Legal Aspects of Prior Informed Consent on Access to Genetic Resources: An Analysis of Global Lawmaking and Local Implementation Toward an Optimal Normative Construction

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ABSTRACT

Since the Convention on Biological Diversity (CBD) has been in force, national implementation of the access to and benefit-sharing (ABS) requirement on genetic resources has been flourishing. A requirement of prior informed consent (PIC) by the people controlling access to genetic resources constitutes a major instrument to deter illegal bioprospecting and to ensure fair access to genetic resources.

This Article aims to analyze the continuing global lawmaking on PIC and to conduct a comparative study on how genetically rich nations implement the PIC requirement with a view to examining whether the genuine mandate of the CBD has been fulfilled.

This Article argues that the will of local indigenous communities should be respected, regardless of whether they are

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entitled to give consent. Further, national operation of PIC should be under an adequate international supervision to prevent the misuse or abuse of PIC and to ensure that implementation of PIC conforms to the CBD objectives.

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I. INTRODUCTION: THE CONSOLIDATION OF INTERNATIONAL MOVEMENTS TO CONTROL GENETIC RESOURCES

The Convention on Biological Diversity (CBD) provides that genetic resources (GR) originate in plants, insects, animals, and microbes. As a result, human genes are practically excluded from the definition of GR. The value and significance of GR has become increasingly prominent in recent years, playing a significant role in the spheres of agriculture, bio-industries, and medicine, as well as the global economy. Notably, the modern biotechnology industry substantially relies on bioresources to produce commercial products.

Prior to the adoption of the CBD, there had been a push to place GR under international control so that the benefits of GR would be available or accessible to all humankind instead of being dominated by each sovereign nation alone. The effort of the United Nations Food and Agriculture Organization (FAO) to preserve agricultural genetic resources represents a leading model in the movement to classify GR as international common property. The International Undertaking on Plant Genetic Resources, adopted in 1983, cites as its basis “the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction.”

In an earlier stage, the text aimed to

2. The CBD defines GR as “genetic material” of actual or potential value, and considers genetic material to be “any material of plant, animal, microbial or other origin containing functional units of heredity.” Id. art. 2.
3. See generally GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 1 (2000) [hereinafter DUTFIELD, INTELLECTUAL PROPERTY RIGHTS] (stating that plant GR have incalculable value to agriculture, human welfare, and the world economy and that plant GR are perhaps the most important category of biological resources); GRAHAM DUTFIELD, INTELLECTUAL PROPERTY, BIOGENETIC RESOURCES AND TRADITIONAL KNOWLEDGE 18–20 (2004) [hereinafter DUTFIELD, BIOGENETIC RESOURCES] (discussing the commercial importance of biogenetic resources and traditional knowledge); MITSUO MATSUHITA ET AL., THE WORLD TRADE ORGANIZATION: LAW, PRACTICE AND POLICY 413 (2003) (describing the impact of Article 15 of the Convention of Biological Diversity on access to genetic resources).
6. Id. art. 7.
7. Id. art. 1.
8. Id.
ensure that GR would not be monopolized by the private sector but would benefit all humans. The designation of GR as a part of the common heritage of mankind (CHM) would help reduce national control of GR and thus make the resources more easily accessible.

The idealistic equation of GR with CHM notwithstanding, it is difficult to vindicate the universal prevalence of the move, particularly in light of current developments. First of all, the Undertaking, which is soft law in nature, is not a legally binding instrument. Secondly, the notion of equating GR with CHM has hardly been practiced by either developed or developing nations. Developed countries initially expressed reservation to the idea promoted by the Undertaking. It is also clear that the doctrine of global genetic commons is no longer honored, even by the developing world. Rather, developing countries have already been inclined to argue that GR should be under sovereign domain and to favor a strong and effective national regulation of GR access within national boundaries.

Third, the global commons of GR would meet with difficulties in its management. Given that most GR, apart from those located under the high seas, are within certain countries’ boundaries, the internationalization of GR would certainly encounter resistance from GR-providing nations.

The tendency during recent decades has been to shift from the global commons approach to GR to the sovereign dominance approach. In particular, developing countries continue to voice intolerance and resentment toward biopiracy and misappropriation of their GR. These nations consider tighter regulation of GR access

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9. Jeffery, supra note 4, at 758 n.58 (further observing the failure of the Undertaking to achieve its primary purpose).

10. Atul Kaushik, The Indian Experience in the Field of IPRs, Access to Biological Resources and Benefit Sharing, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 255, 256 (Christophe Bellmann et al. eds., 2003); see also Sabrina Safrin, Hyperownership in a Time of Biotechnology Promises: The International Conflict to Control the Building Blocks of Life, 98 AM. J. INT’L L. 641, 644–45 (2004) (tracing the transition from common ownership of genetic information to more restricted ownership).

11. Safrin, supra note 10, at 644 n.15.

12. Jeffery, supra note 4, at 759.


14. Biopiracy means “the unauthorized, uncompensated removal of genetic resources from a source country.” See Jeffery, supra note 4, at 757, n.53 (defining biopiracy in the context of regulation). Developing countries have endeavored to revoke bad patents that were granted as a result of biopiracy. See also Kuei-Jung Ni, The Incorporation of the CBD Mandate on Access and Benefit-Sharing into TRIPS Regime: An Appraisal on the Appeal of Developing Countries with Rich Genetic Resources, 1 ASIAN J. WTO & INT’L HEALTH L. AND POL’Y 433, 437–38 (2006) (discussing cases of biopiracy harming countries with rich genetic resources and such country’s attempts to revoke bad patents obtained by biopiracy). See generally DUTFIELD, INTELLECTUAL
and fair benefit sharing to be essential in preventing the injustice of biopiracy and assuring equity in bioprospecting.

The conclusion of the CBD in 1992 echoed the call for proper control of GR mainly by requiring a fair and equitable sharing of GR interests as one of its three objectives. Concerning its authority and competence to regulate GR access, the CBD confers power to contracting parties while reaffirming the sovereign rights of states over GR. Though skepticism toward the CBD mandate remains, the sovereign control of GR is arguably a reflection of customary international environmental law. Further, given the worldwide accession to the CBD and the irreplaceable function of national governments in this regard, national authority has already played a crucial role in regulating GR.

More importantly, the CBD stipulates the regime of access to and benefit sharing (ABS) of GR. The prior informed consent (PIC) requirement, borrowed from a restriction on doctors’ ability to treat
patients, is incorporated into ABS. A PIC requirement that obliges GR users to seek consent from GR providers before accessing the resources in question may reduce the effects of biopiracy and unchecked bioprospecting that disrespect the free will of GR providers. The mechanism can also ensure ‘fair access’ to GR. Most national legislatures use PIC as a core element and condition of the approval of applications for GR access.

A variety of national and international stakeholders are interested in GR access; it is essential to take their interests into account in implementing the PIC mandate. Local GR providers, indigenous peoples, and local communities should be allowed to voice their concerns on any access project because GR in their territories are often integral components in their traditional life and culture. Bioprospecting researchers and companies have an interest in GR exploration because the value of GR can hardly be realized or commercialized without the use of their advanced biotechnology. In effect, they may assert that the freedom of bioprospecting and research should be recognized, and they oppose unnecessary restrictions on GR exploration. Of course, as major and dominant GR providers, national governments may consider themselves indispensable actors in regulating activities under their jurisdiction, including exploration of GR.

In practice, because political and social structures in individual nations differ, there seems to be no entirely consistent pattern of PIC requirements. Some legislatures recognize the decisive role of indigenous or local communities in the operation of PIC, making access to GR impossible without their genuine consent. However, to ensure more efficient access, several governments control the PIC process so as to make the will of local people relatively marginal or to

21. See infra Part II.A (discussing the incorporation of PIC into international environmental law).
22. See infra Part III (reviewing the different national practices implemented to achieve PIC).
23. See Jeffery, supra note 4, at 791 (arguing for the need to balance commercial profits with the indigenous need for resources).
24. See id. at 790 (mentioning that industry is the driving force of profit creation arising from use of genetic resources). Apart from bioprospecting activities, the disclosure of significant GR involves many scientific stages, including sampling, screening, extracting, testing, undertaking clinical trials, and other steps involving biotechnology. See id. at 755–57, 757 n.51.
25. Scientists and academic researchers are increasingly criticizing the tight control of GR by national governments. See Andrew C. Revkin, Biologists Sought a Treaty; Now They Fault It, N.Y. TIMES, May 7, 2002, at F1 (describing that current biology restrictions prevent justifiable scientific research); Jeffery, supra note 4, at 793 (pointing out that states may unduly restrict access to genetic resources for scientific research because of worry about the exploitation of state resources for commercial purposes).
treat their wishes only as one factor in the determination of whether to grant final consent.\textsuperscript{28} The different practices have drawn criticism and complaints from scholars, researchers, and GR users. Some critics are skeptical of an overly burdensome PIC procedure that could make a desirable bioprospecting project collapse unreasonably.\textsuperscript{29} Critics have also targeted the neglect of local voices by national authorities in obtaining PIC.\textsuperscript{30} Further, there is a grave concern that access-restrictive regimes inspired by the CBD “have driven companies away from bioprospecting.”\textsuperscript{31} Thus, not surprisingly, it is argued that the increasingly excessive protection of GR by national authorities should be replaced by a more access-friendly system of GR regulation.\textsuperscript{32}

After the CBD, which confirmed states’ authority to regulate GR access, international efforts to ensure better implementation of ABS continue to make progress. In addition to the CBD Bonn Guidelines,\textsuperscript{33} which promise capacity building for contracting parties, especially developing countries, efforts have focused on negotiating and elaborating an international regime on ABS with possible enforcement power.\textsuperscript{34} Of course, the treatment of PIC in the current draft of the proposed international regime merits assessment given the document’s potentially binding nature.\textsuperscript{35}

The increasing global concern over the GR access system cannot produce a satisfactory outcome without proper enforcement on a local basis. This Article will, therefore, engage in a comparative study concerning how genetically-rich nations implement the PIC requirement with a view toward examining whether the objectives of the CBD have been fulfilled. Following the analysis of the legal implications of PIC embodied both in national and international

\textsuperscript{28}. Id. at 652.
\textsuperscript{29}. Id. at 655–57 (assessing a failing bioprospecting project between a U.S. government agency and Mexican indigenous peoples).
\textsuperscript{30}. Id. at 658–60 (arguing that a robust state GR control ignoring the consent right of local GR providers “threaten[s] the autonomy and interests of individuals and indigenous communities”).
\textsuperscript{31}. Id. at 668.
\textsuperscript{32}. Id. at 668, 680–85 (arguing that a more open system of access to genetic material would encourage innovation, promote conservation of such material, and facilitate collaboration between developed and developing countries and highlighting significant problems with sovereign ownership and control of genetic material).
\textsuperscript{34}. See infra Part II.C.
\textsuperscript{35}. See id.
contexts, this Article argues for an optimal normative construction of PIC, either locally or globally.

After reviewing PIC’s origin and its application by international environmental rules, Part II continues to disclose the legal implications of PIC under the CBD and its subsequent developments. Part III engages in a comparative study of national implementations of PIC, particularly by analyzing their pertinent laws and regulations. The analysis of developing countries’ practices constitutes the major content, given that most of the world’s GR are located within their territories. Further, in light of an overall assessment of the global and local practices, Part IV will reveal some critical issues facing the PIC system with a view toward proposing a regime better designed to serve the interests of all humankind. Finally, Part V offers a conclusion.

II. THE CBD AND SUBSEQUENT LAW MAKING OF PIC ON GENETIC RESOURCES ACCESS

A. The Origin of PIC and Its Incorporation in International Environmental Rules

Informed consent constitutes a cornerstone in the patient–physician relationship. In effect, physicians are obliged to “disclose information to the quality of a patient’s or subject’s understanding and consent.” The patients are entitled to be informed of any risk and consequence of medical treatment. In addition, medical treatment normally cannot proceed without this informed consent. Informed consent is concerned with minimizing risk and “avoiding unfairness and exploitation.” However, the practice of mandating informed consent has also evolved to protect patients’ and

36. However, some access systems in developed countries may provide a useful reference and experience. For instance, the U.S. Yellowstone National Park has signed agreements with bioprospectors to engage the latter in research on bioresources within the park. Further, the U.S. has prescribed laws and regulations over GR access in its national parks. See Communication from the United States, Access to Genetic Resources Regime of the United States National Parks, IP/C/W/393 (Jan. 28, 2003), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. Australia has also developed legal systems regarding access to its rich GR, such as in the area of the Great Barrier Reef. See Sally Petherbridge, Australia: Draft Regulations on Access and Benefit Sharing, in Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity 201, 201–23 (Santiago Carrizosa et al. eds., 2004); see infra Part III.F.


38. Id.

39. Id.

40. Id.
subjects’ right of autonomy. In the practice of medicine, informed consent proceeds via the following five-step sequence: (1) competence; (2) disclosure; (3) understanding; (4) voluntariness; and (5) consent.

