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Patentability and Bioprospecting

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ABSTRACT

Most best selling drugs across the globe have a biological source. If this is true, one might want to ponder over the drug manufacturers' inclination for chemicals and synthetics. Fortunately, there are some who are more inclined towards nature and exploring her gifts for the benefit of mankind by looking out for the right bark, leaf, twig or seed rather than some chemical composition. In other words, we can say that bio-prospecting is searching for answers from nature. Technically, the process is the search for commercially valuable biochemical and genetic resources in plants, animals and microorganisms. These resources may be used in food production, pest control, the development of new drugs and for other related applications. Bio-prospecting is as old a concept as medicine itself is. However, its application has not found place in medical research, at least in India, till recently. Over the years, research activity in India has been highly constrained, largely guided by the contemporary culture. "Initially there were botanists who just went and studied some plants and came back. Bio-prospecting in India has specific issues, paving a path to self sufficiency, bagging more patents and claiming a significantly stronger position in the global market.

Key words : Bio-prospecting , Patentability, Pharmaceuticals. Intellectual Property Rights

INTRODUCTION

Bioprospecting is an umbrella term describing the discovery of new and useful biological samples and mechanisms, typically in less-developed countries, either with or without the help of indigenous knowledge, and with or without compensation.[1] Bioprospecting is the exploration of biodiversity for new biological resources of social and economic value. It is carried out by a wide variety of industries that include pharmaceuticals, botanical medicines, crop protection, cosmetics, horticulture, agricultural seeds, environmental monitoring, manufacturing, and construction. In this way, bioprospecting includes biopiracy and also includes the search for previously unknown compounds in organisms that have never been used in traditional medicine.[2] 'Bioprospecting' is a word that has recently been coined to describe the centuries-old practice of collecting and screening plant and other biological material for commercial purposes, such as the development of new drugs, seeds and cosmetics.

Well-regulated bioprospecting contributes to the joint goals of ecosystem conservation and social and economic development through partnerships and benefit-sharing. Bioprospecting can achieve multiple goals: generating revenues for protected areas, conservation projects, and local communities; building scientific and technological capacity to study and manage biodiversity; enhancing biodiversity science; raising awareness of the commercial and noncommercial importance of biodiversity; creating businesses dependent upon the sustainable management of resources; and, in rare instances, generating large profits for corporations and shareholders. These benefits may occur at local, regional, or national scales. Market trends vary widely according to the industry and country involved, but many bioprospecting activities and revenues are expected to increase over the next decades. Several major new industries, such as bioremediation and biomimetics are well established and appear set to increase, while others have a less certain future. The current economic climate suggests that pharmaceutical bioprospecting is likely to increase, especially as new methods that use evolutionary and ecological knowledge enhance productivity.

Scope in India:

Bioprospecting in India has specific issues, largely extending from the laidback mindset of researchers to lack of awareness among the business community and investors. Few are disappointed by the fact that the idea hasn't found enthusiasts while many more are still not aware of the potential that the concept holds. Everyone has heard about the immense biodiversity in India, but that is only the tip of the iceberg. Some facts and figures could put things in perspective:

- Three out of 34 global biodiversity hotspots in the world are in India
- India's Western Ghats has been ranked fifth in the world in terms of the potential it holds
- There are about 18,000 known species of plants in India alone, medicinal implications of a large number them is still mystery.

As Professor Shanker puts it, "We are sitting on a mine of green gold." And we have been just sitting on it for centuries. With all the above-mentioned resources, there are only about five or six crystalline compounds that are exported from India and many millions worth of drugs are being imported every year. Shanker says, "I think it is a shame that even with all the biodiversity in India, we have nothing to show." Putting pride aside, the economic consequences of any such achievement could be mammoth. Especially with global competition firming up, figuring out more ways to make a mark is necessary for companies. "Industry can proactively engage work in this area. They have to identify what is their requirement and collaborate with academia in finding new solutions," suggests Shanker. And that is surely a fair task as industry would enjoy a great proportion of success resulting from such efforts. Having said that, if there is an opportunity, the industry has been undoubtedly eager to tap it. Hence, it is essential for industry to realise the potential that bioprospecting holds for them in reducing outward dependence, paving a path to self sufficiency, bagging more patents and claiming a significantly stronger position in the global market.3

