7

Transparency in the Governance of Access and Benefit Sharing from Genetic Resources

Amandine Orsini, Sebastian Oberthür, and Justyna Pożarowska

Transparency is a central element in the international governance of genetic resources (GR) under the Convention on Biological Diversity (CBD). GR is material coming from plants, animals, or microorganisms that can be used for commercial applications, among others. Before being commercialized, genetic resources are often transformed by means of biotechnology. The core of the governance of GR under the CBD is known as "access and benefit sharing" (ABS), itself an implication of the CBD's recognition of states' "sovereign right to exploit their resources pursuant to their own environmental policies" (CBD, article 3). As a consequence of this sovereign right, potential GR users are required to receive permission by providers in order to be able to access GR on the latter's territory. In exchange, the GR providers should receive their fair and equitable share of the benefits arising from the use of these GR, as stipulated in the CBD, which establishes fair and equitable benefit sharing as one of its three core objectives in its article 1 (next to the conservation of biological diversity and the sustainable use of its components).

Underlying the ABS mechanism was the idea that the valorization and commercialization of GR, mostly through biotechnology, could create an international market for GR, which would enhance interest in the conservation of biological diversity and the sustainable use of its components (Brand et al. 2008). Given the rise of biotechnology, the benefits arising from the use of GR could be considerable. Genetic resources have been used in bioinventions that have received protection through intellectual property rights (IPRs) such as patents. Depending on the methodology used and the scope of the products considered, the value of the market for products based on GR has been estimated to account for US$220–800 billion annually in the 2000s (Deke 2008, 120).

Transparency of the conditions for getting access to GR and the benefits subsequently generated from their use is central to the effective

functioning of the overall system. This double-sided transparency is thus at the core of the ABS regime under the CBD, culminating in adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD in 2010 (henceforth Nagoya Protocol).[1]

Traditional knowledge (TK) related to GR forms an important part of the issue area and the overall debate. In many if not most cases, the value and use of GR are linked to associated TK, that is, the know-how, skills, innovations, and practices of indigenous and local communities (ILCs). Such TK frequently allows identification of useful GR and its added value—although this is often not acknowledged.[2] At the same time, ILCs that hold TK contribute to the conservation and sustainable use of biological diversity, as also acknowledged by the CBD, including in its articles 8(j) and 10(c). Article 8(j) of the CBD therefore commits parties to respect, preserve, and maintain TK and to "encourage the equitable sharing of the benefits arising from the utilization of such knowledge." Our following discussion therefore relates to GR and associated TK, and unless otherwise specified, a reference to GR includes the TK associated with their use.

Another important feature of international ABS governance is that it has been structured by a North-South conflict, although significant differences within both groups of countries, and especially as regards emerging economies, should not be neglected. On the one side, developing countries belong to the most biodiversity-rich countries with dominant GR-TK provider interests, which have led them to insist on the benefit-sharing side of the equation, including through changes to the IPR system. Among developing countries, there are important differences with regard to capabilities for the valorization and marketization of GR by means of biotechnology and the implementation of domestic infrastructures of ABS governance. Developed countries, on the other side, have dominated biotechnological development so far and have thus been particularly interested in ensuring access to GR, while staving off attempts to enhance benefit sharing with providers and interference with the IPR system (Brand et al. 2008). The share of countries in biotechnological patent applications, displayed in table 7.1, indicates the major GR-user countries and resultant diverging interests of developing and developed countries.

It should be noted that the CBD is not the only forum for international ABS governance but is rather at the center of a complex of relevant international institutions. Nearly a dozen other global institutions contribute to ABS governance in different ways. These include the World Trade

Organization (WTO), the UN Convention on the Law of the Sea, the World Intellectual Property Organization (WIPO), the Antarctic Treaty System, the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization (FAO), the World Health Organization and others. The CBD and its 2010 Nagoya Protocol are central to this complex because they are the only global institutions to address all aspects of ABS governance (Oberthür and Pożarowska 2013). However, other institutions are also important. The WTO and WIPO are particularly relevant to the debate on transparency because of their role in patent regulation.

Against this backdrop, this chapter explores the evolution of global ABS governance under the CBD from the perspective of transparency, taking into account the 2010 Nagoya Protocol. In line with the overall framework of this book, we discuss, first, the emergence and framing of transparency in this area of governance. We argue that transparency, which was not initially envisioned as a policy solution, has increasingly moved to center stage in the debate on ABS governance under the CBD, which especially builds on bilateral contracts between providers and users. This move results, not least, from a growing marketization of GR and increasing awareness (through, for example, NGO campaigns) of the lack of information about GR uses. Subsequently, we outline the main elements and instruments of the transparency infrastructure elaborated, and given legal force, in the Nagoya Protocol, including the bilateral, contract-based approach to ABS governance therein. We then discuss the (in)effectiveness of governance by disclosure thus far, as well as prospects

Table 7.1
Biotechnology Patent Applications: Patent Cooperation Treaty 2006.

Country/Region	%	Country/Region	%
United States	41.5	China	1.9
EU-27	27.4	India	0.9
Japan	11.9	Russian Federation	0.8
Canada	3.2	Brazil	0.3
South Korea	3.0	South Africa	0.1
Australia	2.1	Other	6.9
		TOTAL	100

Source: OECD 2011.

for improvement, especially through the Nagoya Protocol. The overall CBD system has performed weakly since the 1990s. Even after negotiation of the Nagoya Protocol, there remains a lasting imbalance between relatively advanced standards and practices for transparency for access and more problematic and imperfect standards for transparency for benefit sharing, which disadvantages least-developed countries and results in calls for capacity-building efforts. The conclusions summarize the results of the analysis.

