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Global biodiversity research tied up by juridical interpretations of access and benefit sharing

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Abstract The toolbox of instruments regulating access, transfer and use of biological material is currently re-equipped: the Nagoya Protocol was initiated to provide a legal framework to the third objective of the Convention on Biological Diversity – the fair and equitable sharing of benefits arising from the utilisation of genetic resources and associated traditional knowledge (an aspect not discussed here). In the ongoing implementation of the protocol, potentially harmful and far-reaching effects on biological research become evident. Here, we illustrate how vague definitions, lack of legal clarity and coordination, and often restrictive and complex regulations affect the transfer of biological material and associated data. Instead of promoting basic research in conservation and biodiversity, the current situation potentially jeopardises international collaboration, biodiversity research and its applications in monitoring, biocontrol and food safety. We address these challenges and discuss possible options for its practical implementation in the future.

Keywords Nagoya Protocol · Access · Benefit sharing · Ex-situ collections · Information networks · Code of conduct

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Introduction

The justified original goals of the Convention of Biological Diversity (CBD) and the Nagoya Protocol (NP) are to conserve the biological diversity on Earth, to lay down conditions that allow a sustainable use of these biological resources under fair and equitable conditions and to address access to these genetic resources (GR). One of the original ideas of the CBD was to counteract one-sided exploitation or downright biopiracy for the benefit of few. The CBD (CBD 1992) determines three main objectives: biodiversity conservation, the sustainable use of biological resources and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources. While the first two objectives aim to sustain biodiversity, the third is to balance the costs of conservation and to support the socio-economic development of biodiverse countries of the Global South, by sharing monetary or non-monetary benefits that arise from utilisation of GRs with original providers of biological material. To achieve this, the CBD introduces the concept of Prior Informed Consent (PIC) for access and Mutually Agreed Terms (MAT) for the utilisation of GRs in bilateral agreements between providers and users. Following the coming into force of the CBD on 29 December 1993, biodiversity rich countries established laws to regulate access. However, the envisioned benefits largely failed to materialise and economic benefits delivered to provider countries and local

communities through access and benefit sharing (ABS) legislation remain marginal (Prathapan & Rajan 2011). Frustrations and suspicions grew on all sides due to the lack of clarity.

Shortcomings during the implementation process

Since adoption of the CBD in 1992 and its entry into force in 1993, consistent efforts towards operational provisions did not start until 1999, which resulted in the development of the "Bonn Guidelines" (SCBD 2002). This additional toolkit of voluntary benefit-sharing obligations was eventually adopted in April 2002, and included instruments intended to support negotiation of bilateral agreements for access and benefit sharing and the establishment of administrative, legislative and policy matters (SCBD 2002; Reichman et al. 2016). But the toolkit remained provisional and largely failed to implement internationally accepted and legally binding user measures and thus did not meet the concerns of providing countries (Reichman et al. 2016; Kamau et al. 2010). This situation can be attributed to the opposition of the industrialised North against a legally binding regime. While the abilities to analyse the global biodiversity have dramatically increased with the analytical and technological advances in the recent past, the future of studied organisms and their threatened ecosystems is by no means assured. Instead of taking advantage of these opportunities and expanding the good working relationships in the different sectors of science, the established functioning relationships in both academic basic research and commercial applied research significantly decreased (SCBD 2010a). Consequently, the first two objectives of the CBD (conservation and sustainable use of biodiversity) seem to be increasingly lost in legal and political interpretations that hardly conceal commercial interests (Buck & Hamilton 2011; Koester 2012; Rabitz 2015; Rosendal & Adresen 2016; see also Text Box 1). A direct reflection of the existing mistrust on both sides is the fact that as of 2010 "although more than 75 Contracting Parties have been involved in ABS law and policy development, only 26 of the 188 Contracting Parties of the CBD have adopted ABS laws and procedures" (SCBD 2010a). In this climate, long lasting negotiations towards legally binding benefit-sharing agreements began.

The Nagoya Protocol: regaining trust?

One of the core demands of Providing Countries was to establish an international framework that implements benefit-sharing obligations in national laws of user countries to ensure that revenues materialise (Wallbott et al. 2014; SCBD 2010a). Independent of the question of how such "payment for ecosystem services" could be designed and successfully implemented, operational and consistent ABS-systems are needed (Rosendal et al. 2016; Schindel et al. 2015), not only to realise the third objective of the CBD but to establish both transparent and straightforward measures on access in national laws. During negotiations for the protocol in Nagoya, Japan, CBD parties again agreed to "create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries" (article. 8a of the NP). Close to the finishing line, the remaining critical hurdles were the concept of utilisation (what constitutes utilisation?), derivatives (would the use of derivatives be covered?) and the temporal scope (to cover new utilisation of GR which are kept in collections outside the original sourcing country). After the presentation of a compromise of the Japanese Presidency in Nagoya close to midnight, a small core team including the EU, Brazil, Norway and the African Group took the last obstacles and reached a final compromise (Wallbott et al. 2014). Not all CBD parties perceived this as the genuine compromise and some strongly opposed these backroom negotiations, but the text was finally agreed and adopted. With ratification of the European Union (EU) and single European countries inside and outside the EU, the NP entered into force on 12 October 2014. For the first time industrialised countries set out a legal framework to ensure that GRs are utilised in compliance with provider countries' laws and that users are obliged to meet the requirements of contractual agreements with providing countries. Instead of becoming fully operational and to support the generation of benefits in the commercial and non-commercial sector by overcoming persistent hurdles and increasing research collaborations (SCBD 2010a) as envisioned in the Strategic Target 16 by 2015 (SCBD 2014), the disappointing process to reach a conclusion and the alleged deficiencies in the text seems to have opposite effects (McNeely 2010) and apparently are solidifying entrenched positions. At the end of September 2017, only 9 additional countries established national ABS measures and submitted them to the ABS Clearing House, even though 102 nations ratified the NP.

