Patenting Life?

Biodiversity and Intellectual Property Rights

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Introduction

The last millennium saw India becoming a global power in intellectual areas, like software and technology, including nuclear. This was accompanied by wars over India's biodiversity and traditional knowledge. For instance, specific applications of neem, turmeric and basmati rice were patented in the USA. These foreign monopolies over Indian heritage raised a hue and cry. Indian government fought and even won the turmeric war by getting the patent revoked. Basmati conquest is still elusive but the European courts recently questioned the neem patent. This article outlines these issues, especially emerging challenges and strategies.

This is particularly important for students of biotechnology, an industry that might soon constitute half the world economy. By using biodiversity as raw material, biotechnology industry may release new pest and stress resistant crop varieties, new medicines, new sanitation methods like microbial digestion of mining waste and so on. Most of these innovations will be patented. Thus, we must master this game.

Patenting Globally

Nature of Intellectual Property Rights (IPRs) varies across countries (see *Box* 1). Thus, an Indian patent is not automatically valid in another country, say USA and vice versa. A fresh patent thus needs to be obtained in every country, raising costs and efforts. To reduce these difficulties, developed countries made several efforts to expand IPR regime worldwide. Most significant of such an extension began since 1994, with the General Agreement on Trade and Tariff (GATT), an international treaty.

Box 1. Intellectual Property Rights (IPRs)

IPR is the government protection to the first innovator for solely manufacturing and marketing an innovation for a limited period, prohibiting others unless licensed by the IPR holder at the cost of royalty payment. Due to lack of competition, the IPR holder may even charge an exorbitantly high price, since the needy consumers are left with no choice. However, after the protection period, anyone can freely produce and market the protected innovation and the costs come down. IPRs are divided into several categories depending upon subject matter, public disclosure, protection period, etc. *Copyrights* protect artistic expressions like literary works up to 50 years. *Patents* primarily protect industrial innovations for 7 to 20 years, depending upon the country. Unlike copyrights and patents that protect the public information, *trade secrets* protect the undisclosed information like recipes and formulae against unfair access and use, a famous case being the Coca-Cola recipe. Trade secrets are renewable every 7 years. *Plant breeder's rights* are similar to patents, but protect only the new varieties of crops for 15 to 20 years. Trademarks are used to protect the symbols like logos. *Geographical indications* are used to protect regional affiliation in the nomenclature of a commodity such as Champagne wine or Darjeeling tea. Of late, protection of *integrated circuits*, *databases*, etc. is also sought.

It includes Trade Related IPRs (TRIPS) agreement enforcing member countries to protect innovations from all the fields of technology, whether domestic or foreign. Accordingly, a US patent can hold in India and vice versa, from 2005 AD onwards. Natural plants, animals and essentially natural methods for their reproduction may be excluded from patentability but not the microorganisms. New crop varieties may be protected through patents or any other efficient system. Patent protection period must be uniformly 20 years and must cover processes, products or both (see *Box* 2).

These changes have raised major concerns for the health and food sectors where many countries till recently provided partial or no IPR protection. For instance, India granted no patents in agricultural sector and only granted process patents in the pharmaceutical sector, lasting only 7 years. This helped Indian companies to import drugs patented abroad, invent slightly different production methods and protect these re-inventions through Indian process patents. The drugs were then produced on large scale and exported abroad at much lower prices than the foreign drugs, due to cheap labour and infrastructure here.

Box 2. Patenting Procedure

Patents are granted on innovations that are proven to be *novel, non-obvious* and *useful*. Public knowledge is not novel and hence, not patentable, for instance, the Ayurvedic formulations as such. If the claim is a mere discovery and not a human invention, it is considered obvious and not patentable e.g. new species of natural organisms. The innovation must also have a tangible commercial application. Thus, just the knowledge of using a plant or a mixture of herbal extracts to cure a disease or neem syrup as pesticide may not be patentable. However, screening, isolation of active ingredients and developing marketable drug/ chemical may be patentable, like stabilising neem extract and increasing its shelf life. A patent application must *specify the methods* adequately enough to enable anyone skilled in that art to reproduce the innovation independently. The public knowledge must be adequately disclosed to demonstrate the inventiveness. Insufficient, vague or fraudulent disclosures can disqualify the application. Based on such specifications, the patent authorities and technical experts *scrutinise* the application by also referring to their *literature sources and patent documents.* Besides, the patent claims and summary are made public for information and inviting *oppositions*, if any. This is akin to government invitation for public claims before acquiring or disposing any vacant property. In most countries including India patent oppositions are invited through the notification in the gazette four months prior to the grant. Unfortunately, there are no pre-grant oppositions in US though well substantiated post-grant contentions may revoke the patent. A patent must be maintained by paying annually increasing renewal fees.

These cheaper drugs swept the markets antagonizing their original producers abroad. This industrial unrest led the developed countries to force India to amend its patent law to provide for product patents soon, besides process. That would end the reverse engineering i.e. import-dismantle-reassemble technologies of the Indian drug manufacturers, hastening an industrial crisis and making drugs costlier. Seeds, grains and other biotechnological products will also be costlier.