PIC has effectively been incorporated into international environmental rules—it has already become a useful mechanism in regulating the transboundary movement of substances that may pose risks of potential harm to national or local environments. For instance, the Basel Convention requires that hazardous waste not be exported without written consent from the importing state. Upon receipt of a request to export waste, the importing state may respond to the request by consenting, denying the transboundary movement, or requesting additional information. Additionally, the recent Cartagena Protocol on Biosafety has effectively helped to regulate the international movement of Living Modified Organisms (LMOs). To safeguard the domestic health and environment, the Protocol employs a similar mechanism to that of the Basel Convention, requiring an advance informed agreement (AIA) prior to any transboundary movement of LMOs. The procedure to secure an AIA also mirrors the rules of the Basel Convention.

Overall, states’ observance of PIC represents a sort of good neighbor policy. Forms of PIC modified to fit the needs of individual multilateral environmental agreements (MEAs), rather than used uniformly, have been applied regularly in MEAs as a mechanism to ensure respect for the autonomy of nations likely to be affected by transboundary activities. Of course, the implementation of PIC could also safeguard national public interest from undesirable damage as a result of unregulated transnational activities.

B. The CBD and Bonn Guidelines

During the era of free access to GR, national governments, indigenous peoples, and local communities were generally not formally informed of any bioprospecting activities occurring within their territories. As a result, the biosearching activities were

41. Id.; see also ROBERT M. VEATCH, THE BASICS OF BIOETHICS 72 (2d ed. 2003) (discussing the importance of informed consent in patient care and human subject research).
42. BEAUCHAMP & CHILDRESS, supra note 37, at 79.
44. Id. art. 6(2).
46. Id. art. 7.
47. Id. arts. 8–10, 12; Basel Convention, supra note 43, art. 6.
conducted without the approval or consent of the relevant stakeholders. Of course, bioprospecting can lead to the discovery of valuable GR, which can lead to large profits. Nevertheless, unregulated exploration often causes damage to the territory being explored. Thus, the CBD incorporates the spirit of PIC into the GR access regime, providing that “[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.” The CBD simply declares its intention to mandate PIC in the GR access process without defining it. In effect, a GR user is required to obtain PIC before accessing GR in states that possess GR. GR providers are entitled to choose whether to consent to such applications. However, the CBD itself does not articulate the details of the requirement.

The absence of both a clear definition of the term and a detailed configuration of the PIC system to sustain it leaves much to be filled in. The single provision of the CBD alone cannot provide resolution for a variety of issues that may be of critical importance, including, inter alia, the following:

1. Who is entitled to consent to GR access: national governments, private owners, or local communities?
2. Should PIC consent be granted on a single-subject or multi-subject basis?
3. What are the specific rights and obligations allocated among GR providers and users? For instance, what sort of information should GR users submit to obtain the consent?
4. What is the due procedure governing a PIC system? What role should PIC play in the context of access to GR?

At the CBD’s fifth meeting in Nairobi, Kenya, in May 2000, the Conference of the Parties (COP) created an Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing (Working Group),

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49. Id. at 790.
51. CBD, supra note 1, art. 15(5).
52. See Jeffery, supra note 4, at 786 (observing that uncertainty as to who owns the consent right will create particular difficulties for bioprospectors because the GR users will not be able to “determin[e] with whom they should be providing information and from whom they should be containing consent”).
53. See also Laurel A. Firestone, You Say Yes, I Say No; Defining Community Prior Informed Consent Under the Convention on Biological Diversity, 16 GEO. INT’L. ENVTL. L. REV. 171, 185 (2003) (dissecting the elements under the CBD); Jeffery, supra note 4, at 786 (discussing the requirements, methodologies and procedures used in implementing a PIC); Chasek et al., supra note 50, at 72–74 (discussing difficulties in determining whom to inform and what information should be disclosed).
which aims to help nations implement the ABS regime by developing guidelines and other approaches.\textsuperscript{54} Engaging in negotiations and deliberations in Bonn, Germany, during October 2001, the Working Group finished a draft of the Bonn Guidelines.\textsuperscript{55}

At its sixth meeting, in the Hague in April 2002, the COP adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.\textsuperscript{56} The Bonn Guidelines are designed to assist parties in effectively and optimally implementing the ABS mandate.\textsuperscript{57} Despite their voluntary nature,\textsuperscript{58} the Guidelines may help clarify the otherwise vague access and benefit-sharing provisions of the CBD.\textsuperscript{59}

The Guidelines provide a roadmap to assist relevant GR players, such as GR providers, users, and indigenous and local communities, in realizing their duties and rights within the ABS regime.\textsuperscript{60} As a result, the major contributions of the Guidelines are to help nations identify the steps involved in the process of ABS and to provide them with useful guidance in the design and establishment of an appropriate national regime.

Like the CBD, however, the Guidelines do not define PIC; nonetheless, the instrument does formulate a set of useful references upon which parties may rely to achieve better management of a PIC system.\textsuperscript{61} Primarily, it specifies certain basic principles of a PIC system, which include:

\begin{enumerate}
\item Legal certainty and clarity;
\item Facilitation of access to genetic resources at minimum cost;
\item Restrictions on access to genetic resources that are transparent, based on legal grounds, and that do not run counter to the objectives of the Convention; and
\item Consent of relevant competent national authorities in the provider country, and also consent of relevant stakeholders, such as
\end{enumerate}


\textsuperscript{56.} Id. ¶ 12.

\textsuperscript{57.} Id. ¶ 11.

\textsuperscript{58.} Id. ¶ 7.

\textsuperscript{59.} However, irrespective of their usefulness, the Guidelines do not aim to change the rights and obligations of contracting parties under the Convention on Biological Diversity. See id. ¶ 2 (highlighting how a party’s obligations under the CBD remain unaffected).

\textsuperscript{60.} Id. ¶¶ 13–16.

\textsuperscript{61.} Id. ¶ 26.
indigenous and local communities, as appropriate to the circumstances and subject to domestic law.\textsuperscript{62}

The application of the principles of legal certainty, economy, and transparency in PIC will help national GR access systems facilitate bioprospecting and avoid unnecessary barriers and restrictions against GR prospective users.\textsuperscript{63} The principles send a clear message to national governments that they should refrain from abusing or misusing the system and are expected to run it on a fair and open basis.

Moreover, with respect to which entity has the legal power to consent, principle (4) clearly specifies that competent national authorities (CNAs) are the primary entities that can consent to GR access.\textsuperscript{64} However, principle (4) also acknowledges the important role of indigenous and local communities in the consent process—they may share the right to consent in accordance with domestic law. The move to support the participation of relevant stakeholders in a PIC process is significant and suggests progress. Yet, the phrase “as appropriate to the circumstances and subject to domestic law” indicates that local stakeholders’ consent carries less weight than that of CNAs.\textsuperscript{65}

In addition, some suggested elements of a PIC system are as follows:

(a) Competent authority(ies) granting or providing for evidence of prior informed consent;
(b) Timing and deadlines;
(c) Specification of use;
(d) Procedures for obtaining prior informed consent;
(e) Mechanism for consultation of relevant stakeholders; [and]
(f) Process.\textsuperscript{66}

The Guidelines indicate the establishment of a CNA as the critical element for running a PIC system. Despite the possible difficulty of establishing such an authority in certain countries,\textsuperscript{67} a well-functioning authority responsible for PIC may reduce

\textsuperscript{62} See Jeffery, supra note 4, at 797 (outlining the necessary elements for a PIC system to succeed).
\textsuperscript{63} Bonn Guidelines, supra note 33, ¶¶ 15, 28, 32 (describing the ability of national authorities to retain control over consent or to delegate that control to another party).
\textsuperscript{64} Id. ¶ 26.
\textsuperscript{65} Id. ¶ 27.
\textsuperscript{66} See Jeffery, supra note 4, at 798 (pointing out that the factors causing such difficulty include the system of government in a particular country; the overlapping jurisdiction of various agencies, and the interface with established legal rights of indigenous and local communities associated with the genetic resources being accessed).
transaction costs for the private sector. More importantly, the establishment of a CNA would curtail notorious biopiracy activities. As Jeffrey has argued, “[T]he establishment of competent national authorities and the appropriate focal point to coordinate and disseminate access information may also serve to discourage biopiracy, some of which may owe its existence to frustration in obtaining relevant information as opposed to deliberate intention to avoid obtaining PIC.”

Moreover, element (1) further elaborates on basic principle (4) by reiterating that a PIC application, in principle, shall be obtained from the CNA of a contracting party that possesses GR. Meanwhile, the authorities governing the system are required to respect the “established legal rights of indigenous and local communities associated with the [GR] being accessed.”

Element (2) simply calls for PIC to be sought adequately in advance so as to be meaningful for both those seeking and those granting access. To avoid unreasonable delay, national authorities are expected to make the decision on applications for access “within a reasonable period of time.”

Element (3) suggests that PIC be based on the specific uses for which consent has been requested. A new application for PIC may be required upon any change of use, including transfer to third parties.

In particular, the Guidelines provide a number of constructive clues as to what information should be submitted by GR applicants under element (4). The suggested list contains the following items:

(a) Legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution;
(b) Type and quantity of genetic resources to which access is sought;
(c) Starting date and duration of the activity;
(d) Geographical prospecting area;
(e) Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;
(f) Accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization);
(g) Identification of where the research and development will take place;
(h) Information on how the research and development is to be carried out;

68. Id. at 799.
69. Id.
70. Bonn Guidelines, supra note 33, ¶ 28.
71. Id. ¶ 31.
72. Id. ¶ 33.
73. Id. ¶ 34.
(i) Identification of local bodies for collaboration in research and development;
(j) Possible third-party involvement;
(k) Purpose of the collection and research and expected results;
(l) Kinds/types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from the commercial and other utilization of the genetic resource;
(m) Indication of benefit-sharing arrangements;
(n) Budget;
(o) Treatment of confidential information.\textsuperscript{74}

The proposed list of required information should be complete and sufficient so as to facilitate reasonable, informed decision making by national authorities. However, for researchers or companies, the disclosure of sensitive or confidential information poses a significant challenge, especially in the case of information relating to research and development, as suggested in item (8) above.\textsuperscript{75} There is some concern that the demand for disclosure of information contradicts the parties’ right to confidentiality.\textsuperscript{76} Thus, not surprisingly, a commentator is skeptical of applicants’ willingness to submit information critical to their business or research.\textsuperscript{77}

In addition, difficulties may arise as to how to ascertain or evaluate the promising benefits of GR access when the GR exploration in question has yet to proceed. “[T]he high risk and concomitant lack of certainty involved in commercialization of genetic resources” may also frustrate efforts to identify real benefits relating to the resources.\textsuperscript{78} Item (12) simply suggests submitting the “kinds or types” of such benefits instead of detailed benefits; however, this allowance may reduce the burden of disclosure for GR applicants.

The content of the suggestions in the list will continue to be questioned. The Guidelines do indicate, however, that the disclosure of information included in the list is optional and that its use may be adapted to national special needs.\textsuperscript{79}

The Guidelines do not specify details on element (5) either. It is clear, however, that a PIC system could not operate in an optimal manner without the formulation of a mechanism for consultation of relevant stakeholders.\textsuperscript{80}

\begin{thebibliography}{99}
\bibitem{74} \textit{Id.} ¶ 36.
\bibitem{75} Chasek et al., \textit{supra} note 50, at iii.
\bibitem{76} \textit{Id.}
\bibitem{77} E\textsc{lli} Louka, \textsc{International Environmental Law: Fairness, Effectiveness, and World Order} 313 (2006).
\bibitem{78} Jeffery, \textit{supra} note 4, at 801.
\bibitem{79} Bonn Guidelines, \textit{supra} note 33, ¶ 36.
\bibitem{80} This element of PIC echoes the Guidelines’ device on “Participation of Stakeholders” at Part III, proposing that relevant stakeholders should be consulted and their views taken into consideration on ABS issues. In addition, the Guidelines
\end{thebibliography}
With respect to element (6), in terms of the form of applications to obtain PIC and the decisions on the grant, the Guidelines require the process to be “documented in written form.” \(^{81}\) GR access, as suggested, could be granted “by issuing a permit or license.” \(^{82}\)

The Bonn Guidelines aim to aid parties in building their capacity to implement an ABS regime, but they are not legally binding. Using the term “should” instead of “shall” has relieved contracting parties of many obligations under the Guidelines. However, the Guidelines do provide countries with a useful reference, such that the influence of the document should not be underestimated. \(^{83}\)

Admittedly, the Guidelines’ perspective on PIC may clarify some of the questions raised above in this Subpart and may help parties manage a PIC system. Overall, the Guidelines are delicately constructed and are devoted to the creation of a balance of rights and obligations between PIC seekers—namely GR applicants—and consent givers, CNAs and domestic stakeholders with a view to encouraging the disclosure of necessary information and avoiding the abuse of consent rights. However, in terms of distributing consent power among domestic entities, the Bonn Guidelines have confirmed the primary legal capacity and indispensable role of national authorities in governing a PIC system. \(^{84}\) Though the instrument clearly emphasizes the significant status of indigenous and local communities in a PIC mechanism, nations maintain the discretion to determine what role they will play.

Lastly, in balancing the major power of CNAs in granting PIC, the Bonn Guidelines also call for authorities to be responsible for the design and monitoring of a national ABS regime, including matters of GR access. \(^{85}\)

advise contracting parties to set up national consultative committees to include relevant stakeholder representatives. \(\text{Id.} \ ¶¶ 18–19.\)

\(^{81}\) \(\text{Id.} \ ¶ 38.\)

\(^{82}\) \(\text{Id.} \ ¶ 39.\)

\(^{83}\) \text{See} Jeffery, \(\text{supra} \) note 4, at 795 (arguing that effective Bonn Guidelines are critical to overall success of the CBD).

