformed into a global manufacturer of generic drugs by providing access to medicines with lower cost.[15] However, in the year 2005, because of its obligation under the TRIPS agreement, 1995, India was forced to amend its patent law to render product patent protection to pharmaceuticals and also it extended the period of protection from years to 20 years.[16]

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[8]Justice Rajagopal Ayyanger Committee Report, 1959.

[9]Patent Act, 1970, Section 5 excludes patents on "substances intended for use, or capable of being used, as food or as medicine or drug."

[10]*Supra* note 9.

[11]Mueller, *Supra* note 5 at 515.

[12]ShamnadBasheer, India's Tryst with TRIPS: The Patents (Amendment) Act, 2005, 1 *Indian J.L. Tech.* 15-17 (2005).

[13]AntaraDutta, From Free Entry to Patent Protection: Welfare Implications for Indian Pharmaceutical Industry, 93 *Rev. Econ. & Stat.* 160, 162 (2011).

[14]Mueller, *Supra* note 5 at 514-515.

[15]William Greene, The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market, 2-3, Office Econ. U.S. Int'l Trade Comin'n Working Paper No. 2007-05-A (2007).

[16]Basheer, *Supra* note 12.

TRIPS established certain unambiguous requirements. Patents must be conferred for inventions in "all fields of technology." Subject to limited exceptions[17] and need to last no less than a quarter century.[18] A few different prerequisites are ambiguously characterized; nevertheless, nations have had some flexibility in characterizing the specific contours of the TRIPS requirements. In the 2005 Amendment to the Patent Act, India brought product patents on pharmaceuticals into effect by just repealing Section 5 of the Patent Act. However, the 2005 Amendments likewise contained various access friendly policy levers, or "TRIPS flexibilities," that the Indian generics industry could bring forth to negate brand-name and bring generics to the market, regardless of reintroduction of product patents.

III. RIGHT TO HEALTH: INDIAN LEGAL FRAMEWORK

Henry Sigerist[19] has rightly observed that health is one of the goods of life to which man has a right; wherever this concept prevails, the logical consequence is to make all the measures for protection and restoration of health to all and the same becomes a public function of the State.

According to Black's Law Dictionary, health means, "freedom from pain and sickness, the most perfect state of animal life and natural agreement and concordant disposition of the parts of the living bode."[20] Health is defined as an ideal condition and an important social and political good[21] and also is "the state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity."[22] The Preamble of WHO further 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."[23] Therefore, the human right to health means that everyone has the right to highest attainable standard of physical and mental health, which includes access to all medical services.

Under the Constitution of India

Article 21[24] (Part III, Fundamental Rights) of the Constitution of India, 1950 casts an absolute obligation on the State to life. The Supreme Court of India has time and again categorically emphasized that Article 21 also includes, in its ambit, the Right to Health.[25]

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[17]TRIPS Agreement, Article 27.

[18]TRIPS Agreement, Article 33.

[19]Ravi Duggal, Operationalizing Right to Healthcare in India, available at http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf. (last visited on 31 Aug. 2016).

[20]MallikaRamchandran, The Right to Health and the Indian Constitution, 1 *Delhi Law Review* 1 (2004).

[21]G.R. Lekshmi, Access to Healthcare: Problem and prospects, *Cochin University Review* 271 (2007).

[22]Preamble of the WHO Constitution.

[23]WHO Factsheet No. 31, Right to Health.

[24]"Protection of life and personal liberty: No person shall be deprived of his life and personal liberty except according to procedure established by law."

[25]*Parmanand Katara v. Union of India,* (1989) 4 SCC 286; *Kirloskar Bros. Ltd. v. ESI Corpn.,* (1996) 2 SCC 682; *State of Punjab v. Mohinder Singh Chawla,* (1997) 2 SCC 83; *Paschim Bengal Khet Mazdoor Samity v. State of W.B.,*(1996) 4 SCC 37.

Article 47[26] (Part IV, Directive Principles of State Policy) of the Constitution of India also stresses on the improvement of public health and government has an obligation to regulate the prices of drugs and medicines so that they are available to the citizens at affordable prices. Thus, the policy makers must bear in mind that providing "right to health" is their constitutional obligation.

