

RECENT DEVELOPMENTS ON ACCESS AND BENEFIT SHARING RELATING TO GENETIC RESOURCES (ABS) IN INTERNATIONAL LAW

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1. Introduction: The Challenge to International Law

One of the most important, complex and critical challenges that international law faces in these times of fast technological and scientific developments is certainly that of the management of “genetic resources”¹. These are extremely precious resources, which can be used for economic and/or research purposes in different crucial fields, thus contributing significantly to the promotion of relevant rights and attracting different interests within the international community as a whole.

Genetic resources are used extensively to develop pharmaceutical products or vaccines², thus contributing to the

¹ According to the definition provided by Art. 2 of the Convention on Biological Diversity (Rio de Janeiro, 5 June 1992, entered into force on 29 December 1993; hereinafter CBD), genetic resources means any material of plant, animal, microbial or other origin containing functional units of heredity, of actual or potential value.

² On this particular aspect see P.G. Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, New York, 2005; A. Bonfanti, S. Trevisanut, *Intellectual Property Rights Beyond National Jurisdiction: A Regime For Patenting Products On Marine Genetic Resources Of The Deep Seabed and High Seas*, infra in this volume. See the example of the “Ziconitide”, a toxin extracted from a Philippine sea snail (*Conus Magus*), patented by a US pharmaceutical company and used to produce a pain killer which earned more than \$80 million in the first year of marketing (R.K. Joseph, *International Regime on Access and Benefit Sharing: Where are We Now?*, in *Asian Biotechnology and Development Review*, vol. 12, no. 3, 2010, pp. 77–94, at 78 ff.), and of the “Epibatidine”, a toxin extracted from an endangered poison dart frog from Ecuador (*Epipedobates Tricolor*) also used to produce an analgesic (M. Ruiz Muller, I. Lapeña, *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows*, Gland, Switzerland, 2007, p. 71).

implementation of the right to health³. They are used in agriculture, including through biotechnological applications, thus promoting food security and the right to food⁴. Research and biotechnological developments on genetic resources can help our understanding of the environment and our adaptation to environmental changes (in particular crucial adaptation to climate change⁵), thus advancing environmental protection and the right to a healthy environment. Finally, genetic resources can help providing other useful products and services⁶ and, more generally, due to their overall above-mentioned potential, can be important factors in the fight against poverty and to guarantee the right to development⁷.

As one may expect, several interests belonging to different “actors”⁸ of the international community tend to converge over such resources, not always in a coherent and harmonious manner. First of all, given the importance of some of the potential implications mentioned above for the fundamental rights of all, genetic resources’ management should (at least from an ethical standpoint) benefit mankind as a whole. At the same time, however, one should also consider the existence of specific interests of individual actors (or groups of them), having a

³ This is clearly stated in the CBD, Preamble: “Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential”.

⁴ *Supra*, n. 3 and *infra*, n. 89; see also E. Caliceti, *Il regime giuridico delle risorse fitogenetiche per l'alimentazione e l'agricoltura: dalla sicurezza alimentare al diritto al cibo*, *infra* in this volume.

⁵ In this regard see E. Morgera, *Faraway, So Close: A Legal Analysis of the Increasing Interactions Between the Convention on Biological Diversity and Climate Change Law*, in *Climate Law*, vol. 2, 2011, pp. 85–115. See also *infra*, n. 89.

⁶ See the example of the *Hoodia*, a plant found in the Kalahari region, used by the local *San* people to quench thirst and hunger, which became an attractive appetite suppressant for diet products on the international market (R. Wynberg, D. Schroeder, R. Chennells (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Dordrecht, 2009), or the *Camu Camu*, a plant from the Peruvian Amazon, rich in vitamin C, used for many different purposes, from food to cosmetics (R.K. Joseph, *op. cit.*, p. 79 ff.; D.F. Robinson, *Traditional Knowledge and Biological Product Derivative Patents: Benefit-Sharing and Patent Issues Relating to Camu Camu, Kakadu Plum and Açai Plant Extracts*, in *UNU-IAS Traditional Knowledge Bulletin*, 2010, pp. 1–14).

⁷ *Infra*, n. 89.

⁸ The general term “actors” is being used on purpose to include what are technically considered “subjects” of international law (e.g. States), as well as entities whose subjectivity is discussed (e.g. indigenous peoples or local communities).

peculiar connection with such resources. In this regard, on the one hand, developing countries are often the richest ones in terms of genetic resources on their territories, and they have always logically claimed sovereignty over them, in order to retain the consequential full control and benefits. On the other hand, developed States have always claimed the possibility to have access to such resources, mainly for the benefit of their private entities, but while this has been pursued in order to exploit the resources for their own profit, it is also a solution that should ideally benefit (at least indirectly) the international community as a whole, since it is mostly through developed countries' technological capacity that genetic resources' use can reach its full potential. Finally, specific groups, like farmers or indigenous and local communities, can invoke particular interests in connection with such resources, as to resources that are essential for crop production and food security⁹, or for those that can be found in indigenous territories and that are connected with indigenous traditional knowledge¹⁰.

The role of international law in this field is a crucial and difficult one, as it is in constant search for solutions to balance genetic resources' exploitation with their conservation (in view of long term sustainability), to ensure that they are equitably used (taking into account all the above mentioned interests and actors), and to harmonize the different areas of international law that are involved with this intrinsically multifaceted and cross-sectoral issue (such as international environmental law, when dealing with genetic resources' conservation, the international protection of human rights, as to the protection of specific groups' rights relating to such resources, the law of the sea, for marine genetic resources¹¹, or international economic law, addressing issues relating to trade and patents connected with these resources). It would be clearly impossible to address all these challenging issues in the present contribution¹², which will therefore focus on some of the most interesting ones (in our opinion) and, in particular, on the recent developments, relating to this important area of international law.

⁹ See E. Caliceti, *op. cit.*

¹⁰ *Infra*, Sect. 3.3.

¹¹ See A. Bonfanti, S. Trevisanut, *op. cit.*

¹² For an overview and a thorough analysis see N. Boschiero (ed.), *Bioetica e biotecnologie nel diritto internazionale e comunitario. Questioni generali e tutela della proprietà intellettuale*, Torino, 2006; F. Francioni, T. Scovazzi (eds.), *Biotechnology and International Law*, Oxford, 2006; F. Francioni (ed.), *Biotechnologies and International Human Rights*, Oxford, 2007.

2. *A First Answer: The General Legal Framework of the CBD*

How did international law take upon at least some of the challenges illustrated above? One of the fundamental steps has certainly been the adoption of the CBD, which has, among its objectives, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to the latter (in short “access and benefit sharing” or, even shorter, “ABS”)¹³.

Before the CBD, the legal framework on ABS was quite uncertain¹⁴. Alongside the argument that genetic resources, as any other

¹³ CBD, Art. 1. On the CBD and ABS see M. Bowman, C. Redgwell (eds.), *International Law and the Conservation of Biological Diversity*, London, 1996; L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, Gland, Switzerland, 1998; M.J. Jeffery, *Bioprospecting: Access to Genetic Resources and Benefit-Sharing under the Convention on Biodiversity and the Bonn Guidelines*, in *Singapore Journal of International & Comparative Law*, 2002, pp. 747–808; P. Sands, *Principles of International Environmental Law*, Cambridge, 2003, p. 515 ff.; S. Carrizosa et al. (eds.), *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*, Gland, Switzerland, 2004; R. Pavoni, *Biodiversità e biotecnologie nel diritto internazionale e comunitario*, Milano, 2004, chapter III; N.P. Stoianoff (ed.), *Assessing Biological Resources: Complying with the Convention on Biological Diversity*, The Hague, London, New York, 2004; J. Cabrera Medaglia, C. López Silva, *Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty*, Gland, Switzerland, 2007; M.W. Tvedt, T. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, Gland, Switzerland, 2007; S. Bhatti et al. (eds.), *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts*, Gland, Switzerland, 2009; E.C. Kamau, G. Winter (eds.), *Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit Sharing*, London, 2009; M.C. Maffei, *La protezione delle specie, degli habitat e della biodiversità*, in A. Fodella, L. Pineschi (eds.), *La protezione dell’ambiente nel diritto internazionale*, Torino, 2009, pp. 263–314, at 286 ff.; S. Peña-Neira, *Balancing Rights and Obligations in Sharing Benefits from Natural Genetic Resources: Problems, Discussions and Possible Solutions*, in *Anuario Mexicano de Derecho Internacional*, vol. IX, 2009, pp. 153–165; T. Greiber et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*, Gland, Switzerland, 2012, Introduction; M. Ruiz, R. Vernooij (eds.), *The Custodians of Biodiversity. Sharing Access to and Benefits of Genetic Resources*, New York, 2012.

