

Beyond Nagoya:
Protecting Indigenous Rights, Combating
Biopiracy, and Promoting Biodiversity Planning

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Bioprospecting

- 1970s: WHO recognizes need to *integrate indigenous knowledge*.
- Drug companies have recently focused on *biodiverse environments* and *ethnomedicine* for potential drug development.
 - These areas are *concentrated in worlds' poorest regions*.
 - Deemed *bioprospecting*.
 - *Key biomedical advances*: PCR medical application.

Biopiracy

- But ...
- *Biopiracy*: bioprospecting used to *exploit indigenous knowledge and biodiversity resources* to gain *exclusive intellectual property rights (IPRs)*,
 - *without indigenous population/community consent or benefit sharing* and
 - *without attention to biodiversity resource management*.
- Because of the *global nature* of bioprospecting, biopiracy, and biodiversity, *effective management may be best performed through global governance*.

Global Governance Failure

- Yet *global governance has been ineffective.*
- Competing models:
 - Global IPR rules focusing on *private party* economic incentives under WTO TRIPS regime,
versus
 - International *sovereign-based* approaches.
- *Both have failed* to protect indigenous rights OR promote responsible biodiversity management.

WTO TRIPS

- *Global IPR regime.*
- WTO has *forums* for adjudicating anti-competitive claims by sovereignties.
- WTO members:
 - Must implement *minimum IPR protections* and exclusivity; and
 - Specifically *allow patenting of living organisms* and/or their processes.

WTO TRIPS

- Resulted in:
 - Legitimate *bioprospecting.*
 - But also, *biopiracy.*
 - Patenting seeds, trees, hybrid plants/crops, plants, blood lines/tissues.
 - *"All and any Neid tree insecticidal and fungicidal applications now and forever known or noted or observed while in use for such insecticidal and fungicidal application(s) or while in use for any other such related application(s)."*

WTO TRIPS

- BUT: Biopiracy NOT simply corporate plundering!
- *Sovereignties* theoretically have domestic powers and obligations to *protect indigenous populations*.
- Yet they have NOT *ensured protection* against *sovereign unilateral biopiracy actions*.
 - Sale of Hoodia to Phtopharm by sovereignties that provided NO benefit to indigenous peoples from which knowledge and use arose.
 - Phytopharm patented Hoodia and sold it to Pfizer for \$21 million.

CBD: Sovereign Approaches

- Due to *economic pressures* of 1990s, *developing countries severely depleted biodiversity reserves*.
- In response, "International Convention on Biological Diversity" aka CBD **implemented**.
- Focus:
 - *Sovereign-led biodiversity conservation*;
 - *Promoting equitable benefits sharing* by sovereignties.

CBD Issues

- Broad aims of *public actor-led* conservation, sustainability, and biodiversity benefits sharing as sovereign resources
in stark contrast
- with strong TRIPS *private IPR incentives*.
- *Private actors well funded and nimble*.
- *Public actors have limited resources and knowledge* to protect indigenous peoples and biodiversity and a *short term focus*.

Result

- *Private IPR efforts have predominated.*
- *Biopiracy yields global imbalance* of benefits sharing, use, and products between developed and developing countries.
- Amazing implication:
 - *Private IPR owners may prevent local communities from legally using their OWN indigenous knowledge and ethnomedicines.*
- Big problem for *developing countries*:
 - *limited resources* preclude access and use.
 - *lack of cultural competency*: may be no indigenous community IP concepts.

Nagoya Protocol

- October 2010: CBD members *adopted Nagoya Protocol*.
 - “Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity”
- Attempts to *address biodiversity benefits with indigenous peoples and responsible diversity management*.

Nagoya Protocol

- Addresses biopiracy and biodiversity by:
 - Accessing indigenous knowledge *only with informed consent*;
 - Providing *methods of compensation* for indigenous knowledge and ethnomedicine;
 - Emphasizing *equitable financial and nonfinancial benefits sharing* with indigenous community; and
 - Setting *sovereign targets* to *preserve biodiversity*.
- Protocol requires ratification by 50 nations before implementation.

