Regulating Bioprospecting

Institutions for Drug Research, Access and Benefit-Sharing
Bioprospecting

- Is the search for potentially valuable genetic resources and biochemical compounds in nature (Eisner, 1991)

- Politicized issue in international negotiations since the Agreement on Trade Related Aspects for Intellectual Property Rights and the Convention on Biological Diversity
Scope for Conflict

• Property rights recognized under two separate international agreements that have diverse policy aims.
• The Agreement on Trade Related Aspects for Intellectual Property Rights, 1995 is an agreement on intellectual property.
• Art. 27(3)(b): patents on life forms and a *sui generis* system for the protection on plant varieties.
• Convention on Biological Diversity, 1993 is an international environmental Agreement.
• Articles 8(j): right of local and indigenous communities on their traditional knowledge, innovation and practices
• Article 15: Sovereign rights of States over their natural resources.
Scope for Conflict

- Genetic resources and traditional knowledge: located in the Southern (developing) countries
- Technological know-how: located in Northern (industrialized) countries
- Viewed against
  - Tense backdrop of stronger IP protection
  - Rights of communities is at its infancy in developing countries
  - Fear of biopiracy (Neem, Ayahuasca)

HAS rendered the issue very political and charged.
Present Situation

- Several property rights definitions for rights to access and traditional knowledge within source countries
- Legal uncertainty in national bioprospecting frameworks: 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.
- Examples of previous contracts.
Book therefore focuses on examining optimal property rights structures and institutional arrangements for bioprospecting, using an inter-disciplinary perspective.
Methodology: Law and Economics

- 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-do the others, and also help design optimal regulatory frameworks for bioprospecting.
- Legal and economic literature on bioprospecting are both fragmented and do not have a holistic approach to bioprospecting.
Defining rights and enabling contractual frameworks

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

2. How does the market look?
   Imperfections caused by: (a) economic limitations of the drug R&D process – high levels of risk, uncertainty and high uncertainty
   (b) Traditional knowledge is an informational good, so poses serious problems in the design of efficient contracts
Defining rights and enabling contractual frameworks

• Parties contract with information that cannot be verified on the spot and information (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 addresses how optimal property rights definitions and regulatory frameworks for bioprospecting.
MAIN RESULTS: LEGAL ANALYSIS

• No direct legal conflict between the TRIPS Agreement and CBD

• Controversy is the result of vague wording in the provisions and contrasting interpretations amongst various groups of countries.
MAIN RESULTS. Definition of Traditional Medicinal Knowledge

- Property rights suggestions: no IP protection (already existing knowledge and therefore public domain) to *sui generis* IP protection.
- 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?: requires a process-oriented view.
  - A starting process of drug R&D (pharmaceutical research) or the product itself (botanical medicines)
- Argues for the definition of traditional knowledge as confined to 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 umbrella property right.
• Main issues in access:
  (a) Why should access be regulated for BP?
  (b) Under what circumstances are the investments for setting up access institutions in source countries justified?
• Access regulation justified only when environmental costs (externalities) to third parties due to over-harvesting of genetic resources
• Book sets out conditions under which (a) environmental costs are created and (b) potential revenues from bioprospecting can off-set the costs of setting up access institutions.
MAIN RESULTS
Contractual Facilitation Through The Access Authority

• 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 programmes

• The rights in bioprospecting have complimentarities. When rights have complimentarities in long-term relationships that require huge investments into the production process, then economic rationale would be to allocate them to one deciding party.

• Intermediary structure: market’s rational response to an imperfect regulatory framework and a very complex economic process
1. Focus should be on effective laws and institutions that balance needs and expectations of all right holders and stakeholders involved.  
TK: focus on usefulness and tradability  
Access: focus on effects to be achieved and facilitation of the market for contracts.  
TK: trade secrets and Access: Individual transferable quota (ITQ) system

2. View BP as part of wider health care

3. Harness BP collaborations to boost local traditional medicine.
KEY POLICY INSIGHTS

4. Options for leveraging international negotiations
   E.g.: International system of certification
THANK YOU

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