

THE NEED FOR AND MODALITIES OF A GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

SUBMISSION

Prepared by the ICC Commission on Intellectual Property (Task Force on ABS)

Summary and highlights

- Consideration of the need for a Global Multilateral Benefit Sharing Mechanism (GMBSM)
- Consideration of situations in which a GMBSM might or might not be required

Introduction

Members of the International Chamber of Commerce (ICC) appreciate the opportunity to submit comments and views on the need for and modalities of a global multilateral benefit-sharing mechanism (GMBSM). ICC has previously prepared a submission on the GMBSM (Doc. No. 450/1069, 18 November 2011), and we supplement the comments in that publication with additional views based on the requests contained in the present notification.

In addition to the comments below, we would like to note that the efforts necessary to consider adding another layer of complexity, such as a GMBSM, to the international ABS framework, are likely to disperse the energy and resources available for the implementation of the Nagoya Protocol at the national level. Considerable efforts are currently being made by Parties and stakeholders to implement the Protocol and we suggest that national implementation be prioritized, rather than considering additional mechanisms.

The need for and modalities of a global multilateral benefit-sharing mechanism

(i) Situations which may support the need for a global multilateral benefit-sharing mechanism that are not covered under the bilateral approach

It is important to note at the outset that Decision NP-1/10 requests first whether there is a need for a global multilateral benefit-sharing mechanism. As ICC noted in its 2011 publication, and reiterates here, there is no demonstrated need for a GMBSM. Article 10 refers to only three situations under which a GMBSM may be considered necessary. These are:

1. where the genetic resources and traditional knowledge associated with genetic resources occur in transboundary situations; or
2. where it is not possible to grant prior informed consent in respect of the genetic resources and traditional knowledge associated with genetic resources; or
3. where it is not possible to obtain prior informed consent in respect of the genetic resources and traditional knowledge associated with genetic resources.

The basis for ICC's position is found within the text of the CBD and the Nagoya Protocol (NP).

First, Article 11 of the NP defines the instances in which transboundary cooperation is required, and imposes an obligation on Parties to enter into good faith actions with the aim of reaching an agreement on coordinated action. As stated in this Article 11 of the NP, where *in situ* genetic resources and/or traditional knowledge are shared amongst more than one Party or indigenous or local community, the Parties shall cooperate to implement the Protocol. Thus, the NP explicitly envisions and addresses issues of transboundary genetic resources found *in situ*, as well as of transboundary traditional knowledge associated with genetic resources.

Article 11 balances the rights of Parties to making unilateral decisions with the expectation that such decisions will take into consideration other Parties' (and/or local communities') interests. Article 11 clearly acknowledges the need for cooperation between Parties in transboundary situations, without undermining the notion of sovereign rights of the Parties over their genetic resources, as enshrined in the NP. This is further substantiated by the fact that Article 11 does not specify which measures Parties need to adhere to in the context of transboundary cooperation. Two examples of successful transboundary cooperation are worth mentioning: 1) the 1996 Andean Community regime on genetic

resources created a committee to deal with management, monitoring and control of access authorisations related to genetic resources existing in two or more member countries; 2) the well-known case of the traditional knowledge related to hoodia, where San tribes (living in South Africa, Namibia, Angola and Botswana) formed a council to negotiate benefit sharing agreements among themselves. In addition, bilateral or regional agreements within the context of Article 11 could also result in specialized ABS agreements, as explicitly envisaged by Article 4 of the NP. Last, but not least, the ABS Clearing House should be a supporting tool in implementing Article 11.

A GMBSM would completely undermine the rights and obligations of Parties as established by Article 11, and counter the principle of the Parties' sovereign rights over their genetic resources, as well as the bilateral logic of the NP.

In addition, Article 3 of the CBD makes it clear that "[s]tates have...the sovereign right to exploit their own resources pursuant to their own environmental policies...." Article 6 (1) of the NP reaffirms this principle of national sovereignty over genetic resources.

