Global Public Health and Intellectual Property

Intellectual Property Regime and Developing Country Health Concerns

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Intellectual property, especially patents, are considered to be incentives for innovation and thereby expected to benefit society by making the products of innovation available to the society. However, the developing country experience shows that such incentives focus on the market demand rather than the need of the society and this is more conspicuous in the health related innovation. This prompts one to think about alternatives to intellectual property based incentives in addressing the health concerns of developing countries.

Keywords: Intellectual property, innovation, public health, developing countries

Intellectual property rights, especially patents, is said to have considerable significance in incentivizing innovation in the pharmaceutical sector than in any other sector. The recent developments in biotechnology, bioinformatics, genomics, nanotechnology etc., along with a strong intellectual property protection internationally, ensured by the TRIPS Agreement, have rejuvenated pharmaceutical R&D. In spite of these technological abilities to provide access to lifesaving medicines, millions of people suffer and die in developing countries simply because such means are neither available nor accessible to them.

Commission of Intellectual Property Rights, Innovation and Public Health, an independent commission entrusted by the WHO with the task of studying the key issue of the relationship between intellectual property rights (IPR), innovation and public health, decries this situation as morally unjustifiable. Access to essential medicines is a decisive factor in ensuring the human right to ‘the highest attainable standard of health’. Right to health is a universal and inalienable right and it should take precedence over commercial interests and it is the duty of governments to ensure universal health coverage. There is a moral as well as legal imperative to share the benefits of innovation in the field of medicines and pharmaceuticals globally. However, it is quite disturbing that this requirement is never satisfied. Neither the benefits of such innovations reach the poor masses in both developed and developing countries, nor is there enough research, development and innovation in relation to diseases which disproportionately affect developing countries. Paradoxically, intellectual property rights are, directly or indirectly, responsible for this unfortunate outcome.

Pharmaceutical and biotech industries were among the major players in the international intellectual property norm setting which led to the TRIPS Agreement. No wonder Section 5 of the TRIPS Agreement, dealing with patents, is fraught with elements which support the interests of these industries. This is evident from the changes mandated in the domestic patent laws of WTO member countries by Article 27 of the TRIPS Agreement. Therefore, in the context of developing country health concerns, it is pertinent to examine the relevance of two major justifications for patent protection, namely, incentivizing innovation addressing actual health needs and facilitating access to the products of such innovation to the general public: How far patent rights promote access to the new pharmaceutical products to the needy? And how far they are incentivizing innovation to cater to the developing country health needs?

Patents and the Developing Country Health Concerns

The major public health concerns of developing countries are manifold: Lack of affordable access to the existing preventive, diagnostic and curative pharmaceutical products; insufficient research and development addressing the special health needs of developing countries; and absence of technology transfer and capacity building enabling developing countries to become self-sufficient in areas of drug

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discovery, development and delivery. In the context of globalization of IPR norms, it is pertinent to examine its significance with reference to all these aspects.

**Intellectual Property Rights and Affordable Access to Existing Pharmaceutical Products**

Globalization of IPR brought in a number of additional burdens on developing countries in relation to providing universal access to public health. The changes required to be made in the domestic patent law of WTO Member countries by the TRIPS Agreement have taken away the freedom enjoyed by those countries prior to the formation of WTO in designing their patent laws to serve domestic needs, especially the health needs. Thus many countries were either excluding inventions in certain crucial areas of public interest like the pharmaceutical sector from the scope of patent protection or extending differential treatment to inventions from such areas by limiting protection to innovative processes alone and not to products, or by fixing a lesser term of protection. These differential treatments to pharmaceutical inventions encouraged competition and facilitated infrastructure building in developing countries. Such freedom also helped to considerably enhance affordability of pharmaceutical products to wider strata of people belonging to developed as well as developing countries. India is a good example of this. Apart from building a strong infrastructure in domestic pharmaceutical sector, this policy helped the country to supply generic medicines to other developed as well as developing countries. However, by 2005 India shifted to the product patent regime and may now lose the status of ‘pharmacy’ of the developing world. By 2016 TRIPS will harmonize internationally pharmaceutical patenting and thereafter generic manufacturing and the consequential competition will be totally absent unless measures like fixing of high standards of patentability or invoking compulsory licensing provisions etc., are resorted to by the countries having manufacturing abilities.

