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UNU-IAS Report

User Measures

Options for Developing Measures in User Countries to Implement the Access and Benefit–Sharing Provisions of the Convention on Biological Diversity

2nd Edition

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Options for Developing Measures in User Countries to Implement the Access and Benefit–Sharing Provisions of the Convention on Biological Diversity

With Foreword and Executive Summary in Spanish

Medidas del Usario

Opciones para desarrollar mecanismos de implementación de las disposiciones del Convenio de Diversidad Biológica sobre acceso y distribución de beneficios en los países usuarios

Con prólogo y resumen ejecutivo en español

2nd Edition

March 2003 / Revised & Reprinted December 2003

Contents

Foreword

In the decade since the Convention on Biological Diversity (CBD) has come into force, efforts to implement the CBD's provisions on access and benefit–sharing (ABS) relating to genetic resources and related traditional knowledge, have resulted in development of national ABS legislation, model contracts, and other instruments in over 50 countries. The majority of attention so far has focused on developing regimes to control access. Less attention has been paid to developing enforcement measures to ensure that users of genetic resources fulfil their responsibilities.

As the CBD matures, and begins to establish international norms and procedures for the implementation of its provisions, increasing attention has been given to discussion of a range of measures that countries—particularly developed countries—could take in their role as users of genetic resources accessed from other parties. The call of the World Summit on Sustainable Development (WSSD) to develop an 'international regime' on benefit–sharing arising from the utilisation of genetic resources provides further impetus for investigating and implementing 'user measures'. Any international regime will need to be a cooperative enterprise between providers and users of genetic resources and traditional knowledge, and will require both to take action in mutual support of the common CBD goal of equitable benefit–sharing.

This study is a first attempt to elaborate and analyse potential options for ABS user measures. It examines the legal basis for development of user measures in CBD decisions, and explores a number of options for both voluntary and mandatory legal measures. It also addresses the practical question of 'access to justice' in the ABS sphere: i.e. what steps can be taken to ensure that the provider of genetic resources or traditional knowledge—often far down a line of transactions, geographically distant, and with little information and few financial resources—can seek redress against users of those resources who may have acquired or used them in violation of ABS laws or contractual terms?

The report's objective is to provide information on a number of available options, in order to contribute to a more informed and productive debate on this important topic in the development of the CBD.

Development of this report is part of the wider programme on biodiversity at the United Nations University Institute of Advanced Studies (UNU-IAS). The Institute was established in 1996 as a research and training centre of UNU to undertake research and postgraduate education on emerging issues of strategic importance for the United Nations and its Member States. Pursuant to its Statute, UNU-IAS undertakes its work in an independent, neutral, and objective manner. A key purpose of the Institute is to promote the interactions between the UN System and the academic community. UNU-IAS work is currently focusing a significant amount of its efforts on research of international biodiversity policy, with a particular emphasis on ABS issues.

This report is one of a series which are being published by UNU-IAS on issues relevant to international ABS governance. The report was first presented at the MYPOW meeting in Montreal in March 2003. Based upon comments received at and following MYPOW, the report has been revised and republished as a 2nd edition in order to bring it up–to–date. To this end the section on disclosure of origin has been completely rewritten. UNU-IAS has also published reports on ABS and Protected Areas, Bioprospecting in Antarctica, and the Role of Databases and Registers in the Protection of Traditional Knowledge, which are available for download from the UNU-IAS website.

A H Zakri
Director, UNU-IAS
March 2003/December 2003

Executive Summary

In the decade since the Convention on Biological Diversity (CBD) entered into force, governments have made significant efforts to implement the CBD's provisions on access and benefit–sharing (ABS). The majority of attention so far has focused on developing regimes to control access. Less attention has been paid to developing legislative, administrative, and policy measures to promote compliance by users with their obligations, and to ensure equitable sharing of benefits, including technology transfer. This resulted in a perception amongst many developing countries that developed countries were not meeting their obligations under Articles 15(7), 16, and 19 of the CBD.

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization thought to address this issue, stating that:

> Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted.

The Bonn Guidelines suggest a number of measures that Contracting Parties could consider to support compliance by users with the ABS objectives of the CBD. These include mechanisms to provide information to users; measures to ensure disclosure of origin of genetic resources and traditional knowledge; cooperation between parties to address alleged infringements; voluntary certification schemes; and measures to discourage unfair trade practices.

The responsibility of users will be the subject of more attention as a result of World Summit on Sustainable Development (WSSD), which invited governments to "[n]egotiate 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 utilisation of genetic resources". The issue of 'user measures' was placed upon the agenda of the second meeting of the Ad Hoc Working Group on Access to Genetic Resources, in Montreal in December 2003. The report of the Working Group and the results of World Summit on Sustainable Development (WSSD) will both be considered at the seventh meeting of the Conference of the Parties in March 2004.

This report provides a preliminary analysis of various potential user measures, focusing on a number of measures proposed for consideration by governments in the Bonn Guidelines. These include voluntary certification; import controls; disclosure of origin of genetic resources and traditional knowledge in applications for intellectual property rights (IPR); and judicial remedies and cooperation to investigate alleged infringements of ABS laws, regulations, and contractual agreements.

This selection of potential and existing measures is neither exhaustive nor exclusive of many other user measures, nor is it intended to prioritise these measures over other potential measures, and it is intended that future work under the project "Options for Developing ABS Measures in User Countries" will include consideration of an ever wider range of user measures.

A number of important areas that have not been addressed in any detail in this study are technology transfer and compliance with Articles 16 and 19 of the CBD, as well as the issue of unfair trading practices and competition/antitrust law. Both these areas pose complex legal and technical challenges, which time and resources have not permitted an adequate examination of for this report. Nevertheless, UNU-IAS recognises their importance and proposes to consider these issues in future institutional research and publications. It is also the intention of the Institute to carry out more detailed analysis of intellectual property rights and the extent to which they may be made more supportive of the CBD's objectives.

The following is a brief summary of the main conclusions about each type of user measures examined in the report.

Information, Codes and Certification

1. A number of private firms and research institutions involved in the international genetic resource trade have adopted polices in response to the CBD's ABS provisions. While this is a welcome development, establishment of individualised policies is unlikely to be a sufficiently comprehensive response to ensure equitable distribution of the benefits.

2. A number of trade associations, research consortia, and professional associations have also developed codes of conduct on ABS. Such codes help to 'level the playing–field' among such actors, and increase peer pressure upon others within the sector to adopt the common code and develop individual policies to implement it. These measures are unlikely to be sufficient or comprehensive enough to address the wide range of situations covered by the CBD.

3. The Bonn Guidelines have suggested that each country could explore the establishment of a voluntary certification system for genetic

resources transactions. It is unclear, however, whether such a system would be feasible due the complexities of the trade in genetic resources and associated traditional knowledge.

4. A more systematic and integrated approach to voluntary measures would involve the development of broadly endorsed international standards and associated best practices, supported—if found to be feasible—by a certification system to verify compliance with the standards.

5. Whether or not ABS certification turns out to be a practical option, the development of a widely supported set of international ABS standards and best practices appears to be a potentially fruitful avenue for further investigation and discussion. While such a process would build on the Bonn Guidelines, it would need to be a truly multi–stakeholder initiative to develop standards agreed to by governments, the private sector, NGOs, indigenous peoples, and other stakeholders.

Import and Transport Regulations

1. Using existing customs procedures to regulate the import of genetic resources is a relatively simple measure for controlling cross border flow of genetic resources. Many countries have extensive regulations and procedures in place to monitor the importation of animals, plants, micro–organisms, and their parts or derivatives.

2. Import controls are less useful where movement of physical samples are not required, as in cases where analysis is carried out in the country of origin, and only the resulting information is 'exported' (e.g. over the internet) or where traditional knowledge is being used.

3. A problem with using import controls also arises where providing countries lack clear ABS legislation, making it difficult for importers to provide documentary evidence showing that they have obtained prior informed consent (PIC) for export of the material in question from the country of origin.

4. Establishment of a standardised international system of documentation to identify the existence of PIC would assist customs authorities in processing genetic resource and traditional knowledge importation, and thus make the use of import controls a more practical user measure option. Establishment of these standards may be possible though adapting the existing international regime managed by the World Customs Union.

5. Utilisation, for ABS purposes, of the rules governing international transport of goods are another practical measure that could be used to encourage users to fulfil their obligations

6. None of the existing regimes on international transport comprehensively or simply covers the scope of potential users and uses of genetic resources subject to ambit of the CBD.

7. The legal and institutional complexity of the relevant international rules for transport means that any specific procedures developed for user measures need to be drafted carefully and precisely. It is difficult to envisage that a single generic approach to the issue will be effective.

8. Several schemes (such as the OECD Schemes for the Varietal Certification of Seeds Moving in International Trade) are worth considering in more detail.

Disclosure of Origin

1. According to the World Intellectual Property Rights Organization (WIPO), the essence of the patent system is transparency and disclosure.

2. A range of voluntary and mandatory measures relating to disclosure of the origin of genetic resources and traditional knowledge and evidence of prior informed consent for their use have been adopted by national governments in developing and developed countries, and regional economic groupings in their procedures for intellectual property (IP) protection.

3. There is a tendency for developed countries to adopt voluntary requirements, failure to comply with such requirements would not affect the validity of an application or of any patent, although there may, in some cases, be criminal sanctions for supplying false information. Developing countries have tended to adopt mandatory disclosure, requiring the provision of evidence of both the origin of resources and of prior informed consent for their use

4. At the international level proposals for inclusion of disclosure requirements in IPR law has been made by both developing and developed countries in the TRIPS Council and WIPO, respectively.

5. Decision VI/24 encourages parties to CBD to invite applicants for patents to disclose the origin of genetic resources and/or the source of traditional knowledge used in the development of the invention for which a patent is sought. The decision also asks WIPO to provide advice on the compatibility of disclosure requirements with international IPR law.

6. There is a range of methods for requiring disclosure that are consistent with the essential elements of patent law and key aspects of WIPO treaties and which may entitle imposition of significant sanctions where there is a failure to comply with such requirements. These may be positive obligations such as those relating to the right for the inventor to be named in the application, or requiring adequate description of the invention, or they may be implicitly consistent in the sense that they do not conflict with treaty requirements.

7. It is already customary practice in IP applications to disclose the geographical origin of plants with limited distribution and of associated traditional knowledge when describing compounds isolated from plants in patent applications.

8. The legal position of a stand–alone or distinct disclosure requirement such as a separate reporting obligation to disclose the origin or legal provenance of genetic resources and/ or traditional knowledge as a substantive requirement for granting of a patent requires further clarification. Some commentators believe they could infringe Article 27 of the WTO Agreement on Trade Related Intellectual Property (TRIPS).

9. Views differ as to whether establishing obligations for disclosure as a procedural requirement for processing patent applications could amount to 'reasonable procedures' within the meaning of Article 62 of TRIPS.

10 If the implementation of benefit–sharing underthe CBD framework is a matter of vital importance to countries from both an economic and technological perspective, then a requirement to disclose the origin and legal provenance of genetic resources and traditional knowledge in IP laws may be compatible with TRIPS.

11 Where an IP right is obtained without complying with requirements for disclosure, the patent–holder may potentially be deprived of the right to exercise their derivative rights—such as the right to prevent third party infringement of the patent—under the legal doctrine of ' unclean hands'.

12. Disclosing traditional knowledge in patent applications may help identify use, but may also endanger traditional rights over knowledge if the result is to place it in the public domain for the first time.

13. ABS disclosure requirements might also be incorporated into product approval processes, and into the requirements for obtaining government research grants.

