InnovationMatters

Consulting Editor: **Terry A. Young**

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July 15, Volume 1 Issue 4



# InnovationMatters

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## THE NEWSLETTER

*InnovationMatters*
is a twice-monthly electronic newsletter designed for managers of innovation and technology transfer around the world, as well as the attorneys and other service firms that support the innovation industry.

*InnovationMatters*
identifies, selects and reports relevant and current news, resources and events in innovation management, and includes one or more original papers describing best practices.

## WHO WE ARE

Technology Innovation Group, Inc. (TIG) is a group of internationally recognized experts that assists individuals, institutions, companies and communities to convert technology to wealth. TIG also creates and builds community and regional wealth through entrepreneurship, incubation, technology-based economic development and technology commercialization.

www.techingroup.com

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## Japan Overhauls Higher Education System

On July 9, the Japanese Diet enacted a set of bills that implements the broadest changes in the country's higher education system since World War II. Under the new laws, the country's 89 national universities will operate as independent administrative institutions beginning in April 2004, eliminating the civil service status of approximately 125,000 faculty members. Other reforms include greater fiscal responsibility on each campus, reduction in the number of faculty members, creation of professional graduate schools, and the merger of several campuses. The reforms also will affect technical colleges as well as private universities receiving government subsidies. The impact of the legislation on the nation's technology transfer system and the Japanese TLO Association remains to be seen.
[Source: Chronicle of Higher Education, July 11, 2003]

## Software Patents Vote Delayed in European Parliament

A proposed vote expected during the last week of June on a controversial software patents proposal in the European Parliament has been delayed until at least September 2003, amid criticism that the legislation would result in a US-style system that would be detrimental to European small businesses and open-source software developers. EU member states currently have different criteria for accepting the validity of software-related patents, a situation that the proposed legislation would remedy. For a news feature on the delay see: http://news.zdnet.co.uk/story/0,,t269-s2084931,00.html
For the proposed legislation: http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcedureView?lang=2&procid=5974

## India and U.S. Sign Historic Biotech Agreement

The Indian Department of Biotechnology (DBT) and the United States Agency for International Development (USAID) executed an agreement on June 27th to establish formal research collaboration in agricultural biotechnology. Research will focus upon drought, nutritional improvements, and plant traits that are controlled by several genes. The DBT and USAID will promote public-private partnerships to establish common research facilities, and to identify and implement specific research projects in functional genomics. The goal of the collaboration is to boost food security, economic growth, nutrition and environmental quality. The agreement specifies that India will remain free to change or amend its guidelines on biosafety and intellectual property rights, in line with its national legislation. This agreement marks the first formal long-term collaboration between the two countries in crop biotechnology. http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=888&language=1

***The goal of the collaboration is to boost food security, economic growth, nutrition and environmental quality.***

## China Provides Tax Exemptions to Science Communicators

Organizations that promote science communication are now exempt from import duties, value added tax (VAT) and sales taxes under new legislation adopted in China in June. Organizations now exempt from the taxes include publishers of scientific and technological publications, as well as science museums, planetariums, and laboratories in colleges and research institutions that regularly open their doors to the public. This new law marks the first time that the country has implemented a preferential tax policy to enhance public understanding of science. http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=893&language=1

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## European Innovation Manager (EIM) Profile Survey Underway

The Instituto Tecnológico de Castilla y León (ITCL, Spain) is coordinating a pioneer project in collaboration with other prestigious research centers in Germany, Romania, the U.K. and Spain to develop the European Innovation Manager (EIM) Profile. In addition, an accredited certification system for EIM professionals will be developed by 2005. An on-line poll now is open to solicit input to describe the knowledge base or background that an EIM professional should possess. See: http://www.itcl.es/proyectos/innoman (in Spanish language) or contact the project director, Dr. Javier Cebellos of ITCL at jceballos@itcl.es

## New Initiative to Research Neglected Diseases

Six eminent public research institutes from around the world have established a new organization – the Drugs for Neglected Diseases initiative or DNDi - to address the lack of R&D for drugs for neglected diseases. Only 10% of global health research is devoted to diseases that account for 90% of the global disease burden. DNDi's six founding partners are: the Indian Council of Medical Research (ICMR), the Organization Médecins Sans Frontières (MSF), the Institut Pasteur, the Kenya Medical Research Institute (KEMRI), the Oswaldo Cruz Foundation, and the Malaysian Ministry of Health. DNDi will seek to enhance R&D capacity in developing countries affected by the diseases. It was registered as a not-for-profit organization in Geneva on July 3rd. http://www.who.int/mediacentre/releases/2003/pr51/en/

