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Right To Health India Anddrugs Regulation: An Analysis

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Abstract

The Constitution of India does not expressly mention a fundamental right to health. However, the various judgment of Apex court pronounced to public health and on the role of the State in the provision of healthcare to citizens. The Part IV of the India Constitution provides a basis for the right to health. Article 39 (E) directs the State to secure health of workers, Article 42 directs the State to just and humane conditions of work and maternity relief, Article 47 casts a duty on the State to raise the nutrition levels and standard of living of people and to improve public health. The Right to Health comes inevitably in conflict with the patents on pharmaceutical products which block the transition of a new medicine to the status of generic medicine. Indeed a generic can be produced and commercialized cheaply because it is not submitted to the payment of royalties and can thus be distributed on a large scale via the public health systems of poor countries. This paper explores the various aspect of Right to Health India and drugs Regulation in India.

Keywords: Constitution of India, Fundamental Right To Health, Generic Medicine And Pharmaceutical Products.

Introduction

Health is the most attentive and common theme in most cultures. Undoubtedly every community of the society have their concept of health , as an essential part of their culture. In simple turn we can say that the health is the "absence of disease".

In some cultures health & harmony are considered equivalent, Harmony being defined as "being at peace with the self, the community god and cosmos." The ancient civilization shares this concept and attributed diseases to disturbances in bodily equilibrium of what they called" "humors" Modern medicine is often accused for its preoccupation[1]

It is settled principle of the society that the health is the one of the most essential to the human condition. A healthy body & healthy mind is not the only matter related to an individual it is the matter concern with entire society or world, and the only reason behind it is that, without a healthy population no sustainable economic, scientific and technological development is possible.Another fact of individual's is health is directly related to the enjoyment of all other Human Rights and it is the precondition of full participation in Social, political, economic & personal life.

Recognizing health as a HR and FR shows that health has a special importance to the life and survival of individual as it is the most concerning matter at the International level as well as National level.

What Is health

An understanding of health is the basis of all health care the concept of health is perceived in different angles by–Socialists, Scientists Health Administers and Ecologists and it actually creates a big confusion to understand the concept of health.

The world is dynamic so the concept of health is being changed with the new patterns of thoughts. However, health has evolved over the countries as a concept from an individual concern to a world wide social goal and encompasses the whole quality of life.

The language of the highest attainable standard of health is one of the fundamental right of every human being without distinction of race, religion, political belief, economic and social conditions. It shows that the status of health is determined in a large measure with the degree to which human Rights are enjoyed. It includes the implementation of human rights percepts to schemes and programmes of health system.

Now it is very much clear that health is one of the most important aspect of Human Right and both are so intrinsically involved with each other that the attainment of other rights is possible only when an individual take proper care to

maintain own health. Every human being is entitled to the attainment of adequate standard of health to enjoy his life with dignity.

The implementation of the Right to Health is undertaken through a number of different approaches such as the formulation of health policies or the realisation of health programmes initiated and developed by the world Health Organization, the adoption particular legal instrument. Moreover, the Right to Health includes certain components which are legally enforceable. The Right to Health contains both freedoms and entitlement. The freedom includes the right to be free from interference, such as the right to be free from torture, non consensual medical treatment and human experimentation, and the Right to control one's own health and body, such as sexual & reproductive freedom.

The entitlement includes the Right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health, meaning the probability that one will not die from a disease pre-maturely, whether that premature death is brought about by misguided health care, wrong distribution, ecological imbalances and lack of self reliance[2]

Why do we need Right to Health

Right to Health considered to be the Right to the personal liberty not only one should keep healthy, rather it is the duty of the state to provide healthy atmosphere and other facilities which are closely concern with the bodily Rights so that one should keep them healthy. The honourableSupreme Court and the High Court has delivered the land mark judgments over the Right to Health

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*ParmanandKatara vs. Union of India[1]*Supreme Court held that whether the be an innocent person or be a criminal liable to punishment under the law. It is the obligation of those who are in charge of the health of the community to preserve life so that innocent may be protected and the guilty may be punished.

*CESC Ltd vs. Subhash Chandra Bose[2]*In this case SC held that Right to Health is a fundamental Right. The term health implies more than an absence of sickness. Medical care and health facilities not only protect against sickness but also ensure stable manpower for economic development.

Health and having a sound body are purely personal matters. Nothing is more intimate than the experience of conceiving and bearing a child and giving birth to a unique human being. We can not live with fear or pain of our love ones, and death itself is something we can not share, however real the grief we suffer.

Infect when we or our close one face illness or chronic suffering at that time we perceive that health is in reality a very public issue. Policies which dictate what level of health care provision is guaranteed, what kind of service will be offered, how priorities are established between competing claims, where resources are concentrated, and what alternatives are available all become more for more immediate when they affect us or our loved ones.

