

Section IV

Intellectual Property Rights and Access to Medicines

The idea behind intellectual property rights is that the fundamentals of an invention are made public while the inventor for a limited time has the exclusive right to make, use or sell the invention. It can legitimately be argued that the notion of IPR is built on a contradiction: in order to promote the development of ideas, it is necessary to reduce the freedom with which people can use them. This contradiction is a running thread in all debates on IPRs, and is sought to be resolved in laws related to IPRs by attempting a balance between public interests and rights of the inventor. Two contrasting interests, that often manifest as contrasting opinions are reflected in the following statements.

"The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed -in every country- of the economic and social consequences of the TRIPs Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents."

UNDP Human Development Report 1999

"The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in R&D".

IFPMA, ASEAN Workshop on TRIPS, Jakarta, May 2000

Genesis of Intellectual Property: Since it is now possible to convey ideas from one mind to another without ever making them physical, ideas themselves are sought to be given ownership, and not

merely their expression. And since it is likewise now possible to create useful tools that never take physical form, there is a move towards patenting abstractions, sequences of virtual events, and mathematical formulae - the most unreal terrain imaginable.

We are now entering an era where major parts of the world economy are based on ideas and knowledge, i.e. goods that take no material form. The central distinction ideas and physical property is that information can be transferred without leaving the possession of the original owner. Unlike physical goods, there are no physical obstacles to providing an abundance of ideas. *Intellectual property can thus be conceived as an attempt to create an artificial scarcity in order to give rewards to a few at the expense of the many.*

IPRs also pose another kind of dilemma. Open ideas can be examined, challenged, modified and improved. But IPRs, by converting scientific knowledge into a commodity, arguably inhibits science. We also see the development of a new contradiction -- information or ideas are sought to be commodified at the same time as technology makes it possible to exchange ideas in a radically free environment. If ideas are to be exchanged in the marketplace, the basic assumption of the marketplace, as it is with regard to physical objects -- that value increases with scarcity -- should hold good. But this is contrary to the nature of information, which would -- in most cases -- increase in value with dissemination.

The evolution of the way Intellectual Property is rewarded by society, has also changed in a fundamental manner. Starting from a "reward" or a "grant" to the inventor by society for full disclosure of the contents of an innovation, Intellectual Property is now seen as a "right".

Monopoly as a Facilitator of Creativity?: Central to the projected utility of Intellectual Property Rights is the notion that creation is facilitated by the provision of a temporary monopoly.

This notion had a certain kind of validity in the context in which the concept of IPRs developed. The earliest Patent and Copyright Laws were geared, to an extent, to benefit the individual artisan, or the author of a literary piece or a musical score. Today, IPRs help create monopolies of a different order, and thereby place enormous power at the disposal of a handful of corporations.

The importance of the knowledge based sectors to the US (and global) economy can be gauged from the performance of large companies today. Among the top fifteen companies with the highest returns (profits) on Revenues (turnover), six are pharmaceutical companies and five are from the information technology sector.

The principal arguments of the pharmaceutical industry are related to its claims that it invests huge amounts in the development of new drugs and hence deserves returns for such investments. The important point to be underscored is that after the claimed investments are made on R&D the pharmaceutical sector has consistently been the most profitable sector. A perusal of the profitability in different sectors based on data from the top 500 globally, shows that profitability in the pharmaceutical sector is way ahead of all other sectors.

To look at it in another way, if profit margins of top pharmaceutical companies were to have been less by a third of current levels -- which would still make them more profitable than any other sector -- a benefit of about 11 billion dollars could have been passed on to consumers. That is in fact more than the projected 10 billion dollars that are required to provide access to anti-AIDS drugs to all HIV positive patients in the world!

High prices, driven by patent monopoly based incomes are just one part of the story. The frantic search for the next "blockbuster", skews drug development in favour of new drugs for which there are buyers who are willing to pay prohibitive amounts. The basic qualification for the next "blockbuster" is that it should be possible to sell it in the market, not that it should address real medical needs.

Hence, more and more drugs being introduced are "copycat" drugs or drugs like Pfizer's sildenafil (Viagra) that mainly address "lifestyle" needs and not, predominantly, medical needs and do not significantly alter prevalent therapeutic practices (See Table below).

Patents are granted with the understanding that they will be accompanied by "full disclosure" about the contents of the Patent.

Table: Assessment of New Drugs Introduced Between 1981-2000		
Category	Number	Percent
Major therapeutic innovation in an area where previously no treatment was available	7	0.31
Product is an important therapeutic innovation but has certain limitations	67	2.96
Product has some value but does not fundamentally change the present therapeutic practice	192	8.51
Product has minimal additional value, and should not change prescribing habits except in rare circumstances	397	17.59
Product may be a new molecule but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product	1427	63.23
Product without evident benefit but with potential or real disadvantages	58	2.57
Editors postpone their judgements until better data and a more thorough evaluation of the drug is available	109	4.83
<i>Source: Prescrire International</i>		

"Full disclosure" usually means providing enough detail for a "person skilled in the same or the most clearly related area of technology to construct and operate" the patented object. Strong patent protection is now moving the pendulum away from the concept of "full disclosure" and it is a matter of grave concern for the scientific community. Clearly, patents have ceased to be a vehicle of dissemination of knowledge and have become the tools to constrain its spread -- quite the antithesis of what good science requires.

Domestic industries outside the developed countries have been able to develop in places where strong patent production has not been allowed. India is representative of such a situation, where the Indian Patents Act of 1970 allowed the development of a strong vertically integrated pharmaceutical industry. It was facilitated by the ability of Indian companies to develop and market generic versions of patented drugs. The primary issue is not just that it allowed cheaper versions of patented drugs to be sold in the Indian market. It allowed the development of world class sophisticated chemistry and reverse engineering, followed by manufacturing capabilities in a developing country. This that is sought to be taken away by large pharmaceutical companies through the medium of TRIPS.

Further, the problems associated with more liberal patent provisions are manifest today in the huge numbers of Patents that are granted in many developed countries. Companies today, instead of inventing new drugs, are engaged in inventing patents by seeking protection for trivial advances on existing medicines, in the form of isomers, polymorphs, esters, etc. The result is that thousands of pharmaceutical patents are granted in a year but only a handful of NCEs are introduced in the area. A majority of patent being filed and granted constitute "patent thickets" i.e. patents that prevent others from research in certain areas and also prevent introduction of generic drugs.

It also needs to be realised that entry cost into the patent system is very high. It can cost anything between US\$10,000 - US\$50,000 to

file a global patent. The cost of maintaining a patent after it is filed, including tracking of infringements globally, litigations if there are infringements, etc. could cost over a million US dollars.