## WIPO Survey of Intellectual Property Services of European Technology Incubators

This paper presents the results of a survey of intellectual property (IP) services offered to tenant firms in high-technology incubators in Europe. Issues addressed include: (a) the extent to which IP services are provided by incubators, (b) the range, type and modality of IP services provided to incubator tenants, and (c) reasons why SMEs and start-ups make inadequate use of the IP systems and services. The survey reveals that the majority of incubators (60%) has staff responsible for IP assistance and considers IP ownership either very important or quite important at the time of selecting tenants for the incubator (57%). While few incubators provide financial support for the application for IP rights, 40% provide assistance in-kind. The survey also indicates that the types of IP services offered by incubators to tenants vary significantly. Incubators often act as a "first line of support," and often rely upon external service providers for more specialized support. European incubators provide direct assistance with patent searches (90%) and assistance for negotiating licensing agreements (84%). http://www.wipo.int/sme/en/index.html?wipo_content_frame=/sme/en/documents/pdf/incubator_survey.pdf

## MAP-TN: Thematic Network on Best Practices for Multi Actors & Multi Measures Programmes

MAPs (Multi Actor and Multi Measure Programmes) are complex RTD funding programmes addressing not an individual firm or research institution but whole systems of innovation (e.g. science-industry co-operation). The main objective of the MAP-TN is to bring together managers,

***The knowledge gained over a two-year period will be codified in a handbook, called "RoadMAP".***

complementary organisations and policy-makers to exchange experience and to create common and codified knowledge on the specific challenges connected with the complexity of these programmes. The final aim is to advise the European Commission (EC) and other policy-makers and programme managers on good practice in MAP development, implementation and evaluation which would lead to increased efficiency of the whole RTD programme. The knowledge gained over a two-year period will be codified in a handbook, called "RoadMAP". Interim results are published in the monthly newsletter "NewsMAP". MAP-TN is financed by the EC within the 5th Framework Programme, and will run from 2002 until mid 2004. For more information contact birgit.baumann@tig.or.at or barbara.kunz@tig.or.at or see www.map-network.net

## World Bank Solicits Entries for "ICT Stories Competition 2003"

The World Bank is soliciting entries for its "ICT Stories Competition 2003," describing projects that use Information and Communication Technologies (ICTs) as tools for achieving economic development. The ICT Stories objective is to capture the learning process that accompanies the introduction and implementation of ICTs in projects in exemplary stories. Three winning stories will be selected. The writers of these stories will be given the opportunity to travel to Switzerland to present their findings at the World Summit on the Information Society in Geneva in December 2003, with an additional cash prize awarded to the winner whose project contributes most to poverty alleviation. The deadline for submission is September 26, 2003. For entry submission guidelines, see: http://www.iicd.org/stories/

## Egypt Ratifies Patent Cooperation Treaty (PCT)

Egypt has become the 121st contracting state of the Patent Cooperation Treaty (PCT); the Treaty will enter into force for Egypt on September 6, 2003. In any international application filed on or after September 6, 2003, applicants may designate Egypt (country code: EG). Egypt may also be elected for the purposes of international preliminary examination.

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## "Public Sector Intellectual Property Resources for Agriculture (PIPRA) Launched

A team of 14 universities and plant research centers, supported by the Rockefeller and McKnight Foundations, have formed the Public Sector Intellectual Property Resources for Agriculture (PIPRA), to overcome the intellectual property barriers that often block biotechnology developments. PIPRA seeks to establish new principles of public sector licensing of agricultural and biotechnology technologies, with contract terms – such as "humanitarian use" license provisions – that would assure that public research entities do not grant exclusive licenses to enabling technologies for projects that could benefit the developing world.

***PIPRA seeks to overcome the intellectual property barriers that often block biotechnology developments.***

PIRPA's three goals are:

- To prevent public research organizations from granting exclusive, worldwide intellectual property rights to a single company desiring the license for limited commercial use, instead reserving rights in the technology application in developing countries.
- To create a public database or clearinghouse for genes, proteins, traits, processes and other applicable discoveries.
- To combine various innovations into useful "packages," permitting "one-stop shopping" for potential users.

PIPRA has outlined a plan for implementation of the initiative over the next few months:

- Establish a board of directors.
- Develop a business plan for securing additional funds (the initial start-up funding from the Rockefeller and McKnight Foundations totaled $500,000).
- Recruit additional universities and research organizations to join the initial founding fourteen institutions.
- Identify a participating institution to donate space to house the organization.
- Hire staff, proposed at a level of four professionals with administrative support.

The website for PIPRA: http://www.pipra.org [cut and paste into browser]

[Sources: *SCIENCE*, July 11, 2003; *Chronicle of Higher Education*, July 11, 2003; *Washington Post*, July 10, 2003; *Wall Street Journal*, July 10, 2003; *New York Times*, July 10, 2003.]

## House Committee Reviews Technology Transfer at the NIH

On July 10, the House Energy and Commerce Health Subcommittee convened a meeting to review and take testimony regarding technology transfer at the National Institutes of Health (NIH). Issues up for consideration included:

- Does the federal government fairly recoup its investments in research at NIH?
- How would "reasonable pricing" requirements or other price control mechanisms in license agreements affect R&D and technology commercialization?
- Do technology transfer policies and practices of the NIH enhance the development of new products for public health?