14. Establishment of a standardised system of documentation for identifying the origin of genetic resources or traditional knowledge, and for providing evidence of the existence of PIC, could facilitate compliance with disclosure requirements in IP applications.

15 It is important for parties to the CBD to consider the extent to which the proposed Substantive Patent Law Treaty being negotiated within WIPO is supportive of or might run counter to the CBD.

15 The practicality, feasibility and cost of disclosure requirements should be the subject of increased attention and analysis of the relative merits of such systems should include comparative case studies on specific industry sectors. Such studies could examine the possible advantages od developing some form of bloc exemptions for particular industry sectors such as food and agriculture, if approapriate.

Measures to Address Infringements

1. Opportunities to seek redress for breaches of rights over genetic resources and traditional knowledge already exist under tort and contract law in many developed country jurisdictions.

2. Effective access to justice, in foreign jurisdictions, is subject to both technical/legal issues (such as rules on enforcement of foreign judgments, standing before the courts, evidentiary standards, and burden of proof) and practical issues (such as knowledge of rights and of the possibility of obtaining relief, legal representation, language, availability of visas, and costs).

3. There is a need for further investigation and consideration of measures for promoting cooperation to address alleged infringements of ABS agreements. Possible measures include investigation of claimed breaches; facilitating access to information on use of resources and knowledge; notification of patent applications; assisting service of court documents; identifying the location of defendants; flexibility of rules for accepting evidence by affidavit or audio/visual recordings; recognition of standing; provision of legal aid; provision of visas; and alternative, reduced–cost dispute resolution mechanisms including arbitration.

4. A practical measure to begin to address the technical and practical issues may be the designation of an ombudsman to provide a point of contact for receipt of ABS claims, carry out preliminary investigation of alleged infringements of rights over genetic resources and traditional knowledge, and monitor breaches of contractual obligations. There may be a role for an independent ombudsman or complaints board

to work alongside the Secretariat of the CBD with a mandate to support promotion of alternative dispute resolution mechanisms at the regional and international level.

5. Development of a body of international guiding principles of equity, drawn from multiple sources of national and international law as well as from the customary law and practice of indigenous and local communities, would serve to assist arbitrators in resolving ABS conflicts.

An International System for Documenting the Flow of Genetic Resources

1. A standardised system for documenting evidence of PIC and tracing flows of genetic resources and traditional knowledge is a feasible and practical measure that could significantly contribute to enhancing transparency, equity, and compliance with ABS arrangements.

2. Such a measure could enhance the effectiveness of ABS governance, and be part of a response to the WSSD's call for negotiation of an international regime on ABS.

3. The Secretariat to the CBD is currently charged with investigating the feasibility of an international 'certificate of origin' system. This will require consideration of the role any system of certification would play, either to identify the country of origin, source, or legal provenance of resources.

4. In order to avoid the potential confusion arising from the use of terms it is suggested that the Secretariat redefine its mandate to consideration of the potential role which a standardised system for tracing the flow of genetic resources and/or traditional knowledge may play in securing the CBD's ABS objectives.

5. There is a need for preparation of cases studies regarding tracing of gene flows from a number of differing industry sectors in order to determine the most effective means for implementing such a scheme.

6. Governments should further explore potential mechanisms for developing such a system.

Prólogo

Desde la entrada en vigencia del Convenio de Diversidad Biológica (CDB), los esfuerzos para implementar las disposiciones del CDB sobre acceso y distribución de beneficios (ADB) relacionadas con los recursos genéticos y el conocimiento tradicional asociado han dado como resultado, en más de 50 países, la elaboración de legislación nacional sobre ADB, contratos modelo, entre otros instrumentos. Sin embargo, hasta la fecha, la mayor atención se ha concentrado en el desarrollo de regímenes para controlar el acceso. En cambio, se ha prestado menor interés al desarrollo de mecanismos de implementación y de medidas coercitivas que garanticen que los usuarios de recursos genéticos cumplan con sus responsabilidades.

A medida que el CDB madura y comienza a establecer normas y procedimientos internacionales para la implementación de sus disposiciones, se presta cada vez mayor atención a la discusión acerca de las diversas medidas que los países—en particular los países desarrollados—pueden tomar en su rol de usuarios de los recursos genéticos provenientes de otras Partes Contratantes. El llamado de la Cumbre Mundial sobre Desarrollo Sostenible para desarrollar un "régimen internacional" sobre recursos genéticos y distribución de beneficios, alienta la investigación e implementación de las llamadas "medidas del usuario" ("user measures"). En efecto, cualquier régimen internacional requerirá de un esfuerzo de cooperación entre los proveedores y los usuarios de recursos genéticos y conocimientos tradicionales, y necesitará que ambos tomen acciones de apoyo mutuo a los objetivos comunes del CDB, referidos a la distribución equitativa de beneficios.

Este estudio constituye un intento inicial de elaborar y analizar las posibles opciones de medidas para regular el uso relacionado al ADB, examinando la base legal para el desarrollo de condiciones de uso en las decisiones del CDB y explorando una serie de opciones de mecanismos legales vinculantes y voluntarios. Además, aborda la pregunta práctica sobre el "acceso a la justicia" en la esfera del ADB: por ejemplo, ¿qué pasos pueden ser tomados para asegurar que el proveedor de recursos genéticos o conocimiento tradicional—que usualmente se encuentra muy lejano a las transacciones mismas, en términos geográficos, con escasa información y recursos económicos—pueda buscar una compensación por el uso de aquellos recursos que pudieran ser adquiridos o utilizados violando las leyes de ADB u obligaciones contractuales?

El objetivo de este documento es proporcionar información acerca de una serie de opciones disponibles, a fin de contribuir a un debate más informado y productivo sobre este importante tema en el desarrollo del CDB.

La elaboración de este documento forma parte de un programa más amplio sobre biodiversidad del Instituto de Estudios Avanzados (IAS, por sus iniciales en inglés) de la Universidad de las Naciones Unidas (UNU). La UNU-IAS fue creada en 1996 como un Programa y Centro de Capacitación de la UNU, para llevar a cabo cursos de postgrado e investigaciones sobre temas emergentes de importancia estratégica para las Naciones Unidas y sus Estados miembros. En virtud de su Estatuto, la UNU-IAS realiza su trabajo en forma independiente, neutral y objetiva. Un propósito clave del Instituto es promover la interacción entre el sistema de las Naciones Unidas y la comunidad académica. Actualmente, la labor de la UNU-IAS concentra una significativa parte de sus esfuerzos en investigaciones sobre política internacional de biodiversidad, con particular énfasis en temas de ADB.

Este documento forma parte de una serie de artículos elaborados por la UNU-IAS sobre temas relevantes para la gobernabilidad internacional referida a ADB. Este informe fue presentado por primera vez en la MYPOW, en marzo del 2003 en Montreal. El presente reporte ha sido reeditado, en base a los comentarios recibidos en la MYPOW y aquellos enviados con posterioridad a la misma, con el fin de actualizar su contenido. En este sentido, la sección referida a divulgación del origen ha sido re–escrita en su totalidad. UNU-IAS también ha publicado estudios sobre ADB y áreas naturales protegidas, bioprospección en la Antártida y el rol de las bases de datos y los registros en la protección del conocimiento tradicional. Se puede accederse a estos estudios a través de la página website.

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Marzo, 2003/Diciembre, 2003

Resumen Ejecutivo

Durante la vigencia del Convenio de Diversidad Biológica (CDB), los gobiernos han realizado esfuerzos significativos para implementar las disposiciones del CDB sobre acceso y distribución de beneficios. Sin embargo, hasta la fecha, la mayor atención se ha concentrado en el desarrollo de regímenes para controlar el acceso. En cambio, menor atención se ha prestado al desarrollo de medidas legislativas, administrativas y de política para promover que los usuarios cumplan con sus obligaciones y para asegurar una distribución equitativa de beneficios, incluyendo la transferencia de tecnología.

Las Directrices de Bonn sobre acceso a recursos genéticos y distribución justa y equitativa de los beneficios derivados de su utilización, abordaron este tema, señalando que:

> Las Partes Contratantes que tienen usuarios de recursos genéticos dentro de su jurisdicción deben tomar las medidas legales, administrativas o de políticas adecuadas, según corresponda, para asegurar el consentimiento informado previo de la Parte Contratante proveedora de dichos recursos y el cumplimiento de los términos mutuamente acordados en base a los cuales el acceso fue autorizado.

Las Directrices de Bonn sugieren una serie de medidas que las Partes Contratantes pueden considerar para facilitar que los usuarios cumplan con obtener el consentimiento de los proveedores. Estas incluyen, mecanismos para proporcionar información a los usuarios; medidas para asegurar la divulgación del origen de los recursos genéticos y el conocimiento tradicional; cooperación entre las Partes Contratantes para atender las supuestas infracciones; sistemas de certificación voluntaria y medidas para desincentivar prácticas comerciales desleales.

La responsabilidad de los usuarios será objeto de mayor atención como resultado de la Cumbre Mundial de Desarrollo Sostenible (WSSD, por sus siglas en inglés), la cual invitó a los gobiernos a "[n]egociar dentro del marco del Convenio de Diversidad Biológica, teniendo presente las Directrices de Bonn, un régimen internacional para promover y salvaguardar la distribución justa y equitativa de los beneficios derivados de la utilización de los recursos genéticos". El tema de las ´medidas del usuario´ fue incluido en la agenda de la segunda reunión del Grupo de Trabajo Ad Hoc sobre Acceso a Recursos Genéticos, realizada en Montreal en diciembre de 2003. Asimismo, tanto el reporte del Grupo de Trabajo como los resultados del WSSD serán tomados en cuenta en la séptima reunión de la Conferencia de las Partes del CDB que se llevará a cabo en marzo de 2004.

Este documento proporciona un análisis preliminar de diversas y potenciales medidas del usuario, enfocándose en una serie de medidas propuestas en las Directrices de Bonn para ser evaluadas por los gobiernos. Estas incluyen: la certificación voluntaria, los controles a las importaciones; la divulgación del origen de los recursos genéticos y el conocimiento tradicional en las solicitudes sobre derechos de propiedad intelectual (DPI); y algunos recursos legales y cooperación para investigar las supuestas infracciones a las leyes, regulaciones y acuerdos contractuales sobre ADB.

Esta selección de medidas, tanto existentes como potenciales, no es exhaustiva ni excluyente de otras medidas del usuario; tampoco tiene la intención de priorizar estas medidas por encima de otras posibles. Por lo tanto, es nuestra intención que el trabajo futuro dentro del proyecto "Opciones para desarrollar mecanismos de ADB en los países usuarios" de la UNU-IAS, incluya el análisis de un rango aún más amplio de medidas del usuario.

Otras áreas de gran importancia que no han sido abordadas en detalle en este estudio son: la transferencia de tecnología y el cumplimiento de los artículos 16 a 19 del CDB; así como las cuestiones referidas a las prácticas comerciales desleales, las leyes que regulan la competencia y las normas antimonopolio. Debido a que estas áreas afrontan complejos desafíos legales y técnicos, las limitaciones de tiempo y recursos no han permitido un adecuado análisis de las mismas en este documento. Sin embargo, la UNU-IAS reconoce su importancia y propone que sean consideradas en futuras investigaciones y publicaciones institucionales. Es además la intención de nuestra institución llevar a cabo un análisis más detallado sobre los derechos de propiedad intelectual y sobre hasta qué punto estos pueden mejorarse para proporcionar un mayor apoyo a los objetivos del CDB.

El siguiente texto constituye un breve resumen de las principales conclusiones obtenidas acerca de cada clase de medidas del usuario examinadas en este documento.

