

# Right to Health Care in the Regime of Patent Laws

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## PROLOGUE:

The laws dealing with patents seem to confront with health care measures on various issues like patenting the medical discoveries, the process of making drugs and the most pertinent issue is TRIPs obligations. Under these obligations the TRIPs require the WTO member governments to give copyright and patent protection for 20 years to a wide range of new products, including pharmaceutical goods. During this period, no one may use, make or sell a product without the owner's authorization. After the patent expires, other firms can sell "generic" versions of the product. It was contented that after a period of twenty years the composition of said drug or product might be out-dated and there is possibility of invention of new or better version of the medicine. Secondly, since the production of such a drug would be done only by one manufacturer so the price would certainly be higher.

## RIGHT TO HEALTH AS A FUNDAMENTAL HUMAN RIGHT:

Right to health is fundamental to the very exercise of all human rights. Globally the concept of right to human health is a crucial, rapidly increasing discourse in the context of international health care policy and concomitant to realizing this goal are the issues pertaining to the role of various international laws and specialized agencies viz. WHO, FAO, etc. According to WHO, health has been expansively defined as meaning "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." In fact health is a stepladder to development and therefore, a vital link for the realization of not only civil and political rights but also socio-economic and cultural right. Right to health care can be defined as the right to share the benefits of health care and health services available in the society. The right to health care is primarily an obligation imposed on states to provide sufficient means to guarantee its citizens a certain standard of health, as well as equal access to health care services which also includes medicines at affordable prices.

So far the term "right to health care" has not been used in

any of the major international instruments. However, the right to health care can be derived from different formulations, such as:

Universal Declaration of Human Rights under Article 25 provides that "Everyone has the right to a standard of living adequate for the health, and wellbeing of himself and his family..."

International Covenant on Economic, Social and Cultural Rights under Article 12 provides that "a right to the enjoyment of the highest attainable standard of health...."

Preamble to the constitution of World Health Organization, declares that it is one of the fundamental rights of every human being to enjoy "the highest attainable standard of health".

African Charter on Human and Peoples' Rights under Article 16 provides that everyone has "a right to enjoy the best attainable state of physical and mental health."

American Declaration of the Rights and Duties of Man under Article 11 provides that everyone has "a right to the preservation of health"

European Social Charter under Article 11 provides that everyone has "a right to health protection"

Inherent in the right to health is the right to the underlying conditions of health as well as medical care. Despite this significance the Indian Constitution also doesn't expressly recognize right to health as fundamental right though imposes several related obligations on the State under Part IV, dealing with Directive Principles of State Policies, wherein it is provided under Article 47 that "the 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."

## THE PATENT REGIME:

A PATENT is an exclusive right granted by sovereign state to a person who invented a new article or an improvement of an existing article or a new process of making an article. It consists of an exclusive right to manufacture the new

article invented or manufacture an article according to the invented process for a particular period. Thereafter it passes into the public domain.

The object of granting a patent is to encourage and develop a new technology and industry. An inventor may disclose the new invention only if he is rewarded, otherwise he may work it secretly. Thus the theory upon which the patent system is based is that the opportunity of acquiring exclusive rights in an invention stimulates technical progress in four ways as given by Justice Rajagopala Ayyangar in his report in the year 1970 and also reiterated by Justice Jeevan Reddy in *Vishwanath Prasad v. Hindustan Metal Industries* (1979 (2) SCC 511):

- It encourages research and invention;
- It induces an inventor to disclose his discoveries instead of keeping them as trade secret;
- It offers the reward for the expenses of developing invention to the stage at which they are commercially practicable; and
- It provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embark on them simultaneously.

The World Trade Organization after bringing the TRIPs Agreement in 1994 has shared the responsibility of providing affordable health care measures to the people globally, so that the right to health and right to life of the people will not be affected. However, by making product patent compulsory, the monopolies are strengthened and the prices of drugs are apt to rise, leaving the poor and their right to life to lethal destiny in developing countries and least developing countries. Thus the multinational pharma companies will monopolise the drug market. Prior to 2005 the prices of pharma products in India were the lowest in the world due to competitive environment.

### **IMPACT OF TRIPs AGREEMENT ON INDIA :**

The TRIPs Agreement imposes significant impact on the Indian system of patenting. The Patents Act, 1970 which allowed only process patents and not product patents in respect of food, drug and chemical substances, provided shorter protection periods and excluded agricultural methods, processes of medicinal, surgical etc. treatment of human beings, animals or plants from the scope of patentability. This scheme of India was seen by many as a model for the other developing countries. However, with other WTO member countries, India was under a binding commitment to alter its national system of patenting in accordance with the provisions of TRIPs Agreement. Therefore, the Patents Act has undergone several amendments in The Patents Act, 1970 to bring it in line

with TRIPs Agreement:

- Patents (Amendment) Act, 1999,
- Patents (Amendment) Act, 2002 &
- Patents (Amendment) Act, 2005.

Thus, TRIPs Agreement imposed drastic changes to the Indian patenting arrangement after the amendments. Firstly it requires the availability of product patents in the field of Chemicals and Pharmaceuticals. Second, it imposes a uniform duration of twenty years for patent rights. Third, compulsory licensing is only allowed within specific limits. Fourthly there is lot of changes in the process of compulsory licensing, which has given a leeway to the developing countries to grant compulsory licenses for both production and importation of the patented drugs or drugs produced from patented process.

The recent amendment heralds a new era in the growth of pharmaceutical industry in India. Though India has to phase out the process patent system in drugs and pharmaceuticals, agrochemicals and food, which was replaced by product patent regime effective from January 1, 2005, it could still maintain production of generic drugs process patent subject to the payment of royalty to the patent holders. The changing scenario has brought exorbitant increase in the private R & D spending in order to capture burgeoning global pharma market whereas India's pharma market is merely 1 percent of the world market. This major development will encourage innovations in India that will lead technological development and thus economic growth, though this is a long term process.

### **DOHA DECLARATION:**

Doha Declaration on TRIPs and public health is termed as real victory for the developing countries in which a judgment has been given favouring developing countries' concern of the availability of medicines at the affordable prices in case of national emergencies. In this regard the compulsory licensing was given much emphasis.

In the Declaration the members of WTO recognize the gravity of the public health problem afflicting developing countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Members have recognized that protection of intellectual property is important for the development of new medicines and the affordability of the common people for such medicines at a lower price.

### **EPILOGUE:**

The Indian patent system had been designed and amended to promote innovation and, at the same time,

offer a mechanism ensuring that the fruits of that innovation are accessible to society. In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the needs of the general public. India has complied with its TRIPs obligations by amending the Patent Act thrice, out of which the most pertinent provision is product patent. Now the transitional system of giving 'Exclusive Marketing Rights' to ensure the interests of the domestic manufactures who mainly survived on off patenting and reverse engineering of patentable bulk drugs and formulations for a long time has been unveiled.

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