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Overview

This document is based on a forthcoming book that examines issues in bioprospecting and the search for useful biochemical compounds and genes in nature. Bioprospecting has been the focus of international negotiations for more than a decade, yet the debate on the terms for access to genetic resources, traditional knowledge and benefit-sharing is far from settled.

This is one of the first books to address the contractual complexities of bioprospecting for drug research and is thus a key text for policy makers, practitioners and scholars in the areas of law, economics, ethnobotany, anthropology and environmental sciences.

Policy Brief written by
Padmashree Gehl Sampath

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Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit-Sharing

This policy brief summarizes the main arguments and conclusions of a forthcoming book by United Nations University Press, which examines the regulation of bioprospecting for drug research from an interdisciplinary law and economics perspective. Bioprospecting was once touted as a promising opportunity for collaborative ventures in biotechnology-based research and development (R&D) between the genetic resources-rich South and the technology-rich North, especially in the case of drug research. However this promise has yet to materialize. Understanding why this is so is a central policy question for countries in the South that wish to leverage their biodiversity endowments in the development process.

A new book, authored by Padmashree Gehl Sampath (UNU Press, 2005), examines optimal property rights structures and institutional mechanisms for regulating bioprospecting for drug research. Focusing on the economics of the contracting process, it shows that the rights exchanged at each stage of drug R&D based genetic resources are complementary to one another. Therefore, if they are to realize the potential of bioprospecting for sustainable development and biodiversity conservation, source (developing) countries need to ensure that their attempts to define and enforce rights for access to genetic resources and traditional medicinal knowledge are not isolated from the drug R&D process.

The Issues Raised by Multi-Level Regimes and Contrasting Country Agendas

The Convention on Biological Diversity, 1993 (hereafter, CBD), provides a good starting point for a constructive dialogue on the roles and responsibilities of users and providers in bioprospecting. Several provisions of the CBD bear an impact on how bioprospecting frameworks should be designed, two of the most significant ones being Articles 15 and 8(j). Article 15 recognizes the rights of national governments to regulate access to genetic resources situated within their territories, while Article 8(j) recognizes the rights of indigenous and local communities on their traditional knowledge, innovation and practices.

But regulating bioprospecting at the micro level is not a simple task. In reality,

countries are torn between the provisions of the CBD and the Agreement on Trade Related Aspects of Intellectual Property Rights, 1995 (hereafter, TRIPS Agreement), on the one hand, and conflicting political interests on the other. As a result, national attempts to regulate bioprospecting have largely been tardy, incomplete and unsuitable for addressing the complexities of drug R&D based on genetic resources. The creation of enabling bioprospecting frameworks at national levels has also been complicated by continuing international negotiations on several aspects of bioprospecting. These include an international regime on access and benefit-sharing, and the inter-relationships between intellectual property rights, genetic resources and traditional knowledge. It is hardly surprising, therefore, that drug companies pressured by legal uncertainties and unrealistic expectations of benefit-sharing are exploring alternative technologies rather than using natural products for drug R&D.

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How Can a Law and Economics Framework Help Explain These Issues?

Legal rules can be seen as incentives that influence all decisions of parties in certain socially desirable ways. Therefore, a systematic law and economics approach, when applied to bioprospecting, helps predict which property rights' options can out-do the others for the rights to access and traditional knowledge and also help design optimal regulatory frameworks for bioprospecting contracts.

Legal and economic literature on bioprospecting

Existing legal literature on bioprospecting has largely dealt with questions of TRIPS-CBD interface in bioprospecting. Alternatively, it has focused on presenting arguments to support the interests of one or the other rights holder/ stakeholder groups in the bioprospecting process, for instance, the communities, firms or source countries. While this has led to suggestions on different property rights' options for both the right to access and traditional knowledge, the literature has largely neglected the underlying economic exchange processes within which these rights have to operate. Economic literature on the topic is fragmented, and focuses on specific aspects of the debate – such as the valuation of genetic resources, and the conditions under which bioprospecting can provide a market-based incentive for biodiversity conservation – but it does not have a holistic approach to the debate. As a result, it is not possible to integrate these results into legal policy making in a meaningful way.

The strengths of an interdisciplinary approach

The laws and institutions for bioprospecting are the key mechanism for attaining the right balance between economic efficiency, and the goals of the CBD and the TRIPS Agreement vis-à-vis the terms and conditions for the exchange of access and traditional knowledge rights.