The latest trend in pharmaceutical research is to concentrate more on incremental innovation, improvements or derivatives, rather than on inventing new molecular entities or other breakthrough research products. This has resulted in lowering of patentability standards and patent evergreening. This trend has negative implications on public health as it unjustifiably protects public domain subject matter or extends the period of monopoly protection beyond its legitimate term resulting in enhanced pricing of such products.

Moreover, irrespective of the fact that data exclusivity is not mandated under Article 39.3 of the TRIPS Agreement, the demand from the leading pharmaceutical companies and technology rich countries for test data protection often forces many developing countries to implement such protection. Data exclusivity prevents generic companies from using the clinical trials data submitted to regulatory authorities by the patented drug company for getting regulatory approval for the generic medicines that are bio-equivalents of the patented drugs. This unnecessary duplication of the efforts of getting regulatory approval by the generics is much against public interest as unnecessary clinical trials, which are costly, unethical and even harmful to human beings, force generic companies to wait until the period of exclusivity ends. In effect, data exclusivity creates a regulatory barrier for the approval and marketing of generic drugs thereby extending the monopoly period and avoiding competition. This will, in turn, result in high price of patented medicines making them unaffordable to the public. There are also attempts to link patents with regulatory approval and to block regulatory approval for those generic drugs which imitate patented drugs.6

All these indicate that the TRIPS regime stands for stronger private property rights and there is no equal attempt to balance patent protection with affordable access to patented products worldwide. Thus, the benefits and costs of globalization of intellectual property norms are unevenly distributed among the developed and developing countries. It is true that a considerable amount of flexibility is available under the TRIPS Agreement. But since the primary aim of the TRIPS Agreement is promotion of free trade in goods and services embodying IP and not promotion of innovation and public access to the products of innovation, its provisions, except the preamble and the objectives and principles, are not concerned about how strong IP protection mandated by it affects innovation or access to knowledge or other public goods such as public health. The entire TRIPS Agreement is built on the assumption that strong IP protection is good and necessary for innovation and technological advancement and lack of strong IP protection is barrier to free trade. It is, therefore, not concerned about creating a balanced IP regime. Despite the fact that the role of IP in economic and technological development is context sensitive and depends very much on the technological capacities
and the social and economic structure of specific countries, the trend reflected in the TRIPS Agreement, always, is to promote stronger IP protection by broadening private rights and narrowing domestic exceptions. TRIPS Council, while monitoring TRIPS compliance by Member countries, and the WTO dispute settlement mechanism, while enforcing TRIPS compliance, interpret the TRIPS Agreement in such a way as to encourage the view that what mattered more in TRIPS is private property rights and not the issue of how the developing countries could make better use of TRIPS flexibilities in designing their IP laws to suit their domestic developmental needs. This interpretation was also used while extending technical assistance as mandated by Article 67 of the TRIPS Agreement in the shape of model, ready-made IP laws, to developing countries by WTO and WIPO. Such laws paid scant attention to how TRIPS flexibilities could be made use of effectively addressing the public health needs of developing countries.

Thus, most often use of research, experimental or regulatory use exceptions, and limitations like compulsory licensing or other TRIPS flexibilities like parallel importing, which were meant to promote competition and thereby public interest, were often very restrictively interpreted. For example, in the Canada–Patent Protection of Pharmaceutical Products Case, the panel of the WTO Dispute Settlement Body interpreted Article 28 and 30 quite narrowly by outlawing stockpiling exception. The WTO panel disregarded the objectives and principles of the TRIPS Agreement and the third parties’ interests such as public health, and social and economic interests of the users of IP, in confining patent protection strictly to twenty years. It, by simply ratifying the developed country laws and refusing to go beyond them, failed to respect the freedom of member countries under the TRIPS regime to make full use of the available flexibilities.

As a result of this trend to strengthen monopoly rights in total disregard to the equally important access rights, the price of pharmaceutical products has gone up, both in developing and developed countries. Health insurance schemes available to the rich in developed countries might have reduced the burden of higher price of medicines in those countries, but the developing country people, who are destined to pay for the medicines out of their own pockets, had to bear the brunt of it. For example, in 1980s North America and Europe were suffering the most from the burden of death and disease due to AIDS. But by the mid 1990s their death rates started to fall dramatically, while the death toll from AIDS shot up in Africa. This was due to the magical effect of the invention that combinations of antiretroviral (ARV) medicines could effectively block replication of the virus within the human body. Once viral activity was suppressed, the damaged immune system could be restored. Immediate results were found among the patients suffering from AIDS after the treatment and AIDS-related illnesses and deaths declined dramatically in the West. However, deaths due to HIV/AIDS victims of Africa were only increasing since the treatment was unaffordable to the majority of HIV/AIDS patients. Despite the fact that deaths of these people were unnecessary and avoidable, they were doomed to die because the result of such medical advancements was beyond their reach.