Información, códigos y certificación

1. Una serie de empresas privadas e instituciones de investigación involucradas en el comercio internacional de recursos genéticos han adoptado políticas como respuesta a las disposiciones sobre ADB del CDB. Aun cuando esta iniciativa es bienvenida, es poco probable que la creación de políticas individualizadas constituya una respuesta suficiente para asegurar la distribución equitativa de beneficios.

2. Los códigos de conducta sobre ADB también han sido desarrollados por diversas sociedades comerciales, consorcios de investigación y asociaciones profesionales. Dichos códigos ayudan a "nivelar el campo de juego" entre estos actores e influyen para que los demás actores del mismo sector los asuman, con el fin de adoptar un código común y desarrollar políticas individuales para implementarlo. Sin embargo, resulta improbable que estas medidas sean suficientemente integrales para cubrir el amplio rango de situaciones cubiertas por el CDB.

3. Las Directrices de Bonn han sugerido que cada país puede explorar el establecimiento de un sistema de certificación voluntaria para las transacciones sobre recursos genéticos. Sin embargo, no resulta del todo claro si dicho sistema podrá ser posible, dada la complejidad del comercio de recursos genéticos y el conocimiento tradicional asociado.

4. Un enfoque más sistemático e integral de las medidas voluntarias involucraría el desarrollo de estándares internacionales sobre ADB y las correspondientes "mejores prácticas" ("best practices"), ampliamente respaldados y complementados—si se considera viable—por un sistema de certificación que verifique el cumplimiento de dichos estándares.

5. Sea que la certificación para ADB resulte ser una opción práctica o no, el desarrollo de un conjunto de estándares ampliamente aceptados internacionalmente, sobre ADB y las "mejores prácticas", parece ser un camino potencialmente fructífero para fomentar la investigación y la discusión sobre este tema. Si bien dicho proceso podría ser construido sobre la base de las Directrices de Bonn, será necesario que ésta sea una auténtica iniciativa multisectorial para el desarrollo de estándares aceptados por los gobiernos, el sector privado, las ONGs, los pueblos indígenas y demás sectores.

Importación y regulaciones sobre transporte

1. Utilizar los procedimientos aduaneros existentes para regular la importación de recursos genéticos es una medida relativamente simple para controlar el flujo internacional de recursos genéticos. Diversos países tienen regulaciones y han puesto en práctica procedimientos para monitorear la importación de animales, plantas, microorganismos y sus partes o derivados.

2. Los controles a las importaciones son menos útiles cuando no se requiere el desplazamiento de las muestras físicas. Por ejemplo, en los casos en que el análisis es llevado a cabo en el país de origen y sólo se "exporta" la información resultante (p.ej., a través del Internet); o cuando se trate de la utilización de un conocimiento tradicional.

3. También surgen problemas con los controles a las importaciones en los países usuarios cuando los países proveedores carecen de legislación clara sobre ADB. Esto hace difícil para los importadores proporcionar pruebas documentales que muestren que se ha obtenido el consentimiento informado previo (CIP) para la exportación del material en cuestión del país de origen.

4. El establecimiento de un sistema internacional estandarizado de documentación para identificar la existencia del CIP puede ayudar a las autoridades aduaneras a procesar las importaciones de recursos genéticos y conocimiento tradicional y, de esta manera, hacer que el uso de controles a las importaciones sea una opción más práctica de "medidas del usuario". El establecimiento de estos estándares puede ser posible a través de la adaptación de regimenes internacionales existentes administrados por la Unión Mundial Aduanera.

5. La utilización de las reglas que gobiernan el transporte internacional de bienes, para fines de ADB, es otra medida práctica que puede ser utilizada para alentar a los usuarios a cumplir con sus obligaciones.

6. Ninguno de los regímenes de transporte internacional existentes cubren de manera suficiente o simple el ámbito de los potenciales usuarios y usos de recursos genéticos que caen dentro de la esfera del CDB.

7. La complejidad legal e institucional de las normas internacionales relevantes sobre transporte, hace necesario que cualquier procedimiento creado para desarrollar medidas del usuario deba ser elaborado cuidadosamente y en forma precisa. Es difícil vislumbrar que un único enfoque sobre el tema será efectivo.

8. Diversos esquemas, tales como el esquema de la OCDE para la certificación varietal del movimiento de semilla en el comercio internacional, merecen ser considerados con más detalle.

Divulgación del origen

1. Según la Organización Mundial para la Propiedad Intelectual (OMPI) la esencia del sistema de patentes es la transparencia y la divulgación.

2. Una serie de medidas voluntarias y obligatorias relacionadas con la divulgación de la información sobre el origen de los recursos genéticos y el conocimiento tradicional, así como sobre la evidencia del CIP para su uso, han sido adoptadas por los gobiernos, tanto de países en desarrollo como desarrollados, y alianzas económicas regionales en sus procedimientos para la protección de la propiedad intelectual (PI).

3. Existe la tendencia entre los países desarrollados de adoptar requisitos voluntarios. El incumplimiento de dichos requisitos no afectaría la validez de una solicitud o de una patente, aun cuando en algunos casos pueden existir sanciones penales por proporcionar información falsa. En cambio, los países en desarrollo se han inclinado a adoptar normas que establezcan requisitos obligatorios sobre divulgación, que proporcionen evidencia tanto del origen de los recursos como del consentimiento informado previo para su utilización.

4. A nivel internacional las propuestas para la inclusión de requisitos de divulgación en la legislación sobre PI han sido planteadas tanto por países en desarrollo como países desarrollados, en el Consejo del ADPIC y en la OMPI, respectivamente.

5. La Decisión VI/24 alienta a las Partes del CDB a invitar a los solicitantes de patentes a que divulguen el origen de los recursos genéticos y/o la fuente del conocimiento tradicional utilizado en el desarrollo de la invención para la cual la patente es solicitada. Dicha Decisión pide además a la OMPI que proporcione asesoría respecto a la compatibilidad de los requisitos de divulgación con las normas internacionales sobre PI.

6. Existe una gama de métodos para exigir la divulgación del origen, que son consistentes con los elementos esenciales de las leyes de patentes y los aspectos claves de los tratados de la OMPI y que pueden permitir la imposición de sanciones significativas en los casos en que se incumpla con dichos requisitos. Estos pueden plantearse como obligaciones positivas, tales como aquellas relativas al derecho del inventor de ser nombrado en la solicitud o exigir una descripción adecuada de la invención; o también puede ser consistentes implícitamente, en el sentido de que no entran en conflicto con las exigencias establecidas en los mencionados tratados.

7. Actualmente, se acostumbra en las solicitudes de PI divulgar la información sobre el origen geográfico de las plantas de distribución limitada y del conocimiento tradicional asociado a las mismas, al momento de describir los componentes aislados de plantas en las solicitudes de patentes.

8. La posición jurídica referida al establecimiento de un requisito de divulgación independiente o distinto; como por ejemplo, la obligación de elaborar un reporte aparte con la divulgación del origen o la procedencia legal del recurso genético y/o el conocimiento tradicional, como requisito sustancial para otorgar una patente, requiere mayores precisiones. Algunos expertos son de la opinión que este requisito podría infringir el artículo 27 del Acuerdo sobre Aspectos de los Derechos de Propiedad Intelectual Relacionados con el Comercio (ADPIC), de la OMC.

9. Las opiniones difieren respecto a si el establecimiento de obligaciones para la divulgación de información como un requisito procesal para tramitar una solicitud de patente, podría interpretarse como "procedimiento razonable" en el marco del Artículo 62 de ADPIC.

10. Si la implementación de la distribución de beneficios dentro del marco del CDB es un tema de vital importancia para los países, tanto desde una perspectiva económica como tecnológica, entonces el requisito de divulgar la información sobre el origen y la procedencia legal de los recursos genéticos y el conocimiento tradicional en las normas sobre PI puede ser compatible con lo que establece el ADPIC.

11. En los casos que un derecho de PI sea obtenido sin cumplir con el requisito de divulgación de información, el titular de la patente puede verse potencialmente privado de la facultad de ejercer otros derechos relacionados—tales como el derecho a prevenir el uso indebido de la patente por terceros—bajo la doctrina jurídica de "manos sucias" ("unclean hands") del Derecho Anglosajón.

12. La divulgación de información sobre el conocimiento tradicional en las solicitudes de patentes puede ayudar a identificar el uso, pero también puede poner en peligro los derechos tradicionales sobre el conocimiento si la divulgación trae como resultado que dicho conocimiento sea puesto en el dominio público por primera vez.

13. Existe la necesidad de clarificar si los requisitos para la divulgación del origen y la procedencia legal se aplicarán a todos los recursos genéticos o sólo a aquellos que caen dentro del ámbito del CBD. Asimismo, si estos se aplicarán a todos los conocimientos tradicionales o sólo a aquellos que aún no han entrado en el dominio público.

14. Los requisitos para la divulgación de información sobre ADB también podrían ser incorporados dentro del proceso de aprobación de un producto y de los requisitos para obtener financiamiento del gobierno para fines de investigación.

15. El establecimiento de un sistema estandarizado de documentación para identificar el origen de los recursos genéticos o el conocimiento tradicional, así como para proporcionar evidencia de la existencia del CIP, podría facilitar el cumplimiento de los requisitos de divulgación de información en las solicitudes de PI.

16. Es importante para las Partes del CDB considerar hasta qué punto el propuesto Tratado sobre el Derecho Sustantivo de Patentes, que viene siendo negociado dentro de la OMPI, es fiel al CBD o se opondría a éste.

Mecanismos para sancionar las infracciones

1. Actualmente, existe la posibilidad de solicitar compensación ante la violación de derechos sobre los recursos genéticos y el conocimiento tradicional, bajo las leyes de responsabilidad civil extracontractual y las normas sobre contratos, dentro de la jurisdicción de varios países desarrollados.

2. El acceso efectivo a la justicia, en jurisdicciones extranjeras, está sujeto tanto a cuestiones técnico/legales (tales como normas para la aplicación de sentencias extranjeras, comparecencia en los tribunales, estándares para la presentación de pruebas y carga de la prueba), como a cuestiones prácticas (tales como el conocimiento de las normas y la posibilidad de obtener ayuda, representación legal, idioma, viabilidad de visas y gastos judiciales).

3. Es necesario realizar mayores investigaciones y evaluaciones sobre medidas que promuevan la cooperación en el juzgamiento de supuestas infracciones a los acuerdos sobre ADB. Entre las posibles medidas se incluyen: investigación sobre los reclamos a las violaciones de derechos, facilitar el acceso a la información sobre el uso de los recursos y el conocimiento; notificación de solicitudes de patentes; asistencia para la preparación de documentación para los tribunales; identificación de la ubicación de los defendidos; flexibilidad de las reglas para aceptar pruebas mediante declaración jurada o grabaciones audio/visuales; reconocimiento de la comparecencia; ayuda legal; facilitar la obtención de visado; y, alternativamente, reducir los costos de los mecanismos de resolución de conflictos, incluyendo el arbitraje.

4. Una medida práctica para empezar a abordar las cuestiones técnicas y legales puede ser: la designación de un defensor del pueblo (ombudsman) como punto de contacto para recibir los reclamos relacionados al ADB; llevar a cabo la investigación preliminar de las demandas de violación de derechos sobre los recursos genéticos y el conocimiento tradicional; y monitorear si existe incumplimiento de las obligaciones contractuales. Asimismo, puede haber un rol para un defensor del pueblo independiente o un tribunal de quejas que trabaje conjuntamente con la Secretaría del CDB y que tenga el mandato de apoyar en la promoción de mecanismos alternativos de resolución de conflictos a nivel regional e internacional.

