ACCESS AND BENEFIT-SHARING IN PRACTICE: LEGAL OBSTACLES FACED BY NON-COMMERCIAL RESEARCH SCIENTISTS IN ACCESSING GENETIC RESOURCES

Summary

Many scientists in the biological disciplines require access to genetic resources to conduct research. In 1992 the Convention on Biological Diversity (CBD) affirmed that genetic resources, previously deemed the ‘common heritage of humankind’, are in the sovereign domain of nation-states. In accordance with the CBD and its Nagoya Protocol, scientists who previously enjoyed relatively unfettered access to genetic resources must now enter into access and benefit-sharing (ABS) agreements with the providing nation to use their genetic resources. The overarching objective of ABS is to channel the benefits of research and development to provider nations and to encourage the conservation and sustainable use of genetic resources. Unfortunately, ABS has not delivered substantial benefits and has had the unintended consequence of impeding scientific research. This article addresses the barriers encountered by non-commercial research scientists who are likely to apply to use minute quantities of genetic resources. Scientists typically pose no existential threat to the genetic resources they wish to study, yet they are often expected to meet the same regulatory requirements as bio-prospectors with commercial intent. There is growing evidence that, as a result, academic scientists are altering their research practices to accommodate or avoid ABS regulations. It is reasonable to expect that those who generate profits from research activities share those benefits with the nations providing essential genetic inputs. However, the international ABS regime as it is currently organized is inefficient at sharing benefits and discourages scientific research. It is time to consider more efficient models of benefit-sharing that reduce the legal barriers to accessing genetic resources for non-commercial research purposes.

Introduction

Scientists from biological disciplines require access to genetic resources like DNA, RNA, related derivatives like proteins, and other biochemical compounds in order to conduct foundational research. Prior to the introduction of international access and benefit-sharing (ABS) rules in the early 1990s, genetic resources were considered the ‘common heritage of humankind’ and biological samples were sourced directly and freely from the environment (see e.g. Tilford 1998). In 1992, the United Nations’ Convention on Biological Diversity (CBD) affirmed the sovereign rights of nation-states over their biological resources, including genetic resources. States can therefore regulate access to genetic resources sourced from within their territories and can exercise sovereign rights over the intangible information and data associated with the physical resources. Accordingly, ABS rules impact biological research across disciplines including botany, zoology, biochemistry, microbiology entomology, veterinary science, ecology, and environmental sustainability. Ready access to pathogenic genetic resources is particularly important in the field of public health where research is time-sensitive and new samples are continually required to conduct up-to-date disease surveillance. Biological research activities cut across government, academic, and private
This article posits that research scientists with non-commercial intent are altering their research activities because ABS policies under the CBD and its associated protocols are dysfunctional. While there are examples of ABS “success stories”, most detail ABS arrangements for extensive, nationwide bioprospecting sweeps undertaken with overarching commercial intent. Such examples usually feature ABS agreements made by large pharmaceutical companies or research consortia with the financial resources, time, and legal professionals to interpret and abide by the domestic laws of the countries within which they wish to operate. Those case studies are touted as exemplars of ABS providing a win-win opportunity for both the provider nation and commercial institutions. What is not made clear, however, is whether those sorts of long-term, bilateral ABS arrangements can be successfully applied to non-commercial operators who do not necessarily have the expertise to navigate the legal terrain of the countries from which they require specimens. Most success stories focus on the financial, environmental, or experimental outcomes of bioprospecting projects. Others focus on the ABS policy itself and how it relates to social justice or sustainable use agenda. While the literature is full of policy-level assessments of ABS, there is considerably less attention paid to how ABS policies play out in practice.

This article will first provide an overview of the international legal framework for accessing genetic resources. This will offer a basis for investigating how ABS regulations impact research scientists with non-commercial intent. There is evidence that many researchers are unfamiliar with international ABS requirements in general and are unlikely to possess specific legislative or policy knowledge of the international jurisdictions from which they seek access. Moreover, many non-commercial scientific researchers are unlikely to have the support of anything other than rudimentary legal advice or a public relations team. Accordingly, this article will examine the obstacles encountered by non-commercial research scientists when undertaking the process of becoming informed of their jurisdiction-specific ABS obligations and attempting to comply with the relevant rules to access the genetic resources that are integral to their research.

As this article will examine the procedures of ABS, the legal intricacies of various jurisdictions’ ABS rules will not be addressed other than to provide enough context about the legislative, administrative, and policy measures to highlight the extent to which they impede access to genetic resources. Barriers to access can be as significant as the permit application process itself but can also include ostensibly trivial issues like departmental name changes, language barriers, and high transaction costs. Scientists must also try to reconcile the inherent cultural differences between the open access ideals of science with the more restricted nature of regulated materials access.

The culmination of these barriers renders some biological research untenable and can result in the abandonment of research projects before they even commence. This stands to limit the bounds of public knowledge and will have a significant toll on the scientific endeavour. It also adversely affects the generation of information, data, and downstream innovation that can be used for environmental conservation purposes, in direct conflict with the principal intent of the CBD. Whether they have commercial or purely academic intent, all research scientists should be encouraged to engage in international collaborations and the sharing of non-monetary benefits like information, expertise, and technologies with provider nations. Benefit-sharing of this nature often occurs, but it is not clear that it is occurring because of the provisions of CBD and the Nagoya Protocol. There is, however, a growing body of evidence demonstrating that those instruments are hindering scientific research.

This article closes with a consideration of alternative modes of benefit-sharing to capture monetary benefits to return to provider nations. The current system regulates genetic resources at the point of access. A more efficient model would require benefit-sharing only when the use of previously accessed genetic resources has a proven potential to generate benefits. This could be achieved by taxing innovations at the market end of the innovation process and returning a portion of profits to the countries of origin. There is already a push for product developers to declare the country of origin of genetic resources on patent applications, that if mandatory, could present a mechanism for imposing such a tax. These options would not only make benefit-sharing more efficient, but it would also ameliorate the adverse effects that current ABS policies are having on biological research.

