REGULATING BIOPROSPECTING

Institutions for Drug Research, Access and Benefit-Sharing

Padmashree Gehl Sampath

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United Nations
University Press

TOKYO • NEW YORK • PARIS

Contents

1

Bioprospecting for drug research: An overview

Introduction

Biodiversity prospecting or *bioprospecting*, which refers to the process of looking for potentially valuable genetic resources and biochemical compounds in nature (Eisner, 1991; Ried et al., 1993), is not a new phenomenon. Both natural products and traditional knowledge have contributed extensively to drug research for several centuries now. Aspirin® (derived from Willow Bark used as a painkiller), Reserpentine (from the Indian Snake Root for hypertension), D-tubercurarine (from arrow poisons used as a muscle relaxant in surgery), Artemisin (derived from *Artemisia Annua* or the Quinhaosu used as an anti-malarial agent), and Vincistrine and Vinblastine (derived from Rosy Periwinkle used as anti-cancer drugs) are some frequently cited examples of drugs discovered from natural products.

But in recent times, the increased use of natural products and traditional medicine in drugs, and the sizeable market revenues associated with such use, has renewed focus on their role in pharmaceutical drugs and botanical medicines. Enhanced market prospects have been accompanied by concerns on how the benefits are to be shared from such commercialization activities, the potential impact of the growing use of natural products in the drug industry on sustainable use and conservation of genetic resources, and the implications of this industrial activity on capacity building in developing and least developed countries.

Against these concerns, the recognition of the rights of national governments to regulate access to genetic resources (Article 15) and the rights of indigenous and local communities on their traditional knowledge, innovation, and practices (Article 8(j)) under the Convention on Biological Diversity (1993) was championed as the starting point of a fruitful discourse on the roles and responsibilities of users and providers in bioprospecting for drug research and development (hereafter, R&D).

But just over a decade after the Convention on Biological Diversity (hereafter, the CBD or the Convention), the interest in bioprospecting as a source of new drugs seems to be waning. Developing countries, which were so optimistic of making a headway into the biotechnology era through their genetic resources, are caught up with problems of enacting enforceable national regimes on access to genetic resources and traditional knowledge. With international negotiations continuing on several issues that affect bioprospecting – such as an international regime to govern access to genetic resources, a certification system to prove source of origin of genetic resources, and traditional knowledge – the legal situation too is in a constant state of flux. Drug companies, stuck between the choice of exploring newer, more promising technologies and using natural products for drug R&D amidst legal uncertainty and potentially unrealistic benefit-sharing expectations, are seemingly choosing the former option. According to recent reports, major companies such as Monsanto and Bristol-Myers Squibb have shut down their natural products divisions entirely, while Merck has discontinued collaboration with INBio of Costa Rica after a last grant of US$130,000 in 2001 (Dalton, 2004b: 599). Many other large drug companies have scaled back on bioprospecting and depend on smaller biotechnology companies for natural products-related services (Dalton, 2004a: 576).

Regardless of international mandates within the CBD and other international agreements such as the Agreement on Trade Related Aspects of Intellectual Property Rights, national laws on bioprospecting that define property rights on genetic resources and traditional knowledge and prescribe rules of contracting are the most critical factors to enable bioprospecting in a balanced way. This book is an investigation into optimal property rights structures and institutional mechanisms that can facilitate the process of bioprospecting for drug research while balancing the goals of optimal drug R&D with the diverse demands placed by recognition of rights over traditional knowledge and access to genetic resources, benefit-sharing, and biodiversity conservation. Using an interdisciplinary law and economics methodology, the focus of the analysis is on the economics of contracts in the drug R&D process using genetic resources, to show that the rights that are exchanged at each stage of the process are complementary to one another. Therfeore, attempts to define and en-

force the rights on access to genetic resources and traditional knowledge in isolation with the drug R&D process result in a failure to realize the economic potential of bioprospecting for sustainable development and biodiversity conservation in source 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.

International law and the politics of bioprospecting

The coming into force of the CBD in 1993 was largely welcomed for its paradigm shift from free and unilateral exchange (from the genetic-resources-rich South to the industrialized North), to a more restricted and increasingly codified exchange of genetic resources and traditional knowledge, where exchange was made conditional on several factors, the most important one being the sharing of benefits between users and providers (Etkin, 2003).