5. El desarrollo de un código internacional de principios de equidad, recogidos de distintas fuentes provenientes de leyes nacionales e internacionales, así como del derecho consuetudinario y de las prácticas de las comunidades indígenas y locales, servirían para ayudar a los árbitros a resolver los conflictos relacionados al ADB.

Un sistema internacional para documentar el flujo de los recursos genéticos

1. Un sistema estandarizado para la documentación de pruebas para el CIP y el rastreo del movimiento de los recursos genéticos y el conocimiento tradicional, son medidas prácticas y viables que pueden contribuir significativamente a elevar la transparencia, equidad y cumplimiento de los acuerdos de ADB.

2. Dichas medidas pueden elevar la efectividad de la gobernabilidad sobre ADB y ser parte de una respuesta al pedido del WSSD para negociar un régimen internacional sobre ADB.

3. La Secretaria del CDB está actualmente encargada de investigar la factibilidad de un sistema internacional de ´certificado de origen´. Ello va a requerir el análisis del rol que podría jugar cualquier sistema de certificación, sea para identificar el país de origen, la fuente o la procedencia legal de los recursos.

4. A fin de evitar la posible confusión que pueda surgir del uso de determinados términos, se sugiere que la Secretaria redefina su mandato, para considerar el posible rol que pueda jugar un sistema estandarizado para el rastreo de la circulación de los recursos genéticos y/o el conocimiento tradicional para garantizar los objetivos de ADB del CDB.

5. Existe la necesidad de preparar estudios de caso relacionados con el rastreo de los flujos de genes, que provengan de diferentes sectores de la industria, a fin de determinar los medios más efectivos para implementar dicho esquema.

6. Los gobiernos deben explorar más profundamente los potenciales mecanismos para desarrollar dicho sistema.

Introduction

The trade in genetic resources, which has come to be known as biodiversity prospecting or 'bioprospecting' for short, has gone on since earliest times. Saragon brought figs and roses back to Mesopotamia in 2500 BC, while Egyptians travelled to the land of Punt (Somalia/Ethiopia) to collect plants whose fragrant resins produced frankincense in 1495 BC, and the Japanese brought citric fruits from China in 61 AD.[1] The importance of genetic resources in socio–economic and cultural evolution was clearly recognised by US President Thomas Jefferson who once said that the greatest service that could be rendered to any country was to add a useful plant to its culture.[2]

In recent times, as technology has developed allowing for greater access to genetic information incorporated in biological resources, the international trade in genetic resources has grown dramatically. Genetic resources now provide valuable inputs for numerous commercial enterprises including the biotechnology, pharmaceutical, agro–industrial, cosmetics, and natural products industries.[3] Many genetic resources of interest to scientific and commercial researchers were originally identified, researched, utilised, and developed by indigenous peoples and local communities, whose traditional knowledge is often sought after as a source of valuable information for research and development activities. Traditional knowledge now plays an important role in the development of pharmaceutical and botanical drugs, new varieties of agricultural and horticultural crops, crop protection products, and personal care and cosmetic products.[4]

Although genetic resources and traditional knowledge provide valuable resources for international trade, historically they were treated as free access goods. Genetic resources were traditionally considered as part of the common heritage of humankind and traditional knowledge of indigenous peoples was largely unprotected against unapproved use by third parties.

With the entry into force of the Convention of Biological Diversity (CBD) in 1993, the inequities of this situation began to be addressed. The CBD recognised that countries of origin of genetic resources have a sovereign right to control access to and use of their genetic resources. The CBD has also recognised the interests of indigenous and local communities over their traditional knowledge, innovations, and practices relating to the conservation and sustainable use of biological diversity, and requires States to seek prior informed consent of such communities before promoting wider use of their knowledge.

Currently in excess of fifty countries either have adopted or are in the process of developing measures to exercise and secure their sovereign rights over genetic resources. Similarly, there has been much interest in the development of mechanisms to protect traditional knowledge, and a number of countries and regional economic groupings have adopted legislation requiring prior informed consent of indigenous and local communities as a precondition for access to and use of their traditional knowledge.[5] More recently still, a number of countries, including Costa Rica, Panama, Portugal, Venezuela, and Peru[6] have adopted legislation to recognise and protect rights over traditional knowledge.

Despite these efforts, many developing country providers of genetic resources, and indigenous peoples and local communities, who are sources of traditional knowledge, continue to express concerns that existing measures are not sufficient to secure the objectives of the CBD. A growing list of cases, in which intellectual property rights (IPR) have been granted for products based upon resources considered to be part of national or cultural patrimony, by countries of origin and indigenous peoples, such as patents over basmati rice, neem, quinoa,[7] turmeric, karela (bitter gourd), brinjal (eggplant), amla, jarmala, rupununine, maca, and ayahuasca, continues to fuel concern in countries of origin and their indigenous peoples that their rights are not adequately protected under existing ABS regulation.[8] This has led to calls for modification of international IPR law in many international forums.[9]

The CBD's provisions on ABS do not focus only on rights to control access. The CBD also establishes obligations for countries to take measures, "...with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the contracting Party providing such resources" (Article 15(7)). This includes adopting measures with the aim of ensuring that countries providing genetic resources are provided access to and transfer of technology, which makes use of those resources (Article 16(3)). Furthermore, Contracting Parties are obliged to take measures to facilitate access and transfer of technologies relevant for conservation and sustainable use of biological diversity or which make use of genetic resources, including measures with the aim that the private sector facilitates access to joint development and transfer of such technologies (Article 16(1) and (4)). Article 19 creates obligations to adopt legislative, administrative, and policy measures to provide for effective participation in biotechnological research activities by countries providing genetic resources, where feasible in the providing country (Article 19(1)). Moreover, priority access is to be provided to developing countries on a fair and equitable basis to the results and benefits arising from biotechnologies based upon genetic resources provided by them.

While numerous publications have recorded many national experiences in the implementation of ABS regulations to control access, and experiences with bioprospecting agreements[10], to date there has been little published research regarding analysis of the measures that have been or might be taken by countries to meet their obligations to promote compliance by users and to facilitate access to technologies developed utilising genetic resources in accordance with Articles 15(7), 16, and 19 of the CBD.[11]

The result has been a perceived imbalance in commitment between provider (mainly developing) countries and industrialised countries towards securing implementation of the CBD's ABS objectives. This amongst other things inspired the Like–Minded Megadiverse Group of countries to sponsor proposals calling for the development of a binding international regime on benefit–sharing. The call by the WSSD in Paragraph 44 (o) of the Plan of Implementation for negotiation of an international regime on benefit–sharing relating to genetic resources within the framework of the CBD, and bearing in mind the Bonn Guidelines, may be seen as being an indirect result of this perceived imbalance. User measures may be seen as a mechanism for redressing the balance between providers and users. The commitment shown in the implementation of user measures and, most importantly, those legally binding user measures relating to technology transfer which are specified in articles 16 and 19 of the CBD, will no doubt have an important bearing on how the issue of negotiation of an international regime will develop from here on.

It is considered important to draw attention to the fact that there is already an international system of ABS governance which includes both hard and soft law. Hard law elements include, for example, the CBD, TRIPS, and the International Treaty on Plant Genetic Resources for Food and Agriculture, regional law such as that of the Andean Community, and national ABS and relevant IPR law. Soft law includes the Bonn Guidelines and relevant regional measures such as the Organization of African Unity Model Law and national policy including NBSAPs. The customary law and practice of indigenous and local communities may be seen either as hard law, where recognised by national law or soft law. There is, therefore, an already existing international ABS regime, including both binding and non–binding legal and policy instruments. The question then arises as to what focus countries will take in the negotiation of an international ABS regime. Options include negotiation of a new legal instrument, of a protocol to the CBD, of a system of enforcement to secure compliance with obligations under the CBD, including in particular compliance with Articles 16 and 19, or to make the Bonn Guidelines legally binding. Alternatively parties may seek to identify gaps in the existing ABS regime and to negotiate measures to fill such gaps. In this sense, user measures may play an important role in helping in the consolidation of effective international ABS regime.

UNU-IAS has launched a project entitled "Options for Developing ABS Measures in User Countries" which seeks to respond to this significant gap in information relating to implementation of the CBD. The project aims to contribute to and promote research in existing and potential measures that users and countries may wish to consider within the context of the CBD's ABS objectives. The project has commenced with the preparation of this working document to help stimulate debate regarding user measures. UNU-IAS is also promoting regional and thematic workshops to discuss user measures, with a view to determining their feasibility, practicality, potential effectiveness, and cost. To this end UNU-IAS is collaborating with a range of institutions and in September 2003 held a symposium in Tokyo on Commercial Prospects of Access to and Benefit–Sharing of Genetic Resources relating to ABS, together with the Japanese Bioindustry Association, which sought to engage the private sector in wider debate of issues of compliance with ABS obligations. In November 2003, in collaboration with the Institute de Developpement et des Relations Durable Internationales (IDDRI)l UNU-IAS held a roundtable on User Measures and International ABS Governance in Paris. It is hoped that this document and meetings will play a part in the progressive consideration of user measures.

There are a multiplicity of potential user measures, which may merit investigation including voluntary and regulatory measures, contractual arrangements, issues of access to justice and enforcement of rights, intellectual property rights regimes and their role in ABS, the role of incentive measures for technology transfer, and many others. Consideration of all such user measures is beyond the scope of this preliminary study.

UNU-IAS has decided to focus this preliminary study on specific areas highlighted in the Bonn Guidelines. These are:

- Information, Codes and Certification
- Import and Transport Regulations
- Disclosure of Origin
- Measures to Address Infringements
- An International System for Documenting the Flow of Genetic Resources

This selection of potential and existing measures is neither exhaustive nor exclusive of many other user measures, nor is it intended to prioritise these measures over other potential measures. Indeed, it is intended that future work under the project "Options for Developing ABS Measures in User Countries" will include consideration of an ever wider range of user measures.

A number of important areas that have not been addressed in any detail in this study are technology transfer and compliance with Articles 16 and 19 of the CBD, and the issue of unfair trading practices and competition/antitrust law. Both these areas

pose complex legal and technical challenges, which time and resources have not permitted an adequate examination of for this report. Nevertheless, UNU-IAS recognises their importance and proposes to consider these issues in future institutional research and publications. It is also the intention of the Institute to carry out more detailed analysis of intellectual property rights and the extent to which they may be made more supportive of the CBD's objectives.

1 Background and Rationale

1.1 Rationale and Legal Basis for Considering Options for User Measures

While most countries are both 'providers' and 'users' of genetic resources, there has been a tendency in the international debate on access to genetic resources and benefit–sharing (ABS) to view developing countries as primarily 'providers' of such resources, while more industrialised, developed countries—and, specifically, the private sector businesses and scientific research institutions within their jurisdictions—have been portrayed as 'users' of these genetic resources. Such generalisations are of course not absolutely true and in many cases industrialised countries, such as Australia, are also important providers, while some developing countries, such as Brazil, have highly developed biotechnology and agro–industrial capacities. This study is based on the premise that user measures should at first instance be adopted primarily by countries with extensive biotechnology, pharmaceutical, and agro–industrial capacity to control use of genetic resources for scientific and commercial research and development activities in their jurisdictions. The feasibility, practicality, and effectiveness of developing and requiring adoption of user measure regimes in countries with little if any industrial biotechnological capacity, and with limited markets for such goods, may be questioned and will need to be considered in more depth in future analysis of these issues.