Under the Patent Act, 1970

India joined the WTO in 1995, it became subject to the agreement on TRIPS, which requires it, among other things, to restore product patents on drugs by a certain date. The 2005 Amendment of Patent Act did just that, additionally it also incorporated various provisions, called "TRIPS flexibilities," and intended to decrease the blow regarding access to affordable drugs. The fundamental TRIPS flexibilities, creating access to affordable drugs, are:

Evergreening of Patent: Section 3(d)

The most disputed provision, and the most astounding source of concern for the pharmaceutical sector, is Section 3(d) of the Patent Act. Section 3(d) is the principal provision of the Indian Patents Act regarding patent eligibility. Additionally limiting the extent of patentability, particularly for pharmaceutical inventions, Section 3(d) states that a patent may not be granted for:

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.[27]

Thus, in India, patent law bars minor enhancements on medications, basically prohibiting evergreening. In effect, a drug patent holder may not restrict or prevent competition from generic manufacturers by baselessly extending the patent term.[28] The Supreme Court of India in *Novartis AG v. Union of India,*[29] by holding the right to health of its people as paramount, ruled that Section 3(d) serves as an additional bar for drugs to clear in order to prevent "evergreening," the practice of making trivial changes to an existing product simply to extend the patentee's exclusive rights over the product. One of the core issues of the case is whether, under Section 3(d) of the 2005 Amendment, the final version of Gleevec enhances the "know efficacy" of the previous form of the drug. Novartis contended that Section 3(d) was immaterial to the case, but the court didn't find this argument persuasive. Therefore, in India, patents are granted only to those pharmaceutical products that have altogether upgraded the "efficacy" of the product.

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[26]"Duty of State to raise the level of nutrition and the standard of living and to improve public health: The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement ofpublic health as among its primary dues and, in particular, the State shall endeavor to bring about the prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health."

[27]The Patents (Amendment) Act, 2005, No. 15, Section 3(d).

[28] Inderjit Singh Bansal, *et al., Evergreening: A Controversial Issue in Pharma Milieu,* 14 J. Intellectual Property Rights, 299-300 (2009).

[29](2013) 6 SCC 1.

The Novartis case is important because it highlighted that its no longer acceptable to the global public that hundreds of millions of people are denied access to life-saving drugs, because of monopoly pricing, adversely affecting their right to health.

Compulsory Licensing: Section 82-94

The WTO established the TRIPS agreement to strike a balance between protecting patent holders and giving the public access to inventions. The agreement included a provision for compulsory licensing[30] that would permit a government to allow someone else, usually a generic manufacturer, to produce a drug without the explicit consent of the patent owner. Although TRIPS defined certain qualifications for issuing compulsory licenses, countries retained broad discretion over when to grant compulsory licenses and how to establish adequate remuneration. The Doha Declaration,[31] enacted in 2001, was intended to clarify some of the confusion about compulsory licenses but instead left the adequate remuneration language untouched.[32]

The Indian Patent Act provide that an application for the grant of compulsory license can be made only after three years from the date of the grant of patent unless exceptional circumstances like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date. Three broad grounds for the grant of compulsory licenses are: i) Reasonable requirements of the public with respect to the patented invention have not been satisfied; ii) The patented invention is not available to the public at a reasonably affordable price; & iii) The patented invention is not worked in the territory of India. The Patent Act sets out the circumstances under which "reasonable requirements of the public" would not have been met.[33]

In *Natco v. Bayer Corporation*[34] India's Controller of Patents granted a compulsory license to Natco over Bayer's Naxavar drug. This move was taken to achieve access to medicines for the protection of right to health.[35]

Shamnad Basheer,[36] has pointed out that "I think compulsory licensing is the way forward… In the entire debate about patents, this is the middle path."

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[30]TRIPS Agreement, Article 31.

[31]The Doha Declaration recognized that member nations should not strive to uphold the TRIPS Agreement at the expense of the nations' public health. The clarification embodied in the Doha Declaration resulted from an increasing concern over public health problems affecting the developing and least-developed countries.

[32]The Doha Declaration did try improving access to some drugs by allowing counties to use their power issue compulsory licenses to support the production of generic drugs for export. However, the effort has proven to be insufficient and leaves the current system of state by state policy making relatively untouched.

[33]RicadoMelendex-ortiz& Pedro Roffe (eds.), *Intellectual Property and Sustainable Development Agenda in A Changing World* 106 (Edward Elgar Publishing Ltd., Massachusetts, 2009).

[34]*Bayer Corporation v. NatcoPharma Ltd.,* Order No. 45/2013.

[35]Vikas Bajaj & Andrew Pollock, India Orders Bayer to License a Patented Drug, N.Y. Times, March 12, 2012, available at: www.nytimes.com/2012/03/13/india-overrules-bayer-allowing-generic-drug.html. (last visited on 15.12.2017).

[36]He is a Professor at West Bengal National University of Juridical Sciences.