Embracing Transparency

In considering the dynamics underpinning an uptake of transparency in ABS governance in this section, we engage also with the first hypothesis advanced in the introduction to this volume: that democratization and marketization are driving the uptake of transparency in global environmental governance. The foundations of ABS governance can be traced to the 1992 CBD agreement, which established the role of transparency herein, especially through the "nationalization" of GR. At this time, ABS was framed as a matter of fairness, property, and redistribution around the broader normative context of justice. Previously, GR were mostly freely accessed under the common heritage principle. Not least because of related IPRs such as patents, they generated significant profit that was generally appropriated by GR users (mainly from developed countries) without significant sharing of these benefits with the GR providers (principally developing countries). On the one hand, as mentioned previously, the CBD established, in its article 1, ABS as one of its three objectives, thus calling for a redistribution of a fair part of the commercial value of GR to the providers (and protectors)—mainly to national governments and ILCs (Rosendal 2006, 431–432). On the other hand, the convention also firmly established the sovereign rights of states over their natural resources in its preamble and articles 3 and 15.1. The heart of the ABS regime therefore became constructed as a bilateral exchange between individual providers and users of GR (rather than as a multilateral exchange system, as we also discuss subsequently).

Transparency of ABS was not a major focus during the CBD negotiations themselves, because developing countries were concerned mainly about sovereignty over natural resources, finance, and technology transfer (Svarstad 1994, 47). Their securing of sovereign rights over GR provided the basis for their request for financial redistribution and compensation. NGOs present at the time noted that the dominant discussion

was related to "the idea to link the access to biodiversity to some sort of compensation to the holders, either financially or in terms of technology or end-products" (Arts 1998, 192). Yet, provisions on ABS were included mainly in the convention because of insistence by developing countries as the main providers of GR and TK. In particular, members of the Amazon Cooperation Treaty (Bolivia, Brazil, Colombia, Equator, Guyana, Peru, Surinam, and Venezuela) drafted CBD article 15. These countries had reiterated their sovereign rights over their natural resources in 1992—in the so-called Manaus Declaration—to establish that users had to comply with their national legislation in order to receive access. In the CBD negotiations, they pushed to exchange access to GR for reciprocal benefits, such as, for example, receipt of developed countries' technologies.[3] For them, ABS was still a central part of the negotiations (Rosendal 2000). By contrast, it was not central to developed country governments, who felt that biosafety (i.e., the safe handling, transfer, and use of genetically modified organisms) was a much more central concern (Hopgood 1998, 134; see also Gupta, this book, chapter 6).

Given the uncertain and variable value of GR, concrete benefit-sharing arrangements necessarily had to be established and agreed case by case. Consequently, the CBD determined, in its articles 15.4 and 15.7, that ABS shall be on "mutually agreed terms" (MAT)—a concept introduced in the 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture (articles 5 and 7.2) of the FAO. Accordingly, as for the exchange of plant GR under the International Undertaking, the terms of ABS needed to be agreed on mutually by providers and users. Furthermore, the concept of prior informed consent (PIC) by the providers of GR was enshrined in article 15.5 of the CBD. In practice, PIC can be defined as "a set of administrative procedures for deciding on whether to grant access to genetic resources on defined terms" (Pisupati 2007, 15; see also Jansen and Dubois, this book, chapter 5; Gupta, this book, chapter 6). The concept has its roots in international regulation of transboundary movements of chemicals and hazardous wastes, including the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. Whereas PIC was first introduced as a requirement for the import of hazardous substances or materials, in the case of GR it is required for the access to (and export of) GR.

Expectations about these arrangements were fostered by marketization dynamics, including several apparently promising examples of commercial exchanges of GR known as bioprospecting agreements. The most well-known of these was the INBio/Merck agreement signed in 1991 in

Costa Rica. Merck, the leading global pharmaceutical company at that time, agreed to pay US$1 million, including US$135,000 of laboratory equipment, and to train local scientists, in exchange for access to Costa Rican GR. It also agreed to redistribute up to 3 percent of the royalties obtained from any commercialized product derived from the accessed GR to the Costa Rican institute INBio, the main public institute responsible for nature conservation, in collaboration with the Costa Rican Ministry of Natural Resources. Such a contract-based approach to ABS appeared to be a promising way to ensure that GR providers (mainly developing countries) could finally benefit from GR users' profits and invest in domestic biodiversity conservation programs (Rodriguez 1993, 138).

In such a bilateral system, there was a twofold demand for transparency: on the one side, potential users, mainly from developed countries, required information on how to receive PIC for accessing GR in provider countries, including requirements for benefit sharing to be reflected in MAT (if such requirements existed). Provider countries and their stakeholders (including ILCs), needed, on the other hand, information on GR used in user countries as well as the benefits generated in order to identify whether PIC and MAT requirements had been complied with and to enforce MAT. Whereas transparency received little attention in CBD negotiations, the resulting bilateral, contract-based approach to ABS governance nevertheless framed the demand for and the ensuing debate about transparency.

The importance of transparency also gained recognition as the optimism about bioprospecting agreements made way for more sobering assessments of their potential. In the Merck/INBio case, NGOs such as Friends of the Earth and the Tropical Rainforest Coalition expressed concerns about Merck's intentions because the corporation had a total research and development budget that exceeded the Costa Rican national income (Rodriguez 1993, 137). Critics requested information on the exact content of the agreement, in which the most specific provisions were protected by industrial confidentiality (Rodriguez 1993, 138). NGOs and ILCs also revealed that Merck exploited TK in the search for interesting natural compounds, without rewarding such knowledge: the indigenous population that was employed to collect plants and biological samples was paid as a basic work force, despite the dangers involved and their actual participation as biodiversity specialists. Moreover, the very idea of selling public natural resources to a private company was questioned. Such resources could have been valorized in other ways that might have been identified in national consultations, if only they had taken place

(Rodriguez 1993, 137–138; see also Miller 2006). Further scandals about unclear bioprospecting agreements occurred. States were negotiating these contracts with restrained disclosure (in particular due to commercial confidentiality and nonmandatory obligations), and civil society and ILCs were often left out of the debate. Consultation on the commercial exploitation of national GR was lacking and the TK used to facilitate research and development remained uncompensated. Moreover, local communities living dependent on the resources in question were excluded (Burrows 2005).