Problems

- Nagoya: *few specifics on addressing key issues.*
- NO:
 - *forum for indigenous peoples* to be heard on biopiracy claims (not just sovereignties),
 - *strong penalties* to disincentivize biopiracy,
 - *guaranteed indigenous access* to developed drugs,
 - *means of assistance for planning and implementation* for biodiversity and healthcare infrastructures planning, and
 - *promotion of public-private partnerships* (PPPs) leveraging resources from each.

Beyond Nagoya

- Employing a joint economics-health committee comprised of WHO-WTO, the *Joint Committee on Bioprospecting and Biopiracy.*
- Joint Committee function *integrated with:*
 - Nagoya provisions,
 - differential pricing and penalties,
 - Global Biodiversity Fund, and
 - PPPs.
- "Fix the past, plan the future."

Differential Pricing and Penalties

- *Joint Committee would have the power to assess if biopiracy has occurred.*
- The Nagoya standards for benefits sharing shall be deemed *presumptively appropriate* if followed, but *subject to challenge* given special considerations.
- *Beyond Nagoya:* a biopiracy claim may be lodged against an entity *by indigenous peoples directly, OR by sovereignty, but only with consent of the indigenous community.*

Differential Pricing and Penalties

- If *biopiracy has occurred*:
 - *Private Entities*:
 - be required to provide *deeply discounted pricing* and/or donated pharmaceutical products to the country for the *biopirated material*; *as well as*
 - *all other medicines* sold in that market by the offending entity.
 - In addition or in the alternative, Joint Committee may rule that the *claimant may access TRIPS rights under the Doha Declaration*.
 - Allows *sovereign IPR suspension* in a public health emergency and drug production and sale by non-IPR holders.
 - *Public Entity*:
 - be required to *compensate indigenous communities* for its loss/transfer biopiracy gains to the indigenous community.
 - be *subject to WTO anticompetitive penalties*.

Global Biodiversity Fund

- Developing countries *lack resources* to plan/ implement *biodiversity-sustaining efforts* and develop *appropriate infrastructure for healthcare* delivery.
- Need *stable resources to sustain biodiversity and develop healthcare infrastructures*.
 - Particularly important so as to *avoid 1990s policymaker short term approaches* depleting biodiversity resources.

Global Biodiversity Fund

- Companies engaged in bioprospecting should pay a *global bioprospecting user fee* paid to the Joint Committee.
 - Similar to FDA user fee for drug review [currently \$1 million/review].
- A fraction should be *allocated to a Global Biodiversity Fund (GBF)* administered by Joint Committee.

Global Biodiversity Fund

- GBF will be used for:
 - Underwriting *responsible biodiversity development* planning and best practices;
 - Creating *health infrastructures* in developing countries.
 - Model: **World Bank grant platform** for developing countries.
 - Establishing *culturally-competent education to indigenous communities* about Nagoya Protocol.
 - Including *informed consent* and *standardized access and benefit sharing provisions*.
- *Beyond Nagoya*: GBF addresses:
 - identified challenges of *sovereign limited resources* and knowledge to create sustainable biodiversity plans,
 - *needed health infrastructure investment* to avoid short term focus, and
 - *cultural competency* concerns.

PPPs

- Reflecting reality of biodiversity development, *future is in cooperative PPPs*.
- Models already extant.
 - Examples: Merck-Costa Rica *Instituto Nacional de Biodiversidad*; International Cooperative Biodiversity Groups Program.
- Importantly, innovative PPPs can be:
 - *expanded* to include indigenous communities;
 - *promote identification of knowledge* that can be shared for public health benefit globally; and
 - *create otherwise unrealized economic benefit* for other social needs via PPPs.

PPPs

- PPPs supported by *earmarking a percentage of bioprospecting user fees* to test innovative, mutually beneficial PPPs on grant basis.
- At a minimum, should require:
 - *substantive representation* of local communities/ indigenous peoples where bioprospecting is occurring;
 - *Nagoya Protocol benefits-sharing and implementation provisions* as baseline; and
 - *demonstrated incentive alignment and shared, coordinated decisionmaking*.

Overall

- *Bioprospecting is a key strategy* promoting drug development.
- *Global governance efforts* to address **biopiracy** and **sustainable biodiversity**, including the recent Nagoya Protocol, *still leaves key issues unaddressed.*
- A *WHO-WTO Joint Committee* may address these issues and create opportunities for PPPs benefiting **indigenous communities**, **companies responsibly developing products**, as well as local and global health.