1 Any organization with sufficient resources to navigate the ABS legal frameworks and application procedures within the jurisdictions they wish to operate are probably well placed to find ways to avoid their ABS obligations altogether. There are undoubtedly many ABS loopholes to exploit within domestic ABS frameworks, and large commercial entities are in the best position to either creatively comply with, or avoid their legal obligations.
The international legal framework for accessing genetic resources

The United Nations’ Convention on Biological Diversity (CBD) entered into force on December 29, 1993 and has near universal acceptance. The CBD outlines three objectives: “[1] the conservation of biological diversity, [2] the sustainable use of its components and [3] the fair and equitable sharing of the benefits arising out of the utilization of genetic resources”. Article 15(1) of the CBD affirmed “the sovereign rights of States over their natural resources” and in doing so, shifted how the international community views and regulates genetic resources. What was previously treated as ‘common heritage’, meaning belonging to all nations and people, was now considered to lie unequivocally within the sovereign domain of nation-state. Article 15(1) further provided that “the authority to determine access to genetic resources rests with the national governments and is subject to national legislation”. States can therefore determine the terms of access to their genetic resources and demand a reciprocal share in the benefits arising from their use in exchange for that access. Much of the motivation behind the CBD was to enable developing countries to address the inequitable accumulation of wealth to already wealthy nations through the exploitation of developing countries’ natural resources. Many of the problems of distribitional justice and development that were at the heart of the CBD negotiations in the late 1980s remain salient today.

State sovereignty, in the context of the CBD, applies to “genetic resources” which means “genetic material of actual or potential value” where “genetic material” is defined as “any material of plant, animal, microbial or other origin containing functional units of heredity”. Under the CBD’s ABS scheme, access to genetic resources must occur with the prior informed consent of appropriately authorized providers—usually the country of origin—and on mutually agreed terms. Access and benefit-sharing agreements that confirm prior informed consent and specify mutually agreed terms vary in complexity. They can be a straightforward permit, where the issuing authority provides permission to access and use the genetic resources as stipulated, or a uniform material transfer agreement with standard benefit-sharing clauses. More complicated contracts are often the result of negotiated bilateral deals between the user and providing nation-state.

As well as being able to determine what constitutes prior informed consent and mutually agreed terms, nation-states can implement whatever ABS measures they see fit “with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources”. Provider countries may be tempted to dictate strict access requirements to leverage advantageous benefit-sharing arrangements and some developing countries have introduced measures that are highly protectionist. However, strict access standards can act as a deterrent to potential user parties because of the burden of regulation. The tension between restricting access to genetic resources enough to leverage benefits, but not so much to discourage their use and the associated generation of benefits, highlights one of the key difficulties in developing ABS policies at the domestic level and the importance of striking a workable balance when applying ABS measures in practice.

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 (Nagoya Protocol) was adopted by the governing body to the CBD in 2010 and entered into force on October 12, 2014. The Nagoya Protocol aims to clarify the ABS provisions for nation-states and applies “to genetic resources within the scope of Article 15 of the [CBD] and to the benefits arising from the utilization of such resources”. In addition to genetic resources, the Nagoya Protocol applies ABS to “derivatives” of genetic resources which it defines as any “naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources”. The Nagoya Protocol also clarifies that the term “utilization of genetic resources” means “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”.

The only genetic resources that are explicitly excluded from the scope of the CBD are human genetic materials. All other genetic resources, and potentially even the genetic sequence data gleaned from the physical resources themselves, are subject to regulation under the CBD and Nagoya Protocol. For scientists in any of the biological fields, the resources regulated under these instruments captures most, if not all, non-human natural research subjects. They may also cover many common biological laboratory tools such as enzymes, cell cultures, and various animal models. Indeed, there are very few limits to what a sovereign state can choose to regulate within the

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2 Convention on Biological Diversity, opened for signature June 5, 1992, 1760 UNTS 79. The CBD has 196 Contracting Parties. The United States of America has signed but not ratified the CBD, and the only other non-party is the Holy See. See https://www.cbd.int/information/parties.shtml.
It is important to highlight that not all uses of genetic resources are intended to generate a product for the marketplace. A distinction can be made between foundational scientific research with academic intent and applied research and development with commercial intent. Certainly, the distinction is not clear-cut. Foundational science is very often translated into marketable products, and industry has been an important source of academic funding for decades. The negotiators of the CBD and Nagoya Protocol recognized that ABS rules could increase the regulatory burden on those conducting foundational research and included provisions to ensure ease of access to genetic resources for non-commercial purposes. The CBD states that “each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses”. Further, the Nagoya Protocol states that when developing national ABS rules, each party should “create conditions to promote and encourage research ... including through simplified measures on access for non-commercial research purposes”. Such “simplified measures” should also take into account situations where foundational research may lead to the development of a downstream commercial product. Some have discussed the inclusion of “come-back clauses” in non-commercial access contracts where any downstream users with commercial intent are required to return to the original resource provider to negotiate benefit-sharing obligations new. However, tracing the secondary use of genetic resources and associated information in commercial applications is complicated, and there are undoubtedly cases where commercial users attempt to sidestep ABS obligations by accessing just the intangible aspects of the resources.

**Practical barriers to accessing genetic resources**

It is important to address the discord between how ABS is written in the CBD and Nagoya Protocol and how ABS operates in practice. During the original CBD negotiations and in the early ABS forums organized by the CBD’s governing body, there was a general “lack of scientific involvement”. Accordingly, little consideration was given to the effects ABS could have on non-commercial scientific research.