The main rights that are exchanged in the drug R&D process based on genetic resources, and that need to be enforced through national bioprospecting frameworks, are rights over tangible genetic resources (including rights to regulate access vested in national governments and private property holders on whose property the genetic resources may be situated), and rights on traditional knowledge and intellectual property rights on R&D findings and marketable products. Options proposed for access include a user-based fee, a user tax, and an umbrella property right, whereas options for traditional knowledge include a system of traditional resource rights, community intellectual property rights, trade secrets and know-how licenses.

At present, there is an absence of process-oriented information on how the drug industry makes use of traditional knowledge and genetic resources, and how this affects the incentives of parties to use, trade or undertake research on genetic resources. Under these conditions it is not possible to decide upon the best property rights' option that best fits genetic resources and traditional medicinal knowledge, and the contractual needs of all parties.

Incorporating economic use processes into the analysis helps in two ways. First, it helps test the viability of one form of property rights' structure over another. As a result it is possible to answer the larger question generated by the multitude of national approaches in this area: Are there so many effective ways of regulating one and the same activity, namely bioprospecting? Two likely scenarios are possible: either all these institutional mechanisms are similar in matter and content, or they only look similar but, content-wise, there are certain key differences that affect their efficiency properties. Second, it helps predict optimal contracting between the parties, for instance, access authorities, traditional knowledge holders, owners of tangible genetic resources and firms.

The book analyzes optimal property rights and contractual structures for bioprospecting for both the pharmaceutical and botanical sectors, taking care to highlight the differences in intellectual property protection issues, traditional medicinal knowledge aspects and biodiversity conservation issues between the two sectors at every stage.

Major Challenges of Enabling Bioprospecting Frameworks in Source Countries

Developing countries face several challenges in enacting an effective regulatory framework for bioprospecting.

1. Reconciling the policy conflict between the TRIPS Agreement and the CBD

Contrary to the widely held view, there is no direct legal conflict between the provisions of the TRIPS Agreement and the Convention on Biological Diversity on the question of bioprospecting. Much of the controversy surrounding Article 27(3)(b) of the TRIPS Agreement (on patents on life forms) and Articles 15 and 8(j) of the CBD (on rights of countries to regulate access and rights of local and indigenous communities on their traditional knowledge) is a consequence of the vague wording of these provisions and the contrasting interpretations amongst various groups of countries intent on pursuing their individual interests. Countries need to recognize this and build consensus in the main spheres of interaction between intellectual property rights, biotechnology, and biodiversity *in order that* national bioprospecting frameworks can set out the rules and responsibilities of users and providers in access and traditional knowledge laws in an optimal way. With regard to bioprospecting, the right to access is the more significant law for two main reasons. First, traditional knowledge is optional for

Padmashree Gehl Sampath is a Researcher at the United Nations University Institute for New Technologies (UNU-INTECH) Maastricht, The Netherlands. Her research specialisation is in biotechnology, with a particular emphasis on pharmaceuticals/health and other issues relating to the global protection of intellectual property rights in developing countries. She has consulted to the WHO Commission on Intellectual Property, Innovation and Health, UNCTAD, the European Commission, and the German Government.

firms that wish to bioprospect for drug research, but access to genetic resources is the *sine qua non* of such an endeavor. Second, a detailed analysis of the CBD clearly reveals that the access authority is potentially best placed to achieve many of the CBD's objectives with respect to sustainable use and conservation as well as the representation of indigenous and local communities. But this might not be a realistic option in practice due to regulatory limitations, capacity deficits, transparency and accountability issues and political instabilities in developing countries.

2. Understanding the consequences of lack of property rights/ badly defined property rights on bioprospecting contracts

The bioprospecting market is not a competitive market with efficient resource allocation. It is characterized by various transaction costs or imperfections that affect contracting possibilities between access authorities, local and indigenous communities and intermediaries or firms. The drug R&D process within which both traditional medicinal knowledge and tangible genetic resources play a role has its own economic properties and limitations. These include high levels of risk, uncertainty and high up-front investments. In addition, traditional medicinal knowledge is an informational good, and therefore poses several problems in the design of efficient contracts. Both tangible genetic resources and traditional knowledge have to be contracted in a complex process, amongst partners with differing expectations and risk preferences. All these factors impose transaction costs on parties at each stage of the contracting process that stall or hinder the bargaining procedures. Many of these can be eliminated through well-defined property rights on access and traditional knowledge. Well-defined property rights lead to contracts that achieve three main goals: (a) incorporation of all values that users associate with the resource (potentially, even cultural and spiritual values) into the market price of the resource being traded (b) competitive bargaining conditions so that no one party has an advantage in the negotiation process, and, (c) lack of external effects on third parties or society, such as biodiversity depletion. Such contracts that provide an environment for mutually beneficial exchange with fair distribution of benefits can only be enabled through well-defined property rights that are enforceable in a transparent and accountable regulatory framework.

