

# Regulating Bioprospect Institutions for Drug Rese Access and Benefit-Sha



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# Regulating Bioprospect

- Book looks at bioprospecting for drug m and mainly from a plant genetic resource perspective.
- It tries to place the debate within the la of biodiversity conservation, international capacity building.

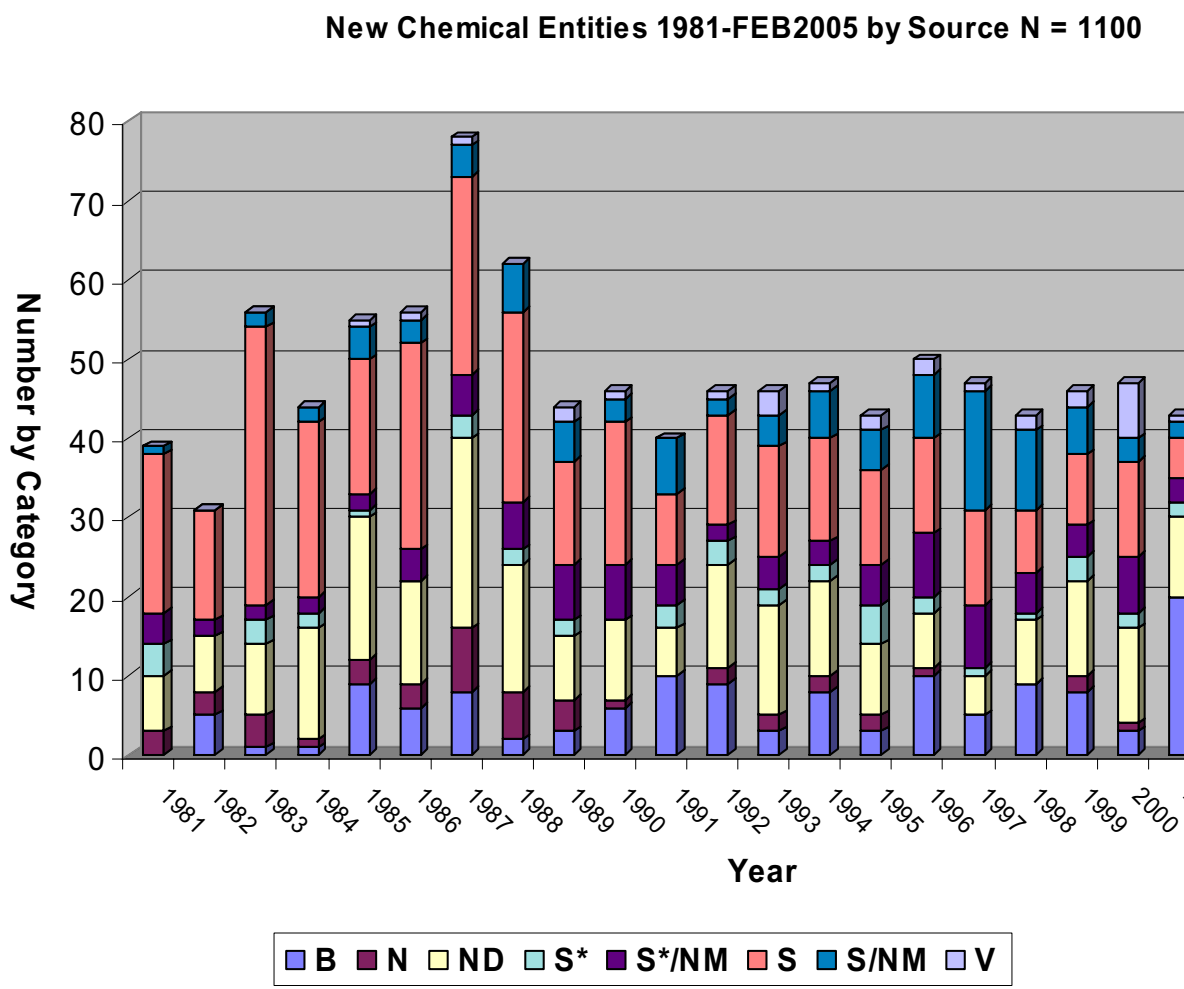


# Bioprospecting and international trade

- Important for the north-south debate from several perspectives:
  - Medical importance: Natural Products are the source of all new molecules discovered in drug research between 1981-2002 (Newman et al, 2003).
  - By major disease categories, 79% of anti-cancer drugs, 79% of anti-infectives and 79% of anti-bacterials, are discovered between 1981-2002.
  - Drugs is the area par excellence where IPR is a barrier for innovation.
  - Current debate about the spreading of IPR in the south direction: bioprospecting, as well as downstream processing and epidemiological data.



# Sources of Approved Drugs (01/1981-02/2005)



# Policy concerns

- Importance for public health and capacity building
  - Solving issues of public health and capacity building in developing countries.
  - Genetic wealth could pave the way for useful partnerships and knowledge flows.
- Central topic of debate in both North and South
  - Technological divide and access barriers to technology (in the North) despite genetic resources endowments (of the South).
  - Resulting in biodiversity use issues, drug research, public health, IPRs and excessive pricing issues with significant welfare implications.
  - Irrational incentives for investment in R&D and marketing, with an emphasis of drug innovation on needs of the North, with significant global welfare implications.



