as a means for the expropriation of indigenous and traditional knowledge, and the push for access to information for biodiversity conservation and biotechnology development could be seen as a threat to the commons of indigenous and traditional peoples that could potentially lead to even further loss of control and increased misappropriation.

The UNU-IAS report on "The Role of Registers and Databases in the Protection of Traditional Knowledge"[6] examines both the strengths and limitations of registers and databases for protecting traditional knowledge, and proposes the possibility that databases holding traditional knowledge should assume a voluntary trust arrangement that treats all traditional knowledge as being held on behalf of indigenous peoples. The report highlights the "Catch 22" position whereby indigenous peoples are required to have their knowledge registered in the public domain to prevent biopiracy, but in doing so lose control over its subsequent use.

Revising the concept of public domain

The dominant discourse on public domain tends to present a view that there is only one public domain. A contrasting view however, may be proposed based upon the experience of aboriginal peoples in Australia who have their own systems for sharing knowledge governed by specific customary law and practice. This leads to a proposal that there is not one, but rather a number of different, overlapping public domains or knowledge-sharing spaces – each defined according to a range of national, international, or community laws and practices. Indigenous peoples, for instance, have knowledge-sharing spaces that have served many purposes, including the conservation of information, knowledge, and biological and genetic resources. These spaces allow for access to relevant information subject to compliance with specific cultural norms and practices, which may differ from those applicable under national or international law. Information shared freely within one knowledge-sharing domain may be shared subject to certain constraints on subsequent use; such sharing does not, therefore, necessarily imply an intention that the relevant information should become a part of the global public domain.

It is increasingly clear that we need to revisit the notion of "the public domain". Examples such as the Peruvian "Protection Regime for the Collective Knowledge of Indigenous Peoples Derived From Biological Resources" and the South Pacific proposed model law on traditional knowledge directly challenge the belief that traditional knowledge is the common heritage of humankind, and cannot be protected after it has fallen into the public domain. These experiences demonstrate nascent attempts to develop appropriate mechanisms to secure traditional knowledge rights so that further loss of control and misappropriation cannot continue, and so that biodiversity conservation can continue in a fair and equitable manner.

1 See the NatureServe Explorer database at http://www.natureserve.org/explorer/ and the World Bird Database at http://www.birdlife.net/datazone/.
2 See http://www.iabin.net/english/bioinformatics/databases.shtml.
3 Elizabeth Longworth, "The Role of Public Authorities in Access to Information: The Broader and More Efficient Provision of Public Content," *Infoethics 2000*, p. 5, UNESCO.
4 Stephen Brush, "Bioprospecting the Public Domain," *Cultural Anthropology* 14 (4):535-555, 1999.
5 Tulalip Tribes of Washington, *Statement by the Tulalip Tribes of Washington on Folklore, Indigenous Knowledge and the Public Domain July 09, 2003,* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Fifth Session, Geneva, July 15-17, 2003.
6 Available online at http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf.

Access Regimes and Intellectual Property Rights: Exploring the Interface for Drug Research

By Padmashree Gehl Sampath

Advancing the discussion on the interface between access regimes and intellectual property rights requires focus on questions of legal and institutional design at the national level, and calls for positioning of bioprospecting strategically within broader challenges in the area of intellectual property protection, drug R&D, and public health.

The policy interface between access regimes and intellectual property rights has been amongst the hardest to resolve in the debate regarding the relationship between the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Convention on Biological Diversity (CBD). This is due in part to the polarization of issues amongst countries, and in part to the overarching impact of intellectual property rights (IPR) on most issues within bioprospecting. Among the main aspects of this interface that have received widespread attention in the past decade are:

- the limitations of an IPR-like *sui generis* right for protection of traditional knowledge;
- the potential of IPR to undermine benefit-sharing with local and indigenous communities;
- the documentation of traditional knowledge as "prior art" to prevent its undue appropriation;
- the viability of a certification system to trace the origin of genetic resources and/or traditional knowledge; and
- the inter-relationships between IPR and sustainable use and conservation of genetic resources.

Avid controversy on the interface between access regimes and IPR has ensued in various international forums, with several organizations (such as the World Intellectual Property Organization (WIPO), the Conference of the Parties to the CBD, and the World

Trade Organization) actively involved.[1] Whereas some of these issues require multilateral consensus and are being considered in the context of the international access and benefit-sharing (ABS) regime (as discussed in other articles herein), other issues in the access-IPR interface need to be sorted out at the national level. Therefore, moving the discussion on resolving the interface forward requires that countries focus on questions of legal and institutional design at the national level, and that they position bioprospecting as one activity within broader science and technology policy needs of developing countries in the health sector.

