Access to Genetic Resources and Benefit Sharing 25 Years on:

Progress and Challenges

Manuel Ruiz Muller

ICTSD

International Centre for Trade and Sustainable Development

Issue Paper No.44

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ABBREVIATIONS

ABS	access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation
CBD	Convention on Biological Diversity
COP	Conference of the Parties
DSI	digital sequence information
FAO	Food and Agriculture Organization
GMBSM	global multilateral benefit-sharing mechanism
IP	intellectual property
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	mutually agreed terms
PGRFA	plant genetic resources for food and agriculture
PIC	prior informed consent
R&D	research and development
SMTA	standard material transfer agreement
TK	traditional knowledge (associated with genetic resources)
US	United States of America
WHO	World Health Organization

FOREWORD

Over the past two decades, ICTSD has supported a vast exploration of possibilities of policy and international cooperation frameworks to deliver innovation for sustainable development. In this context, our analytical work and expert and multistakeholder policy dialogue platforms have covered a wide range of issues, often guided by rigorous enquiries around intellectual property as a tool for innovation, development, and the pursuit of broader societal interests. Our aspiration has been to inform policymakers with evidence-based and policy-oriented analysis that assists in the implementation of policies consistent with sustainable development objectives and international undertakings

From the outset, recognition of the economic value of genetic resources and associated traditional knowledge as well as a momentum for increased protection of biotechnological inventions has framed our work. At the time of this paper, such trends are confirmed by renewed interest and have prompted biodiversity-rich countries and traditional-knowledge holders to position concerns about the misappropriation of genetic patrimony at the forefront of international trade and intellectual property frameworks.

Access and benefit sharing (ABS) constitutes the core principle of the existing multilateral framework enshrined in the 1992 Convention on Biological Diversity (CBD), further supplemented in 2010 by the Nagoya Protocol on Access and Benefit Sharing.

In this discussion paper, Manuel Ruiz, Director at the Peruvian Society for Environmental Law, presents his views on recent experience in implementing the ABS system. He distills lessons, progress achieved, and challenges emerging from the system in its quarter century of existence. While reviewing recent technological changes and, more broadly, research and development on genetic resources, the author highlights the limitations of the existing framework. He argues that the CBD principles of sovereignty, prior informed consent, and mutually agreed terms are being challenged as to their appropriateness in responding to an increasingly, but not wholly new, disruptive technological paradigm.

This thought-provoking paper will be followed by further analytical work and opinion notes on the issues addressed by the author. In the well-established tradition of ICTSD, we hope that you will find the publication and the series to be a useful contribution to building bridges between different stakeholders and advancing mutually acceptable solutions to complex issues.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

EXECUTIVE SUMMARY

The technologies that have arisen in research and development (R&D) of genetic resources—some in place for more than two decades—highlight, more than ever before, the limitations of frameworks on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (ABS), particularly with regard to fairness and equity in sharing of monetary benefits.

The principles of sovereignty, prior informed consent, and mutually agreed terms, as enshrined in the Convention on Biological Diversity, are being challenged as to their appropriateness in responding to an increasingly, but not wholly new, disruptive technological paradigm. With "information" extracted, disembodied, or dematerialised from genetic resources, questions arise regarding the relevance of biological material in relation to ABS and as the vehicle for that disembodied information. The importance of biological materials may vary from sector to sector.

This paper argues that there is evidence to suggest the need for a shift in the narrative on, and policy options for, ABS that is adapted to a changing R&D landscape. As a result, a new global regime for ABS may be required, particularly to support realisation of the fair and equitable sharing of benefits. The paper ends with some suggestions on the elements for such a regime and how it could be developed.

1. INTRODUCTION

Criticism of access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (ABS)[1] can be expressed through the following questions: Why have ABS projects not delivered fair and equitable monetary benefits? Or any significant monetary benefits? What do fairness and equity mean in the context of ABS? How is ABS contributing to the realisation of the objectives set out in the Convention on Biological Diversity (CBD) and achieving the Aichi Biodiversity Targets, set out in the CBD, and Sustainable Development Goals? Why are scientists still concerned about the chilling effects of ABS? What should be the focus of ABS?

Despite tens of millions of dollars spent since the CBD entered into force on capacity-building, awareness-raising, and policy and legal research through innumerable projects and initiatives, measurable monetary benefits have been limited at best.[2] Benefits for the conservation of biodiversity seem even less apparent. Indeed, initial enthusiasm for ABS in the 1990s has given way to a degree of scepticism.[3]

The question "How can we make ABS work?" remains as valid today as it was 25 years ago, albeit more pressing as the suggested solutions have remained more or less the same over all that time. For many people engaged in ABS and related issues,[4] frustration with progress cannot be downplayed. However, there is reason for hope as new actors and scholars become engaged in ABS,[5] more focused and innovative ideas enter discussions, and policy processes become more receptive.[6] After more than 25 years, the need to rethink ABS in the context of technological change is finally

1 Notice how ABS is universally translated and referred to as "access and benefit-sharing" and not "access to genetic resources and fair and equitable benefit-sharing." While seemingly an innocuous practice of saving words and shortening a phrase, this is not a minor detail. Within the discourse of ABS and over time, this practice has placed equity and fairness in the margins of discussions.

2 Contracts and agreements that have delivered monetary benefits do exist. However, not all of these would fall under the narrow scope of ABS suggested throughout this paper, Furthermore, the question remains as to whether these benefits under a bilateral system meet the standards of being fair and equitable or are the consequence of an intrinsically asymmetric negotiation. The former is probably true. For a survey of contracts and agreements that have delivered benefits, see Robinson (2015).

3 Well-argued concerns were raised by the scientific community even as ABS frameworks were being developed and approved. See, for instance, Grajal (1999) and Hoagland (1998), published by ASCOLL, which is now part of the Natural Science Collections Alliance. Recent critiques include Prathapan et al. (2018). Within the social sciences, concern originates in the periphery of disciplines, albeit growing in number. Criticism has led to analysis of the reception of stakeholders to the application of economics to ABS; see Oduardo-Sierra, Vogel, and Hocking (2012). Critical views on the policy and legal side include Kamau and Winter (2013) and Wynberg (2018). See also the visionary work of Parry (2004, 249–262), who early on recognised the importance of the informational dimension of genetic resources and difficulties of assigning rights and monitoring their flows under the CBD framework.

4 Given its complexities, a reflection on traditional knowledge associated with genetic resources (TK) demands a standalone paper. While acknowledging the relations between TK and access to genetic resources and biodiscovery, this research paper focuses on ABS as the specific topic of analysis. Some references are made to TK when essential and deemed necessary to clarify certain ideas.