A panel of government officials discussed NIH patent and licensing protocols, as well as efforts to assure a speedy drug approval process in the United States. Several university officials, including Jon Soderstrom of Yale University and Andrew Neighbor of UCLA, addressed the important role and benefits of NIH support and policies in enhancing university resources, advancing knowledge, and contributing to economic development. The prepared testimony of the witnesses is posted on the Subcommittee's website at: http://energycommerce.house.gov/108/Hearings/07102003hearing990/hearing.htm

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## New GAO Report Examines Impact of Federal Rights to Sponsored Inventions

On July 7, the General Accounting Office (GAO) released a new report, "Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions" (GAO-03-536).

GAO identified that the government uses its license rights in biomedical inventions under the Bayh-Dole Act primarily for research; few products commonly purchased by the government are claimed by federally sponsored patents. Furthermore, contrary to an interpretation of Bayh-Dole held by many universities, the GAO represents that the government is not entitled to price reductions on products that incorporate technology subject to Bayh-Dole. Rather, the GAO suggests that the government is not liable for patent infringement if it contracts with a third party to make a product for government purposes that incorporates a federally funded invention. However, GAO concedes that such right has never been exercised for biomedical inventions. Other conclusions of the report are equally valuable and important for universities and public research organizations that conduct research subject to the Bayh-Dole Act. The full report is available for download at: http://www.gao.gov/cgi-bin/getrpt?GAO-03-536

## NIH Interpretation of SBIR Regulations Eliminating Some Potential Applicants

A story in the *Boston Globe* on July 5th reported that the NIH is enforcing a decades-old regulation more strictly recently, eliminating some potential applicants from submitting proposals to the Small Business Innovation Research (SBIR) program. Created in 1982, the SBIR program is offered by 10 federal agencies to businesses with fewer than 500 employees, and granted $1.5 billion to 5,000 companies in 2002.

SBIR rules state that in order to qualify, the applicant must be at least 51% owned and controlled by "individuals." According to the Globe article, the NIH began this spring to disqualify applicant companies that were majority-owned by venture capital (VC) firms, as such firms were not "individuals." VCs and entrepreneurs suggest that the new interpretation is shutting off funding to the companies that have the best chance of success. Many biotech companies have represented that they are now prohibited from making application, even though they have received SBIR funding in the past. An NIH spokesman defended the agency as "administering the program in accordance with the directives from the Small Business Administration" (SBA). In response to appeals from companies and associations, the SBA has represented that it will review the SBIR regulations regarding this question.

***VCs and entrepreneurs suggest that the new interpretation is shutting off funding to the companies that have the best chance of success.***

[SOURCE: *The Boston Globe*, July 5, 2003, "NIH Rule Hits Some Bio-Tech Start-Ups," by Chris Gaither]

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**Click on the blue title to access each publication.**

## The E-Business Institute

The E-Business Institute is a new "virtual campus" offering free tutorials, workshops, educational resources, and business training and counseling tools to assist entrepreneurs with business start-ups. Developed by the U.S. Small Business Administration (SBA), the virtual campus offers 16 training categories with more than 70 interactive courses and electronic guides to provide educational tools and resources on entrepreneurship. The online format makes the SBA's business management resources available anytime and anywhere. The E-Business Institute also features a virtual library with more than 200 free E-books and publications, as well as links to other important resources.

## Venture Capital 101

This 70-page PDF book presents an introductory look at the world of venture capital, providing a framework for raising venture capital, and identifying the characteristics venture capitalists find attractive. The author, Bill Snow, seeks to close the "enormous gap between perception and reality" in the world of venture capital.

## The Disclosure and Licensing of University Inventions

This study by Richard Jensen (Notre Dame), Jerry Thursby (Emory University) and Marie Thursby (Georgia Institute of Technology), examines the relationships between the faculty, the technology transfer office (TTO), and the university's central administration in managing the disclosure and transfer of innovations with commercial potential. Based upon survey results, the study recognizes that the interests of the faculty and the objectives of the university may not always be congruent, and suggests the importance of balancing the two with the TTO serving as a "dual agent." Other findings:

- The disclosure and commercialization process is time-consuming and distracting to faculty, and it is often the "higher quality" or "most productive" faculty members that are least likely to become involved in the process.
- Many TTO directors consequently believe that the most commercially valuable innovations are never disclosed by faculty, and that many of the innovations disclosed are of low quality.
- Sponsored research funding was viewed as an important licensing outcome by faculty (75%), but less so by the university administration (48%) and TTOs (34%).
- Conversely, royalty income was seen as an extremely important outcome of the licensing process by 71% of TTOs and 69% of university administrators, but only by 41% of the faculty inventors.
- TTOs are more closely aligned with the interests of the university administration than the faculty, not surprising since the measures of success for the TTO typically are focused upon royalty income.
- Furthermore, emphasis upon income as the primary measure of success has resulted in TTOs focusing their efforts on inventions that require the least "time-to-market." This emphasis may discourage disclosures at the proof-of-concept stage, where the "higher quality" faculty members are more likely to report a discovery.

