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SHOULD MEDICINES AND DRUGS BE KEPT OUT OF PATENT REGIME?

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Abstract

Health is one of the most basic fundamental rights of a human being and adequate measures needs to be taken in order to protect it. Providing access to essential drugs and medicines is one of the means by which this essential right of individual could be protected. The question whether drugs and medicines should be granted patent protection or should they be kept out of patent protection regime is one of the hotly debated questions to the World Trade Organization. The issue has attracted strong views and comments from people all across the globe.

Keywords: *Compulsory Licensing, Indispensable medicines, Lifesaving or Vital Drugs, Trade Related Aspects of Intellectual Property Rights (TRIPS)*

INTRODUCTION

The need to facilitate access to essential medicines for those with life threatening or fatal diseases like HIV, Tuberculosis, and malaria has generated significant interest. Yet, an inevitable tension exists between the need for pharmaceutical companies to profit from their patented inventions and the desire to provide access for impoverished persons. Developing nations have attempted to resolve this tension through the issuance of patent compulsory licenses.[i]

The statement by the Secretary General of the United Nations, Kofi Annan in 2001, that "IPR protection is the key to bring forward new medicines, vaccines and diagnostics urgently needed for the health of world's poorest people" was refuted when at the Inter- Ministerial Conference in Doha in 2001, representatives of the developing countries stated that IPR stood in the way of access to drugs for the poor.[ii]

Public health is one of the major concerns of the developed and least developed countries and now it has become a global problem. Diseases such as HIV/AIDS, Malaria, and Tuberculosis are affecting the developing world profoundly. According to the World Health Organization estimates, more than 2 billion[iii] people or nearly 400 million people of the world have insufficient or no access to indispensable medicines or drugs with more than 50 per cent of population in India and Africa still in need of access to most critical and fundamental drugs.[iv]

MOST RESPONSIBLE FACTORS FOR NON-ACCESS OF DRUGS

There are many factors that are responsible for non-access to essential drugs in the developing and least developed countries for instance socio political circumstances existing in the underdeveloped countries have an immense role to play in the extensive spread of diseases in these countries. The lack of adequate infrastructure such as proper roads, transportation facilities, fully equipped hospitals, the neglected rural population and unavailability of basic sanitation facilities are some of the problems that which have led to public health crisis in the developing world and this needs to be tackled post haste. Poor standard of living, poverty, unemployment, less scientific development, lack of education and health care professionals, government instability, corruption and inefficiency are few other factors which aggravate the

situation in these countries.

This non accessibility of vital drugs and medicines has increased tremendously with the introduction of the patent system, as pharmaceutical companies being commercial entities have their only motive as profit making. This crisis is prevalent not only developing and least developed nations of the world but even the developed nations are struggling for access to drugs and medicines.

TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The introduction of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) in the year 1994 which tries to employ a standardized set of intellectual property protection practices across the nations of the world to offer better strength in global economic associations had mandated stricter standards for the protection Intellectual Property Rights. The agreement required the member nations to comply with its provisions by 2000, 2005, 2016 depending upon their level of development. The TRIPS agreement requires granting of product patents and drugs and medicines are not exempted from this while prior to this agreement coming into force countries like India used to grant only process patents.

It has created a divide between the promoters of Intellectual Property Rights on one hand and various public health activists and patients on the other. The Intellectual Property Rights advocates are of the opinion that granting of patent protection to drugs is essential and fundamental for encouraging investment in research and development and other related activities. The Patent Protection System provides for exclusive monopoly and ownership rights to the patent holder to market the drug and recover the high expenditure and costs incurred by them in discovery of the drug, research and development activities, manufacturing the drug, marketing and promotion or advertising the drug through the sale of the drugs. On the other hand, various public health activists and supporters and patients are of the view that granting of patents rights especially to vital and essential drugs would confer the patent holder with monopoly rights to manufacture and market the drug and prevent other generic pharmaceutical companies from manufacturing and marketing the same. This would lead to serious inhibition of competition in the market for these drugs which would correspondingly result in high prices of these drugs and less access to majority of population who are poor and cannot afford the drugs. For example 150 mg of the HIV drug fluconazole would cost $55 in India where it has not been given patent protection as against $697 in Malaysia, $703 in Indonesia, and $817 in the Philippines where it enjoys patent protection.[v]