The text of the CBD, a global framework to regulate issues of sustainable use and conservation of biological diversity, is novel in the sense that it seeks to address the problem from both ecological and economic perspectives. Its main objective is the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the commercialization of genetic resources (Article 1). Identification of rights on access to genetic resources, traditional knowledge and provision for benefit-sharing are to play a role within this broader scheme. Yet, these provisions impose ''fragile obligations'' on drug companies to ensure that exchange of genetic resources and associated traditional knowledge occurs in a context where providers are guaranteed equitable returns (Hayden, 2003: 1). But the CBD's biggest shortcoming is that it ''lacks contextualization to local ecopolitical circumstances and its integration across local, regional, commercial and environmental frontiers has been lax'' (Etkin, 2003).

The vagueness of mandates contained in the CBD have posed major hurdles in reaching consensus on optimal national legal frameworks for bioprospecting. Not only have policy dialogues on the meaning and import of these provisions been polarized amongst countries of the South and the North, but they have also been rendered more complicated by the Agreement on Trade Related Aspects of Intellectual Property Rights (1995) (hereafter, the TRIPS Agreement), an annex to the Agreement that created the World Trade Organization. The TRIPS Agreement, which deals with aspects of intellectual property protection, has brought to the fore issues pertaining to the interaction between intellectual prop-

erty rights on results of drug R&D and access, traditional knowledge, and benefit-sharing provisions of the CBD. As a result, regulation of bioprospecting has proceeded with an ignorance of the complexities of biotechnology-based drug research, the challenges in leveraging both genetic resources and traditional knowledge, and the need for a comprehensive approach to promote local capacity in developing countries in this regard (see for example, Miller, 1997; UNCTAD, 2000, 2001).

Access and traditional knowledge: Different stakeholder interests

The ongoing debate over what form the mandates on access and traditional knowledge ought to assume at the national levels, and how these should be reconciled with the provisions of the TRIPS Agreement, reveals different levels of interests involved in bioprospecting.[1] At the supra-national level, there is the overall global long-term interest in conserving genetic resources and related traditional knowledge as laid out by the CBD. At the national level, there are the interests of the source countries in regulating access and ensuring that the benefits accruing from commercialization of traditional knowledge are shared with its indigenous and local communities and those of user countries in ensuring efficacious access to genetic resources. Source countries' interests are further split between conservation of biological diversity and ensuring that benefits for the use of genetic resources and traditional knowledge are shared with the holders of these resources. The interests of indigenous and local communities, to be consulted in the rule-making process for access and benefit-sharing in order to ensure that the use, exchange, and benefit-sharing aspects respect their customary laws and institutions, act at the local level. But an interest permeating through all these levels that cannot be neglected is that of the scientific research and international trade which depends on proper and reliable access to genetic resources and traditional knowledge-based information. The design of successful legal instruments for the protection and realization of the economic potential of genetic resources and traditional knowledge depends on the way the first three levels of interests are balanced with the needs of drug R&D.

Stakeholder lineage has conditioned different perspectives on whether countries can reconcile their obligations under the CBD and the TRIPS Agreement to cater for issues of conservation, sustainability, and equity simultaneously.[2] Each one of these stakeholder perspectives presents simplistic interpretations of complex policy issues (Svarstad, 2000). Although several other categories of stakeholders can be delineated (see for example, Hayden, 2003), at a broad level three main perspectives operate. There are those who believe that countries can reconcile their

obligations between the TRIPS Agreement and the CBD to their advantage. There are others who feel that such contracts will serve the short-term profit goals of firms more and neglect impending issues of conservation of biodiversity and equitable benefit-sharing with indigenous and local communities. Some others feel that the difficulty in negotiating such contracts is the main reason why the goals of conservation and equity will not be attained. These different perspectives depend on the stakeholder interests that parties represent and their ability (or inability) to balance their interests with the restrictions placed by the drug R&D process itself.

The ''biopiracy'' perspective

Shiva defines biopiracy as a process by which the rights of indigenous cultures to their genetic resources and associated traditional knowledge are replaced by monopoly rights of those who exploit these resources (Shiva, 1997: 31). The biopiracy view finds its basis in arguments of neo-imperialism, where bioprospecting is depicted as one of those processes that supports the usurpation of resources and knowledge of indigenous people by firms and other Western counterparts. ''Bad patents'' issued on uses of traditional knowledge such as Turmeric, Neem, and Ayahuasca (see Chapter 3) have been used by proponents of this perspective to make the case that intellectual property rights as propagated by the TRIPS Agreement contain a built-in bias against traditional knowledge and rights of indigenous communities. Stringent regimes for access and traditional knowledge have been seen as a major way of preventing such unfair enrichment.

