Biodiversity and Benefit-Sharing: University of Illinois at Chicago

Communities in developing countries have not always benefited from bioprospecting inside those countries; conventional methods of benefit sharing and capacity building may marginalize the knowledge and contributions of traditional communities and plant genetic resources.

This disparity in conventional IP (intellectual property) law is beginning to be recognized, and attempts are being made to incorporate and reward indigenous knowledge and plant genetic resources involved in bioprospecting activity. The University of Illinois at Chicago (UIC) initiated and maintains a project that promotes bioconservation, health, scientific and legal capacity, and wealth creation in developing countries, "Studies on Biodiversity of Vietnam and Laos," an International Cooperative Biodiversity Groups (ICBG) project.

The project aims to undertake an inventory of seed plants in Cuc Phuong National Park in Vietnam and of medicinal plants in Laos, as well as to discover novel biologically active molecules from these plants as possible candidates for drug development in the treament of malaria, cancer, TB, and AIDS. The project also aims to improve the living standards of the communities involved, as well as promoting scientific development and technology transfer.

A formal memorandum of agreement (MOA) was entered in 1999 between UIC; the Academy of Science and Technology, Vietnam; Cu Phuong National Park, Vietnam; Traditional Medicine Research Centre (TMRC), Laos; and Glaxo-Wellcome Research and Development, U.K. The MOA was revised when Purdue University and Bristol-Myers Squibb later joined the partnership. The Fogarty International Centre of the U.S. National Institutes of Health provided the funding.

The MOA aimed to recognize and manage IP rights, to obtain prior informed consent to access genetic resources and indigenous knowledge, and to ensure benefit sharing that could arise from the collaborative effort.

Royalty sharing was originally assigned through a trust fund based at UIC. However, the model, which was based on the UIC office of technology management strategy for sharing funds, proved to be problematic. The trust-fund approach was discarded in favor of using contracts to safeguard and manage IP rights; these contracts specify that countries from which plants are discovered can use the monies derived from benefit-sharing to set up their own trust funds or other organizations. Some developing countries' institutions do not use trust funds. In this case, based on a payment made to the project by Glaxo-Wellcome, Laos has created a trust fund and Vietnam is initiating a foundation.

One patent application has been filed on a bioactive compound. The project has resulted in a better understanding on the benefits and risks of bioprospecting among all the parties. Numerous new compounds have been described, conservation and educational capacity have been improved at the park, research capacity has also been upgraded at TMRC, and various benefits to local people have come about as a result of the project. The benefits have included scientific personnel exchange, education and collaboration, and new equipment.

Soejarto DD, C Gyllenhaal C, JA Tarzian Sorensen, HHS Fong, LT Xuan, LT Binh, NT Hiep, NV Hung, TQ Bich, BM Vu, BV Southavong, K Sydara, JM Pezzuto and MC Riley . 2007. Biodiversity and Benefit-Sharing: University of Illinois at Chicago. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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In the ICBG project, if UIC labs make a discovery, UIC is required to obtain IP protection, determine ownership in accordance with applicable national law, and take responsibility for the management and licensing of inventions. Similar arrangements exist in the contract for discoveries made by industry partners that analyze project samples in their labs.

This plant-based pharmaceutical discovery project represented a novel approach to IP management for UIC. It resulted in modifications to UIC's other contracts for international collaborations in discovering natural product drugs. Previously, if UIC discovered a compound, it would take the lead role in developing the intellectual property. The standard contract is now structured so that whatever country in a collaboration is capable of IP management can take the lead if they choose to do so.

Sustainability is a critical issue in bioprospecting. There is a need to look at whether a plant source is required for commercial production of a drug. Other considerations include how to deal with economic changes in communities that cultivate the plant, how to ensure replacement of food crop fields that are converted to drug plant production, and what should be the role of science and technology in, for example, developing new genotypes of the drug source plant.

When prospecting, there are opportunities for value-added discoveries if uses of plants are found that do not exist in traditional medicine. If a plant species is found useful as the object of bioprospecting, the plant's economic value goes up, but this can expose the local plant population to over-harvesting. Participatory conservation becomes crucial in such circumstances.

Importantly, informed consent in both the collection and use of plant/genetic materials, as well as acquiring information on their uses, is integral to any successful bioprospecting collaboration. Prior art must also be defined before any agreement is made, in consultation with both scientific and traditional communities. As plant collection proceeds, appropriate prior informed consent and plant collecting permits are obtained from Ministry, province, and local-level governments to ensure that collection is legal and source country/indigenous group rights are honored.