> Applying CBD provisions … out of context has encouraged consistent ignorance of the complexities of biotechnology-based drug research and sustainable development, and the conservation needs of source countries."

3. A sui generis intellectual property right on traditional medicinal knowledge

A well-defined right on traditional medicinal knowledge is one that is clearly based on the contribution that such knowledge can make to modern R&D processes and biodiversity conservation, and identifies a clear set of beneficiaries who can enforce the right. Emphasizing the nature of the information itself serves as the best parameter to map the limits of "community/communities" and to determine the types of knowledge that ought to be protected and made contractible through an intellectual property right. When viewed as part of the cumulative innovation process in drug research, traditional medicinal knowledge can have two distinct contributions. When used as a tool to select genetic resources, it can serve as the starting point of drug research, or in other cases (especially in the botanical sector), it can even be the main information on which a drug is based.

These contributions of traditional medicinal knowledge to drug research, substantiated by evidence from the pharmaceutical and botanical sectors as well as investigations of ethnobotany and ethnopharmacology, make the case for a narrower definition for traditional knowledge that confines it to ethnobotanical knowledge. A narrower definition also helps to clearly demarcate communities with distinct identities.

Two main incentive effects accrue from such a definition: the incentive to keep the knowledge pool in its entirety and the incentive to reveal valuable information. Additionally, if communities are given a right to restrict access to territories occupied by them in combination with the right to ethnobotanical knowledge, it can also encourage them to conserve *in situ* biodiversity. In this regard, the two most appropriate forms of protection for the right are trade secrets and community intellectual property rights.

This does not mean, however, that knowledge falling outside the purview of ethnobotanical knowledge should not be protected. In fact, similar exercises should be conducted in the case of traditional agricultural knowledge vis-à-vis agricultural biotechnology, traditional folklore vis-à-vis the music industry, and so on, so that well-contoured and enforceable rights can be derived.

4. Rights to regulate access to genetic resources

In the case of the right to access, there are two important questions that need to be addressed. First, under what circumstances can regulation of access be justified for purposes of bioprospecting? Second, under what conditions is it worthwhile for the source country to set up a costly institutional apparatus, as the CBD expects, in order to regulate access to genetic resources for bioprospecting?

Access regulation for bioprospecting can be justified only when externalities can be proven to result from drug R&D based on genetic resources. For this to happen, a clear-cut link needs to be established between marketable products in the drug industry, their R&D/ production process, and the unsustainable use of genetic resources. Furthermore, unless genetic resources have a positive economic value beyond conservation of species that call for such investments to enable scientific or commercial bioprospecting, the costs that source countries have to incur in setting up access institutions may be too high.

The analysis in the book shows that there are conditions under which there is a clear link between externalities in biodiversity use and the drug R&D/ production process. It also clearly sets out the conditions under which potential revenues from bioprospecting in the pharmaceutical and botanical sectors can be high enough to offset the costs that source countries have to incur in setting up access institutions. An individual transferable quota (ITQ) system has been proposed as the appropriate rights' structure to regulate access to genetic resources and its advantages over other proposed forms in the literature have been presented.

5. Contractual facilitation through the national access authority

Well-defined rights over traditional medicinal knowledge and access is the first step in exploiting the potential of bioprospecting for sustainable development and biodiversity conservation in source countries. The onus is on source countries to design institutions that will put these rights into an enforceable framework. In the case of traditional medicinal knowledge, regulatory institutions will have two major tasks irrespective of the intellectual property right option chosen: that of representing the communities effectively and of providing contractual rules that take into account the difficulties of dealing with information as a resource. Several checks and balances should be put in place to minimize problems between communities (the principal) and the access authority (the agent) in bioprospecting contracts. These have been dealt with in detail in the economic analysis in the book.