It needs to be reconfirmed that, in principle, a Party has the prerogative to decide whether it requires prior informed consent or not for the activities as intended by the user. In case a Party does not (yet) have an established national legal framework on ABS, a potential user will not have any specific ABS obligations. In the case where a Party has a national legal framework on ABS, but has explicitly decided that no prior informed consent is required, any user can use the genetic resources of such a Party without restrictions (it is acknowledged that mutually agreed terms might have to be agreed upon and commercial use might be subject to prior informed consent). In any case, all obligations will be defined within the relevant national ABS law. A party has a legitimate right not to require prior informed consent, which is not to be overruled by a GMBSM.

There should be no instances in which prior informed consent cannot be obtained in the case of genetic resources obtained from ex-situ collections. If the resources were accessed and put in the collection before the entry into force of the NP, in accordance with all applicable laws, the national ABS laws of the country where the collection is based will govern the potential need for and modalities of prior informed consent concerning access from the collection. In such cases, some Governments and stakeholders have argued that users accessing these genetic resources from the ex situ collection must obtain PIC from the country from which the GRs were originally obtained. However, such a requirement would create a retroactive obligation, which neither the CBD nor the NP contemplates.

If the GRs had been accessed and deposited in an ex-situ collection after the implementation of the NP, the collection should already have evidence of the PIC obtained at the moment of initial access from the source country, and be able to transfer this to the user. In the event that the initial access rights granted to the ex-situ collection are too limited in scope (e.g.. no prior informed consent for commercial use has been secured by the collection), the user might need to go back to the source country, to obtain the prior informed consent required for the scope of activities envisioned by the user, and negotiate mutually agreed terms as and when required.

Thus, none of the three situations elaborated in Article 10 of the NP justifies the need for a GMBSM.

(ii) Possible modalities for a global multilateral benefit-sharing mechanism as well as information regarding the implications of different scenarios on these modalities

ICC believes that any discussion of possible modalities for a GMBSM would be premature, in light of the lack of demonstrated need. As noted above, ICC is of the view that there is no need for such a system. Moreover, those who believe such a system is necessary have not responded to fundamental matters of sovereignty and applicability within the agreed scope of the NP.

(iii) The areas requiring further consideration, as identified in paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol.

ICC provides its concise views below:

(a) Whether or not there is a need for a GMBSM

ICC members have been unable to ascertain the need for a GMBSM. On the contrary, ICC has provided detailed arguments demonstrating the lack of such a need.

(b) Whether there is sufficient experience with implementation of the Protocol to determine whether such a need exists

According to the Access and Benefit-Sharing Clearing House of the CBD, out of the 59 Parties to the NP, 11 Parties, as well as the European Union, have developed legislative, administrative, or policy measures aimed at implementing the Nagoya Protocol. However, to date, there has been little to no substantive discussion of the national experience in those countries or regions. In fact, of the 28 Member States of the European Union, only two have implemented national legislation regarding access and benefit-sharing. Therefore, we believe there is vastly insufficient experience from which to draw in determining the need for a GMBSM. It is only after a sufficient number of countries have implemented the NP that we will be able to assess the effectiveness of the transboundary cooperation mechanisms envisioned under Article 11. Without that experience, there is no basis for any assertions that Article 11 would be insufficient.

(c) Whether the utilization of genetic resources without PIC would entail benefit-sharing obligations that could be met through a GMBSM

For the purposes of Article 10, there are three instances in which PIC could not have been obtained: (i) where the genetic resource or traditional knowledge associated with genetic resources was accessed prior to the entry into force of the Nagoya Protocol in a particular jurisdiction; (ii) where the genetic resource or traditional knowledge associated with genetic resources is accessed from a Party that has not implemented the Protocol in a manner that provides for how and from whom PIC should be obtained; or (iii) where the genetic resource or traditional knowledge associated with genetic resources was accessed from a Party that has decided not to require PIC.