The pharmaceutical industry is understandably cautious about traditional knowledge and biodiversity: the results to date are meager, there are problems with fulfilling demand, bioprospecting can become an emotive and complicated issue, and recreating a natural process through chemical means is not always obvious. At this time, universities and small companies that are well-schooled in the ethics of bioprospecting and the methodology of natural product drug discovery are likely to serve as sources of lead compounds for drug development by industry.

IP RIGHTS DECISIONS AND IP MANAGEMENT

The ICBG MOA provides that UIC take the lead in IP management and bear the cost of it as well. Patent ownership follows U.S. patent law and the Patent Cooperation Treaty. No provision was made for assigning joint ownership to those who are party to the MOA unless they are legally recognized as inventors on discoveries. Reservation of rights for further academic use of products would be negotiated in licensing agreements. Expenses for managing the project intellectual property may be deducted from any revenue earned from licensing the intellectual property. Equal shares of net revenue are allocated to a fund for the use of the plant source country and to a common fund for inventors, the technology management office, and collaborating institutions. A chapter by Soejarto and colleagues[1] describes further distributions of net license income. The UIC researchers have joint authorship status on scientific papers with developing country scientists, collectors, and indigenous informants who have made appropriate scientific contributions. The technology transfer office generally does not manage copyright and data ownership rights. The sense of collaboration and mutual benefit is an imperative for the researchers, who see the success of their research program as generating mutual respect, consideration, and sharing based on fundamental ethical principles.

The original intent of the university-based trust fund model of benefit-sharing was to bridge the knowledge gap between the developed U.S. research enterprise for handling innovation, and the traditional-knowledge based systems of biodiverse regions such as Vietnam and Laos. The rationale for using this vehicle was to build an international forum for openly sharing knowledge of IP assessment, value, protection, and strategic management, as well as for funding of development projects in participating developing countries. However, the model took on connotations of imperialism, as a U.S. entity (UIC) was originally proposed to run it. The label *trust fund* seemed to trigger this, along with UIC lead management. Therefore, UIC later focused on the new contract model and abandoned the university-based trust fund. Vietnam and Laos have created trust funds or foundations in which to deposit income that may be generated under the MOA or resulting technology commercialization. Goals of these organizations are to support biodiversity conservation, health, and economic development. By-laws and operational methods have been developed based on models set out by international conservation organizations. The Laos trust fund now makes grants to small communities, and is searching for further funding sources.

The first patent application based on the project was filed in 2007. The development of the model, has had a substantial impact on UIC's other natural product bioprospecting projects: a new template

agreement for such projects, completed in 2003, features enhanced revenue sharing for developing country research partners.

EXTERNAL FACTORS THAT AFFECTED DECISION MAKING

A number of considerations influenced the strategies and decision making of UIC and its partners. These include:

- need for cultivating a spirit of partnership, value, and mutual respect in bioprospecting
- need for building knowledge of IP systems in economies based on traditional knowledge
- desire to promote bioconservation
- need to deal with accusations of biopiracy on the part of industrialized nations
- desire to seed self-sustainable economic development

KEY LESSONS LEARNED AND HEALTH-ACCESS ISSUES

The following items represent key lessons from UIC's biodiversity project, which may be applicable to other companies that aim to utilize traditional knowledge and biological resources:

- Industrialized nations' ideas of publication, work-product ownership, confidentiality, data ownership, and knowledge ownership cannot be presupposed to be operating in developing countries.
- Mutual respect, benefit, and value require trust and give and take, and need time to cultivate. Misplaced expectations of short-term returns on bioprospecting projects may arise in negotiations; such returns are, in practice, long term (at least 10 to 15 years) and successful therapeutic products are, in fact, extremely rare.
- Improved scientific collaboration, enhanced research infrastructure, improved household economies of participating communities, and advances in bio-conservation and education are the more realistic returns on bioprospecting projects. ■

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1 Soejarto DD, C Gyllenhaal C, JA Tarzian Sorensen, HHS Fong, LT Xuan, LT Binh, NT Hiep, NV Hung, TQ Bich, BM Vu, BV Southavong, K Sydara, JM Pezzuto and MC Riley. 2007. Bioprospecting Arrangements: Cooperation Between the North and the South. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.