¹⁴ In this regard see R.K. Joseph, *op. cit.*, p. 78 ff.; E. Morgera, E. Tsioumani, *The Evolution of Benefit Sharing: Linking Biodiversity and Community Livelihoods*, in *Review of European Community & International Environmental Law*, vol. 19, no. 2, 2010, pp. 150–173 at 152 ff.; G.S. Nijar, *The Nagoya Protocol on Access and Benefit*

natural resource, would belong to the State on whose territory they were to be found (in conformity with the basic sovereignty principle), another one emerged, claiming that, because of their importance and peculiarities, they had to be considered “common heritage of mankind”. Behind these arguments lay important implications, linked with the interests surrounding ABS: while the sovereignty argument entailed that developing States had full control over their genetic resources, the common heritage one was used to allege “free access” to them, particularly in the interest of developed States and their private entities¹⁵. In that context of legal uncertainty, it was not uncommon for companies (mostly coming from developed countries) to access genetic resources in developing States, and exploit them for their own and only profit (for example by patenting and marketing products or services using such resources), without any consideration for the interests and role of the State providing the resources, or for the local and indigenous communities therein (with the latter often being the real holders of the resource and of the traditional knowledge that was essential for the resource’s use). Such practice was (and, to some extent, still is) referred to as “biopiracy”¹⁶.

The CBD was adopted also to react to such insecurity, to create a general legal framework that clarified the legal status of genetic resources and set down the fundamental principles and rules for their access and benefit sharing (mainly concentrated in its Article 15¹⁷), balancing the different interests involved.

Sharing of Genetic Resources: An Analysis, CEBLAW Brief, Kuala Lumpur, 2011, p. 14 ff.

¹⁵ See E. Caliceti, *op. cit.* for an analysis of the situation in relation to plant genetic resources for food and agriculture. The concept of “common heritage” seemed misused in such context: in fact, such idea has been developed mainly with reference to resources or areas that are not under the jurisdiction of any State (e.g. the deep seabed), and that are subject to some form of collective management by the international community as a whole, ideally for the benefit of mankind (A. Fodella, *I principi generali*, in A. Fodella, L. Pineschi (eds.), *La protezione dell’ambiente nel diritto internazionale*, Torino, 2009, pp. 95–131 at 114 ff.). It is conceptually difficult to connect biodiversity that is on the territories of States, and under their sovereignty, to that idea, and it is even harder to derive from it a right for each State to have free and unlimited access to another State’s genetic resources, in order to exploit them for its own individual benefit.

¹⁶ For an overview of the biopiracy concept see T. Greiber et al., *op. cit.*, p. 12 ff.

¹⁷ “Art. 15. Access to Genetic Resources. 1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. 2.

The Convention crystallized the debate over the legal status of genetic resources, by defining the conservation of biological diversity as a “common concern of humankind”¹⁸. This diluted the somewhat extreme positions highlighted above (full and exclusive sovereign State control over resources, as opposed to free unrestrained access to them), for a middle ground. This meant clarifying and reaffirming that States have sovereignty over their own biological resources, including genetic ones¹⁹, and therefore that access to such resources must be subject to the prior informed consent (PIC) of the sovereign State²⁰. However, the fact that biodiversity is a common concern of humankind means also that the same sovereign States must “endeavour to create conditions” to “facilitate access” to their own genetic resources by other contracting Parties²¹. In exchange (so to say) for the access to their own genetic resources, provider States (mainly developing countries, as already reminded) would receive a fair and equitable share (in various forms²²) of the benefits deriving from the exploitation of such resources, by the user States²³.

Alongside inter-States relations, the CBD took also into account the role of indigenous and local communities in connection with biodiversity, by protecting their traditional knowledge over

Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention. [...] 4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Art.. 5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. 6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. 7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms”.

¹⁸ CBD, Preamble.

¹⁹ CBD, Preamble, Art. 3, 15.1 (supra, n. 17).

²⁰ CBD, Art. 15.5 (supra, n. 17).

²¹ CBD, Preamble, Art. 1, Art. 15.2 (supra, n. 17).

²² These can include obviously monetary benefits, but also, for example, access to research results and to technology using the genetic resources (CBD, Art. 15.6-7, on which supra, n. 17, Art. 16.3, 19.1-2).

²³ CBD, Art. 1, 15.7 (supra, n. 17), 16.3-4, 19.

biological resources, and by encouraging States to share with them the benefits relating to such knowledge²⁴.

The CBD thus created a general framework, providing legal certainty as far as the fundamental principles in this field are concerned. It also addressed the different interests involved, with a mechanism that, at least theoretically and indirectly, encouraged technological progress by favouring access to resources, while at the same time promoting equity, technology transfer and biodiversity conservation at the international, national and local level, mainly through the benefit sharing component. However, the Convention still left some questions unanswered. The legal framework was too general in many respects and needed further development. Moreover, it provided for the protection of the interests of indigenous and local communities only to an unsatisfactory, limited extent: the Convention recognised their rights only in relation to their *traditional knowledge* over genetic resources, not in connection to the use and exploitation of the *resources as such*, and with a weak formula in Art. 8.j that left wide discretion to States²⁵.

For these reasons, ABS remained one of the major focus on the CBD agenda until further legal developments were achieved. In 2002, the Conference of the Parties (COP) of the CBD adopted, with COP6 Decision VI/24, the “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization” (hereinafter Bonn Guidelines), which contained much needed new and detailed specific legal elements on ABS, but were still a soft law instrument (useful as guidelines, yet non-binding)²⁶. It was

²⁴ CBD, Preamble; Art. 8.j (infra, n. 25).

²⁵ “[Each Contracting Party shall...] (j) *Subject to its national legislation*, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and *encourage* the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices” (CBD, Art. 8.j – emphasis added). The weak formula is evident, since the duty to respect traditional knowledge is “subject to States’ national legislations”, and benefit sharing is not compulsory but merely “encouraged”. See also E. Morgera, E. Tsioumani, *op. cit.* p. 159 ff.

²⁶ See W.B. Chambers, *Emerging International Rules on the Commercialization of Genetic Resources: The FAO International Plant Genetic Treaty and the CBD Bonn Guidelines*, in *Journal of World Intellectual Property*, vol. 6, no. 2, 2003, pp. 311–332; M.J. Jeffery, *op. cit.*; S. Tully, *The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing*, in *Review of European Community & International Environmental Law*, vol. 12, no. 1, 2003, pp. 84–98; S. Peña-Neira, *Equitativa división de beneficios*

clear that a treaty would have been essential to properly regulate such a sensitive and complex issue and to complete the work initiated within the CBD on this subject²⁷. Nearly 20 years after the CBD, at the end of a lengthy and difficult negotiation process, States eventually reached an agreement in this regard, adopting the Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya, 29 October 2010; hereinafter Nagoya Protocol) with COP10 Decision X/1²⁸, the most important legal development in this field, and one of the most significant steps in international environmental law in recent times.