Access to health care becomes dependent on the individual's capacity to pay, patients are turned from citizens who have rights and responsibilities in to clients or consumers. The questions of financing the health care now become more technical, what kind of cost recovery and insurance mechanisms "work", and in what circumstance? The goal of "Health for all by the Year 2000" is eroded into one of "Health for those who can pay today".

Current trends suggest that "the enjoyment of the highest attainable standard of health" which WHO describes as "One of the fundamental rights of every human being" is seen almost as a by product and while seven out of ten of the world's poorest people are female, women's health needs are widely neglected, whatever their background yet, if development is not for health, what is it for end who can expect to enjoy it?[3]

Development of the Concept of the Right to Health:

Earlier it was the concept of health that health was personal subject rather then public but now the philosophy and the concept rapidly are going to be change. Being a part of Human Right health become the public subject rather personal.

Health was also understood as the "absence of disease" the first law containing health related provisions go back to the era of industrialization. The Right to Health is a fundamental Right to which Indian Judiciary recognized under Article 21 of

Indian Constitution.[1] Traditionally the scope of fundamental Rights guaranteed by Indian Constitution has been expended on the basis of International human rights institutions. Internationally recognized human right, including the Right to Health, are directly enforceable through domestics Courts in the absence of contradictory domestic law,or by virtue of there in corporation in to domestic statuary law.[2] The Right to Health is covered by several International human rights instruments, includingArticle 12 of the International covenant on economic & social & cultural rights.[3]

Specific obligations are set out by general comment 14 under which countries are bound to respect, protect and fulfill the Right to Health & make good quality services & goods available, accessible & acceptable. Access to affordable drugs has been interpreted to be part of the Right to Health competition from generic companies is the key to affordable drugs. The absence of patent protection for drugs in India from 1972 to 2005 allowed drug companies to use alternative non infringing process to manufacture generic drugs. Generic companies in India can therefore produce drugs at price that are lowest in the world. This cost advantage mans more than 80% of the adult and antiretroviral drugs purchased from donor funded programmes in the developing worlds are supplied by companies in India.

In 2005 India reintroduced patent protection for drugs to comply with its obligation under the agreement on trade related aspect of intellectual property Rights (TRIPS).[4] However TRIPS allowed countries substantial flexibilities towards protecting public Health. India has made use of the transition period by introducing patent eligibility criteria, disallowing the new forms of known substances without clear enhancement of efficacy.

Procedure for opposition & revocation of compulsory licensing and governmental use of patent are also being used to provide space for generic competition. The governments of developed Nations, under pressure from multinational drug company are employing new ways to thwart competition from generic drugs. The European union and India free Trade Agreements seeks to introduce TRIPS – Plus[5] and other measures, such as patent term extension, data exclusivity increased border and enforcement measures, and investment protection agreements, all of which would impede generic competition.

The move to raise global standards inforcement of intellectual property Rights through the proposed multilateral Anti-Counterfeiting Trade Agreement (ACTA) will also deter generic competition.[6] The agreement purportedly response to the global trade counterfeit and pirated goods, negatsthe flexibilities available to World Trade Organization members under TRIPS with respect to enforcement of intellectual property rights.

Over the past 4 years alone, six major drug manufacturers in India were bought out by foreign multinationals at a total cost of US $ 10.5 billion.[1] These purchases are a cause for concern for the Indian generics Industry, the reduced competition, which is likely to result, will endanger the availability of low-cost generic drugs in India and the developing world.

The Right to Health comes inevitably in conflict with the patents on pharmaceutical products which block the transition of a new medicine to the status of generic medicine. Indeed a generic can be produced and commercialized cheaply because it is not submitted to the payment of royalties and can thus be distributed on a large scale via the public health systems of poor countries. But treat medicines and health like any other good in the epitome of the capitalist market; demanding the respect of IP rights in this filed will inevitably increase in the final cost of medicines and health.

India has on obligation under domestic and international law to respect, protect and fulfill the Right to Health of its people. To meet its health care obligations India must guarantee the continued domestic production of generic drugs. International agreements that interfere with India's use of TRIPS flexibilities and require TRIPS Plus and other measures must, therefore be resisted. Foreign investment in the drug industry must also be regulated to preserve India's Fundamental and Constitutional Right to Health for its citizen.