Revocation of Patent: Section 66

Section 66[37] of the Patent Act enables the central government to revoke a patent where it is observed to be mischievous to the State and prejudicial to the public. The government of India has revoked just two patents so far, *i.e.,* evocation of Agraceru's Patent in 1994 and Revocation of Avasthagen's Patent in 2012. Section 66 works as a remedial provision and the government is considered as the adjudicating authority which guarantees that public interest is given more priority than individual interests.

Bolar Provision: Section 107A(a)[38]

The Bolar exemption is very relevant to the Indian scenario as it plays a crucial role in protection of major part of the population in India that is suffering from deadly diseases. The Bolar provision gives an exception from patent infringement to the generic manufacturers from utilizing and importing patent drugs for the sole purpose of R&D, so that they will be ready with their generic version to get regulatory approval before the patent on that product expires.

Section 107 (b) of the Act implies that "importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights." For instance, an MNC acquires a patent on a pharmaceutical product in India and, furthermore, offers a similar product more economically outside of India, say Somalia. A third party who purchases a product from the patentee, or its agent, in Somalia and imports it into India for re-sale then they would not be liable for infringement of patent. This result is consistent with the traditional view of international exhaustion as one in which the patentee has obtained its "reward" by th first sale anywhere in the world.

IV. CHALLENGES WITH RESPECT TO ACCESS TO MEDICINES

Development of Medicines: Needs R&D

Intellectual property law and policy has a notable connection with the promotion of R&D for primary health needs and access to affordable essential medicines.[39] Where primary health needs are not effectively tackled by existing medicines, the right to access to medicines imposes a duty upon the States, parties to the ICESCR,[40] to take required measures to ensure R&D for new medicines addressing primary health needs.[41] The

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[37]Where the Central Government is of the opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity of being heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.

[38]Certain acts not to be considered as infringement: For the purpose of this Act - (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; shall not be considered as an infringement of patent rights.

[39]Report of the High Commissioner for Human Rights, Para 30.

[40]The International Covenant on Economic, Social and Cultural Rights.

[41]*Supra* note 39 at Para. 31.

diseases which aren't given much attention by the pharmaceutical companies, due to the poor purchasing power of people as well as less number of patients, are called 'Neglected Diseases,' such as, Leishmaniasis (Kala-azar), Onchocerciasis (River blindness), Chagas disease, Leprosy, Schistosomiasis (Bilharzia), Lymphatic filariasis, African trypanosomiasis (Sleeping sickness) and Dengue fever. Malaria and Tuberculosis are also often considered to be neglected diseases.[42] Such diseases, in spite of the fact that they are seriously disabling and life-threatening, attract inadequate R&D. the pharmaceutical companies invest more on marketing and promotion than on R&D. it is interesting to note that many of the pharmaceutical companies don't even have their own manufacturing plants and thereby they are involved in third party manufacturing.

Quality of Medicines

It is the duty of the State to guarantee that the medicines of good quality are available throughout its jurisdiction. Thus, effective medicine regulation is required to ensure the safety, efficacy and quality of medicines available in public and private sector, as well as the accuracy and appropriateness of medicine information available to health professionals and public.

While the safety and quality of medicines is a problem in India, the magnitude of the problem is much greater, as the poor quality medicines may be the only ones to reach the poor. Many of the anti-malaria drug samples failed quality control tests, while more than half of anti-retrovirals didn't met the set standards. The Central Drugs Standard Control Organization (CDSCO) of India has inadequate capacity to regulate the medicines market. The inadequacy of such an authority is clearly inconsistent with the right to the highest attainable standard of health. In the absence of a standard medicines regulatory system, the Indian Medical practitioners depend upon the reputation of those pharmaceutical companies who have exhibited their devotion to quality over the time. Moreover, once a manufacturer obtains a license, after quality check, there is no criteria for further quality check of medicines.

In India, the actual problem is not only about the expensive branded medicines versus cheaper generics but it is also about the quality medicines versus suspect quality medicines. The Medical Practitioners have come to trust certain companies and their brands over time. Therefore, it is difficult for them to shift this trust to generics, manufactured by unknown companies. Also, inmany of the cases, the alleged generics are also marketed and promoted with a brand name - the sole difference being that these brand names are not that extensively promoted and publicized. Moreover, if the Medical practitioner prescribes a medicine with its pharmaceutical salt name, then in all probability, the pharmacist will dispense it with another branded generic drug of dubious quality.

As the discussion about the affordable medicines gets overshadowed by drug safety, it is suggested to have a glance at the findings of a recent report on substandard and spurious drugs by the National Institute of Biological for CDSCO. The report established that branded medicines are in no way assurance of quality.

[42] *Supra* note 23 at 8.

