Right to Health and Patent Regime in India

Abstract

Implementation of TRIPS flexibilities is vital if a country is to achieve the objective and abide by the principles outlined in the TRIPS agreement. Only few developing countries have implemented TRIPS flexibilities. This is due to a variety of reasons i.e. lack of awareness or understanding about the available flexibilities, lack of legal expertise on IP related issues in government departments, inappropriate or inadequate laws on TRIPS flexibilities and finally pressure from developed country governments and the industry in particular the large multinational Pharmaceutical industries to not use these flexibilities.

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Introduction

> "Health is one of the goods of life to which man has a right; whenever this concept prevails the logical sequence is to make all measures for the protection and restoration of health to all, free of charge; medicine like education is then no longer a trade- it becomes a public function of the state"
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> - Henry Sigerist

At first glance, it might seem misplaced to speak of health as a right when ever increasing segments of the world's population are witnessing a steady degradation in the state of their health, to the point where their very existence is threatened. Over the last decade, public health and development issues have become topics of great international concern. Public health in many parts of the world has reached crisis level: over 14 million people are killed by infectious diseases each year and 90% of it are from developing countries; more than 40 million people globally are infected with HIV/AIDS and 90% of it are from developing countries. The more alarming is the fact that while most illnesses specially infectious diseases are preventable or treatable with existing medicines, the WHO estimates the over 1.7 billion people nearly one third of world's population have inadequate or no access to these essential medicines. [1] Another study recently found that 10 million children in a year die from preventable diseases and conditions, with almost all these deaths occurring in poor nations. [2]

Right to Health

The right to life is a fundamental human right, and the exercise of this right is essential for the exercise of all other human rights. In essence, the fundamental right to life includes not only the right of every human being not to deprive of his life arbitrarily, but also the right that he will not be prevented from having access to the condition that guarantee a dignified existence. States have the obligation to guarantee the creation of the conditions required in order that violation of this basic right does not occur.

Health and health care is now being viewed very much within the rights perspective and this is reflected in the Article 12 "The right to the highest attainable standard of health" of the International Covenant on Economic, Social and Cultural Rights to which India has acceded. According to the General Comment 14 the Committee for Economic, Social and Cultural Rights states that the right to health requires availability, accessibility, acceptability and quality with regard to both health care and underlying preconditions of health. The committee interprets the right to health, as defined in Article 12.1, as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health.

Article 21 of the Indian Constitution guarantees protection of life and personal liberty by providing that no person shall be deprived of his life or personal liberty except according to the procedure established by law. As a result of liberal interpretation of the world 'life' and 'liberty' Article 21 has now come to invoked almost as a residuary right. Public interest petitions have been found on this provision against health hazards from harmful drugs; for redress hazards from harmful drugs;

hazards from harmful drugs; for redress against failure to provide immediate medical aid to injured persons; scores of other aspect which make life meaningful andnot a mere vegetative existence. The Supreme Court of India by imposing a positive obligation upon the state has held that the right to live with human dignity enshrined in Article 21derives its life and breath from the Directive Principles of State Policy particularly Articles 39(e) & (f), 41 and 42 and would therefore include protection of health as envisaged in the directives.[3]

Right to Health & Patent Regime in India

The patents are the ultimate beneficiaries of the pharmaceutical research and developments. By denying product patents India will be able to encourage bulk generic drug production at cheap prices. However, generic drugs are not the only solution to counter the problem of access to medicines. It will not necessarily result in the innovation of new and more effective drugs and not only acknowledging innovation India will run the risk of not having access to future medicines which will in turn affect public health. Denying patents and allowing the generic companies to freely copy the new drug cannot be the solution to deliver medication to the too poor to buy them, be in rural or urban India.

The actual problem lies in the fact that the product patents not only increase the cost of the drugs and medicines but that most of them fail to introduce research and development in the neglected diseases. Lack of accesses to affordable medicines was the reason for the vast majority of deaths that took place due to HIV/AIDS in the developing countries. Hence while on one side the introduction of product patents will help in development of new or more effective drugs the problem still remains that the research and development undertaken by the drug manufactures evade the neglected disease and the diseases which are region specific such as medicines for malaria and tuberculosis which are found prevailing in developing countries like India.

The New Patent Regime

The Patent (Amendment) Act, 2005 Section 2(a) defines 'pharmaceutical substance' as 'any new entity involving one or more inventive steps'. This has alarmed that anti product patents activities as they claim it must read as 'any new chemical/molecule entity' to restrict the scope of patent protection. It enables applicants to take advantage of this definition and claim entities which are not in true sense new chemical entities but even for formulations.

The Patent (Amendment) Act, 2005 section 11A (proviso 3 to sub section 7) protects the interest of generic producers whose business interests may be affected in the patent regime. The provision states that;

"Provided also that after a patent is generated in respect of applications made under sub section (2) of section 5, the patent holders shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concern product prior to the 1st day of January 2005 and which continues to manufacture the product covered by the patent on the date of grant of patent and non infringement proceedings shall be instituted against such enterprises".

'Reasonable Royalty' has not been defined in the provision. Neither has 'Significant Investment'. This has led to many commentators criticizing the provisions. The amended enactment allow the pre grant oppositions to patents vide section 25(1). This has been used a number of times in the pharmacy industry. Generally, existing Indian pharmas challenge application of foreign firms. e.g. [4]

1. Ranbaxy has filed for pre-grant opposition against Pfizer's anti fungal drug Voriconazole; and
2. Hetero has successfully opposed Wockhardt's patent application on anti-bacterial drug Nadifloxacin.