3. *The Nagoya Protocol on ABS as the Ultimate Response?*

Does the Nagoya Protocol properly complement the CBD in eventually providing the final response to the challenges posed by ABS? The negotiations of the Protocol predictably catalysed again the debate between the different actors and interests involved in the ABS arena, which the CBD had never solved completely. The result is a

provenientes de la utilización de recursos genéticos y la necesidad (o no) de un protocolo basado en las directrices de Bonn, in Anuario Mexicano de Derecho Internacional, vol. IV, 2004, pp. 499–517.

²⁷ In this regard, the Plan of Implementation adopted at the Johannesburg World Summit on Sustainable Development in 2002 highlighted that a more efficient and coherent implementation of the CBD's objectives required actions to negotiate, within the framework of the CBD and bearing in mind the Bonn Guidelines, an international regime on ABS (*Report of the World Summit on Sustainable Development*, Johannesburg, South Africa, 26 August - 4 September 2002, Doc. A/CONF.199/20, p. 6 ff., para. 44.o). As a consequence, the CBD COP decided in February 2004 to give the mandate to a Working Group to elaborate the regime (COP7 Decision VII/19).

²⁸ The official text of the Treaty is available at <http://www.cbd.int/abs/text/>. The Protocol, which has so far been signed by 92 States and ratified or accepted by eight (source <http://www.cbd.int/abs/nagoya-protocol/signatories/>, accessed on 28 October 2012), shall enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the CBD (Nagoya Protocol, Art. 33). In view of its future participation in the Treaty, the European Union has recently issued a *Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, Doc. COM(2012) 576 final, 2012/0278 (COD), 4 October 2012, available at http://ec.europa.eu/environment/biodiversity/international/abs/pdf/PROPOSAL_FOR_A_REGULATION_EN.pdf.

compromise which does not seem to be entirely satisfactory, at least from the point of view of the author of this contribution. While there are certainly many positive aspects to it, there are still few relevant gaps and uncertainties that have been left open, and it seems *prima facie* that some interests have been privileged over others: despite being a giant step forward, it is probably not the end of the journey. What follows is an attempt to address some of the most relevant issues (from an obviously subjective point of view) in this regard²⁹.

3.1. *The General CBD Framework Specified and Developed*

The objective of the Protocol, which echoes that of the CBD, is the “fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies,

²⁹ It would be impossible to analyse the entire Protocol in details on this occasion. For a detailed and comprehensive study see T. Greiber et al., *op. cit.*; E. Morgera, M. Buck, E. Tsioumani (eds.), *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges (forthcoming)*, 2012; E. Morgera, M. Buck, E. Tsioumani, *Commentary on the Nagoya Protocol on Access and Benefit-Sharing (forthcoming)*, 2013. See also E.C. Kamau, B. Fedder, G. Winter, *The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community?*, in *Law, Environment and Development Journal*, vol. 6, no. 3, 2010, pp. 246–262; E. Tsioumani, *Access and Benefit Sharing “The Nagoya Protocol”*, in *Environmental Policy and Law*, vol. 40, no. 6, 2010, pp. 288–293; J. Beqiraj, *L’equa condivisione dei benefici derivanti dall’utilizzo delle risorse genetiche secondo il Protocollo di Nagoya: fra obblighi degli Stati e diritti delle comunità indigene*, in *Diritti Umani e Diritto Internazionale*, vol. 5, no. 1, 2011, pp. 188–193; M. Buck, C. Hamilton, *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*, in *Review of European Community & International Environmental Law*, vol. 20, no. 1, 2011, pp. 47–61; S.R. Harrop, “Living In Harmony With Nature”? *Outcomes of the 2010 Nagoya Conference of the Convention on Biological Diversity*, in *Journal of Environmental Law*, vol. 23, no. 1, 2011, pp. 117–128; E. Morgera, E. Tsioumani, *Yesterday, Today and Tomorrow: Looking Afresh at the Convention on Biological Diversity*, in *Yearbook of International Environmental Law*, 2011, pp. 1–38, at 14 ff.; G.S. Nijar, *op. cit.*; G.S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*, South Centre and CEBLAW Research Papers n. 36, 2011; V. Koester, *The Nagoya Protocol on ABS: Ratification by the EU and its Member States and Implementation Challenges*, IDDRI Studies n. 3/12, Paris, 2012.

and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components”³⁰, in particular by effectively implementing relevant CBD provisions, such as Art. 15 on access to genetic resources³¹ and Art. 8.j on traditional knowledge of indigenous and local communities³².

In this regard, the Protocol confirms the principles already contained in the CBD and specifies them effectively, with more precise and detailed norms, procedures and obligations (mainly regarding provider States’ duties), thus enhancing transparency and legal certainty. In particular, it provides for specific obligations, requirements and procedures relating to PIC and to the establishment of “mutually agreed terms” (MAT) (i.e. the reaching of an agreements between genetic resources’ providers and users upon which benefit sharing is based³³). The Protocol also introduces interesting and functional innovations, such as the establishment of an international “Access and Benefit-sharing Clearing-House” to share information relating to ABS³⁴. Such mechanism should become particularly valuable, as national access permits (indicating also MAT) that are notified by the relevant State to the Clearing-House become “internationally recognized certificates of compliance” which should increase certainty and transparency in transactions relating to genetic resources³⁵.

3.2. *Some Critical issues*

3.2.1. *Ensuring Compliance*

While it is fair to say that the above-mentioned innovations address mostly the concerns of genetic resources’ users, who demanded legal certainty, efficiency and transparency on the “access-side” of the ABS process (essentially to safeguard their investments), the Protocol

³⁰ Nagoya Protocol, Art. 1.

³¹ *Supra*, n. 17.

³² *Supra*, n. 25.

³³ CBD, Art. 15.4-.5, .7 (*supra*, n. 17); Art. 16.3, 19.2. Nagoya Protocol, Art. 5.1-.2, 6-7, 12.3, 13.1-.2, 14.2, 15.1, 16.1, 17-19.

³⁴ Information include measures adopted to implement the Protocol at different levels, relevant national institutional frameworks, and specific decisions relating to ABS procedures (Nagoya Protocol, Art. 14).

³⁵ Nagoya Protocol, Art. 6.3.e, 17.2.

arguably falls short of providing a full and effective mechanism to ensure compliance with its regulatory system (in particular to avoid resource misappropriation and misuse, as well as to ensure benefit sharing), a gap that may affect in particular the interests of genetic resources' providers, and that has unsurprisingly attracted criticism especially from developing countries³⁶.

In this regard, the Protocol does not establish directly an international system to monitor compliance with its provisions; instead, it leaves the COP with the task to "consider and approve cooperative procedures and institutional mechanisms to promote compliance" and to "address cases of non-compliance", including "provisions to offer advice or assistance"³⁷, i.e. envisioning the establishment of a future compliance mechanism, following what is now common practice in multilateral environmental agreements (MEAs)³⁸. The effectiveness of any such mechanism will obviously depend upon what the COP will decide in this regard (if a decision will be adopted³⁹). Prima facie, the wording of Art. 30 (referring to a mechanism "to promote compliance", offering "advice or assistance"), and the experience with other MEAs, suggest that this is likely to be a "soft" mechanism, i.e. one that aims mainly at assisting the non-compliant party, or at best at declaring that there has been non-compliance, but it is hardly going to have any compelling, "sanctionary" or dispute resolution function⁴⁰. However, the idea that the mechanism should generally "address cases of non-compliance" is broad enough to offer alternative, stronger solutions,

³⁶ See in particular R.K. Joseph, *op. cit.*; G.S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis*, cit., p. 15 ff.

³⁷ Nagoya Protocol, Art. 30.

³⁸ On such mechanisms in MEAs see T. Treves et al. (eds.), *Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements*, The Hague, 2009.

³⁹ Whether the establishment of the mechanism is mandatory or not seems to be, to some extent, an uncertain element. Art. 30 of the Protocol provides that the COP "shall consider and approve" the procedure. This wording appears to indicate that the mechanism must be established, especially if we compare it with the clearly "optional" formula used for the future "global multilateral benefit-sharing mechanism" in Art. 10 (*infra*, Sect. 3.2.3, in particular n. 79). However, the expression falls short of a more clear-cut wording (e.g. "shall adopt"), leaving a remote possibility to interpret it as a mere obligation of conduct (i.e. a mere duty to consider the adoption of the mechanism, with the possibility of not adopting it).

