## Innovation, Intellectual Property Protection and New Business Development: the Needs of the Developing Countries

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Having lived, studied, worked and finally been involved in teaching in a medical center in the United States for the last forty years, but frequently visiting educational and research institutions as well as attending conferences in many developing countries, I am keenly aware of the many differences between my adopted country and the country I was born and raised (India), as well as other developing countries. The economic prosperity and military might aside, one of the major differences between the United States and most developing countries is the awareness of the importance of science and technology in industrial and economic development. United States is a highly industrialized country where new scientific and technological processes and products are constantly being developed and marketed worldwide. In contrast, most developing countries generate very few new globally marketable products or technologies. Thus the economic gap between the developed countries such as the G8 countries (eight most industrialized countries) and the rest of the world keeps widening, often creating social tensions and political problems.

Why this difference and what to do about it? Most people will agree that a large part of this difference is due to heavy emphasis that the developed countries place on their scientific and technological infrastructure and a spirit of innovation. A culture of engagement in science and technology, thinking outside of the box for bringing new products in the market and ensuring that such scientific innovations are translated into intellectual property of immense value have transformed the developed countries into the most desirable place to live and work, draining technologically savvy people from the rest of the world to participate in such a culture. Somehow, the developing countries never quite got around to this, because of social, cultural and political reasons as well as for lack of natural resources and sometimes a difficult climate. The situation is, however, about to change, thanks to the emergence of rapid transport, a highly efficient communication network, a favorable political

climate fostering co-operation among nations and an emerging 'can do' attitude among people in developing countries who now understand the basis for prosperity among developed countries and are determined and eager to emulate it.

For the developing countries to move forward, an essential feature is to upgrade their educational system, particularly with respect to science and technology. Economic development in almost all cases requires new useful product development that can be sold in the global market. This in turn requires that the developing countries use both their human and natural resources to evaluate what are the needs for a worldwide growing market and how to meet such needs. A spirit of innovation is the key to meeting such needs. Sometimes a country tends to develop an attitude that's contrary to the spirit of innovation. Since I am from India, let me give an example of the Indian scenario, because it most likely mirrors the attitude of most developing countries. If a country is going to come up with innovative products for global marketing, it is essential that the products be legally protected from being copied by other industries. This is done by a country's legal system, often called the intellectual property or IP laws which include patents, copyrights, trademarks and even trade secrets. The framers of the U.S. constitution, Thomas Jefferson and James Madison, knew the importance of IP all too well so that the foundation of the patent law in the United States is in the Constitution itself which gives Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries", Article I,  $\delta$  8, cl. 8, of the U.S. Constitution. Soon after the adoption of the U.S. Constitution, the First Congress enacted the Patent Act of 1790, which allowed the grant of limited exclusive right of 14 years to any applicant that had invented or discovered any useful art, manufacture or device, or any improvement therein not before known or used. The US patent system allows protection of both innovative products and processes, including biotechnology and genetic products made by man. Thus innovators from all around the world moved to the United States, including from developing countries in the last 50 years, to participate in the cutting-edge research and development which ultimately helped to create a thriving industrial base and economy.

Contrast this with the patent laws in India between 1970 and 2004. The Indian Patent and Designs Act of 1911, modeled around the British law, was amended in 1970 to include process patents but rejected patenting of foods, drugs and medicines or substances produced by chemical processes or chemical synthesis. The exclusion of the product patent allowed India to make generics out of patented or off patent products, thereby helping to create a thriving generics industry. However, generics made out of patented products could not be sold in the developed countries where the patents were still valid and therefore the markets were very limited for such products. The major downside of such a patent policy in India was the lack of innovation. Because India did not recognize product patents, there was very little incentive to produce innovative products in India, since such products had no patent protection. Consequently, India had a thriving copy cat generics industry with a limited market reach, but no innovative globally marketable product. I suspect that this is true of most developing countries.