The bioprospecting perspective

The ''bioprospecting'' perspective expresses optimism that through bioprospecting, all three objectives of the CBD – sustainable use, conservation of biological resources, and benefit-sharing – can be met. In this perspective, bioprospecting is seen a venue of revenue generation from potentially valuable traditional knowledge and genetic resources situated in the South. In the presence of well-designed laws and contracts, bioprospecting presents a ''win-win'' situation where benefits generated can be used for a range of purposes – improvement to livelihoods of indigenous and local communities, biodiversity conservation programmes and biotechnological capacity building (see, among others, Ried et al., 1993; Balick et al., 1996; Svarstad, 2000).

The sceptics

The category ''sceptics'' is self-explanatory to a large extent. The perspective is marked by large-scale scepticism of the impact of drug

R&D on creating incentives for biodiversity conservation in source countries (see, for example, Simpson, Sedjo, and Ried, 1996; Simpson and Sedjo, 2004). There is also a great deal of scepticism that the CBD and its unrealistic expectations on benefit-sharing may render drug R&D unprofitable.

Achieving clarity: The main issues

National bioprospecting frameworks have to create a balance between the promotion of R&D into new drugs or related products for consumers the world over, recognition of rights of traditional knowledge of indigenous and local communities, conservation of local biodiversity, and possibly harness other potential positive economic effects of such contracts, such as local capacity building.

But split between the various stakeholder perspectives, there is still a pervasive lack of clarity on fundamental issues of relevance to bioprospecting frameworks. The main issues that still need to be resolved are as follows:

Subject Matter: The nature and scope of countries' rights to regulate access to genetic resources, and how they should be reconciled with the rights of private property owners and the rights of holders of traditional knowledge are not at all clear. Assuming that the *sui generis* right on traditional knowledge should be an intellectual property right, there is confusion on what the subject matter of the right should be. There needs to be a systematic attempt to clarify the information categories that could be called ''traditional knowledge'' which list the plausible contribution of respective traditional knowledge categories to collaborative research precisely. Rights structures for traditional knowledge should be decided upon based on these categories.

Identification of Beneficiaries: Associated with the above-mentioned issue is the issue of identification of beneficiaries. How should benefits that accrue from access to genetic resources be split between the national government, private holders of genetic resources, and holders of traditional knowledge? Should the right to traditional knowledge be defined as broadly as possible in order that as many communities as possible are included, or should it be defined in accordance with the needs of the process of which it is a part (e.g. R&D).

The Issue of Biodiversity Conservation: It is widely acknowledged that a key reason for the recognition of countries' rights to regulate access to genetic resources is biodiversity conservation. Yet what the main functions of the right to access are, and how these can be performed to complement national biodiversity strategies, is still relatively unexplored. The same can be said of the link between revenues generated through the

regulation of access to genetic resources and biodiversity conservation. Article 8(j) is also titled *in-situ* conservation. The nature of the contribution that the grant of rights on traditional knowledge could have on *in-situ* conservation efforts of communities, and the institutional mechanisms that could foster them, are also not clear.

Specific Attributes and Implementation Mechanisms: The attributes of the rights to access and traditional knowledge vary from country to country. The different features reveal a lack of clarity (or disagreement) on critical features such as the duration of the rights, implementation mechanisms and nature of overlap between these two rights themselves, and between the rights to access and traditional knowledge and other rights in the drug R&D process.

The need for a process-oriented approach to policy making

Ultimately, how rights to traditional knowledge and access should be defined depends less on the text of the CBD or the extent of flexibility allowed in the TRIPS–CBD interactions, and more on the structure of the drug industry, the economic exchange between the various actors in the R&D process, and how best these rights cater to the contractual needs of the actors.

In contrast to the simplistic view that considers bioprospecting to be a one-shot contract between the end-developer drug firm, the national access authority, and the community that possesses traditional knowledge, in reality there seem to be very few cases where large firms approach source countries directly for access. Genetic resources and traditional knowledge, wherever applicable, are sourced through a variety of channels – private individuals, specialized agencies, firms, or even botanical gardens – all of whom render such services for varying rates (Laird, 1993). Making huge upfront payments is also not the general rule due to the rampant uncertainty inherent in drug research.

Large-scale neglect of the economic exchange processes within which the rights over access and traditional knowledge have to operate have led to extremely bureaucratic and unrealistic laws that mostly view bioprospecting contracts as single strategic agreements. Such laws, which reflect neither the complexity of the contracts nor of the drug R&D process, act as a major disincentive for interested parties to explore the potential of bioprospecting.

In reality, the contract that each actor in the R&D process would like to sign is a reaction to various market imperfections and incentive problems in the market for bioprospecting. National laws and institutions for bioprospecting are key mechanisms for attaining the right balance be-

tween economic efficiency, the TRIPS Agreement, and the goals of the CBD vis-à-vis the terms and conditions for the exchange of genetic resources and traditional knowledge.