The fine-print and implications of the CBD & NP

Despite the encouraging intentions and language for the promotion of basic research, definitions in the CBD (CBD 1992) and NP (NP 2011) remained vague and usage of terms inconsistent (Kamau & Winter 2015; Tvedt & Schei 2014; von Kries & Winter 2015; see also Text Box 2). Negative trends of over-restrictive access laws of Providing Countries in combination with cumbersome regulations governing utilisation in user countries become evident (Pisupati 2014) and potentially have deleterious and far reaching effects on biological research and international research collaboration (Prathapan et al. 2008; Reichman et al. 2016; SCBD 2010a; Schindel 2010). Taxonomists and other scientists in basic research,

who are willing to engage in international biodiversity assessment and monitoring activities as encouraged by the original goals of the CBD, are increasingly challenged by the reluctance of CBD parties and legislators (for examples, see Text Box 3).

Contrary to Article 15.2 of the CBD, few national laws "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties" but are rather suited to "impose restrictions that run counter to the objectives of this Convention" [cf. Art 15.2, CBD] (McNeely 2010) and "proved a nightmare for users" (Kamau 2015a). This affects not only taxonomic or ecological studies, but biodiversity assessment, biocontrol and food safety globally (Jayaraman 2008; Jinnah and Jungcurt 2009; Pethiyagoda et al. 2007; Rajan and Divakaran 2009; Reichman et al. 2016; van Lenteren et al. 2011).

Because the Nagoya Protocol and the respective laws implemented on the national level use a broad, sometimes even vague language, key definitions remain unclear and compliance has to rely on juridical interpretation and commentaries at the expense of legal certainty (Buck & Hamilton 2011; Koester 2012; Rabitz 2015). This is one of the main concerns in the area of basic research the authors of this article experienced during various ABS workshops on the national and international level during the past 5 years. Unclear definitions have a potential to challenge user compliance: firstly, both the CBD and the NP fail to define *access*. Thus, it could either be interpreted as *gaining ownership* over GR, i.e. the moment or act of taking (as implied in articles. 13.2, 14.2 or 17.3 of the NP) or as *accessing the genetic information* of samples for research and development (Winter 2015), i.e. the moment of taking and using as implied in art. 6 of the NP (Kamau 2015a). Another key question is what is a "genetic resource"? According to the CBD, "genetic resources" means "genetic material of actual or potential value" with "genetic material" being defined as "any material of plant, animal, microbial or other origin containing functional units of heredity". The broad definition of GR in Art. 2 CBD includes any object containing genetic material and is not restricted to DNA or RNA (SCBD 2010b). Thus, the NP covers a broad range of living or dead organisms, including cultivars and propagules (Vogel 2013), but potentially also soil samples, drill cores, or archaeological remains depending on the researcher and his or her research discipline (Tvedt & Schei 2014; Watanabe 2015; Welch et al. 2013; see also Text Box 2). In the pure biological understanding, functional units of heredity would exclusively be found in living cells.

Secondly, the NP lacks provisions on its temporal scope. This lack and the unclear definitions have fuelled the heated debates on CBD-compliant access and further debates on what the temporal scope of the NP should be (cf. article 15.3 NP) (Rabitz 2015). Some parties demanded the inclusion of utilisation of samples accessed after 1993 (when the CBD entered into force), others, even more retroactively, requested the inclusion of *future utilisation* of pre-CBD material claiming that these utilisations fall under the ABS regime (e.g. from ex-situ in botanical gardens and museum collections (Kamau 2015a; Rabitz 2015), and the strictest interpretations would even like to cover access to sequence data (Tvedt & Schei 2014; Watanabe 2017).

Thirdly, from a legal standpoint, bilateral contracts such as Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) should be negotiated between providers and users of genetic resources and detail how the kinds of benefits should be shared and at which stage of the agreement their delivery is due. However, in basic research, the exact delineation of provider and user is often blurred. Samples in international research collaborations such as taxonomic revisions or phylogenetic studies are often pooled, resulting in more than one user, in the inclusion of colleagues or submission of samples of users in developing countries. Typically, for a joint publication collaborators contribute different sets of samples, but the sequencing is done by the principal investigator and senior author of the paper, usually because of established sequencing routines for studied target organisms, while the lead author successfully established the analytic pipeline, which produced the research results. Which person should be identified as responsible user?