⁴⁰ This may be indirectly confirmed by the fact that, according to Art. 30 of the Nagoya Protocol, the future non-compliance mechanism is not going to affect the dispute settlement procedures and mechanisms under Article 27 of the CBD.

should the Parties wish to follow such path⁴¹. Considering the central role of indigenous and local communities within the framework of the Protocol⁴², it is submitted that their interests should be taken into account in the design of the compliance mechanism itself, for example by permitting them to trigger the compliance procedure, or by allowing their representatives to be members of the compliance monitoring body, as it happens in other compliance mechanisms that are strongly connected with public participation⁴³.

At least for the time being, and in any case for more stringent measures, everything seems to be on the States' shoulders. In this regard, the Protocol requires each Party to take measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC, and that MAT have been established, as required by the domestic legislation or regulations of the other Party⁴⁴, as well as to take measures to address situations of non-compliance⁴⁵, including through cooperation in cases of alleged violations⁴⁶. Similar provisions are also established for compliance with ABS requirements relating to traditional knowledge associated with genetic resources⁴⁷. The principle that user States, in their jurisdiction, must ensure compliance with the requirements established by provider States is a most welcome key innovation to the CBD, and an essential element to guarantee that rules are respected along the entire ABS process and biopiracy is eventually stopped⁴⁸. However, when one looks at how such mechanism has been

⁴¹ It must be highlighted, however, that should the Parties choose a stronger mechanism, they should also consider establishing it with a stronger, legally binding, basis, as it is argued, *mutatis mutandis*, for the legal basis of the "global multilateral benefit-sharing mechanism" (infra, Sect. 3.2.3).

⁴² Infra, Sect. 3.3.

⁴³ E.g. the non-compliance mechanism of the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus, 25 June 1998), on which see C. Pitea, *Procedures and Mechanisms for Review of Compliance under the 1998 Aarhus Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters*, in T. Treves et al. (eds.), *Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements*, The Hague, 2009, pp. 221–250.

⁴⁴ Nagoya Protocol, Art. 15.1.

⁴⁵ Nagoya Protocol, Art. 15.2.

⁴⁶ Nagoya Protocol, Art. 15.3.

⁴⁷ Nagoya Protocol, Art. 16.

⁴⁸ Provider States can obviously regulate ABS and enforce regulations within their jurisdictions. However, without compliance control also by user States in their own territories it would be very easy to circumvent the system: user States are practically

designed in details, the general “duties to take measures” in Art. 15-16 appear insufficient, as well as too general and vague to be really effective⁴⁹. Few specific, stringent and intertwined solutions were put forward during the negotiations (some already embodied in the Bonn Guidelines): these included the obligation to establish specific “checkpoints” to be entrusted with compliance control duties⁵⁰, the introduction of mandatory “disclosure requirements”⁵¹, and the establishment of effective enforcement measures, including the prohibitions to use genetic resources obtained in violation of provider countries’ requirements⁵². These solutions have been eventually watered down in the final text of the Treaty. They could still have a role to play, since the general duty to take compliance control measures⁵³, coupled with the principle of good faith in treaties’ implementation⁵⁴, could arguably imply a presumption in favour of the adoption of the most effective measures to achieve the treaty’s objective; however, the absence of specific, common, mandatory standards leaves an extremely wide margin of discretion to the Parties, particularly from the user States’ point of view, thus weakening the compliance component of the Protocol.

and legally in a better position to address non-compliance by users that operate in their jurisdictions (see also *infra*, n. 50, 51, 52), and in the most frequent scenario (when user States are developed countries) they often have better capacity and more resources to carry out the task.

⁴⁹ In this regard see also R.K. Joseph, *op. cit.*, p. 83 ff.; G.S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis*, cit., p. 18 ff.

⁵⁰ Patent offices in user countries were seen as an ideal solution in this regard, in view of their privileged position in terms of compliance control and enforcement potential, since they could effectively verify and enforce compliance with provider countries’ requirements and other Protocol’s relevant provisions within their routine patent licensing process (see also *infra*, n. 51, 52).

⁵¹ This refers to the user’s duty to disclose, ideally to patent offices and as a requirement for patent application (*supra*, n. 50), the origin of the genetic resources and traditional knowledge thereof, as well as the evidence of the PIC and MAT obtained for the genetic resource’s use. See also immediately *infra*, par. 3.2.1.1.

⁵² Such prohibition could be most effectively enforced by patent offices, by refusing to grant patents in the absence of the abovementioned requirements (*supra*, n. 50, 51).

⁵³ Nagoya Protocol, Art. 15.

⁵⁴ Vienna Convention in the Law of Treaties (Vienna, 23 May 1969; hereinafter Vienna Convention), Art. 26.

3.2.1.1. *The Relationship with the Agreement on Trade-Related Aspects of Intellectual Property Rights*

One of the reasons for the exclusion of an the explicit mandatory “disclosure requirement” from the Protocol⁵⁵ was allegedly the need to address the matter within relevant processes of the World Intellectual Property Organization (WIPO) or under the specific Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) adopted within the framework of the World Trade Organization (WTO)⁵⁶. In particular, there has been discussion about possible amendments to the TRIPs (specifically to its Art. 27 and 29 that set out conditions for the granting of patents), in order to incorporate additional ABS-related requirements for patentability (such as the disclosure requirements discussed here), that are presently not mentioned therein⁵⁷.

The Nagoya Protocol, in this regard, seems to acknowledge the work undertaken in other international fora, stating that “due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the

⁵⁵ Supra, n. 51, 52.

⁵⁶ Agreement Establishing the World Trade Organization, Annex 1C (Marrakesh, 15 April 1994).

⁵⁷ See, for example, the amendment proposal included in WTO Trade Negotiations Committee, *Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement and the Convention on Biological Diversity*, Doc. TN/C/W/59, 19 April 2011, available at <http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/c/W59.doc>. On the discussion about the relationship between the CBD-related ABS regime and TRIPs see R. Pavoni, *op. cit.* p. 185 ff.; M. Chouchena-Rojas et al. (eds.), *Disclosure Requirements: Ensuring Mutual Supportiveness between the WTO TRIPS Agreement and the CBD*, Gland, Switzerland, 2005; N. Kuei-Jung, *The Incorporation of the CBD Mandate on Access and Benefit-Sharing into TRIPS Regime: An Appraisal of the Appeal of Developing Countries with Rich Genetic Resources*, in *Asian Journal of WTO & International Health Law and Policy*, vol. 1, no. 2, 2006, pp. 433–464; J. Carr, *Agreements that Divide: TRIPs vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, in *Journal of Transnational Law & Policy*, vol. 18, no. 1, 2008, pp. 131–154; J. de Werra, *Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?*, in *Vanderbilt Journal of Transnational Law*, vol. 42, 2009, pp. 143–179; E. Morgera, E. Tsioumani, *The Evolution of Benefit Sharing: Linking Biodiversity and Community Livelihoods*, *cit.*, p. 168 ff.; M. Buck, C. Hamilton, *op. cit.*, p. 53 ff.; A. Bonfanti, S. Trevisanut, *op. cit.*

objectives of the Convention and this Protocol”, and takes into account other treaties in this field, establishing that the Protocol must be “implemented in a mutually supportive manner” with other relevant international instruments⁵⁸.

This seems to be enough to uphold that, should the TRIPs negotiations eventually lead to the introduction of the mandatory disclosure requirement in the Agreement, the same requirement would have to be considered as mandatory also by the Nagoya Protocol, in light of the abovementioned duty of “mutually supportive” implementation, an obligation that reflects also general principles of treaty interpretation⁵⁹. The introduction of a mandatory disclosure requirement under the TRIPs would also improve compliance and enforcement of the legal framework on ABS, since this would eventually fall under the WTO dispute settlement system, which is among the most effective in international law.