Therefore, the uptake of transparency as a governance tool was directly linked to the marketization of GR on the one side and to concerns over biopiracy on the other, providing support for the hypothesis advanced in the introduction that uptake of transparency is being fueled by a marketization, commodification, and valuation dynamic to global environmental governance. With transparency moving center stage in global ABS governance, we can describe what ensued as a battle between developed countries advocating "transparency for access" and developing countries demanding "transparency for benefit sharing." On the one side, the GR users claimed that it was difficult to ensure PIC and MAT because of uncertainties regarding national legislation and the procedures they were expected to follow. They advocated a contract-based transparency mechanism that respected market liberalism (free trade in GR) and intellectual property rights, including the possibility to patent GR- and TK-based innovations. In such contract-based transparency, the content of contracts often reflected power asymmetries between users and providers that favored the users.

On the other side, the GR providers requested transparency about the GR being accessed and used, the intentions of the users (including any change of intentions), and the benefits generated and to be shared. Developing countries wanted such information to be available to provider countries and to a much lesser extent to ILCs. One of the main proposals was to have a mandatory requirement to disclose the origin of any GR or TK used and other relevant information in patent applications, as discussed further in the following section. On these grounds, by 1995 developing countries, ILCs, and NGOs denounced any kind of international use of natural GR that did not respect the PIC and MAT requirements as "biopiracy" (Bled 2010, 583). The bioprospecting-biopiracy controversy placed transparency in the center of the battleground for ABS.

In addition, several developing countries developed their own national ABS legislation from the mid-1990s. Following the INBio/Merck

controversy, Costa Rica, for example, conducted consultations in 1996 and established a national commission in 1998 (Comisión Nacional para la Gestión de la Biodiversidad), including indigenous peoples' organizations to devise access procedures. Moreover, the Costa Rican law required that 10 percent of the research and development budget as well as 50 percent of the royalties earned for any GR-based products had to be redistributed to the providers (the exact beneficiaries being designated by the commission) (Miller 2006). Brazil adopted similar national legislation in 2000, following a biopiracy controversy with the multinational corporation Novartis. Overall, some forty developing countries, including major biodiversity-rich countries such as India, South Africa, and Brazil, established national ABS legislation by 2007 (CBD 2007b). However, such national action by provider countries could not effectively control transnational flows and use of GR by biotechnological industry and other users.

The double-sided request for ABS transparency was addressed to some extent in the so-called Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization adopted by the parties to the CBD in 2002 (CBD 2002). The voluntary guidelines first elaborated the contract-based approach to marketization and valorization of GR outlined in the CBD (Brand et al. 2008, 93–95), promoted international standardization of ABS contracts, addressed the rights of providers and users, and supported transparency. The guidelines elaborated on "transparency for access" by inviting parties to designate national focal points with the task to inform, through the CBD's clearing-house mechanism, potential users about procedures for PIC and MAT. Competent national authorities, to be established, were responsible for granting access and giving directions on negotiating ABS contracts, including establishment of PIC and MAT. Legal certainty and clarity were highlighted as basic principles for PIC and MAT, resulting in a call for any restriction on access to be transparent (CBD 2002, paras. 13, 14, 26, and 42). On the side of "transparency for benefit sharing," however, the possibility of noting the country of origin of GR or TK in IPR applications was only mentioned (CBD 2002, para. 16; see also para. 53). Overall, there was a greater emphasis on "transparency for access" than on "transparency for benefit sharing," and the contract-based approach pursued by the guidelines was the one favored by developed countries.

In practice, however, the Bonn Guidelines did not solve the ABS battle over transparency for a number of reasons. The guidelines were voluntary

and, as such, did not satisfy developing countries as key providers. They did not redress the problem that, given the rather "soft" CBD provisions on ABS, parties have no firm obligations to introduce the proposed provisions (for example, there is no compliance mechanism). Countries remained free to regulate ABS within the scope of their national legislation. As a result, many CBD parties, in particular developed countries, did not establish national measures to address ABS at all. Other parties adopted very different approaches, some of which were seen as inefficient or not providing satisfactory guarantees for fair benefit sharing (CBD 2007a, 2007b).

In this context, transparency increasingly moved front and center in global ABS governance and became inextricably linked to calls for substantive regulation. On the access side, transparency with respect to PIC and MAT had to be established by individual states: what would be the procedures for granting PIC, and what kind of terms would be accepted as mutually agreed? On the benefit-sharing side, there was a need to establish measures for cases of noncompliance by users (enforcement or sanctions). Thus, transparency increasingly became a major ingredient in a broader regulatory mixture structured and shaped by the CBD approach of bilateral, contract-based exchange relations.

Further efforts to elaborate, strengthen, and complement the CBD approach (and the Bonn Guidelines) were necessary, leading to the adoption of the Nagoya Protocol in October 2010. The protocol was pushed for by developing provider countries, who created the coalition of "Megadiverse Countries" in 2002 (comprising Bolivia, Brazil, China, Colombia, Costa Rica, Equator, India, Indonesia, Kenya, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela). These countries succeeded in receiving a mandate at the Johannesburg World Summit on Sustainable Development in September 2002 to negotiate an international regime on ABS under the CBD.[4] On their side, developed countries increasingly recognized their interest in securing access to GR as a basis for important industries (see, for example, Holm-Müller et al. 2005 for Germany). They also recognized that they might also themselves be or become GR providers in the future. A central component of the ensuing negotiations again revolved around securing a balance between "transparency for access" and "transparency for benefit sharing."

An important characteristic of this battle between the two sides of transparency has been that the marketization of GR fueling disclosure has involved public and private actors on the two opposing sides of the exchange relation. On the provider side, granting of access—resulting

from recognition of "sovereign rights"—typically involves public actors such as "competent national authorities" following publicly defined governmental procedures, which may include subnational political entities such as ILCs. The user side, by contrast, primarily features private market actors (biotechnological companies, research institutions). Transparency of GR use thus does not primarily require adaptation of government behavior and procedures, but rather regulation of economic actors and their "private" behavior in the context of market economies (partially considered confidential). This dynamic has also contributed to transparency for access being privileged in ABS governance, given that the behavior of public actors may be more easily addressed through public international law and regulation, in comparison to putting a "burden" on private actors and their market activities.