Access institutions have a critical role to play in providing contractual mechanisms to parties to deal with information asymmetries (differences in information levels amongst the various parties to bioprospecting contracts). Access institutions can help signal the quality of genetic resources and ethnobotanical knowledge within a country, and also screen for contract-worthy firms. When access institutions add value to *in situ* genetic diversity by creating inventories of genetic resources, and investing in ethnobotanical databases to clarify the interface between ethnobotanical knowledge and modern drug research, they can facilitate better bargaining conditions amongst parties.

If bioprospecting were to be one single strategic agreement between the end-developer drug firm, the access authority and the community, all parties would make relation-specific investments. All the property rights held by these parties have strong economic complementarities. For optimal incentives to invest in bioprospecting, there should be an *ex ante* bundling of these rights through a bioprospecting contract. The analysis in the book also predicts the conditions under which the bundled rights will satisfy the aims of conservation, fair benefits and efficient bioprospecting simultaneously, and who the owners of this bundle should be.

Key Policy Insights

National bioprospecting frameworks that meet the needs and expectations of both providers and users of genetic resources and traditional medicinal knowledge require that a number of issues are urgently addressed.

1. Effective policies and institutions

Source countries should focus on enacting effective laws and institutions for bioprospecting that take into account the economic realities of the drug R&D process, and clearly balance the needs and expectations of all right holders and stakeholders involved. Although the laws may by themselves not necessarily increase a transaction's legal certainty, an environment of uncertainty created by inadequate laws and badly defined property rights' structures is a great incentive for genetic resource users to go elsewhere or to choose options other than those that employ bioprospecting

2. Viewing bioprospecting as part of wider health care

Several issues faced by developing countries in the area of drug research and health care provision are inter-linked. These include low technical and institutional capabilities, a lack of access to affordable medicines and an inadequate public health infrastructure. The extravagant expectations of source countries on the potential of their "green gold" has ignored the fact that benefit-sharing in bioprospecting contracts can be used to address some of their public health and capacity-building issues in a systematic way. This needs to be revisited.

Key considerations for developing countries in this regard include:

- Devising strategies to leverage access to proprietary knowledge and capacity development assistance that suit their local innovation systems and health care needs best.
- Recognizing that while bioprospecting can provide some solutions, its potential application will vary greatly across countries.
- Understanding that the use of partnering and liaisons to negotiate for leg space at international forums must be balanced by the recognition that source countries are operating in a competitive environment as suppliers of genetic resources and traditional knowledge. Thus source countries need to offer incentives to firms to invest if they are to harness the true potential of these resources.

3. Harnessing bioprospecting collaborations to boost local traditional medicine

According to recent studies, an estimated three billion people world-wide, most of whom live in developing countries, rely on traditional medicines for their health care. A major focus of source countries in bioprospecting should be to use its potential to enhance the efficacy and reach of their local traditional medicinal systems to benefit local populations. In order to achieve this, sustainable capacity-building programs in developing countries need to be based on detailed surveys of their internal scientific and technological capacities, policy frameworks, patterns of linkage in the economy and much more. Gaps identified in internal scientific and technological capabilities can thus be filled up through international alliances and collaborations, including those in bioprospecting.

4. Options for leveraging international negotiations

Whereas the continuing negotiations for an international system on access and benefit sharing, which include a system of certification going on under the Conference of Parties to the CBD are a very important step, such an international system can have its own limitations. These limitations have to be adequately recognized and supplemented in national frameworks. For instance, an international system of certification can only help when firms apply for patents on their products, and therefore it is likely that a vast majority of botanical medicines that are protected as trade secrets will not be covered by such a system.

Without keeping in mind the complexities of the economic exchange process, the achievement of goals like new medicines, and recognition and benefit-sharing for the communities, the conservation of biodiversity and positive economic effects for developing countries from genetic resources will remain an elusive goal. Every actor in this process, be it communities, drug firms or governmental authorities from source and user countries has to be aware of the fact that high short term profits in an imperfect legal framework is sub-optimal to the long-term collaborative drug R&D option.

Bioprospecting is not a panacea, it is only one solution to the health care problems faced by developing countries.

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INSIDE:

Policy Brief

"Regulating Bioprospecting"

Analysis of policy options and institutions to regulate the search for new drugs based on genetic resources, and to share the benefits equitably.

United Nations University Institute
for New Technologies
Keizer Karelplein 19
6211 TC Maastricht
The Netherlands

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Institute for New Technologies

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