Challenging environment for collections

This catch-22 situation destabilises and threatens the functioning of biodiversity research centres and repositories (Reichman et al. 2016). The complexity of international specimen exchange and persisting operational challenges of biodiversity repositories are addressed in Watanabe (2015) and in Renner et al. (2012). Vogel (2013) questions the latter's confidence that researchers collecting in the field can cope with all applicable regulations as summarized in their two-page landscape table. Generally, public natural history museums and botanical gardens de facto restrict utilisation of their GR to non-commercial end uses and the code of ethics of the International Council of Museums (ICOM) defines museums as non-for profit organisations (ICOM 2013). The difficulty, obviously, is to define clear points were non-commercial research ends and the value chain in commercial research starts (von Kries & Winter 2015; Reichman et al. 2016; Winter 2015). In 2008, a working group with representatives of developed and developing countries, research funding agencies, Natural History Collections, NGOs, and lawyers specialised in this field produced a working paper under the umbrella of the CBD (SCBD 2009b) which attempted to overcome the obvious problems stemming from vague definitions. They developed "an operational definition for non-commercial research" (i.e. research with the goal of adding knowledge to the public domain, without restrictions or proprietary ownership, is non-commercial in nature), suggested "simplified, standardized access procedures", and ways to address "changes of intent",

"third party use of samples" and "proactive measures that promote trust" (SCBD 2009a). Unfortunately, these efforts were widely ignored. Neither the NP nor the national ABS laws governing "utilisation" differentiate between commercial and basic (e.g. taxonomic) research uses (Kamau & Winter 2015) even though practical approaches are discussed (Rana 2015; von Kries & Winter 2015). Interestingly, only article 8a of the NP details terms of "access" and explicitly requires NP parties to create simplified measures for non-commercial research – which implicitly suggests that commercial access should have to follow more elaborate rules.

Globally harmonised measures of NP parties for simplified access under article 8a NP are not in sight (Watanabe 2017). Even the member states of the EU, who represent a major group of industrialised user countries, did not consider harmonising access requirements within the EU and some have quite different understandings on *ownership* and the requirements for *legal access* which may require permits, notifications or no legal documents at all from respective National Authorities (Coolsaet 2015).

The same applies for *utilisation* of GR with many examples. Since 12 October 2014, users inside the EU – including non-EU citizens utilising GR inside the EU such as PhD candidates from developing countries – have to comply with the regulation (EU) No. 511/2014 (EU 2014) and the respective implementing regulation (EU 2015). Similarly, users in non-signatory states to the protocol are legally required to adhere to it, if their home countries mandate compliance with export requirements of the original sourcing country. The Canadian Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act (WAPPRIITA 1992) explicitly prohibits the importation of "… any animal or plant that was taken …, or any part or derivative of an animal or plant, that was possessed, distributed or transported in contravention of any law of any foreign state …". Originally restricted to CITES-listed representatives of fauna and flora, its scope was broadened in the subsequent Memorandum D19-7-1 (2013) to include any specimen of any species of animal or plant, including egg, sperm, seed, spore, pollen, tissue culture or embryo. In the USA, which has not formally ratified the CBD, users and institutions may be affected by the Lacey Act (2004). This much-amended US law that dates back to 1900, basically mandates compliance with all local, state, national and foreign laws regarding collection and transport of biological specimens. Although originally enacted to regulate the commercial trade in bird feathers to be in agreement with the original sourcing country laws regulating those feathers, it has since been amended to apply to fish and wildlife or plants, and their parts or products. As other countries implement the Nagoya Protocol, their legislation will therefore be binding on US institutions, despite the fact that the USA is not a party to the CBD.

Research facilities and collection holding institutions, including institutions in the USA, will almost certainly have to introduce ABS measures for compliance. This means that each institution or scientist using GR has to develop procedures to manage ABS obligations – according to the provenance of samples and depending on the interpretations of *use* in respective export permits of the providing country, under which these samples were acquired. All this adds to the wide range of possible interpretations and juridical uncertainties linked to the access of GR in providing countries and the utilisation of these resources in another country, regardless of whether a country is party to the NP or not. Practicable solutions for GR used for non-commercial biodiversity research were suggested early during negotiations of the NP (SCBD 2009a), but found no consideration. Now, scientists face especially challenging negotiations during the current transition phase when long-standing north-south collaborations have to be renegotiated to renew trust (Cressey 2014).