The following section analyzes the further elaboration and institutionalization of transparency within ABS governance under the CBD, as it has evolved within the Nagoya Protocol.

Institutionalizing Transparency

We analyze the main elements of global ABS governance under the CBD relating to transparency here in two steps. We first address elements relating to transparency for access, followed by those for benefit sharing. In so doing, we also engage with the second hypothesis advanced in the introduction to this book (Gupta and Mason, chapter 1), that an institutionalization of transparency may decenter state-led regulation and open up political space for new actors. We pay particular attention to what the Nagoya Protocol has contributed in this respect.

Institutionalizing Transparency for Access

PIC and MAT are at the core of the ABS governance system under the CBD. They are constitutive of the decentralized, contract-based marketization approach on which this governance system is based. According to the CBD, the Bonn Guidelines, and the Nagoya Protocol, access to GR is subject to PIC of the contracting party providing such resources, unless otherwise determined by that party (CBD, article 15.5; CBD 2002,- Bonn Guidelines, part IV letter C section II; Nagoya Protocol, article 6). The CBD requirement to establish MAT, enshrined in articles 15.4 and 15.7 of the convention, is closely intertwined with the issue of PIC because the establishment of MAT is usually a requirement for granting PIC. MAT are contractual arrangements containing detailed terms and conditions

for access agreed on by the provider and the user (Pisupati 2007). The exchange of GR is thus to occur on the basis of PIC and MAT.

The main contribution of the Nagoya Protocol to the preexisting system of PIC and MAT is to further elaborate mandatory "international access standards," building on core elements already contained in the nonbinding 2002 Bonn Guidelines. The Nagoya Protocol's additional requirements thus primarily aim at enhancing "transparency for access," which should facilitate legal access to GR by users in compliance with substantive PIC and MAT requirements of the provider country. First, as reflected in article 6.3 of the protocol, these access standards provide for enhanced transparency with regard to the conditions and procedures to be followed for receiving PIC. Accordingly, the developing country or provider parties to the protocol, who wish to require PIC, have to take a number of measures. These include providing for legal certainty, clarity, and transparency of domestic ABS legislation. Also required are fair and nonarbitrary rules and procedures on access, information on how to apply for PIC (available from national focal points), a clear and transparent written decision by a competent national authority, and the issuance of a permit (or equivalent) as evidence for the granting of PIC and the establishment of MAT.[5] Further requirements regarding the information a permit should contain are laid down in article 17.4 of the protocol. In accordance with articles 5.2, 5.5, 6.2, and 7, access to GR and TK that is held by ILCs is also subject to PIC by these communities and requires the establishment of MAT.

The national-level institutional infrastructure imported into the Nagoya Protocol from the Bonn Guidelines also primarily seems to strengthen transparency for access. This national-level infrastructure includes "national focal points" and "competent national authorities." According to article 13.1 of the Nagoya Protocol, the primary task of national focal points is to furnish information on PIC and MAT to applicants seeking access to GR and TK. Focal points are also expected to provide information on competent national authorities, relevant ILCs, and stakeholders. As specified in article 13.2 of the protocol, competent national authorities are responsible for granting access or issuing a permit as evidence that access requirements have been met (which after registration in the ABS Clearing-House becomes an internationally recognized certificate of compliance; as discussed subsequently). They are also responsible for advising users (and others) on applicable procedures and requirements for obtaining PIC and entering into MAT, a task that seems to somewhat overlap with that of national focal points. Countries may allocate the functions

of the national focal points and the competent national authority to one single entity (article 13.3). Whereas each party to the protocol is obliged to designate a national focal point and one or more competent national authorities, the aforementioned task descriptions make it clear that both institutions primarily serve GR users and aim to enhance transparency for access.[6]

Institutionalizing Transparency for Benefit Sharing

MAT provides a link between providers and users that aims to ensure benefit sharing, and as such is also a means to advance transparency for benefit sharing. The annex to the protocol containing a nonexclusive, essentially illustrative list of potential monetary and nonmonetary benefits to be used in MAT, as well as the encouragement to develop sectoral and cross-sectoral model contractual clauses for MAT included in article 19, may be considered to strengthen transparency for benefit sharing. However, the soft character of these provisions contrasts sharply with the hard requirement for provider countries requiring PIC, included in the international access standards listed in article 6 of the protocol, to establish *clear rules and procedures* "in writing" for requiring and establishing MAT. These rules and procedures may include a dispute settlement clause, terms on benefit sharing (including in relation to IPRs), terms on possible subsequent third-party use, and terms on changes of intent of GR use.

In contextualizing the "user measures" through which the Nagoya Protocol has enhanced "transparency for benefit sharing," it is important to note that the long-standing central request of developing provider countries—to make disclosure of certain relevant information a mandatory requirement for the patenting of GR- and TK-based innovations internationally—has not become part of the system. The request of developing countries referred to the disclosure of four elements: (1) the origin or source[7] of the GR acquired by a user, (2) PIC (if obtained or not), (3) MAT (if established or not), and (4) benefit sharing (if occurred or not and in what form). This information enables checking if access to GR was legitimate and occurred based on fair benefit sharing. Since the 1990s, developing countries have requested that disclosure of the aforementioned information become mandatory in patent applications and a precondition for granting a patent.[8] This is seen as having the potential to significantly strengthen the implementation of fair and equitable benefit sharing. If adopted, however, this would significantly condition IPR protection for biotechnological innovations. It would also conflict with minimum requirements for patentability laid down in the WTO Agreement on

Trade-Related Aspects of Intellectual Property Rights. As such, developed countries have opposed these proposed disclosure requirements (referred to as "disclosure of origin"). Moreover, they have refused to discuss disclosure at the CBD, considering WIPO or the WTO to be the more appropriate fora (Bled 2010, 573; Medaglia 2009).