In the absence of process-oriented information on how the drug industry makes use of genetic resources and traditional knowledge, and the economics of the use process and how it may affect incentives of parties to use, trade, or conduct R&D on genetic resources, it is not possible to decide upon which property rights allocations suit the needs of the resources and the needs of the contracting parties best.

Therefore, any analysis of optimal property rights allocation for bioprospecting has to start with the drug R&D process. Incorporating the economic use processes into the analytical framework not only helps predict the optimal legal framework to regulate access and traditional knowledge, it also helps test the viability of one form of property rights structure over another. Using this, one can also answer the larger question that the multitude of national approaches to regulate bioprospecting raises: can there be many effective ways of regulating one and the same activity – namely, bioprospecting. Either these institutional mechanisms are all similar in matter and content, or they only look similar but, content-wise, there are certain key differences that affect their efficiency properties, or, finally, they are different but these differences do not matter.

Book structure and organization of chapters

To be able to predict property rights structures that can outdo others in regulating bioprospecting, the analysis begins with the stages of the drug R&D process, the parties involved, and the rights that are exchanged at every stage. Chapter 2 looks at the structure of the industry, the various actors involved, and the precise role of traditional knowledge and genetic resources in drug R&D. The exercise is to explain, from a user perspective, what these resources are worth to the drug R&D process and the contractual aspects relevant for their exchange.

Taking this as the vantage point, Chapter 3 is an analysis of the main legal provisions of the CBD and TRIPS Agreement that affect bioprospecting. The legal and political reasons that divide countries on questions of interpretation of the key provisions in both agreements are highlighted. This chapter tries to separate the main legal policy conflicts from the political controversies on bioprospecting. By doing so, the chapter shows that when the rights on access to genetic resources and traditional knowledge are considered in conjunction with the limitations that the CBD itself places on their nature and context, the main legal controver-

sies regarding their scope and context can be resolved to a large extent. The chapter also derives key legal conclusions for operationalizing the rights to access and traditional knowledge at national levels.

Optimal legal frameworks for bioprospecting that balance the needs of the R&D process and all stakeholder interests in order to foster sustainable collaborations between communities, access authorities, and firms will require taking market realities into account in a comprehensive way. Chapter 4 is an investigation into the market imperfections in drug R&D based on genetic resources. Owing to the fact that the drug R&D process is a long and risky one involving costs and investments at each stage, these contracts are essentially incomplete.[3] The imperfect market conditions between the various actors that have to exchange these property rights create a series of transaction costs that stall or hinder the bargaining procedures. The role of law in such a market is to provide a set of default rules that facilitate optimal contractual arrangements to deal with risk-sharing and distribution of benefits, as well as the right incentives for mutual collaboration and biodiversity conservation by clearly laying down the bargaining thresholds. This would mean not only a framework of well-defined and enforceable property rights, but also appropriate institutional arrangements that provide for the optimal conditions for the exchange of these property rights through contracts. Chapter 4 analyses these market imperfections using transaction cost economics and the economic theories of contracting. Whereas several of the market imperfections enumerated in this chapter can be solved through well-defined property rights on traditional knowledge and access, many others call for institutional mechanisms that facilitate contracts.

Chapter 5 is a law and economics investigation into a well-defined and enforceable property right for traditional medicinal knowledge. Chapter 6 similarly deals with finding a precise definition of the right to access.

To show how the market imperfections related to asymmetric information and uncertainty can be solved through appropriate contractual structures, the latter half of Chapter 6 explores how access, through contractual facilitation, can help reduce these information asymmetry and uncertainty-related problems in bioprospecting contracts. Chapter 7 contains a summary of results and policy recommendations.

General usages in this work

Efficiency is used in the sense of maximizing the sum of producer and consumer surpluses minus environmental externalities of unsustainable resource usage. In this case, the producers are institutions involved in the R&D and drug production process, namely, pharmaceutical firms, in-

termediaries, research institutions, communities as holders of traditional knowledge, and the owners of natural resources (such as private holders, communities, or states). The consumer surplus is to be measured by the utility of the consumers the world over. The greater the number of medicinal products that can be made available at competitive prices and at better quality, the higher the utility of the consumers. Thus defined, efficiency has to take care of the wealth of every group involved, be it firms, countries, or local and indigenous communities minus the externalities generated by the entire process. If the legal rules enable contracting to take place under competitive conditions, then parties will get shares as part of the total surplus according to their respective contributions. Any inefficiency in the organization of economic activity represents an unrealized opportunity. In this definition of efficiency, distribution of surplus from economic activities plays a key role. Benefits have to be shared amongst each party that participates in the contracts, be it communities, source countries, firms, or other individuals, in accordance with their extent of contribution to the creation of contractual surplus. The contribution of any individual or group to the creation of surplus is measured by the productivity of their assets and/or efforts. Economic criteria of efficiency is also restricted by the rights that are granted. When rights are granted over certain assets, such as rights to traditional knowledge, access, or other forms of IPRs, efficiency demands that these rights are not exchanged without the permission of those in whom the rights are vested.