The Doha WTO Ministerial Conference adopted on 14 November, 2001 recognized the significance of public health problems affecting many developing and least developed countries especially those resulting from HIV/AIDS, malaria, tuberculosis and other epidemics. It stressed the need for the TRIPS Agreement to be part of the wider national and international action to solve these issues. It acknowledged that fact that Intellectual Property Protection is crucial for the growth of new medicines and also recognized the concerns about its effects on prices. The declaration agreed that the TRIPS Agreement does not and should not thwart signatory nations from adopting measures to protect public health. Consequently, while reiterating its commitment to the TRIPS Agreement, it confirmed that the Agreement could and should be

construed and executed in a manner which would be compassionate towards the WTO members' right to safeguard public health and in particular to encourage access medicines for all.[vi]

The declaration provided for certain flexibilities that the member nations could adopt while maintaining their commitment towards the TRIPS agreement. The flexibilities included right to employ certain pro-competitive methods, notably compulsory licenses and parallel imports, as required to improve access to health care in the developing and least developed nations.

COMPULSORY LICENSING PROVISIONS

As per Section 84[vii]any person, regardless of whether he is the holder of the license of that Patent, can apply to the Controller General for grant of compulsory license on expiry of three years, when any of the following conditions is fulfilled –

1. The reasonable requirements of the public with respect to the patented invention have not been fulfilled
2. The patented innovation is not accessible to the public at a reasonable price.
3. The patented invention is not functioned in the territory of India.

Further, compulsory licenses can also be issued suomotu by the Controller under section 92 of Indian Patent Act 1970, pursuant to a notification issued by the Central Government if there is either a "national emergency" or "extreme urgency" or in cases of "public non-commercial use".

The provision of compulsory licensing also dealt under Article 31 of the TRIPS Agreement. Compulsory licensing is a provision whereby the government authority of a particular nation is authorized to license the exploitation of a patented invention to a government agency or a third party without the express approval of the patent holder. There exist certain requirements that need to be satisfied in order to get a compulsory license. Prior to getting such a license, the person or authority who requires such license should have taken pains to obtain permission from the patent holder on realistic commercial conditions and terms. In case the efforts made did not lead to positive and favorable results within a reasonable period of time then the proposed person or authority could ask for a compulsory license. Nevertheless, in conditions of national emergency or other situations of severe exigency or in cases of public non-commercial usage, such prerequisites could be done away with. Notwithstanding all this the patent holder is compensated with sufficient royalty after taking into consideration the economic value of the permission.[viii]

The provision of Parallel Imports authorizes the import of the patented products from the market of a nation, where the patent-holder has put up the invention for sale. The TRIPS agreement under its provision contained under Article 6 protects the practice of Parallel import from any challenge under the WTO dispute settlement mechanism. In addition to this, each of the signatory nations of WTO is open to institute its own system for such exhaustion without it being to test. The method of parallel imports is useful for those nations who are economically poor and have inadequate infrastructural facilities to manufacture these inventions.

In response to the question should medicines and drugs be kept out of patent regime, it is strongly felt that certain very vital lifesaving drugs should not be granted patent, as health of people should be given a priority over individuals economic interest as the patent holder enjoys monopoly rights over the patented invention. Other nonlife saving drugs could be granted

patent as only that would spur innovation and investment in research and development of these drugs. As the TRIPS Agreement provides for patent protection to all drugs and medicines, certain measures are recommended whereby the interest of both the patent holder and the poor masses could be protected, even though health of the masses should remain the priority consideration.

The patent protection regime with regard to drugs and medicines should be adopted only when the nations become economically developed, for instance among the key drug manufacturing countries, United Kingdom had initiated drug product patent protection only in 1949, France in 1960, Germany in 1968, Japan in 1976, and Switzerland in 1977.[ix]Thus, it won't be ethically and morally right on part of the developed countries to seek the developing and least developed nations to enforce stricter patent protection regime when they themselves did not do so at their corresponding stage of development, and enjoyed the privileges of not granting patent protection. Hence the TRIPS Agreement should relax its provisions for the underdeveloped countries and allow these countries more time to implement these policies.