\(^{84}\) \(\text{Id. at} \) 798–99.

\(^{85}\) The Bonn Guidelines provide the following:

Competent national authorities, where they are established, may, in accordance with applicable national legislative, administrative, or policy measures, be responsible for granting access and be responsible for advising on:

(a) The negotiating process;
(b) Requirements for obtaining prior informed consent and entering into mutually agreed terms;
(c) Monitoring and evaluation of access and benefit-sharing agreements;
(d) Implementation/enforcement of access and benefit-sharing agreements;
(e) Processing of applications and approval of agreements;
(f) The conservation and sustainable use of the genetic resources accessed;
C. The Proposed International Regime

1. An Overview of the Regime to Enforce PIC

The non-binding character of the Bonn Guidelines may not satisfy the expectation that the CBD should play a more dominant role in the supervision and facilitation of ABS for genetic resources. Accordingly, a special international institution empowered with legally binding instruments and concerted enforcement devices was initiated shortly after the adoption of the Bonn Guidelines.

The idea of an international regime to govern ABS for genetic resources originated at the World Summit on Sustainable Development held in Johannesburg in September 2002. Paragraph 42(o) of the Plan of Implementation adopted by the Summit explicitly called for action to “negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.”

The task of formulating the context of the international regime was allocated to the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing with the aim of addressing the process, nature, scope, elements, and modalities of the regime. A preliminary work prepared by the Working Group regarding the negotiation of an international regime was then submitted at the seventh meeting of the COP to the Convention on Biological Diversity in Kuala Lumpur, Malaysia, in February 2004. Section D of Decision VII/19 adopted by the COP addressed the “International Regime on Access to Genetic Resources and Benefit-Sharing.” The decision also requested that

(g) Mechanisms for the effective participation of different stakeholders, as appropriate for the different steps in the process of access and benefit-sharing, in particular, indigenous and local communities;

(h) Mechanisms for the effective participation of indigenous and local communities while promoting the objective of having decisions and processes available in a language understandable to relevant indigenous and local communities.

Bonn Guidelines, supra note 33, ¶ 14.


88. Id.

the Working Group, with the collaboration of the Ad Hoc Open-Ended Inter-Session Working Group on Article 8(j), ensure the wide and effective participation of relevant ABS stakeholders, including indigenous and local communities and NGOs, among others.90

Further, the terms of reference underlying the process, nature, scope, and elements for consideration in elaboration of the regime are included in the annex to Decision VII/19 D.91 In contrast to the literally non-binding nature of the Bonn Guidelines, the terms of reference suggest that the instruments of the regime could be of a legally binding character in order to effectively safeguard the ABS mandate of the CBD.92 In addition to genetic resources, it also expands the scope of the regime to the protection of traditional knowledge (TK), innovations, and practices originally covered by Article 8(j) of the CBD.93 In terms of access to GR, the draft contemplates that the regime should give indigenous and local communities a more vocal status. In effect, it suggests that measures to ensure compliance with the PIC of these local groups holding TK associated with GR should be considered by the Working Group as a component of the regime.94

The content of the international regime was further refined during meetings of the Working Group based upon Decision VII/19 D.95 At its eighth meeting in Curitiba, Brazil, in March 2006, the COP adopted decision VIII/4 A,96 in which a more delicate arrangement of the designated international regime was revealed in its Annex.97 Yet much of the language, with or without compulsory effect, remained undecided. Thus differential, even conflicting, views were marked with brackets. The 2006 text simply reflects the divergent visions of all parties,98 subject to future negotiations.99

90. Id. at 300.
91. Id. at 301.
92. Id.
93. Id.
94. Id. at 302.
95. See International Regime on Access and Benefit Sharing, supra note 87 (noting that two meetings were held by the Working Group in Bangkok, Thailand, Feb 14–18, 2005, and in Granada, Spain, Jan. 30–Feb. 3, 2006, respectively)
97. Id. at 54.
98. See generally Chee Yoke Ling, CBD Meeting Ends with Draft Elements of Access and Benefit Sharing Regime, THIRD WORLD NETWORK, Feb. 3, 2006, http://www.twnside.org.sg/title2/twninfo342.htm (showing that there were disagreements on many issues among developed and developing countries, including the following: the need for a new instrument and whether it should be legally binding;
On the element of PIC covered by the mandate of the regime, the text reiterates the authority of GR-providing parties to grant PIC. More importantly, the text expands the scope of PIC to include interaction between contracting parties of origin and contracting parties that are not countries of origin of the GR but hold certain GR. This design requires the latter to restrict access to any GR in question without the PIC of the former, which may reinforce the consent right of GR origin countries.

Certainly, the most novel and ambitious initiative pursued by the international regime is the establishment of a compliance and enforcement mechanism. Not surprisingly, the international regime may play a key role in ensuring compliance of the countries providing GR with regard to PIC. In effect, it might be the regime’s task to prevent misappropriation and unauthorized access to and use of GR, which, of course, includes GR access without PIC. However, the proposed text has yet to determine whether such an agenda is a mandate of the regime or should be imposed at the regime’s discretion.

In addition, with a view toward establishing a notion of global responsibility to enforce the ABS mandate irrespective of the country of GR origin, the 2006 text obliges all parties to ensure that the utilization of GR within their jurisdictions complies with the CBD and the conditions under which access was granted. Thus, any violation of the mandate by GR users should be sanctioned on a national basis.

Moreover, in response to a number of patents that were granted as a result of the absence of a proper access regime, the 2006 draft restricts recipients of GR from applying for patents related to such resources without PIC. This move simply reflects the general

the inclusion of derivatives and products of genetic resources and associated traditional knowledge; disclosure requirements in applications for intellectual property rights; and enhanced participation of indigenous and local communities in the ABS negotiations).

99. COP Decision VIII/4(A), supra note 96, at 52 (stating that the Working Group was requested to continue the formulation of the regime and to complete its work before the tenth meeting of the COP).

100. Id. at 55.

101. Id.

102. Id.

103. Id. at 59 (providing a list of activities constituting misappropriation, which includes use of GR without compliance with the provisions of the regime).

104. See id. ("[International regime [shall] [may] contain measures to [[promote] and [ensure]] compliance with the prior informed consent of the country providing genetic resources, . . . ."] (emphasis added).

105. Id. at 60.

106. Id.

107. Ni, supra note 14, at 437–39. See generally DUTFIELD, BIOGENETIC RESOURCES, supra note 3, at 52–59 (stating that the undesirable granted patents have been labeled as a result of biopiracy).

views of developing countries with rich genetic resources who favor compliance with ABS requirements as a condition upon which patents related to certain GR can be legally granted.  

Since then, under the intense negotiations and labor of the fifth and sixth meetings of the ABS Working Group, the configuration of the international regime has been further debated and elaborated. At its ninth meeting in Bonn, Germany, in May 2008, the COP adopted a decision confirming the ongoing progress made in the Working Group, mainly highlighting Annex I to the decision. But, as in the 2006 draft, the essence of the objective, scope, and subject matter of the regime remain unsettled, and

109. See Communication from the United States, Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, IP/C/W/434, pt. II (Nov. 26, 2004), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm (stating that the United States supports the generally shared objectives including achieving equitable sharing of the benefits arising from the use of traditional knowledge and genetic resources). Since the launch of the WTO Doha round negotiations, the issue of preventing biopiracy that leads to the grant of undesirable patents based upon illicit access to GR has been formally introduced into the forum. Developing countries have been calling for revision of the TRIPS agreement to oblige member states to mandate a disclosure of ABS elements as a prerequisite to grant patents. Their appeal, however, has met strong resistance from some industrialized countries, especially the United States. See id. (arguing that TRIPS and the CBD agreements can coexist and stating the U. S. position against new patent disclosure requirements); Communication from the United States, Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, IP/C/W/449 (June 10, 2005) (arguing same); see also Communication from the United States, Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, IP/C/W/469 (Mar. 13, 2006) (same). See generally Ni, supra note 14, at 446–58 (analyzing the agendas of developing countries).


112. See generally Fifth Working Group Meeting Report, supra note 110 (illustrating the debate over the configuration of the international regime); Sixth Working Group Meeting Report, supra note 111 (same).


114. Id.

115. Id. at 53.
different “options” for a single issue are plainly presented in the Annex.\(^{116}\)

In contrast to other elements of the regime, the 2008 text has elaborated on the topic of “compliance,” especially by alleviating the attempt of the 2006 draft to oblige GR countries to enforce ABS. Such a development may be a reflection of Switzerland’s balanced compromise approach.\(^{117}\) To distinguish matters on which consensus has been reached from those to be further discussed and negotiated,\(^{118}\) the 2008 draft divides the proposed elements into two categories: first, components to be further elaborated with the aim of incorporating them in the international regime, and second, components for further consideration.\(^{119}\) Under each category, the compliance mechanism is classified into three groups and levels: development of tools to encourage compliance, development of tools to monitor compliance, and development of tools to enforce compliance.\(^{120}\)

The first category actually contains quite few items, referring only to awareness-raising activities, information exchange, and internationally recognized certificates, all of which are relatively soft compliance mechanisms.\(^{121}\) As a result, many critical and controversial issues are placed in the second category and await further discussion. For instance, the second category includes an understanding of the problem of misappropriation of GR, to be considered for the development of tools for encouraging compliance.\(^{122}\) International access standards, largely a concern of GR users, has been raised and negotiated during the meetings of the Working Group. After many developing countries voiced their objection to placement of the item under “development of tools to enforce compliance,” they reached a compromise with the EC and its member states and also placed it under the heading “development of tools to encourage compliance.”\(^{123}\)

Disclosure requirements, a major compliance and enforcement concern of GR-providing countries, fall under the grouping “development of tools to monitor compliance,” as do some technical instruments to support compliance, like tracking systems.\(^{124}\)

The group of components to consider in the “development of tools to enforce compliance” is necessary to ensure the effectiveness of ABS compliance. A number of significant items fall under this heading.

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118. Sixth Working Group Meeting Report, \textit{supra} note 111, ¶ 61.
119. \textit{Id.}
120. COP Decision IX/12, \textit{supra} note 113, at 56–57.
121. \textit{Id.}
122. \textit{Id.} at 57.
123. Sixth Working Group Meeting, \textit{supra} note 111, ¶¶ 62, 68.
124. COP Decision IX/12, \textit{supra} note 113, at 57.
including measures to ensure access to justice, dispute settlement mechanisms, enforcement of judgments and arbitral awards across jurisdictions, information exchange procedures between individual CNAs and benefit sharing to assist GR providers in obtaining information regarding breaches of PIC requirements, and remedies and sanctions.\textsuperscript{125}

To assist the Working Group by providing legal and technical advice, the ninth COP also decided to establish three distinct groups of experts, including an expert group on compliance.\textsuperscript{126}

2. A Critique on the Regime’s Preliminary Design of PIC Compliance

Both the CBD and Bonn Guidelines delegate the major authority in enforcing ABS to GR-providing nations.\textsuperscript{127} The proposal to create an international regime is motivated by the concern that the implementation of ABS solely at a national level would be insufficient to achieve the objective of the CBD. Given the transnational nature of bioprospecting activities, the ongoing lawmaking in relation to ABS demonstrates a resolve to enhance the international regulation of GR by establishing a regime to coordinate and consolidate collective strength. Thus, it is no surprise that the compliance and enforcement mechanism has become a focal point in the negotiations of the designated regime.\textsuperscript{128} From the perspective of GR-providing countries, the prevention of misappropriation and unauthorized access to and use of GR remains their major concern.\textsuperscript{129}

It is obvious that the 2006 configuration may be short of well-balanced because it largely serves the best interests of GR-providing countries, especially GR-origin countries that support a more consolidated international mechanism on ABS.\textsuperscript{130} Arguably, this text

\begin{footnotesize}
\textsuperscript{125} Id.  \\
\textsuperscript{126} See COP Decision IX/12, supra note 113, at 51–52 (showing that the COP established an expert group on concepts, terms, working definitions, and sectoral approaches and an expert group on traditional knowledge associated with genetic resources, in addition to an expert group on compliance).  \\
\textsuperscript{127} See Susan Bragdon et al., Safeguarding Biodiversity: The Convention on Biological Diversity (CBD), in The Future Control of Food ch. 5 (Geoff Tansey & Tasmin Rajotte eds., 2008), available at http://www.idrc.ca/en/ev-119955-201-1-DO_TOPIC.html (stating that the CBD relies on the parties for enforcement and do not include a specific compliance mechanism and that the Bonn Guidelines make little to no mention of enforcement issues).  \\
\textsuperscript{128} COP Decision VIII/4(A), supra note 96, at 58–59.  \\
\textsuperscript{129} See id. (suggesting that the 2006 draft tends to touch upon the issue of preventing grants of intellectual property rights (mainly patents) for an invention that derives from illegal bioprospecting or biopiracy).  \\
\textsuperscript{130} Group of Like-Minded Megadiverse Countries, Ministerial Session, Jan. 20–21, 2005, New Delhi Ministerial Declaration of Like Minded Megadiverse Countries on Access and Benefit Sharing, available at http://www.undp.org/biodiversity/docs/}
\end{footnotesize}
puts disproportionate weight and emphasis on reinforcement of sovereign control over GR by advocating a concerted collective enforcement effort.