The role of biodiversity repositories and researchers is currently unclear. The CBD encourages the scientific community to complete freely accessible world species libraries that are referenced taxonomically with genomic data and DNA barcodes (SCBD 2014). This requires contributions from researchers in provider and user countries and inclusion of in-situ and ex-situ materials. Ex-situ collections play a leading role as data repositories and are regarded as sources of digitalized form of DNA and RNA data with a crucial informational dimension, but are also seen as source for the "production of compounds naturally occurring in genetic material" (SCBD 2010b). There is no doubt that ex-situ collections have a key role and institutions need to take responsibilities to facilitate the goals of the CBD. Unfortunately, museums and botanical gardens have been stigmatised as *biopirates* for holding ex-situ GR without permission (Reichman et al. 2016) and allegedly directly or indirectly supporting *bioprospecting* (Berne Declaration 2013; Natural Justice and Berne Declaration 2013; Rabitz 2015). Publication of research results has been denounced as digital biopiracy as reported by Bagley (2015). This severely undermines public trust in biodiversity research (Biber-Klemm et al. 2015; Reichman et al. 2016) and biocontrol (Cock et al., 2010; Prathapan et al. 2008). It further discredits ex-situ collections in provider and user countries and the longstanding common practice of these institutions in sharing non-monetary benefits, e.g. in the training of taxonomists from developing countries (Buck & Hamilton 2011; McNeely 2010; Pethiyagoda et al. 2007; Prathapan & Rajan 2011; Schindel & du Plessis 2014; Welch et al. 2013). Thus, capacity-building efforts in the developing world is compromised (CBD 2012a & 2015), particularly in countries lacking collection-based institutions (Miller & Rogo 2002; Paknia et al. 2015).

Implications for the functioning of the CBD

Taxonomists, ecologists and other biodiversity experts conducting non-commercial research remain surprisingly quiet, despite the deleterious effects that restrictive national

access and benefit sharing requirements have on basic biodiversity research especially in developing countries (Prathapan et al. 2008) – little has changed since the cautionary remarks by Jinnah and Jungcurt (2009). So far, commercial benefits delivered to providing countries proved to be too insignificant to counteract socio-economic problems or to contribute to a sustainable development of local communities (Prathapan & Rajan 2011; Richerzhagen 2014) and may even compromise the integrity of local communities by creating unrealistic expectations (Myburgh 2011).

All cases of alleged biopiracy summarised by Reichman et al. (2016) were filed to prevent monopolisation of GR or to counteract privatising revenues resulting from their utilisation. This is a legitimate interest but it is a misconception that GR themselves have an ultimate intrinsic research or market value that leads to direct commercialisation; the precompetitive input to science resulting from their utilisation at the very beginning of the user chain is essential to generate the knowledge that may lead to useful innovations further downstream (Reichman et al. 2016). At the same time, it is evident that bureaucratic and financial burdens impede taxonomic and conservation studies (Pethiyagoda et al. 2007; Prathapan et al. 2008; Prathapan & Rajan 2011). A decline in access to and use of GR from in-situ sources, however, leads to a decline in international research collaborations (Kamau & Winter 2015), and to a decrease in the generation and delivery of non-monetary benefits. This includes a decrease rather than increase of anticipated fair research partnerships with developing countries along with training and technology transfer leading to capacity-building (Reichman et al. 2016) as originally envisioned in the third principle of the CBD (SCBD 2010a; SCBD 2014).

This unstable environment even threatens the capacity-building strategies of the CBD parties in the promotion of the conservation and sustainable use of biodiversity (Oberthür & Rosendal 2014). It hinders establishment of tools to assess, compare, identify and describe biodiversity, e.g. development of sequence-based DNA barcode reference libraries (CBD 2015). Open access to biodiversity research data and corresponding specimens in repositories is vital for basic non-commercial biological science (Kemp 2015; Schindel et al. 2015) and essential for supporting the objectives of the CBD, the strategic goals C and E of the Biodiversity Strategy, to reach Aichi Target 13 and 19 (Watanabe 2015) and for Strategic Actions 3 and 4 of the capacity-building strategy for the Global Taxonomy Initiative (GTI) (CBD 2012a).

Ironically, while publicly funded non-commercial (basic) research is under increasing legal scrutiny (Reichman et al. 2016; Watanabe 2017), results stemming from commercial research (which often remain unpublished and are kept secret) or research and development remains largely unaffected by ABS provisions. This is the result of the shift in the focus of advanced biosciences that moved to gene expression and direct analysis of naturally occurring compounds that result from gene expression (Buck & Hamilton 2011) without initial sequencing of biological materials. Since the US Supreme Court invoked a "product of nature" doctrine to invalidate patents covering genomic DNA or complimentary DNA (Bagely 2015; Reichman et al. 2016), there has been a movement to protect innovations under trade-secret or copyright laws to keep inventions under private control and outside the reach of national compliance measures established to implement the NP (Reichman et al. 2016). Benefit sharing from commercial utilisation of GR could also be circumvented through other juridical manoeuvres, e.g. due to the ambiguous status of many indigenous communities as a legal entity and contracting party (Myburgh 2011) and because intellectual property regime concepts could allow patenting of the pure functioning of a gene (von Kries & Winter 2015) or microbial-related processes and inventions (Reichman et al. 2016) without disclosing the origins of the biological material from which this knowledge has been gained (Koester 2012). In the absence of internationally agreed norms and standards, practices and definitions for patent applications on information contained in genes or in living organisms and microbes differ widely for example in the USA, the European Union and Japan (Reichman et al. 2016).