The findings raise the interesting question: can the technology transfer process be structured to better balance the interests of the university administration and the faculty; and if so, would greater success in commercialization be an outcome?

This study from the U.S. National Bureau of Economic Research (NBER) may be downloaded for $5, but is free to readers in many countries.

## WIPO Guide to Intellectual Property Worldwide

The World Intellectual Property Organization (WIPO) offers a valuable country-by-country on-line guide to the intellectual property systems of 219 countries.

## Valuation of Intellectual Property Assets

One of the most complex tasks in managing a company's or university's intellectual property rights (IPR) is placing a monetary value on the IPR assets. IPR valuation is an ever evolving skill in which different methodologies with varying degrees of complexity and effectiveness have been developed. To describe current methodologies used by technology transfer professionals, the WIPO has collected 17 presentations delivered at various WIPO seminars over the past six years on the subject of IPR valuation.

## New INSME Web Portal for Small and Medium Enterprises (SMEs)

The International Network for SMEs (INSME) has launched a valuable new web-based information portal or hub, representing a virtual platform for SMEs to share knowledge and experiences, exchange information and good practices, and find business partners, as well as initiate joint pilot projects for innovation and technology transfer.

## Cities and Communities that Work: Innovative Practices, Enabling Policies

Innovative cities do not just happen, they are fostered. This study by the Canadian Policy Research Network identifies seven "building blocks" to successful community-based innovation:

- Identification of one or more local champions of innovation
- Formation of institutional intermediaries
- A commitment to equitable participation
- A civic culture of creativity
- Provision of financial and technical resources by the community
- Robust accountability mechanisms
- Relevant indicators to benchmark progress

The paper presents 11 case studies from cities in Europe and North America, highlighting their commonalities and key differences as "drivers of the new economy."

## Tax Incentives for Research and Development: Trends and Issues

An increasing number of governments are offering special fiscal incentives to business to increase spending on research and development (R&D), with many redesigning their incentives to make them more productive in increasing investments in R&D. This study compares the generosity of R&D tax measures across member countries of the Organization for Economic Cooperation and Development (OCED), as well as presents various designs for tax incentives such as tax credit versus tax allowance, targeted incentives, and definitions of qualifying R&D.

## The Innovation Management Toolkit

The Innovation Management Toolkit produced by the Government of Canada is comprised of interactive, easy-to-use Internet-based tools to improve innovation in any organization, from business to academia. One of the most valuable features of the Toolkit is a "diagnostic" to access an organization's capacity for innovation, in such thematic areas as leadership, organizational culture and management of technology.

## A Tutorial on the Intellectual Property Regime of the Sixth Framework Programme

This tutorial outlines the intellectual property (IP) provisions of the model contract that participants in the Sixth Framework Programme will sign with the European Commission. All participants in the Programme will be required to execute contracts with the Commission having the standard IP terms set forth in this tutorial.

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# Biodiversity Research, Genetic Resources, and Traditional Knowledge: What Every Company And Institution Needs To Ensure Its Own Sustainable Development

*by Nancy Kremers*

***Nancy Kremers is an intellectual property lawyer and private consultant on traditional knowledge and biodiversity issues. With offices in Houston, TX and the Washington, DC area, she is an adjunct professor of law at George Mason University. She has served as in-house counsel in the international departments of two multinational corporations and as general counsel for an Internet company. Ms. Kremers holds a B.A. in International Relations from Stanford University, an M.S.F.S. and a J. D. from Georgetown University, and is currently completing her thesis on traditional knowledge and genetic resources for her LL.M. (Intellectual Property) from the University of Houston Law Center. Pleased to discuss traditional knowledge or intellectual property issues, she can be reached at nkremers@hal-pc.org.***

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Many private enterprises and academic institutions in industrialized nations today are heavily invested in exploring diverse applications for new genetic material and associated traditional knowledge gleaned from indigenous societies around the world. Much of this material and knowledge is obtained, directly or indirectly, from less developed countries that may be technology-poor but rich in biological diversity. Potential commercial applications cut across many economic and business sectors, and active research efforts are now widespread in the biotechnology, pharmaceutical, agriculture, horticulture, cosmetics and personal care products, and food and beverage sectors. Indigenous people are attracting similar increased interest in their traditional cultural expressions (a subset of traditional knowledge), not just from anthropologists and social scientists at academic institutions, but also from executives seeking fresh material for the exploding digital entertainment industry.