The 2008 text, on the other hand, demonstrates the political will to pursue a more balanced approach. The inclusion of both “misappropriation” and “international access standards” in the group of considerations for encouraging compliance reflects compromise between GR-providing and GR-using parties. But this level of compliance mechanism is clearly short of a mandatory and generates only a weak commitment for all parties.

The 2008 draft, like the 2006 draft, calls attention to the issue of disclosure requirements for intellectual property rights (IPR) applications, listing them as one component to consider in the “[d]evelopment of tools to monitor compliance.” However, it leaves the content of the disclosure requirements to be filled in later.

Even though the current text manages to adopt a balanced approach by, inter alia, addressing the issue of international access standards favored by GR-using countries, it seems no solid mechanism has yet been formally crafted to ensure that GR-providing nations may fairly open their GR markets to foreign access. It should be noted that the CBD explicitly requires GR-origin countries to “facilitate” access to GR and “not to impose restrictions that run counter to the objectives of the CBD.” At the very least, in terms of PIC and ABS implementation, it appears that the current draft falls short of providing a necessary mechanism to prevent national governments from abusing their right to reviewing access applications. The failure to create an efficient instrument to monitor whether countries providing GR exercise their sovereign rights in good faith may dissuade developed GR-using countries that favor a

Attachment_18_Accepted_New_Delhi_declaration.doc. It is not difficult to imagine why GR-rich countries, mainly developing countries, favor such an approach. Their views were disclosed in a meeting held in India in January 2005, in which Bolivia, Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, the Philippines, South Africa, and Venezuela participated. See id.

131. COP Decision IX/12, supra note 113, at 56.
132. Id.
133. See COP Decision VIII/4(A), supra note 96, at 58. The 2006 proposal merely reiterates some elements suggested by the Bonn Guidelines, providing that: “Access procedures shall be clear, simple and transparent and provide legal certainty to different kinds of users and providers of genetic resources with a view to the effective implementation of Article 15, [paragraph 2], of the Convention on Biological Diversity.” Id.; see also COP Decision IX/12, supra note 113, at 56 (reaffirming these Bonn principles in the 2008 text). But, according to these texts, no further device can be found regarding the enforcement of such a mandate. As mentioned earlier, there is growing concern and criticism over many access regulatory regimes that have been considered too restrictive. See generally Safrin, supra note 10, at 646–52.
134. CBD, supra note 1, art. 15(2).
reasonable and transparent access system from upholding the regime.\textsuperscript{135}

Of course, as mentioned above, the effort to build an international regime will continue until 2010, and the present proposed text may be modified accordingly. But without first clearly defining the obligations of each party, it would be legally infeasible to build an effective compliance and enforcement mechanism, including a dispute-settlement system. If no definite obligations are imposed on parties to enforce ABS mandates, international institutions hardly have grounds to force a party to deal with a presumed ABS violation.

In spite of the current draft’s noted deficiencies, it is heartening that the present text tends to include a dispute-settlement mechanism as one of the functions to be performed by the regime.\textsuperscript{136} The establishment of an impartial and independent dispute-resolution system will certainly enhance the credibility of the regime\textsuperscript{137} and could ensure the obligations and rights of parties to be squarely performed.\textsuperscript{138}

Whereas the Bonn Guidelines balance the rights and obligations as to PIC between GR users and providers, the proposed international regime must avoid the tendency to serve the interests of GR-providing parties only—i.e., reinforcing the sovereign right of parties over GR—and instead strive for a proper balance of rights and obligations between GR-origin and GR-using countries. It may be acceptable that international access standards would not be mandatory on GR-providing countries,\textsuperscript{139} but the operation of the

\begin{itemize}
\item[135.] See Ling, supra note 98 (showing that during the negotiation of the international regime, developing countries opposed the notion of the “facilitated access” favored by major developed countries). Many developed countries insist that there should be an international obligation to provide access to genetic resources and disfavor the regime to be legally binding instrument. See Chee Yoke Ling, CBD Meeting Dominated by Talks on Access and Benefit Sharing Regime, THIRD WORLD NETWORK, May 29, 2008, http://www.twnside.org.sg/title2/intellectual_property/info.service/2008/twn.ipr.info.080604.htm (summarizing the negotiations related to benefit sharing regime).
\item[136.] Sixth Working Group Meeting Report, supra note 111, § III(C)(2)(3). Most environmental treaties have not yet set up a compulsory dispute-settlement system. Birnie & Boyle, supra note 18, at 226.
\item[137.] See Birnie & Boyle, supra note 18, at 226 (stating that the major function of establishing a dispute-settlement mechanism is to provide an authoritative decision on issues regarding the interpretation or application of a given treaty).
\item[138.] See Uruguay Round of Multilateral Trade Negotiations, Apr. 12–15, 1994, Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22, in General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, 33 I.L.M. 1125, 1226, 1239 (1994) (stating as an example that the Dispute Settlement Body of the World Trade Organization has the power to enforce compliance by imposing sanctions on a breaching party).
\item[139.] It should be kept in mind that by no means are the Bonn Guidelines intended to unify national access regulatory regimes.
\end{itemize}
access regime—namely, the PIC system—must be scrutinized. The GR-providing nations should consider allowing oversight of their national authority in exchange for the willingness of GR-using countries to undertake more obligations to enforce ABS, such as preventing misappropriation and providing for sanctions on the violation of GR-providing countries’ access laws. Otherwise, the future of the international regime may not be bright, and the regime may turn out to be a soft compliance instrument without teeth.

III. NATIONAL PRACTICES OF GENETIC-RESOURCE-RICH COUNTRIES ON PIC REQUIREMENT

Since the inception of the CBD and the subsequent adoption of the Bonn Guidelines, many developing countries rich in genetic resources have started to formulate regulations relating to the implementation of an ABS mandate.\(^{140}\) Part III aims to identify a number of leading national practices and focus on how those nations manage their PIC mechanisms by examining relevant laws.

A. India

India is renowned for its biodiversity and wealth of genetic materials.\(^{141}\) The GR in India, especially plants such as the neem tree and turmeric, have long been explored, identified, and used in traditional practices.\(^{142}\) Indeed, several notable incidents of GR biopiracy and misappropriation have transpired in connection with these plants.\(^{143}\) Such a record may explain why India has been inclined to tighten GR access as much as possible in recent years.

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140. Safrin, supra note 10, at 641 n.4–5, 649 n.56 (stating that more than forty nations have enacted or are drafting ABS laws); see Convention on Biological Diversity, Access to Genetic Resources and Benefit-Sharing Case Studies, http://www.cbd.int/abs/cs.shtml (last visited Jan. 6, 2009) (collecting many national ABS case studies).
141. See DUTFIELD, BIOGENETIC RESOURCES, supra note 3, at 166–67 (stating that India accounts for about 7%–8% of the Earth’s biodiversity).
143. See DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, supra note 3, at 65–66 (stating that the most cited cases of biopiracy of Indian GR are those of bad patents granted for native Indian plants such as neem and turmeric); Suman Sahai, Indigenous Knowledge and Its Protection in India, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY, supra note 10, at 166, 168. For a discussion on the background that promotes international movement toward tightening the access to national genetic raw materials, see Ni, supra note 14, at 437–41; Safrin, supra note 10, at 646–52 (not particularly mentioning the biopiracy issue, but emphasizing the intention of those developing countries to consider GR as green oil and to own it exclusively).
The enforcement of such rigid laws governing GR access is a clear attempt on the part of the Indian government to mitigate problems associated with the previously loose control of GR.\footnote{144}{See Safrin, supra note 10, at 665–66 (providing a general description of the practice of requiring patent applicants to demonstrate compliance with GR access laws); Ni, supra note 14, at 446–59 (analyzing the approach used by India and Brazil to amend TRIPS to mandate all members link patent applications to the observance of access regulations of GR providing nations).}

Enacted in 2002, the Indian Biological Diversity Act\footnote{145}{The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, available at http://envfor.nic.in/divisions/biodiv/act/bio_div_act.htm. For the legal developments regarding the management of Indian biodiversity, see Shalini Bhutani & Ashish Kothari, The Biodiversity Rights of Developing Nations: A Prospective from India, 32 GOLDEN GATE U. L. REV. 587, 605–25 (2002); Kaushik, supra note 10, at 259–62.} is a relatively new piece of legislation that implements the CBD’s mandates in a straightforward manner.\footnote{146}{The Biological Diversity Act § 1. The preamble to the Indian Biological Diversity Act explicitly indicates a close linkage of the law to the CBD. Id.} To echo the call of the Bonn Guidelines in establishing a competent national authority, the law created the National Biodiversity Authority (NBA)\footnote{147}{Id. §§ 8, 18.} responsible for, \textit{inter alia}, regulating attempts to access resources.\footnote{148}{Id. § 2. In terms of ABS system, the bioresources governed by the Indian law are broader than that of the CBD. The former refers to “biological resources,” which means “plants, animals and micro-organisms or parts thereof, their genetic material and by-products with actual or potential use or value.” Id. § 2(c). By contrast, the CBD access regime covers GR only. See generally CBD, supra note 1, arts. 2, 15 (defining genetic resources as “genetic material of actual or potential value” and covering genetic resources only in its access regime).} Foreigners are prohibited from obtaining any biological resources endogenous to India or from procuring knowledge associated thereto for research purposes, commercial utilization, or for bio-survey and bio-utilization without the previous approval of the NBA.\footnote{149}{The Biological Diversity Act § 3(1).} In contrast, Indian citizens may obtain access to biological resources after giving prior notice to the relevant established authority.\footnote{150}{Id. § 7. It has been argued that the differential treatment of foreigners and nationals is rational because it would be easier to bring citizens under jurisdiction than foreigners. Kaushik, supra note 10, at 260. But this argument seems weak because normally foreigners are easily identified.}

The NBA literally monopolizes the PIC system and ignores the consent rights of other local stakeholders because the Indian law only requires the NBA to engage in “consultation” with local biodiversity committees.\footnote{151}{The Biological Diversity Act § 41(2).} Further, there is no established role for individuals, indigenous people, or local groups in the PIC-granting process. The absence of those stakeholders’ contributions to the GR access approval process is indicative of the single-consent nature of the governing statute. Indeed, in a broad sense, the Indian access regime...
represents a very typical model of the centralization of GR control by government.  

Strictly speaking, Indian law that negated the consent rights of other civil GR providers is not considered incompatible with the CBD or Bonn Guidelines because the supranational provisions do not explicitly recognize the consent right of those parties. However, such a move to disregard the consent rights of certain stakeholders seems a clear deviation from increasing international momentum to respect or recognize the right of indigenous and local peoples to participate in any decision or process relating to the usage of natural resources associated with their lives.  Likewise, “the paternalistic model” described by Safrin is likely to pose a challenge to “the autonomy and interests of individuals and indigenous communities.”

B. Brazil

Since 1994, the Brazilian government has initiated several proposals to regulate GR access, though none have resulted in legislative enactments. The Brazilian states of Amapa and Acre, however, have enacted relevant state-level legislation. While the stipulation of any federal GR access law is still pending, the central government relies on a Provisional Measure issued in 2001 to govern ABS matters. The initiative aims to regulate not only access to genetic heritage but also the protection of and access to associated traditional knowledge (TK); it also concerns the transfer of technology relating to the conservation and use of GR and TK. Thus, the regulation seems to pursue a broader objective than that of the original CBD mandate regarding GR management, irrespective of its interim nature.

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153. See infra Part IV.A.
156. Erdos, supra note 155.
157. Medida Provisória No. 2.186-16, de 23 de agosto de 2001 (Brazil), available at http://www.grain.org/brl/?docid=850&lawid=1768. Authorized by Article 62 of the Brazilian Constitution, the President of Brazil has the power to adopt the Provisional Measure. Id.
158. Id. The Brazilian law that applies to genetic heritage rather than genetic resources focuses on the “information of genetic origin.” Id. art. 7(I). The range of the regulation seems broader than that of CBD. Id. art. 7(I).
159. Id. pmbl.
The Provisional Measure created the Council for the Management of Genetic Resources under the Ministry of the Environment as a CNA responsible for the authorization of GR access.\(^{160}\) Notably, such an approval for access can only be given to a domestic public or private institution,\(^{161}\) which appears to exclude foreigners from conducting bioprospecting in Brazil. Such a discriminatory policy might violate Article 15(2) of the CBD, which requires nations housing GR to facilitate GR access for foreign bioprospectors.\(^{162}\)

While the Council governs the approval of GR access applications, the Brazilian Code recognizes the status of GR “owners” in a manner such that the access authorization cannot be granted without the PIC of relevant stakeholders.\(^{163}\) The parties who may give consent are, therefore, quite numerous, including both public and private entities.\(^{164}\) For endangered species from which GR are sought, PIC must be obtained from the competent body;\(^{165}\) otherwise, interested parties who are entitled to give PIC include the following:

1. The indigenous community involved, the views of its official representative body having been heard where access occurs on indigenous territory;
2. The competent body where access occurs in a protected area;
3. The owner where access occurs on private land;
4. The National Defense Council where access occurs in an area indispensable to national security;
5. The maritime authority where access occurs in Brazilian territorial waters, on the continental shelf or in the exclusive economic zone.\(^{166}\)

Exceptionally, a public interest defined by the Management Council may prevail over the will of the stakeholders specified above.\(^{167}\) Therefore, their PIC is not a requirement for access authorization.\(^{168}\)

Although Brazil generally gives stakeholders the right of consent, national authority remains the final decision maker on GR access. Unsurprisingly, as with India, the centralization of GR access has been accused of adversely affecting the inherent interests of individuals and indigenous peoples.\(^{169}\) Nevertheless, in contrast to the want of any PIC from local stakeholders in the Indian legal

\(^{160}\) Id. arts. 10, 11.
\(^{161}\) Id. art. 16.
\(^{162}\) Id. art. 15, § 2.
\(^{163}\) Id. art. 16, § 8.
\(^{164}\) Id.
\(^{165}\) Id.
\(^{166}\) Id. art. 16, § 9 (emphasis added).
\(^{167}\) Id. art. 17.
\(^{168}\) Id.
\(^{169}\) Safrin, supra note 10, at 658–60.
system, the Brazilian model has taken into account the position of GR-interested parties to some extent.

