

Integrating Biodiversity Management and Indigenous Biopiracy Protection to Promote Environmental Justice and Global Health

Tim K. Mackey, MAS, and Bryan A. Liang, MD, PhD, JD

Many potentially useful medicines arise from developing countries' biodiverse environments and indigenous knowledge. However, global intellectual property rules have resulted in biopiracy, raising serious ethical concerns of environmental justice, exploitation, and health disparities in these populations. Furthermore, state-based approaches have not led to adequate biodiversity protection, management, or resource sharing, which affect access to lifesaving drugs.

In response, country delegates adopted the Nagoya Protocol, which aims at promoting biodiversity management, combating biopiracy, and encouraging equitable benefits sharing with indigenous communities. However, the effectiveness of this framework in meeting these objectives remains in question.

To address these challenges, we propose a policy building on the Nagoya Protocol that employs a World Health Organization–World Trade Organization Joint Committee on Bioprospecting and Biopiracy. (*Am J Public Health*. 2012;102:1091–1095. doi:10.2105/AJPH.2011.300408)

BIOMEDICAL RESEARCH AND the discovery and development of medicines often focus on naturally occurring materials for products and applications. Searching for such compounds in diverse environments (e.g., rainforests, deserts, and hot springs) is deemed “bioprospecting.”^{1,2} Bioprospecting has resulted in key advances (e.g., making polymerase chain reaction processes stable for medical application) and has led to lifesaving advances in medicines and population health.¹ It has also established economic value for these resources and supported biodiversity conservation and indigenous communities.²

However, biopiracy occurs when bioprospecting is used to appropriate knowledge and biodiversity resources to gain exclusive use through intellectual property rights (IPRs) without benefits for indigenous populations.^{2,3} In addition to raising serious environmental justice issues, biopiracy adversely affects the health of local populations that fail to benefit from economic and medical gains derived from the biodiversity and indigenous knowledge that originated in their communities. The global health consequences of biopiracy include lack of access to medicines, failure to compensate for valuable traditional knowledge, and depletion of biodiversity resources that are needed by indigenous communities for their own ethnomedicine and health

care. These impacts are particularly problematic because the health of these communities can be poor.⁴ Because of the global nature of bioprospecting, biopiracy, and biodiversity, effective management—including environmental protection and sustainable development approaches—may be best performed through global governance.

Global governance, however, has been ineffective in protecting biodiversity from biopiracy. Global IPR rules comprise domestic, multilateral, and supranational systems that establish minimum intellectual property standards. These global IPR systems focus on patent systems and private economic development under the World Trade Organization (WTO) TRIPS regime (Agreement on Trade-Related Aspects of Intellectual Property Rights) and on activities of the World Intellectual Property Organization. However, they have failed to protect indigenous rights, promote access to lifesaving drugs, prevent biopiracy, or provide for responsible biodiversity development.^{5–9} Governance relies on market forces and state entities of independent governments within a defined territory, which preclude the participation and protection of indigenous communities (both in developed and developing countries) that comprise groups of diverse social self-identification. This traditional state-focused governance model has not created incentives for developing

countries to invest in adequate conservation, and thus, biodiversity resources in these countries are in danger of being depleted.^{4,6}

In response, in October 2010, the UN Convention on Biodiversity adopted the Nagoya Protocol, which attempts to protect biodiversity and sets rules on how nations access and share biodiversity benefits.¹⁰ It successfully introduces key components of resource sharing of biodiversity benefits by establishing a framework for norms and rules that may be implemented by member states in the future. However, the protocol does not adequately address several concerns, including the following: a forum for indigenous peoples to adjudicate biopiracy claims, strong penalties to create disincentives for biopiracy, ensured indigenous access to developed drugs, promotion of the planning and implementation of sustainable biodiversity conservation and investment in public health infrastructures in developing countries, and adequate promotion of public–private partnerships (PPPs) that can leverage resources from both public and private stakeholders. We therefore propose a policy employing a joint health–economics committee, a World Health Organization (WHO)–WTO Joint Committee on Bioprospecting and Biopiracy, to address these equity issues and promote sustainable and responsible global governance in biodiversity management.