## Evolution of Biodiversity Resource Management

This "new frontier" of scientific and creative material was long unregulated, sourced as it was in some of the most geographically and socially isolated parts of the world. Until very recently, genetic material and traditional knowledge were generally viewed as part of the "common heritage of mankind". Thus, it was considered freely available to anyone willing to go to the time and expense to obtain it.

Developing countries' increased awareness of the value of intellectual property rights, though, began to change this view. Communications growth and raised consciousness among indigenous peoples concerning their own human rights and self-determination have markedly affected the political and legal climate in countries controlling much of this material. No longer viewed as a global resource, genetic material and traditional knowledge are now legally considered the exclusive property of the nations in which they originate, and are subject to national and local regulation of ownership, access, and use.

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Enforcement of the Trade-Related Aspects of Intellectual Property (TRIPs) Agreement and the Convention on Biological Diversity (CBD) has lent international legal legitimacy to this change in philosophy, and most international dialogue about best practices in research and development of these resources now proceeds wholly from this standpoint. While the United States has not yet ratified the CBD, it is a signatory; and most government and industry participants in biodiversity research agree that it is only a matter of time before ratification occurs.

**A Shift in the Biodiversity Research Paradigm**

A permanent paradigm shift has occurred.[1] It is one that private enterprise and academic institutions alike would be wise to accept—and indeed embrace –if they plan to engage in continued research using any of this material. While the shift may not yet be fully recognized or accepted by U.S. industry and government, it is widely acknowledged outside America, and foreign institutions and enterprises are moving ahead with research and business plans based on these new parameters.

This ownership paradigm shift has brought about changes in other research parameters as well. Scientists and researchers can no longer afford to isolate themselves as they have in the past from ethical, legal and social issues connected with their study subjects. Instead, they—and their companies and institutions at home –must develop a detailed understanding and awareness of the issues, people, and ecology interconnected with their particular objectives. They must plan to invest substantial time and effort into establishing and maintaining good long-term relationships with those who own and control the raw material. A collaborative approach with local participants toward common goals and interests, rather than the typical hierarchical power relationships of the past, must be envisioned and nurtured from the earliest conceptual stages of any research project, or it will never reach fruition in today's climate.

Unfortunately though, at the same time field personnel are facing these increased multidisciplinary demands on their time and talents, they often also feel conflicting pressure to specialize and narrow their skills, and to compete for scarce research funding within their sponsoring institutions, whether private or public. They may not feel they have the time, money or ability to focus on relationships and issues they view as tangential to their main objectives. In today's research climate though, field personnel must be aware of all potential commercial applications of their research as early as possible, and they must be equally familiar with international, national and local legal constraints governing their activities.

Smart companies and home institutions will not underestimate the value of "soft" components, such as social and ethical ramifications, to the ultimate success of their biodiversity-related research projects. Management can no longer operate from a distance in "purely technical" projects such as scientific observation or sample collections efforts. Because of the paradigm shift in ownership and control, home enterprises cannot safely assume that scientific field personnel will appropriately notice and handle the complexities of the governmental, intermediary, local and community relationships now necessary to any successful biodiversity research project. At the same time, scientists and other field personnel need a source of practical guidance when new legal or ethical issues arise in the field (as they now inevitably and frequently will) that must be immediately addressed without benefit of direct home office communication. Enlightened corporate and institutional leadership will realize that field personnel in today's biodiversity research environment need greater guidance and participation from the home office to ensure optimum project growth.

**Protocols for Research:**
**Code of Ethics and Practical Guidelines**

Every academic institution and commercial enterprise must establish a code of ethics and practical guidelines specifically tailored to its biodiversity research projects. While all companies and institutions have a general mission statement, and those involved in scientific research often also have written research protocols, most

have not thought much about their meaning, except as general aspirational goals, nor have they consistently applied them to day-to-day operations. To successfully navigate the legal and social labyrinth of today's biodiversity paradigm however, research protocols in the form of clear ethical rules and understandable practical guidelines have become a necessity for corporations and academic institutions alike.

Clear policies should be drafted to reflect the unequivocal intent of all parties to comply with CBD and national law provisions concerning access to biodiversity resources. They should specifically address:

- The scope of research activities and biodiversity resources covered by the policy;
- Acknowledgment of the institution's obligation to obtain prior informed consent of owners or custodians (at all levels—national, regional, local and indigenous community) before acquiring or using any genetic resources or traditional knowledge (including traditional cultural expression) connected with the research project;
- Acknowledgment of the institution's obligation and intent to share equitably any results and benefits of the research project with the contributors of biodiversity resources, including knowledge resources;
- Acknowledgment of the institution's intent to respect the rights of contributor local communities concerning dissemination and use of contributed biodiversity resources;
- Title to contributed resources, resultant research, and any associated intellectual property;
- Commitment to sustainable sourcing and conservation of biodiversity resources;
- Periodic reporting on protocol implementation, through establishment of objectively verifiable use indicators; and,
- Commitment to long-term implementation and continuous review and revision of ethical codes and best practice guidelines.