This opens the door for even more legal interpretations, and has the potential to block upstream research activities not only in developing but also in industrialised countries, as the Taq Polymerases Case tellingly demonstrates (Reichman et al. 2016). Taq polymerases was isolated from a microbe that was obtained from the American Type Culture Collection and originally had been sourced from hot springs in the Yellowstone National Park in the USA. Patents on the PCR technique blocked progress in academic research for years because of the high prices the patent holders charged for Tag polymerases. The estimated revenues generated up to $85 million annually, and even though the isolate of *Thermos aquaticus* was sourced from Yellowstone via a public repository, a court ruled that the licencing of Taq polymerases was within applicable laws and no benefits or royalties needed to be shared with the National Park or the public collection. Because of this and other similar cases, most developing countries not only strictly oppose the concept of patent applications for living organisms but also aim to regulate access to ex-situ material stored in repositories outside the original sourcing country.

For the same reason, the acquisition date of ex-situ material and whether or not the utilisation of samples that were accessed pre-Nagoya would fall under the CBD are controversies discussed between provider and user countries. User countries in particular contend that legally binding benefit-sharing obligations can only be implemented for materials that were sourced in providing countries after the entering into

force of the NP (compared to pre-NP agreements that were established on a voluntary basis under the CBD – or not) which restricts the applicability of compliance measures to materials accessed since 12 October 2014. Many providing countries anticipate substantial shortcoming of benefit sharing if (pre-NP) ex-situ material from public repositories is sourced for research and development and the generated knowledge is freely shared and exchanged without any obligations of users to come back to original providers or to share benefits. Thus, many providing countries are less enthusiastic about the stimulus that non-commercial research results generate for the benefits of society if they are shared freely in the public domain (Kamau 2015b). This points to fundamental problems which are the missing obligation (1) to disclose the original providing country of GR and to support traceability of utilised GR inside the value chain (Kamau 2015a), (2) to negotiate benefit-sharing agreements whenever commercialisation is intended (Rosendal et al. 2016; Watanabe 2017; Winter 2015) or patents are filed (Bagley 2015) and (3) the missing balance between trade-related aspects of intellectual property rights and the intentions of the CBD to use GR in a sustainable way and to share arising benefits equally (Oberthür & Rosendal, 2014; Rabitz 2015; Reichman et al. 2016; Rosendal et al. 2016).

Downstream compliance

Open exchange and providing access to collection material for researchers are the core functions of publicly funded collections (Biber-Klemm et al. 2014; Reichman et al. 2016). Ex-situ collections do provide information on the provenance of samples when providing or transferring material. The major challenge, however, is the downstream monitoring and tracking of utilised GR and associated viral contract clauses which ensure that the provenance of utilised samples remains transparent at all points in the value chain to control NP-compliant transfer and utilisation and to ensure benefit sharing (Kamau 2015b; Rosendal et al. 2016; Winter 2015). Controlling downstream compliance is typically beyond the responsibility of ex-situ collections as they neither have the means nor the mandate to police compliance in the user chain. Building an operational pipeline and informatics platform to reflect the complex research work flow for millions of biomaterial transactions and reciprocal interaction to increase traceability is ambitious (Welch et al. 2013) and requires changes in standard exchange procedures for specimens and data (Reichman et al. 2016; Winter 2015). Natural history repositories storing, maintaining and transferring ex-situ material can play a key role to support the successful implementation of the NP (Biber-Klemm et al. 2014) and to establish downstream tracing systems (Schindel et al. 2015), but they become increasingly understaffed and under-resourced (Kemp 2015; Watanabe 2017) and do not receive direct beneficiaries of the system but have to cope with the increased administrative and bureaucratic burdens (Biber-Klemm & Martinez 2015; Reichman et al. 2016; Watanabe 2017). From an informal survey carried out by Biber-Klemm and Martinez (2015) among researchers in Switzerland in 2009, there is considerable fear among provider countries that they will lose control over accessed material even though ABS negotiations took place and agreements were reached. The need of basic and publicly funded science to publish research results and make them available to a wide audience further raised the fear that these results could be used by "biopiracy enterprises".

This concern is in the centre of the discussion that was raised during the conference of CBD parties in Cancun in December 2016 (CBD 2016) on digital sequence information and the potential uses of published molecular (genomic) data. Should phylogenetic analysis using GenBank sequence data from the public domain be considered *utilisation* and thus fall under the NP (Kamau 2015a; Rabitz 2015; SCBD 2017)? Who holds the rights over species that occur in more than one country? Given all these constraints, clear provisions for simplified compliance measures for international biodiversity research (Schindel 2010) and uniform solutions for all non-commercial ex-situ collections (Biber-Klemm et al. 2014; Kamau 2015b) are desperately needed.