5 See, for example, Deplazes-Zemp (2018), Pauchard (2017), and Angerer (2011).

6 The CBD, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the World Health Organization (WHO), and the Commission on Genetic Resources for Food and Agriculture, for example, have started to address the policy, social, institutional, and legal implications of extensive use of digital sequence information (DSI) for a wide range of purposes, and what this means for ABS. The CBD Secretariat has developed a specific webpage to collate what has been done and other useful information on DSI, including discussions by an expert working group and a scoping study; see www.cbd.int/abs/dsi-gr.shtml. The ITPGRFA offers a particular insight into the issue: although it has defined the concept of "genetic parts or components" as "the elements of which they are composed or the genetic information/traits that they contain" in its new standard material transfer agreement (SMTA), the actual way in which genetic information will be regulated and addressed has not been defined or specified.

gaining traction.[7] More and more, stakeholders realise the potential impact of ABS and how the current legal and regulatory frameworks must be able to accommodate the realities of research and development (R&D) and urgently catch up with technological advances.[8]

The potential for a global multilateral benefit-sharing mechanism (GMBSM) under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (2010) for genetic resources that are transboundary or for which prior informed consent (PIC) is not possible is opening up space for creative thinking and new policy reflection. Moreover, synthetic biology and digital sequence information (DSI) have also triggered a wave of interest and call into question whether the current ABS model is appropriate as an enabler of fairness and equity in benefit-sharing and as an incentive for the overall conservation of biodiversity.

This discussion paper addresses three fundamental questions: first, whether benefit-sharing to date has been fair and equitable and whether ABS has served to support conservation in a measurable way; second, what can be done to improve benefit-sharing; and third, how can change be achieved on the policy, institutional, and regulatory fronts. The rest of the paper is divided into five sections. Section 2 sets the stage, providing a brief historic description of the key milestones in ABS policy, legal, and institutional developments. Section 3 analyses the fundamental reasons for why ABS has not delivered or had the impacts expected in light of investments and efforts made by governments, academic researchers, funding agencies, and nongovernmental organisations. This section also provides a critique of sovereignty, PIC, and mutually agreed terms (MAT) and their effects on benefit-sharing possibilities. Section 4 offers an initial conceptual approach to rethinking ABS and building its institutional and legal foundations on more compelling economic arguments. The section reviews the notion of "bounded openness for natural information" as a potential underpinning for an efficient ABS regime. Section 5 develops some of the elements of an international regime on ABS that may contribute to efficiency and the realisation of fair and equitable benefit-sharing. Section 6 provides suggestions for navigating a complex institutional setting for ABS, with a view to triggering a reinvigorated policy process within the general framework of the CBD and Nagoya Protocol. Some conclusions and recommendations close the paper.

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7 Although information technology and its offshoots (e.g. big data, artificial intelligence, gene editing, bioinformatics, genetic engineering) put in increasing relief the relevance of information to ABS, it was already possible to foresee in the 1990s that ABS should have focused on the informational, intangible dimension of genetic resources as the object of access. See, for example, the inexplicably overlooked works and papers by Timothy Swanson, Joseph H. Vogel, and Brownyn Parry, in particular Swanson (1992) and Vogel (1994). Also of interest is Parry (1997).

8 Policymakers are obliged to reflect on whether legal measures need to be adjusted and whether or not suggested measures may contribute or become detrimental to research, technological advancement, and development in general. The United Nations Climate Change Convention and the Kyoto Protocol are excellent examples: the original climate change regime of the 1980s and 1990s has morphed and dynamically changed into tools and instruments better suited to address the challenges of climate change pressures. Modern international agreements are frameworks themselves and can conceivably evolve quickly.

2. A BRIEF HISTORY OF ABS

The history of ABS can be reviewed and told in many ways.[9] One fairly simple approach is to look at the key international instruments that, at different times in history, have reflected policy, social, cultural, legal, and economic concerns with regard to genetic resources, their control, and their use. Table 1 briefly describes these moments and summarises their importance.

Table 1: Key access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (ABS) milestones in history

Instrument	Year	Significance
International Undertaking on Plant Genetic Resources	1983	First international legal (non-binding) instrument addressing access to and use of plant genetic resources. Its principles extended in practice to all genetic resources. Recognised that genetic resources were the common heritage of humankind, later modified through Food and Agriculture Organization resolutions. The International Fund for Plant Genetic Resources, a key multilaterally oriented component for benefit-sharing purposes, never gained sufficient political traction or support for implementation
Convention on Biological Diversity	1992	First legally binding international instrument regulating ABS principles with regard to all genetic resources, from all sources. Recognises, inter alia, principles such as sovereign right to exploit natural resources and responsibility not to cause damage to the environment of other states, prior informed consent (PIC), and mutually agreed terms (MAT) to achieve benefit-sharing. Countries begin developing ABS policy and legal frameworks. Strong vindication by southern countries of sovereignty and their rights over their genetic resources and indigenous peoples' traditional knowledge (TK). Defines genetic resources as "material" but does not define "material." Emphasis on contracts as the key enabling tool to achieve fairness and equity in benefit-sharing
International Treaty on Plant Genetic Resources for Food and Agriculture	2001	Binding international regime on ABS for a closed list of plant genetic resources for food and agriculture only. Other uses excluded from facilitated access under a multilateral system of ABS. A standard ABS agreement developed and approved—the Standard Material Transfer Agreement, which has recently been adjusted. Mostly implemented by ex situ centres of the Consultative Group for International Agricultural Research. Farmers' rights recognised. Monetary benefits channelled to the Benefit-Sharing Fund to support in situ conservation by small-scale farmers

9 Pistorius (1997) offers a comprehensive review of the early history of the politics and institutional developments of the plant genetics resources movement since the early 1960s.

Table 1: *(Continued)*

Instrument	Year	Significance
World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore	2001	International process launched to evaluate possible ways to protect TK and genetic resources and traditional cultural expressions. Draft texts have been developed on all three issues; the first focuses on disclosure and the others on a menu of measures to legally protect TK and traditional cultural expressions. Mandate pending for diplomatic conferences for final negotiation of international agreements
Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization	2010	Specific international binding ABS instrument finetuning scope of ABS to "utilisation" of genetic resources, including through research and development of resources and biochemical components. Affirms PIC and MAT (contract) principles and recognises indigenous peoples' TK related to genetic resources. Includes possibility of developing global multilateral benefit-sharing mechanism for cases where genetic resources are transboundary and where PIC may not be possible

Source: Author

The Food and Agriculture Organization (FAO) International Undertaking of 1983 was the result, among other factors, of increased political pressure by alliances between biodiversity-endowed countries that acknowledged an historical process of continued, uncompensated free flow of genetic resources towards developed, technologically advanced countries (Pistorius 1997). Although the Undertaking was non-binding, it greatly assisted the international community in understanding the intricacies and far-reaching implications of the politics of genetic resources and their control and rights thereof, including farmers' rights (Andersen 2008).

A decade later, the CBD revitalised discussions on ABS and traditional knowledge (TK) as a reaction to various parallel processes that addressed rights pertaining to genetic resources and the protection of new technology developments, including through intellectual property (IP). Central during this time were biotechnology, utilisation of genetic resources, and protection of innovations through IP. Decisions by the United States (US) Supreme Court such as in the case of *Diamond v. Chakrabarty* (1980), changes in US innovation policies to allow private investment in publicly funded R&D through the Bayh-Dole Act (1980), and inclusion of IP as a pillar of the World Trade Organization created in 1994 highlighted the growing relevance of biotechnology. As a result, the focus on control and rights over genetic resources and biotechnologies also took centre stage in the CBD.[10] Sovereignty, PIC, and MAT became the key principles and tools to ensure realisation of benefit-sharing.