Reliable System for the Supply of Medicines:

Whether it goes for a supply system that is public, private or mixed, a State has a legal duty to make sure that there is an authentic, dependable, efficient and transparent mechanism for the supply of quality affordable medicines.The supply mechanism should be accustomed to prevalent needs, get good value for money, reduce waste and prevent corruption. Most importantly, it must be designed to assist those living in destitute and remote areas, as well as to do urban classes.[43] As half of the medicines, prescribed by the government medical practitioners, are not available in the pharmacy of such government hospitals, given the fact that the medicines available in the government pharmacy are cheaper than the private pharmacies. Therefore, the customers are bound to rely on private pharmacist for such prescribed medicines.

Price Control in India

India is among the countries with the highest Out of Pocket expenses (around 67% as per NSSO 68th Round 2011-12) on health care. Expenditure on drugs constitutes over 67% of out of pocket expenditure. As per WHO study estimates, "about 65%of the Indian population lacks regular access to essential medicines." It creates an inconsistency in itself because of the fact that India is one of the largest manufacturer and supplier of the generic medicines to the world.

The Drug Pricing Control Order (DPCO) is the main regulatory system which controls the prices of medicines in India and is controlled and monitored by the National Pharmaceutical Pricing Authority (NPPA). DPCO are issued for enabling the government to declare a ceiling price for essential and lifesaving medicines (as per prescribed formula) so as to ensure that these medicines are available at a reasonable price to the general public. The latest DPCO was issued on 15.05.2013. Under the DPCO 2013, the prices of only those medicines that figure in the National List of Essential Medicines (NLEM), are monitored and controlled by the regulator, the NPPA. However, the pharmaceutical companies in order to exclude their medicines from the DPCO add any chemical entity which is not covered under DPCO to the existing medicines covered under DPCO. This results in rise of the price of medicines due to the exclusion from the purview of DPCO, even though such addition of chemical entity doesn't enhance the efficacy of such medicines. For instance, Cefixime, an antibiotic used for bacterial infection, is covered under DPCO 2013, with a price capping of Rs. 7.90. The pharmaceutical manufacturer named Cadila added Lactobacillus, which is available in the market at Rs. 0.40/- as a finished product, to Cifixime and sells a new finished product in the name of Symbiotik with an MRP of Rs. 32.82.

The entire issue of cheaper generics is based on the premise of measurable and enforceable assurance about quality through bioequivalence tests and other globally mandated parameters. To ascertain the quality of medicines, the Indian Medical practitioners have to depend upon the reputation of companies like Cipla, Sun and hundreds of others who have displayed their devotion to quality over the time and become trusted names in the eyes of Medical practitioners and patients.

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[43]Paul Hunt & Rajat Khosla, "The Human Right to Medicine" 8 *International Journal on Human Rights* 88 & 106 (2008).

Responsibility of the State:

The CESCR[44] sets out four elements of the right to health that have to be ensured; that is, all health care facilities, goods and services, including medicines, shall be - i) available in sufficient quantity within the State party; ii) accessible to everyone without discrimination, economically as well as physically; iii) acceptable culturally and in light of medical ethics; & iv) of good quality."[45] States, therefore, are required to resort to a variety of economic, financial and commercial incentives in order to influence research and development into specific health needs. In short, States not only have a duty to ensure that existing medicines are available within their territory, they also have the responsibility to take reasonable to take reasonable measures to ensure that there is dire need to develop new medicines and accordingly make them available.[46]

States have the duty to respect, protect and fulfill the right to access to medicines as they have with regard to other rights.[47] The duty to respect requires the State to refrain from action that interferes with the right to access to medicines. The duty to protect obliges the State to ensure that third party doesn't hinder the access to medicines. The duty to fulfill compels the State to embrace suitable legislative, administrative, budgetary and other measures towards the attainment of the access to medicines.[48] For instance, State is required to avail requisite information on essential medicines.[49]

The government of India came up with its National Health Policy, 2017 and planned to improve the Public Sector Capacity for manufacturing the Essential Drugs and Vaccines[50] and to stimulate innovation and new drug discovery as required to meet health needs.[51] But the actual situation shows something different and raises an alarm. The latest survey shows that the government of India spends only about 0.6-0.7% of its annual GDP on R&D, which isn't going t fulfill its duty making the medicines available, affordable and acceptable with good quality. Moreover, the status of the Central Public Sector Enterprises (CPSEs) is also not showing good picture. There are five CPSEs under the administrative control of the Department of Pharmaceuticals. Out of these five PSUs, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) and Bengal Chemicals & Pharmaceuticals Limited (BPCL) are sick and referred to Board of Industrial & Financial Reconstruction. Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL) has also reported losses since the year 2013-14. Karnataka Antibiotic & Pharmaceuticals Ltd. (KAPL) is the only profit making CPSE.[52]

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[44]United Nations Committee on the Economic, Social and Cultural Rights.

