Conflicting interests in drug pricing: Innovation vs social needs

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'An over two hundred and sixty-nine billion rupee industry in terms of turnover, an annual growth rate of 6.4% and an export surplus of one hundred and twenty-three billion, the Indian pharmaceutical industry never fails to raise eyebrows.'

Patenting of drugs has always provoked a strong and contrasting debate between those who champion social welfare and broad availability of drugs, and those who contend that it is crucial to provide incentives for innovation, especially considering the exorbitant costs and the time factors that are involved in drug research and development. Social welfare has always been a necessary consideration for every policy decision, especially in the context of any sort of drug monopoly being granted to a particular pharmaceutical company. While such considerations are indispensable, it is also necessary to realize that the pharmaceutical industry is under tremendous financial pressure from the shareholders and market forces.

Social welfare: An indispensable consideration

India had a product patent regime for all inventions. However, in 1970, the Indian Government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was initiated to undermine India's dependence on imports for bulk drugs and provide for development of a self-reliant, indigenous pharmaceutical industry[1]. The Patents Act of 1970 did not provide product patent protection for medicines and food; it provided only process patent protection to medicines and food.

This has however changed now, with the introduction of product patent protection for medicines and agro-chemicals as part of India's obligation under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The Indian Patents Act of 1970 was amended in 1999 and 2002 to make it TRIPS compliant, which necessitates member countries to provide a universal minimum standard of protection for various types of intellectual property rights.

The Doha Declaration affirms that TRIPS should be 'interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'[2]. India as a party to the International Covenant on Economic Social and Cultural Rights (ICESCR), has an international obligation to protect peoples' right to health[3]. Clearly, accessibility to and availability of drugs are recognized as important components of right to health.

The Supreme Court of India recognized the enforceability of right to health within the scope of Article 21 of the Indian Constitution[4]. Further, Article 15(1)(b) of the ICESCR recognizes 'the right of every individual to enjoy the benefits of scientific progress and its applications'. The Supreme Court often interpreted fundamental rights in consonance with international treaties. Hence, the implementation of product patent should not result in the denial of rights guaranteed under the Constitution of India and the ICESCR. According to Section 2(d) & (f) of Protection of Human Rights Act 1993, rights under the ICESCR are the rights that the National Human Rights Commission (NHRC) has to protect[5]. A key objective of policy-makers in the developing world is to ensure the availability of new medical treatments, at affordable prices, to patients in the region.

We suggest the setting up of governmental drug research and development establishments and non-profit organizations to promote drug discovery and development, with an objective to make affordable novel drugs to major infectious diseases. Also, novel drugs for diseases like tuberculosis (TB) and malaria, which are under patent protection, can be made more accessible to the common man by the Government, which can provide subsidies for such drugs.

Pharmaceutical industry perspective: Must protect the cost of innovation?

Inventor firms tend to develop a new medical intervention only if the expected value of the temporary monopoly pricing power they might gain, discounted by the probability of failure, is greater than the full development and patenting costs. They have no incentives, then, to try to develop any intervention needed by those unable to afford it at a price far above its cost of production[6].

Clearly, the monetary investment and the time that goes into drug research is colossal. The patent regime awards the pharmaceutical company a monopoly over the drug only after the drug has been tried, tested, proven to be a success and is fit to be marketed. This in itself involves several stages and levels of research, trial and assessment, including extremely expensive clinical trials. Invariably, several such attempts fail or are unsuccessful and the fact is that an overwhelming majority of such new drugs has to be aborted at some stage of development. The very minute fraction that passes such scrutiny involving cost and time-intensive trials must then be so priced, not just to make a profit, but to also offset the cost of the failures. Obviously, any encouragement and support that is provided to such companies is restricted to only successful marketable drugs. Thus the massive investment that goes into the dead-end research that had to be aborted has to be endured entirely by the pharmaceutical company.

Taking into account these factors, pharmaceutical companies understandably have in the past and will continue to make attempts to recover these costs through various means, either by charging exorbitant prices for the drugs that are monopolized by them, or in some cases even by seeking out various ways to extend the patent duration. This seems to have been illustrated in the very recent Novartis case, where the whole concept of 'evergreening of patents' arose.

Irresolvable conflict of interests?