Given the express recognition of unsolved issues regarding plant genetic resources for food and agriculture by the CBD, the FAO pursued a parallel process that led to the development and approval of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in 2001. The ITPGRFA developed a multilateral ABS system, based on the use of a standard material transfer agreement (SMTA), a set list of plant genetic resources for food and agriculture (PGRFA), fixed monetary benefits in cases of commercial

10 See introductory section and Articles 15, 16, and 19 in Glowka et al. (1994). See also Chandler (1993).

use and success, and a multilateral approach to non-monetary benefits. Such non-monetary benefits are being sought through financing conservation activities via the Benefit-Sharing Fund, capacity-building processes, and information exchange through the Global Information Exchange Mechanism on PGRFA, among others.[11] In light of the limited monetary benefits collected from the utilisation of PGRFA, a process is under way within the ITPGRFA to explore new ways to enable realisation of this form of benefits.[12] The FAO treaty has served primarily to regulate and create legal certainty in the transfer of PGRFA by and within the International Agricultural Research Centres of the Consultative Group for International Agricultural Research system (see Table 1 for an outline).

Finally, the Nagoya Protocol was adopted in 2010 for the purpose of responding to difficulties faced by countries of origin in securing benefit-sharing and the monitoring and tracking of their genetic resources, based solely on national action including legislation and regulations. It soon became apparent from experiences in implementing national ABS regimes from 1996 onwards that existing frameworks are insufficient to realise benefit-sharing. More concerted action and coordination would be required among parties to the CBD and, in particular, among users of genetic resources and associated TK.

Disclosure requirements are possibly the most visible form of user measures and are now mainstream in all ABS- and IP-related discussions and in various legal and regulatory frameworks (WIPO 2017a).[13] Both developing and developed countries have adopted and incorporated forms of disclosure requirements, but implementation is still a challenge and an ongoing process.[14] A more recent form of user measure are due diligence requirements enshrined in the European Directive for compliance with the Nagoya Protocol.[15]

11 See www.fao.org/plant-treaty/en/.

12 See Correa (2013). See also FAO Resolution 2/2017 (IT/GB-7/17/Res2) Measures to Enhance the Functioning of the Multilateral System of Access and Benefit Sharing (www.fao.org/3/a-mv104e.pdf).

13 See also WIPO (2017b).

14 So-called "user measures" were all but ignored during the 1990s. By 2002, when the Bonn Guidelines on ABS were adopted, it had already become clear that concrete actions were required by provider countries from which genetic resources were being transformed through R&D to support realisation of the CBD objectives. The Andean process to develop Decision 391 on ABS started in 1994, and this Decision became the first legal instrument to incorporate conceptual discussions on user measures and legal measures therein. Tobin came up with the idea of "disclosure" around 1993 and developed it in a paper a few years later (Tobin 1997). For a detailed analysis of Decision 391 and the Andean process, see Rosell (1997). For a fully operational disclosure mechanism, legally certain, clear, and widely accepted ABS laws, regulations, and procedures are required, complemented by internationally recognised instruments (e.g. certificates of compliance). Efficient disclosure is a complement to efficient ABS frameworks.

15 Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511).

3. KEY REASONS WHY PROGRESS HAS BEEN SLOW IN ABS

More than two decades of multiple experiences in ABS justify a critical assessment of why benefit-sharing in ABS has been elusive (see Table 2) in an otherwise multibillion-dollar industry.[16] The mere existence of ABS laws and projects, programmes, contracts, funding opportunities, case studies, and so on[17] does not necessarily mean substantive progress.[18] In the spectacular case of the National Institute of Biodiversity of Costa Rica, the once very popular model, and almost a brand, has ceased to undertake bioprospecting due to limited successes and other problems associated with general operating costs (Fonseca 2015). One area where some progress has been made is in increasing overall awareness of the different issues surrounding ABS. What in the 1990s was the exclusive domain of a few experts and scholars, mostly lawyers, has now become mainstream with many more stakeholders engaged.

The confidentiality clauses of contracts render impossible any quantitative assessment of ABS. Nevertheless, knowledgeable observers can gauge trends in their qualitative assessment of the shifting interests by parties and stakeholders in the various dimensions of ABS over time (Figure 1). Investments in ABS (e.g. projects, capacity-building, research papers) seemed to peak in the early 2000s and then turn down. Sustained media coverage also seems to flatten, notwithstanding blips around the time of the Conference of the Parties (COP).

However, and much more substantially, limitations of ABS persist, as is reflected in the following: almost no monetary benefits shared; unavailability of commercial ABS contracts to assess their fairness (i.e. due to confidentiality clauses); noticeable imbalance between investments in ABS (high) and concrete returns and results (low) (Figure 1); and, ultimately, underlying inefficiency issues in an ABS regime that relies on contracts to capture fair and equitable benefits.

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16 See the work by Sarah Laird and Rachel Wynberg for the ABS Initiative, analysing a set of industrial sectors (biotechnology, botanicals, agriculture, cosmetics, pharmaceuticals) that access and utilise genetic resources. When added together, these industries are part of a multibillion-dollar bio-economy. These studies are available at www.abs-initiative.info/knowledge-center/publications/.

17 Dozens or more case studies of "successful" ABS (including of legislation and actual projects and bioprospecting activities) have been prepared, published, or made available over the past two decades. The very few studies of examples deemed "unsuccessful" usually point to process issues—for example, indigenous peoples were not consulted, or the activities ended because a state agency took too long to issue permits or negotiate contracts. All take it for granted and it goes unquestioned that benefit-sharing conditions negotiated in contracts were fair and equitable or that conditions set out in legislation will lead inevitably to fairness and equity. A comprehensive and critical analysis is long overdue. Useful sources of "successful" case studies include Lewis-Lettington and Mwanyki (2006). This is an extremely detailed, well-documented, comprehensive analysis of legislation and agreements, which falls short of a substantive reflection on whether fair and equitable benefit-sharing is even possible under a bilateral approach. More recently, a publication edited by Paterson and Lima (2017) showcases a number of projects and contracts, and a series of bioprospecting initiatives related to drug discovery and the pharmaceutical industry. While all chapters make interesting reading in terms of how bioprospecting is being undertaken in the search for useful molecules from ocean, marine, and soil bacteria, there seems to be limited questioning as to whether contractual approaches and ABS in this field can be fair and equitable, or even possible. This may be part of a broader analysis that the authors did not intend to undertake at this stage. See also the various ABS case studies from around the world included in Robinson (2015).

18 The CBD Secretariat, in accordance with Article 31 of the Nagoya Protocol and Decision NP-2/4, is conducting an assessment of the Protocol (one key component within a broader ABS regime), based on a series of elements, including an assessment of progress by parties in establishing institutional structures and access and benefit-sharing measures to implement the Protocol; establishment of reference points to measure effectiveness; and stock-taking of the use of model contractual clauses, codes of conduct, guidelines, best practices, and standards as well as indigenous peoples' and local communities' customary laws, community protocols, and procedures. None of these elements seems to relate to equity and fairness in benefit-sharing and the realisation of this particular objective of the CBD and the Protocol. See www.cbd.int/abs/assessment-elements.shtml.