This reveals the hollowness of the claim that society at large will be able to benefit from strict enforcement of patent protection. Where the majority of consumers of health products are poor, the monopoly costs associated with patents diminish the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices.

R&D on Neglected Diseases

In contrast to developed countries, developing countries are increasingly suffering from the double burden of disease because of the high rate of communicable, maternal, prenatal and nutritional diseases in those countries combined with injuries and increasing rate of non-communicable diseases. Though deaths from communicable diseases in developing countries are expected to fall 13% by 2015, the health situation remains bleak due to the apprehension that disease burden of non-communicable diseases in developing countries may be double the burden of communicable diseases by 2015. Thus, both communicable and non-communicable diseases pose severe health concerns to developing countries.

The Report of the Commission on Intellectual Property, Innovation, and Public Health, addresses the issue of availability of and affordable access to pharmaceutical products, including vaccines, diagnostic techniques and medical devices for Type II and Type III diseases and for addressing the special health needs of developing countries in relation to Type I diseases. The Commission has observed that
sufficient R&D initiatives addressing the challenges posed by Type II and Type III diseases to developing countries are not available despite the strong intellectual property protection available internationally as a result of the TRIPS mandate. In the case of Type I diseases, though pharmaceutical companies have a strong incentive to invest in the development of preventive, diagnostic and therapeutic tools for the developed country markets, the major challenges faced by developing countries are affordability and adaptability of such products to the resources and the social, economic and environmental conditions of developing countries. Developing countries, constituting 80% of the world’s population, are responsible only for about 10% of the global sales of pharmaceutical products (in terms of value not volume). This lack of effective market demand – not need – is the major reason behind the lack of effective R&D initiatives for developing new pharmaceutical products capable of addressing the health needs of developing countries. Pharmaceutical industry the world over considers investing in this field unprofitable and thereby unattractive. Where there is no purchasing power, either in the government or the patient – the market and the incentives such as patent protection, often fail to address health needs. Only less than 10 % of global health research is directed towards diseases that afflict 90 % of the world’s population. It shows that market demand rather than health need is the driving force behind patent based incentive model of innovation.

The response of Indian pharmaceutical companies is no way different from that of the Big Pharma. Though the pharmaceutical industry has achieved considerable growth in India (third largest in the world in terms of production volume behind the US and Japan) due to the process patent regime that existed in India until 2005, the industry has shown little interest in investing in pharmaceutical R&D targeting local health issues. This is because of two main reasons: the risk involved in investing in R&D and the quantum of investment needed; the great market potential of generic medicines available in the developed and developing world.

In brief, the patent based incentive model of R&D developed by technologically rich affluent countries is designed only to meet the market demand. Where there is no market it will not work. Such a model is quite insufficient to stimulate R&D for diseases that disproportionately affect developing country population. In other words, patents which are meant for incentivizing research, development and innovation cater to the needs of market demand rather than public health needs.

The market failure of patents in the developing countries has to be addressed by resorting to alternative models of innovation. Collaborative open models of research with public private partnership, if properly monitored, could be an alternative model provided the research costs are effectively delinked from the price of innovative products.

Intellectual Property, Transfer of Technology and Capacity Building

Another major problem faced by the developing countries in the post-TRIPS era is the inadequate technological and industrial infrastructure in the pharmaceutical sector. This lack of self-sufficiency forces them to rely on the developed countries and their innovation models for meeting the local/domestic public health needs. Prior to TRIPS, countries were free to design IP laws which catered to their public health needs. Using this freedom, countries could develop their patent laws so as not to hinder technological development and capacity building. However, the TRIPS Agreement has snatched away this freedom. The TRIPS Agreement has recognized in its very objectives the obligation on the developed countries to transfer technology in consideration of the developing countries’ enforcement of IPR. In addition, Article 66.2 of the TRIPS Agreement mandates developed country members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country members in order to enable them to create a sound and viable technological base, and the Doha Declaration on TRIPS Agreement and Public Health has reaffirmed it. However, Suerie Moon, in a study on the effectiveness of Article 66.2 in encouraging technology transfer to the least developed countries (LDC) based on an analysis of the country submissions to the TRIPS Council during 1999-2007, has identified that of the 292 programmes projected by the developed countries during this period, only 22% is technology transfer targeting LDC members of WTO and 29% including LDC non-members of WTO.