Today, the drug industry takes a different view. Protecting its intellectual property

rights is a major priority, even if that means preventing poor countries from making cheap copies of the drugs that they urgently need[7]. Hence giving rise to the question, once vested with the power of monopoly, do the companies have a tendency to overlook their duty?[8]

Till 2000, anti-retroviral treatment (ART) drugs were not accessible to a vast majority of people living with HIV/AIDS all over the world, because of the exorbitant price charged by the multinational companies, which was anywhere between US$ 12,000 and 13,000 annually per person. The price started falling when manufacturers from India introduced generic versions of ART drugs. Now these generic drugs are given at a cost as low as US$ 140 annually per person through certain international organizations like the Clinton Foundation. This was legally possible because of the absence of a product patent regime in India[9]. The most striking incident is the impact of product patent on access to HIV/AIDS drugs. It is, however, interesting to note that even at this low pricing, the Indian pharmaceutical company was still making reasonable profit!

Nonetheless, as developed nations have argued, higher prices are crucial to ensure the delivery of new medical treatments in the future. Is it really so? The Rs 40,000 crore Indian pharmaceutical industry has now entered a new and challenging phase of product patent recognition, leaving behind the reverse-engineering copycat era, which fostered the growth of the domestic drug industry for three decades and helped to bring affordable medicines to the people.

There are differences in the disease pattern; many diseases are global in nature and their therapies have worldwide market, whilst others primarily afflict people living in poor countries. Cancer and lifestyle diseases have significant presence globally, while diseases such as malaria, TB, HIV/AIDS, etc. are predominant in the under-developed and the developing world. Thus, drugs against the former have a huge market worldwide, making it irrelevant whether consumers from developing countries are purchasing them or not, as long as the wealthy are more than willing to pay any price for them. Hence, research on medical treatments for the rich-man's disease is likely to continue apace, regardless of the patent regime in the developing countries.

For diseases such as malaria and TB, in contrast, there are no significant markets in the developed nations. Consequently, stringent intellectual property protection in the developing nations is likely to induce research aimed at developing new and better medical treatments for these ailments. But one should not forget that this alone is unlikely to do the trick, because the small, low-income markets in these countries cannot support the price–volume combinations needed to make such research and development projects commercially viable.

Hence, the net result of the TRIPS accord has been high cost of medicines and the consequent denial of access to medicines by low-income groups across the globe.

A viable alternative

Thus a balance of the above discussed two crucial issues is long sought after and is a necessity in modern times. We propose to resolve this conflict by a method of optimal pricing that is consistent with broadly defined social objectives. The policy to be endorsed is to link the degree of monopoly provided to the patent owner in a particular country, to the Gross Domestic Product of that country. Thus, higher the GDP of a nation, wider the extent of monopoly available to the patent owner. Countries like USA have a GDP of 13,244,550 million USD, which is in stark contrast to countries such as Bhutan, whose GDP is 983 million USD[10]. Thus the pharmaceutical pricing must accommodate such stark differences in the economy of various nations. This proposition may come across as being overly simplistic and idealistic. However, all facts considered, such a policy is practical and implementable. The essential point to be kept in mind is that such a design of the price structure will yield the required revenue and perhaps is the only way to reconcile such violently conflicting and fundamental interests.

1. Jean, O. LAnjouw and MacLeod, M., 2005, **40**, 4232–4234.
2. WTO, Ministerial Conference – Fourth Session, WTO Doc WT/MIN(01)/DEC/2, 2001, Doha Declaration.
3. Bhatnagar, M. P., *Country Reports: TRIPS Implementation in India, Intellectual Property Rights: A Global Vision*, 2003, 1st edn, p. 510.
4. Vincent Panikurlangara v Union of India, 1987 (2) SCC 165.
5. http://www.unhchr.ch/html/menu3/b/a_cescr.htm
6. www.hf.uio.no/ifikk/forskning/etikkprogrammet/ISTANBpogge.doc/
7. Under the new WTO rules, however, strict American intellectual property rights rules, which extend patent rights for 20 years, have become standard. All 140 WTO member countries must change their laws to conform, although some developing countries have been given more time, until 2006 to make the change.
8. The companies have always argued that patents are their lifeblood. Unless they have the monopoly right to market their inventions for a fixed period, there is no point in investing huge amounts in researching and developing new remedies. The actual costs of manufacturing most drugs are not huge. Without patents, competitors could rip-off their inventions and they would never recoup their investment.
9. http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf
10. According to the 2006 list by the International Monetary Fund.

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