INDIGENOUS KNOWLEDGE, INTELLECTUAL PROPERTY, AND BIOPROSPECTING

Since the 1970s, WHO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) have recognized the need to integrate indigenous knowledge—defined broadly as all forms of knowledge accumulated over generations by a local community living in a particular environment—to improve global health.^{11,12} The public health importance of indigenous traditional medicine, or ethnomedicine, is well established. The corporate biotechnology sector also recognizes the value of indigenous knowledge.¹¹ In combination, indigenous knowledge and ethnomedicine have resulted in global patenting of ingredients, drug development, and product commercialization, primarily by multinational firms that obtain IPR protection by filing applications in multiple countries.⁷

Globalization and biotechnology have created vast, interdependent systems of economic trade in the life sciences. Accompanying this development is the globalization of intellectual property regimes, largely due to the efforts of organizations such as the WTO.⁹ However, with expanded global economies made possible through multilateral agreements combined with international standardization of certain IPRs through TRIPS, serious questions regarding IPR distribution and biopiracy have arisen that relate to global equity and justice.⁵

Under the current system, WTO member states must implement minimum IPR protections, specifically including patentability of living organisms or their processes.² However, these IPR

processes, and the infrastructure to support them, are often beyond the capabilities of indigenous communities, significantly limiting their access to the legal rights afforded by these systems.¹¹ This has formalized bioprospecting and allowed companies to gain IPRs for biodiversity forms and their chemical structures, including in the formulation of medicines. This process has often involved the exploitation of indigenous knowledge, which may prevent indigenous communities from realizing social and financial benefits.¹¹ Indeed, even if bioprospecting and biopiracy only use small amounts of the biodiverse resource, uncompensated indigenous communities are often precluded from benefits that could underwrite important public health and biodiversity management efforts. Thus, although TRIPS has stimulated bioprospecting by pharmaceutical companies, it has also allowed them to commercialize and monopolize the use of prospected resources without benefits sharing, which is biopiracy.¹¹ This can have short-term and long-term implications for indigenous communities.

Biopiracy has included companies patenting seeds, trees, hybrid plants and crops, plant species, and blood cell lines and tissue.¹¹ Indeed, even developed countries' regulators questioned some of these efforts—for example, the patenting (and subsequent revocation of the issued patent) of neem tree insecticidal and fungicidal applications by the European Patent Office.²

Importantly, however, biopiracy activities have not been limited to corporations. They have also included unilateral actions by national governments without the consent of indigenous groups—for example, South Africa's

Council for Scientific and Industrial Research's sale of hoodia (a cactus) to the pharmaceutical company Phytopharm while ignoring the indigenous communities' economic and health access needs.¹¹ Phytopharm later patented and sold it to pharmaceutical giant Pfizer for \$21 million.¹¹ Such case studies exemplify inequitable resource transfer for environmentally related resources. They also demonstrate the need to reexamine current global governance structures that magnify health disparities between developed interests and indigenous communities.

PROBLEMS WITH BIODIVERSITY EFFORTS

Developed countries and drug companies have recognized the need to search for natural resources in locations with the greatest biological diversity. These areas are concentrated in the world's poorest developing regions, areas often ravaged by disease and poor health care infrastructure.¹³ Yet biopiracy can occur anywhere in the world where the potential to explore, and possibly exploit, indigenous knowledge or biodiversity exists.

Because of the economic pressures of the 1990s, developing countries severely depleted their biodiversity reserves to realize short-term economic gain. Subsequently, there have been global efforts to protect biodiversity by promoting sustainable development in these countries.¹³ In the early 1990s, the International Convention on Biological Diversity (CBD), an international treaty driven by the UN Environment Program, was implemented to create incentives for developing countries to conserve biodiversity and practice sustainability in

resource extraction while promoting benefit sharing through development of state-based property rights for biodiversity. (The United States, Andorra, and the Holy See were the only states not to ratify the CBD).¹³

However, the CBD's broad aims of public actor-led conservation, sustainability, and sharing of biodiversity benefits as state-based resources are in stark contrast to and conflict with the strong TRIPS private IPR incentives.² Although the CBD establishes commercial value for biodiversity in developing countries, it also relies on state-based actors in these countries.