As a result, information disclosure requirements have so far become part of global ABS governance in a rather soft form (and unrelated to patents). Whereas disclosure was "encouraged" by the 2002 Bonn Guidelines, the Nagoya Protocol, in its article 17, goes further by obliging its parties to require users to provide information related to PIC, to the source of the GR, to the establishment of MAT, and/or to the use of GR (as appropriate) to so-called checkpoints. According to article 17.1(a) of the Nagoya Protocol, each party shall designate one or more such checkpoints that are to collect or receive, as appropriate, the aforementioned information. Checkpoints should provide this information to relevant national authorities, to the party providing PIC, and to the ABS Clearing-House, without prejudice, however, to the protection of confidential information. The question of which entities may serve as checkpoints was deliberately left open (with developing countries arguing for these to be patent offices; see Buck and Hamilton 2011, 53; Nijar 2011).

Another element of transparency for benefit sharing was the establishment of an "internationally recognized certificate of compliance." The idea of a "certificate of origin" was introduced in the 1990s. Such a certificate could serve as a passport that would allow for the monitoring and verification of the different stages of GR flows (collection, transfer to user countries, research, development, commercialization) (CBD 2006). By confirming that the user met the access requirements of the provider country, the certificate could facilitate GR flows by increasing transparency, building trust, and fostering cooperation among users and providers. Eventually, the idea found its way into the Nagoya Protocol. As soon as a provider country notifies the ABS Clearing-House of the issuance of a permit for access (as mentioned previously), this permit constitutes an "internationally recognized certificate of compliance" (Nagoya Protocol, article 17.2). Article 17.4 provides certain minimum requirements for the information to be included in the certificate (and thus also in the preceding permit).

Overall, it remains questionable whether the Nagoya compromise on the issue of "disclosure of origin" can ensure transparency for benefit sharing. Although the disclosure of relevant information is to be mandatory, there is no immediate incentive for GR users to comply with such a

requirement. Providing such incentives and enforcing such a requirement is largely left to the discretion of each individual party (see also Buck and Hamilton 2011, 53–54).[9] The internationally recognized certificate of compliance remains facilitative and nonmandatory under the protocol because it is not legally required for the use of GR. Finally, it is noteworthy that the aforementioned advances of Nagoya apply to GR but not to TK.

Beyond the issue of the "disclosure of origin," information on how to enforce the terms of the contract, that is, the MAT, becomes particularly important in an ABS system based on bilateral contracts. The CBD itself had been rather silent on this aspect, and the Bonn Guidelines only mentioned the possibility of "cooperation between Contracting Parties to address alleged infringements" of ABS agreements (CBD 2002,- Bonn Guidelines 2002 para. 16(d)(iv)). The Nagoya Protocol advanced this aspect to some extent. First of all, each party (in its role as a user) has to take measures providing that GR or TK used within its jurisdiction have been accessed in accordance with PIC and that MAT have been established, as required by the domestic ABS legislation of the provider country. It also has to take measures to address situations of noncompliance (articles 15 and 16). Therefore, all parties will have to put into place some sort of ABS legislation or administrative or policy measures. Moreover, each party has to provide an opportunity to seek recourse under its legal system in cases of disputes arising from MAT (article 18.2). Each party also has to take measures regarding "access to justice" and "the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards" (article 18.3).

Finally, at the international level, the ABS Clearing-House established by article 14 of the protocol facilitates international information exchange and furthers "transparency for access" *and* "transparency for benefit sharing." Each party shall make key information about ABS available to the Clearing-House, including information on legislative, administrative, and policy measures on ABS; national focal points and competent national authorities; and access permits (which thereby become internationally recognized certificates of compliance). Checkpoints are also required to furnish information on the use of GR to the Clearing-House (article 17.1(a)). The conference of the parties to the protocol is mandated to develop the Clearing-House mechanism further.

Overall, the transparency provisions aim to bring states back into ABS governance. As such, our case does not support the hypothesis advanced in the introduction that an institutionalization of transparency decenters

state-led regulation. However, the bilateral, contract-based approach chosen also provides states with great flexibility when implementing ABS provisions by favoring national measures over international ones. Whereas improvements are noticeable after the adoption of the Nagoya Protocol, such flexibility leads to mixed results in terms of efficiency, in particular due to national imbalances regarding capacities for implementation.

Effects of Transparency

In line with the typology of effects proposed in the introduction to this book, this section analyzes the normative, procedural and substantive effects of transparency in global ABS governance, in two steps. We first assess the performance and effects of the framework prior to the Nagoya Protocol, before looking into the likely changes brought about by the protocol.

Pre-Nagoya Normative and Procedural Effects: Partial Transparency

Prior to the Nagoya Protocol, we can identify a general lack of transparency in ABS governance, leading to limited normative and the procedural effects. Transparency for access clearly remained deficient. In many (provider) developing countries, ABS regulations did not exist at all. As of 2012, the database on the CBD website still counted fewer than forty developing countries with relevant measures in place.[10] Where regulations existed, they displayed a wide divergence of approaches as well as a lack of clarity and legal certainty. This limited the ability of potential GR users to actually access GR. Transparency for benefit sharing was even more lacking, with little information being generated that would empower providers to seek and enforce fair benefit sharing. Only a few countries, and none of the main user countries, had introduced limited mandatory disclosure requirements. Legislation or measures that had been introduced were in several cases found to be ineffective or not providing satisfactory guarantees for fair and equitable benefit sharing. In general, it was very hard or even impossible to systematically identify whether GR (including TK) that was used had been accessed legally and on what terms, and whether any MAT that had been concluded were actually complied with. Provider countries thus lacked information about the use of GR (lack of normative effectiveness), which undermined their ability to pursue and enforce fair benefit sharing (procedural effectiveness).[11] As such, disclosure of so-called biopiracy—that is, access and use of GR without PIC and MAT in accordance with the requirements of the

provider country—had to rely especially on NGO activities and information gathering (Bled 2010; Burrows 2005).