After India introduced patent regime for drugs, there has been an explosion of opposition proceedings. There are other provisions like post grant oppositions [5] and counter claim for invalidity before any infringement case. The use of a patented invention will not be infringement if it is for the purpose of development and submission of information to the Regulating Authority in India or abroad for the grant of marketing approval for the patented invention.[6]

Developing Countries and Access to Medicines for Poor

Among many issues dealt with by the amendments to the Patent Act required by the agreement on Trade related Aspects of Intellectual Property Rights (TRIPS), one of the most debated questions has been their impact in the health sector and more specifically on access to medicines. We have to look back since 1970.

The law adopted then drastically restricted the right of holders of medical patents to faster the availability of cheaper medicines. The patent legislations together with other measures such as price control has had significant positive impacts. Medicine prices have, for instance, decreased significantly since the 1960s compared internationally. Further, there is now a vibrant local generic pharmaceutical industry. While discussing the post 2005 healthcare scenario, one of the major concerns is the issue of the impact of the emerging product patent on drug prices in India and other developing countries, which did not permit patenting of drugs per se under their earlier legislations. The general impression is that drugs which are under patents are expensive compared to generic products and since the product patent regime is in place, they are unaffordable to the majority of countries of the developing world and as a consequence their health care status is seriously affected. High price of patented drugs affect not only the patients in developing countries, but also in the developed world.

Access to medicines, especially in developing countries and least developed countries, is a real and growing concern. Many medicines that could save or extend lives are unavailable, inaccessible or unaffordable to those who need them most. There is a pressing need for measures to ensure access to existing medicines and the development of new medicines that effectively address the global disease burden.

The TRIPS agreements has to a large extent harmonized the standard for patents; notably, it makes it mandatory for countries to ensure that patents protection is available in all fields of technology, for both process and product inventions. Thus, it is no longer possible for countries to exempt Pharmaceuticals from patent protection as a number of countries did before TRIPS came into force.

HIV/AIDS alone have caused death of about 3 million people in 2002, including 60000 children. Around 5 million new patients were victimized by it. Around 95% of the 42 millions AIDS victims are the people living in developing countries. Only 3 lakh of 60 lakh advance stage patient of HIV have access to life saving medicines in the third world countries. These figures and facts are clearly indicating the adverse effect to TRIPS provisions in the form of restrictions on access to essential medicines to the poor people and diminishing possibilities of introduction of new drugs for their diseases.

Role of WTO

In the wake of Doha Declaration on the TRIPS agreement and public health, the role of WHO in ensuring that intellectual property rights do not undermine the public health objectives came to force. Though WHO resolution mentioning IP and its potentially negative consequences date further back, the Doha Declaration had a catalytic effect in the WHO. Consequently, in its resolution on ensuring the accessibility of essential medicines in May 2002, the World Health Assembly welcomed the Doha declaration and urged WHO Member States "to continue monitoring the implications on access to medicines of recent patent protection laws and compliance with WTO's agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)." [7] This was followed in the succeeding years with intensified discussions culminating in the adoption, in May 2008, of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights. [8]

Conclusions

In developing countries, the TRIPS agreements have exacerbated conflicts between private corporate interests and the public interest including public health. The controversy over access to medicines has highlighted just one aspect of the imbalance within TRIPS agreements which is too heavily titled in favour of private right holders and against the public interest. There is growing evidences of social and economic problems caused by the introduction and enforcement of stricter intellectual property rights which developing countries are obliged to implement as a part of their obligations under TRIPS. This has resulted in calls for a re assessment of the Agreement itself. Implementation of TRIPS flexibilities is vital if a country is to achieve the objectives and abide by the principles outlined in the TRIPS agreement. Only few developing countries have implemented TRIPS flexibilities.

With regards to access to drugs, there have been substantive debates about the impact of the change in India's patent regime. It is argued that the adoption of the 'process patent' standard will impede the capacity of Indian Pharmaceutical firms to replicate life saving drugs in a cost effective manner. It must be remembered that the changes in the patent regime were necessary to give Indian Pharmaceutical firms access to foreign market as well as the entry of foreign firms in the Indian Market i.e. an environment of open competition, it is the consumer who benefits from wider choice and better pricing.

New patent regime is a fairly balanced law. It is also a reflection of the confidence of Indian drug companies which are going global and so long the process of developing new product through their in-house R & D. Indian Pharmaceutical industry is among the most globally competitive industries that we have today with over one-third of its output being exported. It is in our interest to have a modern patent regime in line with what most countries have already adopted.

References

1. WHO, The World Medicine Situation 61 (2004) availableathttp://www.searo.who.int/LinkFiles/Report_World_Mediciens_Situation.pdf
2. Robert E. Black, where and why are 10 million children dying every year?, 361 The Lancet 2226 (2003)
3. State of Punjab v. Makinder Singh Chawala, AIR 1997 SC 1225
4. Muralidharan, R, Indian Patent Regim & Its Impact on Generic Industry, Krishna & Saurastri Associates (12 June 2007)
5. The Patent (Amendment) Act, 2005, Section 25(2)
6. Ibid, Section 107A (a)
7. Resolution WHA55.14 of 18 May 2002, available athttp://ftp.who.int/gb/archive/pdfjiles/WHA55/ewha5514.pdf
8. Resolution WHA61.21 of 24 May 2008, availableathttp://www.who.int/gb/ebwha/pdfjiles/A61/A61_R21-en.pdf.