Table 2: Examples of failed bioprospecting projects in selected Latin American countries

Project	Country	Year	Reason for failure (interruption of project)
Bioandes and Andes Pharmaceuticals (US)—bioprospecting project in search of active components in medicinal plants (genetic resources and derivatives) in the national parks system[a]	Colombia	1997-1998	National competent authority (Ministry of the Environment) denied company access to Colombian genetic resources on grounds of insufficient benefits would result
International Cooperative Biodiversity Groups (ICBG) — bioprospecting project in search of active compounds from medicinal plants of indigenous communities[b]	Peru	1993-2000	Final collecting permits not issued by national authority at time (National Institute for Natural Resources), after university responsible for collecting waited almost 4 years
ICBG—bioprospecting project in Chiapas region in search of medicinal compounds from plants[c]	Mexico	1999-2000	Disputes with Mayan indigenous peoples regarding prior informed consent (PIC), benefit-sharing, land rights, traditional knowledge (TK), and procedural issues
Biozulua Project—project to document TK related to medicinal plants of indigenous communities[d]	Venezuela	2000-2002	Ministry of Environment suspended project because project had not obtained PIC from indigenous communities for use of TK
Pro Benefit Project—project sponsored by German Society for International Cooperation to support a PIC and mutually agreed terms (MAT) process to initiate bioprospecting activities[e]	Ecuador	2003-2007	Ministry of Environment unable to provide and formalise PIC and MAT and celebrate access contract with Pro Benefit partners, who decided to terminate project on amicable terms.

[a] *See Echeverri (2010, 157).*

[b] *See Tobin and Taylor (2009) and Greene (2004).*

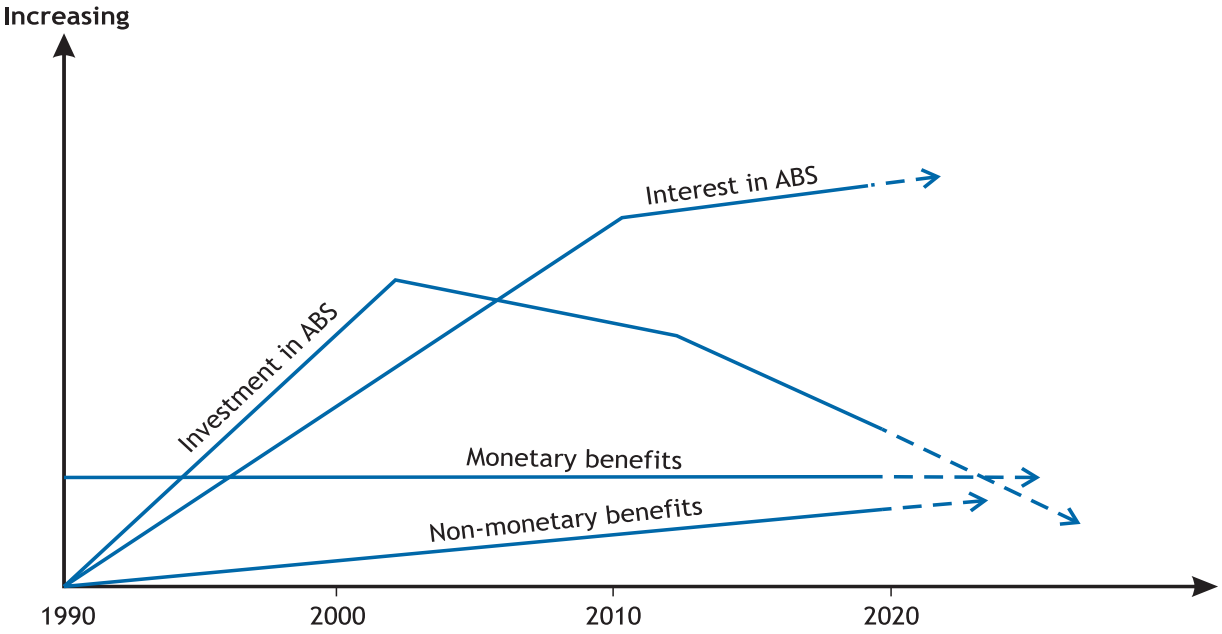
[c] *See Maya ICBG Bioprospecting Controversy (http://en.wikipedia.org/wiki/Maya_ICBG_bioprospecting_controversy).*

[d] *See Centeno (2009, 4).*

[e] *See Ploetz (2005).*

Source: Adapted from Ruiz (2015).

Figure 1: Personal assessment of access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (ABS) over time



Note: The graph reflects 25 years of the author's engagement in ABS processes throughout the world and impressions of future trends.

Source: Author

Figure 1 basically shows high investment in ABS (e.g. projects, capacity-building, research papers) until the mid-2000s and then a marked downturn; heightened interest in ABS over time, peaking as COPs approach, with many more actors involved in discussions and new scholars paving the way for innovative ideas; monetary benefits "flatlining," meaning no significant benefits shared in a large global bio-economy; and non-monetary benefits, which, although difficult to quantify, have certainly been generated as part of more classic research cooperation activities between countries and institutions.

Why has monetary benefit sharing been insignificant in an otherwise multibillion-dollar market? The answer may lie in a limitation within the CBD, which has permeated national and international ABS frameworks—and gone mostly unquestioned over time: the definition of "genetic resources" as genetic material of actual or potential value, where "material" is interpreted as "matter." During initial debates in the 1980s and 1990s, ABS was never intended to be about access to biological materials but, rather, about the application of modern biotechnology and assessing the usefulness of genes and biochemicals. This comprises a small, albeit important, portion in the general "use of the biodiversity universe" made by humanity (Figure 2).[19] Biotechnological R&D can be a key phase in adding value to genetic resources across all imaginable fields, and biotechnology[20] remains at its core, mostly in terms of "extracting/decodifying/dematerialising/disembodying"[21] information from biological entities.[22]

19 The Nagoya Protocol has turned its focus to the "utilization of genetic resources," which it defines as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."

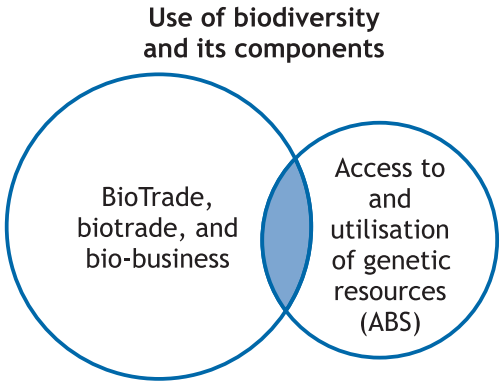
20 Biotechnology is defined in the CBD as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."

21 These are the different concepts used to convey the idea from institutionalist economics that resources do not exist per se but become in light of emerging technologies. In this case, genetic resources "become" a useful intangible, informational asset through use of different bio-related technologies. See, for example, Bagley (2018).

22 See also the Samoa Mamala case study in Robinson (2015).

Within this context, the notion of "access and benefit-sharing" was intended to apply neither to biotrade, or BioTrade,[23] nor to uses of raw or semi-processed biological materials.[24] Unfortunately, conflating bio-businesses with ABS has blurred, stretched, and confused debates. The focus of ABS should be modern biotechnologies and application of high-end technologies in general. Likewise, the emphasis placed on genetic resources as "material"[25] has also obscured the true object of ABS: information, whether natural information or DSI, as is commonly used.[26]

Figure 2: Access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (ABS) as part of the use of biodiversity



Note: The distinction between BioTrade and biotrade is explained in the body of this paper.
Source: Ruiz (2018)

23 A distinction must be made between broad sustainable biotrade and bio-businesses, and BioTrade, which is a specific creation of the United Nations Conference on Trade and Development in 1996 and covers a set of activities (mostly biodiversity value chains) that respond to BioTrade principles and criteria, including sustainability, benefit-sharing, and protection of traditional knowledge. Mostly, BioTrade involves trading in biodiversity commodities, including natural extracts and biological resources, and to which technology and other tools such as certification, trademarks, and branding in general are applied to phases in the value chain. See Jaramillo and Onguglo (2017).

