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When the cure kills—CBD limits biodiversity research

National laws fearing biopiracy squelch taxonomy studies

By **K. Divakaran Prathapan¹, Rohan Pethiyagoda², Kamaljit S. Bawa³, Peter H. Raven⁴, Priyadarsanan Dharma Rajan⁵**, and **172 co-signatories from 35 countries***

The Convention on Biological Diversity (CBD) commits its 196 nation parties to conserve biological diversity, use its components sustainably, and share fairly and equitably the benefits from the utilization of genetic resources. The last of these objectives was further codified in the Convention's Nagoya Protocol (NP), which came into effect in 2014. Although these aspirations are laudable, the NP and resulting national ambitions on Access and Benefit Sharing (ABS) of genetic resources have generated several national regulatory regimes fraught with unintended consequences (1). Anticipated benefits from the commercial use of genetic resources, especially those that might flow to local or indigenous communities because of regulated access to those resources, have largely been exaggerated and not yet realized. Instead, national regulations created in anticipation of commercial benefits, particularly in many countries that are rich in biodiversity, have curtailed biodiversity research by in-country scientists as well as international collaboration (1). This weakens the first and foremost

objective of the CBD—conservation of biological diversity. We suggest ways that the Conference of the Parties (CoP) of the CBD may proactively engage scientists to create a regulatory environment conducive to advancing biodiversity science.

The opportunity to ever know about many of the kinds of organisms with which we share this world is rapidly slipping through our fingers. Of the estimated 12 million species of eukaryotes on Earth, fewer than 2 million have been named. Current estimates are that 20% of the species on Earth are in danger of extinction, driven primarily by a range of human activities. Although biological resources had long been treated as a common heritage of humankind, the CBD reinforced the notion of sovereign rights of nation states over biological resources within their political boundaries and entrusted the nation parties to take measures to share benefits arising from the utilization of genetic resources. In most countries, particularly developing countries, the agendas of numerous pressure groups, many of them well-intended but not prioritizing science, get mixed up during the legislative process, while conservation biologists and taxonomists, a vanishingly small constituency, hold little leverage. Thus, the resulting national legislations vary greatly, from being extremely prohibitive of research, to a very few that are relatively enabling, such as Costa Rica and South Africa. The problem is particularly acute where there is a poor policy-science interface resulting from weak scientific institutions.

In many developing nations, conservation approaches may be largely reduced to mere protectionism—preventing deforestation and

Taxonomy of many species of *Rhododendron* from the Himalaya (four are seen flowering) is uncertain.

prohibiting the destruction of fauna and flora. Given the magnitude of the threats, effective conservation also demands the scientific understanding of species, the anthropogenic and other disturbances they face, and the development of scientific conservation interventions. None of this is possible unless scientists have access to the resources they seek to study, and ability to share resources and expertise with other countries. No one country will ever have the expertise to identify all the plants, animals, fungi, and protists that it contains.

COMMERCIAL VALUE: HYPE VERSUS REALITY

The CBD inspired many biodiversity-rich nations to entertain unrealistic expectations regarding the commercial value of their native species. It is true that important medicines have been derived from plants, and less commonly, animals. However, a widely publicized example (2) that captured the public imagination and the attention of governments, estimating that “11 of the top 25 best-selling pharmaceutical products are entities derived from natural products,” is misleading. These “natural products” are derived largely from ubiquitous organisms over which sovereign ownership or community interest could not be reasonably or practically asserted. Eight are derived from fungi common in soil or similar environments, and two are obtained from genetically engineered bacteria or ovarian cells (2).

Additionally, high-throughput screening, combinatorial chemistry, synthetic biology, and other advanced methodologies have largely replaced the role of natural products in the discovery of new molecules for developing new drugs, rendering physical access to biological material less important than it has been in the past. Modern technologies, including CRISPR gene editing, are redefining the modalities of access and utilization of biological resources in ways that were not foreseeable during NP negotiations.

Overall, examples of financially significant ABS agreements, a quarter-century after the CBD was signed, are scarce. Often-mentioned cases are marginal arrangements for the use of plant extracts for treatment of bone fractures as is traditional in the Cook Islands, the failed Merck-INBio initiative in Costa Rica, and the now discredited case of the “Indian ginseng.” A survey of mostly megadiverse countries having functional ABS legislation showed that very few commercial ABS agreements (2.05 per year per country) have been concluded (3), suggesting lack of demand for genetic resources by potential users, as well as restrictive procedures for access, as factors for the poor performance.