During the decade since the Convention on Biological Diversity (CBD) came into force, efforts to implement the CBD's ABS provisions at the national level have generally focused on establishment of national ABS legislation and mechanisms to regulate the provision of genetic resources by developing countries. The result is that there has been extensive development of national ABS legislation, model contracts, and other instruments and enactments in numerous developing countries, much of which has been reported in case studies and official national reports. Conversely, there has been much less reported on actions taken by countries to regulate use within their jurisdictions of foreign genetic resources and associated traditional knowledge.

In appraising the efforts of countries in such cases, evidence of the extent to which they have adopted legislative, administrative, or policy measures with a view to implementing their obligations to promote fair and equitable sharing of benefits (Article 15.7) and the transfer of technologies (Article 16) and of biotechnologies (Article 19) is particularly germane. At the same time, it is necessary to keep in mind the nature of the social compact which is set down in the CBD. That is, the CBD may be seen as a contract under which biodiversity–rich countries (primarily developing countries) agree to provide facilitated access to genetic resources in return for benefit–sharing; in particular, through access to technologies. The effective implementation of the agreement requires that both sides comply with their commitments.

In determining the adequacy of international ABS governance, it is necessary to identify whether rights over genetic resources and traditional knowledge are protected at all times, not simply when they are acquired for use. To this end it is necessary to examine existing legislation in both provider and user countries. Controls over users and providers must be considered together, because, as experience has shown, the efficacy of one is dependent upon the other.

These links between effective and practical controls over access and use is recognised in the provisions of the CBD. For example, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, state that:

> Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted.

The Bonn Guidelines propose that user countries could consider, *inter alia*, the following measures:

(a) Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;
(b) Measures to encourage disclosure of the country of origin of the genetic resources and the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;
(c) Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;
(d) Cooperation between Contracting Parties to address the alleged infringements of access and benefit–sharing agreements;
(e) Voluntary certification schemes for institutions abiding by rules on access and benefit–sharing;
(fi) Measures discouraging unfair trade practices;
(g) Other measures that encourage users to comply with provisions under sub–paragraph 16 (b) of the CBD.

Sub–paragraph 16(b) states that users should, *inter alia*, seek prior informed consent (PIC); respect customs, traditions, values, and customary practices

of indigenous and local communities; respond to requests for information from indigenous and local communities; only use genetic resources for purposes consistent with the terms and conditions under which they were acquired; seek PIC for new uses; maintain records of PIC and of use; endeavour to carry out use of genetic resources in the providing country; ensure third parties agree to honour terms and conditions attaching to genetic resources; and, ensure fair and equitable benefit–sharing, including technology transfer, in conformity with agreed terms established with indigenous and local communities and other stakeholders.

Moreover, the COP has decided that user measures require further attention at the international level as well. In its Decision VI/24, the COP requested the Ad Hoc Open–Ended Working Group on Access and Benefit–Sharing, to advise the COP on, *inter alia*:

> ...Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted in Contracting Parties with users of genetic resources under their jurisdiction.

Decision VI/24/C proposes specific action on user measures, inviting parties and governments to encourage the disclosure of the country of origin of genetic resources and of relevant traditional knowledge innovations and practices of indigenous and local communities in applications for intellectual property rights.[12] Decision VI/24/C also requests the Secretariat to undertake information gathering and analysis of a number of issues relevant to user measures, including:

(a) Impact of intellectual property regimes on access to and use of genetic resources and scientific research;
(b) Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;
(c) Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;
(d) Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re–examination of intellectual property rights granted;
(e) Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;
(f) Feasibility of an internationally recognised certificate of origin system as evidence of prior informed consent and mutually agreed terms;
(g) Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.[13]

The debate on user measures is likely to receive even more attention as a result of the World Summit on Sustainable Development (WSSD) Plan of Implementation, which calls on governments to "[n]egotiate 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".

In considering the issue of user measures, two important additional factors need to be borne in mind. Firstly, the wider objectives of the WSSD Plan of Implementation must be taken into account, including poverty eradication, changing unsustainable patterns of consumption and production, and protecting and maintaining the natural resource base of economic and social development, as far as the negotiation of an international regime may have bearing upon the realisation of one or more of these objectives. Secondly, attention must be given to the special treatment of plant genetic resources for food and agriculture under the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty).[14] Any process for the negotiation of an international regime on ABS will therefore have to take into consideration multilateral measures for distribution of benefits under the International Treaty, which may also function as a form of user measure.

The development of user measures may be seen as a tool for returning benefits to providers from users.[15] It may also be seen as a means for avoiding the development of restrictive ABS laws in provider countries.[16] In designing such measures, it will be necessary to take into consideration the fact that situations vary greatly amongst product sectors. For example, in pharmaceuticals, an extract may be fundamental, whereas in cosmetics, the container may be more valuable than the contents. With functional foods, nutriceuticals and ornamental plants, the issues are also different. It is therefore important to ensure that in designing measures, they do not end up unnecessarily restricting access rather than facilitating it.[17] One thing that has been agreed by most commentators is that there is clear need to engage the private sector in order to secure their awareness of the CBD and Bonn Guidelines provisions on ABS and their commitment to its implementation and the development of adequate and effective user measures.

The present analysis of user measures does not consider the possible role of capacity development as a mechanism through which users may in fact help to secure the CBD's objectives. It is recognised that this is an important issue, both with regard to development of ABS law and policy in provider countries and the strengthening of their capacity, as well as that of

indigenous and local communities to negotiate fair and equitable agreements. However, it falls outside the scope of the present report which focuses on measures taken to control use within the boundaries of national jusrisdictions into which resources have been imported.[18]

1.2 Definitions: 'Users', 'User Countries', and 'User Measures'

Prior to considering options for user measures it is important to define what is meant by 'users', 'user countries', and 'user measures'.

'Users' of genetic resources are those individuals or entities that actually import and utilise genetic resources, whether for commercial or purely scientific purposes. Examples include botanic gardens that collect, display, and conduct research on plant species from other countries; pharmaceutical and biotechnology firms engaged in drug discovery and product development based on genetic resources accessed from another country; and cosmetic and nutritional companies that import, process, and sell a wide variety of consumer goods that are based on natural products.

In considering the proposed definitions the inherent limitation of developing definitions to cover a wide range of potential users making multiple and varied use of genetic resources under differing socio–economic conditions were recognised. It is clear that as discussion of user measures develops, it will be important to take into consideration whether the diversity of potential users of genetic resources, and the multiplicity of uses which may be made of resources, requires the tailoring of user measures in order to limit their scope to regulation of particular industry sectors or specific uses of genetic resources. Further investigation may identify sound reasons for creating exemptions from obligations to comply with user measures for certain industry sectors or uses, where the feasibility, practicality, and cost of user measures would not merit their implementation.

'User countries' are those competent legal and political authorities with jurisdiction over the actions and operations of users of genetic resources. Depending on the country, the relevant authorities may be at the national/federal or state/provincial level. Specifically, these authorities may include:

(a) CBD Competent National Authorities (CNAs) and National Focal Points (NFPs);
(b) Executive agencies of government with authority over, *inter alia*, customs rules and procedures, the criteria for which patents are granted on products using genetic resources, and the approval for commercial sale and use of products utilising genetic resources;
(c) Legislative bodies;
(d) Courts and other judicial bodies which hear contractual disputes related to genetic resources, and also often interpret the statutes and administrative regulations under which executive agencies function.

'User measures' have been defined by the Scoping Meeting on Capacity Building Approaches for Access to Genetic Resources and Benefit–Sharing,[19] as:

A package of legal, administrative and policy measures designed to promote compliance by users of genetic resources and traditional knowledge with obligations regarding Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and Benefit–Sharing (BS). These measures can be applied by either the private or public sector and may be mandatory or voluntary.[20]

2 Information, Codes, and Certification

2.1 Information on ABS Requirements

An important user measure (and the first listed in the Bonn Guidelines) is to develop mechanisms for providing users with access to information about their obligations under the CBD and its ABS obligations. The need to do more in this respect has been repeatedly recognised.

ABS National Focal Points and Competent National Authorities in user countries can play an important role in raising awareness amongst users. They can act as a clearinghouse for information on the ABS laws of provider countries, and may also provide information on comparative experiences in bioprospecting including information on market rates for the collection and use of genetic resources and traditional knowledge. They can also be an important source of information on model contracts, import and export requirements, and on the relevant national focal points and authorities for seeking PIC in provider countries. They could also provide information to their counterparts in provider countries regarding users seeking access to genetic resources and traditional knowledge. In some case databases already exist which maintain records of genetic resource collections and on MTA's, such as in the Netherlands.[21]

At the date of publishing, only forty–five parties have nominated ABS National Focal Points and National Authorities. Moreover, from information that is available through the Internet about these institutions, few of them are actively providing this type of information or implementing programmes to raise awareness amongst users.[22]

Countries such as the Netherlands, Switzerland, Norway, and Japan are already making serious efforts to promote private sector awareness of the Bonn Guidelines and of corporate responsibility regarding ABS, through the adoption of national policies and awareness–building programs. In Switzerland, the focus to date has been on information dissemination. This has included meetings with stakeholders that may be involved in accessing genetic resources, where there was a great lack of information on users responsibilities and obligations on ABS. Regarding implementation, Switzerland is promoting a voluntary approach which is seen as more flexible rather than a regulatory one which would also take longer to implement.[23] Likewise, Norway has established an expert committee on ABS to look at implementation of Article 15 (7) relating to benefit–sharing. The committee will present its report at the end of 2003.[24]

The importance of increased transparency is one of the fundamental pillars of the dialogue on genetic resources.[25] To this end a more detailed study of the activities of past and ongoing activities to promote information dissemination, along with a survey of user perceptions about their responsibilities, is probably warranted.

2.2 Corporate and Institutional Policies

2.2.1 Individual Policies

Individual firms and institutions that use genetic resources may and do adopt their own individual ABS policies. Ten Kate and Laird (1999) reviewed the policies of a large number of firms in the pharmaceutical industry, and summarised the policies of five firms with policies in place. Essentially, these policies express the firms' support for the CBD, and commit the companies to make efforts to:

- Require suppliers to provide evidence of prior informed consent in the acquisition of, and legal title to, the genetic resources they provide;
- Include a wide range of benefit–sharing provisions in their ABS agreements; and
- Avoid collection of endangered or otherwise biological sensitive species.[26]

While such policies are useful, they would appear to be the exception rather than the rule. In fact, ten Kate and Laird (1999) observed "very few companies have developed policies in response to the CBD, let alone clear and detailed public documents designed to ensure that the acquisition of materials complies with the CBD and national laws on access".[27] Even where firms do have policies in place, there appears to be no objective and external mechanism to monitor or verify whether the policies are being followed.

A number of non–profit research institutions have also developed their own policies in response to the CBD. The Royal Botanic Gardens, Kew (UK), for example, began developing its ABS policies in the early 1990s, and in 1998 issued its "Policy on access to genetic resources and benefit–sharing". This relatively comprehensive policy covers acquisition of genetic resources, their supply to third parties by Kew, benefit–sharing with providers, and commercialisation. The New York Botanical Garden, the Missouri Botanical Garden, the London Natural History Museum, the University of the South Pacific, and the South Africa Council for Scientific Research have developed similar policies.[28]

The International Cooperative Biodiversity Groups (ICBG), a natural products drug discovery programme funded by the US National Institutes of Health since 1993, has developed perhaps the most elaborate and refined set of ABS best practice guidelines of any major institution actively involved in accessing genetic resources. ICBG funds consortia of research institutions, commercial firms, NGOs, and community and indigenous groups to carry out bioprospecting

activities in developing countries, and subsequent drug discovery and development. All grantees are required to follow the ICBG ABS Principles, which cover information disclosure and prior informed consent, contracts and mutually agreed terms, intellectual property rights, benefit–sharing arrangements, information sharing, and compliance with national and international law.[29]

A significant problem in understanding the effectiveness of these types of measures is the absence of any recent assessment of these measures. The most recent comprehensive survey of industry was published in 1999.[30] Since then there is anecdotal evidence that many more companies and institutions have adopted policies in response to the CBD ABS provisions.[31] In the absence of more recent analysis, it is difficult to draw meaningful conclusions about the extent that these measures are adequately meeting users' obligations. Moreover, based on existing market information about such measures, a number of shortcomings can be identified. Perhaps the most important one is that there appear to be no mechanisms for independent verification of their implementation. Where policies are public, most large corporations are likely to loathe operating in a manner which is inconsistent with such policies, due to the possibilities of public criticism and reduced credibility.[32] However, individualised policies in the current climate are unlikely to be a sufficiently comprehensive response to meet the concerns of many providers.