24 Businesses in biodiversity components (e.g. BioTrade or trade in biodiversity products in general) are critically important and a source of direct jobs, income, tourism opportunities, and so on. These businesses are pragmatically governed by principles and rules regarding natural resources management plans, environmental impact assessments, non-timber product trade, fair trade and fair prices, B-enterprises, community management plans, and so on. Only marginally should they entail ABS obligations, as is the case when modern biotechnology is applied to a phase in the development of a value chain. But this should be the exception rather than the rule, unless countries decide in their national legislation to bring BioTrade within the scope of ABS. The worries of countries about "derivatives" being a loophole for ABS have contributed to the unnecessary expansion of ABS. See Ruiz (2017).

25 Some parties and stakeholders argue that under the definition of "genetic material," information is already present (e.g. "the carrier of hereditary information; in higher organisms it is duplex DNA"—The Free Dictionary). While this may be so from a basic definitional approach, it still may not sufficiently emphasise that the information element of genetic resources is the basis of R&D. Indeed, "material" is (mis)interpreted as only matter in most national legislations.

26 These are some of the different concepts currently used in the debates. The concept of "digital sequence information" is being used as a temporary "placeholder" (http://enb.iisd.org/vol09/enb09702e.html), as many parties and experts agree that it is limited and does not capture the various nuances associated with the informational dimension of genetic resources. See a critique of the notion in SPDA (2017). A more robust and elegant concept, strongly founded on science, is that of "natural information," which—though seemingly self-explanatory—can be defined as "any non-uniformity, difference, or distinction not intentionally produced by *H. sapiens* which derives from thermodynamically open systems to dissipate energy gradients and create copies of itself." A more colloquial and maybe legal definition could also be "any non-uniform expression, difference or distinction produced by nature." These are still working definitions under review by Joseph H. Vogel, Manuel Ruiz, and Klaus Angerer (personal communication, 4 July 2018). Dutfield (2012) has also pondered the question of what, in essence, genetic resources are. He argues that analogies, metaphors, and homology serve reductionist science well to conceptualise and develop its theories and method about genes and molecular biology in general.

This informational dimension in biotechnological R&D is especially relevant for ABS.[27] Quite surprisingly, however, the policy, legal, and economic implications of information-based technologies have gone largely unnoticed in the ABS narrative—until fairly recently.[28] Biotechnology, genomics, gene editing, bio-nanotechnology, synthetic biology, bioinformatics, and big data are just some manifestations of disruptive technologies and tools. The convergence between biological, digital, and material systems is having noticeable

Box 1: Illustrious antecedents: genetic resources as natural information

The identification of genes as information was intuited even before the actual discovery of genes. Whether as a form of metaphor, analogy, or homology, scientists have long referred to an informational perspective on life. In the *Origin of Species* (1859), Charles Darwin understood that there was descent with modification even though he was unaware of the mechanism of transmission. Unbeknownst to Darwin, his contemporary Gregor Mendel published *Experiments on Plant Hybridisation* (1865) and got closer to genes as information when typifying the "characters" of peas. In *What is Life?* (1943), physicist Edwin Schrodinger was the first to state explicitly that "every individual cell, even the most insignificant, must possess a double copy of the code or script." The discovery of deoxyribose nucleic acid (DNA) by Watson and Crick in 1953 was expressed using the metaphor of information (e.g. a "possible copying mechanism for the genetic material") and later explicitly described as such by Crick in his *Central Dogma of Molecular Biology* (1970), which specifically refers to "genetic information." *In Genes for Sale*, Vogel (1992) fleshes out the homology with a common origin in the model of Shannon-Weaver or the isomorphic equation of Boltzmann (information theory). Scientific popularisations have also stressed genes as information. In *Global Action for Biodiversity* (1997), Swanson refers to the information values of biodiversity as essential in the context of biotechnology and intellectual property. In *Rivers out of Eden* (1995), noted evolutionist Richard Dawkins goes so far as to say that genes are pure information and rivers of information. More recently, the concepts of "intangible, information element" have been highlighted in *Genetic Resources in the CBD: the Wording, the Past, the Present and the* Future by Tvedt and Schei (2013); "digital sequence information" in *Sequence Data and benefit Sharing* by Hammond from TWN (2017); "natural information" in *The Intellectual Property of Artificial and Natural Information* by Vogel (1991); "bio-information" in *Trading the Genome: Investigating the Commodification of Bioinformation* by Parry (2005); and "informational good" in *Global Status and Trends in Intellectual Property*

Claims: Genomics, Proteomics and Biotechnology by Oldham (2009), and have been used to highlight the importance of genetic resources as information for R&D in a policy or institutional context. Unabashedly reductionist, genes and metabolites as information serve well to develop conceptual and policy approaches.

Source: Adapted from Ruiz (2015).

27 The term "Fourth Industrial Revolution" is defined, broadly, as "the transformative change in data and technology capabilities, combined with a merging of digital, physical, and biological realms, and its consequences on society" (World Economic Forum 2018, 3).

28 Organisations such as the ETC Group (formerly RAFI) have always been at the forefront of, and pioneers in, efforts to call attention to the risks and challenges new technologies pose. *Extreme Genetic Engineering: an Introduction to Synthetic Biology* (ETC Group 2007) marked a milestone. Other organisations, such as the Wilson Centre, have provided important insights into legal and policy aspects of synthetic biology. SPDA, the Peruvian Society for Environmental Law, was also highlighting the challenges of new technologies to ABS frameworks around the same time; see Ruiz and Pastor (2008). Scholars such as Paul Oldham were also noticing the problems faced by ABS in the light of genomics and related tools. Joseph H. Vogel has explored ABS continuously since before the ratification of the CBD as an application of the economics of information (Vogel 2007; Vogel 1994). Until the advent of synthetic biology, the reception to the economic approach has been limited. See Vogel (2008).

impacts on industrial biotechnology, food and agriculture, and the health and pharmaceuticals sectors, with new ways of breeding improved plant varieties and animal breeds, undertaking clinical diagnosis, producing personalised medical treatments for diseases, and enhancing agricultural and industrial production in general. It is ironic that the informational component of the biological world was intuited early (see Box 1) but has only recently received the attention it deserves in the context of the CBD wider ABS policy discussions.

More recently, the placeholder "digital sequence information" and controversies surrounding synthetic biology have highlighted the importance of the informational dimension of genetic resources—something long overdue.