C. The Philippines

The initial regulatory attempt of the Philippines on GR bioprospecting is regarded as one of the earliest national legislative responses to the CBD’s call for incorporating the ABS requirement. In 1995, even before adoption of the Bonn Guidelines, the country preliminarily issued Executive Order No. 247 (EO 247 or the EO), entitled Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes.

The Inter-Agency Committee on Biological and Genetic Resources is charged with the enforcement and implementation of the EO. Operating under the Department of Environment and Natural Resources (DENR), the Committee is composed of representatives from relevant governmental agencies. The approval of a bioprospecting project depends on Committee’s recommendation and the adoption of a research agreement between applicants and the Philippine government.

The EO represents a model GR policy that is extremely supportive of the interests of indigenous peoples and local communities in a PIC process. The EO preserves the rights of those groups to the extent that it sets out a special clause—Consent of Indigenous Cultural Communities—that requires PIC from such communities as a prerequisite for authorization of bioprospecting activities. This clause also mandates that applicants prepare a research proposal to be delivered to the leaders of those communities.

170. See Safrin supra note 10, at 654–55 (noting that the Association of South East Asian Nations (ASEAN), of which the Philippines is a member, concluded the Draft Framework Agreement on Access to Biological and Genetic Resources in 2000, and also noting that, concerning PIC, the draft mandates that all national and local resource providers be involved in the process). The Draft Framework Agreement has yet to be adopted. See GARFORTH ET AL., supra note 155, at 15.

171. GARFORTH ET AL., supra note 155, at 19.


173. Id. § 6.

174. Id. Apart from DENR, the other agencies involved in the function of the Committee include the Department of Health, Agriculture, Science and Technology, Foreign Affairs, and National Museum. Id.

175. Id. § 3.

176. Id. § 2(b).
and deliberations for a period up to sixty days are required before a decision on the application can be made. Furthermore, it is the duty of the Inter-Agency Committee to ensure that the rights of indigenous and local communities are protected. The Committee is also obligated to stipulate guidelines for PIC implementation to assist local communities in the PIC process.

While the EO gives full consideration to the rights of indigenous people of PIC, the EO’s Implementing Rules and Regulations (DAO No. 20) address the interests of other stakeholders. According to the DAO, PIC shall be secured from subjects including the Local Community, Indigenous Cultural Communities or Indigenous Peoples (IPs), the Protected Area Management Board (PAMB), or Private Land Owners. The rules of the DAO also require full disclosure of “the intent and scope of the bioprospecting activity, in a language and process understandable to the community.”

The procedure to obtain PIC from communities was considered burdensome for applicants and was a potential deterrent to proper identification of consent-giving communities. Not surprisingly, at least one critic is skeptical of the effectiveness of the Philippine multiple-consent system and has accused the system of creating a risk of anti-commons.

To some extent, however, the arduousness of the PIC process has been ameliorated by the subsequent enactment of the Wildlife Resources Conservation and Protection Act. The Act effectively addresses its relationship with previous regulations, such as EO 247

177. See id. § 4 (explaining requirement of sixty-day waiting period after delivery of proposals before action is taken).
178. Id.
179. Id. § 7(e).
181. Id. § 2.1(w).
182. Id.
183. Safrin, supra note 10, at 653–54. The “anti-commons” refers to a non-economic outcome in which too many entities own exclusive rights or decision-making powers over limited resources. See Michael A. Heller, The Tragedy of the Anticommons: Property in the Transition from Marx to Markets, 111 HARV. L. REV. 621, 624 (1998) (noting that, in an anti-commons, “multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use. When there are too many owners holding rights of exclusion, the resource is prone to underuse.”).
and DAO No. 20, by superseding inconsistent laws, orders, and regulations. For instance, while the multiple-consent system remains a requirement in accordance with existing laws, the sixty-day deliberation period has been replaced by "a reasonable period." However, despite the revisions, only two access projects had been approved as of early 2004.

D. Costa Rica

Noted for its richness of biodiversity and GR, Costa Rica swiftly implemented the CBD mandate through a comprehensive legal framework on biodiversity. The Biodiversity Law of Costa Rica was enacted in 1998 and managed to coordinate and integrate existing regulations on wildlife, forest, and national park systems. The object of the law almost entirely mirrors that of the CBD.

The law assigns the task of national biodiversity administration to two organs: the National Commission for the Management of Biodiversity (CONAGEBIO) and the National System of Conservation Areas under the Minister of the Environment and Energy. The CONAGEBIO is responsible for the formulation and coordination of GR access policy. It set up a specialized subunit of the Technical Office to review applications for access to biodiversity resources. The Commission may revoke the Office's decisions on project access.

The law specifies that PIC constitutes one of the basic requirements for access approval, so it mandates a double-layered
First, applicants must obtain PIC from local interested parties closely linked to the GR to be used. The legislation expressly identifies the following holders of the consent right: proprietor of the landed estate where activities will take place, an indigenous community in whose territory the GR is located, and the director of the Conservation Area. In order to give full respect to local opinions on GR access, the law further recognizes the right of local communities and indigenous peoples to oppose any access to their resources and associated knowledge because of cultural, spiritual, social, economic, or other concerns.

In contrast to other multi-consent system practices, the Costa Rican law involves the Technical Office in the local PIC process by specifying that the Office’s function includes coordinating PIC access matters with PIC givers. To facilitate the exercise of local PIC, the Office must prepare a model contract upon which those PIC givers may rely to finalize their consent. The Office also has the discretion to make field consultations to verify the terms of PIC, if necessary. The Technical Office plays an active and attentive role in the procedure of obtaining local GR access consent. Of course, the Office cannot override the will of those interested parties if they later decide not to consent to a GR project.

Upon securing such local PIC, any GR access project must then obtain the Office’s final approval to receive access permission. Scant complaints have been raised against the country’s access regulations despite the multi-consent character of its PIC system that fully respects local voices.

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197. Id. art. 63(1)–(2).
198. Id. arts. 63(1), 65.
199. Id.
200. Id. art. 66.
201. Id. art. 17(2).
203. Id. art. 12.
204. See Biodiversity Law arts. 63(1), 66 (noting that prior informed consent from interested parties is a basic requirement for access and that interested parties can decide not to consent to a GR project for any motive at all).
205. Id. art. 63(2).
206. Most of the bioprospecting activities in Costa Rica have been performed by the National Biodiversity Institute (INBio), a nongovernmental, nonprofit association. GARFORTH ET AL., supra note 155, at 12. The Costa Rican practice has often been acclaimed as a model of national implementation of the CBD’s mandate on GR access regimes. The agreement between INBio and Merck, a transnational pharmaceutical company, appears to be one of the most prominent GR access arrangements cited. See Edgar J. Asebey & Jill D. Kempenaar, Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention, 28 VAND. J. TRANSNAT’L L. 703, 725–30 (1995) (noting
E. Peru

A member country in the Andean Community, Peru is renowned for its wealth of bioresources, numbering in the top eight in biodiversity globally. Peru ratified the CBD soon after it was opened for adoption and passed a law implementing it thereafter—the Law on the Conservation and Sustainable Use of the Biological Diversity. The Act focused on conservation issues and does not specifically consider regulation of any GR access system. It simply recognized the role of the state as a party that might participate in the GR access procedure and places some conservation-based limits on such access.

Peru did not establish a comprehensive legal framework on GR access until the 1999 approval of the Decree to Regulate Access to the amount of positive public relations and international media exposure that the signing of the agreement generated for Costa Rica and INBio; Christopher J. Hunter, Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials, 25 B.C. ENVTL. AFF. L. REV. 129, 159–62 (1997) (specifically referring to the agreement as a “landmark contract” and noting that INBio attracted international attention through the signing of the agreement); McManis, supra note 142, at 270 (praising the agreement as a “seminal example” of the type of sustainable bioprospecting access arrangement that countries should be making more of); Gerald J. Mossinghoff, The Biodiversity Convention and Intellectual Property Rights: Conflict or Harmony?, 106 PAT. WORLD 27, 29 (1998), available at http://www.oblon.com/media/index.php?id=203 (“Perhaps the most widely publicized arrangement between a leading research-based pharmaceutical company and a developing country providing access to its biological resources is the agreement between Merck and a non-profit research and conservation organization in Costa Rica—the Instituto Nacional de Biodiversidad or more simply ‘INBio.’”); Safrin, supra note 10, at 684 (“INBio’s agreement with Merck is the most heralded and often-cited bioprospecting agreement. It . . . inspired countries to include terms on access to genetic resources in the Convention [Convention on Biological Diversity], as it served as the primary example of the value of genetic resources and their money-making potential.”).

207. The Andean Pact community includes five nations: Bolivia, Colombia, Ecuador, Peru, and Venezuela. These countries are considered to “harbor the largest proportion of the world’s biological diversity.” Chasek et al., supra note 50, at 34.


211. Id. arts. 3, 4.

212. Id. art. 28.

213. Id. art. 29.
The Decree aimed to assist in the application of Decision 391 of the Andean Common Regime on Access to Genetic Resources. The National Commission of Genetic Resources (CONARGE), as a competent national authority, is bound to enforce GR access regulations; no party can obtain and use GR without a resolution delivered by the Commission authorizing access.

In terms of PIC, the Peruvian decree adopts a multi-consent system and pays due regard to the consent rights of indigenous communities. The regulation does require the express consent of indigenous populations in whose territories GR are located. A summary of the access request must be published in the relevant area, and any interested parties may submit their opinions to the CNA within fifteen days. Access applications to be reviewed by the Authority must include an agreement between the communities and applicants as an accessory contract. Nevertheless, the Decree fails to provide officials with any normative basis by which to facilitate or assist the completion of such an agreement.

Upon the procurement of local consent, access applicants must disclose information to the Authority, including the identification of stakeholders such as the requester, GR providers, involved parties, national support institutions, and responsible technical persons. The applicants must submit a complete and detailed access project. After reviewing the access project and relevant information, the Authority may reject or approve the access in the form of a

215. See id. arts. 1, 2 (“The present Supreme Decree establishes the complementary norms for the application of Decision 391 of the Commission of Cartagena Agreement on the Common Regime of Access to the Genetic Resources.”); Common Regime on Access to Genetic Resources, Andean Community, Decision 391, July 2, 1996, available at http://www.comunidadandina.org/INGLES/normativa/D391e.htm (“The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products . . . .”). The regime provides a common system for the Andean countries dealing with GR access issues. See Chasek et al., supra note 50, at 34 (noting that the regime proceeded from a perceived need for a common system to increase control over the Andean countries’ vast genetic resources); Safrin, supra note 10, at 649–51 (especially pointing out the influence of the regime).
216. Bill to Regulate Access to Genetic Resources, supra note 214, art. 29.
217. Id. arts. 17–18.
218. Id. art. 6. The term “indigenous populations” is defined more broadly in the decree; it comprises “native communities, campesino [communities] and indigenous communities.” Id. art. 1.
219. Id. art. 6(3).
220. Id. art. 12.
221. Id. art. 15. This provision also provides that such accessory contracts shall not prejudice the access agreement between the State and the access requester. Id. arts. 15, 21.
222. Id. art. 11.
223. Id.
resolution. If an access project is approved, the Authority issues a resolution that perfects the access contract between the state and access requester and authorizes access to GR. According to Article 19 of the Decree, this resolution is equivalent to the PIC of the state. However, very few access projects have been approved.