2.2.2 Collective Policies: Codes of Conduct

In addition to these individual efforts, a number of trade associations and research consortia have developed common policies, or 'codes of conduct' that are meant to guide the ABS activities of their members. This approach has the advantage of 'levelling the playing field' among such actors, and increasing peer pressure for others within the sector to both adopt the common code and develop their own individual policies to implement it.

One example of this type of measure is the "Principles on Access to Genetic Resources and Benefit–sharing", together with "Common Policy Guidelines to assist with their Implementation" developed by a group of twenty–eight botanic gardens and herbaria from twenty–one countries.[33] These principles commit participating institutions to implement the spirit and letter of the CBD, the Convention on International Trade in Endangered Species (CITES) and laws related to ABS and related traditional knowledge, and contain specific provisions covering acquisition, use, and supply to others of genetic resources, the use of written agreements, benefit–sharing, curation of samples, and the development of individual institutional policies for implementation of the principles. To date, nineteen botanic gardens have formally endorsed these principles.[34]

Another example, the Micro–Organisms Sustainable Use and Access Regulation International Code of Conduct,[35] has the purposes of supporting CBD implementation for microbial genetic resources (MGRs), facilitating access to MGRs, and helping partners to make appropriate agreements when transferring MGRs. Its key principles are identification of the in situ origin of MGRs via initial PIC; and monitored transfer of MGRs under a Material Transfer Agreement (MTA), the terms of which are defined by both provider and recipient. There are also provisions requiring mutually agreed terms and discussing the importance of and options for benefit–sharing.

The Japan Bioindustry Association, a non–profit organisation that represents a great proportion of the users of genetic resources in Japan, has developed a Statement of Policy on Access to Genetic Resources and Benefit–Sharing. The statement endorses the objectives of the CBD, recommends joint research agreements as the preferred vehicle for achieving prior informed consent and mutually agreed terms, and endorses the sharing of both monetary and non–monetary benefits.[36]

The FAO Code of Conduct for Plant Collecting and Transfer of Germplasm is another example of a Code, albeit of a looser affiliation of partners.

There has been no recent survey of the effectiveness of such codes of conduct. In the absence of such an analysis, it is difficult to draw any conclusions about the effectiveness of these measures. For example, even though they also appear to lack mechanisms for independent verification of their implementation other factors make this less of an issue than for individual policies. Where membership in a prestigious group is made dependent upon complying with such a code of conduct, then this may play an important role in promoting sound ABS practices. In addition, where codes of conduct help secure facilitated access to genetic resources for their members, there may be less of a need for compliance procedures. Moreover, their effectiveness will vary depending upon the nature of the sector that the code addresses. For instance, in a highly organised and professional industry, codes will probably be more effective than in a heterogeneous open industry.

2.2.3 Professional Codes of Ethics

Distinct from the policies of particular institutions, individuals within particular professions—such as ethnobotanists or natural products chemists—have adopted codes of ethics and associated 'best practice' research guidelines for their work. While institutional codes of conduct are aimed at the policies and practices of a particular organisation (or group of organisations); professional codes are aimed at individual professionals within a given field, acting collectively within the framework of their respective professional associations.

A code of ethics is a public moral system that encourages, requires, or prohibits certain forms of behaviour and is subscribed to by the members of a particular profession. Research guidelines provide details on the current standards of best practice to implement an ethical code in practice. Ideally, the two are combined. Professional Codes of Ethics and Research Guidelines related to genetic resources and related traditional knowledge have been formulated and adopted by, *inter alia*, the International Society for Ethnobiology, the American Anthropological Association, the Society for Economic Botany, and the American Society of Pharmacognosy.[36]

Professional codes of ethics are therefore a useful complement to voluntary measures taken by institutions. Ideally, they are mutually reinforcing, with individuals committing to a certain set of ethics and practices in their daily work, and the institutions within which they work committing to the same ethics and practices in the conduct of their business. However, as with other measures covered in this section, there is only a relatively small body of literature and analysis of their effectiveness, and it is not possible to draw any impartial observations about their effectiveness in promoting compliance amongst users.

2.3 Voluntary Certification

In the context of user measures, a relatively novel and innovative user measure mentioned in the Bonn Guidelines, is voluntary certification schemes for institutions abiding by rules on access and benefit–sharing. Such measures have been used to great effect for a wide variety of purposes under the International Organization for Standardization (ISO).[37] Alternative specialised schemes have also been used for some forest products, various fisheries, and marketing of organic foods. The Government of Switzerland has launched a pilot project to test the feasibility of such a measure for promoting proper use of genetic resources.

Certification is a method for verifying compliance with a set of agreed standards.[38] Implementation of best practices[39] can serve as evidence of compliance, but ultimately certification processes focus on whether a standard has been met or not, regardless of the means employed to do so. Certification might be self–implemented (an organisation assessing its own practices against a standard), implemented by a second party with an interest in the organisation's practices (such as buyers of an organisation's product or service), or by an independent third party. Most of the systems of certification in environmental and social sectors characterise themselves as 'third party certification systems'.

'Third–party certification', as it has evolved for certification of forest products, various fisheries, organic foods, and other environmental and social sectors, includes an independent standard setting body; one or more assessor organisations; an agreed procedure for carrying out certification assessments; issuance of a written certificate verifying compliance with the standards; and establishment of an appeals process for certification (or non–certification) decisions. In many cases, the standard setting body will also produce a set of 'best practice' manuals to assist potential applicants in preparing for certification.

Certification systems can also operate on a 'step–by–step' basis, with increasing levels of certification being issued as an organisation's practices improve on a graduated scale. This approach is particularly attractive in sectors where industry transition to the new standards involves significant changes in business practices that may be costly and take time to implement.

Depending on the situation, certification may be purely voluntary, market–driven, or a legal requirement. Since certification is essentially a market–driven phenomenon, however, it is generally thought to function better when it is voluntary.

The feasibility of developing a certification system for ABS activities was examined in a study commissioned by the Government of Switzerland.[40] This study concluded that:

> Certification is a tool that has already been applied to a wide range of situations. At least in theory, a bioprospecting certification system would be feasible to create. There is nothing to suggest that certification could not be applied to bioprospecting activities. Notwithstanding this general conclusion, outstanding issues, such as cost and demand, make it difficult to definitely say whether a bioprospecting certification system would be feasible to create and operate in practice.[41]

Implementing a practical and useful certification scheme poses many challenges.

Certification is largely premised on market demand. Hence, certification of sustainably produced timber and fisheries products has enjoyed some success due to the existence of market demand from consumers who do not want to buy products whose production is implicated in destruction of the natural environment. A similar market dynamic may indeed exist for genetic resources directly used in consumer products such as cosmetics and herbal remedies, where the market chain from provider to consumer is relatively direct. However, this is not likely to be the case for pharmaceuticals derived from natural products research for two reasons. First, the market chain is far longer, and the role of raw genetic resources in the final product is generally much smaller. Second, it is highly unlikely that questions of how genetic

resources—accessed perhaps a decade before—were obtained will influence the behaviour of consumers (and their doctors) when purchasing drugs to preserve their health or save their life.

Users of genetic resources may still have an incentive to participate in a certification scheme for at least four reasons. First, a credible certification scheme may lessen the chances of restrictive legal measures. Second, a certification system may be very useful, from the users' perspectives, where genetic resources are obtained from countries that do not have ABS legislation in place. Third, there may be public relations gains to being certified. Fourth, certification may help companies to attract investors who use social and environmental criteria to make their investment decisions.

Certification processes typically involve examination of production processes on the one hand, and the 'chain of custody' through which a resource moves from its source to the end–user on the other. In the case of genetic resources, both would probably be necessary.

Certification of the 'production process' for genetic resources would likely cover assessment of prior informed consent, negotiation of mutually agreed terms, and benefit–sharing arrangements. These would be measured against both compliance with national law and the internationally agreed set of standards and best practices under which the certification system would operate. Such an assessment is certainly feasible, but would be particularly difficult in determining whether benefit–sharing arrangements are 'fair and equitable', since the financial terms of bioprospecting contracts are generally confidential, and the assumption, when two parties enter into a voluntary contract, is that both parties find the terms to be fair.

'Chain of custody' certification covers 'traceability'—"how an organisation keeps track of a product's inventory and handling up to the point of the product's sale or transport to other parties, ideally providing an unbroken trail of accountability that ensures the physical security of samples, data, and records".[42] Careful documentation of the chain of custody would be an important part of any ABS certification system. Tools exist for tracking the movement, transfer, and uses of genetic resources—such as Material Transfer Agreements—but they would need to be standardised and coordinated to be of use within an ABS certification system.

The confidentiality of proprietary information may also pose a challenge to certification. Providers are particularly interested in knowing to what specific commercial uses their genetic resources are being put, whereas companies may be reluctant to disclose information on specific research and development activities, or on the roles of various partner organisations.

Certification systems cost money to establish and run, and current social and environmental certification systems are not self–financing. How users of genetic resources might be persuaded to fund such schemes is not clear. Funding becomes even more uncertain in this context because a comprehensive ABS certification system, encompassing standards for both providers and users, would have to be global and not national or local.

It needs also to be borne in mind that in order to avoid potential conflicts with the disciplines of the World Trade Organization (especially the SPS Agreement and TBT Agreement) any ABS certification system will need to be purely voluntary and managed by a private organisation, not a government.

It is not clear whether it is ultimately feasible to establish a voluntary, independent, third–party certification system covering the acquisition and use of genetic resources and traditional knowledge. The current pilot project by the Government of Switzerland to test the certification concept may provide useful insights regarding the feasibility of this measure.

3 Import and Transport Regulations

Utilising existing customs and transport regulations and procedures to regulate the import of genetic resources is a measure that could encourage users to comply with their obligations. Detailed regulations govern the import and transport of plant material, wildlife, and micro–organisms in virtually all countries. Governments regulate imports and transport for many different purposes, including implementing obligations under international treaties and, in some cases, to ensure that the item imported was obtained in compliance with the laws of the country of source.