Research community based approaches

As with many other comprehensive international treaties, the CBD and NP are not perfect; however, after initial uncertainty, ambiguities are likely to decrease while clarity and common sense will hopefully prevail (Biber-Klemm & Martinez 2015; Oberthür & Rosendal 2014). ABS-compliant international networks of ex-situ collections (Biber-Klemm et al. 2014; Jinnah & Jungcurt 2009; Welch et al. 2013) building on trust and strong ties of participating researchers and institutions could support and strengthen North-South research collaboration and help to remove obstacles and rebuild trust. Practical needs rather than theoretic political and scientific policy issues should be moved in focus of a directed discussion between the scientific community, policy makers and participating governments. In the centre of such efforts should be the strong inputs from scientific communities and bottom-up, research-driven user groups and associations (Reichman et al. 2016). Such engagement could lead directly to the successful establishment of transnational ABS management tools, respecting the concerns of providers and the needs of users. If acknowledged by CBD Parties, such community or network-based instruments would not only supplement the ABS-toolbox but lead to the implementation of commonly agreed measures (e.g. best practices) to promote CBD-compliant biosciences (Biber-Klemm et al. 2014; Schindel et al., 2015; SCBD 2014), and allow simplified exchange of GR within these networks or communities for mutual benefit (Biber-Klemm

et al. 2015; Prathapan & Rajan 2011). Voluntary codes of conduct, guidelines and best practices (cf. article 20 NP) are an opportunity to recognise good practice and should be understood as such. Ideally, they develop into a sectoral standard that promotes simplified access with fair and equitable benefit sharing. Recognition and application of best practices may not only be suited to raise trust among providers, but have the potential to enhance compliance and ease the reporting burden of users. Such an element was added to the EU ABS legislation (EU 2014, article 8) – it allows associations of users to submit best practices to the European Commission for official recognition. Acknowledged best practices are seen as a useful element to encourage users or association of users to develop "procedures, tools or mechanisms" for the successful management of existing ABS obligations and to meet the requirements and obligations of the EU ABS regulation.

Such harmonized best practices have been developed by the Botanical Gardens Conservation International (BGCI), the Consortium of European Taxonomic Facilities (CETAF) or the Global Genome Biodiversity Network (GGBN) (Biber-Klemm et al. 2015). They establish voluntary standards for ABS management and for monitoring material exchange and multi-use practices resulting from physical availability of specimens in collections (Welch et al. 2013). BGCI's International Plant Exchange Network (IPEN) is an established CBD-compliant network designed to facilitate non-commercial transfer of living plants (Biber-Klemm et al. 2015). The GGBN (Coddington et al. 2014) is positioned to cover transactions of all other organismal samples. Other, more specialised scientific networks like the International Barcode of Life (Schindel et al. 2015; Vogel 2013) could develop tools to cover project-specific collaboration models (e.g. outsourcing of analytical services done by or with GR of developing countries). The CETAF Code of Conduct and annexed best practices that was submitted for official recognition as acknowledged best practice under EU ABS regulation (EU 2014) is currently considered as a prime example for the development of such community-based tools inside the European Union.

Moreover, open and free information networks promote open access of biodiversity data in line with the mandate of the CBD's GTI (CBD 2012a & 2015) and facilitate submission of this referenced and traceable information into public portals such as the Barcode of Life Database (BOLD) and GenBank or the Global Biodiversity Information Facility (GBIF). The need to contribute and share biodiversity-related data and information is highlighted in Aichi Target 19, and by the fact that much data and information remain inaccessible and capacity is lacking to mobilize them in many countries (SCBD 2014). The overwhelming value of GR and information on where such material can be found and is available to public researchers is a prerequisite to create royalties and applications further downstream. The same applies for data hubs such as BOLD, GenBank or GBIF and is the reason for their impressive success during the last decades because they address the needs of science, such hubs offer a sustainable and hopefully secured future for uploaded data and – most important – because data users and data providers need and want them. These hubs are also seen vital for "delivering biodiversity knowledge in the information age" (SCBD 2014).

Naturally occurring genetic traits in GR and structures encoding expression or functioning of genes in the public domain are prior art and have important functions as a public good. Networked global search engines gather digital sequence data which is usually scattered in print publications (with limited access) and databases which otherwise may or may not be available online for computational searches. The institutions supporting key-infrastructures such as GBIF, BOLD and GenBank provide and maintain such data in the public domain. This allows free access to the information in the public domain but also prevents patents or other proprietary claims on this information because of lack of novelty by any third party (Rabitz 2015; Reichman et al. 2016; Rosendal et al. 2016). Data releases of researchers or institutions are not only based on common procedures and policies for data entries into the public domain, but they also warrant the perpetuation of data on the origin of the samples during data release or other publication of research results. Thus, claims of intellectual property rights (IPR) by third parties are excluded and recognition of the original organism and providing country through the utilisation chain is ensured (Bagley 2015; Reichman et al. 2016). Contrary to the requirements for the claim of IPR, the release of such research results into open data portals is both a prerequisite for research publications as well as a common scientific standard for maintaining the validity and verifiability of research results. CBD-compliant networks would thus enhance global tracing of biomaterial and recognition of the original providing country. This traceability of utilised GR offers a practicable solution for enhancing ABS-compliance and assists providing countries to maintain benefit sharing through the utilisation chain even under conditions of the public domain (Kamau 2015b; Rabitz 2015; Winter 2015). It is also in line with the definitions offered for non-commercial research (SCBD, 2009a; Winter 2015).