Pharmaceutical Bioprospecting:

Interest in novel products from biodiversity has varied greatly in the last decade, with a general decline in pharmaceutical bioprospecting by major companies, although resurgence is expected (Chapman 2004). Based on the knowledge that many important drugs, such as aspirin, were derived from natural products (Jack 1997)—that is, generated in the tissues of native species—the industry has at various times invested heavily in the exploration of species-rich communities such as rain forests and coral reefs in search of commercially profitable pharmaceuticals (Ismail et al. 1995; Bailey 2001). Alarming levels of antibiotic resistance in many human pathogens is likely to provoke an increase in pharmaceutical bioprospecting, which remains a vital source of lead drug discovery (Wessjohann 2000; McGeer and Low 2003; Newman et al. 2003). Malaria, one of the world's most deadly diseases, has been treated historically with drugs derived from natural products—quinine, chloroquine, mefloquine, and doxycycline—and today the artemisinins derived from the Chinese herb Qinghao (*Artemesia annua*) are at the forefront of the battle against this parasite.

Some compounds from natural resources approved for marketing the probability that any single discovery actually reaches the marketplace remains low, however. For example, 75% of the drugs that entered phase 1 clinical trials in the United States in 1991 went on to phase 2, 36% entered phase 3, and only 23% received FDA approval. From another perspective, the probability of a drug being launched into the market was 5–10% during the pre-clinical research and development phase, 30% during phase 2A, 40% during phase 2B, 70% in phase 3, and 90% during the period of regulatory review (ten Kate and Laird 1999). This is because the conventional process of drug discovery has several distinct and increasingly expensive stages: acquisition of the natural material; extraction of the active compounds; primary screening against a range of human disease organisms; isolation and chemical characterization of the active compounds; secondary screening assaying the compounds in tissue cultures and experimental animals; structural chemistry and synthesis; pre-clinical development with a view to human trials; and clinical development, marketing, and distribution. The magnitude of the resource was illustrated by Henkel et al. (1999), who provided a summary of the wide range of organisms from which drugs have been derived, including bacteria and fungi (both terrestrial and marine), plants, algae, and a variety of invertebrates, including worms, insects and mollusks.

Munro et al. (1999) demonstrated the importance of marine animals among diverse organisms screened for clinically significant cytotoxicity (such as is useful for anti-cancer drugs) and compared the relative importance of terrestrial versus marine organisms for this particular pharmaceutical activity. They also showed the widespread distribution of this cytotoxicity among marine phyla, reminding us that many are relatively little known either to the general public or to the bulk of scientists. They include the Porifera (sponges), Bryozoa (sea mosses), Cnidaria (jellyfish), and Echinodermata (starfish and their relatives). Natural products are still important sources of novel compounds for pharmaceuticals. An average of 62% of new, small molecule, nonsynthetic chemical entities developed for cancer research over the period 1982–2002 were derived from natural products. In antihypersensitive drug research, 65% of drugs currently synthesized can be traced to natural structures. This emphasizes the important role of many natural products as blueprints rather than the actual end points. Newman et al. (2003), who assembled these data, noted that they had not been able to identify a *de novo* combinatorial compound approved as a drug during this time frame, despite massive investment in this technique by pharmaceutical companies.

Legal and policy framework:

Many significant changes in the legal and policy framework over the past decade have set the scene for better recognition of the rights of indigenous and local communities in transactions involving genetic resources and traditional knowledge. These changes include intergovernmental agreements, national measures, and the various codes, statements, and policies adopted by communities, researchers, and companies.

Intergovernmental Agreements:

In recent years, states have agreed on a range of intergovernmental agreements that include provisions supporting the rights of sovereign nations to control access to their genetic resources and the rights of local and indigenous communities to control the use of their traditional knowledge systems and thus benefit from them. Some agreements, such as the CBD, the Convention to Combat Desertification, and the International Labour Organization’s Convention No. 169 Concerning Indigenous Peoples (in 1989), are legally binding. Others, such as the 1994 United Nations Draft Declaration on the Rights of Indigenous Peoples, *Agenda 21* from the Earth Summit, and the Rio Declaration of 1992, are not legally binding but place a moral obligation on signature countries to conform with the provisions.