An underlying reason why ABS with regard to monetary benefits has not been successful lies in misplaced confidence by parties to the CBD on the applicability of principles of sovereignty, PIC, and MAT as inevitably enabling a fair and equitable sharing of benefits.[29] Only recognition exists that most genetic resources are shared among countries and characteristics of interests for R&D, also dispersed across taxa.[30] Dispersion of species makes claims over sovereignty pointless as multiple countries usually share the same species or species containing the same biochemical compounds or genes. This transboundary situation over the natural information behoves users to jurisdiction shop and choose the countries with the lowest barriers to access.[31] Whenever the genetic resource is extant in the non-party, that of course is absolutely preferred. The Nagoya Protocol puts in high relief the limitation and even error of defining genetic resources as "material" and then interpreting material as only matter. Because matter cannot be in two places at the same time, the widespread distribution of the natural information therein contained is not an issue. However, the consequence of jurisdiction shopping among parties leads to monetary benefits so low that often they are not disclosed. Articles 10 and 11 of the Nagoya Protocol offer the possibility of developing a global multilateral ABS system that responds to these features.[32]

Furthermore, the almost inexhaustible sources of natural information from online databases and ex situ specimens make physical controls or monitoring possibilities over genetic resources virtually impossible.[33] Ultimately, the ability to liberate all information from biological matter will make physical checkpoints pointless.[34]

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29 There are accumulative reasons as to why reluctance to review the CBD in its ABS content has been so consistent and strong. These include *stare decisis* (stand by the decision), group-think, and path dependency. See Ruiz (2015).

30 It is interesting to note that according to patent activity over biotechnologies, patents are concentrated around a small and well-known group of cosmopolitan species and that "species that are limited to one or a very small number of countries are likely, on the basis of available distribution data, to be the exception rather than the rule." See Oldham, Hall, and Forero (2013).

31 See Vogel et al. (2018).

32 Articles 10 and 11 of the Nagoya Protocol, Article 10: "Global multilateral benefit sharing mechanism. Parties shall consider the need [exceptional] for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations [exceptional] or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally." Article 11: "Transboundary cooperation. 1. In instances [exceptional] where the same genetic resources are found in situ within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol."

33 In recent times, blockchain technology and related smart contracts have been heralded as potential tools to support implementation of ABS under the Nagoya Protocol, particularly in the context of monitoring and tracking. They do not, however, address the core problem undermining fairness and equity, namely bilateralism (World Economic Forum 2018).

34 See Oldham (2004).

4. TOWARDS A ROBUST CONCEPTUAL UNDERPINNING FOR ABS

Fair and equitable monetary benefits will never arise from the bilateral negotiation for access to genetic resources.[35] Introductory economics reiterates that competition drives down the price to the marginal costs of production, which is essentially nothing for information. Jurisdiction shopping "for the best deal" will ensue. Multiple examples of pitiful royalty rates have emerged despite confidentiality clauses in the world of commercial contracts and ABS agreements.[36]

While it is becoming gradually accepted that the informational dimension in genetic resources is key in R&D, it remains baffling that limited attention has been given to fairness and equity in ABS, particularly as it relates to bilateral negotiation of contracts.[37] There is a well-established economics of information that recognises that for artificial informational goods and innovations (e.g. from music to literary creations to inventions in the non-life sciences), exclusive rights in the form of, for example, patents or copyright are the most efficient way to align incentives to stimulate creativity. Given the impossibility of creating physical barriers to "protect" these goods, time-limited monopoly IP is a solution for artificial information. A similar solution needs to be built to address natural information from genetic resources as an intangible asset.[38]

At the same time, considering that bilateralism is not fulfilling expectations of fairness and equity, what alternatives are there? Multilateralism is the answer. If it is accepted that the subject matter and true object of R&D are natural information, then sound economic, legal, and policy options are readily available. Based on insights from several disciplines, the notion of "bounded openness" seems a robust conceptual approach to ensure the fair and equitable sharing of benefits arising from access and utilisation of genetic resources.

Bounded openness in the context of genetic resources would mean that genetic resources can continue to flow freely (the openness) but would no longer be free of cost (the boundedness) (Vogel et al. 2018). This responds well to a problem many researchers have been complaining about: excessive regulations in ABS frameworks, which act as disincentives to compliance.[39] Under bounded openness, any form of in situ- or ex situ-based R&D of genetic resources, including any beyond national jurisdictions[40]

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35 As much as contracts are the key preferred tool to enable negotiation of conditions for access, they become unsuitable in the context of fairness and equity when applied to shared and widely disseminated resources, some of which lie in the jurisdiction of a mega diverse non-party. To express it succinctly, try selling something if somebody else is giving it away for free. The 400-plus page guide by Young and Walloe-Twedt (2017) on how to negotiate "successful" ABS contracts is also a case in point on complexity, without even touching on the equity and fairness possibility aspect.

36 Drahos (2014, 141–156) refers to receiving "peanuts for biodiversity." Without entering into an in-depth analysis of this phrase, what should be extracted from it is that something is not right in the way that benefits (money) are being shared. For a review of some of the royalties negotiated in ABS contracts over time, see Ruiz (2015, 38–49).

37 De Jonge (2011) also claims that, given the non-rival nature of information and given that plants (in this particular case) are non-excludable, "it is rather hard, therefore, to envisage how the genetic information contained in any specimen (or part thereof) of a particular plant species, could become subject to a fair and equitable exchange between two parties." What he is saying is, in simple terms, that bilateral contracts are unsuitable to ensure fairness and equity.

38 For over two decades, Vogel has been designing and refining a technically consistent and sound conceptual economic framework to address ABS in the light of economics and natural information; see Vogel et al. (2011, 54–55).

39 A group of Brazilian researchers in *Science* calls the new and innovative ABS regulation (based on standard bilateral contracts) in Brazil, widely heralded as progressive, "a monumental set-back" in terms of its effects on national biodiversity research (Bockmann et al. 2018). This should send a message as to what is happening with the current ABS models.

40 Blasiak et al. (2018) show the limitations of ABS and complexities that would ensue if a bilateral approach was applied to bioprospecting activities in international waters and oceans.

(whether commercial or non-commercial), would be possible, indeed encouraged, and should proceed unimpeded—for legal and environmentally sound purposes. The only exception would be compliance with existing national rules for biological sample collecting, field work, or similar requirements, for which PIC (e.g. permits) and MAT (e.g. collaborative agreements) may be relevant. Openness also conforms well with an often overlooked CBD principle, which calls for parties to create conditions to facilitate access and not impose conditions that run counter to the Convention.[41]

Boundedness calls for fixed royalties, agreed upon by the CBD COP, to be levied ex post utilisation of natural information, if and when IP derives into a commercially successful innovation. The income or monetary benefit would then be distributed to the countries of origin of species from which natural information was extracted, proportional to the habitat where these exist in situ, thus supporting fairness and equity, which has eluded the CBD, according to conservation criteria.[42] Two critical issues remain: (i) the mechanism to identify the countries of origin of the specie(s) from which natural information could have been extracted and used in a particular commercial product; and (ii) negotiation of a table of fixed royalty rates based upon a combination of characteristics including industrial sectors and type of IP protection. Under bounded openness, access is facilitated absolutely while a fair and equitable benefit is charged and shared among countries of origin.

41 Article 15 of the CBD: "2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention." For specific examples of how bounded openness would operate in practice, see case studies by Klaus Angerer (University of Giessen) on *Epipedobates anthonyi* and Omar Oduardo-Sierra (University of Puerto Rico) on *Lepidium meyeni* in Ruiz (2015, 98–117).