Community-based sectoral approaches for storage and user-systems as established by institutions united under CETAF or BGCI enhance (1) ABS-compliance for utilisation and sharing of samples within and between signatory and non-signatory states and (2) compliance with ABS legislation of provider countries (Koester 2012; Winter 2015). Further, they could be a source to evolve digitally integrated data portals along these lines and avoid overly bureaucratic formats by focussing on the needs of science (Biber-Klemm & Martinez 2015) leading to integration of "open access principles that are essential for the public-good functions of a true research

commons" (Reichman et al. 2016). In combination with an ABS-compliant release of data of those institutions and their researchers, these sectoral approaches may contribute to the promotion of biodiversity-related research as has expressly been conceived in several meetings of the Conference of the Parties of the CBD and by the Global Taxonomy Initiative (GTI) since 1996 (CBD 2012b). This is of special importance since the responses to the biodiversity crisis and the models trying to quantify progress and responses to the Aichi Targets still suffer from limited taxonomic expertise and coverage (Pisupati 2014; Tittensor et al. 2014). Efforts to fight global biodiversity loss require intensified access to and research of in-situ and ex-situ material by taxonomists and biodiversity researchers. Despite the 250 years of taxonomic research that produced approximately 1.2 million species entries in public online catalogues and databases, this apparently represents only 14% of the terrestrial and 4% of the marine life on Earth (Mora et al. 2011). The fight requires free access to information and data made publicly available as a common good, including digital sequence information. Both are essential tools for a successful CBD implementation and are required to identify threats to biodiversity, to determine priorities for conservation and sustainable use of biodiversity and to enable targeted and cost effective management tools to combat biodiversity loss (SCBD 2014; CBD 2015; Oberthür & Rosendal 2014).

During informal discussions at the first Conference of Parties, several countries renewed their interest in international non-commercial research collaborations for the discovery, documentation and management of a country's biodiversity (Schindel & du Plessis 2014). Referenced and traceable data on the provenance of specimens interlinked with (genomic) research results of users of GR that are accessible via public domain network portals are a key-tool in the ABS-compliance system (Schindel et al. 2015; Winter 2015; CBD 2015). Strategic Goal C of the Strategic Plan for Biodiversity 2010–2020 mandates to "improve the status of biodiversity by safeguarding ecosystems, species and genetic diversity" (SCBD 2014). This requires transnational acknowledgement of ABS-compliant, community-based network approaches and best practices as major step towards harmonised and simplified access to and transfer of specimens and data within the non-commercial scientific community and ex-situ collections to prevent the decline of basic biodiversity research at large and to protect the original goals of the CBD.

Text Box 1

From an economic perspective, both the CBD and NP can be understood as implementation of an ecosystem service that generates monetary or non-monetary benefits from biological material "containing functional units of heredity with an actual or potential value". Thus, through "utilisation of genetic resources" these actual or potential values are created and can be embedded in a global market system for genetic resources. Wolff (2014) sheds an interesting light on such "debt-for-nature swaps". Various such mechanisms have been introduced since the late 1980s, including the CBD/NP, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the Kyoto Protocol which introduced a trade system and global market for carbon dioxide emissions, and forest carbon as an instrument aimed at "reducing emissions from deforestation and forest degradation in developing countries" (REDD+). The latter aims to compensate developing countries either through a direct international payment system or by redirecting revenues generated through an international carbon market. The similarities to implement a "market for ecosystem services" on global scale are obvious.

Thus, it is unsurprising if developing countries understand their sovereign rights over GR occurring inside their national borders also as an economic instrument to profit from these ecosystem services and from the goods and information such biodiversity and ecosystem services generate. Biodiversity and taxonomic research undergirds these proposed ecosystem services by providing the principal understanding and identification of these different units, which is a prerequisite to manage them in the proposed ecosystem services and the sharing of potential or actual revenues arising out of their utilisation. While, in theory, an "actual or potential value" can be reached by generally "utilising" biological materials, in practice the scientific value of research typically is generated by publishing data and analytic results: scientific knowledge.

The fundamental problem lies in the fact that scientific results arising out of the utilisation of GR are fundamental research without regard to commercialisation. They are cultural assets, not tangible goods or marketable objects to be managed through market-based instruments. Accordingly, it is and will be very difficult to apply successfully market-approved management instruments to govern an interwoven scientific network accessing, utilising, analysing and investigating GR from various perspectives with largely pure research interests and motivations. In addition, scientific value is based on the recognition and reputation of the results of researchers, regardless of the actual or potential value of the analysed objects.