If negotiations do not achieve such result, and in any case for the time being, the relationship between the Nagoya Protocol and the TRIPs is probably going to remain surrounded by uncertainty. However, it is argued here that the disclosure requirement could still be an option as a measure to ensure compliance with the Protocol. In fact, there has been debate about whether ABS-related measures (such as the disclosure requirement) adopted within the framework of the CBD (and now also of the Protocol) are incompatible with the TRIPs⁶⁰, and there are arguments in favour of the compatibility between the two regimes⁶¹.

⁵⁸ Nagoya Protocol, Art. 4.3.

⁵⁹ Art. 31.3.c of the Vienna Convention establishes that when interpreting a treaty there shall be taken into account inter alia “any relevant rules of international law applicable in the relations between the parties”. This requires to interpret each treaty (e.g. the Nagoya Protocol) in light of any other relevant treaty (at least those binding upon the relevant parties) (e.g. the TRIPs), and any other relevant international customary norm.

⁶⁰ A detailed analysis of the TRIPs and CBD provisions and their relationship is beyond the scope of this study. To this end, see the literature mentioned supra, n. 57 (in particular A. Bonfanti, S. Trevisanut, *op. cit.*).

⁶¹ See WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities and their Member States dated 16 September 2002, “Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore”*, Doc. IP/C/W/383 of 17 October 2002, available at <http://docsonline.wto.org/imrd/directdoc.asp?DDFDdocuments/t/IP/C/W383.doc> and a

Moreover, even assuming an incompatibility with the TRIPs, this would not necessarily and automatically rule out the disclosure requirement option, which in itself is adopted within the framework of another treaty (the Nagoya Protocol). The Protocol's provision on the relationship with other international agreements and instruments does not seem to be conclusive on the matter. In fact, the ambiguous compatibility clause in Art. 4.1 provides that the Protocol shall not affect Parties' rights and obligations deriving from existing international agreements, but "except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity"⁶² and, in any case, specifying explicitly that the same rule "is not intended to create a hierarchy between [the] Protocol and other international instruments". Neither does the already mentioned coordination clause in Art. 4.3 establish a clear-cut priority of the TRIPs over the Nagoya Protocol, since the latter requires "mutually supportive implementation" with other instruments, and to "pay due regard" to relevant "works or practices" under other international organizations and instruments, something that in both cases appears to fall short of a legal subordination by the Protocol to other "sources"⁶³. Finally, one should not forget that TRIPs provisions must be interpreted in their context and in light of the Treaty's object and purpose⁶⁴, i.e. also according to the Preamble of the Agreement Establishing the WTO, whereby the Parties recognize that they should allow "for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment", as well as in light of other rules of international law (including international environmental law instruments, such as the Nagoya Protocol)⁶⁵.

Be that as it may, potential overlaps and lack of coordination between the regime on ABS and that on intellectual property rights are

Swiss proposal discussed in M. Chouchena-Rojas et al., *op. cit.*, p. 39 ff. See also R.K. Joseph, *op. cit.*, p. 82 ff.

⁶² One could argue that the mandatory disclosure requirement is a key mechanism to ensure compliance with ABS and thus to protect biodiversity.

⁶³ This should not be a surprise in the case of the unusual reference to other "works" and "practices": it would be hard to think that the Protocol is intended to let such vague concepts (akin to soft law) prevail over a treaty; in any case, according to Art. 4.3, these are taken into consideration only if they are supportive of the CBD and the Nagoya Protocol's objectives.

⁶⁴ Vienna Convention, art. 31.1-.2.

⁶⁵ *Supra*, n. 59.

one of the main obstacles for a harmonious development of international law in this field and the Protocol represents a missed opportunity in this regard⁶⁶.

3.2.2. *An uncertain scope of application*

Among the most criticised aspects of the Protocol, particularly from the point of view of developing countries, one may mention some important outstanding issues affecting the certainty of the Protocol's scope of application.

Firstly, full agreement could not be reached on the Protocol's applicability to so-called "derivatives". These are naturally occurring biochemical compounds (e.g. antibodies, vitamins, resins, alkaloids, enzymes) resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity⁶⁷. Their importance derives from the fact that scientific research and consequential economic exploitation of key genetic resources' properties can be technically carried out also using such derivatives, without actually having access to the genetic resource itself⁶⁸; this is the reason why developing countries pushed for the inclusion of derivatives in the Protocol's scope of application, while developed ones were against it (a discussion that had been going on also regarding the CBD's scope of application). The result is a confusing compromise solution, which leaves the scope of the Protocol still somehow uncertain on this point⁶⁹.

⁶⁶ See the analysis by A. Bonfanti, S. Trevisanut, *op. cit.* from the point of view of marine genetic resources.

⁶⁷ Nagoya Protocol, Art. 2.e.

⁶⁸ Relevant examples include the *Epibatidine* and *Camu Camu* cases mentioned supra (n. 2), whereby toxins and extracts deriving from the genetic resources (rather than the genetic resources as such) have been used for research, development and exploitation.

⁶⁹ Derivatives are defined as such in the Protocol, Art. 2.e and they are indirectly included in the notion of "utilization of genetic resources", since the latter means "to conduct research and development on the genetic and/or biochemical composition of genetic resources, *including through* the application of *biotechnology*", and biotechnology means "any technological application that uses biological systems, living organisms, *or derivatives*" (Art. 2.c, .d – emphasis added). However, they disappear from the operative part of the Treaty (notably also from Art. 3 on the scope of application of the Protocol), leaving some controversy over the extent to which they are covered by the Protocol. In this regard, see International Centre for Trade and

Secondly, a final solution could not be found with regards to the Protocol's temporal or geographical scope of application. As far as the temporal scope is concerned, it was impossible to accommodate explicitly the different positions of most developing countries, who claimed that the Treaty should have applied (particularly as far as benefit sharing obligations are concerned) to genetic material (and associated traditional knowledge) *acquired before* but *used after* the Protocol's entry into force, and those of developed States, who conceived such position as entailing an unacceptable retroactive application of the Treaty⁷⁰. As far as the geographical scope is concerned, no direct and explicit solution could be found for the critical issue of ABS relating to genetic resources in areas beyond States' national jurisdictions (for example in the high seas or the deep seabed⁷¹). An answer to both these significant outstanding issues could come from the adoption of the future "global multilateral benefit-sharing mechanism" which is discussed immediately below.

Sustainable Development (ICTSD), *CBD Clinches ABS Protocol in Nagoya*, in *Bridges Trade BioRes*, vol. 10, no. 20, 2010, pp. 3–5; R.K. Joseph, *op. cit.*, p. 79 ff.; E. Tsioumani, *op. cit.*, p. 289; M. Buck, C. Hamilton, *op. cit.*, p. 56 ff.; G.S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis*, *cit.*, p. 21 ff.; T. Greiber et al., *op. cit.*, p. 61 ff.; E. Morgera, M. Buck, E. Tsioumani, *Commentary on the Nagoya Protocol on Access and Benefit-Sharing (forthcoming)*, *cit.*

⁷⁰ E. Tsioumani, *op. cit.*, p. 290 ff.; G.S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis*, *cit.*, p. 27 ff. For a very detailed analysis of all the options relating to this issue see E. Morgera, M. Buck, E. Tsioumani, *Commentary on the Nagoya Protocol on Access and Benefit-Sharing (forthcoming)*, *cit.*

⁷¹ *Prima facie*, the Protocol does not seem to apply to such resources. Art. 3 of the Protocol states that it "[...] shall apply to genetic resources within the scope of Article 15 of the [CBD] Convention [...]", and Art. 15 of the CBD deals with genetic resources under the jurisdiction of States (*supra*, n. 17). However, the latter should be interpreted in light of the entire CBD text, including its Art. 4 which establishes that the CBD applies "(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and (b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction *or beyond the limits of national jurisdiction*" (emphasis added). In this regard see also A. Bonfanti, S. Trevisanut, *op. cit.* Moreover, Art. 3 of the Protocol continues by stating that the Protocol "shall also apply to traditional knowledge associated with genetic resources within the scope *of the Convention*" (emphasis added), thus referring to the CBD as such, not limited to its Art. 15. Therefore, the fact that the Protocol is not applicable as such and as a whole to genetic resources beyond national jurisdictions does not seem to be an obvious conclusion.