42 See Vogel (2007, 92–115).

5. BASIC COMPONENTS AND ELEMENTS FOR A NEW AND EFFICIENT INTERNATIONAL ABS REGIME

If it were generally accepted by parties, first, that the discussion of ABS should centre on information, rather than material, as the subject matter for a multilateral ABS policy and legal framework and when it comes to monetary benefits, and, second, that the concept of bounded openness may provide a reasonable underpinning to solve the many challenges currently affecting ABS,[43] then the key components of a new international regime or mechanism would include:

- a global benefit-sharing fund or mechanism that would disburse monetary benefits according to spatial distribution of species (or a to-be-defined taxonomic level) in habitats containing species from which natural information was obtained;
- a geographical distribution determination mechanism (e.g. International Barcode of Life Initiative, World Conservation Monitoring Centre) that has the technology, or will gradually develop it, to determine spatial distribution of species in habitats;[44]
- a universal obligation in the patent regime to simply disclose use or not of natural information in biodiversity- or biotechnology-derived innovation applications;[45]
- the definition of a fixed and agreed upon (by parties to the Nagoya Protocol) royalty on products and services protected by IP that are commercially successful and according to a combination of characteristics through a negotiation process within the CBD COP;
- national regulatory regimes that cover biological research collaborations and activities through classic PIC and MAT tools such as permits, authorisations, and agreements.

Such an international ABS regime would ensure predictability, reduce transaction costs, and support efficiency, while still enabling countries to undertake R&D collaboration and use bilateral contracts, agreements, or any similar instrument to define non-monetary benefits. The legal vehicle would be the modality left undefined in the Article 10 of the Nagoya Protocol, namely the GMBSM.

Most importantly, such an ABS regime would contribute to aligning incentives to allow parties to prevent habitat loss and offset the huge pressures to change land use, transform habitats, and erode biodiverse ecosystems. Some nuances are required: equitable and fair sharing of monetary benefits may not necessarily address conservation in a direct or linear manner. Monies could go to activities with the highest social value at the time—maybe supporting a school, or a community centre, or a medical post, or maybe conservation itself as a means to improve livelihoods and contribute

43 Some of these challenges include issues about retroactivity, non-parties, areas beyond national jurisdiction, ex situ centres and their collections of genetic resources and natural information, and databases, as noted in Section 4.

44 The system recognises distribution cannot be established with ease. The empirical estimates of distribution would only be for cases of successful utilisation and would find assistance in existing technologies and institutions, including the Global Biodiversity Information Facility, the International Barcode of Life, and the World Conservation Monitoring Centre, and others that are advancing towards making identification of species distribution more and more precise. See, for example, a recent press release by the CBD Secretariat "Big Data for Biodiversity: Global Biodiversity Information Facility Surpasses One Billion Records," which indicates that "records provide researchers and policy makers with [an] unrivalled information resource, bringing together evidence on where and when species have been observed or collected" (https://www.gbif.org/news/5BesWzmwqQ4U84suqWyOQy/big-data-for-biodiversity-gbiforg-surpasses-1-billion-species-occurrences).

45 If a species is known ex ante (at the time of the application), then all the better; if not known, then determination will be made ex post, once monetary benefits are produced and the geographical distribution determination mechanism has the capacity to make this calculation in a cost-efficient manner.

towards local sustainable development. The total sum of the values of an ecosystem, supported through carbon sink protection schemes, ecotourism, and ABS benefits, among others, could then serve to counter the appeal of short-term income generated by changes in land use and ecosystem degradation. And so, in a way, an international ABS regime based on a concept such as bounded openness would help to strengthen countervailing powers as a means to protecting sensitive habitats (Vogel 1994).

6. NAVIGATING THE INSTITUTIONAL AND POLICY CHALLENGES

What realistically can be done to shift discussions and policies in ABS, and who can lead the way? There are two options for addressing the situation described in this paper. One (the easiest) is to ignore the mounting evidence about the shortcomings in the current ABS approach and hope that, by keeping moving in this direction, somehow solutions will be identified and improvements made over time. The justification for this option would probably be something along these lines: "Given that the policy process is so complex and so much has been invested and done already in ABS, we might as well keep moving in this direction, and keep training, building capacities, and so on." This would be, in the best-case scenario, a mistake—and even more so in a context where technically sound decisions or evidence- or fact-based decision-making have become such a challenge.

The alternative is to address the challenge and proceed to recognise that the CBD is, after all, a framework agreement and may require some reinterpretation of its ABS provisions; to begin a discussion on the need for a GMBSM as it may apply to widely disseminated or transboundary DSI and natural information as soon as possible and identify its key objective—namely to address fairness and equity in monetary benefit-sharing;[46] and to analyse and reflect on the advantages that a system based, for example, on bounded openness could bring to all parties involved, even if counterintuitively it may seem otherwise, especially to biodiversity-endowed countries, which might resist revisiting the notion of sovereignty and their right to negotiate contracts.[47]

Leading such an effort would not be easy, but shifts and variations in the international process to address climate change, for instance, show it is possible. Resistance to change in trends and dominant narratives is always strong, particularly when much has been invested over time, and a certain self-critique is required to understand the magnitude of the adjustments needed. In any case, if the CBD and the Nagoya Protocol want to keep pace with technological advances, then the time for adjustment and change is now. First and foremost, parties need to understand that a new, revised ABS system is in their best interests—tremendously so. Second, the CBD Secretariat should stimulate activities that call upon ABS stakeholders to think jointly and reflect upon ABS. For instance, multistakeholder dialogues and focused research might be one way to proceed, as has been the case on other occasions. Third, an assessment of ABS could consider substantive

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46 The CBD Secretariat and a few institutions have already started to assess the potential and need for a GMBSM, particularly as part of the discussions on transboundary genetic resources, which could also be applied to cases of disseminated and diffused DSI and natural information or cases where contracts are inviable. Interest is extremely high, judging by contributions and submission by parties and actors to the scoping study on DSI commissioned by the Secretariat (Decision XIII/16; see www.cbd.int/abs/dsi-gr/ahteg.shtml). These are all very positive signs. See also the results and report of the Ad Hoc Technical Expert Group on Digital Sequence Information (Montreal, February 2018, CBD/DSI/AHTEG/2018/1/4 20; www.cbd.int/doc/c/4f53/a660/20273cadac313787b058a7b6/dsi-ahteg-2018-01-04-en.pdf).

47 Although there is no formal call for the negotiation of a GMBSM under the Nagoya Protocol, discussions on DSI are paving the way for further analysis of whether a GMBSM and its modality (a regime in its own right? a benefit-sharing mechanism only?) may be required. In terms of specific advances, a CBD Secretariat-sponsored expert meeting on Article 10 was held in 2013, which identified a number of areas of common understanding and areas for further examination. These are reflected in the meeting report (UNEP/CBD/ABSEM-A10/1/3). The first meeting of the COP serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP) held in Pyeongchang in the Republic of Korea in 2014 adopted Decision NP-1/10 on the need for and modalities of a GMBSM. The CBD Secretariat has since then organised, among others, an online discussion to respond to the call by Decision NP-1/10. The most recent development has been a report by the Subsidiary Body of Implementation (Second Meeting, Montreal, 2018), which acknowledges that the need for a GMBSM has been sufficiently demonstrated; although not explicitly associated with DSI, it is highly likely that this particular aspect of ABS will be raised as part of the call to continue exploring the form and structure of the GMBSM for subsequent recommendations to COP-MOP 4 (see www.cbd.int/doc/recommendations/sbi-02/sbi-02-rec-04-en.pdf).

questions regarding whether or not fairness and equity in monetary benefit-sharing under the current bilateral model are possible. The case has been made here and elsewhere that it is impossible. How would advocates of bilateralism defend the possibility? Finally, civil society and the academic sector have a role to play in stimulating discussions with due attribution that can move the debate further forward.