Issues that should be specifically addressed in connection with prior informed consent include: 1) ensuring that full disclosure of known and foreseeable commercial uses of the resource material is made to all resource contributors, 2) requiring that resource contributors supply the researching party with appropriate proof of ownership and legal capacity to make their contributions to the project, 3) ensuring that full discussion, understanding, and agreement by all parties is reached concerning the eventual publication, ownership, use and dissemination of research results and associated or derived intellectual property; and 4) identifying and agreeing upon junctures during the research project at which renewed discussion of issues (1)-(3) will recur, ensuring that consent remains knowing and informed as the project evolves.

Issues that should be specifically addressed in connection with equitable benefits-sharing include: 1) identifying a range of monetary and non-monetary benefits to be shared, 2) timing of the sharing of benefits of various types, 3) identifying the range of parties with whom benefits should be shared (national governments, local communities, local research and educational institutions, non-governmental organizations, etc.), 4) a disclosure of origin of contributed material (including traditional knowledge) in patent and other intellectual property applications arising out of the research project, and 5) using materials transfer agreements that embody, among other things, the agreed resolution of prior informed consent and benefits-sharing terms between parties to the research project.

Drafting codes of ethics and guidelines for best practice in research procedures gives a company or institution a golden opportunity not just to become familiar with the international and national laws shaping the biodiversity research environment today, but to directly affect the enlightened evolution of those laws, since current industry practices are closely monitored by legislatures considering drafting laws in this area. The experience should be viewed in-house as a long-term process, rather than a short-term task to be performed, since, even though a code of ethics and guidelines will be disseminated within a reasonable time, the protocol needs to be continuously monitored, revised and perfected over time for optimal effectiveness.

The process should begin with appointment of one or more persons whose time will be allocated specifically to creating an initial draft of a protocol, consisting of a code of ethics and a set of best practice guidelines. The guidelines may be categorized into "must", "should follow", and "may follow" terms if desired. Hiring outside consulting expertise in the voluminous law and literature of biodiversity resources is often a cost-effective way to initially organize the protocol drafting, but outsiders should ALWAYS work closely with in-house personnel to ensure an end product appropriate to the enterprise.

Once an initial draft is written, it should be circulated for comment internally among management and field personnel, and then revised to incorporate relevant comments. After the first revision, it should be circulated again, this time both internally and to outside counsel and appropriate representatives of the biodiversity communities in which major research is planned or is ongoing. This process encourages internal personnel education on the legal and ethical issues, as well as discussion of the practical realities and legal requirements in major field locations. It also facilitates communication among a variety of participants, fosters a sense of corporate/institutional sensitivity to community needs, and creates trust relationships.

Once the protocol is satisfactorily written and disseminated, it should be continuously monitored for implementation. Regular verification of use in the home office and field locations must be carried out. The protocol should also be subjected to regularly scheduled review and revision, based on comments systematically gathered from in-house users and resource contributors. In this way, a company or academic institution is most likely to develop a protocol that really does reflect best practices in its particular area of research, one that can actually be used to minimize conflict with contributor nations. This, of course, cannot help but favorably affect the enterprise bottom line.

**Protocol Models**

One of the difficulties of drafting a research protocol is that it cannot be effective unless tailored to the specific type of research at issue. While many different sets of research protocols exist, no single protocol is currently accepted by all sectors involved in biodiversity research activities. Difficulties also arise when research projects are funded or developed jointly by academic institutions and commercial enterprises. (One alternative, in this scenario, is to draft a two-tier protocol: the first tier applicable in any purely "academic" phase of research, with the second tier kicking in as soon as potential commercial applications are envisioned). But in any event, every company or institution setting out to draft its own protocol can benefit by considering some of the major protocols in use among various organizations today.

Most important among these are the Bonn Guidelines (Decision VI/24) on access and benefits-sharing related to genetic resources, promulgated by one of the CBD working groups and available on the CBD website at www.biodiv.org. (It is important to recognize that this set of guidelines is intended to apply only to non-human genetic material.) The World Intellectual Property Organization has also made available through its website, in the traditional knowledge (global issues) section, a large amount of material useful to understanding the general intellectual property issues in genetic resources and traditional knowledge. This material also includes a database of contract clauses for agreements on access and benefits-sharing of biodiversity material. The WIPO material relevant to these issues may be found at www.wipo.int/globalissues.