Biopiracy

Developed world industries resent losses from the counterfeit goods and pirated technology in the developing countries. A new drug takes 10 to 20 years and up to $ 400 million to develop. IPRs are justified to protect this huge investment, the drugs being easy to copy and manipulate. However, historical events make this argument look hollow. A country like USA freely acquired most of its crops from its neighbours. Developed world also looted medicinal plants, dyes, spices, etc. from developing

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countries, leading to discovery and conquest of India, South America and South East Asia. New drugs like Resperine used against hypertension, derived from an Indian plant Sarpagandhi (*Rawolfia serpentina*), has enormously enriched foreign pharmaceuticals! Genes from the Pattambi rice variety in Kerala in southern India were used to induce pest resistance in rice crop of South East Asia saving it from the brown leaf hopper attack during last decade. The Pattambi farmers are still poor but the seed companies flourished.

Likewise, the developed world has never paid for the benefits it exploited from the tropics. Nevertheless, the derived products are patented and sold much costlier even in countries that contributed the raw material or basic knowledge. Since IPRs protect only the commercial inventions, domestic and ongoing use of bioresources is not prevented. Thus, grandmothers or Ayurvedic vaidyas can continue to use or market powders or syrups as usual. However, they cannot claim a share in the profits generated from a derived drug. There has been growing discontent amongst developing countries about this biopiracy i.e. unfair exploitation and monopolization of public domain knowledge and resources.

Benefiting Developing World

Concerned about halting or slowing down the rapid erosion and extinction of biodiversity, most countries in the world negotiated the International Convention on the Biological Diversity (CBD) of the United Nations in 1992. Besides promoting conservation, CBD also encourages sustainable use and equitable sharing of benefits, primarily due to the pressure by the developing countries. It basically reaffirms the sovereign rights of the countries to their biodiversity resources. Thus, USA for instance, cannot anymore whisk away crops or medicines from any other country without its prior informed consent (PIC). Unwilling to bow before developing countries of tropics, USA remains the only major nation not seeking CBD membership yet, unlike 170 other nations including India.

CBD conditions, however, apply only to acquisitions after but not before 1992. For instance, Kew gardens from UK, has richer, pre-independence collection of Indian plants than any Indian institution. These specimens especially living plants could be used to extract genetic material, without consulting India, like in the basmati case. CBD's requirements of prior approval also apply only to undisclosed information. Unfortunately, much of the traditional knowledge is already public e.g. ayurvedic texts, ethnobotanical publications, computerized databases in public domain, etc. Further, the industry is also actively engaged in tapping folk knowledge or resources of the villagers through agents. Despite such limitations, CBD remains the only legal platform to fight such misappropriation. However, countries wishing to benefit from CBD must enact matching legislations. Only a few tropical countries like Costa-Rica, Eucador, Philippines, etc. have enacted supportive legislations. India has prepared a draft in 1998 but not tabled and enacted it in the parliament yet, due to want of public pressure.

Patent Wars?

CBD pioneered a formal encounter with the IPR regime. Environmental and social activists anyway reject patenting of life as being socially unjust, environmentally unsustainable and unethical. Specifically, monopolies disadvantage the poor; promote monocultures for quick profits and falsely imply humans as creators. But these debates notwithstanding, if we don't abide to our voluntary WTO commitments, we will only invite multilateral sanctions, starting with US sanctions since March 2000 due to copyrights violations of movies and software. Keen to avoid sanctions, the Indian government has tabled corresponding IPR bills and amendments in the Parliament. Fortunately, besides addressing the WTO mandate, the bills also recognise traditional knowledge even if oral, as 'prior art', in the spirit of CBD.

These defensive strategies notwithstanding, the premier government research agency, the Council for Scientific and Indus-

trial Research (CSIR) has advocated a 'patent for patent' approach. It has already secured many costly patents relating to specific uses of Indian plants like neem in the US but without any marketed products yet. Even in private sector, few Indian companies have formidable patents. No wonder, foreign companies still secure nearly two thirds of the annual patents granted in India. This proportion might only grow henceforth. The impending patent wars necessitate innovative strategies like amending IPR laws to enforce mandatory disclosure of all the available public knowledge regarding the innovation and employing computerised databases in its scrutiny.

Registering Public Knowledge

Reliable databases need documented evidence about the knowledge and resources, beyond confusing oral claims. Such evidence can disqualify fraudulent claims as in the turmeric case. To prepare such countrywide databases, all schools and colleges can prepare registers of biodiversity in their neighbourhood and related knowledge with the help of the local experts. Research institutions can integrate this information and material with the existing public databases and repositories. The contributors can be provided with incentives like grants for conservation, development and documentation. This may be supported through the biodiversity and gene funds proposed under the draft legislations on 'biological diversity' and 'plant variety protection and farmers rights'. Social incentives like recognition through public felicitations, media publicity and training opportunities are also important. This fund can be built by taxing biodiversity based products and diverting perverse incentives like fertiliser subsidies that only erode diversity. India must even argue for such an international fund. TRIPS does not forbid such socially just measures, so we must surge ahead with enough of these for a self-reliant and even prosperous future.

Suggested Reading

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