These actors may not honor indigenous community rights or have sufficient institutional knowledge or capacity to protect biodiversity from the efforts of private, well-financed companies from developed countries to gain exclusive rights to these resources.¹³

Instead, private IPR efforts have predominated, and biopiracy has created a global imbalance of benefits sharing, use, and products between developed and developing countries, especially in access to development of pharmaceuticals.⁵ Indeed, under exclusivity provisions,⁷ IPR owners may prevent local communities from legally using their own indigenous knowledge and ethnomedicine,⁹ increasing locally produced medicine costs.⁷ This is especially dire for developing countries, whose limited resources may preclude access to pharmaceuticals and the health care infrastructures to use them, and it further widens the gap in health disparities between rich and poor.

Developed countries also show a lack of cultural competence regarding indigenous communities' IPR perspectives and understanding.⁷ The concept of private commercial rights to intellectual

property and medicine is primarily an idea adopted by developed countries and may not be understood by indigenous communities.⁷ Such cultural nuances are not recognized by the current international IPR system,¹³ where rights are governed by global legal regimes that do not allow local communities to be represented; consequently, indigenous community needs may not be heard or met.¹⁴

THE NAGOYA PROTOCOL

The Nagoya Protocol (in full, the 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), which followed 6 years of negotiation, represents a potential watershed in reforming drug discovery practices, protecting indigenous communities, and promoting responsible global biodiversity management.¹⁵

The protocol sets targets for preserving biodiversity and establishes rules on members' cooperation in accessing biodiversity and sharing resource benefits.¹⁰ The protocol also includes methods for providing compensation for traditional medical knowledge that is presently being used, patented, or sold, including indigenous knowledge and ethnomedicine obtained through bioprospecting.¹⁰ Other efforts to preserve the rights of indigenous communities include emphasis on the fair and equitable sharing of financial and nonfinancial benefits with indigenous communities, access of indigenous knowledge only with adequate informed consent, designation of checkpoints to monitor compliance (including issuance of internationally recognized certificates of compliance), and community protocol

development that includes minimal if any restrictions on indigenous communities' right of customary use and ethnomedicine.¹⁶ The protocol requires ratification by 50 nations before it can be implemented.¹⁶

CHALLENGES AND POLICY

Although the Nagoya Protocol covers some critical issues regarding current global biodiversity, environmental and health justice, drug discovery governance, and international IPR frameworks, it offers few specifics on addressing drug access, adequate representation, and equitable compensation, which are key concerns of indigenous communities. In addition, it does not address biodiversity management or public health and health care infrastructure investment. Importantly, it lacks the specific language necessary to provide indigenous community education and the mechanisms of benefits sharing and access to both traditional and patented medicines derived from biodiversity resources.¹⁰ It also lacks necessary strong disincentives and penalties for biopiracy and has no funding mechanisms for planning and implementing biodiversity sustenance and development nor for investing in public health and health care infrastructures.¹⁰ It relies on individual nations to enact and enforce domestic laws and checkpoints for protecting indigenous community resource holders, even though many governments have acted against indigenous interests in the past.¹¹ Finally, it does not provide innovative, sustainable partnerships between governments, local communities, and pharmaceutical manufacturers that recognize the economic importance of

responsible biodiversity development and shared stakeholder interests that also promote environmental and health justice.

Consequently, although the protocol may represent an important first chapter in biopiracy and biodiversity management, addressing indigenous community economic and public health needs as well as biodiversity planning requires a more comprehensive approach. Our strategy would employ a Joint Committee on Bioprospecting and Biopiracy and include a differential pricing system, a global biodiversity fund, and development of PPP models. This global governance structure would allow for uniformity in decision-making protocols regarding possible biopiracy violations and implementation of clear disincentives from engaging in such activity.

DISPUTE SETTLEMENT

To address the provision of appropriate access for communities where biodiversity drugs originate and to promote needed public health initiatives, the Nagoya Protocol requires that such communities have fair and equitable access to the benefits of modern drug discovery and development through mutually agreeable terms. The protocol offers an opportunity to negotiate appropriate access to the final developed medicine. The specific needs of indigenous communities, the biodiversity in question, and other unique characteristics will need to be taken into account in individual cases.