7. CONCLUSIONS

Biological and genetic resources as material are absolutely essential for life on the planet. But they are also the vehicles for DSI or natural information that can be unlocked (disembodied or dematerialised) through many technological pathways. A reductionist approach is needed for ABS to construct a policy and regulatory action that addresses the real subject matter of interest to biotechnology and all related technologies: the informational component in genetic resources. If this can be accepted, then solutions for ABS can almost naturally fall into place.

Accepting that information is the key subject matter in ABS will mean reconsidering prior assumptions, principles, and norms concerning the CBD and the Nagoya Protocol. Sovereignty, PIC, and MAT may become less useful in the context of a GMBSM—at least in the context of monetary benefit-sharing. Although there is a natural and understandable reluctance to stray too far from existing legal and policy trends, fuelled by *stare decisis*, group-think, and path dependency, there is also a growing recognition that something needs to change, and that this may not be simply cosmetic or an add-on but, rather, a substantive shift in ABS policy, laws, and regulations. The policy and legal process surrounding climate change, mainly the United Nations Framework Convention on Climate Change and the Kyoto Protocol, offers an example of how these shifts can be possible, given good economics, scientific foundations, and legal and institutional alternatives.

Incorporating bio-businesses, BioTrade, and any other similar category in the ABS discussions often distracts attention and unnecessarily complicates issues. Likewise, including TK in ABS discussions becomes a distraction. Such forms of use of biodiversity and its components, as well as TK, are critically important and essential to the biodiversity debate; however, they belong to a separate discussion that involves analysis of value chains, fair trade, certification, management plans, environmental assessments, and intellectual property—and, in the case of TK, reference to developments in cultural protection frameworks, collective rights, IP, and land and territorial rights, among others. Access and benefit-sharing—as viewed through the more focused lens suggested in this paper—are only marginally relevant to these aspects. Other spaces within the CBD process and other forums may be better suited to serve TK in a more effective way.[48]

MAT and PIC are still relevant in the context of non-monetary benefits, where institutions and collaborations have a long-standing practice of concluding agreements, memorandums of understanding, contracts, and so on to define the terms of technology transfer, co-authorship, and so many other forms of non-monetary benefits (see the complete list of examples in the annex to the Nagoya Protocol). But their usefulness as enablers of fairness and equity in the case of monetary benefit-sharing is absolutely limited. Compelling economic reasons exist as to why contracts are intrinsically unfair and inequitable in the context of widely dispersed, shared, and diffused DSI and natural information. But other reasons also exist and may be more subtle. In a curious kind of way, the higher the transaction costs, the greater the need for lawyers to "disentangle" complexities that could be solved through, for example, a GMBSM based on appropriate incentives and conceptual approaches such as bounded openness. More tellingly, if extensive manuals and guides, and expensive legal expertise, are required to negotiate ABS contracts and navigate administrative and regulatory procedures, then this is not a good sign for an efficient and win-win ABS regime for all.

48 Not everyone would agree with this. It has been noted in studies that biodiscovery and misappropriation have been, to some extent, led by TK. In recent patent landscaping analysis, it seems clear that there is still extensive patenting based on natural products with TK leads—though not in the "high-end" technologies. Rather, biodiscovery and misappropriation seem to be concentrated in the cosmetics, herbal treatments, and lower-end technologies—but the argument can also be made that, given that "utilisation" (R&D) takes place and they are being patented regularly, there should be a connection to ABS nonetheless. See Robinson and Raven (2017).

8. RECOMMENDATIONS

A broad and objective assessment of the effectiveness and efficiency of the ABS regime worldwide, using fairness and equity as key measures, is urgently required. Whereas national reports and a few comprehensive analyses of ABS offer an initial appraisal, their focus on the number of laws, strategies, plans, projects, regulations, or contracts as the main indicators of success provide a limited, partial, and misleading picture. Additional and more substantial indicators for a global assessment of ABS could include:

- identifying level of royalties and other forms of monetary benefits agreed in contracts, and comparing those to global sales, revenues, or other measurable factors per specific industrial or commercial sector;

- identifying not only how much genetic resources are being used in industry, but also how much DSI and natural information are being applied in R&D in biotechnology in particular;

- calculating investments in ABS workshops, projects, programmes, and other initiatives vis-à-vis benefits shared over the past two decades, with an emphasis on monetary benefits;

- surveying whether and if DSI and natural information are being considered in ongoing policy, regulatory, and institutional developments, especially at the national level and particularly as part of Global Environmental Facility and other international funding mechanisms;

- calculating how much DSI and natural information are being used worldwide, and the channels through which they currently elude ABS.

The economics of information offers a unique and coherent framework to shape policy and legal decisions when subject matter is recognised as informational in nature. Training and building capacity on the basics of the economics of information as it applies to ABS is an urgent first step to improve understanding of this particularly critical issue.

Discussions and a fresh analysis of ABS should concentrate on what is important: how technologies use the informational dimension of biodiversity components, and thus, for the purpose of focus and not prejudging their importance, sway away from biotrade, BioTrade, and TK protection dimensions. BioTrade and biotrade and other uses of biodiversity and its components should certainly include fairness and equity in the sharing of benefits, but they should also be part of existing regulatory regimes and tools, such as management plans, environmental assessments, and certification schemes.

Fairness and equity should not be taken for granted in ABS and are worthy of much greater scrutiny and thought than has been the case for over 25 years. Actors engaged and involved in ABS should pay close attention to these mostly overlooked concepts, embedded deeply in the notion of “access and benefit-sharing” but bypassed by the term “ABS.” Fairness and equity should be studied and evaluated practically in terms of how these goals can ultimately be achieved through policy and regulatory measures.

Just as the Keystone Dialogues and the Crucible Group discussions in the early 1990s allowed serious initial reflection on ABS, a new transparent, open, frank, evidence-based, and ABS self-critical process is required to address the technological challenges that have affected ABS for the past 25 years head on. To make it worthwhile, this process should not shy away from asking hard questions about established principles and long-standing assumptions surrounding ABS.

Honest self-critique by all actors and interested parties in ABS is a prerequisite for reflecting on moving forward, 25 years on. This is likely to lead to the conclusion that the path taken to regulate certain aspects of ABS may have

been incorrect. There is a need to leave behind the idea that, given that the ABS process has gone on for so long, it might as well continue moving in its current direction as long as there are projects, investment by international cooperation, and a safe arena in which to discuss issues that do not imply major policy and legal shifts. If fairness and equity are treated as add-on elements of ABS and simply "theoretical" issues of minor importance, then true progress and advancements will continue to be elusive.

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