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OBSTACLES TO RESEARCH

The principles underlying the CBD and NP are laudable, and underscore that international collaboration in research is crucial for conservation of biodiversity and that access to genetic resources should be facilitated. However, even as national governments, following the CBD, began to enact legislation to regulate access to their biological resources and benefit-sharing from the derived products, consequences of such actions on biodiversity research and food security were pointed out by the science community (4–6). About 100 countries have enacted, or are considering, laws that regulate access by scientists to biological material and benefit sharing. Since the CBD came into effect, and especially after the NP led nation states to step up legislative processes to tighten their control over genetic resources (1, 7), obtaining permits for access to specimens for noncommercial research has become increasingly difficult in many countries in South Asia, East Africa, and South America, including megadiverse countries and biodiversity hotspots (8). More than 1200 Brazilian researchers recently submitted an appeal to the Ministry of the Environment to differentiate taxonomic studies from commercial research under the New Biodiversity Law (9). In some cases, researchers have even been prosecuted.

Although the importance of biological inventories and taxonomy is widely appreciated, especially by the CBD itself, for most nations, including those with the largest numbers of species, the cataloging of species remains woefully incomplete, an already difficult challenge made more so by legislation ensuing from the CBD (1, 4). Taxonomy involves comparison of preserved specimens, including types scattered across the world's natural history museums. Although most countries have established institutions for regulating access and material transfer, cross-border exchange and loaning of such historical specimens, and taxonomic revisions and monographic studies on widely distributed groups of organisms, can now be extremely challenging, if not impossible owing to fears of biopiracy. Although the system works well among developed countries, museums may be wary of risks of loaning specimens to scientists in developing countries, fearing that their return may not be permitted. Biodiversity research has seemingly become suspect in the minds of many regulatory bodies, owing to fear that a taxonomic discovery today might conceivably translate into a commercial development tomorrow. Meanwhile, biodiversity is vanishing and scarce talent is walking away from research.

The recent decision to consider the use of digital sequence information (DSI) under the framework of the CBD and NP (10) may

go beyond physical access to genetic materials and run counter to the larger overall goals of the CBD. Scientific information in the form of DSI is increasingly being published through portals of the International Nucleotide Sequence Database Collaboration (INSDC) such as GenBank. Unlimited and open access of DSI encourages collaboration to gain insights into the evolution, maintenance, conservation, and sustainable use of biological diversity.

Although NP Article 8(a) appears to encourage regulations that do not impede bona fide scientific research, the NP's definition of the "utilization of genetic resources" as the "means to conduct research and development on the genetic and/or biochemical composition of genetic resources" (Article 2c) makes no exceptions for purely academic or conservation-related biodiversity research, such as taxonomic studies. The protocol cautions nations to take into account "the need to address a change of intent for such research," effectively warning regulators of the "risk" of pure research spawning commercial applications.

FINDING SOLUTIONS IN SEEDS

With the sovereignty of nations over their biological resources now well established, and the ABS regimes put in place by many countries, individual states are unlikely to discontinue restrictive practices on their own, despite the CBD itself acknowledging the importance of research and knowledge-sharing. Though well-intentioned, the regulations are inimical to the pursuit of basic biodiversity science. The CoP should recognize the problem and urge the parties to establish enabling legal mechanisms for conservation-relevant biodiversity research, including taxonomy. Without close cooperation between scientists and national policy-making bodies, the broader goals of the CBD will be difficult to achieve.

Not-for profit research, such as inventories and taxonomic studies intended for the public domain, should be differentiated from commercial research leading to proprietary rights (8). Access has to be open when the benefits are in the public domain and the providers of the resource are free to make use of the benefits like anybody else. However, if the benefits are confined to the private realm through intellectual property rights, the provider may secure a share bilaterally (11).

The International Treaty on Plant Genetic Resources for Food and Agriculture, popularly known as the "Seed Treaty," provides a promising model. This treaty ensures worldwide public accessibility of genetic resources of essential food and fodder crops. Whereas the CBD and NP necessitate access to genetic resources on a bilateral basis through case-

by-case negotiations, the Seed Treaty adopted a multilateral system for access and benefit sharing (MLS) through a Standard Material Transfer Agreement, averting the need for bilateral negotiations. The MLS established under the Seed Treaty has been viewed as a very successful model in terms of volume of material exchanged (8500 transfers every week) (12), in contrast to the very limited performance of the bilateral system of CBD and NP (3). Exchange of genetic material under the Seed Treaty is exempted from the NP, and the benefit-sharing requirement arises only when access for further research and breeding is restricted through intellectual property rights. One possible course of action for the CoP to the CBD might be to add an explicit treaty or annex to promote and facilitate biodiversity research, conservation, and international collaboration. Such a treaty will address legal uncertainties in the governance of global research commons such as microbial culture collections held by the World Federation of Culture Collections as well as DSI published through the portals of INSDC or taxonomic type materials held in various museums all over the world.

As scientists aspiring to describe Earth's biological diversity in the face of formidable odds, we ask that the parties to the CBD do more to raise the legal curtain that has fallen between biodiversity scientists and the biodiversity they strive to discover, document, and conserve. ■

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