Therefore, in order to meet the twin objectives of ensuring access to existing medicines and to build R&D capacity required for addressing domestic health
needs, the developing countries need to device their own innovation model, along with concentrating more on improving their efficacy in each stage of drug discovery, development and delivery. Apart from improving research tools and platform technology, developing countries need to improve their regulatory framework and health delivery system.

Collaborative research is one method which could be used for capacity building in developing countries. But the attitude of the global pharmaceutical firms is to adopt measures which are not favourable to capacity building in developing countries. But it has its own problems. Abbot and Reichman have pointed out that the wealthy nations might not be inclined to promote the development of world-class pharmaceutical producers in poor countries, for fear of future competition with the existing originators.14 In other words, generally, a profit-making industry will not have the incentive to transfer a technology that will strengthen a competitor. This is evident from the phases in which the MNCs usually invest in developing countries. The Indian example shows that a large number of foreign R&D investment projects in India focus on developing facilities for phase III clinical trials and other such modules that only integrate Indian talent and facilities into foreign pharmaceutical firms’ global objectives.15 This type of foreign investment does not facilitate building pharmaceutical R&D capacity in India. Moreover, the post-TRIPS experience of India shows that foreign firms are investing much less on R&D as compared to domestic firms.15 Therefore, it is evident that the stronger patent protection imposed by the TRIPS Agreement has not induced foreign firms to invest in pharmaceutical R&D in developing countries. In general, post-TRIPS foreign R&D investment in the pharmaceutical sector in developing countries is on the decline.15 Whatever R&D activities the foreign pharmaceutical companies have in developing countries are on formulation drugs rather than on active pharmaceutical ingredients or on bulk drugs development.15

The Way Forward

In order to address the major health concerns of developing countries arising out of lack of affordable access of existing pharmaceutical products or absence of effective medicines due to lack of research, development and innovation to meet the developing country health needs or lack of technological skill, innovation capability, and infrastructural ability, the developing countries need to design an alternative model of research. It is evident that the innovation model designed and marketed by developed countries to promote economic and industrial development rather than health needs, will no way help the developing countries which have insufficient innovation system and very low purchasing power, to meet these glaring health problems. The patent based incentive model and the trade forum are totally insufficient to achieve the objective of universal health care in developing countries. Open collaborative research through public-private participation appears to be a good option provided it is based on the philosophy of delinking the cost of R&D from the price of the pharmaceutical product.16 But when it comes to the production and distribution stage, again there is a chance that market forces may resurface. The right model can be expected to evolve only after long experimentation process. In the case of already existing medicines, the WHO needs to take an active role in ensuring that health concerns are not overpowered by commercial concerns.

References

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3 WHO's Constitution and Article 12.1 and 15.1 (b) of International Covenant on Economic, Social and Cultural Rights (ICESCR).
7 Dr Surinder Singh said: ‘We are going to seek the list of the drugs from innovator companies that have received patent in India. Once we have the database of the drugs which have been granted patent, we will not give any marketing approval to their generic versions’. Fortunately, after the decision in Bayer Corporation and Anr v Union of India (UOI) and Ors, 2010 (43) PTC 12 (Del) the situation has changed.
The diseases are classified into Type I, Type II and type III by the Commission on Macroeconomics and Health (CMH), in its Report *Investing in Health for Economic Development*, Geneva, World Health Organization, 2001. Type I diseases like diabetes, cardiovascular diseases, tobacco-related illnesses, hepatitis B etc., are incident in both developed and developing countries and Type II diseases like HIV/AIDS, TB, Malaria etc., though incident in both rich and poor countries, a substantial proportion of cases occur in poor countries. But in the case of such diseases, the type or strain of the disease in developing countries may frequently differ from that in developed countries (e.g. different clades of HIV are common in developing countries, and the immune system may react differently to TB vaccines) so that solutions in developing countries may need to be different. Type III diseases – African sleeping sickness, African river blindness, chagas disease, etc. are overwhelmingly or exclusively incident in developing countries.

It is evident from the R&D initiatives on two tropical diseases: Leprosy and Malaria. Estimated market for Leprosy in India is smaller than the cost of developing a drug and therefore is not an interesting prospect for a private firm in the absence of public subsidies whereas Malaria treatments are considered profitable as it being rich man’s tropical disease.

Article 7 of the TRIPS Agreement reads: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.