An exciting and promising recent phenomenon is that many developing countries like India have become members of the World Trade Organization (WTO) and a trading partner with developed countries. As part of this trading relationship, these developing countries signed the TRIPS (Trade Related Intellectual Property Rights) agreement which requires the signatory countries to follow a set of rules and guidelines developed by World Intellectual Property Organization (WIPO). One such rule mandates the member countries to afford legal protection to product patents, thereby encouraging product development and its protection in the member countries. After much debate, the President of India promulgated an ordinance in December, 2004, to recognize product patents in India and the Indian Parliament passed a law to this effect in April, 2005 to remain TRIPS compliant. I believe such moves by India and other developing countries bode well for future innovations in science and technology in such countries, contributing to industrialization and economic development.

Much remains to be done. Passing a law to recognize product patents is a small beginning. Making young researchers aware of the potential of their research for possible marketable product or process development and taking appropriate steps such as filing a provisional or full patent application before publication is an important step in creating intellectual property out of

their research. They, together with their patent attorneys, must also be familiar with writing claims that are narrow enough to be accepted by the patent office or the courts, but broad enough to encompass many minor or inconsequential changes in the claims that competitors will like to infringe on to circumvent the patent. Anticipating how competitors may legally infringe on their patents and take appropriate steps to prevent it is an important part of writing a patent. This requires training of law students in developing countries to become smart patent attorneys. Even that is not enough. Patent laws are very complex in developed countries and patent infringement cases abound. Does the judiciary of the developing countries have appropriate training in the changing national and international patent laws to adjudicate complex patent cases in a fair and speedy manner? How should we train judges, who may not have any science background, to decide complex patent cases? Much effort must therefore be expended to train the judiciary in patent laws and have the developing countries set up appropriate specialized patent appeals courts to adjudicate possible patent infringement cases. Of course, patents will emerge only when new scientific and technological developments take place, which requires setting up of appropriate scientific and technological infrastructures such as first-rate research institutions, medical schools for conducting both health-related research and clinical trials, schools of agriculture and environmental health, and of course law schools for training patent attorneys and future judges.

Even when both scientific/technological infrastructure and appropriate legal training centers are in place and fully functional, leading to creation of intellectual property, nothing much will happen unless the intellectual property finds its place in the global market. This requires licensing of the intellectual property either to the originator of the IP to establish a start-up company or to established industries for manufacture and marketing. This requires substantial investment of funds from angel investors or venture capital firms. This is, of course, the strength of the developed countries, particularly the United States, where such funds are usually readily available if the IPs are significant. The United States is a leader in new business development not only because such funds are available but also because of what's known as Bayh-Dole act of 1980, which permits the academic institutions to own IP rights developed under government funding. This has encouraged the US universities and other academic organizations to set up technology management and transfer units which will initially pay for the cost of patent filing and prosecution but will recover the cost as soon as a startup or an established company procures an exclusive or even non-exclusive license from the university. Since patent filing and maintenance costs may be substantial, particularly if multiple patent applications are filed, any organization needs to license such patents prudently and swiftly to recover the patent filing costs as well as have milestone payments as the IP passes the regulatory procedures, if required, to enter the market place. The developing countries, and even some developed countries, will have to face this hurdle of generating venture capital funds as well as set up business schools to train future managers for administering and executing business deals and introduction of new products in the market.

Can the developing countries do it? Of course they can! In a sense it is already happening in countries such as China, India and Brazil. Brazil has recently passed legislation similar to the Bayh-Dole act. India is considering to enact similar legislation. The pace needs to be accelerated and many more developing countries, particularly those in Africa, need to be included. This year the G8 countries have committed themselves to help Africa attain a degree of confidence and selfsufficiency. I only hope the G8 countries will not just offer handouts to African countries but will promote a culture of developing their science and technological infrastructure so that eventually the African countries become a player in the global arena. And I hope this bodes true of all developing countries as well!