India's first ever compulsory license was granted by the Patent Office on March 9, 2012, to NatcoPharma for the generic production of Bayer Corporation's Nexavar, a lifesaving medicine used for treating Liver and Kidney Cancer. Bayers sold this drug at exorbitant rates, with one month's worth of dosage costing around Rs 2.8 Lakh. NatcoPharma offered to sell it around for Rs 9000, making it affordable for people belonging to every stratum. All the 3 conditions of section 84 were fulfilled and the decision was taken for the benefit of general public.[x]

The pharmaceutical industries manufacture and market a wide range of drugs and medicines and patent protection is granted to the majority of them. The patent granted for drugs that is used for curing diseases HIV/AIDS and Cancer should not be given the same importance as the drug or medicine used to cure common cold. It is reasonable and logical to grant 20 years patent protection to ordinary drugs however, the health consideration of the masses needs to be looked into while applying the same protection to essential lifesaving drugs. The TRIPS Agreement should provide for a proper meaning and description of what would constitute a "Lifesaving or vital drug" not by merely providing a list of diseases but by adding a description which distinguishes between lifesaving and non-life saving drugs. Few factors that could be looked into while making the distinction are: the dangerous and risky nature of the disease which the drug is intended to cure, accessibility of the substitute drug and the patent holders ability to sufficiently provide for the market that needs the drug or medication. Two different set of patent protection regimes should be adopted, one for the lifesaving drugs and other for the non-life saving drugs which would imply not granting patent protection to the former while granting patents to the latter. By adopting this measure a balance could be made between the Intellectual Property Rights of the individuals' i.e. pharmaceutical companies and basic fundamental right to health and access to essential medication of the

SUGGESTIONS AND CONCLUSIONS

The provisions of compulsory licensing and parallel imports should be made mandatory by authorized government of each underdeveloped country and needs to be incorporated in their domestic legislation dealing with patent protection and implemented with immediate effect rather than construing these provisions as a mere option which may or may not be

implemented by these countries. Only five nations in the world have adopted these provisions in their domestic legislation[xi]. Rest of the nations should also follow their example. Compulsory licensing and parallel import of vital and lifesaving drugs would help in protecting the health and also provide access to these drugs to majority of masses who are poor in the underdeveloped countries. The right of Patent holder is also protected as adequate compensation is given to the patent holder when license is acquired.

There are two kinds of patents which are usually granted to the inventor, i.e. process patents and product patents. Process patent are granted to the way or procedure which is used to create an invention. On the other hand product patent is granted to the invention itself. The patent holder gets comparatively lesser protection with a process as compared to a product patent. Process patent is basically non-existent under the TRIPS agreement which needs to be amended in order to promote public health across the globe. The process patents rather than the product patent should be given with regard to essential drugs and medicines as it would provide necessary protection to the patent holder stimulating research and development and also allow other pharmaceutical companies to reverse engineer the drug and find an alternative process to manufacture the drug. This suggestion would attract lot of criticism from the supporters of Intellectual Property Rights as it reduces the investment in research and development, therefore some limitations could be placed on the second producer of the drug in marketing the drug in the place where the original manufacturing company of the drug has a sizable market interest. This would be a good incentive to manufacture a drug at the same time health of the patients could be protected as drugs could be available at a cheaper price.
Other suggestions to maximize the access to essential drugs and medication would be by make statutory provisions to control the prices of the drugs, the period of patent granted could be reduced from 20 years and by adopting stricter standards while granting patents to drugs for example in the Novartis case, where stricter standards were adopted to prevent ever greening of patent as the cancer drug was refused patent.
Thus a balanced approach needs to be adopted protecting the interests of the patent holder as well as health of the masses. Developed and developing countries should work together to develop an international pharmaceutical patent system that truly promotes global public health by providing equal access to all.

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