3.1 National Customs Controls of Importation of Biological Material

National authorities in many countries have established elaborate controls on the importation of biological material for a number of reasons, including protection of human, plant, and animal health.[43] The Canadian Food Inspection Agency requires that an importer possess a valid permit in order to import certain plant materials, as well as an appropriate phytosanitary certificate or similar document from the country of origin. All commercial shipments of fresh fruit and vegetables for instance must be accompanied by a fully completed Confirmation of Sale document signed by either the importer or exporter.[44] If a shipment does not pass inspection, it may be refused entry, returned to the originating country, or destroyed upon entry, at the cost of the importer.[45]

Australia has been a pioneer in the development of stringent importation controls to prevent the contamination of its natural environment with foreign biological resources. Many natural products including fruits and vegetables, beans, cereal seeds, live animals and plants (including plant cuttings and biological material such as human and animal vaccines), and veterinary therapeutics, can only be imported if accompanied by a valid import permit.[46]

The US has also established a system of importation permits for etiologic agents, which are micro–organisms that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsiae, protozoans, and parasites, and may also be referred to as infectious agents. Under Federal regulations, an import permit is needed for importation of any infectious agent known or suspected to cause disease to humankind, whether for educational, scientific, commercial, or other purposes.[47]

Even in the case of importation of less obviously dangerous products prior to importing goods into the US, it is necessary to ensure the overseas supplier has marked the goods with the country of origin. There are exceptions to this requirement. For instance, for goods that are incapable of being marked (e.g. fruit), it is appropriate to mark the outer container with the country of origin.[48]

In addition to regulations governing imports of animal, plant, and microbial specimens, many industrialised nations also have a legal and administrative infrastructure in place to control imports of 'pirated' goods (such as computer software). In the US, for example, there are already 20,000 employees working at over 300 points of entry to identify and prevent the illegal importation of pirated goods.[49]

3.2 International Measures to Develop Customs Standards: World Customs Organization

Harmonising standards for documentation is an important means to promote the effectiveness of customs controls as well as ease the burden of such requirements for transport. This probably is the case for any measures to identify the source of genetic resources and traditional knowledge and the rights to import as much as it is the case for other customs requirements. The World Customs Organization (WCO) is the principal international body for promoting a harmonised system of tariff nomenclature. The Harmonized System, as it is commonly known, is an application–based international numerical coding system for commodities, governed by the International Convention on the Harmonized Commodity Description and Coding System. The system covers 98 per cent of the merchandise in international trade comprising more than 5,000 commodity groups and 200,000 commodities. The WCO overseas the implementation of the System, mainly through its Enforcement Committee, which is responsible for monitoring international efforts to eradicate illegal trade.

Traditionally, commodities have been listed under the Harmonized System according to criteria relating to the volume and monetary value in trade. However, this is now changing and new criteria that allow the inclusion of commodities of social or environmental concern are evolving. A number of multilateral agreements, whose objective is to control import and export of various substances/commodities of environmental concern, are in the process of applying to the WCO to use the Harmonized System. The principal advantage identified in using the System is the fact that customs officials are better positioned to control illicit transboundary movement since controlled commodities are coded in an internationally accepted way.[50]

The Harmonised System is also used as a basis for amongst other things, avoiding duplication in rules of origin, and monitoring of imports of controlled goods (including endangered species), by its 161 member countries.[51]

The WCO is currently working on Harmonized Rules of Origin. The WCO Agreement on Rules of Origin defines Rules of Origin as those laws, regulations, and administrative determinations of general application applied by WCO Member countries to determine the country of origin of goods. 'Harmonized Rules of Origin' mean the coherent rules concerning origin determination, which are expected to be set out by co–operative efforts between WCO Member States and applied to non–preferential commercial policy instruments. When they are completed, the Rules will be appended to the Agreement. Appendix 1 to the proposed rules of origin sets forth the definitions of the goods that are to be considered as being wholly obtained in one country. It provides for the origin determination of live animals born and raised in that country, and plants and minerals harvested or taken in that country.[52]

3.3 CITES – The Control of the Trade in Animal and Plants

As previously mentioned, governments regulate imports to implement all sorts of international obligations. A germane example of this is the import measures developed to implement CITES. CITES adopts measures to control the international trade in specimens of endangered species. The Convention requires that all import, export, re–export, and introduction from the sea of species covered by the Convention have to be authorised through a licensing system.

Each party to the Convention must designate one or more Management Authority to administer the licensing system and one or more Scientific Authority to advise them on the effects of trade on the status of the species. A specimen of a CITES–listed species may be imported into or exported (or re–exported) from a State party to the Convention only if the appropriate document has been obtained and presented for clearance at the port of entry or exit. There is some variation of the requirements from one country to another and it is always necessary to check on the national laws.[53]

In the US, imports of CITES Appendix II species must be accompanied by a valid export permit from the country of origin, and may only enter the country through legally specified ports. Even if a shipment of plant materials is coming from a CITES non–member, the US still requires documentation from the country of origin in lieu of an actual permit. Specimens that arrive without proper documentation are subject to immediate seizure by the Animal & Plant Health Inspection Service (APHIS), and the proprietary interest in the specimens is ceded to APHIS.[54]

The US Lacey Act Amendments of 1981[55] go further, making it "illegal to import, export, transport, sell, receive, acquire or purchase in interstate or foreign commerce: fish or wildlife taken, possessed, transported or sold in violation of a state law, state regulation or foreign law..." and provide significant criminal and civil penalties for violations. While the provision on foreign law in the Lacey Act does not apply to plants, micro–organisms, or genetic material in general, the existence of the Act illustrates that, at least in the US, there is no legal or conceptual problem with prohibiting imports of biological resources obtained illegally in their country of origin.

In the European Union, Council Regulation 338/97,[56] which regulates the wildlife trade, establishes a comprehensive permitting regime for all imports of plant and animal specimens, defined as "any animal or plant, whether alive or dead, of the species listed in Annexes A to D, any part or derivative thereof, whether or not contained in other goods...". For import of specimens of species listed on CITES Appendix III,[57] the regulation requires that the applicant furnish "documentary evidence, by means of an export permit issued in accordance with [CITES] by an authority of [the country of origin] competent for the purpose, that the specimens have been obtained in accordance with the national legislation on the conservation of the species concerned".

In the UK, customs authorities check plant products at the point of entry for valid certification and/or letters of authority, and Plant Health and Seeds Inspectors physically check the plants after inspection of the certificates. This applies to both CITES–plants and plant products in general.

3.4 Practicality and Limitations of Import Controls

In summary, most if not all of the countries where the majority of genetic resources users are located already have extensive regulations and procedures in place to monitor the import of animals, plants, micro–organisms, and their parts or derivatives. In the case of CITES, these regulations are implemented to achieve the objectives of an international conservation treaty, and require the importer to furnish a permit as evidence that the specimen or material in question was legally exported from the country of origin. Even so relying upon these measures to encourage users to comply with their obligations has a number of limitations.

To adapt the existing customs regulations, in particular the Harmonized Codes, is a lengthy and costly process. Moreover, expansion of customs import requirements to help enforce the CBD's ABS

regime would entail additional administrative burdens and costs. This burden maybe disproportionate as the small size of genetic resources, which in some cases can be easily hidden or poorly described, would make enforcement more difficult.

A further difficulty that may arise relates to the increased burden that a new set of ABS–related import requirements would put on importing institutions, raising the costs and difficulty of conducting scientific research and developing new products based on imported genetic resources. Users of genetic resources which have already fulfilled the legal requirements of the country of origin would be able to comply with importation disclosure requirements by furnishing customs authorities with documentary evidence of the origin of genetic resources or traditional knowledge and where required of the existence of PIC. Even so, many provider countries do not have clear procedures in place to issue genetic resource export permits documenting compliance with national regulations. Indeed, many countries do not even have a functional ABS focal points let alone regulatory frameworks in place. In fact, the effectiveness of this type of user measure is directly dependent on providing countries taking action to establish clear, unified regulatory measures and focal point agencies for ABS matters. The absence of clear ABS law and/or policy in provider countries and the absence of competent national authorities to make decisions on access will undoubtedly increase costs of meeting additional import requirements.

Furthermore, import regulations are unlikelyto be very effective, for example, in documenting the 'import' of traditional knowledge associated with genetic material. In addition, import regulations are of only limited value application where movement of physical samples is not required because analysis of the samples has been done in the country of origin, and only the resulting information exported (over, for example, the internet).[58]

3.5 Transport Regulations

Related to the use of import measures are the wide array of international measures, standards, rules and initiatives that govern international transport of goods, which often (although not exclusively) build upon import regulations to achieve a variety of purposes. Mostly these regulations are developed for the safe transport of goods, and could cover the shipment of genetic resources. Rarely would they cover the transfer of intangible goods such as traditional knowledge.

These rules tend to be focused on the mode of transport (generally known as modal requirements). For example, the International Maritime Organization (IMO) has developed rules and standards that deal with the transboundary carriage of goods by sea. A well–known set of such standards is the International Maritime Dangerous Goods Code (IMDG Code), but this is by no means the only relevant set of standards developed by IMO. The International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA) have developed rules and standards that govern airfreight, which are applicable to genetic resources (e.g., the ICAO Technical Instructions and IATA Dangerous Goods Regulations). The Universal International Postal Union has developed rules and standards for the shipment of goods by post (see, for example, the 1995 Manual of the Universal Postal Convention) that are also applicable to genetic resources (i.e., the sending of microbial organisms by post). One particularly relevant set of regulations for the purposes of this study is the OECD Schemes for the Varietal Certification of Seeds Moving in International Trade. The OECD Seed Schemes were developed primarily to facilitate international trade in seeds, by harmonising varietal certification procedures and identification labels. The Schemes are implemented by forty–eight member and non–member countries across all continents. Their essential purpose is to harmonise the assessment and certification of identity and purity of cultivated crop plant varieties—including genetically modified ones.

For some classes of goods, especially those that pose a special danger to human or animal health and the environment, more specific or more detailed requirements have been developed by various bodies. For example, international rules governing the transport of dangerous goods, microbial organisms, biological control agents, pests, alien and invasive species, bacteria, pathogens, biological waste products, and even animals will to varying extent cover the transboundary movement of genetic resources. Examples of these include the International Plant Protection Convention (IPPC) and its various codes of conduct (e.g., the Code of Conduct for the Import and Release of Exotic Biological Control Agents) and the United Nations Recommendations on the Transport of Dangerous Goods developed by the United Nations, which are popularly known as the "Orange Book" (document ST/SG/AC.10/11/Rev.3). For example, the UN Recommendations are designed to present a core set of provisions that should "allow for the uniform development of national and international regulations governing the various modes of transport". The Recommendations adopt a system that categorises goods by the types of risk associated with their transportation. Two classifications potentially cover genetic resources.

Over and above international measures are regional and national rules and standards to the same end. For example, the transport of certain genetic resources may need to take account of regulations and standards elaborated by:

- European Culture Collections' Organization (ECCO)
- European Committee for Standardization (i.e. European Standard EN 829:1996 E: Transport packages for medical and biological specimens, requirements, and tests. Brussels: CEN)
- The World Health Organization (WHO) Laboratory Biosafety Manual, 1993

Finally, national regulations will also be relevant. For example, many countries have implemented the modal requirements mentioned above, particularly those related to the transport of dangerous goods. Moreover, in Europe, many of the European Union requirements have been expanded in many of the individual member States. Similarly, other countries have detailed requirements covering the transport of goods, which to some extent will cover the shipment of genetic resources. For example, a survey of regulations in 1997 concluded that within Australia, Denmark, India, the Philippines, Thailand, and the US, there were requirements at the time for specific and detailed packaging requirement to ensure safety during transport and transit of transgenic plants and plant parts, seeds, micro–organisms and/or cells or sub cellular elements, insects, mites and related organisms, or other macroscopic organisms; for research, large scale experiments, production, experimental releases, teaching, exhibition, etc.

Despite the variety and array of existing rules, none comprehensively or simply covers the scope of potential users and uses subject to ambit of the CBD. Many of the relevant rules governing transport only apply within a certain geographical or political region (e.g., the OECD or European Union regimes)—with the consequence that some important countries are not adequately covered. Few of the rules deal with the range of uses covered by the CBD. For example, many of the rules and standards focus on requirements for pathogens or dangerous organisms. As a result, many types of plants, for example, would not be covered by any existing rules and regulations. The stated purpose of most of the existing rules and standards is to protect human, animal or plant health, not the environment. The legal and institutional complexity of the relevant international rules for transport means that any specific procedures developed for user measures need to be drafted carefully and precisely. For example, careful consideration needs to be given as to which rules and bodies are relevant. Given the wide range of situations possible within the scope of user measures, the question is difficult to answer in the abstract, especially because of the rapidly expanding nature of biotechnology and the emergence of new products and applications. In such situations, it is difficult to envisage that a single generic approach to the issue will be effective.