Overall, the system of ABS governance, prior to the Nagoya Protocol, hardly worked. It made little progress toward changing the pre-CBD status quo and ensuring fair and equitable benefit sharing. As such, it failed to empower GR providers, especially ILCs, because they had very limited opportunities to systematically identify cases of biopiracy and enforce PIC and MAT requirements. In terms of normative (in)effectiveness, then, there was a general lack of information on the quantity of GR accessed legally and illegally, making it difficult to assess the situation comprehensively. At the same time, there was no firm data on whether the lack of transparency of access and access requirements (including a lack of legal certainty) hindered actual access to GR on the ground.

Under these circumstances, the normative framework of the CBD at least indirectly empowered some nongovernmental actors, expressly engaged in ABS issues, often benefiting from northern governments' financial support, to problematize and scandalize "biopiracy." The ABS regime under the CBD provided for clarity on the prerequisites of access to GR, namely, the establishment of PIC and MAT, including fair benefit sharing. These international requirements provided a basis and legitimation for selected NGOs to use available information on the use of GR to scandalize particular cases of the use of GR without appropriate benefit-sharing arrangements (Robinson 2010). The creation or at least facilitation of this scandalization potential may be understood as an indirect procedural effect of the CBD system pre-Nagoya enabling the (self-)empowerment of certain NGOs (in the absence of more direct and effective means of governance). The resulting scandalization in turn contributed to an increasing realization by GR users that a sustainable compromise might also be in their interest by providing for greater legal certainty.

Post-Nagoya Normative and Procedural Effects: Imbalanced Transparency

Even though the Nagoya Protocol aims to enhance transparency for access *and* benefit sharing, it does not remove existing key barriers to transparency for benefit sharing, in particular for least-developed, low-income developing countries.

If the protocol is implemented as agreed, "transparency for access" will increase significantly, especially in developing provider countries (in those that have and those that do not yet have legislation and institutions in place). In this context, the onus is on provider countries that wish to require PIC (and MAT) to establish transparent national legislative and

institutional frameworks, as required by the protocol. The protocol thus enhances the users' right to know and be informed about access requirements (normative effects) and, consequently, their right to participate in access procedures (procedural effects). Implementation of transparency for access requirements is likely, however, to present considerable challenges, especially for countries that still have to establish national legislative frameworks, in particular for the least-developed countries among them.

With regard to transparency for benefit sharing, the Nagoya Protocol has also made significant progress. The full implementation of the protocol's relevant requirements regarding access to justice and redressing noncompliance, for example, would significantly enhance the informational basis (normative effects) and the chances to engage and achieve enforcement (procedural effects). However, even if (user) countries fully implement these requirements, important barriers will remain and are likely to severely limit, in particular, the protocol's procedural effects. To begin with, it will remain difficult to identify the use of GR (because there is no obligation or mechanism that would ensure that information on the use of GR would become comprehensively available or be collected in practice). Furthermore, and perhaps more important, enforcement of PIC and MAT requirements relies largely on the providers taking legal action in foreign jurisdictions in case of noncompliance by actual users. The empowerment of providers finds its limits in the knowledge and information of the relevant national legal systems as well as the capacity that is required to enforce compliance. As a result, significant capacity building and assistance to developing countries will be required to ensure that they can take advantage of the increased potential for realizing benefit sharing under the Nagoya Protocol (Medaglia et al. 2011; Oberthür et al. 2011).[12] More generally, arrangements relating to transparency for benefit sharing under the Nagoya Protocol are incomplete, if not questionable.

This brings to the fore, however, that differences in governmental capacities regarding ABS ensure that the powerful gain most from the system, as designed. In the overall assessment of who benefits most from transparency, as designed in the Nagoya Protocol, it is useful to distinguish three groups of countries. First, *developed countries* are further empowered by transparency of access conditions to the extent that developing provider countries implement the international access standards of the Nagoya Protocol. At the same time, developed user countries are also required to facilitate legal action by providers, thus empowering the latter to enforce PIC and MAT requirements under their jurisdiction. Second,

advanced developing countries and emerging economies with relatively advanced domestic legal ABS frameworks (including Brazil, India, Malaysia, Mexico, South Africa, and Thailand) may be more easily able to adapt their national systems, also having significant capacity to make use of enforcement opportunities in developed countries. Third, *less- and least-developed countries* without appropriate domestic ABS legislation in place are likely to face considerable challenges in establishing their own legal frameworks and, on this basis, exploiting the empowering potential that the new enforcement opportunities in other (developed) countries present. Developed and advanced developing countries, in practice, may be able to benefit from enhanced transparency and the empowerment that flows from it, whereas the situation of less- and least-developed countries may change little without targeted capacity building and assistance (Medaglia et al. 2011; Oberthür et al. 2011). Enhanced transparency provisions thus require a functioning infrastructure to become effective in practice, which may not be easy to establish (see also Dingwerth and Eichinger, this book, chapter 10; Gupta, this book, chapter 6). Because users and providers designed transparency provisions of the protocol, they aim to further procedural and normative effectiveness of double-sided transparency. Notwithstanding this, protocol implementation is likely to favor states with significant capacities in GR management.

ABS Governance by Disclosure: Substantive Effects

The substantive, environmental effects of global ABS governance by disclosure are even more questionable. Regulating ABS under the CBD as a multilateral environmental agreement had the rationale that appropriate benefit sharing with the owners and custodians of GR would provide an incentive for them to conserve biological diversity and ecosystems as the pool of GR (Rosendal 2000, chapters 4 and 5). The Nagoya Protocol incorporates this logic in two places. First, article 1 establishes "contributing to the conservation of biological diversity and the sustainable use of its components" as part of the objectives of global ABS governance. Furthermore, article 9 stipulates that "parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components." In terms of transparency, however, no mechanisms exist that furnish information about the actual use of benefits, and the overall effect of ABS governance arrangements in terms of these environmental objectives (let alone ensuring the effective channeling of benefits for that purpose).[13] Under the circumstances, and without further action on this

aspect, the environmental benefits even of an improved system of ABS governance with greater transparency for benefit sharing are unlikely to be significant.