3.2.3. *The global multilateral benefit-sharing mechanism, biodiversity conservation and humankind*

Art. 10 of the Protocol provides that the Parties “shall consider the need and modalities” for a “global multilateral benefit-sharing mechanism” whereby benefits arising from the utilization of genetic resources, and traditional knowledge thereof, “that occur in transboundary situations” or “for which it is not possible to grant or obtain prior informed consent” shall be used to support biodiversity conservation and the sustainable use of its components globally.

The definition of the genetic resources that would be subject to the mechanism is not perfectly clear. The concept of resources and knowledge “for which it is not possible to grant or obtain prior informed consent” could reflect a compromise on the Protocol’s temporal scope of application, in order to cover uses of genetic resources occurring after the entry into force of the Protocol, but relating to resources acquired before the same (for which PIC was not obtained)⁷². However, it is an extremely broad phrasing that does not have an exclusive chronological character, and that could eventually be used to refer to various situations beyond the latter⁷³. The notion of “resources that occur in transboundary situations”, that could be used to tackle the issue of the Protocol’s geographical scope of application⁷⁴, is ambiguous as well. From a strictly literal point of view, it seems to refer to resources that can be found in more than one State. However, that would appear incoherent with the presence of another provision (Art. 11) that is clearly dedicated to that issue using a different wording (and which is not coordinated with Art. 10)⁷⁵. Therefore, the expression in Art. 10 seems to have a wider meaning and, while possibly and partially overlapping with Art. 11⁷⁶, it could refer also to resources that are found in areas beyond the national jurisdiction of States, although

⁷² *Supra*, Sect. 3.2.2.

⁷³ For example, it could even be used to refer to genetic resources in areas beyond the jurisdiction of States, for which the PIC mechanism could not apply as in the usual scenario (see immediately *infra*).

⁷⁴ *Supra*, Sect. 3.2.2.

⁷⁵ Art. 11 of the Nagoya Protocol establishes a duty to cooperate, with a view to implementing the Protocol, “in instances where the same genetic resources are found *in situ* within the territory of more than one Party”.

⁷⁶ For example, since Art. 11 refers to resources “*in situ*” (i.e. in their natural habitats), it could be argued that Art. 10 may apply to those that are found in more than one State *ex situ* (e.g. in botanical gardens).

the lack of a more explicit and unambiguous wording, in line with consolidated international practice⁷⁷, still leaves a doubt in this regard. The ambiguity of these solutions could be solved in the next phase of the two-steps approach that is required for the establishment of the global multilateral benefit-sharing mechanism, eventually enabling the latter to shed light on, or even expand, the Protocol's scope of application. For example, the mechanism could be used explicitly as the legal framework for a solution to the management of marine genetic resources in the high seas or the deep seabed⁷⁸.

Besides, one should not overlook the fact that there is no obligation to establish such mechanism⁷⁹, nor does the Protocol provide for details on its nature, on how it will work, or what its legal basis would be. Everything will depend upon what steps will be taken on the basis of the "enabling clause" contained in Art. 10, if anything will be done at all.

From the point of view of the substance of the mechanism, inspiration could be drawn from the International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, 3 November 2001; hereinafter ITPGRFA), which is also recalled in the Preamble to the Nagoya Protocol itself, and its multilateral ABS system, that creates a "Governing Body" (made of representatives of all Contracting Parties) that administers a "Multilateral System" to manage collective access and benefit sharing for a specific set of crops⁸⁰.

From the point of view of the mechanism's legal basis and nature, one may look at the many non-compliance mechanisms of MEAs⁸¹, which have generally been created on the basis of an enabling clause in the treaty, followed by a Decision of the COP that establishes the substantial and procedural characteristics of the mechanism and creates the relevant institutions. The experience with these non-compliance mechanisms suggests that this may be a workable, flexible and relatively fast solution also within the Nagoya Protocol's context⁸²,

⁷⁷ E.g. areas "beyond the limits of national jurisdiction" (CBD, Art. 4.b – supra, n. 71).

⁷⁸ See A. Bonfanti, S. Trevisanut, *op. cit.*

⁷⁹ The Protocol is quite clear in this regard, since Art. 10 states that "Parties shall consider the need for [...] a global multilateral benefit sharing mechanism" (emphasis added).

⁸⁰ See E. Caliceti, *op. cit.*

⁸¹ Supra, Sect. 3.2.1.

⁸² Art. 10 of the Nagoya Protocol seems to be a proper "enabling clause", and the COP of the Protocol has the competence to establish subsidiary bodies, make

but it may also leave some uncertainty as to the legal basis and effects of the mechanism itself, due to the controversial legal value of COP Decisions⁸³. It would therefore be desirable for the Parties to try and find an agreement to establish the global mechanism with a sound legally binding basis, such as with an amendment or a new annex to the Protocol⁸⁴, or with an additional and separate binding instrument. Albeit entailing a more cumbersome process, this solution may ensure greater certainty and stability in the long term, especially if the Parties wish to design a “harder” mechanism, based on a new institutional framework or intended to have binding consequences for them⁸⁵.

Finally, as to the objective of the mechanism, Art. 10 establishes that it shall be used to support conservation and sustainable use of biodiversity globally. This is a welcome element, as it is notably the only obligation to direct benefits arising from genetic resources’ use to biodiversity conservation and sustainable use, the latter being one of the objectives of the CBD that is recognised also by the Nagoya Protocol⁸⁶, which the latter elsewhere merely promotes or encourages⁸⁷

recommendations and exercise any other function that is necessary for the Protocol’s implementation (Nagoya Protocol, Art. 26.4.a, .b, .f).

⁸³ A. Fodella, *Structural and Institutional Aspects of Non-Compliance Mechanisms*, in T. Treves et al. (eds.), *Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements*, The Hague, 2009, pp. 355–372.

⁸⁴ Amendments and annexes to the Protocol are adopted by the Protocol’s COP (Nagoya Protocol, Art. 26.4.e). Amendments are adopted by consensus or, if that is not reached, by a two-third majority of the Parties to the Protocol, present and voting, and enter into force if at least two thirds of the Parties to the Protocol ratify, accept or approve them (CBD, Art. 29). The same procedure applies for the adoption of annexes, except for an opt-out mechanism that favors their entry into force: Parties that do not want to accept the annex must notify the Depository within one year from the adoption of the annex, otherwise the latter enters into force for them (CBD, Art. 30).

⁸⁵ A. Fodella, *Structural and Institutional Aspects of Non-Compliance Mechanisms*, cit., p. 356 ff. For example, this could be in case of the creation of a new organization (not a simple subsidiary organ of the COP – supra, n. 82) entrusted with the management of the mechanism, or if the mechanism was designed with the ability to alter in any way the obligations deriving from the Protocol (a possible scenario, considering the many gaps left open by the Treaty, which could be filled by the mechanism). It is worth recalling, in this regard, that the very articulated multilateral mechanism of the ITPGRFA mentioned supra (including its institutional structure) is contained in the Treaty itself.

⁸⁶ CBD, Art. 1. The Protocol recognizes the importance of genetic resources for biodiversity conservation and environmental sustainability (Nagoya Protocol, Preamble, para. 7, 14 and Art. 1, supra, n. 30).

⁸⁷ E.g. Nagoya Protocol, Art. 8.a, 9.

(from this point of view as well, the Treaty could have been framed in a more incisive manner).

