Patents and Public health- Price of health and Cost of Monopoly

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Introduction:

The World Trade Organization's decision of August 30, 2003 on the implementation of Paragraph 6 of the Doha Declaration on the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public health was intended to facilitate access to medicines in developing countries. The decision, which was the outcome of nearly two years of strenuous multilateral negotiations, was widely reported in the international press and professional journals. Despite all this attention, the decision has still not been used to bring affordable, life-saving medicines to countries that, judging by severity of their public health challenges, need them desperately. This is an extraordinary fact and one worthy of further enquiry.

At the face of it, Health and Monopoly do not seem to have a copula. Health and Service is more imploring in terms of both meaning and palpability. Affluent societies spend vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life.

The intersection of the Law of Patents- an arcane discipline and the International trade regime, both in its legal rules and in the practical conduct of state-to-state cooperation, need recognition of inherent complexity.

Pharmaceutical products and processes account for a significant part of patents applied for and granted worldwide. As patents confer exclusive rights and lead to increased price of such products, they are of particular concern in developing countries. The adoption of the TRIPS Agreement represented a resounding victory for the international pharmaceutical industry, as it included an obligation to provide patent protection for pharmaceutical products. However, the Agreement did not include specific rules on all aspects relating to the grant of patents.[1] The determination of how the patentability criteria are applied, the form and breadth of claims and the extent of disclosure are some of the core flexibilities available under the Agreement.

The Indian Regime:

Getting into the history of Patent Law in India would not serve the object of this paper. Only the current rules and regulations are the ones which matter. The modern patent system is the outcome of industrial revolution, technological advances, and the international trading system. These aspects led to the setting of new standards through the Agreement on Trade Related Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) in 1995. Most of the member countries including India had to modify their laws relating to patents to comply with the TRIPs obligations. Under these obligations it imposes on the member countries to recognize and strengthen patent protection on pharmaceuticals.[2] The absence of patent protection on pharmaceuticals was regarded necessary in many of the developing countries to promote access to drugs at competitive prices. Therefore, conforming to the TRIPs accoutrements to recognize and strengthen the patent protection on pharmaceutical products and processes causes a hurdle for the developing countries like India. Thus, the implementation of TRIPs led to high drug prices, low access and a weakening national pharmaceutical industry regime. What more than this could be able to affect the Public Health?

Predator Patents v. Poor Patients:

"Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, the drug manufacture has become a powerful industry. My idea of a better ordered world is one in

which medical discoveries would be free of patents and there would be no profiteering from life or death."[3]
The undoubted right to health assured to the Public in the Constitution of the World Health Organization (WHO), brings with it a right to have access to the essential drugs regardless of one's economic position. However, presently in India, even the basic medicines are not within the reach for a greater population. The price is a major obstacle for access to many essential medicines and is far beyond the reach of individuals or even the government. This in turn results in increased ill health and deaths on a large scale.
At a stage where technology has a potential of contributing to human welfare, and also has become the most pronominal determinant of competition in global market, it is very disturbing that the monopoly rights of the inventors of such crucial drugs are being strengthened.
Public health in developed countries is being transformed by breathtaking medical achievements. The major breakthroughs in the detection and treatment of diseases are increasing the probable life span and reducing vulnerability to sickness. But over the course of next year, around 11 million people, most of them in developing and least developing countries, will die from preventable and curable diseases. This is equal to around 30,000 deaths each day.[4] The vast majority of which will be poor; and many millions more will suffer protracted bouts of sickness and disability, with devastating impact on levels of poverty and vulnerability. The health gap between rich and poor countries is reinforcing wider inequalities in income and opportunity, and undermining efforts to meet internationally agreed human development targets.
Under the WTO's IP regime, all the member countries are required to provide exclusive marketing rights to holders of patents on pharmaceutical products for a period of at least twenty years.[5] By restricting the right of governments to allow the production, marketing and import of low-cost copies of patented medicines, also called as 'generic drugs', the WTO's rules restrict competition, increase prices, and reduce the already limited access of the poor to vital medicines.