[45]CESCR, GC No. 14, Para. 12.

[46]Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* 130 (Ashgate Publishing Ltd., 2015).

[47]UN Commission on Human Rights Resolution on "Access to medication in the context of pandemics such as HIV/AIDS, TB and Maleria," (April 16, 2004) 2004/26, Para. 7.

[48]*Supra* note 45 at para. 33, 36 and 37.

[49]*Supra* note 46 at 131.

[50]National Health Policy, 2017, Para. 20.

[51]*Id.* at Para. 25.2.

[52]Annual Report 2016-17, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Government of India, p.63.

Responsibility of Pharmaceutical Companies and Non-state Actors:

Companies constitute powerful global actors in the current world order.[53] in relation to access to medicines, the efforts to give more precision to the scope of pharmaceutical companies' human rights responsibilities was started by the first special Rapporteur on the Right to Health. The Special Rapporteur has prepared the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.[54] The preamble of these guidelines affirms that pharmaceutical companies, including innovator, generic and biotechnology companies, have a human right responsibility in relation to access to medicines.[55]

Under the right to health, States are required to allow for participation of NGOs, civil society groups, community groups and the business sector in the evaluation of indicators and benchmarks of access to medicines. The Declaration of Alma-Ata also stresses the import of civic society participation in health policy decision making. These stake holders both have responsibility under the right to health and enjoy the right to active and informed participation on decisions bearing on their health. Meaningful accountability also requires processes that empower and mobilize ordinary people to become engaged in political and social actions. Thus, State has crucial obligations to cultivate environment that allow groups and individuals to enjoy their right to participate and that encourage key stakeholders to fulfill their duties to improve access to medicines.

V. CONCLUSION

The sustenance of human life is the primary duty of the State, as propounded in the most basic conception of the social contract theory of State formation. Patenting in the context of access to medicines has become a grave issue, which was exacerbated when a number of countries has to introduce strict patenting provisions under TRIPS which resulted in a large section of the world population not being able to access medicines at affordable prices.

No doubt Pharmaceutical patent creates hindrance in the right of people as to access to medicines but in India, the actual factor which is barring the access to medicines is not the patented medicines but the generic medicines. As, in India, the consumption of generic medicines is much more than the patented one. Although, the generic medicines in India are cheaper as compared to other parts of the world, however, the purchasing power of Indians is quite less which results in non-affordability of medicines. As per the latest NSSO survey on healthcare, conducted in 2014, medicines emerged as a principal component of total health expense 72% in rural areas and 68% in urban areas. For a country with one of the highest per capita out-of-pocket expenditure on health, even a modest drop in drug prices will free hundreds of households from the widespread phenomenon of a medical poverty trap.

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[53]Justin Nolan, "With Power comes Responsibility: Human Rights and Corporate Accountability", 28 *The University of New South Wales Law Journal,* 581 (2005).

[54]Report of the Special Rapporteur on the Right to Health, (Aug. 1, 2008) UN Doc.A/63/263.

[55]*Ibid.*

The conduct of the pharmaceutical companies has emerged as one of the challenges to access to medicines as an element of the right to health. The pharmaceutical companies charges100-400 times extra of the actual manufacturing cost of a medicine which results in higher prices for consumers and higher profits for the pharmaceutical companies. Moreover, the role of NPPA while fixing the prices of essential medicines through DPCOs is also questionable to some extent.

The role of the government in this scenario is also significant. Although, the government of India, on one hand came up with National Health Policy 2017 in which it assured an increase in the health expenditure (Centre and State together) from the existing 1.15 to .5% by 2015 but same assurance didn't find any reflection in the budget, 2018.[56] Instead of spending at least 1% of the GDP as proposed by the draft National Health Policy document, the provisions for heal in Union budget presented by Finance Minister, has reduced allocation to 0.29% of the GDP from 0.32% last year.

Further, challenge to the access to medicine in India has increased due to lesser investment on R&D as well as no focus on manufacturing the essential drugs in CPSUs. Moreover, the government of India by imposing high GST rates has contributed to the bundle of impediments to the access to medicines under right to health. Medicines remain overpriced and unaffordable in India. In a country mired in poverty, medical debt remains one of the biggest factor for keeping millions back into poverty.

[56]Indian Express, The Idea Page (last visited on Feb. 3, 2018).