Despite the fact that the CBD has been in force for more than two decades and has been ratified by 196 parties, many countries have not yet implemented domestic legislative, administrative, or policy measures for ABS. Of those that have, many countries are yet to establish infrastructure to execute the ABS processes outlined in their domestic legislation. In his book on benefit-sharing case studies,) noted: *While we assume that governments usually have the appropriate legal expertise and knowledge of ABS to make an informed decision, this may not always be the case, as there are often limited capacities in the departments of environment (or similar) that deal with ABS – just in terms of number of staff, knowledge of ABS, level of education, familiarity with contracts.*

Lack of sufficient expertise is one explanation for absent or deficient domestic ABS systems. Another plausible explanation is a scarcity of interest in the ABS endeavour. One senior liaison officer to the United Nations’ Food and Agriculture Organization noted that “as of 1 October 2017, not even 100 ABS permits or their equivalents had been registered with the ABS Clearinghouse by only six countries”. Given that the value of genetic resources is difficult to establish at the point of access and that the potential benefits from an ABS system may not be enough to offset the investment required to implement and enforce such a regime, many states may not see any clear advantage to regulating access to their genetic resources. Furthermore, a functioning domestic ABS system is not a necessary precondition for states to exercise their sovereign rights over their genetic resources. Instead of dedicating personnel, time, and money to continuously operating a permit system for all potential uses of their genetic resources, a nation-state might instead choose to regulate specific subsets of genetic resources or seek benefit-sharing in individual cases of egregious misuse.

\[^3\] It should be noted that both the CBD and Nagoya Protocol are silent on the issue of temporal scope. Some interpret the triggering event for benefit-sharing obligations as the “utilization” of genetic resources, which would therefore include any new utilizations of genetic resources sourced from pre-CBD ex situ repositories. The custodians of extensive collections of ex situ genetic resources tend to be developed countries (including the EU) who prefer to interpret new in situ “access” events as the triggering event for ABS. However, the point remains that sovereign nation-states are able to determine the point at which ABS obligations are triggered under their domestic legislative, administrative and policy measures. The theoretical debate about temporal scope and ex situ collections continues, but in practice these collections generally operate outside of the CBD and Nagoya Protocol schemes.
Most assessments of ABS do not address the inconsistencies between ABS in theory and ABS in practice. That is perhaps why, for instance, the Australian Commonwealth ABS legislative framework under the Environment Protection and Biodiversity Conservation Act (1999) is repeatedly praised in the literature as being highly-developed and a model ABS system for other countries, despite the fact that the vast majority of the Australian landmass is privately owned and therefore outside the jurisdiction of Australian ABS legislation (Lawson 2011, n. 31). Further, the Commonwealth system has so far resulted in just a single “biodiscovery case involving commercial benefit sharing”. The Australian ABS regime is also praised as being “nationally-consistent”, but closer inspection reveals that some Australian states and territories are yet to implement ABS regimes.  

Access and benefit-sharing is not working as the wealth redistribution or conservation mechanism that was originally envisaged. Meanwhile, it is creating obstacles to accessing genetic resources and discouraging research activities in jurisdictions with restrictive access policies. The following section will address the barriers likely to be encountered by non-commercial researchers in their attempts to access genetic resources in compliance with the international ABS regime.

**Awareness of ABS as legal regulation**

While ABS is a longstanding and familiar concept for international environmental law academics and practitioners, many in the biological sciences remain unacquainted with ABS. This lack of awareness among biological scientists is particularly vexing as much of the standard laboratory materials used in the biological sciences probably fall within the remit of the CBD and Nagoya Protocol, including non-human tissue cultures, plasmids, various enzymes like polymerases, and even laboratory rats and mice. Many scientists still exchange non-proprietary genetic resources informally through personal and professional networks on the basis of reciprocity, professional duty, or commitment to scientific openness. The perception that genetic resources remain the common heritage of humankind persists in many scientific disciplines.

While it is possible that some researchers knowingly avoid ABS laws, others may simply be oblivious to the rights of states over their genetic resources and the legal obligations associated with their use. One recent survey highlighted a lack of awareness about benefit-sharing requirements in staff of botanic gardens, a field that is frequently involved in the international transfer of plant genetic resources. Biological research institutions conduct routine staff training in local biocontainment policies and import and export controls, but there is little indication that ABS considerations are being included in mandatory training packages or in undergraduate biology programs.

The public education and awareness provisions in the CBD are vague and limited to promoting awareness of conservation and sustainable use issues, rather than detailing access procedures. Awareness of ABS as a regulation is greatest in provider countries, primarily in the Global South, where states want to leverage a benefit from the use of their biodiverse resources. However, under the CBD there is little incentive to raise awareness about benefit-sharing obligations in user countries, primarily in the Global North.

The Nagoya Protocol did provide more specific guidelines for awareness raising. Article 21 of the Nagoya Protocol states that “each Party shall take measures to raise awareness of the importance of genetic resources and related access and benefit-sharing issues” and specifically includes “education and training of users and providers of genetic resources about their access and benefit-sharing obligations”. It is not clear to what extent many nation-states have made an effort to raise awareness, even though compliance with the Nagoya Protocol necessarily includes awareness raising measures.

Article 15(1) of the Nagoya Protocol encourages nation-states to ensure “that genetic resources utilized within its jurisdiction have been accessed in accordance with ... the domestic [ABS] legislation or regulatory requirements of the other Party”. Any nation sufficiently motivated to guarantee compliance is wont to ensure that their constituents are aware of their ABS obligations. One such party is Norway, who through their Nature Diversity Act (2009), is one of the few countries that has codified an intention to ensure that any foreign genetic resources utilized within its jurisdiction have been accessed in accordance with the provider country’s ABS rules. Implementation of the compliance provisions of the Nagoya is a key measure that would strengthen the ABS regime globally and would contribute to greater overall awareness of access requirements in scientific research communities.

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4 See e.g., Queensland’s Biodiversity Discovery Act 2004 (Qld) and the Northern Territory’s Biological Resources Act 2006 (NT). West Australia’s ABS regulations are currently in a nascent stage, see Biodiversity Conservation Act 2016 (WA) s 256(3). Australia's other States and Territories do not have ABS regulations.
The search for jurisdiction-specific information in the ABS clearing-house

Clearly, broad international acceptance of the CBD and the concept of ABS, does not equate to commensurate awareness of them. Likewise, a general appreciation of the concept of ABS does not equip a scientist requiring access to transboundary genetic resources with sufficient information to know how to seek access permissions from the provider state. Every country has different ABS legislative, administrative, and policy measures, so the process of accessing genetic resources necessitates navigating jurisdiction-specific practices. While inconsistencies across jurisdictions were anticipated from the outset, the search for information by potential users of genetic resources is not as straightforward as the original negotiators of both the CBD and Nagoya Protocol might have hoped.