To create incentives for companies to follow protocol provisions, we believe penalty provisions should be implemented for potential biopiracy violators through our proposed Joint Committee

on Bioprospecting and Biopiracy. For medicines, the system would permit a local community (or a national government if supported by the indigenous people) to lodge with the Joint Committee a biopiracy claim against an entity. Claims would be adjudicated first by mandatory mediation conferences between the parties. If this effort failed, there would be a formal hearing and binding ruling on states that are parties to the protocol by the Joint Committee, which would be composed of advisers who are experts in the nature of the claim and who would have voting rights in the hearing process; all affected stakeholders would be adequately represented. If the Joint Committee ruled that a violation occurred, the company would be required to provide the affected country or community with free or deeply discounted medical products—those that the company developed using biodiversity and indigenous knowledge or ethnomedicine as well as all other medicines that it sold in the country. Changes to how the company and the indigenous community shared benefits, such as potential profits derived from the medical products, might also be required.

If there was a biopiracy violation under the protocol, the Joint Committee would be empowered to rule that indigenous communities may automatically access TRIPS rights unilaterally—for example, under the Doha Declaration adopted by the WTO Ministerial Conference in 2001, which secures flexibility in bypassing patent rights to protect public health. (Under the declaration, during a public health emergency, states are allowed to suspend IPRs and medicine can be produced and sold by non-IPR

holders).¹⁷ A specified penalty period would apply, depending on the facts and circumstances that gave rise to the biopiracy claim, allowing aggrieved countries or communities sustained and improved access to medicines.

If the biopiracy claim is against a state entity, similar provisions would apply. The Joint Committee would assess the claim by the indigenous community and determine whether the state engaged in biopiracy. If it determined that it did, the committee might require the state to hand over to the indigenous community all or part of the profits derived from sale of the biopirated material. Other penalty provisions might also be applicable, such as invalidation of any established state-based compliance checkpoints or internationally recognized certificates of compliance; again, these would depend on the facts and circumstances of the biopiracy act.

This proposed approach is consistent with European Union efforts to improve access to medicines in developing countries while also providing for private IPR incentives.¹⁸ It addresses biopiracy financial incentives by raising the costs of this inequitable but profitable strategy, while it also ensures that the indigenous populations in question—not simply the national government exclusively—have an express role in challenging biopiracy. This would promote environmental and health justice as well as aid in bridging the gap in health disparities through increased access.

GLOBAL BIODIVERSITY FUND

Although enhanced penalties and settlement of disputes could

provide equitable access to developed medicines and an appropriate biopiracy adjudication forum, most developing countries lack adequate resources to plan and implement biodiversity-sustaining efforts and to develop appropriate infrastructure for public health and health care delivery. We therefore propose that a fund be established to sustain biodiversity and responsible bioprospecting through the development of biodiversity management programs while also providing funding for local public health infrastructures in indigenous communities. This underwriting may also promote longer-term policymaker planning rather than focusing on short-term economic gains of simply commercial valuation of biodiversity resources as was done in the 1990s.¹³

Under our proposal, companies engaged in indigenous community bioprospecting would be required to pay a global bioprospecting user fee to the Joint Committee. This would be similar to the user fees for US Food and Drug Administration drug review, which are currently at \$1 million a review and are being revised.¹⁹ A portion should be directly allocated to a Global Biodiversity Fund administered by the Joint Committee. Similar to other programs such as the World Bank's Health Systems Funding Platform, the fund could underwrite responsible biodiversity development, best-practices dissemination, and health infrastructures in developing countries that could promote health care access and delivery and reduce health disparities.²⁰

These funds could also be used to create focus groups to identify indigenous community needs. They could provide local communities with culturally competent

education about the rights afforded under the Nagoya Protocol, including informed consent, indigenous research protocols, standardized access, and benefits sharing. These programs could better ensure informed decision-making by indigenous communities regarding sharing or protecting knowledge and resources.