Other important and illustrative protocols, which may serve as templates for writing corporate or institutional protocols include:

- International Society of Ethnobiology—Code of Ethics (1998) and Guidelines for Research, Collections, Databases and Publications (draft, 1998)
- The Manila Declaration Concerning the Ethical Utilization of Asian Biological Resources (1992)
- Shaman Pharmaceuticals—Agreement of Principles (1995)
- Glaxo-Wellcome—Discovering New Medicines from Nature: Policy for the Acquisition of Natural Product Source Materials (1992)

- Council for International Organizations of Medical Sciences (CIOMS)—International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)

A list of other protocols may be found at the Oxford University website program for traditional resource rights at http://users.ox.ac.uk/~wgtrr/decin.htm. And last, but far from least, two books which are particularly helpful in gaining an overview of these issues are Beyond Intellectual Property, by Darrell Posey and Graham Dutfield (1996) and Biodiversity and Traditional Knowledge, edited by Sarah Laird (2002).

## Endnote

[1] Sarah Laird has most succinctly discussed this well-recognized shift in the collection of essays she edited and recently released, Biodiversity and Traditional Knowledge (2002). Some of the ideas in the present article are based on her extensive and expert overview of developments in research protocols in the traditional knowledge area.

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## JULY 2003

"AUTM Western Regional Meeting"
**Association of University Technology Managers (AUTM)**
Santa Fe, New Mexico USA
July 20-22, 2003

"Technology Management for Reshaping the World"
**Portland International Conference of Management of Engineering (PICMET '03)**
Portland, Oregon USA
July 20-24, 2003

"AUTM Central Regional Meeting"
**Association of University Technology Managers (AUTM)**
Kansas City, Missouri USA
July 27-29, 2003

NEW "KCA 2003 Annual Conference: Spotlight on Commercialisation"
**Knowledge Commercialisation Australasia (KCA)**
Canberra, Australia
July 30-August 1, 2003

## AUGUST 2003

NEW "Fundamentals of Sponsored Project Administration"
**National Council of University Research Administrators (NCURA)**
Anchorage, Alaska USA
August 4-6, 2003

NEW "Fundamentals of Sponsored Project Administration, Level Two: Critical Issues in Research Administration"
**National Council of University Research Administrators (NCURA)**
Anchorage, Alaska USA
August 4-6, 2003

"Knowledge Management: 3rd Int'l Conference on Knowledge, Culture and Change"
**RMIT University**
Penang, Malaysia
August 11-14, 2003

"2003 University/Industry Conference: Enhancing the Partnership in a Global Economy"
**National Council of University Research Administrators (NCURA)**
San Francisco, California USA
August 17-19, 2003

"TechEnterprise 2003"
Far West & Mid-Continent Regional Meeting
**Federal Laboratory Consortium**
Honolulu, Hawaii USA
August 18-21, 2003

"1st International Mobile IPR Workshop: Rights Management of Information Products on the Mobile Internet"
**Helsinki Institute for Information Technology (HIIT)**
Helsinki, Finland
August 27-28, 2003

"ACU Annual Conference: Universities Engaging with their Communities"
**Association of Commonwealth Universities (ACU)**
Queen's University Belfast, Belfast, UK
August 31-September 4, 2003

## SEPTEMBER 2003

NEW "Third Andean Congress on Informatics Law"
**Alpha-REDI and National University of San Marcus**
Lima, Peru
September 3-5, 2003

AUTM Courses: (i) Basic Licensing, (ii) TOOLS and (iii) Startup Business Development
**Association of University Technology Managers (AUTM)**
Baltimore, Maryland USA
September 7-9, 2003

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"13th Global IntEnt Conference"
**Internationalizing Entrepreneurship Education and Training (IntEnt)**
Grenoble, France
September 8-10, 2003

"2003 Annual Conference"
**Association of University Research Parks (AURP)**
Vancouver, British Columbia
September 10-12, 2003

"Entrepreneurial and Small Business Development Strategies Workshop"
**International Economic Development Council (IEDC)**
Cincinnati, Ohio USA
September 11-12, 2003

"Clusters, Industrial Districts and Firms: The Challenge of Globalization"
**Faculty of Economics, University of Modena and Reggio Emilia**
Modena, Italy
September 12-13, 2003

"2003 Annual Conference: Advancing Economic Development in the 21st Century"
**International Economic Development Council (IEDC)**
Cincinnati, Ohio USA
September 14-17, 2003

"TII Summer School"
**Technology Innovation Information (TII)**
Portugal
September 15-19, 2003

6th Global Conference "Innovative Clusters-A New Challenge"
**The Competitiveness Institute**
Gothenburg, Sweden
September 17-19, 2003

**NEW** "Building Management Support for Technology Transfer"
Southeast Regional Meeting (SEFLC)
**University of Florida Continuing Education**
Charleston, South Carolina USA
September 17-19, 2003

"Open Meeting on Good Practices"
**Business Innovation and Growth from the Exploitation of Academic Research (BIGEAR)**
Vienna, Austria
September 18-19, 2003

"2003 International Conference on Communities & Technologies"
**Communities & Technologies, and University of Amsterdam**
Amsterdam, The Netherlands
September 19-21, 2003

"Golden Opportunities: 2003 Annual Meeting"
**Licensing Executives Society (LES), USA and Canada**
San Diego, California USA
September 21-25, 2003