Biological resources and *genetic resources* are used as defined under Article 2 of the CBD.[4] In the analysis, wherever questions of conservation and sustainable use are discussed, it is done so in the broader sense of ''biological resources''. Access rights and traditional knowledge rights, as well as benefit-sharing issues, are discussed only for genetic resources.

Drug discovery/drug research and development is used interchangeably to denote the process of discovering, developing, and commercializing both pharmaceutical drugs and botanical medicines based on genetic resources (ten Kate and Laird, 1999).

Biotechnology denotes all technological applications that use biological systems, living organisms, or derivatives of living organisms used to make or modify products or processes for specific use (Article 2, CBD).

Source countries denote tropical countries that host genetic diversity and traditional knowledge.

User countries denote the industrialized countries that have the biotechnological capacities and have firms that are interested in accessing genetic resources and traditional knowledge for research purposes. Similarly, *User firm* implies any firm that is interested in using genetic resources or traditional knowledge for its R&D.

Notes

1. These categories are based on those identified by Biber-Klemm (1999: 7).
2. Svarstad presents two main discourses – bioprospecting and biopiracy (2000: 19). She notes that, ''Each of these discourses is constituted by a message, frequent uses of certain metaphors and ways of telling stories of specific incidents of bioprospecting. A common feature, however, is that both proponents and opponents advocate values concerning the well-being of people and the environment in developing countries.''
3. In economic theory, contracts are ''incomplete'' when all the contingencies cannot be provided for in advance. Due to the transaction costs involved, ''the parties will quite rationally leave out many contingencies, taking the point of view that it is better 'to wait and see what happens' rather than cover a large number of unlikely eventualities'' (Hart, 1995: 21–24).
4. Article 2 of the CBD on Use of Terms defines ''Biological Resources'' to include genetic resources, organisms or parts thereof, populations, or any biotic component of ecosystems with actual or potential use or value for humanity. ''Genetic Resources'' means genetic material of actual or potential value.

United Nations University Press
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http://www.unu.edu

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United Nations University Press is the publishing division of the United Nations University.

Cover design by Mea Rhee
Cover illustration courtesy of the National Agricultural Library, United States Department of Agriculture

Printed in the United States of America

ISBN 92-808-1112-6

Library of Congress Cataloging-in-Publication Data

Sampath, Padmashree Gehl.
Regulating bioprospecting : institutions for drug research, access, and benefit-sharing / Padmashree Gehl Sampath.
p. ; cm.
Includes bibliographical references and index.
ISBN 9280811126 (pbk.)
1. Drugs—Patents. 2. Genes—Patents. 3. Drugs—Testing—Law and legislation. 4. Genetic engineering—Law and legislation. I. Title.
K1519.B54S26 2005
344.04′233—dc22 2005011337

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This book examines the optimal property rights structures and institutional mechanisms for regulating bioprospecting for drug research. Focusing on the economics of contracts, it shows that the rights exchanged are complementary at each stage of drug discovery and the development of genetic resources.

Defining and enforcing rights for access to genetic resources and traditional medicinal knowledge should not be attempted in isolation from the realities of drug discovery and development; otherwise the potential of bioprospecting for sustainable development and biodiversity conservation in source countries will not be achieved. This analysis is 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.

"The author examines, with outstanding analytical capabilities, complex economic issues of particular importance to developing countries and the drug industry. The book offers stimulating insights in a rigorous and accessible manner. It will be of great value for researchers, policy makers, managers and all those concerned with the protection and sustainable use of biodiversity."
Professor Carlos M. Correa, University of Buenos Aires, Argentina

"Dr Gehl Sampath's book is a welcome contribution to an important but highly polarized debate. It offers an objective and academically rigorous treatment of what is a highly complex subject, and in doing so should contribute to fairer and more effective bioprospecting regulation."
Graham Dutfield, Senior Research Fellow, Queen Mary Intellectual Property Research Institute, University of London, UK.

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Book information:

ISBN 92-808-1112-6;
200pp; US$36.00

Order from:

United Nations University Press

53-70, Jingumae 5-chome, Shibuya-ku, Tokyo 150-8925, Japan
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