With regard to access prior to entry into force of the NP, we have previously emphasized that neither the CBD nor the NP provides a legal basis for the retroactive implementation of the NP's provisions, including on benefit-sharing. This is further confirmed by Article 28 of the Vienna Convention on the Law of Treaties. Therefore, a mechanism for access to genetic resources or traditional knowledge associated with genetic resources that occurred prior to implementation of the NP, such as a GMBSM, would not be appropriate.

For those Parties to the Protocol that have yet to implement the Protocol, it is important that their sovereign rights should not be undermined by a mechanism such as a GMBSM. It is incumbent on Parties to implement the Protocol in a manner that meets their national needs and interests.

Finally, with regard to Parties that have decided not to require PIC, this is also a matter of national sovereignty that should not be undermined. ICC members do encourage Parties that have made a determination not to require PIC to affirmatively and publicly note this, so as to provide certainty to prospective users.

(d) Whether a Party's decision not to require PIC (e.g. under Art. 6(1)) or to waive PIC (e.g. under Art. 8) can constitute situations for which it is not possible to grant or obtain PIC in the context of Article 10

As noted in the prior response, a Party's decision not to require PIC is a matter of national sovereignty, and this sovereign decision should not be undermined by a mechanism such as a GMBSM.

(e) Whether benefit-sharing requirements are waived when a Party has decided not to require PIC or has waived PIC

ICC views any response to this question as highly fact-determinative. First of all, we would like to confirm the principle that it is the prerogative of each Party whether or not to require PIC and/or MAT. A Party might decide not to require PIC or replace PIC by, for instance, an obligation to notify in the event that a commercial product is being developed, in which case a MAT might still be required. Nevertheless, since this is entirely and solely up to the Party to decide, this question is not relevant for the discussion concerning a GMBSM. Acknowledging this as a relevant question would de facto mean that a Party cannot waive benefit sharing requirements related to a genetic resource over which it has sovereign rights. This would clearly go counter to the bilateral nature of the NP. A fortiori, setting up a multilateral system which would impose benefit-sharing obligations, even if these are not required by a Party, would be an aberration under the NP. The question becomes more difficult when Parties are unclear about their intention to require PIC, MAT, or benefit-sharing. It is for this reason that ICC urges Parties to implement the NP in a way that is clear and provides certainty to potential users.

(f) Whether there is no requirement for benefit-sharing when mutually agreed terms are not required or have not been established

The response to this query is highly dependent on the factual circumstances under which MATs were not established. If a Party has affirmatively indicated that MATs are not required, this clearly indicates that benefit-sharing is not required. There may be several scenarios in which this could occur. For example, a Party may affirmatively indicate that MATs are not required, with the purpose of encouraging the utilization of its genetic resources or traditional knowledge associated with genetic resources as a means of incentivizing the development of new businesses or research clusters. Such development is often accompanied by a number of non-monetary benefits, including increased employment, technology transfer, and educational opportunities. The ability to make such determinations should be left to the individual Parties.

- (g) Whether the absence of ABS legislation or regulatory requirements in a Party due to lack of capacity or lack of governance means that PIC for access to genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC.**

The NP requires Parties to “take the necessary legislative, administrative or policy measures” if they require prior informed consent, including establishing “clear rules and procedures for requiring and establishing mutually agreed terms”. Therefore, if a country has not developed ABS legislation, there is a presumption that PIC for access to genetic resources is not required and that there is no obligation to share benefits. While this might be a situation where it is not possible to grant or obtain PIC, it is not one which would justify a multilateral mechanism such as a GMBSM as it is for Parties to the NP to judge if ABS is sufficiently a national priority to implement meaningful ABS legislation and/or regulations.

- (h) Whether the absence of measures in a Party to implement Article 7 means that PIC for access to traditional knowledge associated with genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC.**

ICC reiterates its position that Parties to the NP must implement ABS legislation and/or regulations in a way that is consistent with their national priorities.