The global biodiversity conservation objective could also be seen as indirectly recognising the interest of humankind. The Nagoya Protocol evidently builds upon bilateral, reciprocal, contractual relationships between genetic resources' providers and users, and the interest of mankind is not taken into consideration per se. It would be desirable that such interest be taken into account more directly in framing the future global multilateral benefit-sharing mechanism, for example by establishing ways to redistribute benefits fairly and equitably (e.g. following the ITPGRFA model), and to facilitate access to scientific results deriving from genetic resources' use at the global level, in line also with the assumption that biodiversity conservation is a "common concern of humankind"⁸⁸ and with the role that the Protocol should have from a broader perspective⁸⁹.

3.3. Developing the rights and interests of indigenous and local communities

What is developed by the Protocol, beyond the original unsatisfactory CBD framework, is the attention to the interests and rights of indigenous and local communities, inter alia since they have an inextricable relationship with biodiversity in their territories and lands, their traditional knowledge is essential for genetic resources' use, and benefit sharing in their favour is also an incentive for biodiversity conservation⁹⁰.

⁸⁸ Supra, n. 18.

⁸⁹ E.g. the Protocol acknowledges the importance of ABS in poverty eradication, food security, or adaptation to climate change, regarding which interdependence between all countries is particularly evident (Nagoya Protocol, Preamble, para. 7, 14, 16).

⁹⁰ Nagoya Protocol, Preamble, para. 6, 22-27. On the issues arising from the connection between indigenous peoples and biodiversity conservation and use see J. Woodliffe, *Biodiversity and Indigenous Peoples*, in M. Bowman, C. Redgwell (eds.), *International Law and the Conservation of Biological Diversity*, London, 1996, pp. 255-270; G. Aguilar, *Access to Genetic Resources and Protection of Traditional Knowledge in the Territories of Indigenous Peoples*, in *Environmental Science & Policy*, vol. 4, 2001, pp. 241-256; F. Lenzerini, *Biogenetic Resources and Indigenous Peoples' Rights*, in F. Francioni (ed.), *Biotechnologies and International Human Rights*, Oxford, 2007, pp. 191-226; G.S. Nijar, *Incorporating Traditional Knowledge in*

In this regard, the Protocol establishes that Parties shall take measures, in accordance with domestic law, to ensure that the PIC or approval and involvement of indigenous and local communities is obtained in order to have access to genetic resources, when the same communities have an “established right to grant such access”.⁹¹ Similar rules are provided for access to traditional knowledge associated with genetic resources that is held by these communities⁹². Moreover, Parties are required to take measures to ensure the fair and equitable sharing (in favour of the same communities) of the benefits arising from the utilization of genetic resources “that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these [...] communities over these genetic resources”⁹³. The Protocol regulates in a similar manner the sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources, with the communities holding such knowledge.⁹⁴ Finally, in implementing their obligations with respect to traditional knowledge associated with genetic resources, States are also required to take into consideration indigenous and local communities’ customary laws, procedures and “community protocols”⁹⁵.

Compared to the CBD⁹⁶, there have been several improvements. Among the most significant ones, States’ obligations relating to benefit sharing in connection with traditional knowledge have been strengthened (since this was previously simply “encouraged”) and access to such knowledge has been regulated (whereas before only benefit sharing was dealt with). Moreover, the reference to indigenous and local communities’ customary laws, procedures and protocols is a recognition of a more direct involvement, according to their own modalities, by such communities in the ABS process and may be a sign of a paradigm shift in this regard. Furthermore, the Protocol now recognises also communities’ rights with regards to ABS relating to *genetic resources as such* (as opposed

an International Regime on Access to Genetic Resources and Benefit Sharing: Problems and Prospects, in *European Journal of International Law*, vol. 21, no. 2, 2010, pp. 457–475.

⁹¹ Nagoya Protocol, Art. 6.2.

⁹² Nagoya Protocol, Art. 7.

⁹³ Nagoya Protocol, Art. 5.2.

⁹⁴ Nagoya Protocol, Art. 5.5.

⁹⁵ Nagoya Protocol, Art. 12.

⁹⁶ *Supra*, Sect. 2, in particular n. 25.

to associated traditional knowledge alone). There are two main obstacles to the full and effective realization of this framework. The first is that the system is affected by the same difficulties in ensuring compliance that have been highlighted regarding the Protocol in general, including the intricate relationship with the intellectual property rights regime⁹⁷. The second is that, as far as rights relating to genetic resources as such are concerned, the Nagoya Protocol shares a weakness with the CBD, insofar as States' obligations are dependent upon domestic legal action (i.e. the rights relating to resources as such are given to the indigenous communities...if States recognise such rights to them). The problem may be solved by looking at the recent evolution of indigenous peoples' rights in the area of the international protection of human rights.

In fact, human rights instruments, as interpreted by the relevant jurisprudence or quasi-jurisprudence, recognize that indigenous peoples have the right to property over natural resources that they traditionally use or that are within their traditional territories and lands; that they have the right to maintain their culture, which means also the right to live according to their peculiar ways of life and economic systems that are associated with natural resources, including through the protection of their traditional knowledge; that their participation and consent is required for decisions affecting them from the environmental and economic point of view; and that they are entitled to a share of the

⁹⁷ Supra, Sect. 3.2.1, 3.2.1.1. In this regard see R. V Anuradha, *IPRs: Implications for Biodiversity and Local and Indigenous Communities*, in *Review of European Community & International Environmental Law*, vol. 10, no. 1, 2001, pp. 27–36; *Symposium: Traditional Knowledge, Intellectual Property, and Indigenous Culture*, in *Cardozo Journal of International and Comparative Law*, vol. 11, no. 2, 2003; O. Arewa, *TRIPS and Traditional Knowledge: Local Communities, Local Knowledge, and Global Intellectual Property Frameworks*, in *Marquette Intellectual Property Law Review*, vol. 102, 2006, pp. 155–180; H. Ullrich, *Traditional Knowledge, Biodiversity, Benefit-Sharing and the Patent System: Romantics v. Economics?*, in F. Francioni, T. Scovazzi (eds.), *Biotechnology and International Law*, Oxford, 2006, pp. 201–229; F.M. Abbott, *Patents, Biotechnology and Human Rights: The Preservation of Biodiverse Resources for Future Generations*, in F. Francioni (ed.), *Biotechnologies and International Human Rights*, Oxford, 2007, pp. 315–331; A. Di Blase, *I diritti di proprietà intellettuale applicabili alla cultura indigena e tradizionale*, in *Comunicazioni e Studi*, vol. XXIII, 2007, pp. 511–563; J.E. Anderson, *Law, Knowledge, Culture. The Production of Indigenous Knowledge in Intellectual Property Law*, Cheltenham, UK, 2009; J. Recht, *Hearing Indigenous Voices, Protecting Indigenous Knowledge*, in *International Journal of Cultural Property*, vol. 16, no. 3, 2009, pp. 233–254.

benefits deriving from the use of their natural resources and knowledge thereof.⁹⁸ Genetic resources can be included in this reasoning⁹⁹. These

⁹⁸ See Art. 27 of the International Covenant on Civil and Political Rights (New York, 16 December 1966), as interpreted by the Human Rights Committee; Art. 11 and 15 of the International Covenant on Economic, Social and Cultural Rights (New York, 16 December 1966; hereinafter ICESCR), as interpreted by the Committee on Economic, Social and Cultural Rights (CESCR); the International Convention on the Elimination of All Forms of Racial Discrimination (New York, 21 December 1965), as interpreted by the Committee on the Elimination of Racial Discrimination; Art. 6, 7.1, 13.1 and 15 of the International Labor Organization (ILO) Convention concerning Indigenous and Tribal Peoples in Independent Countries n. 169 (Geneva, 27 June 1989), as interpreted by the relevant ILO monitoring bodies; Art. 19, 26-28 and 31 of the United Nations Declaration on the Rights of Indigenous Peoples (UN Doc. A/RES/61/295, 13 September 2007; hereinafter UNDRIP) (which is explicitly recalled in the Preamble of the Nagoya Protocol); Art. 21 of the American Convention on Human Rights (San Jose, 22 November 1969), as interpreted by the Inter-American Court of Human Rights; Art. 14, 17, 21 and 22 of the African Charter on Human and Peoples' Rights (Banjul, 26 June 1981), as interpreted by the African Commission on Human and Peoples' Rights (ACmHPR). For an analysis of these instruments and jurisprudence see A. Fodella, *Indigenous Peoples, the Environment and International Jurisprudence*, in N. Boschiero, T. Scovazzi (eds.), *International Courts and the Development of International Law - Essays in Honour of Tullio Treves (forthcoming)*, The Hague, 2013.