Conclusion

The decentralized, bilateral, contract-based approach to global ABS governance enshrined in the CBD and the corresponding GR marketization dynamic have moved transparency to center stage in structuring politics in this policy field (see also Knox-Hayes and Levy, this book, chapter 9). Flowing from the recognition of the sovereign rights of countries to their natural resources, a battleground between GR users (developed countries) primarily interested in transparency of access conditions and GR providers (developing countries) primarily interested in transparency of GR use and benefit sharing (supported by NGOs and civil society protests) was constituted during the course of the 1990s. Ever since, defining the right balance between "transparency for access" and "transparency for benefit sharing" has remained at the center of global ABS politics under the CBD.

Underlying the preferred regulatory approach has been states' willingness to steer a liberal market logic for the marketization of GR as a means toward equity, empowerment and environmentally desirable outcomes (see also Gupta et al., this book, chapter 8). Rather than developing a multilateral governance approach and regulating benefit sharing internationally, the CBD and the Nagoya Protocol aim at controlling the bilateral exchange relations between providers and users of GR. It has defined and established some cornerstones on which the exchange relation can build, including PIC, MAT, and "internationally recognized certificates of compliance" as well as corresponding institutional infrastructures (national focal points, competent national authorities, checkpoints, and the international ABS Clearing-House). It has failed to establish other elements under consideration, most important, a mandatory requirement to disclose the origin of any GR used and related information in patent applications, which would have interfered with a core ingredient of modern market economies, intellectual property rights, with significance far beyond the area of GR.

In this context, the crux of the matter—determining and ensuring the "fair and equitable" sharing of the benefits and thus the pricing of GR—has been largely left to individual providers and users on the basis of, and shaped by, legislation and measures by national governments. Transparency is central to this marketization and to enabling fairness in it and

thus has become a major battleground. Transparency regarding use of resources generated through benefit sharing is also important in terms of the eventual environmental objectives of biodiversity conservation, but this has unfortunately been neglected in the shadow of the fight to balance transparency relating to access versus benefit sharing. The environmental benefits of ABS governance thus remain uncertain, at best.

The result has been a lasting imbalance in favor of transparency for access that especially disadvantages the least-developed countries. The 2010 Nagoya Protocol provides for enhanced transparency of access conditions as well as of use and enforcement conditions. However, it does not undo the preexisting imbalance between the two sides that stems from lower levels of transparency of the behavior of "private" GR users and a greater difficulty to get a regulatory grip on them. As a result, the actual use of GR—mainly in developed countries—remains intrinsically less transparent, even if enhanced by as-yet uncertain controls of "checkpoints." In addition, especially capacity-scarce countries such as least-developed countries are likely to face two kinds of constraints. First, they will find it difficult to fulfill the precondition for benefitting from enhanced transparency for benefit sharing, namely, establishing their own administrative, legal, and procedural systems for access. Second, they will also face difficulties in obtaining knowledge about foreign legal systems and in taking part in legal procedures in foreign jurisdictions that would be required in order to enforce their benefit sharing rules vis-à-vis foreign users. Although the Nagoya Protocol empowers them in principle, they may not be able to exploit this potential in practice.

We end with pointing to two possibilities for advancing international ABS governance that partially transcend the existing system. First, introducing a mandatory requirement to disclose the origin of any GR used and related information in patent applications continues to have a significant potential to enhance the balance between transparency for access and benefit sharing. Discussions on such a disclosure requirement continue within the WTO and WIPO. Second, multilateral, common-pool approaches to ABS governance constitute a possible alternative to the bilateral, contract-based approach under the CBD and its Nagoya Protocol. They do exist in limited pockets of the overall issue area in the form of the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture of 2001 and the WHO's nonbinding Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits adopted in 2011. In both cases, ABS with regard to the respective GR is being internationally administered

in specialized arrangements. The Nagoya Protocol, in its article 4.4, explicitly allows for such specialized arrangements (as long as they are in line with its own objectives). A number of relevant processes provide the opportunity to expand specialized multilateral ABS governance, including for the High Seas, Antarctica, for other GR for food and agriculture and for ex-situ collections (Oberthür et al. 2011). Although such arrangements have their own challenges and may thus not be a panacea, they are not bedeviled by the problems of an intrinsic imbalance of transparency for access and benefit sharing.

Notes

1. As of November 2013, the Nagoya Protocol has not yet entered into force.

2. CBD 2009, especially 7–8; on the importance of TK and its relationship with intellectual property see also von Lewinski 2008; Ullrich 2005.

3. Interview with Colombian delegate, July 9, 2007.

4. See paragraph 44(o) of the Johannesburg Plan of Implementation. Available at http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf.

5. On national focal points, competent national authorities, and permits, see also below.

6. The task of competent national authorities to advise on how to implement and enforce ABS agreements was lost on the way from the Bonn Guidelines to the Nagoya Protocol: compare CBD 2002, para. 14(d), with article 13.2 of the protocol.

7. The "origin" refers to where the GR originated in the first place (i.e., before it was placed in, for example, a collection), whereas the "source" refers to the immediate, last provider (which may be an intermediate organization).

8. Alternative, softer concepts of "mandatoriness" that have entered the debate foresee the possibility of fines for the nonprovision of the information (although patents would still be granted).

9. Some countries, especially provider countries, have implemented a requirement to disclose the origin of GR in patent applications domestically in various forms: CBD 2007b, 18–20; Medaglia et al. 2011.

10. See http://www.cbd.int/abs/measures.

11. On the pre-Nagoya implementation of ABS in provider and user countries, see, in particular, CBD 2007a, 2007b; Tvedt and Young 2007.

12. The Nagoya Protocol foresees cooperation on capacity building in its article 22.

13. It deserves mentioning, though, that some countries (e.g., Brazil) have domestically passed legislation to channel benefits toward the conservation of biological diversity; see, for example, CBD 2007b, 10; Medaglia et al. 2011; Oberthür et al. 2011.