The CBD's voluntary Bonn Guidelines on Access to Genetic Resources and Benefit-sharing provide operational guidance for ''users and providers'' of genetic resources and information for governments that are drafting national laws as well as for governments, communities, companies, researchers, and other parties involved in such agreements. The scope of the guidelines includes ''all genetic resources and associated traditional knowledge, innovations and practices covered by the CBD and benefits arising from the commercial and other utilization of such resources,'' with the exclusion of human genetic resources. The guidelines describe steps in the access and benefit-sharing process, with sections on prior informed consent and mutually agreed terms as well as possible measures that countries and organizations should consider in response to their roles and responsibilities as providers and users of genetic resources and traditional knowledge. They outline recommendations for the participation of stakeholders and refer to incentive measures, accountability, national monitoring and reporting, verification, dispute settlement, and remedies. One appendix sets out suggested elements for material transfer agreements and another describes monetary and non monetary benefits that may be shared. The guidelines state that access and benefit-sharing systems should be based on an overall access and benefit-sharing strategy at the national or regional level. Given the complexity and uncertainty involved in access and benefit-sharing arrangements, such strategies can help communities and other groups to derive optimum benefits (ten Kate and Wells 2001).

Another recent development is the International Treaty on Plant Genetic Resources for Food and Agriculture, which has provisions on prior informed consent, benefit sharing, and farmers' rights. One important element of this treaty, which entered into force on 29 June 2004, is a multilateral system for access, for food and agriculture, to 35 crop genera and 29 forage species and associated benefit sharing. Its conditions for facilitated access to in situ plant genetic resources for food and agriculture allow for the protection of intellectual and other property rights. Benefits such as the exchange of information, access to and transfer of technology, and capacity building will be shared on a multilateral basis rather than with the specific provider of genetic resources. Parties to this treaty agree that benefits should flow mainly to farmers involved in the conservation and sustainable use of plant genetic resources for food and agriculture, particularly in developing countries. The treaty encourages countries to take steps ''to protect and promote Farmers' Rights,'' including protection of traditional knowledge and the right to participate in benefit sharing and in national decision-making. Communities may also benefit through involvement in conservation and sustainable use.

Intellectual Property Rights:

At regional and national levels, there are various initiatives to apply and develop intellectual property law consistent with prior informed consent for access to genetic resources, prior approval for the use of traditional knowledge, and benefit sharing. Of interest in this area are the U.K. Commission on Intellectual Property Rights and Decision 486, ''Common Intellectual Property Regime,'' of the Commission of the Andean Community, adopted in September 2000. The five Andean countries have attempted to introduce provisions in harmony with both theWorld Trade Organization's Trade-Related Aspects of Intellectual Property Rights and the CBD. The decision provides that certain life forms shall not be considered inventions that patent applications based on the region's genetic resources require a copy of an access contract, and that applications for a patent on an invention obtained or developed from traditional knowledge shall include a copy of a license from the community.

At the international level, there are discussions on the review and implementation of TRIPS. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the

World Intellectual Property Organization is considering intellectual property issues that arise in the context of access to genetic resources and benefit sharing, the protection of traditional knowledge, innovations and creativity, and the protection of expressions of folklore. For example, it is reviewing clauses related to IPRs in access and benefit-sharing agreements. WIPO is working on an electronic database of contract clauses and practices concerning access to genetic resources and benefit sharing. It is also considering elements of a sui generis system for the protection of traditional knowledge, and the Intergovernmental Committee has been considering ways to improve access to traditional knowledge for patent examiners so that patents are not improperly granted.

The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources aims to protect biodiversity and livelihood systems with a common tool (Ekpere 2001) and to guide African countries as they tailor national legislation and regional agreements dealing with the exchange of biodiversity knowledge, innovations, and practices. A range of proposals has emerged concerning patents, from the meaning of ''prior art,'' the scope of patents, and the test of ''inventive step'' to procedural requirements such as disclosure of country of origin and even proof of prior informed consent in patent applications. Indigenous groups have engaged with the patent system to challenge the granting of patents. For example, the Coordinating Body of Indigenous Organizations of the Amazon Basin, an umbrella organization that represents more than 400 indigenous groups in the region, joined with the U.S.-based Center for International Environmental Law to file a request before the U.S. Patent and Trademark Office asking it to re-examine a patent issued on a purported variety of *Banisteriopsis caapi*, or Ayahuasca—a plant that has a long traditional use in religious and healing ceremonies. The patent was annulled shortly thereafter but has subsequently been reinstated. Other forms of IPRs are also being investigated as a potential source of protection against expropriation of traditional knowledge. Geographical indications and trademarks have looked particularly promising (Commission on Intellectual Property Rights 2002).