F. Australia

Australia has more biodiversity than most developed nations, with 10% of the world’s species. Approximately 80% of Australia’s native species are not found naturally abroad. Its government is a federal system, consisting of the Federal Government and the eight governments of states and territories. “[E]ach government manages access to biological resources in its jurisdiction under its own laws.” At the federal level, the Environment Protection and Biodiversity Conservation Act 1999 (EPBCA) constitutes the premier legislative instrument for environmental and biodiversity matters in Commonwealth areas. With respect to GR

224. Id. art. 17.
225. Id.
226. Id. art 19.
227. See GARFORTH ET AL., supra note 155, at 13–14 (suggesting that there is only one well-known Peruvian access agreement and a number of obstacles to the signing of more such agreements).
229. Id.
230. The eight states and territories are New South Wales, Victoria, Queensland, South Australia, Western Australia, Tasmania, the Northern Territory, and the Australian Capital Territory. See id. (providing a map and list of the eight Australian states and territories, as well as the Australian external territories).
231. Id.
233. The Commonwealth areas of Australia include:

(a) land owned by the Commonwealth or a Commonwealth agency (including land owned in Norfolk Island) and airspace over the land; (b) an area of land held under lease by the Commonwealth or a Commonwealth agency (including an area held under lease in Norfolk Island) and airspace over the land; (c) land in: (i) an external Territory (except Norfolk Island); or (ii) the Jervis Bay Territory; and airspace over the land; (d) the coastal sea of Australia or an external Territory; (e) the continental shelf, and the waters and airspace over the continental shelf; (f) the waters of the exclusive economic zone, the seabed under those waters and the airspace above those waters; (g) any other area of land, sea or seabed that is included in a Commonwealth reserve.

Id. § 525.
management, Section 301 of the EPBCA, while reflecting the core CBD mandates, simply outlines the framework for future regulations on the control of access to biological resources.\footnote{234}{Section 301 of the Environment Protection and Biodiversity Conservation Act 1999 reads:

(1) The regulations may provide for the control of access to biological resources in Commonwealth areas. (2) Without limiting subsection (1), the regulations may contain provisions about all or any of the following: (a) the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas; (b) the facilitation of access to such resources; (c) the right to deny access to such resources; (d) the granting of access to such resources and the terms and conditions of such access.\footnote{Id.}{\textsection} 301.}

As a result of a lengthy inquiry, a specific and detailed GR rule was finalized in 2005.\footnote{235}{See \textsc{Garforth E\textsc{t} al.}, \textit{supra} note 155, at 23 (referencing the Environmental Protection and Biodiversity Conservation Amendment Regulations 2005 (No. 2), which came into force on December 1, 2005).\footnote{236}{See \textit{generally} Environment Protection and Biodiversity Conservation Amendment Regulations 2005 (No. 2), Select Legislative Instrument 2005 No. 251 (Austl.), available at http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/9A1E98785AA5E3D2CA2570B9000F5A72/$file/MM10491A-050823EV.pdf [hereinafter Australian Environment Protection Regulations].\footnote{237}{Id. \textsection} 8A.06.\footnote{238}{See Australian Government, Department of the Environment, Water, Heritage and the Arts, Access to Biological Resources in Commonwealth Areas, http://www.environment.gov.au/biodiversity/science/access/commonwealth/index.html (last visited Jan. 6, 2009) (explaining that the Genetic Resources Management team within the Parks Australia Division of the Department of the Environment, Water, Heritage and the Arts manages access on most Commonwealth lands and that normally the only way to access such lands is by obtaining a permit). The DEWHA has also accredited the permit systems of other organizations, such as the Australian Government’s Antarctic Division and the Australian Institute of Marine Science. Interview with Officials, Dep’t of the Env’t, Water, Heritage & the Arts, Austl. Govt, in Canberra, Austl. (July 7, 2008) [hereinafter Interview with DEWHA Officials] (on file with author).}} An amendment added a new Part 8A to the existing Environment Protection and Biodiversity Conservation Regulations under the EPBCA, establishing a thorough GR regulatory regime.\footnote{236}{Id.\textsection} 8A.06.

Any person who intends to access bioresources in a Commonwealth area must obtain a permit.\footnote{237}{Id. \textsection} 8A.06. The law treats foreign and domestic bioprospectors the same. Thus, a foreign person can apply for the access permit alone. The Genetic Resources Management section of the Australian Department of the Environment, Water, Heritage and the Arts (DEWHA)—the federal CNA—is responsible for granting access permits.\footnote{238}{See Australian Government, Department of the Environment, Water, Heritage and the Arts, Access to Biological Resources in Commonwealth Areas, http://www.environment.gov.au/biodiversity/science/access/commonwealth/index.html (last visited Jan. 6, 2009) (explaining that the Genetic Resources Management team within the Parks Australia Division of the Department of the Environment, Water, Heritage and the Arts manages access on most Commonwealth lands and that normally the only way to access such lands is by obtaining a permit). The DEWHA has also accredited the permit systems of other organizations, such as the Australian Government’s Antarctic Division and the Australian Institute of Marine Science. Interview with Officials, Dep’t of the Env’t, Water, Heritage & the Arts, Austl. Govt, in Canberra, Austl. (July 7, 2008) [hereinafter Interview with DEWHA Officials] (on file with author).}

The Australian federal access regime adopts a multiple-consent system for GR access sought on indigenous land. With respect to GR access for commercial purposes, the owner of the land or a native

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234. Section 301 of the Environment Protection and Biodiversity Conservation Act 1999 reads:

(1) The regulations may provide for the control of access to biological resources in Commonwealth areas. (2) Without limiting subsection (1), the regulations may contain provisions about all or any of the following: (a) the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas; (b) the facilitation of access to such resources; (c) the right to deny access to such resources; (d) the granting of access to such resources and the terms and conditions of such access.

Id. \textsection} 301.

235. See \textsc{Garforth E\textsc{t} al.}, \textit{supra} note 155, at 23 (referencing the Environmental Protection and Biodiversity Conservation Amendment Regulations 2005 (No. 2), which came into force on December 1, 2005).


237. Id. \textsection} 8A.06.

238. See Australian Government, Department of the Environment, Water, Heritage and the Arts, Access to Biological Resources in Commonwealth Areas, http://www.environment.gov.au/biodiversity/science/access/commonwealth/index.html (last visited Jan. 6, 2009) (explaining that the Genetic Resources Management team within the Parks Australia Division of the Department of the Environment, Water, Heritage and the Arts manages access on most Commonwealth lands and that normally the only way to access such lands is by obtaining a permit). The DEWHA has also accredited the permit systems of other organizations, such as the Australian Government’s Antarctic Division and the Australian Institute of Marine Science. Interview with Officials, Dep’t of the Env’t, Water, Heritage & the Arts, Austl. Govt, in Canberra, Austl. (July 7, 2008) [hereinafter Interview with DEWHA Officials] (on file with author).
titleholder recognized as “access provider”\textsuperscript{239} must give informed consent.\textsuperscript{240} Like the Costa Rican access law,\textsuperscript{241} the Australian rule manages to ensure that PIC proceeds in a meaningful manner and reaches a satisfactory result. The CNA must review the legitimacy of any given informed consent by considering several matters, including the knowledge of an access provider about the governing rules; the capacity of the provider to engage in reasonable negotiations with access applicants; the adequacy of time given to the access provider to consider the application, to consult with relevant people, such as the traditional owners of the land, and to negotiate the benefit-sharing agreement; and independent legal advice about the application.\textsuperscript{242} For noncommercial access, the procedure for obtaining a local PIC is relatively simple and requires only a written permission from each access provider.\textsuperscript{243} In practice, the Australian authority works in partnership with indigenous communities and is keen to assist in their exercise of consent.\textsuperscript{244}

In assessing a permit application, upon its satisfaction that all the PIC requirements have been met, the CNA may consult any person\textsuperscript{245} and will conduct an assessment of environmental impact\textsuperscript{246} to reach a final decision on the permit.\textsuperscript{247}

Based upon the regulations, the Australian government takes the approach of facilitating GR access and making the permit application as simple as possible.\textsuperscript{248} Since 2005, all applications have been approved and around thirty permits issued for noncommercial

\begin{itemize}
\item \textsuperscript{239} In addition to the owner of indigenous people’s land, most access providers refer to “Commonwealth” or “Commonwealth agent.” See Australian Environment Protection Regulations, supra note 236, § 8A.04(1) (providing the definition of “access provider”).
\item \textsuperscript{240} Id. § 8A.10(1).
\item \textsuperscript{241} See supra notes 197–200 and accompanying text (discussing PIC under Costa Rican law).
\item \textsuperscript{242} Australian Environment Protection Regulations, supra note 236, § 8A.10(2).
\item \textsuperscript{243} Id. § 8A.12(1).
\item \textsuperscript{244} Interview with DEWHA Officials, supra note 238; see also Access to Biological Resources in Commonwealth Areas, supra note 238 (stating that Australia seeks to be a leader in the dynamic field of biodiscovery and, in partnership with indigenous people, biotech companies, research scientists and managers of biodiversity, the Australian, State and Territory Governments will ensure practices and advances in biodiscovery are sustainable, inclusive and rewarding).
\item \textsuperscript{245} Australian Environment Protection Regulations, supra note 236, § 8A.15(1).
\item \textsuperscript{246} Id. § 8A.16.
\item \textsuperscript{247} See id. § 17.03A(6) (mentioning other factors to be taken into account in deciding whether to issue a permit, such as the fulfillment of the precautionary principle).
\item \textsuperscript{248} Interview with DEWHA Officials, supra note 238.
\end{itemize}
purposes. Four commercial benefit-sharing agreements have been finalized and another three are currently under negotiation.

At the state and territory level, Queensland enacted its Biodiscovery Act in 2004 and the Northern Territory adopted the Bioresources Act in 2006. In terms of supervising indigenous PIC, the Northern Territory law provides the same content as the EPBC Regulations. The Northern Territory applies the facilitating approach and has approved fifty-five applications for GR access on non-indigenous lands since the inception of the Act. Few access projects have been rejected in the Territory.

To achieve coherent national GR management scheme between governments, each of the nine Australian jurisdictions adopted the Nationally Consistent Approach in 2002. The document states general principles that underpin the development or review of legislative, administrative, or policy frameworks in individual regimes. Nevertheless, some significant inconsistencies among the current three access regimes remain.
In contrast to many GR-rich developing countries’ practices, the Australian system appears indicative of a nation embracing an open policy toward GR access management.

G. Taiwan

1. Rich Genetic Resources in Taiwan and Problems Resulting from a Lack of Proper Regulation

Taiwan enjoys a reputation for abundant GR, although its territory occupies only 0.03% of the Earth’s total land mass. There are 5,000 native plant species in Taiwan that account for 2.1% of the world’s flora. Taiwan’s 29,000 animal species represent 3.4% of the world’s animal species; Taiwan has also more than 10,000 species of microorganisms, accounting for 8.6% of the whole.

The wealth of bioresources in Taiwan has, of course, drawn the attention of bioprospectors. While many foreign individuals, institutions, and companies have been exploring the GR of this island for decades, no legal system has yet been formulated to regulate the activities. Unfortunately, Taiwan has experienced a number of difficulties due to unregulated, uncompensated bioprospecting in the absence of proper regulation.

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259. The CBD regime has proved to be the most influential international institution governing biological diversity mainly because most countries are contracting parties and implement CBD mandates, especially regarding ABS elements. There are two major nations which have yet to accede to the CBD. The U.S. chooses not to join the regime. See Convention on Biological Diversity, List of Parties, http://www.biodiv.org/world/parties.asp (last visited Jan. 6, 2009) (showing that the United States has signed the CBD, but is not a party to the CBD and has not ratified it). Given the unique status of Taiwan, the country is currently not allowed to join most multilateral environmental agreements (MEAs) that generally require statehood as the qualification for their membership. Since, as indicated above, the sovereign control of GR specified in the CBD reflects customary international rule, Taiwan, as a subject of the international communities irrespective of its disputed status, does enjoy jurisdiction over its GR control. Taiwan’s noncontracting party status to the CBD thus cannot diminish the nation’s capacity to engage in the building of a relevant ABS legal system. It is also the Author’s belief that no country would object to Taiwan’s move to control GR. See generally Kuei-Jung Ni, The Status of Taiwan in International Environmental Law, 31 NAT’L TAIWAN U. L.J. 97 (2002) (providing a general review and analysis of Taiwan’s status in international environmental law).


263. Kuo et al., supra note 260, at 38.
For instance, *Nothapodytes nimmoniana*, used to treat colon cancer, provides a leading case. A Japanese company brought the plant, a native species of an offshore island of Taiwan, to southern Taiwan for cultivation upon discovery of its medicinal properties. After extracting the compound camptothecin from the plant, the company has successfully been awarded a number of patents internationally. With the exception of a few local farmers, Taiwan has hardly benefited from the vast commercial exploitation of the plant. This instance of biopiracy was clearly facilitated by the lack of GR regulation in the Taiwanese legal system.

2. The Move to Regulate ABS on Genetic Resources: The State of Play on PIC

International practice has produced two primary GR regulation models. The first model, adopted by India, Costa Rica, and the Philippines, is a formulation of a comprehensive biological diversity law that echoes most of the CBD elements; naturally, GR access control constitutes a part of the law. Some countries, however, opt for a specific law covering GR access or GR management only; Brazil pursued such an approach.

In 2001, the Executive Yuan of the Taiwanese government adopted the Measure to Enforce Biological Diversity, calling for the enactment of GR regulation. The Taiwanese legal systems that currently govern national parks, forests, wild animals, indigenous peoples, and cultural asset preservation are not well suited to carry out a general biodiversity law. The complexity and expense entailed in implementing such regulation have dissuaded decision makers from enacting a comprehensive biodiversity law. Therefore, a consensus has been reached to draft a specific law on GR access.