History of Indian patents system divided in to two parts, before and after the Independence. Before independence it was started 150 years ago, with the promulgation of legislation by Government of India on **28th February, 1856 termed as "Exclusive Privileges for the encouragement of invention of new**

manufactures". The Act of 1856 on protection of invention based on the British Patent Law of 1852. Certain exclusive privileges granted to invention of new manufactures for a period of 14 years. The first application for patent made by Mr. George Alfred De Penning, a civil Engineer on 3rd March 1856 for his invention "An Efficient Punkah Pulling machine". The inventor on 2nd September, 1856 submitted specifications along with drawings illustration. He submitted to more applications in the same years. Calcutta Patent office granted patent for this inventor in the year 1856 and many more in the coming years.

In 1859, the Act modified as **Act XV called Patent monopolies and Exclusive Privileges Act 1859** (making, selling and using inventions in India and authorizing others, to do so for fourteen years from the date of filing specification). In 1872, the patents and Designs Protection Act introduces. In 1883 the protection of Invention Act as the Inventions & Designs Act, in 1911. The Indian patents and Designs Act introduced which granted to the inventors of new manufactures for the period of 14 years protection for their invention. In 1972, the **Patents Act (Act of 39 of 1970)** came in to existence on **20th April 1972.**

Among the salient features of the Patent Act, 1970 and Patent Rules 1970 framed hereunder are: a more elaborate definition of invention, declaration of certain inventions as non-patentable, abolition of product patents for drugs and medicines, stringent requirements regarding description of the invention, extension of grounds for apposing the grant of a patent, etc. **On March 26, 1999, Patents (Amendment) Act 1999 came in to force from 1st January 1995.** According to this Amendment, it is now possible to make an application for patent claiming for a substance itself intended for use or capable of being used as medicine or drug excepting or drug excepting the intermediate for preparation of drug. Exclusive marketing rights would be valid for a period of 5 years on till the date of grant of Patent or date of rejection of the application for the grant of patent whichever is earlier.

The Indian Patents Act 1970 was implemented to encourage innovation by protecting proprietary research and development. Patents issued for methods of producing products (composition of matter), but not for the products themselves (i.e. Pharmaceuticals). As a result of this one can commercialize a drug that was a proprietary product of another as long as one's own method of producing that product was used.

The patent term for chemicals, food and drugs were only 7years which was very short compaired to WTOs mandatory 20 years term from filing date. Protection is not for imported products and only for the means of producing that product. On **March 26, 1999.** Patents (Amendments) Act, 1999 came in to force **from 01-01-1999. In 2002,** the patents (Amendments) Act 2002 again amended which came in to force from 20th May 2003. The latest amendment was on 2005, this patents (Amendments) Act 2005 was effective from **1st January, 2005.**

The major feature of Patents (Amendment) Act, 1970 are provision for 20 years term from the date of filling and this includes so called mail-box applications. Mail box application are product patent applications that were filled with the Indian office from 1st January 1995 to 31st December, 2004, but were held in limbo (and unexamined) pending revolution of policies and laws regarding treatment of there product Patents India amended Patents Act 1970 third time in 2005 and the Patents (Amendment) Act 2005 was ratified by the Indian Parliament in April 2005 and was in force since 1st January 2005 to meet compliance requirements under WTO aggrement on TRIPS it also replaced the Patents (Amendment) ordinance 2004, which was hurried through passage at the end of 2004 in order to meet 1st January, 2005 deadline.

Objective of the Study

The objective of Study to explore Following in reference to right to health and its related issues. The Main Objective of Research is as follows:-

1.To find out how to protect Health as fundamental rights.
2.To analysis of Drug Regulatory Mechanism in India
3.To Sum Up the Reforms in protection of right to Health and its Governance.

Grant of Patent

Property institutions fundamentally shape a society. These legal relationship between individuals, different sorts of objects and the states are not easy to justified. This is especially true of intellectual property. It is difficult enough to determine the appropriate kinds of ownership of corporeal objects, it is even more difficult to determine what type of ownership we should allow for non corporeal, intellectual

object, such as writings, inventions, and secret business information. The complicity of copyright, potent, and trade secret law reflects this problem.

According to one writer "Patents are the heart and core of property rights, and once they are destroyed, the destruction of all other property rights will follow automatically, as a brief post script."[1] Though extreme this remark rightly stresses the importance of patents to private competitive enterprise. Even since the inception of the patent right a number of different justification have been given in support of the patent system. The proponents of patents system have emphasized the natural right of inventors to the products of there mental labour while some have argued that inventors contributions should be recognized by the grant of a reward. The most common theory put forth has been relating to the public benefits that flow from the grant of patent monopoly. These theories have been dominating discussion on the function of the patent system since 19th century.

Legal Position of Pharmaceutical

Protection of public health In India the **Patents Act 1970** provides Sec 3 declares what are not inventions within the meaning of this Act, whereas sec. 4 bans patents on invention relating to atomic energy. The prohibition under sec 3 is provide due to government policies or where subject matter of invention is against natural law or is not an invention but is mere discovery or is against social interest or is protected under any other head of IPRs.