- (i) Whether a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable.**

The NP is built on the premise of a bilateral agreement between the user and provider of a genetic resource. Thus, only the bilateral approach should be applicable, even if a genetic resource is found in more than one Party. This should provide an incentive for potential providers of a widely-available genetic resource to implement the NP in a way that provides certainty to potential users, and to negotiate reasonable MATs with such users. If the same genetic resources are indeed found *in situ* in more than one Party, and those Parties believe it is appropriate to cooperate on principles, legislation, or regulations regarding access to genetic resources, MATs, and benefit sharing, they may do so according to Article 11, as we have explained earlier in this document.

- (j) Whether traditional knowledge associated with a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if traditional knowledge associated with a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable.**

ICC takes the same position as in (i) with regard to traditional knowledge associated with genetic resources, and notes that Article 11(2) addresses traditional knowledge specifically.

(k) Whether Article 11 is sufficient to respond to transboundary situations.

In the event that Parties wish to negotiate with other Parties who hold the same *in situ* genetic resources and traditional knowledge associated with genetic resources, Article 11 is the only provision in the NP that is applicable to such instances. The rights and obligations stipulated in Article 11 provide for a sufficient legal framework to deal with this situation, in line with the bilateral logic of the NP.

(l) Whether a GMBSM should address the sharing of benefits arising from the utilization of:**(i) Genetic resources in ex situ collections in relation to transboundary situations or for which it is not possible to grant or obtain PIC**

As explained in the first part of this document there should be no instances where PIC cannot be obtained for GRs held in ex situ collections. As stated, these GRs fall under the jurisdiction of the Party where the ex situ collection is based/maintained, if the resources were obtained in accordance with all applicable laws before the entry into force of the NP. The national ABS laws of the country where the collection is based will govern the potential need for and modalities of prior informed consent concerning access from the collection. If the GRs in an ex-situ collection have been accessed and deposited in the ex situ collection after the implementation of the NP by the Party in which the collection is based, the collection should already have evidence of the PIC obtained at the moment of initial access from the source country, and be able to transfer this to the user.

(ii) Genetic resources in ex situ collections used for purposes for which PIC was not granted and for which it is not possible to grant or obtain PIC

In the event that the initial access rights granted to the ex-situ collection are too limited in scope (e.g., no prior informed consent for commercial use has been secured by the collection), the user may go back to the source country, to obtain the prior informed consent required for the scope of activities envisioned by the user, and negotiate mutually agreed terms as and when required. There is therefore no need for a GMBSM in this case.

(iii) Genetic resources in areas beyond national jurisdiction or whether this issue falls within the competence of the United Nations General Assembly

According to Article 3 of the Protocol, the provisions of the Protocol apply to genetic resources within the scope of Article 15 of the CBD, which reads: "*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.*" Bearing this in mind, it is understood that the aim of the GMBSM is, in a way, to extend the scope of a harmonized benefit-sharing regime beyond Article 15 CBD, potentially compromising the sovereign rights of States over their natural resources.

Article 3 of the CBD (Principle) suggests that States have the sovereign right to exploit their own resources and carry responsibility for activities within their jurisdictions. Further, Article 4 of the CBD (Jurisdictional Scope) states that in the case of components of biodiversity, the CBD applies to the States in areas within the limits of their national jurisdiction. Therefore, Contracting Parties should not set up rules on genetic resources that lie outside their jurisdictions.

(iv) Genetic resources in the Antarctic Treaty area

ICC reiterates the position stated above with regard to areas beyond national jurisdiction, as it applies equally to the Antarctic Treaty area.

(v) Traditional knowledge associated with genetic resources that is publicly available and where the holders of such traditional knowledge cannot be identified or for which it is not possible to grant or obtain PIC

As there are continuing discussions in other fora on the status and effect of publicly available TK, ICC believes it is premature to address this question.

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