Article 18(3) of the CBD set the scene for the establishment of a clearing-house mechanism to “promote and facilitate technical and scientific cooperation”. Once used solely in a financial sense, the term “clearing-house” includes “any agency that brings together seekers and providers of goods, services or information” with the intention of “matching demand with supply” (Convention on Biological Diversity 2010). Ten years after its implementation, the CBD’s clearinghouse was underutilized (only 40 of 181 parties had operating clearing-house entries) and suffered from major usability issues Nevertheless, the concept of a clearinghouse was also applied to ABS in the Nagoya Protocol.

Through the ABS clearing-house, nation-states are to publicize any “legislative, administrative and policy measures on ABS”, list their “national focal point and competent national authority or authorities”, and can choose to include further information such as “codes of conduct and best practices”. The ABS clearing house is supposed to facilitate “connections between users and providers of genetic resources” and help “users to comply with national ABS measures and requirements”.

In 2004, the CBD’s clearing-house mechanism was criticized as operating “at a relatively general and preliminary level”, and similar criticisms can be levelled today at the ABS clearing-house mechanism. The various lists provided in the ABS clearing-house website are often incomplete or outdated. As of July 2017, some countries, such as Papua New Guinea, do not have any entries when there are indeed access rules in place. Other countries list a multitude of regulations and policies where it becomes difficult to determine what entries may be applicable and to whom. India, for example, has 31 entries in the Legislative, Administrative or Policy Measures category, presenting numerous entry points for users to attempt to access genetic resources depending on the precise geographical location from which they propose to source them.

Even for countries where the ABS clearing-house information is current and relatively transparent, there is often insufficient information to initiate access procedures. The ABS’ clearing house does, for example, provide accurate and current information about the legislation that makes up the Norwegian ABS framework, including an overview of the general purpose of the four pieces of domestic legislation that make up their ABS policies. But there is still no direction as to how to actually go about accessing Norwegian genetic resources. Despite having in place both federal legislation and regulations for more than fifteen years, as at July 2017 Australia does not have a single entry under the “Legislative, Administrate or Policy Measures” category in the ABS clearing house. Indeed, of the eight categories of information listed in the ABS clearing house, Australia provides just a single entry under the category “ABS National Focal Points”. All other information must be accessed directly via Australian Government websites, undermining the utility of the ABS clearing-house as a one-stop information exchange platform.
Language barriers to gaining access permissions

The ABS clearing-house assumes a level of familiarity with the particulars and jargon of ABS, making the database near-impenetrable to the uninitiated. For instance, outside those working specifically on environmental conservation issues, it is unlikely that most scientists are acquainted with terms like National Focal Point and Competent National Authority or are able to readily identify their respective roles in the access process. It is therefore difficult to determine which government body the potential user should approach in order to request access approval.

Furthermore, while “English is the dominant language in science”, it is often the case that the legislation and procedures outlining ABS rules in many biodiverse countries are not provided in English. The information provided in the ABS clearing house for Peru, for example, is presented in Spanish. This forms a two-way barrier, preventing access for the predominately English-speaking scientists in the Global North, and potential missed opportunities for genetic resource providers in the biodiverse countries of the Global South. This is not to suggest that English should be the dominant language of ABS as it is in science, just that many research institutions are unlikely to have the ability to navigate the complex ABS regulatory system in their preferred language or have access to interpreters.

The ABS clearing house is not the “one stop shop” for ABS information that was originally envisaged. Potential users of genetic resources are often left to seek information using third-party sites and internet search engines. The field of ABS is strewn with obscure legal language so even knowing the appropriate terms to input to search engines can be problematic for the uninitiated.

Some online searching may lead scientists to practical guides issued by organizations in user countries. The guides range in quality from providing a theoretical overview of ABS concepts to laying out a set of procedures for undertaking the access. Such guides are usually the most accessible way for non-ABS specialists to identify regulatory support in the resource user’s home country and access authorities in other provider countries.

As ABS procedures in every country differ, the practical guides can only provide general guidance to users in their own country about the processes for accessing resources in other nation-states. Some guides list the known National Focal Points of all provider nations, but this can be problematic as countries frequently change the names of their focal points. Furthermore, some National Focal Points have a dual role as the Competent National Authority, while other states maintain separate entities for these functions. Accordingly, most practical guides simply refer users to the CBD website, which we have already established can be difficult to both navigate and understand.

Further difficulties identifying the appropriate access authority

To demonstrate the obstacles scientists can face in first finding and then navigating the bureaucratic process for obtaining transboundary genetic resources, this subsection starts by stepping through the process of obtaining access information for Papua New Guinea, a megadiverse nation of the Global South. Papua New Guinea ratified the CBD in 1994 but is not party to the Nagoya Protocol.

The ABS clearing-house entry for Papua New Guinea provides no information on their domestic access procedures. It is unwise to assume that simply because a country is not party to the Nagoya Protocol and does not have any entries in the ABS clearing-house, that they do not have any rules associated with the use of their genetic resources. Determining whether Papua New Guinea has access procedures therefore necessitates a search for information outside of the ABS clearing house and recourse to the World Wide Web.

One document from the third-party University of Utah website indicates that Papua New Guinea does indeed have procedures for accessing their genetic resources for research purposes. The document indicates that access can...

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6 National Focal Points are nationally designated entities that report to the CBD Secretariat on behalf of the nation-state (Nagoya Protocol 2010, art 13(1)), while the Competent National Authority is essentially the access authority (Nagoya Protocol 2010, art 13(2)). From the potential user’s point of view, the Competent National Authority is the point of entry when it comes to applying for access to genetic resources, however, the National Focal Point and Competent National Authority can be the same entity in accordance with art. 13(3) of the Nagoya Protocol.

7 It is worth noting that there are multiple versions of the international ABS regime: one for those nation-states that are party to the Nagoya Protocol as well as the CBD, which creates a slightly different set of ABS obligations than for those nation-states that are party to the CBD alone.
only be granted after a full research proposal has been furnished, including an explanation of the research objectives and scientific justification for the project, as well as a full curriculum vitae and professional profile of each of the people working on the project. The proposal is to be filed with the Secretariat of the Papua New Guinea Institute of Biodiversity at least six months prior to the commencement of the proposed research activities.