⁹⁹ The connection has been explicitly made in some instances. For example, Art. 31 of the UNDRIP specifically states that: "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, *traditional knowledge* and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including [...] *genetic resources*, seeds, medicines, knowledge of the properties of fauna and flora [...] They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, *traditional knowledge*, and traditional cultural expressions" (emphasis added). The CESCR, in interpreting Art. 15 of the ICESCR on cultural rights, clarifies that "any scientific [...] production", within the meaning of article 15 [...] refers to creations of the human mind [...] such as scientific publications and innovations, *including knowledge*, innovations and practices of indigenous and local communities [...] States parties should adopt measures to ensure the *effective protection of the interests of indigenous peoples relating to their productions* [...] Such protection might include the adoption of measures to recognize, register and protect the individual or collective authorship of indigenous peoples under national *intellectual property rights regimes* and should *prevent the unauthorized use of scientific [...] productions of indigenous peoples by third parties* [...]" (General Comment n. 17, *The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (art. 15 (1) (c))*, para. 9, 32 emphasis added); moreover, "Indigenous peoples have the right to act collectively to ensure respect for their right to maintain, control, protect and develop their cultural heritage, *traditional knowledge* and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including [...] *genetic*

rules reinforce many of the Protocol's principles and could be used in some cases with a supplementary role¹⁰⁰, for example to help with the interpretation of key Protocol's concepts¹⁰¹, to support specific mechanisms for the Protocol's implementation and compliance control¹⁰², or to maintain that indigenous peoples have the "established right" relating to genetic resources that is required in order to trigger certain obligations contained in the Protocol¹⁰³, also in view of the Protocol's statement that nothing in it "shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities"¹⁰⁴.

The only problem arising from this approach is that the abovementioned rules, developed in the context of the international protection of human rights, are often applicable to indigenous peoples as such but not necessarily to local communities (although the two categories would frequently coincide), with the risk of the creation of two separate legal standards for groups that are considered on the same level by the Protocol.

In any case, at least as far as indigenous peoples are concerned, the human rights approach could be extremely useful also from the procedural point of view, as ABS-related issues could be brought before at least some human rights monitoring mechanisms by

resources, seeds, medicines, knowledge of the properties of fauna and flora [...]" (General Comment n. 21, *Right of everyone to take part in cultural life*, para. 37, emphasis added).

¹⁰⁰ In view inter alia of the recalled duty to interpret treaties in an integrated manner in light of other rules of international law (supra, n. 59).

¹⁰¹ Human rights jurisprudence could provide indications on the notion of "traditional knowledge", which is not defined in the Protocol (e.g. see the CESCR supra, n. 99).

¹⁰² The CESCR, for example, indicates States' obligations to ensure protection of indigenous peoples' traditional knowledge, including through intellectual property rights mechanisms, to prevent unauthorised use by third parties (General Comment n. 17, supra, n. 99). This could arguably and indirectly uphold certain mechanisms to ensure compliance like the mandatory disclosure requirement (supra, Sect. 3.2.1 and 3.2.1.1).

¹⁰³ Supra, n. 91, 93.

¹⁰⁴ Nagoya Protocol, Preamble, para. 27.

indigenous peoples¹⁰⁵, thus allowing in practice for the indirect justiciability of the Protocol¹⁰⁶.

4. Conclusions

While the adoption of the Nagoya Protocol must be considered a crucial advancement in the process of regulating ABS, the Treaty itself has not solved all the critical issues in that regard and, as it has been highlighted, there is still room for improvement.

If one looks at the interests that should be ideally taken into account in the management of genetic resources, it seems that those of resources' users have been privileged over those of providers, and that those of humankind and biodiversity conservation have been somehow overlooked. It is a choice that can be criticised, and it is hoped that Parties will concentrate more on such less-regarded interests in the future, when developing the Protocol's legal framework.

In fact, the Treaty leaves behind few gaps, uncertainties and open issues that could be clarified and finalized by the Parties, in order for the legal framework to be fully operational. From this point of view, the Protocol seems to be the expression of a trend in international environmental law-making, whereby an ever growing importance and responsibility is given to the legal development role of the COPs. States have always sought flexible law-making tools in this sector of international law, in view inter alia of the economic and technical difficulties implied therein, and it seems that, in this regard, a three-steps approach is now commonly adopted, whereby after the initial conclusion of a framework convention (laying down fundamental principles and other essential legal elements, such as financial and institutional mechanisms), the subsequent protocols are unable to fill all the gaps and need to be further elaborated during a third stage (normally by the COPs). There is nothing wrong in this approach, except for few risks. One is that it could be used to delay, or avoid, the

¹⁰⁵ See A. Fodella, *Indigenous Peoples, the Environment and International Jurisprudence*, cit.

¹⁰⁶ Such process would be even more effective if human rights bodies used the Nagoya Protocol as an element for the interpretation of relevant human rights norms. For example, the Protocol could provide detailed indications on how States could implement in practice PIC or benefit sharing obligations that are in principle established also in the human rights regime.

decision over highly controversial issues, eventually leaving crucial uncertainties in the framework and creating a paradoxically slow response to technological changes (whereas the flexible law-making approach was initially adopted *inter alia* to provide a faster answer to modern challenges). Another is that the law-making process is partially shifted into a phase (mainly governed by the work of COPs), and relies upon a type of sources (mainly soft law), that are not always firmly based on a solid legal background (compared to more traditional and well established mechanisms based on the law of treaties). These flexible solutions allow to make progress, which is certainly important also from the symbolic and political point of view, but this should not come at the expense of legal certainty, as it could undermine the framework in the long term¹⁰⁷. It is therefore probably time to focus on how to enhance and improve the law-making process in this area of international law.

A reason to be optimistic comes from the approach taken in dealing with the rights of indigenous and local communities regarding ABS. In this field, the Protocol enhances the role and rights of indigenous peoples, whose profile can be raised also by linking the Protocol to the international protection of human rights, with the two regimes operating in a mutually supportive manner. In fact, such an inter-systemic approach to international law in this field is essential, since it would allow, mainly through integrated interpretation, for the coherent evolution of the law across the different sectors involved, and it could help settle some of the most critical issues relating to the Protocol (e.g. the critical coordination with the TRIPs regime), so as to

¹⁰⁷ Two examples of the risks hinted at above may be mentioned. Within the framework of the Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel, 22 March 1989), one of the most controversial issues has always been the adoption of a ban of hazardous wastes movements from developed countries to developing ones: Parties initially adopted such ban with a series of COP Decisions, but they eventually had to opt for a formal amendment to the Treaty itself (A. Fodella, *Il movimento transfrontaliero di rifiuti pericolosi nel diritto internazionale*, Torino, 2004, p. 173 ff.). During the 15th session of the COP to the UN Framework Convention on Climate Change and 5th session of the COP serving as the Meeting of the Parties to the Kyoto Protocol in 2009, the Parties, who were under pressure to reach an agreement, relying on unusual procedural solutions adopted the so called “Copenhagen Accord”, whose legal status is still not entirely clear (L. Rajamani, *The Making and Unmaking of the Copenhagen Accord*, in *International and Comparative Law Quarterly*, vol. 59, no. 3, 2010, pp. 824–843).

ensure the harmonious management of these fundamental resources for humanity.