National Laws on Access to Genetic Resources and Traditional Knowledge:

The CBD establishes the sovereign rights of states over their biodiversity but leaves parties a great deal of discretion on regulation and access. About 100 countries have introduced or are developing appropriate national legislation and other policy measures. The Philippines and Peru have also introduced legislation to regulate access to traditional knowledge, whether it is obtained in conjunction with genetic resources or not. The CBD states that the right to determine access to genetic resources rests with government, but several national laws on this topic make such governmental consent contingent on prior informed consent and benefit-sharing agreements with the communities involved. The Philippines and the five countries of the Andean Community were in the vanguard of such legislation.

The Philippines Executive Order 247 on Access to Genetic Resources requires the prior informed consent of indigenous communities for prospecting for biological and genetic resources within their ancestral lands and domains. And the Indigenous Peoples Rights Act of 1997 in the Philippines recognizes a wide range of rights held by the country's numerous indigenous groups, including land rights and a considerable measure of self government within ancestral domains, including rights to ''preserve and protect their culture, traditions and institutions.''

The Andean Community's Decision 391 established a Common Regime on Access to Genetic Resources in Bolivia, Colombia, Ecuador, Peru, and Venezuela. It states that an applicant wishing access to genetic resources, their derivatives, or their ''intangible component'' (any knowledge, innovation, or individual or collective practice of actual or potential value associated with them) within the region must secure prior informed consent from, and share benefits with, the respective government, any supplier of an ‘‘intangible component,’’ and, where appropriate, from the ‘‘owner, holder or administrator of the biological resource containing the genetic resource.’’ To complement this, in 2002 Peru introduced a law protecting the collective knowledge of indigenous peoples related to biological resources.

The Indian Biological Diversity Act 2002 stipulates that no foreigner may obtain any biological resource occurring in India or knowledge associated thereto ‘‘for research or for commercial utilization or for bio-survey and bio-utilization’’ without prior approval of the National Biodiversity Authority, nor may foreigners apply for any intellectual property right for any invention based on a biological resource obtained from India without the Authority’s approval. A National Biodiversity Fund will channel benefits received from foreign bioprospectors to ‘‘benefit-claimers,’’ to conservation, and to development for the area from which the genetic resource or knowledge comes. Indian citizens and corporations must also give ‘‘prior intimation’’ to State Biodiversity Boards before obtaining any biological resource for commercial utilization or biosurvey, through which benefits will be shared at the state level. Local bodies are to constitute Biodiversity Management Committees to promote the conservation, sustainable use, and documentation of biodiversity within the area. National legislation is also being drafted to cover issues of access and benefit sharing relating to the use of genetic resources that originate outside the country in question.

Threats to and Impacts of Bioprospecting:

The loss of biodiversity directly removes the resource base for bioprospecting, and declines in abundance of elements of biodiversity can reduce the ability and increase the costs of sampling. In addition to these main threats, the losses of traditional knowledge and modern agricultural practices have also contributed to declines in the potential for bioprospecting industries. Bioprospecting itself also has had impacts on biodiversity, and many legal agreements now specify the need for sustainability with respect to issues such as harvesting from the wild. Sometimes, however, these issues are less relevant because the species of interest for bioprospecting are removed from the wild in such small numbers. For example, an individual termite under investigation for pharmaceutical analysis most likely involves a sample of a few hundred individuals from a single colony containing millions of individuals. Similarly, a bacterium taken from a gram of soil is cultured in the laboratory. At the other end of the spectrum, however, large quantities of species or products such as bark may be required for some pharmaceutical research and development, and special conservation measures may be required.

Biodiversity Loss:

The current and future ability of countries, regions, and localities to generate novel products and industries is likely to be threatened by the loss of the basic resource, biodiversity, at all levels: genes, populations, species, and ecosystems. There is abundant evidence that such losses are widespread (Balmford et al. 2003), and there is little sign that the losses are slowing, except in circumstances specifically aimed at biodiversity protection, such as the establishment of effective protected areas. It is ironic that the recent explosion of new techniques in the biological, chemical, and physical sciences that has generated a vastly improved capacity to understand and use biodiversity has been accompanied by a global decline in this very resource. The loss of biodiversity may not only lead to a loss of commercial opportunity but may also compromise ecosystem function (Loreau et al. 2002; Coleman and Hendrix 2000).