In addition, the Global Biodiversity Fund could act as a vehicle to disburse needed funds to indigenous communities that do not have adequate financial means for legal consultation or representation in dispute hearings. Funds could also be used for limited reimbursement of aggrieved countries and communities when noncomplying corporations or state governments fail to meet financial obligations following resolution of a dispute. Parties who fail to meet these obligations would be in violation of the Nagoya Protocol and could subject themselves to additional penalties and trade restrictions available under existing international and bilateral regimes, including potentially extending to nonmember states.

Through this fixed funding system, communities and countries in which biodiversity resources originate would have access to block grant funds to manage biodiversity while also supporting access to important medicines and investment in local public health infrastructure. The Global Biodiversity Fund would also allow for avenues of additional enforcement for noncomplying parties.

PUBLIC-PRIVATE PARTNERSHIPS

Incentivizing bioprospecting companies to act appropriately and providing developing countries funding for biodiversity and public health infrastructures are

crucial. However, reflecting the reality that the discovery and development of biodiversity-derived drugs is primarily a function of industry, the creation of innovative, mutually beneficial, cooperative PPPs between local communities and pharmaceutical companies with technical expertise should be a priority. PPPs such as *Instituto Nacional de Biodiversidad* (involving Merck and the government of Costa Rica) and the Malagasy Institute of Applied Research, as well as efforts by the International Cooperative Biodiversity Groups Program to promote multi-disciplinary research, represent potential models for nations and companies to collaborate while implementing appropriate benefits sharing.^{21,22} Importantly, innovative PPPs can be expanded to include indigenous communities and to promote the identification of traditional knowledge. This knowledge can be collectively used for the improvement of public health worldwide and for the economic benefit of all PPP members during bioprospecting, the drug research and discovery process, and beyond.

We believe that the development of model systems for PPPs could be encouraged by earmarking a percentage of bioprospecting user fees or the Global Biodiversity Fund toward testing innovative, mutually beneficial PPPs. Importantly, to be eligible, applications should show substantive representation of local communities or indigenous peoples where bioprospecting is occurring and adherence to agreed-upon indigenous research protocols (such as those developed by the Assembly of First Nations) using community-based participatory research to ensure responsible, equitable, and respectful research

practices.⁴ Such PPPs could model the benefits-sharing and implementation provisions of the Nagoya Protocol to ensure standardization, transparency, informed consent, and equity between companies and communities to ensure environmental and health justice. Through this approach, objectives, interests, shared incentives, and decision-making can be coordinated to allow mutually beneficial outcomes.

THE NEXT STAGE

Bioprospecting is a key strategy for promoting the private development of medicines to serve global populations. However, global governance to address biopiracy and sustainable biodiversity, including the recent Nagoya Protocol, still leaves unattended the key issues of outstanding concerns of indigenous communities, biopiracy, and limited resources for biodiversity management and public health infrastructure.

The time to focus on these issues is now. Such efforts are clearly relevant to current and forthcoming global discussions within and among states regarding ratification of the Nagoya Protocol. These debates have the significant potential to recognize the increasing importance of global cooperation in the development of life-saving medicines and clinical interventions through bioprospecting—from both an

economic and global health viewpoint and a biodiversity-sustaining perspective. Core to these principles is the need to share biodiversity benefits equitably and to promote environmental justice and health equity for all. Through a health–economics policy that addresses biopiracy, such as the one we have proposed, bioprospecting can provide economic aid to indigenous communities, allow companies to responsibly develop medicines from these communities, and promote local and global health. ■

About the Authors

Timothy K. Mackey is with the Institute of Health Law Studies, California Western School of Law, San Diego, and the Joint Doctoral Program on Global Health, University of California, San Diego and San Diego State University. Bryan A. Liang is with the Institute of Health Law Studies, California Western School of Law, San Diego, and the San Diego Center for Patient Safety and the Department of Anesthesiology, School of Medicine, University of California, San Diego.

Correspondence should be sent to Timothy K. Mackey, MAS, Global Health Program, University of California, San Diego—San Diego State University, 350 Cedar St, San Diego, CA 92101 (e-mail: tmackey@ucsd.edu). Reprints can be ordered at <http://www.ajph.org> by clicking the “Reprints” link.

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Contributors

T. K. Mackey and B. A. Liang jointly conceptualized the study and wrote and edited the essay. B. A. Liang supervised its legal and policy analysis.

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