"Global Aspects of Technology Transfer: Biotechnology"
**Gordon Research Conferences**
Big Sky, Montana USA
September 21-26,2003

"The Emerging Technologies Conference at MIT and TR100 Awards"
**Technology Review: MIT's Magazine of Innovation**
Cambridge, Massachusetts USA
September 24-25, 2003

"Concepts, Experience and Visions"
**The German Association of Business Incubators and Technology Parks (ADT)**
Berlin, Germany
September 28-30, 2003

## OCTOBER 2003

"Revitalizing Rural Economies"
**Rural Community College Alliance**
San Antonio, Texas USA
October 6-8, 2003

"2003 Cleveland Clinic Medical Innovation Summit"
**The Cleveland Clinic Foundation**
Cleveland, Ohio USA
October 7-9, 2003

"Innovation and Learning in a Globalized World, Experiences of Developing Countries"
**Eindhoven Centre for Innovation Studies (ECIS)**
Eindhoven, The Netherlands
October 10, 2003

"Research Management Conference 2003"
**Australasian Research Management Society (ARMS)**
Auckland City, New Zealand
October 13-15, 2003

"Technology Transfer East Seminar"
**Licensing Executives Society (LES)**
Boston, Massachusetts
October 16-17, 2003

"2003 SRA International Annual Meeting: Building Bridges of Knowledge"
**Society of Research Administrators International (SRA)**
Pittsburgh, Pennsylvania USA
October 18-22, 2003

"NAMTAC Fall Conference"
**National Association of Management and Technical Assistance Centers (NAMTAC)**
Albany, New York USA
October 19-21, 2003

"7th Annual Conference on Emerging Issues in Business and Technology"
**College of Business and Technology, Western Illinois University**
Myrtle Beach, South Carolina USA
October 30 – November 1, 2003

"2003 Fall Institute"
**National Business Incubation Association (NBIA)**
Smithtown, New York USA
October 22-24, 2003

"eChallenges e-2003"
**European Commission and the Information Society**
Bologna, Italy
October 22-24, 2003

"Academic Conference on Entrepreneurship in Latin America"
**Center for Entrepreneurship, Universidad Adolfo Ibanez**
Vina del Mar, Chile
October 26-28, 2003

## NOVEMBER 2003

"Innovations in Early Stage Investing"
**National Association of Seed and Venture Funds (NASVF)**
Baltimore, Maryland USA
November 2-5, 2003

"NCURA's 45th Annual Meeting"
**National Council of University Research Administrators (NCURA)**
Washington, DC USA
November 2-5, 2003

"EPIDOS Annual Conference and PATINNOVA 2003"
**European Commission and European Patent Office**
Luxembourg
November 10-12, 2003

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NEW "Networking for Excellence Conference"
**Forum for European-Australian Science and Technology Cooperation (FEAST)**
Canberra, Australia
November 13-14, 2003

"What Do We Know About Innovation?
A Conference in Honour of Keith Pavitt"
**Science & Technology Policy Research, University of Sussex**
Brighton, UK
November 13-15, 2003

NEW "EARMA Training 2003:
Effective Negotiations"
**European Association of Research Managers and Administrators (EARMA)**
Karlsruhe, Germany
November 27-28, 2003

## DECEMBER 2003

NEW "EARMA Training 2003:
Successful Presentations"
**European Association of Research Managers and Administrators (EARMA)**
Karlsruhe, Germany
December 1-2, 2003

NEW "EARMA Training 2003:
International Project Management"
**European Association of Research Managers and Administrators (EARMA)**
Karlsruhe, Germany
December 4-5, 2003

"AUTM Graduate Course"
**Association of University Technology Managers (AUTM)**
San Diego, California USA
December 4-7, 2003

NEW "World Summit on the Information Society"
**Government of Switzerland**
Geneva, Switzerland
December 10-12, 2003

## FEBRUARY 2004

NEW "2004 Winter Meeting"
**Licensing Executives Society (LES), USA – Canada**
San Francisco, California USA
February 11-13, 2004
*Call for Papers: Presentation Proposals due September 9, 2003*

## MARCH 2004

8th Annual Meeting:
"Education that Works: Invention, Innovation, and Entrepreneurship in Practice"
**National Collegiate Inventors & Innovators Alliance (NCIIA)**
San Jose, California USA
March 18-20, 2004
*Call for Papers: Abstracts due September 12, 2003*

## APRIL 2004

"Changing Collaboration between Government, Industry and University"
**International Association of Management of Technology (IAMOT)**
Washington, DC USA
April 3-7, 2004
*Call for Papers: Abstracts due October 15, 2003*

NEW "EARMA Training 2004:
Effective Negotiations"
**European Association of Research Managers and Administrators (EARMA)**
Karlsruhe, Germany
April 5-6, 2004

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7006 Firewheel Hollow
Austin TX 78750 USA