At the time the University of Utah document was written, PINBio sat within the Papua New Guinea Department of Environment and Conservation. Today, however, PINBio has no online presence, and the Department of Environment and Conservation is defunct. The Department of Environment and Conservation changed to the Papua New Guinea Conservation and Environment Protection Authority in 2014. An extensive search of the Conservation and Environment Protection Authority webpage provides no information about access procedures or to whom one should direct an access application. The only point of contact can be found in a separate document hosted on the University of Utah website, which provides a physical postal address to the now obsolete Department of Environment and Conservation.

The University of Utah’s College of Pharmacy was associated with a large-scale biodiversity conservation program in Papua New Guinea in association with the International Cooperative Biodiversity Groups. Such comprehensive inter-organizational operations (often with a long-term view to commercial product-discovery) are able to direct resources into researching access requirements and directly engaging the governments of host-countries to ensure that access terms are met, and benefit-sharing obligations are mutually agreed. But for non-commercial scientific researchers without a team of specialists or pre-existing diplomatic relationships, the primary avenue for obtaining information is through the internet, and in this instance, there is no official information available and direct communication with the government is made untenable. The barrier to entry is simply too high. The information about access procedures is not readily available, is often confusing and continuously changing, and the access procedures themselves can be outdated and somewhat arduous.

Issues of information flux, staff turnover, and departmental name changes are not unique to lower-middle-income nations like Papua New Guinea. Even high-income countries with entrenched bureaucracies undergo relentless structural disruption that can make access procedures perplexing for outsiders. Genetic resource ABS under Australian Commonwealth jurisdiction, for example, was initially managed by the Australian Government’s Department of Environment and Heritage when both the legislation (Environment Protection and Biodiversity Conservation Act 1999) and associated regulations (Environment Protection and Biodiversity Conservation Regulations 2000) were enacted. Since that time, the Department has changed names five times.8

The information pertaining to Australia’s National Focal Point on the CBD website is regularly updated, making the identification of access authorities for the various state and territory jurisdictions within Australia fairly reliable. However, this does not necessarily make it an easy process.

Federated countries like Australia present another set of challenges when it comes to identifying the appropriate access jurisdictions. Approximately 40 percent of the world’s population live in countries that are structured as a federation of states. Federated countries include Russia, the United States, India, Germany, Canada, Mexico, Brazil, and South Africa. In effect, ABS regulations can vary within nations as much as they do among them.

In Australia, for example, there are different ABS requirements for genetic resources accessed in Commonwealth areas, state and territory land in Queensland and the Northern Territory, and for those on privately owned lands. A more diverse set of requirements can be found in India where the Biological Diversity Act (2002) at the federal level is implemented sub-nationally with separate rules in 29 different states. The problems are manifold in countries like Indonesia (a unitary state) where there are overlapping and disputed land claims and even discrepancies as to which government bureaucracy has authority over certain territories. For scientists without legal training or support, identifying the appropriate access authority becomes exceptionally difficult. For the uninformed, even the entry point for accessing genetic resources in many jurisdictions is unclear.

8 Department of the Environment and Heritage changed at the start of 2007 to the Department of the Environment and Water Resources, which changed again in late 2007 to the Department of the Environment, Water, Heritage and the Arts. In 2010 this changed to the Department of Sustainability, Environment, Water, Population and Communities, in 2013 to the Department of the Environment, and again in 2016 to the Department of the Environment and Energy
Cultural inconsistencies between the scientific discipline and ABS policies

Possibly the greatest barrier to getting scientific researchers to engage in the ABS process is the fundamental disconnect between the principles of ABS and the professional culture of science. The pursuit of scientific knowledge is often touted as being for the good of the whole of society, and scientific professional etiquette creates an expectation that researchers exchange information, data, physical specimens, and other non-proprietary research materials with others in the scientific community. Openness and sharing are often referred to as a Mertonian principle of research, in reference the communalism “institutional imperative” identified in Robert Merton’s 1942 essay on The Normative Structure of Science.

The expectation of openness and sharing in science is reflected in and reinforced by the materials sharing policies found in the publication guidelines of many scientific journals. The publication policy of the journal Nature, for example, states that “authors are required to make unique materials promptly available to others without undue qualifications”. Science, the flagship journal of the American Association for the Advancement of Science (AAAS) is another top-tier research publication that specifically directs authors to provide access to their research materials, stating that “all data and materials necessary to understand, assess, and extend the conclusions of the manuscript must be available to any reader of Science”, and further stipulates that “unreasonable restrictions on data or material availability may preclude publication”. Such materials include genetic resources (and potentially the information and data associated with the physical genetic resources) within the remit of the CBD.

These norms are also reinforced by the longstanding practice of publishing genetic sequence data in open access databases. A mandatory precondition for publication in Nature is that DNA and RNA sequences are submitted to a “community-endorsed public repository” such as GenBank. Science has similar “data deposition” requirements prior to publication (American Association for the Advancement of Science 2017). It is worth noting that these sequence databases broadly acknowledge that there may exist legal interests in the data stored in their repositories and therefore do not extend permission for their unrestricted use. Functionally, however, the genetic sequence data in these repositories are openly accessible to anyone with an internet connection.

The ideals of open data sharing in the biological sciences have been repeatedly stated and codified in various aspirational instruments. The Bermuda Principles (1996), for instance, called for the release of DNA sequence data within 24 hours of sequence generation. In 2003, the Welcome Trust sponsored a meeting that reinforced the Bermuda Principles and adopted the Fort Lauderdale Agreement (2003). The Fort Lauderdale Agreement stated that “pre-publication data release can promote the best interests of science and help to maximize the public benefit to be gained from research”. The Organisation for Economic Co-operation and Development (OECD) released its Principles and Guidelines for Access to Research Data from Public Funding (2007), highlighting “the principle of openness and the free exchange of ideas, information and knowledge” and the importance of open access to data in “policy making”, “the advancement of life sciences” as well as for “environmental and other types of research”. Similarly, the Toronto Statement (2009), reaffirmed pre-publication genomic data release and recommended the extension of this practice to other datasets (Toronto International Data Release Workshop 2009). The professed norm in scientific research is one of accessibility, and open materials and data sharing. The non-commercial research culture both expressed in and reinforced by the publication requirements of scientific journals promote the operation of an unnamed and largely informal research commons.