During 2005, a drafting team comprised of legal and biological professionals was organized and coordinated under the leadership of

265. See id. (explaining patents held by Japanese).
266. See id. (explaining past inability of Taiwanese to exploit the remedy).
268. KUO ET AL. EDS., supra note 260, at 39 (mentioning that the Taiwanese laws relating to GR include National Park Law, Forest Law, Wild Animal Protection Law, Indigenous People Protection Law, and Cultural Asset Preservation).
269. Id.
270. Id.
Professor Kuo at National Taiwan University. After intense consultations and meetings, the team produced a preliminary draft focused on ABS regulation in late 2005.

Generally speaking, the draft, similar to those of India and Brazil, foreign applicants cannot conduct bioprospecting without the participation of local nationals. Instead of establishing an agency, the draft delegates competency over GR to Taiwan’s Council of Agriculture. The draft further requires all GR access applicants to obtain permission from the Council.

In general, the draft distinguishes academic from commercial bio-exploration. It adopts a relatively open policy toward the former, aimed at facilitating the GR access process. In contrast, commercial applicants must fulfill the sound ABS requirements.

With respect to PIC, the draft favors a multiple-consent system to the extent that a GR access project must obtain PIC from the following stakeholders:

- The competent body of the public land where the exercise of a bioprospecting project occurs on public land;
- The indigenous peoples in accordance with Indigenous Peoples’ Basic Law and relevant regulations where the exercise of a bioprospecting project occurs on indigenous peoples’ land;
- The owner where the exercise of a bioprospecting project occurs on private land.

Denial of consent by the above interested parties shall constitute one of the conditions in rejecting an access application.

Taiwan’s approach to PIC is similar to that of the Philippines and Brazil. However, as the law remains in a drafting stage, it is premature to say whether any anti-commons problem will occur. Because the draft takes a comparatively relaxed attitude toward GR access for academic bioresearch, the issue of anti-commons will likely be avoided in those instances. It is, of course, fair to treat GR access for pure research purposes and commercial purposes differently. However, a policy that omits the PIC requirement for the former

274. Id. art. 3. The Council may consult with other organs when necessary. See id. art. 13.
275. Id. art. 8.
276. Id. art. 4, 9.
277. Id. art. 9, ¶ 1.
278. Id. art. 9, ¶ 2.
279. See id. art. 27.
280. Id. art. 23 (4).
raises appropriate skepticism. Given that PIC is intended to preserve the autonomy of stakeholders in participation and decision making, their right to give consent should not be deprived even in the context of GR access for the purpose of pure scientific research. Therefore, the PIC requirement should be maintained in such cases. To avoid imposing unnecessary burdens on academic applicants, the drafters should consider allowing the competent agency to participate in the PIC process or to mediate any disagreement between applicants and the interested parties in such circumstances. To ensure that relevant stakeholders exercise reasonable judgment in granting consent, the drafters should also make detailed rules designed to ensure that GR providers have sufficient information to decide whether to consent.

IV. CRITICAL ISSUES OCCURRING IN PIC PRACTICE: OVERALL ASSESSMENT AND SUGGESTIONS

A. The Role and Status of Indigenous Peoples in Access to Genetic Resources

It is true that the plain language of the CBD does not establish a clear and positive status for indigenous peoples with respect to PIC. 281 The Bonn Guidelines do, however, recognize indigenous peoples as relevant stakeholders whose involvement in the adequate development and implementation of ABS arrangements is essential. 282 The Guidelines also propose that relevant stakeholders should be consulted. 283 To ensure effective participation of stakeholders, national governments should provide information and support for capacity building. 284 Regardless of their useful advice, the Bonn Guidelines, due to their soft-law nature, are incapable of protecting the status of indigenous peoples by obliging nations to recognize fully the peoples’ prerogative regarding PIC. 285

The intimate linkage of indigenous peoples to the territories in which GR exploration often occurs seems to justify their indispensable role in giving consent and participating in the approval process for GR bioprospecting. Jeffery correctly observes that:

These communities are custodians of these resources that form an integral part of their beliefs, practices and cultural traditions. To develop any legal framework that does not fully take into account the needs, aspirations and concerns of these communities and the need to

281. CBD, supra note 1, art. 15(5).
282. Bonn Guidelines, supra note 33, ¶ 17.
283. Id. ¶ 19.
284. Id. ¶ 20.
285. See supra Part II (explaining that the Bonn Guidelines are not legally binding).
provide incentives will inevitably result in a failure with respect to whatever environmental conservation measures are sought to be imposed.286

Not surprisingly, some authors are dissatisfied with current national and international arrangements that give insufficient regard to indigenous peoples’ status in GR access initiatives occurring in their home land.287 In effect, the peoples might be deprived of the right to decide whether to authorize GR access, irrespective of the close relationship between their communities and the GR resources in question.

Safrin identifies two sources of concern that recognizing robust sovereign rights over GR might endanger the interests of local peoples. First, she criticizes that the nationalization of genetic material by states might lead to the suppression of local peoples’ will.288 Thus, given the relatively weak status of indigenous peoples in certain countries, upon encountering a conflict over GR access approval between indigenous peoples and governments, some states may override the wishes of the peoples that disapprove of the project in order to serve their own interest.289 Second, though states do not claim exclusive ownership of GR, Safrin further singles out India and Brazil’s practices of centralized GR access control290 as instances of “paternalism” and suggests that such policies “diminish[] the ability of individual and indigenous communities to control the genetic resources in question for themselves.”291

Any national consent policy that ignores the autonomy and interests of indigenous peoples should be regarded with skepticism. This lack of concern for indigenous peoples is also contrary to recent developments in international law, and the normative position of these peoples in international law informs this discussion to a large extent.

Indeed, since the creation of the United Nations (UN), the international community has formulated numerous documents to uphold the status of indigenous people.292 To some extent, the human rights approach adopted by the instruments may help

286. Jeffery, supra note 4, at 791.
287. See, e.g., Safrin, supra note 10, at 658–63 (discussing the risks that indigenous communities face under sovereign ownership or control of GR).
288. Safrin points out that Colombian law may fit the category, but states that no real incidents reflect such a scenario. Id. at 658.
289. Id.
290. Although the practices of those countries may neglect the interests of local peoples, they also avoid the possible flaw of adopting a multi-consent system of PIC that may unreasonably veto GR access applications in local territory. Safrin considers the multi-consent system may create an anti-commons problem. Id. at 653.
291. Id. at 659.
strengthen the legitimate position of indigenous peoples with regard to PIC and GR access. In particular, the works of the International Labor Organization (ILO) are perhaps the leading instruments in favoring the status of indigenous peoples in each nation whenever any policy or decision making stands to affect their lives and traditions.  

There is much evidence to support the existence of a strong connection between the cultural practices of indigenous peoples and the natural resources surrounding them. Given this exceptional relationship, it would be irrational to neglect their opinions as to whether GR access in their land is permissible. Further, upon full confirmation of an indigenous right of ownership or entitlement to the territory and natural resources, there are persuasive grounds from which to uphold their consent right for GR access. In fact, a number of international documents are inclined to promote indigenous peoples’ rights to the native lands and natural resources adjacent them. For instance, the 1989 ILO Convention Concerning the Indigenous and Tribal Peoples in Independent Countries (No. 169), a progressive improvement upon its previous work in the 1957 Convention (No. 107), requires governments to take steps as necessary to identify the lands traditionally occupied and to guarantee effective protection of those individuals’ rights of ownership and possession. The treaty also proclaims the rights of people interested in the safeguarding of the natural resources pertaining to their lands.

293. See generally International Labor Organization (ILO), Introduction to ILO Convention No. 169 on Indigenous and Tribal Peoples, http://www.ilo.org/public/english/region/ampro/mdtsanjose/indigenous/intro169.htm (last visited Jan. 6, 2009) (summarizing ILO goals and actions to ensure that governments respect the rights of indigenous peoples and that indigenous people are able to participate in decision making and policies that affect them).


295. See Patricia Lucia Cantuaria Marin, Providing Protection for Plan Genetic Resources: Patents, Sui Generis Systems, and Biopartnerships 107 (2002) (advocating application of “prior informed consent” requirement to indigenous peoples’ control over outside access to genetic resources in their rightfully-owned native lands).


297. Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi-Tribal Populations in Independent Countries (I.L.O. No. 107), June 26, 1957, 328 U.N.T.S. 247. One of the major modifications by the latter Convention No. 169 is that No. 169 aims to remove the assimilationist or integrationist orientation of the earlier standards. ILO Convention No. 169, supra note 296, pmbl.

298. ILO Convention No. 169, supra note 296, art. 14.

299. Id. art. 15.
UN efforts to promote and protect the rights of indigenous peoples cannot be overemphasized. The most significant contribution of the UN to date is to conclude the United Nations Declaration on the Rights of Indigenous Peoples in the Human Rights Council in 2006, a document that was subsequently adopted by the UN General Assembly in September 2007. The Declaration was the result of several decades of negotiations based on a previous product of the Working Group on Indigenous Population, a draft Universal Declaration on the Rights of Indigenous Peoples. Echoing the ILO's document, the UN Declaration also recognizes the close relationship between indigenous peoples and their traditionally owned or occupied lands, territories, and resources. In effect, their right to own, use, develop, and control the areas has been affirmed.

From another point of view, it may be safe to say that whether indigenous peoples enjoy a definite right of consent over GR exploration hinges on what role they play in the making of decisions and policy affecting their lives. International society has taken seriously the issues of full participation of indigenous peoples in the dominant society and of true power sharing. The ILO Convention No. 169 (ILO Convention) responds to such needs of indigenous peoples, considerably strengthening their rights with respect to measures that impact them. Article 6 of the Convention provides that concerned peoples should be consulted, through their representative institutions, with regard to legislative or administrative measures affecting them, and that they should participate at all levels of decision making on issues that concern them. Article 7 further recognizes the right of people to decide


303. U.N. Declaration, supra note 301, art. 25.

304. Id. art. 26.


306. ILO Convention No. 169, supra note 296, arts. 3, 6.

307. Id. art. 6.
their own priorities for the development process as it affects their lives, beliefs, institutions, spiritual well-being, and the lands upon which they dwell or otherwise use.308

Like the ILO Convention, the UN Declaration also confirms these privileges of indigenous peoples. In particular, Article 19 of the Declaration incorporates the concept of PIC,309 explicitly obliging states to engage in consultation and cooperation with the peoples concerned in order to obtain their free, prior, and informed consent before adopting any official measures affecting them.310 Further, their right to participate, to be consulted, to give consent, and to determine is reiterated in Article 32, which specifically deals with projects affecting their domain and resources, such as development and utilization or exploitation of their mineral, water, or other resources.311 Of course, such resources should include GR. In terms of PIC and GR access, the provision literally could be the clearest and most powerful ground on which to establish such right of indigenous peoples.

In concluding the discussion of these documents, the great contributions of both the ILO and UN to the promotion of rights of indigenous peoples deserve recognition. Their efforts have been heavily referenced by commentators in order to sustain the essential status of indigenous peoples in the implementation of the Convention on Biological Diversity PIC requirement for GR access.312

From a rigid legal perspective, however, some remain skeptical of the validity of the international documents mentioned above and doubt whether they lay such a solid foundation for indigenous peoples’ status with respect to a biodiversity regime.313 They argue that the weakness of the ILC Convention arises from its scarce endorsement by countries with indigenous populations314 and the limited contribution of indigenous representatives to its drafting.315

Moreover, the text of the CBD deliberately weakens the status of indigenous peoples by “avoid[ing] the use of either the terms ‘rights’

308. Id. art. 7.
309. In addition to articles 19 and 32, a number of provisions of the U.N. Declaration reflect and integrate the idea of PIC, such as articles 10, 11(2), and 29(2). U.N. Declaration, supra note 301, arts. 10, 11(2), 29(2).
310. U.N. Declaration, supra note 301, art. 19; see also ILO Convention No. 169, supra note 296, art. 16 (requiring prior consent of indigenous peoples).
311. U.N. Declaration, supra note 301, art. 32.
312. See MARIN, supra note 295, at 107 n.123, 108 n.127; see also Aguilar, supra note 189, at 178–79.
313. See BIRNIE & BOYLE, supra note 18, at 580 (discussing the ambiguous language of international documents).
314. Id. at 579.
315. See Stamatopoulou, supra note 305, at 66. (“[A]t the International Labor Organization forum almost every article of Convention 169 was voted on and the participation of indigenous representatives during the elaboration of the new treaty was poor.”).
or ‘peoples,’” and by not defining the peoples concerned. Birnie and Boyle thus conclude that “[t]he ambiguous language of the Preamble and Article 8(j) arises from the fact that international law on indigenous peoples and protection of their environment remains controversial.”

Given the uncertainty of the status of indigenous peoples in international law, particularly concerning their rights to nearby genetic resources, it seems that nations do not yet have a definite obligation to recognize a positive right of indigenous peoples to give consent. It may thus be hard to denounce some countries’ policies, such as those of India and Brazil, on grounds that they negate the right of indigenous peoples to consent in a GR access process.