This act of 1970 provides both process and product patents but exclude certain subject matters in which product patent was not granted. The subject matter relating to Pharmaceutical, food and agriculture products were not granted product patent. Pharmaceutical product were not granted product patent because of the fear that prices of essential medicine will rises and it will be out of reach of the general public enlarge due to absence of competition the companies inventing essential drugs will costs high price for them. In India the Pharma industries are growing as they do not spend on research and development (R&D) like other Pharma companies or MNCs. They produce medicines through reverse engineering and cost of these medicine are relatively very low as they have not spend on R &D.

In India, the patent law is in conformity with the TRIPS as it has been recently amended by the patent (Amendment) Act, 2005.

This amendment has provided product patent to pharmaceutical product which was not been provided. Due to this reason the generic companies in India were flourishing. They not only met the domestic need but exported the generic medicines to countries where pharma industries is not self sufficient. Thus Sec. 92(A)[1] has been inserted to protect the interest of the countries depended upon the generic industry of India. It provides CL for export of patented pharmaceutical products in certain exceptional circumstances.

The sec 83 of the patents Act 1970 is the objective clause of the Act which provide that the patents are granted to encourage invention and to secure that the inventions are worked in India on a commercial scale and to the fullest extend that is reasonably practicable without undue delay. It also states that patents granted do not impede and nutrition and should act as instruments to promote public interest specially in sectors of vital importance for socio economic and technological development of India and do not in any way prohibit central Government in taking measures to protect public health. It also says that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of produces and users of technological knowledge and in a manner conductive to social and economic welfare, and to a balance of rights and obligations. This clause not only protect individual interest but also provides protection to the rights of the society. The CL is provided under sec.84 of the patent Act 1970 on the ground of non working of patent invention in the territory of India or the patented product is not available at reasonable affordable price or the requirements of the public are not met. The Act has also legalised the government i.e. if the patented invention is used by the government will not amounts to infringement. The meaning of the use of the invention for purpose of government means: an invention is said to be used for the purposes of government if it is made, used, exercised or vended for the purposes of the central government, State government or government undertaking.[2]

Concluding Remark and Sum up:

Health is one of the most attentive and common theme in most cultures, it is settled principle of society that health is the one of most essential to the human condition. There was hue and cry regarding the grant of product patent in the field pharmaceuticals. The major issue regarding pharma patent was that the medicine will not be accessible to public at large. The developed countries raised the issues that the Right to Health is not the part of right to life. It was said because if the Right to Health was not recognised then non access of medicines will not be an issue.

The instinct to do something new has been at the center of all human civilizations and this is the basic of innovation, which in turn developed in the form of Patent.The Right to Health is recognized by various international documents.Universal Declaration Of Human Rights, International Covenants On Civil and Political Rights-ICCPR,Word Health Organization-WHO Constitution etc. and in India the Right to Health is recognised by the Supreme Court in various cases.The WHO Constitution not only recognizes but also provides that the governments shall be responsible for the protection of this right and must fulfill this obligation.

The issue is not only the Right to Health but the right to property is also recognized as human right, so the protection of this right is also essential. The economic theory also supports the protection of the patent right.But there is a conflict between the right of patentee and the Right to Health.If one is protected then other will be infringed thus we should adopt a middle path for enforcement of these rights. The basic principle of Natural law that is the right of one person extends till it does not infringe the rights of other persons should be applied. Therefore, the rights of the patentee must be protected unless they infringe the Right to Health.

The protection of public health is one the most pressing issues in developing countries. A large part of the world's population still lacks access of essential drugs at reasonable and affordable prices. Whether subject to TRIPS agreement or not government can determine own criteria to assess patent application consistently with our public health policy.Patents regimes are generally part of national technological and industrial strategies, but is also crucial to design them consistently with public health strategies. It is important , in particular, that the scope of patentability be congruent with public health policies and that the government be aware that unduly expending what can be patented may distort competition and reduce access to medicines.

a. Thus it can be said that the challenge before the country to secure the Right to Health can be fulfilled by providing the essential drug at reasonable and affordable price. Generic drugs may be a better option to fulfill the governmentsConstitutional obligation.

b. the government should provide the basic facilities required to maintain a healthy life. The government can maintain it with the development of medical infrastructure so that every person gets the Doctor and can enjoy his fundamental Right to Health in full extent.

c. The issue regarding pharmaceutical product patent are price of medicines and Right to Health and right of the patentee. To solve all these problems some suggestions might prove to be effective.

2. Public health concern should have priority over commercial and industrial concerns.

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