Adding further weight to these norms and an argument that has been repeatedly cited in the push for open access publication models is that scientific research funded by the public through government programs should be made freely available to the public. In her examination of the barriers to open access, notes: Scientific research is predicated on an understanding of scientific knowledge as a public good—this is the rationale underlying today’s multibillion-dollar subsidies of scientific research through various federal and state agencies.

In the US, for example, most scientific research during 20th century was publicly-funded. This only changed in 2004 when, for the first-time, public funding accounted for less than 50 percent of total research funding. The remaining funding was sourced from universities, corporations, and philanthropic organizations. Nevertheless, the US federal government remains the greatest single provider of research funds in the US and there is a growing consensus that the results of publicly-funded research belongs to the public.

Open access norms have also permeated various international legal documents. For example, the Universal Declaration of Human Rights provides that “everyone has the right to share in scientific advancement and its benefits” and the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes “the right of everyone to enjoy the benefits of scientific progress and its applications”. Notwithstanding the non-binding nature
of the Universal Declaration, and the general unenforceability of the Covenant, the presence of these statements in the international arena indicates that the notion of free and open access to the benefits of science is a broader ideal of humanity, held not just by academic scientists. These ideals are not uniformly practiced in the scientific research community and do not constitute a set of unimpeachable rules, but they are generally professed by scientists involved in non-commercial research to be the operating principles of research and the drivers of scientific knowledge.

It is essential to recognize that the scientific community does tolerate a level of access restrictions to certain resources. Indeed, in writing about the economics of science, Victor Rodriguez, argues that the Mertonian principles of science have become an inappropriate framing device for studying “post-academic science”. While the scientific community still espouses open access ideals, there are often accepted economic, intellectual property, and regulatory restrictions on access to scientific information and samples. It is therefore hard to establish precisely why scientists might be so opposed to entering into a transactional arrangement for access to specimens from nature.

Genetic resources are not the only research input in the life sciences. The conduct of scientific research is also contingent on access to laboratory space, equipment, disposable supplies, appropriately trained staff, and compliance monitoring—all of which come at a price. While some may balk at the cost of such resources, there is no fundamental objection to having to pay for these research inputs. There does, however, appear to be some level of human input, a threshold of innovation that must be crossed before scientists are prepared to accept that a genetic resource that originated in nature and was previously freely accessed now carries a cost that they are prepared to pay. Such a threshold might be determined by similar factors that regulate patent eligibility, including novelty, non-obviousness, and utility. Convenience and reproducibility are also undoubtedly factors. Rodents might be readily available in many domestic roof cavities, yet the majority of scientists are still prepared to pay for lab mice, even if the experiment calls for outbred stocks. Perhaps the scientific community will come to a point where genetic resources or genetic sequence data are viewed simply as further research inputs that require payment for access, but for now the notion is still anathema.

Despite the CBD directing nation-states to “create conditions to facilitate access to genetic resources” the concept of ABS within the CBD necessitates a level of restriction on access for the quid pro quo to function. The “sovereign rights of States over their natural resources” reinforced by the CBD can be interpreted as “a form of private property rights” where the rights holder can dictate the terms of access to those resources in order to leverage a benefit from their use. To be effective, states must therefore ensure that their resources are not freely available to potential users through other means. This is not to say that restriction of access is itself bad, simply that it is an unavoidable aspect of ABS if it is regulated at the point of access and as a transactional mechanism.

Given the open access norms for genetic resources and genetic sequence data, it is not surprising when scientists recoil at the spectre of restrictive access to resources that were previously easily accessible, or express reticence in dealing with a system that could slow or otherwise impede access. The opposition to ABS is especially fervent when access requirements stand to obstruct access to genetic resources of public health concern. Such opposition was clearly demonstrated in the moral condemnation of Indonesia’s actions in 2007 after claiming sovereignty over their influenza samples and refusing to share them with the World Health Organization (WHO) unless they could be guaranteed access to the vaccines that resulted from the use of their viruses. The ensuing commentary suggested that nation-states wishing to enforce their sovereign rights over their genetic resources within the remit of the CBD would be met with harsh and sustained international condemnation if those rights conflicted with scientific, public health, and pandemic preparedness goals. The commentary in the wake of Indonesia’s “viral sovereignty” claims, and the resulting contentious and prolonged negotiations that led to yet another international ABS instrument, indicate that there is not yet comprehensive acceptance of the concept of resource sovereignty or ABS, particularly in the Global North.

How scientists use genetic resources provides another hint as to why ABS seems culturally dissonant to scientific researchers. The extraction of genetic materials from biological resources usually requires miniscule samples of the source material and does not pose an existential threat to the biological resource itself, either for individual organisms or as a species. The ABS concept as defined in the CBD is applied to genetic resources, not whole organisms or bulk products like plant crops. Quite often the source material of interest will form a self-replenishing substance produced by the individual organism (such as blood from an animal, spores from fungi, or seeds from a plant), a by-product of the organism (such as fecal matter or spermatozoa), or can be grown and sustained in culture (as is the case with some microorganisms). When researchers require whole organisms, the numbers required are typically orders of magnitude fewer than exist in the environment.
The use of genetic resources by scientists can be characterized as non-exclusive and non-exhaustive. Indeed, legally, the term “access” is considered “the right to interact with a resource and to enjoy ‘non-subtractive’ benefits from it—benefits which, as with pure public goods, do not prevent anyone else from enjoying the same right”. That academic researchers “are often subjected to the same scrutiny as bio prospectors’ when accessing physical specimens of genetic resources under various domestic ABS regulations, represents a fundamental misunderstanding of the way that scientific researchers with non-commercial intent actually use genetic resources.

The taking of physical samples in tiny amounts is unlikely to affect the long-term viability of a species. Accordingly, environmental conservation is not a reasonable justification for targeting ABS regulations towards academic researchers. Certainly, there may be downstream commercial consequences resulting from the initial access to genetic resources, and this is where the financial value of genetic resources usually resides. Potential financial gain from the use of a specific genetic resource will indeed create an incentive for the overexploitation of that resource. However, access to physical samples in case is only likely to occur during the downstream phases of the innovation process. Therefore, targeting ABS regulations at these downstream phases of the innovation process makes more sense from an environmental conservation standpoint and for states hoping to benefit from the use of their resources.