In this context, two sets of thematic issues assume importance:

- Which issues need to be resolved at the national level, such that national access regimes and IPR on drug-related products can be designed in a compatible way, in order to achieve the objectives of the CBD?
- How can countries use national access regimes and bioprospecting venues strategically to deal with broader challenges in the area of intellectual property protection, drug research and development (R&D), and public health?

Making access regimes and IPR more compatible for drug research

The experiences of several host countries, both in enacting legal frameworks and in concluding bioprospecting contracts, show that defining and enforcing rights in isolation from the drug discovery and development process can result in a failure to realize the economic potential of bioprospecting for sustainable development and biodiversity conservation. A process-oriented perspective that helps to achieve consensus about appropriate rights' definitions and institutional structures for access and traditional knowledge is one of the most important prerequisites for resolving many of the frictions between access regimes and IPR. Some of the main questions that can be answered through such a perspective are:

- What kinds of knowledge holdings exist in the case of traditional medicinal knowledge at the local levels, and what are their contributions to modern drug R&D?
- Does IPR present a viable option for protecting them?
- Can bioprospecting create sufficient incentives for conservation of genetic resources (and if so, under what circumstances)?
- Under what circumstances do discovered medicinal values lead to unsustainable use, and what kinds of legal solutions can solve this problem best?
- How can countries negotiate for technology transfer in return for access to genetic resources, and under what circumstances will this help build local capacity?

Recent UNU-INTECH work deals with many of these questions. A forthcoming book, *Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit Sharing,* employs an interdisciplinary law and economics methodology to derive optimal property rights structures and institutional mechanisms for regulating bioprospecting for drug research. The focus of the analysis is on the economics of contracts in the drug discovery and development process, using genetic resources to show that the rights exchanged at each stage of the process are complementary. The thrust of the argument is that attempts to define and enforce the rights on access to genetic resources and traditional knowledge in isolation from the drug discovery and development process (and the IPR therein) result in a failure to realize the economic potential of bioprospecting for both sustainable development and biodiversity conservation in host countries. These analytical results are substantiated by examples of bioprospecting collaborations in several countries, and a critique of the institutional and contractual factors that led to their success or failure.

A UNU-INTECH technology policy brief on "Some Interrelationships Between the TRIPS Agreement and the Convention on Biological Diversity"[2] also looks at questions of positive versus defensive protection of traditional knowledge, technology transfer and the CBD, and future directions pursuant to Paragraph 19 of the Doha Declaration on the TRIPS Agreement and Public Health.

Bioprospecting in the context of broader health sector needs of developing countries

Recent literature and policy negotiations have underscored the need to look at bioprospecting as one activity within the broader health sector needs of developing countries, for several reasons:

- Bioprospecting as a new source of medicines and the promise of benefit-sharing from the international drug industry have, unfortunately, found little corroboration in the past decade. Although natural products continue to be a promising source of new drugs (see Newman et al., 2003)[3], the legal uncertainty surrounding the process and the availability of other techniques in the drug discovery process have both contributed to a hiatus in large bioprospecting collaborations.
- The public health crises in many developing countries, caused by diseases like HIV/ AIDS and malaria, have focused attention on the impact of stronger IPR regimes on affordable access to medicines and alternate ways of building local capacity, at least to boost local manufacturing capabilities.[4]
- The large-scale reliance on traditional medicine for health care in developing countries (discussed in the article on page 27) also calls for exploring ways of strengthening these systems within developing countries for reasons of enabling better local health facilities rather than for the promise of "benefit-sharing".

The last two factors, in particular, call for a more proactive stance in developing countries in order to promote innovation in the health sector.

UNU-INTECH has initiated several research projects to explore the intellectual property-innovation-development nexus in the health sector, and to suggest concrete policy interventions to developing countries on how to boost local technological capacity. The UNU-INTECH project on Health for Development is a comparison of the efficiency properties of alternate IPR instruments that have been proposed to foster R&D into neglected diseases (such as patent pools, prizes, and a global research fund), with a strong emphasis on the potential of building local capacity as a solution. It employs a national systems of innovation framework to survey local capacity in pharmaceutical biotechnology in two Asian and three African countries (Bangladesh, India, Nigeria, South Africa, and Zambia) to suggest concrete policy options for building local capacity.