While there is much debate over exactly how many species are becoming extinct each year, it is abundantly clear that a very high proportion of species are losing their constituent populations at an alarming rate (Hughes et al. 1997; Ehrlich and Daily 1993). In some forested regions there is a direct conflict of interest between logging on the one hand and human health and bioprospecting on the other. In Eastern Amazonia, for example, where native plants provide most of the medicines used locally, the removal of trees that supply medicinal leaves, fruits, bark, or oils has critically diminished the supply of medicines required by both the rural and the urban poor (Shanley and Luz 2003). Short-term, low-value commodities gained by logging may be matched by the sustainable use of non-timber forest products (Emery and McLain 2001) and, in rare instances, superseded by the high-value products that could be gained by bioprospecting. For example, the pharmaceutically important tree species *T. brevifolia* was considered worthless to the timber companies logging the forests where it grew, but its pharmaceutical value has been far greater than that of the timber species around it. Another pharmaceutically important plant species, *Calophyllum lanigerum*, was first collected from the forests of Sarawak, but when teams returned to the original collection area for more specimens they found it had been logged and the remnant populations showed less activity (Laird and ten Kate 2002). While global threats to biodiversity may one day affect bioprospecting, not least for pharmaceuticals (Cragg and Newman 1999; Grifo and Rosenthal 1997), there are few documented cases in which bioprospecting has been compromised by the loss of a natural community or an individual species? Given the many examples in this chapter, however, the indiscriminate loss of species or of the communities where they reside is likely to be a major threat to bioprospecting, even when their values are currently unknown or even suspected. Many species vital for crop protection and hence large commercial revenues, for example, have been discovered in the habitat of the pest species only after intensive and prolonged research. The weevils responsible for the pest control in Australian lakes described earlier, for instance, were virtually unknown until they were needed. The same story applies to hundreds more species used to protect crops worth billions of dollars (Bellows and Fisher 1999; ten Kate and Laird 1999). Thus while the potential threat to bioprospecting through the loss of biodiversity appears very large, the actual consequences of such losses to the industry at present are very small.

Loss of Traditional Knowledge:

Losses of traditional knowledge of biological resources in recent centuries has been well documented, and it is very likely that much local knowledge of medicines has been lost to humanity in general and to pharmaceutical prospecting in particular (Laird 2002). The current situation has been reviewed by Maffi (2001), and a growing literature on the issue (e.g., Mathooko 2001 and other publications from the International Society of Ethnobiology) documents global losses in traditional knowledge of biological sources worldwide, especially as older generations are unable, for various reasons, to pass on their wisdom to the next generations.

CONCLUSION

The current system of patenting and property rights is inadequate to deal with the types of natural resources that are used in biotechnology and pharmaceutical research. The genes, proteins, or molecules used in current research do not “fit” into any of the categories of properties in the patenting system. Genes (or proteins, or chemicals) occur across a population, or even across species, and they are necessary for the life of an organism. Similarly, people’s lives and livelihoods are connected to the species in which genes or materials are being patented. Local traditional use of plants cannot be hampered or disrupted by patents, but pharmaceutical companies’ interests and rights should also be protected. The current IPR system does not function well, stalls research, and is a hindrance. The bottom line is that it needs to be revamped.

If national institutions prioritized investment in research and drug development at the local and national levels, they would be able to participate in developing health products that are necessary for their citizens, focusing on certain diseases or pathogens that are common in their area. This might shift the focus from *resources* in developing countries to *markets* in developing countries. Instead of seeing developing countries as sources for raw materials, they might be viewed as opportunities for developing new products and marketing them. Developing Controversies in Bioprospecting 36 countries comprise the majority of the global population, with billions of people that might be viewed as consumers for marketed products and services (Grayson, 2004; Prahalad, 2004). There are many business opportunities lying dormant in this sector, especially if opportunities help address the needs of so many people. Bioprospecting can help address domestic health needs and domestic economic development simultaneously.

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