Other factors pertaining to how scientists use genetic resources can help to explain why ABS regulations seem so discordant to many scientists. There is often a long delay between accessing genetic resources of interest and the point at which benefits are actually generated, a concept that expresses as “the challenge of time”. Point out this temporal disconnect, as well as the “geographical disconnect between the place of collection and the place of further processing”, and the “legal disconnect between where the resource originates from and the place where further studies are carried out”. Thus, the link between genetic resources and the benefits generated from their use can be difficult to establish, not just at the point of access when it is uncertain what benefits might be generated in the future, but also after the benefits have been commercially realized.

Research projects can span many years and are often collaborations between multiple research groups. The specialization required of scientific researchers today is such that the person collecting samples in the field is rarely the same person conducting the experiments in the laboratory. For many scientists, the samples they are working on are seemingly sourced not from the environment, but from laboratory freezers or liquid nitrogen Dewars, and “the researcher will probably feel psychologically remote from the original access situation”. Scientists tend to assume that they own the samples that are in their custody. This is exemplified by the common practice of scientists “bequeathing” their collections to their colleagues when they retire or taking their biological samples with them when they move from one academic institution to the next, often without any thought as to the ABS implications of such an action. Further psychological distance is created when a physical sample is dematerialized, i.e. turned into digital genetic sequence data. 9

The disconnection between samples and their regulation points to the need for deliberate and thorough record keeping and contract management. But what might seem a basic administrative requirement becomes exceptionally difficult to apply to all accessions of genetic resources in the laboratory. Genes are spliced, amplified, transposed, and cloned. Various portions of originally whole genetic resources will exist as fragments in the laboratory with replicates stored within miniature tubes in various freezers, transferred to collaborators, and hybridized with other genetic fragments from entirely separate origins. The nature of genetic resources is such that their structures are transformed through use in the laboratory and tracing them to their origins is often untenable. Indeed, given the nature of evolution and that genetic resources are not fixed in geographical location, time, or their physical structure, many scientists would have a hard time interpreting precisely what the term “origin” actually means with respect to genetic resources. Even with the best of intentions and robust record keeping, tracing the territorial origins of genetic resources is difficult. The misunderstanding of how scientists use genetic resources has resulted in inefficient regulation that negatively impacts both non-commercial users and the providers of genetic resources. Ultimately, ABS regulations as they are currently structured will require

9 There is ongoing debate as to whether genetic sequence data should be included in ABS regimes in international forums, including the CBD and World Health Organization. See Conference of the Parties to the Convention on Biological Diversity, Decision XIII/16 Digital Sequence Information on Genetic Resources (2016) CBD/COP/DEC/XIII/16; Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Decision 2/14 Digital Sequence Information on Genetic Resources (2016) CBD/NP/MOP/DEC/2/14; and World Health Organization, Review of the Pandemic Influenza Preparedness Framework Report by the Director-General (2016) EB140/6, 48-54. This has created some confusion for scientists who use genetic sequence data in their research. See, e.g. Christopher Lys’s comments in Cressey, Daniel. 2014. “Biopiracy ban stirs red-tape fears” Nature 415: 14-15.
amendments to remove arbitrary barriers for the users of genetic resources and ensure a more efficient distribution of the associated benefits to providers.

**The circumvention of ABS by scientists**

Unless there is a specialized ABS instrument in place for a subset of genetic resources the CBD and Nagoya Protocol provide for ABS agreements to be made on a case-by-case basis. As discussed, this can be a time-consuming exercise, particularly for scientific researchers with no intention to commercialize their research. As mentioned, the CBD directs nation-states to facilitate access to genetic resources. The Nagoya Protocol is more prescriptive about facilitating access, stating that nations should afford the party requesting access “a clear and transparent written decision in a cost-effective manner and within a reasonable period of time”. There is no clarification as to what might be considered “a reasonable period of time” and researchers are often faced with lengthy delays. notes: A taxonomist from the Museum of Natural History in Paris, for example, recently spent two years negotiating with local officials in the Philippines before obtaining a permit to collect species of marine invertebrate. In other countries, such as Indonesia, India or Colombia, waiting periods of a year are common, and many credible projects never gain access.

The combination of inconvenience, significant delays, legal uncertainty, and high transaction costs create clear disincentives for scientists to access genetic resources through official channels, particularly when there are other options available to them.

Other access options can provide scientists with a means to avoid the ABS system altogether, essentially circumventing the sovereign rights of nation-states. One 2011 survey of 411 US university and government researchers using non-plant, agriculturally-relevant genetic resources revealed that 96 percent of genetic resources from domestic sources and 93 percent of internationally-sourced genetic resources came from “friends and colleagues”. A 2014 survey of 327 researchers in Malaysia revealed that there were “an important number of individuals who do not use [material transfer agreements], even for sending material abroad” and that many genetic resources were “entering Malaysia from abroad without any formal agreements”.

Perhaps most concerning for nation-states wanting to directly benefit from ABS regulations, were the insights from a 2016 survey of 209 researchers involved in the US Agency for International Development (USAID) Feed the Future Innovation Laboratory Network, who were using genetic resources for food and agriculture research. The majority of respondents from the US were accessing genetic resources from US university or government collections (53 percent) or existing personal collections (18 percent). There was a different response distribution for non-US respondents, but they too were accessing most of their genetic resources from non-state sources, including more than a fifth from the collections of the Consultative Group for International Agricultural Research.

That scientists have a means to avoid ABS regulations does not necessarily mean that their research is immune to problems associated with ABS. The Feed the Future Innovation Laboratory Network survey also revealed that 53 percent of respondents reported having delayed their research projects, and 41 percent reported changing their collaborators because of issues associated with resource availability. There is no evidence to suggest that researchers are engaging in collegial sharing practices with the specific intent of avoiding ABS obligations, however, this is precisely their effect.