Text Box 2

The broad definition of "genetic resources" in the CBD (material of actual or potential value) and "genetic material" (any material of plant, animal, microbial or other origin containing functional units of heredity) was chosen carefully and is key to the implementation of access

and benefit sharing. Firstly, this definition converts all biological life into objects (genetic material) – regardless of its nature or from where or which object these organisms have been sourced. Because of this definition as an object, regulation in a legal system becomes possible (which would be a difficult task in the case of universally occurring biological life). Secondly, by assigning a value to these objects (material of actual or potential value) they are turned into goods, which allow governance and mercantile management of such objects. Utilisation of resources thus generates advantages or information that can be traded or marketed. It is interesting to note that the failure to generate such anticipated results or advantages because the utilisation "fails" – for example because the DNA of the biological material was too degraded or the findings were useless or even harmful – is rarely considered. Alexander Fleming surely never won the Nobel Prize because he planned to have an untidy lab to trap the mould *Penicillium notatum* on his Petri dishes. *Failure* is an important and common phenomenon in research and for scientific advancement.

Many problems stem from this new conceptual interpretation that turns *genetic resources* into defined objects of ownership or property rights. This divergent legal understanding of a common good (nobody previously owned nature) was introduced into international law for the first time with the CBD (Tvedt & Schei 2014). Besides the lack of political consent on the definition of *genetic resources* itself (what is covered), a legal definition needs to be flexible enough to include future applications, especially in such a highly dynamic research sector experiencing rapid analytic advances and technological development.

From the beginning, "functional units of heredity" has been the centre of the debate. When originally drafted in 1992, it meant the role of genetic material in heredity and parent to child biological reproduction. However, with the advance of PCR and sequencing technology, the need for a more flexible, inclusive and dynamic concept of interpretation became obvious (Tvedt & Schei 2014). As they point out, even though it might be difficult to capture the complete meaning of "functional units of heredity' as "an enforceable legal term", the word *functional* added a second connotation. Specifically, *functioning*, *working or operating* (inside the organism) can be interpreted as a "molecular construct inside cells or organisms […] functioning on micro-organic level" or even outside an organism, referring both to the "genetic structure per se and to the information encapsulated in the DNA sequence (nucleotide) that can be screened and transferred into digital form and become functional in a new, digital form."

The interpretation for *material* is similarly broad, which could include "intangible/informational elements", i.e. "i) the micro/physical component […] ii) the information […] and iii) the intangible and tangible used together" (Tvedt & Schei 2014). The latter is especially controversial regarding digital sequence information because if "the medium into which the heredity information is later transferred is not decisive for whether it is being included in the definition" (Tvedt & Schei 2014). This imminent reduction to *anything of biological origin* that has *any potential or actual value* entirely ignores how science works, the essence of scientific value, and how scientific knowledge grows. Scientific value does not fit into such a strict unidirectional economic scheme.

Text Box 3

The Biosphere Reserve Cuatro Ciénegas, an 850 km^2 area of isolated springs, pools and swamps in a highly arid environment in northern Mexico, is severely threatened by groundwater removal. To support protection and develop cash-back systems to local communities from sustainable use of the reserve's genetic resources to reduce groundwater removal by surrounding dairy farms, a Mexican molecular biologist "wrangled a permit from the federal government" (Jones 2011) granting permission to commercialise useful genes. Getting a permit from the Mexican government was "not easy" and "frustrating" but in the end successful (Jones 2011). However, reaching consent and agreement with the eight local communities in this area was even more difficult. After 1 year of negotiations, six communities agreed to future financial restitution and two demanded upfront-cash payments. Even though the project identified promising genes that will likely lead to patents channelling back revenues into the communities, ground water removal continues. Alternative income sources generated from the sustainable use of genetic resources in the area, however, are unlikely to materialise, because the largest pond dried out, as will others before the benefits appear (Jones 2011). The state and local communities were reluctant to take the necessary measures to protect the reserve. At a larger scale, many biodiversity-rich countries have tightened regulation of genetic resources because they perceive that sovereign genetic resources could lead to economic success. As Prathapan and Rajan (2011) showed in several examples for India and other countries, direct commercial benefits are marginal to date. Despite high investments and research inputs in several examples the proposed monetary benefits did not materialise because (i) a realistic price for the commercial product did not compensate for royalty payments and original investments, (ii) the drug had unexpected and unwanted side-effects that immediately terminated further research activities or (iii) the original assumptions proved to be too hypothetical to lead to any realistic application.

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List of acronyms used in this paper *ABS*, access and benefit sharing; *BGCI*, Botanical Gardens Conservation International; *BOLD*, Barcode of Life Database; *CBD*, Convention of Biological Diversity; *CETAF*, Consortium of European Taxonomic Facilities; *CITES*, Convention on the International Trade of Endangered Species of Wild Fauna and Flora; *EU*, European Union; *GBIF*, Global Biodiversity Information Facility; *GGBN*, Global Genome Biodiversity Network; *GR*, genetic resources; *GTI*, Global Taxonomy Initiative of the CBD; *IPEN*, International Plant Exchange Network; *IPR*, Intellectual Property Rights; *LMMC*, Like-Minded Megadiverse Countries includes 17 states: Bolivia, Brazil, China, Colombia, Costa Rica, the Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, the Philippines, South Africa and Venezuela; *MAT*, Mutually Agreed Terms; *NGOs*, Non-Governmental Organisations; *NP*, Nagoya Protocol; *PIC*, Prior Informed Consent; *SCBD*, Secretariat of the Convention on Biological Diversity;

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