Pipeline threats: Implications for treatment of drug resistant diseases

Most of the drugs that will come on stream as the new WTO rules are implemented have been developed with a view to patenting and marketing in rich countries. This has created unwarranted complacency about the implications of TRIPS for developing countries. In reality, many of the new anti-bacterial drugs now being developed could bring enormous benefits to poorer countries, provided that they are delivered on affordable terms. This is especially true with respect to the treatment of drug-resistant strains. Drug-resistance poses an enormous threat to poor communities across the developing world. It means that illness is less susceptible to treatment, and that the costs of treatment increase- in some cases dramatically. The danger is that, in the absence of competition from generic-drugs producers, new patented drugs will be placed far beyond the means of the poor. Examples of drug resistance include:

- Pneumonia (3.5 million deaths annually)

Formerly effective front-line medications used to combat pneumonia and other respiratory tract infections now fail in the treatment of over 70 percent of chest infections, according to a WHO study. Trials for several drugs potentially effective against resistant forms of pneumonia are now in an advanced stage. These drugs, which will be patented, include faropenem(Bayer) and levaquine (RW Johnson).One of the most promising drugs in this area is Ketek, the first in a new generation of antibiotics which is proving highly effective against pneumonia and influenza. Aventis is expected to launch the patented version of the drug in 2001.Restrictions

on the development of generic versions will place it beyond the means of most sufferers in poor countries.[6]

- Diarrhea (2.2 million deaths annually)

Shigella is a highly virulent microbe responsible for half of all episodes of bloody diarrhea in young children. It is directly responsible for an estimated 375,000 child deaths. In the past, many deaths from diarrhea could be easily controlled with cheap generic drugs such as co-trimoxazoleorampicillin. However, resistance to these drugs is now very common (in over three-quarters of all cases in Tanzania, for example).Ciprofloxacin is one of the most effective of these drugs. The patented version is marketed by Bayer in Pakistan and in South Africa (where the patent has been filed) at prices respectively eight and twelve times higher than the generic version in India. Restrictions on the availability of generic ciprofloxacin resulting from more stringent patent rules would have grave public-health consequences. Several drugs relevant to the treatment of diarrhea are now on trial.

- Malaria (1.1 million deaths annually)

Resistance to the lowest-cost front-line treatment, chloroquine, is now widespread in over 70 countries where the disease is a major killer, and resistance to sulfadoxine /pyrimethamine is growing. GSK's Malarone has proved 98 per cent effective in the treatment of drug-resistant malaria. However, it is too expensive for most patients. Competition from generic producers is not permitted due to its patented status.

- Gonorrhea (62 million new cases annually)

The development of anti-microbial resistance in gonorrhea has been described by the WHO as 'One of the major health care disasters of the 20th Century'. It has made gonorrhea a driving force in the HIV/AIDS epidemic. Effective treatment is available in the form of ciprofloxacin and ceftriaxone (patented by Roche). However, the costs of effective treatment are relatively high. As with all sexually transmitted infection, women are particularly susceptible, with untreated gonorrhea greatly enhancing the risk of HIV/AIDS infection, infertility, and miscarriages. There are other examples of the potential costs which may be associated with patenting. Drugs on trial for the treatment of hepatitis (such as Entecavir, produced by Bristol-Myers Squibb) and viral meningitis, along with other anti-infective drugs and vaccines, offer potential benefits for developing countries, even though they have been developed with the US market in mind. But these benefits will be lost if prices in developing countries reflect the
application of strict patent protection.[7]

The application of strengthened patent rules to medical products is already causing serious problems, notably in relation to the treatment of HIV/AIDS. Patented versions of anti-retroviral therapies which are used to keep HIV in check, and other drugs effective against diseases which accompany HIV and cause opportunistic infections, typically cost between 3 and 15 times as much as their generic equivalents. [8]However, this problem extends beyond HIV as well. Prices for non-patented or generic versions of antibiotics used to treat major childhood killers such as diarrhea and chest infections are often marketed at prices less than $1/8^{th}$ of those for equivalent patented products.[9] But, the next generation of medicines which could be used to combat these and other infectious diseases will be, if the existing WTO rules persist, marketed in developing countries at prices which reflect the monopolistic pricing opportunities provided through patents. WTO rules provide limited public health safeguards, especially in the case of national health emergencies. These are hedged in by onerous conditions and, in practice; efforts to apply these measures have been fiercely contested by pharmaceutical companies.