If ABS regimes continue to be inefficient and frustrating for scientists, they are likely to retreat further into their collaborating networks for access to genetic resources or resort to accessing pre-CBD collections which largely operate without regard to ABS regulations. These non-state sources of genetic resources function outside the practical reach of the CBD and Nagoya Protocol and mean that nation-states are missing out on opportunities to negotiate prior informed consent and mutually agreed terms for the use of resources that originated in their territories. Thus, for non-commercial research, ABS policies can create a lose-lose scenario where states invest in ineffective ABS regulations and infrastructure while the biodiversity readily available to scientists is limited to those genetic resources collected without regard to ABS rules.
Conclusion

This article has demonstrated that not only is there a major disconnect between the theory and practice of ABS, there is also dissonance between ABS and scientific research culture. This, in part, is a reflection of the lack of scientific input at the negotiation stage of the CBD and a consequent lack of understanding as to the exchange practices of scientists and how genetic material is used in foundational research. The practical application of the ABS provisions in the CBD and Nagoya Protocol are negatively impacting academic research. Scientists are starting to avoid working on genetic resources that have strict access requirements, are seeing a reduction in international collaborations, and are changing research questions based on resource availability.

Negotiators of these instruments did attempt to institute some provisions and structures for simplified access for users with non-commercial intent. However, simplified access procedures only require that procedures are less onerous than for commercial users, not that they are, in fact, simple. Even if the simplified access provisions in the CBD and Nagoya Protocol and the ABS clearing-house worked as originally envisaged, there still exists “a significant burden for users in terms of becoming familiar with all of these rules and procedures – advantaging well-resourced user groups”.

This article has argued that scientific researchers with non-commercial intent are not generally well-resourced user groups, nor are they in a position to directly drive conservation efforts. Both a lack of awareness and procedural access barriers have encouraged a continuation of the informal trade of genetic resources between scientists and the sustained collection of biological samples outside of the appropriate access authority in each jurisdiction. Researchers at the upstream end of the innovation process are inefficient and ineffective targets of ABS regulation.

As awareness of ABS obligations increases within the scientific research community, many scientists may attempt to follow the access procedures to ensure that their projects meet regulatory requirements and ethical standards. There is no doubt that some researchers will find ways to bypass ABS requirements if lengthy or burdensome. The analysis in this article suggests that users will either shop for access to genetic resources in jurisdictions with the weakest access requirements or request genetic resources from a collaborator in the country of origin. Those collaborators may be able to collect such samples domestically, thereby avoiding international access processes, and personally ship them to the researcher without registering with the appropriate access authority. Such practices are not ideal from the originating state’s perspective as it means their access rules have been circumvented.

Alternatively, researchers may opt to access genetic resources from repositories holding material that was collected prior to the entry into force of the CBD to ensure the legal legitimacy of their research. Robinson has noted that “this has probably already become a common trend in bioprospecting activities where researchers and institutions prefer the legal certainty of acquiring genetic resources from gene banks, repositories or other institutions”. Indeed, legal certainty is perhaps the greatest incentive for researchers to comply with ABS obligations, as some researchers have been prosecuted in instances of disputed access.

Those engaging in research with non-commercial intent may unexpectedly generate ideas or innovations that present a commercial opportunity. Some researchers may not possess the capital or infrastructure required to translate their ideas and innovations or take them to the marketplace and may therefore wish to engage third-party investors, developers, and marketers to see their ideas to fruition. Not being able to guarantee the legal legitimacy of the original access and utilization of input genetic resources presents a potential liability for third-parties which may jeopardize their involvement with the downstream phases of the innovation process.

Perhaps the most worrying side effect of arduous access rules for non-commercial researchers is the outright abandonment of various research projects. It is impossible to determine how many scientific projects have been affected because of onerous ABS requirements. If researchers cannot obtain the genetic samples they require in a timely fashion and with some assurance that they will not be prosecuted for biopiracy, their best option may be to simply move on to a different project that does not have the same level of bureaucratic, political, or legal uncertainty.

Some of the barriers to accessing genetic samples will ultimately force scientific researchers to become more parochial when proposing research projects— looking solely within their own territorial borders for genetic samples on which to conduct research. By collecting their genetic resources domestically, scientific researchers can guarantee the origin of their samples and ensure that they are not acting in contravention of CBD and Nagoya
Protocol. But by only collecting locally, researchers restrict valuable scientific insights to those countries with the resources to dedicate to academic research. The technology-rich countries of the Global North that conduct the vast majority of academic research will therefore be discouraged from engaging in projects that are relevant to the countries of the biodiverse Global South. Furthermore, if researchers choose to source samples only from repositories outside of the remit of the CBD, the scientific record will be date-limited. That is, 1993 will become the point at which the processes of genetic change and evolution effectively halt in the scientific record. These forecasts may seem overwrought, but such grim predictions could result if ABS policies are enforced as they are written in some jurisdictions.

It is inappropriate to ignore this state of affairs any longer. One option is to make the patchwork of ABS measures internationally consistent across all jurisdictions. Those wishing to access genetic resources for research and development would not have the option of shopping for preferential access terms, and ignoring genetic resources from protectionist jurisdictions. A multilateral ABS system with standard material transfer agreements like that created by the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) would also offer a means of standardizing access practices around the world.

There have been suggestions to exempt non-commercial research from the international ABS regime altogether. This could alleviate some of the problems addressed in this article. For instances where what was initially non-commercial research later results in a marketable product, disclosure of the country of origin of genetic resources in patent applications offers a mechanism for determining when monetary benefit-sharing is necessary. Country of origin disclosures have been under consideration at the World Intellectual Property Organization since 2000. Despite some resistance to the measure from biotechnologically advanced countries like the United States, disclosure requirements have been adopted in many countries.

Given the overall inefficiencies of the current international ABS regime and its inability to deliver promised benefits for everyone, it may be time for a more comprehensive overhaul of the system. Negotiations are just starting for a new scheme dealing with genetic resources in areas beyond national jurisdiction. This is the opportunity to go back to basics and work out the precise problems that ABS is seeking to solve and what solutions will best achieve that.

The problem of conservation and sustainable use has now been more comprehensively articulated in the Sustainable Development Goals. Issues of distributional justice and the concerns of the Global South about access to finances and technology transfer are much more difficult to address. Clearly, however, targeting complex and detailed benefit-sharing obligations at the point of access for scientific researchers is not an efficient way to share benefits. It has not worked and shows no signs of improving.

References


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