References

Arts, Bas. 1998. *The Political Influence of Global NGOs*. Utrecht: International Books.

Bled, Amandine J. 2010. Technological Choices in International Environmental Negotiations: An Actor-Network Analysis. *Business & Society* 49 (4): 570–590.

Brand, Ulrich, Christoph Görg, Joachim Hirsch, and Markus Wissen. 2008. *Conflicts in Environmental Regulation and the Internationalisation of the State. Contested Terrains*. London: Routledge.

Buck, Matthias, and Clare Hamilton. 2011. 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. *Review of European Community & International Environmental Law* 20 (1): 47–61.

Burrows, Beth, ed. 2005. *The Catch: Perspectives in Benefit Sharing*. Washington, DC: The Edmonds Institute.

CBD (Convention on Biological Diversity). 2002. *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization*. Montreal: Secretariat of the Convention on Biological Diversity.

CBD. 2006. *Consideration of an Internationally Recognized Certificate of Origin/Source/Legal Provenance*. Convention on Biological Diversity, UN doc. UNEP/CBD/GTE-ABS/1/2, November 28.

CBD. 2007a. *Analysis of Gaps in Existing National, Regional and International Legal and Other Instruments Relating to Access and Benefit-sharing*. Convention on Biological Diversity, UN doc. UNEP/CBD/WG-ABS/5/3, September 13.

CBD. 2007b. *Overview of Recent Developments at National and Regional Levels Relating to Access and Benefit-sharing*. Convention on Biological Diversity, UN doc. UNEP/CBD/WG-ABS/5/4, August 30.

CBD. 2009. *Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing*. Convention on Biological Diversity, UN Doc. UNEP/CBD/WG-ABS/8/2, July 15.

Deke, Oliver. 2008. *Environmental Policy Instruments for Conserving Global Biodiversity*. Berlin: Springer.

Holm-Müller, Karin, Carmen Richerzhagen, and Sabine Taüber. 2005. *Users of Genetic Resources in Germany. Awareness, Participation and Positions Regarding the Convention on Biological Diversity*. Berlin: Bfn (Federal Agency for Nature Conservation).

Hopgood, Stephen. 1998. *American Foreign Environmental Policy and the Power of the State*. Oxford: Oxford University Press.

Medaglia, Jorge Cabrera. 2009. *Study on the Relationship between an International Regime on Access and Benefit-sharing and Other International Instruments and Forums That Govern the Use of Genetic Resources: The World Trade Organization (WTO); the World Intellectual Property Rights Organization (WIPO); and*

the International Union for the Protection of New Varieties of Plants (UPOV). UN doc. UNEP/CBD/WG-ABS/7/INF/3/Part.2, March 3.

Medaglia, Jorge Cabrera, Frederic Perron-Welch, and Olivier Rukundo. 2011. *Overview of National and Regional Measures on Access to Genetic Resources and Benefit Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol*, December. Montreal: Centre for International Sustainable Development Law.

Miller, Michael J. 2006. Biodiversity Policy Making in Costa Rica: Pursuing Indigenous and Peasant Rights. *Journal of Environment & Development* 15 (4): 359–381.

Nijar, Gurdial Singh. 2011. *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*. Kuala Lumpur: Centre of Excellence for Biodiversity Law.

Oberthür, Sebastian, Christiane Gerstetter, Christine Lucha, Katriona McGlade, Justyna Pożarowska, and Florian Rabitz. 2011. *Intellectual Property Rights on Genetic Resources and the Fight against Poverty*. Brussels: European Parliament, Directorate-General for External Policies of the Union.

Oberthür, Sebastian, and Justyna Pożarowska. 2013. The Impact of the Nagoya Protocol on the Evolving Institutional Complex of Global ABS Governance. In *Global Governance of Genetic Resources: Access and Benefit-Sharing after the Nagoya Protocol*, ed. Sebastian Oberthür and G. Kristin Rosendal, 178–195. Abingdon, UK: Routledge.

OECD. 2011. *Key Biotech Indicators, Share of Countries in Biotechnology Patents Filed under PCT, 2007–09*. Available at www.oecd.org/dataoecd/41/46/48719943.xls.

Pisupati, Balakrishna. 2007. *UNU-IAS Pocket Guide—Access to Genetic Resources, Benefit Sharing and Bioprospecting*. Yokohama, Japan: United Nations University Institute of Advanced Studies.

Robinson, Daniel. 2010. *Confronting Biopiracy: Challenges, Cases and International Debates*. London: Earthscan.

Rodriguez, Silvia. 1993. *Conservation, Contradiction and Sovereignty Erosion: The Costa Rican State and the Natural Protected Areas (1970–1992)*. PhD Thesis in Philosophy. Madison: University of Wisconsin.

Rosendal, Kristin G. 2000. *The Convention on Biological Diversity and Developing Countries*. Dordrecht, the Netherlands: Kluwer.

Rosendal, Kristin G. 2006. Balancing Access and Benefit Sharing and Legal Protection of Innovations from Bioprospecting: Impacts on Conservation of Biodiversity. *Journal of Environment & Development* 15: 428–447.

Svarstad, Hanne. 1994. National Sovereignty and Genetic Resources. In *Biodiplomacy: Genetic Resources and International Relations*, ed. Vicente Sánchez and Calestous Juma, 45–65. Nairobi: ACTS Press.

Tvedt, Morten W., and Tomme R. Young. 2007. *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*. Gland, Switzerland: IUCN.

Ullrich, Hanns. 2005. *Traditional Knowledge, Biodiversity, Benefit-Sharing and the Patent System: Romantics v. Economics*. EUI Working Paper LAW No. 2005/07. Available at http://dx.doi.org/10.2139/ssrn.838107.

von Lewinski, Silke. 2008. *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge, and Folklore*. Alphen aan den Rijn, the Netherlands: Kluwer Law International.