The affordability of medicines is only one of the problems facing poor countries. Inadequate and inequitable public spending on health infrastructure, weak planning, failure to prioritize preventive interventions and ineffective service provision are also contributory factors. But

the price of basic medicines is a vital factor in determining public health. The price of medicines is a critical issue in rich countries as well as in poor. In Britain and the United States, the budget implications of escalating drug prices are a matter of mounting political concern. But it is the poor countries, where budget resources are more limited, and where household poverty is most widespread, that face the gravest threat from rising drug prices.[10]

The rule reforms:

It is a truism that patents often cause price rises. A variety of tools exist to regulate such price rises and ensure affordable access to consumers, particularly in the context of drug patents and developing countries. Indeed most such measures revolve around ex-post regulatory mechanisms such as compulsory licensing that help limit the impact of patents and in the process promote public health goals. To evaluate the patent and public health interface from the point of view of ex-ante mechanisms i.e. ways in which countries have sought to limit the grant of patents to certain categories of subject matter in a bid to promote access to public health goods.

The TRIPS Agreement establishes minimum standards for intellectual property protection, including the right to exclusively market patented product for at least 20 years. Some Northern Governments are using bilateral and regional trade agreements to negotiate even more stringent protection for patents under so-called TRIPS 'plus' agreements.[11]

WTO rules recognize the potential conflict between public health interests and the private interest of patent holders. Under Article 31 of the Agreement, governments can issue compulsory licenses to authorize production without the consent of patent holders, subject to adequate compensation.[12] Another measure open to governments is that of parallel importing, whereby governments allow the importation of a patented product which is marketed elsewhere at prices lower than those in domestic market. These safeguards should be strengthened. There is a need to clarify and broaden the criterion or introducing compulsory licenses, and to diminish the burden of proof currently placed on Governments seeking to establish Public health threats as grounds for compulsory licensing. In the event of a dispute, patent holders should be required to prove that there is no threat to public health from the strict application of their patent privileges. Even with less onerous conditions for compulsory licensing, countries with limited production capacity or small internal markets will find it impossible to obtain the required drug at an affordable price, unless there is a larger country which is producing it under a compulsory license and which is willing and able to export it to them.

The important steps to be taken to address the issue include the following:

- Change trade rules to cut the cost of vital medicines
- End Rich-country bullying in negotiations on patents
- Invest in research fund for diseases of the poor
- Pharmaceutical giants should cut the costs of key medicines to developing countries and balance health and patent claims in poor countries
- Assess the impact of stronger patents on poor people
- Establishment of an International fund to subsidize drug purchases and delivery systems in the poorest countries.

Patent rights are becoming ever more complicated and comprehensive and the winners in the system of global ownership will be those with the sources to play the game. It is very difficult to see how the world's poorer countries will be amongst them. This is fundamental and it

carries real risks for the future. 'Evergreening' results in infinite monopoly or a lifetime of artificially high-priced medicines, as only one manufacturer is allowed to supply the drug in the market during the existence of patent right.
Pharmaceutical companies have instigated a well-funded and well-organized campaign to block generics from entering the market place and that is not good for competition. The argument here is not against Patents, but against Monopoly. If the drug companies really mean business, they should waive their patent rights and let developing countries make the drugs themselves under their supervision.

Conclusion:

Although this area is couched in science, medicine, economics or law, it should not be forgotten that there is an underlying moral issue. For the poor, the drugs are an unaffordable luxury, sickness is a fear and it means falling into debt to try and afford the price of health and the cost of monopoly. The potential benefits of International Cooperation to control infectious diseases are enormous. For the poor communities currently bearing the brunt of global disease burden, the benefits are self-evident. Apart from reducing suffering, improved health is a pre-condition for achieving more sustainable livelihoods and greater prosperity. But the benefits extend beyond households. Reducing avoidable death, enhancing prospects for child survival and improving the quality of life for the poor is a moral imperative for all people. It is also a matter of shared interests. Infectious diseases do not respect national borders and none of us is immune to the consequences of the poverty associated with the widespread sickness.

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