The recently concluded UNU-INTECH project on the Nigerian (Bio)pharmaceutical System of Innovation, taken up on the initiative

of the Nigerian National Biotechnology Development Agency, similarly surveys the Nigerian sectoral system of innovation in pharmaceutical biotechnology to propose policy interventions. UNU-INTECH has also conducted research on (bio)pharmaceutical systems in Cuba, Egypt, Ghana, India, and Taiwan to demonstrate different pathways to building local capacity in this sector for developing countries. These studies are intended to be published as part of a forthcoming book on bioprospecting.

1 Various decisions of the Conference of the Parties to the CBD have dealt in great detail with aspects of the interface between access regimes and IPR. WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore also has been actively involved in this area. More recently, Paragraph 19 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/1) instructs the TRIPS Council to examine the interrelationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore, apart from other new developments that may emerge from the implementation of Article 71.1 of the TRIPS Agreement.

2 Available online at http://www.intech.unu.edu/publications/technology_policy/tpb_v3_02_2004.pdf.

3 David J. Newman, Gordon M. Cragg, and Kenneth M. Snader, "Natural Products as Sources of New Drugs over the Period 1981-2002," *Journal of Natural Products,* Vol. 66 (2003), pp. 1022-1037.

4 The Doha Declaration on the TRIPS Agreement and Public Health and the 30 August decision of the WTO on implementation of Paragraph 6 of the Declaration deal with allowing countries that have no local manufacturing capabilities to make use of compulsory licensing as contained in Article 31 of the TRIPS Agreement. This has been followed by extensive debate on how local manufacturing capabilities can be built, at least within a select group of least developed countries.

The Role of Customary International Law in Governance of Human Cloning

By Chamundeeswari Kuppuswamy, Darryl Macer, Mihaela Serbulea, and Brendan Tobin

Efforts at the UN to develop a convention banning human reproductive cloning have failed. Instead, a non-binding declaration was adopted. As a result, research into human cloning will likely continue, and birth of the first cloned human may be only a matter of time. UNU-IAS research examines the ethical basis for a ban on cloning and the status of customary international law in this area.

One of the most highly controversial and emotive issues in the global bioethics debates is the issue of cloning of human embryos. Since the cloning in 1997 of the first mammal (a sheep named Dolly), there have been numerous cases of animal cloning in about 10 species of mammals. Animal cloning has brought with it both the pros and cons of human cloning. Ethical concerns related to the uncertainty of scientific outcomes, and issues of individual identity and human dignity, are at the heart of a wide consensus in the international community on the need to ban reproductive cloning, at least in the short term.

There are, however, a growing number of countries – along with numerous scientists and patients' groups – who insist on the merits of what is known as "research" or "therapeutic" cloning. Many believe research cloning holds the possibility of cures for millions of people suffering from various conditions such as Alzheimer's disease, spinal cord injury, and diabetes mellitus.

Debate on these issues has found its way to the UN, where there has been extensive discussion on the need for an international convention on cloning. Although widespread consensus for the banning of reproductive cloning appeared to exist, lack of unanimity on research cloning led to a stalemate – as a result of which, plans for a convention have been shelved. A compromise solution proposed by Italy led to the adoption of a non-legally binding UN Declaration on Cloning in early March 2005.

The Declaration, adopted following a divisive vote, has been the subject of severe criticism from a number of angles; in particular, use of the term "human life" is seen as an attempt to prescribe all forms of cloning activity. The failure of negotiators to overcome ideological and ethical differences provides maverick scientists, determined to clone human embryos, with an opportunity to seek out countries that d not ban reproductive cloning in order to carry on their experiments. At the moment, only a limited number of countries have banned cloning. The impasse at the UN, therefore, makes it almost inevitable that research on cloning of human embryos will continue.

Research carried out at UNU-IAS examines the distinction between reproductive and research cloning and gives an overview of the ethical arguments relating to each. A preliminary report based upon this research notes that the apparent consensus on the need to ban reproductive cloning is, in part, based upon concerns regarding the state of technological capacity and not merely upon ideological and religious or other moral objections to cloning per se. The report argues that obtaining the consensus necessary to adopt a binding legal instrument to ban reproductive cloning may prove more difficult in the future as technology advances and the risks of harm and deformities decrease.

A UNU-IAS study has identified an emerging principle of customary international law supporting a ban on human reproductive cloning, which may strengthen the basis for international efforts to prevent such activities in the absence of a binding international instrument. However, failure to adopt a binding convention will be argued by some to be evidence that there is insufficient international consensus to support claims for the existence of a customary ban of reproductive cloning.