Nonetheless, it should be noted that, in contrast to the CBD and Bonn Guidelines, the adoption of the UN Declaration on the Rights of Indigenous Peoples reflects a relatively novel determination of the international community to protect and promote the rights of indigenous peoples. More importantly, the concept of PIC has been explicitly incorporated into the Declaration, which may strengthen the legitimacy of recognizing indigenous peoples’ PIC rights. Of course, the current CBD that has failed to formally confirm any definite consent right of indigenous peoples prevails over the U.N. Declaration, a non-binding document. However, regardless of the form of soft international law, it is possible that the UN agenda of promoting the human rights of indigenous peoples will inspire or influence the future development of GR access regimes, either in the CBD or in national practices.


Under international law, states enjoy the discretion to adopt either a single- or multiple-consent system of PIC. According to certain aforementioned national laws, local interested parties, like indigenous peoples, are able to share the right of consent to GR access. In effect, national authority would not authorize GR explorations without the approval of the stakeholders.

316. BIRNIE & BOYLE, supra note 18, at 579.
317. Id.
318. Id. at 580.
319. See discussion supra Parts III.A–B (explaining that neither the CBD nor the Bonn Guidelines explicitly recognize the consent right of indigenous peoples).
320. See generally MARK JANIS, AN INTRODUCTION TO INTERNATIONAL LAW 51–52 (3d ed. 1999) (noting that even legally non-binding resolutions of international organizations could be relied on by international tribunals and that the documents may harden into customary international law).
321. As indicated above, a number of national practices, like the Philippines, Costa Rica, and Australia, adopt the system. See discussion supra Part III (discussing
However, the multi-consent system evokes criticism regarding its lack of efficiency and related problems. Sometimes the lengthy process to obtain the consent of local communities can discourage applicants from applying to access GR in that area. For example, to some extent, the Philippine law that adopts an extremely complicated and multi-layered consent process has hindered the attempts of foreign bioprospectors to seek GR access there.\footnote{322}

Moreover, even if local peoples and identities agree, such consent cannot guarantee the ultimate permission of authorities because the final decision for any bioprospecting project may hinge on other considerations.\footnote{323} Thus, costly efforts to win local support may be in vain due to a contrary political decision.

It is true that some experience has underlined unpleasant events owing to the failures of multi-consent PIC schemes. The collapse of the ICBG-Maya project\footnote{324} in Mexico is an infamous failure of multi-consent system.\footnote{325} Indeed, the ICBG (International Cooperative Biodiversity Group) was willing to follow the CBD’s PIC requirement\footnote{326} and made every attempt to secure the approval of the Mayan people.\footnote{327} After nearly two years of consultation and communication,\footnote{328} local ethical groups finally consented to the project.\footnote{329} Nevertheless, NGOs, mainly the Rural Advancement Foundation International (RAFI, now known as ETC Group)\footnote{330} and

\footnote{322. Although a very small portion of bioprospecting applications were finally approved in the Philippines, the national practice there fully respects and protects the rights of local peoples to consent to GR access. See Safrin, supra note 10, at 660 (discussing the access-restricting regime utilized in the Philippines).}

\footnote{323. Costa Rica Decree, supra note 202, art. 14 (providing that the Technical Office will consider public interest criteria, including development options for the future generations, food security, ecosystems conservation, and human health in the evaluation or approval of the application).

324. See International Cooperative Biodiversity Groups (ICBG), http://www.fic.nih.gov/programs/research_grants/icbg/index.htm (last visited Jan. 6, 2009). The ICBG was initiated by the U.S. National Institutes of Health (NIH), aiming to integrate improvement of human health through drug discovery, creation of incentives for conservation of biodiversity, and promotion of scientific research and sustainable economic activity that focuses on environment, health, equity, and democracy. Id.

325. See Safrin, supra note 10, at 655–57 (discussing the failure of the ICBG-Maya project).


327. Safrin, supra note 10, at 656.

328. Id.

329. Id. (stating that nearly fifty Mayan communities expressed their consent to the project and forty-six communities agreed to participate in the project); Hardison, supra note 326, at 1.

330. ETC Group (Action Group on Erosion, Technology, and Concentration) is an international non-governmental organization (NGO) and was known as the Rural
the Consejo de Médicos y Parteras Indígenas Tradicionales de Chiapas (Council of Traditional Indigenous Doctors and Midwives from Chiapas) (COMPITCH), strongly opposed the project for several reasons.\textsuperscript{331} First of all, they disagreed that the ICBG had finalized the local PIC process.\textsuperscript{332} Even though the ICBG never consulted with most of the local Mayan communities, RAFI and COMPICH complained that the group failed to obtain the consent from the traditional community assemblies of the Mayan people.\textsuperscript{333} Further, they considered the information provided by the ICBG to be insufficient, as the group did not disclose detailed information about future treatment and handling of genetic information being collected.\textsuperscript{334} Although neither RAFI nor COMPICH were entitled to officially participate in the GR review process in Mexico, it was obvious that their objections proved so influential that the permission for the ICBG project was blocked.\textsuperscript{335}

However, it seems unfair to contend that the undesirable outcome of the project should be fully attributed to the exercise of a multi-consent system. Instead, the international community should learn from the story to avoid a repeat of the incident. The disappointing conclusion to the process for foreign bioprospectors was actually a result of the lack of PIC regulations. The relevant Mexican law simply provided that “PIC shall be obtained from the legal possessor of the land where sample collecting takes place”;\textsuperscript{336} it failed to define which local entity should be informed and who has the right to give consent, nor did it specify what information the applicants were to disclose.\textsuperscript{337} The normative vacancy and ambiguity created the uncertainty that ignited conflicting views on the PIC regime.

\begin{footnotesize}
\begin{enumerate}
\item[	extsuperscript{331}.] See Hardison, supra note 326, at 1 (explaining that the ICBG-Maya project has come under attack by RAFI and COMPITCH).
\item[	extsuperscript{332}.] Id.
\item[	extsuperscript{333}.] Id.
\item[	extsuperscript{334}.] They worried that “[g]enetic information . . . held in confidentiality by one of the ICBG-Maya partners, could become the unregulated property of another company, should the partner ever sell its assets.” Id.
\item[	extsuperscript{335}.] See Safrin, supra note 10, at 656–57 (explaining that, due to objections by these groups, the bioprospecting permit did not issue).
\item[	extsuperscript{337}.] Jorge Larson-Guerra et al., supra note 336, at 128–30.
\end{enumerate}
\end{footnotesize}
among relevant stakeholders. The dispute between ICBG, RAFI, and COMPICH could have been avoided by clearly delineating the rules of the game. Accordingly, it has become an urgent task for the Mexican government to engage in lawmaking and a capacity-building process so as to fill the normative vacuum and rectify this issue.

The time-consuming process and a variety of complicating factors challenge bioprospecting applicants to predict the final decision of multiple-consent PIC regimes. The risk and cost of a negative decision may be too high and ultimately unaffordable for some potential applicants. However, it appears unrealistic to expect all GR access applications to be approved as long as the final authorization remains at the discretion of national government. GR users must realize this and accept the risk of rejection by GR providers while navigating the GR access system.

C. Reshaping the Function and Role of Competent National Authority

It is quite obvious that international normative structures such as the CBD, as well as national practices, have confirmed the central role of a CNA in a GR access regime. In effect, national governments remain the dominant consent givers for many bioprospecting applications. Irrespective of continuing complaints regarding sovereign control over GR resources, it is difficult to reverse the prerogative of governments. As Jeffery explains:

> National states will continue to play a pivotal role with respect to the development of any international legal framework regulating the access and use of genetic resources due to the fact that it is the States, which retain both sovereignty and responsibility for conserving biodiversity within their jurisdiction. It is primarily for this reason that the implementation of the CBD has devolved upon that nation states and their sovereignty over these resources will necessarily determine the effectiveness of any access and benefit sharing arrangements including the enforcement aspects associated with these arrangements.\(^{338}\)

As the role of a CNA can hardly be replaced, it will serve the best interests of all GR stakeholders for respective governments to manage GR access mechanisms in a transparent, impartial, and effective manner.

First, states should be constantly reminded that they are both the guardians and trustees of GR. The control and management of GR is not only a sovereign right but also a responsibility to promote the public interest. National governments must accept that such a task mandates that they strike a proper balance among the conflicting interests of all interested parties, including bioprospecting researchers or applicants, national conservation organs, local

\(^{338}\) Jeffery, supra note 4, at 791–92.
communities and indigenous peoples, and NGOs. Aguilar correctly observes that “the developing countries must work on ways of acting as the ‘guardians’ of biodiversity at the place where these genetic resources are located and of creating ‘tools’ that will allow them to define the rights and obligations of the different actors involved with respect to access to genetic resources.”

Second, it would be utterly irresponsible for governments to leave a PIC process to be handled by local peoples in countries that recognize the consent of local groups as a prerequisite for the final authorization of a GR project. The role of a CNA as a capacity builder as proposed by the CBD and Bonn Guidelines is essential. Authorities must assist and educate local peoples in exercising rational judgment on a GR proposal so as to give a meaningful consent or a rejection in order to avert any unreasonable veto on GR access. As a result, the multi-consent system could be run in a manner that reduces the anti-commons effect.

In addition, governments could play an even more constructive role. Firestone suggests that governments assume the role of an intermediary in the form of an active negotiating agent or passive supervisor:

An agent would negotiate on the community’s behalf and facilitate a PIC process. Such a body should have the necessary technical and legal capacity, as well as great familiarity and accountability with local communities. A supervising body could observe negotiations and PIC, and provide support as necessary. Such a body might provide a safeguard for abuse and intimidation, without running the risk of imposing its own practices and views on communities. Such a supervising body might also facilitate PIC by housing information on the structure and practices of both communities and access-seekers and could be the first recourse for complaints, questions, or concerns.

The Costa Rican and Australian access regimes exemplify such a role.

Third, the interest of bioprospectors should be properly safeguarded. In particular, a government should not abuse its right of PIC as so to deliberately exclude a reasonable request for GR access, especially from foreign bioprospectors. For instances when local communities have consented but CNAs reject a request, the relevant authority should create an appeal mechanism by which applicants may seek modification of the decision and redress.

Finally, international supervision over CNAs should be established. The CBD has not yet created a suitable mechanism to monitor the national operation of PIC. But is expected to formulate a...
device to supervise this activity. A dispute-settlement system should be established to provide a remedy for foreign GR users whose bioprospecting applications have been unreasonably denied. The designated international ABS regime should be competent to undertake this duty, although its mandate has not yet been settled.\textsuperscript{343}

V. CONCLUSION

A strong voice against the national and international trends of delegating full control of GR access to state governments has yet to diminish. The consolidation of a decision making mechanism for national authorities could be also problematic and may create unsatisfactory results. Nonetheless, international law has squarely confirmed the right of states to regulate access to their genetic resources. Further, practically speaking, the role of a CNA is essential in a GR management regime. To prevent abuse of the national prerogative, the imminent question facing the international community is how to ensure transparency and fairness for GR access and hold each national authority accountable for regulating bioprospecting activities under their jurisdiction.

It was certainly a wise political decision to incorporate PIC in the Convention on Biological Diversity’s ABS regime as a means to safeguard national GR from misappropriation. In terms of distribution of PIC rights in the national legal system, it remains at the discretion of states to adopt either a single- or multiple-consent system. The national legal arrangements and practices reviewed in this Article reveal discrepancies in the national implementation of PIC. Of course, it is not the intention of the CBD to unify national practices, and states should be allowed to decide the detailed operation of a PIC system at national and local levels. Although national government remains the eventual access granter, it is by no means the intention of the CBD to allow states to monopolize PIC without regard for the interests of parties whose lives would be affected by bioprospecting.

In contrast to the notion of informed consent in medical treatment, PIC in national GR access management appears to be more complicated and normally involves a variety of local stakeholders, especially indigenous peoples. Their will and opinions should be properly respected in reviewing access projects, even though they may not be entitled to enjoy the consent right under their respective legal systems.

\textsuperscript{343} See discussion supra Part II.C (discussing ideas for a regime to govern ABS for GR).
A multiple-consent system is likely to result in some unsatisfactory results. Such issues highlight the exigency and importance of building a good practice in securing local PIC so that the abuse or misuse of the consent right by local peoples to some extent can be mitigated or avoided. National governments should ensure that PIC givers have sufficient capacity to perform their right; they must be fully informed so as to make a reasonable decision on their consent.

While recognizing the PIC rights of contracting parties, the CBD has yet to impose any obligation upon states regarding PIC operation. The Bonn Guidelines, as indicated above, do formulate some principles of legal certainty and clarity, economy, and transparency for a PIC system, but they are not legally binding. The unbridled use of the system by a state government could harm foreign bioprospectors and conflict with the objectives of the CBD. In formulating a fair and effective supervision mechanism, the CBD should ensure that national implementation of PIC is in conformity with the aims and objectives of the CBD. Ideally, the currently proposed international regime on ABS should fulfill the goal and undertake the duty. Unfortunately, the substance of the present draft appears inclined to protect and enforce sovereign control of GR. To reach a proper balance of rights and obligations, future drafts should include a mechanism to oversee the national exercise of jurisdiction as to GR access and to ensure that the access regulatory regime is managed in good faith.

The evolution of the PIC practice reveals the dynamic interplay between national norm building and global regulatory construction. The interaction and mutual supportiveness of these processes will be instrumental in formulating an optimal, mature, and credible PIC regime that is necessary to protect the interests of all GR stakeholders.