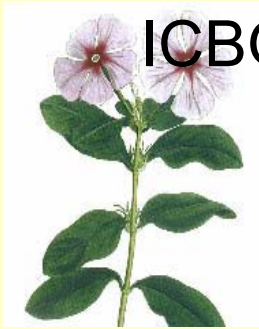
# Scope for Conflict

- Politicized issue in international negotiations s  
rights recognized under two separate internati  
agreements that have diverse policy aims.
- The Agreement on Trade Related Aspects for I  
Property Rights, 1995 is an agreement on intel  
property.
- Art. 27(3)(b): patents on life forms and a *sui g*  
for the protection on plant varieties.
- Convention on Biological Diversity, 1993 is an  
environmental Agreement.
- Articles 8(j): right of local and indigenous com  
their traditional knowledge, innovation and pr
- Article 15: Sovereign rights of States over their  
resources.



# Present Situation

- Several property rights definitions for rights to genetic resources and traditional knowledge within source countries
- Legal uncertainty in national bioprospecting either due to lack of laws or unclear laws. This extenuates the lack of trust and also leads to unrealistic expectations of parties in contracts.
- Several contractual examples are discussed including ICBG initiatives, NIH collaborations, Merck-I



Book therefore focuses on examining optimal property rights structures institutional arrangements for bioprospecting, using an inter-disciplinary perspective



# Uses Law and Economics Methodology where

- Legal rules are incentives that influence decisions of parties in socially desirable ways.
- A systematic law and economics approach can
  - help predict which property rights' options can out-compete others;
  - And as a consequence help design optimal regulations for bioprospecting;
  - Raises interesting second order questions about the impact of international trade and IP rules to facilitate welfare from contracts in this area;
  - Is there scope for an "international" optimal regulation (for issues such as an international system of certification) that helps global social welfare?
  - Helps integrate results from legal and economic literature on bioprospecting which are fragmented and do not have a systematic approach.



# Defining rights and enabling contracts:

1. Main rights exchanged in the drug R&D process are:
  - right on tangible genetic resources (right to access of the country and right to private property holder)
  - right on traditional knowledge (if used in R&D)
  - rights on IP findings and marketable products.



# How does the market lo

Imperfections caused by:

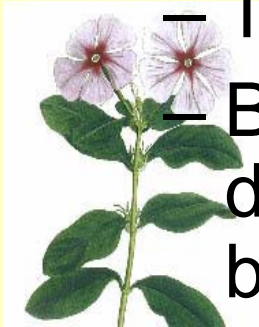
(a) economic limitations of the drug  
R&D process – high levels of  
uncertainty and high ex-ante  
investments



(b) Traditional knowledge is an  
informational good, so poses s  
problems in the design of effici  
contracts

# Defining rights and enabling contracts:

- Parties contract with information that can be verified on the spot and information that (potentially) gains value tremendously as it passes from one stage of R&D to another.
- Both factors play a crucial part in how parties behave before and after contract formation.
- This leads to transaction costs.
- Book shows how optimal property rights definitions and regulatory frameworks for bioprospecting **can deal with this.**



## MAIN RESULTS: LEGAL ANALYSIS

- There is no direct legal conflict between the TRIPS Agreement and Capacity Building of the Convention on Biological Diversity.
- Controversy appears more the result of the wording in the provisions and contrasting interpretations amongst various groups of countries.



# MAIN RESULTS. Definition of Trad Medicinal Knowledge

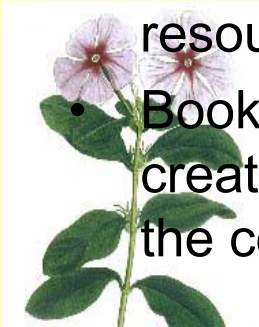
- Property rights suggestions: no IP protection (already knowledge and therefore public domain) to *sui generis*
- A well-defined right on TK:
  - (a) based on its contribution to R&D and conservation
  - (b) clear set of beneficiaries who can exercise the right
- What role does TK plays in the drug R&D process?: process-oriented view.
  - A starting process of drug R&D (pharmaceutical research product itself (botanical medicines)
- Argues for the definition of traditional knowledge as ethnobotanical knowledge on grounds of: IP Aspect and contractibility.



# MAIN RESULTS:

## Definition of the Right to Access

- Property rights suggestions range from a tax to an unregulated right.
- Main issues in access:
  - (a) Why should access be regulated for BP?
  - (b) Under what circumstances are the investments for access institutions in source countries justified?
- Access regulation justified only when environmental costs (externalities) to third parties due to over-harvesting of resources



- Book sets out conditions under which (a) environmental costs are created and (b) potential revenues from bioprospecting exceed the costs of setting up access institutions.

# MAIN RESULTS

## ACCESS AS THE “MARKET MAKER”

- Access is the “market-maker” in BP
  - can help eliminate contractual problems in the market for bioprospecting.
  - represent communities that hold TMK
  - devise and implement sustainable conservation programs
- The rights in bioprospecting have complementarities. In long-term relationships that involve investments into the production process, then economic efficiency would be to allocate them to one deciding party.
- Intermediary structure: market’s rational response to a complex regulatory framework and a very complex economic process



# Conclusions: Policy Ins

- Focus should be on effective laws and institutions that balance needs and ex of all right holders and stakeholders in
  - Traditional knowledge: focus on usefulness and
  - Access: focus on effects to be achieved and fa market for contracts.
  - Bioprospecting should be viewed as part of wi care.
  - Harness Bioprospecting collaborations to boost traditional medicine.
  - Detailed advice on options for leveraging inter negotiations, e.g., an international system of c been provided.



**THANK YOU**