4 Disclosure of Origin

Article 16.5 of the CBD states that intellectual property rights should be supportive of and not run counter to the objectives of the Convention. It was therefore only a matter of time before attention was drawn to the patent application and granting process with a view to promoting their modification in order to make them more supportive of the CBD's ABS objectives. In 1994, two proposals emerged which sought to link ABS with IPR applications procedures. The first of these proposed that applicants for patents be required to disclose information regarding the source of genetic resources and traditional knowledge;[59] the second argued that applicants should not only be required to disclose the origin of genetic resources and source of traditional knowledge, but should also provide evidence of prior informed consent for their use.[60]

With respect to ABS in particular, the Bonn Guidelines have incorporated the principle of disclosure of origin into "soft law". The Guidelines invite parties to encourage the disclosure in applications for IPR, of:

> ...the country of origin of genetic resources where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and mutually agreed terms on which access to those resources was granted.[61]
>
> ...the origin of relevant traditional knowledge, innovations, and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development.[62]

4.1 National and Regional Law and Policy on Disclosure

Analysis of existing experiences in legislating for disclosure of origin and legal provenance in national and regional legislation reveals a variety of approaches being taken or considered, ranging from mandatory obligations set in place by the Andean Community to a purely voluntary regime in the European Union.

The countries of the Andean Community have adopted two binding Decisions which establish mandatory disclosure requirements. Decision 391 (1996) entitles national IPR authorities to require applicants for patents to provide copies of access contracts, where use has been made of the regions genetic resources.[63] Decision 486 (2000) makes the granting of patents dependent upon compliance with international, Andean Community, and national law relating to ABS[64] and obliges applicants to provide copies of agreements to demonstrate the existence of PIC.[65] Failure to provide copies of agreements for use of genetic resources or traditional knowledge can lead to the patent being annulled.[66]

At the national level, Peru was the first country to adopt national legislation requiring disclosure of origin and evidence of legal provenance of biological material in applications for a grant of IPR.[67] Failure to provide the required information in applications for plant breeders' rights may lead to the suspension of an application. Similarly, Costa Rica's biodiversity law requires national IPR authorities to seek evidence of PIC as a condition for granting of patents. India, on the other hand, has adopted legislation, which requires approval of the national biodiversity authority as a condition for applying for any IPR for any invention based on research or information obtained from India.[68]

The European Parliament supported the incorporation of disclosure requirements in the European Directive 98/44/EC on the legal protection of biotechnological inventions.[69] The Parliament proposed that inventions, consisting of or using biological material originating from plants or animals should only qualify for patent protection if the geographical origin of the material is disclosed and evidence provided that the material was used in accordance with the relevant laws on access in the country of origin.[70] The Parliament's proposed amendment was not accepted. The non–binding Recital 27 was incorporated into the Directive's preamble, which states that:

> ...if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known...[71]

This provision is to be without prejudice to the processing of patent applications or the validity of rights arising from granted patents.[72]

Denmark was the first developed country to adopt legislation requiring disclosure of origin in patent applications.[73] The Danish law, which implements the EU Directive on biotechnological inventions, requires that "if an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known."[74] Failure to do so does not impede the granting of a patent or validity of the patent. Breach of this provision could imply a violation of the obligation in the Danish Penal Code (para 163) to provide correct information to public authorities.[75]

The government of Belgium has proposed an amendment to Belgian patent law to state that an invention is contrary to ordre public and morality, when it is developed on the basis of plant or animal material collected or exported in breach of various articles of the CBD.[76] A patent bill currently pending in Germany seeks to implement disclosure obligations along the lines of Recital 27 of the European Directive.[77]

In May 2003, the Norwegian government submitted to parliament a legislative proposal to amend patent law, to require that, "...if an invention concerns or uses biological material, the inventor shall disclose in the patent application the country providing such material and, where different, the country of origin shall also be disclosed. If national legislation in the providing country or the country of origin requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought. Violations of the requirement to disclose are punishable under the penal code."[78] However, the requirement to disclose would not affect the processing of a patent application or the validity of a patent.[79]

Switzerland has indicated its intention to "explicitly enable the national patent legislation to require declaration of the source of genetic resources and traditional knowledge in patent applications".[80]

The distinction between disclosure of origin as required by legislation in Latin America and disclosure of source or geographical origin as set down in the Swiss and other European proposals is an important one.[81] The fundamental question is whether applicants should be required to provide information of the country of origin, or merely of the source from which the resources were obtained. The issue is a complex one and has many political overtones including the status of pre–Convention collections and whether or not these may be legitimate providers of resources for development of commercial products. More recently countries such as Costa Rica and Mexico have begun to utilise what they call certificates of legal provenance. This is an interesting departure but not without difficulties, as the question then becomes under what legal regime are decisions regarding the legality of provenance to be decided. There is clearly a need for further analysis of these various options.

4.2 Disclosure of Origin and International Law

Proposals for disclosure of origin measures have been put forward in many intergovernmental fora including the World Trade Organization (WTO),[82] the CBD,[83] the United Nations Conference on Trade and Development (UNCTAD),[84] and the World Intellectual Property Organization (WIPO).[85] A report by the UK Commission on Intellectual Property Rights has also highlighted the potential role of disclosure of origin as a tool for ensuring equity regarding use of genetic resources and traditional knowledge.[86]

Calls for modification of international law have traditionally come from developing countries. Brazil in a communication to the TRIPs Council on behalf of a group of developing countries proposed that the TRIPs Agreement should be amended to provide that Members shall require, applicants for a patent relating to biological material or to traditional knowledge, as a condition for a grant of a patent, to disclose the source and country of origin, and provide evidence of PIC and of fair and equitable sharing of benefits.[87]

These proposals have not found much support amongst developed nations. The European Community in a communication to the TRIPs Council in September 2002 stated that:

> the EC...agree to examine the possible introduction of a system, such as for instance a self–standing disclosure requirement, that would allow Members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access.[88]

However the communication goes on to state that:

> [F]ailure to disclose or the submission of false information should not stand in the way of the grant of a patent and should have no effect on the validity of the patent once it is granted.[89]

This position has been criticised by NGOs which have argued that the disclosure mechanism offered by the EC would allow patents to be granted on any genetic material or knowledge misappropriated from indigenous farming communities, even where the applicant for the patent intentionally withholds or falsifies information regarding the origin or source of resources.[90]

In May 2003, in a communication to the Council for Trade Related Aspects of Intellectual Property Rights, Switzerland took an intermediate position and stated its intention, "to propose amendment to the Patent Cooperation Treaty to enable Contracting Parties to require patent applicants ... to declare the source of genetic resources and /or traditional knowledge, if an invention is based on or uses such resources or knowledge."[91] The Swiss proposal for amendment to the PCT would entitle Contracting Parties to require an applicant:

- To declare his source of the specific genetic resource to which the inventor has had access, if an invention is directly based on such a resource; if such resource is unknown, this shall be declared accordingly.
- To declare the source of knowledge, innovations and practices of indigenous and local

communities relevant for the conservation and sustainable use of biological diversity, if the inventor knows that an invention is directly based on such knowledge, innovations and practices; if such source is unknown, this shall be declared accordingly.

Based on the links between the PCT and the Patent Law Treaty (PLT, Article 6.1) parties to the PLT would be entitled to adopt national laws making validity of a granted patent dependent upon a making a correct declaration of source. A patent could therefore be invalidated where there was "fraudulent intention".[92] The Swiss proposal has been supported by Norway and a number of developing countries but rejected by the USA, while Japan supported the proposal but took the opinion it should be discussed further in the WIPO Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and the EU believed it should be examined further.[93]

Although, going further than the European position and providing a means for invalidating patents obtained following a fraudulent declaration, the Swiss proposal would not require evidence of PIC as a condition for processing or granting a patent. The proposal is therefore primarily for disclosure as a transparency measure, which may be enhanced by establishing a system for notification of government agencies competent to receive information regarding patent declarations, thereby empowering authorities to police patent applications involving their national resources. The Proposal also claims that adoption of this measure will not require any modifications to TRIPs, and can therefore be adopted in the short term.[94]

4.3 Feasibility and Efficacy of Requiring Disclosure

The COP in Decision VI/24 invited the World Intellectual Property Organization (WIPO) "to prepare a technical study, and to report its findings" to it at its seventh meeting on "methods consistent with obligations in treaties administered by WIPO[95] for requiring the disclosure within patent applications" of, *inter alia*:

(a) Genetic resources utilised in the development of the claimed inventions;
(b) The country of origin of genetic resources utilised in the claimed inventions;
(c) Associated traditional knowledge, innovations and practices utilised in the development of the claimed inventions;
(d) The source of traditional knowledge, innovations and practices;
(e) Evidence of prior informed consent.

In May 2003 WIPO released the comprehensive *Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge (Draft Study)*.[96] The study considered three broad functions for disclosure requirements:

- A transparency function—to disclose use of resources.
- A disclosure of origin function—either country of origin or more specific source.
- A compliance function—to provide evidence of prior informed consent or that the act of applying for the patent was taken in accordance with prior informed consent.

The Draft Study concludes that there is a range of methods for requiring disclosure that are consistent with the essential elements of patent law and key aspects of WIPO treaties.[97] The study states that disclosure requirements may be consistent with WIPO treaties, where they are positive obligations such as those relating to the right for the inventor to be named in the application, or they may be implicitly consistent in the sense that they do not conflict with treaty requirements. The study goes on to state that where there is a stand–alone or distinct disclosure requirement, its legal and practical relationship with the patent approval and grant process may need to be clarified.

The study identifies some key issues for consideration including:

- The relationship between the genetic resource and traditional knowledge on one hand and the claimed invention on the other.
- The range and duration of obligations that may attach to resources and knowledge, within the source country and in foreign jurisdictions
- The legal basis of the disclosure requirement in question, and its relationship with the processing of patent applications, the grant of patents and the exercise of patent rights.

A final report of the WIPO study will be made to COP7 in March 2004.

The Secretariat to the CBD is also compiling information and analysing the potential on the efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re–examination of intellectual property rights granted,[98] and in monitoring compliance with access procedures.[99]

4.4 Compatibility with the International Trade Regime

One area that has not been analysed by the WIPO Draft Study is the extent that disclosure measures are compatible with the international trade regime; in particular, the TRIPS Agreement. Although the issue is extremely complex, and the debate is characterised by diversity of views and opinions rather than clarity and certainty, the following section highlights some of the more important areas in a brief and necessarily simplistic manner.

4.4.1 Conformity with International IPR Regimes

In the case of patents, Article 27.1 of the WTO TRIPS Agreement states, "Patents shall be available for any inventions...provided they are new, involve an inventive step, and are capable of industrial application". This may be interpreted as excluding the imposition of any other conditionality for the granting of patents. Establishing a requirement to disclose the origin or legal provenance of genetic resources or traditional knowledge a condition for the granting a patent, therefore, may be inconsistent with Article 27.1 of TRIPS.

Another basic requirement of patent regimes is for disclosure of claimed inventions "...in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art". Such requirements are common to many patent law regimes, and reflect the standards endorsed by Article 29.1 of TRIPS. It has been suggested that requiring disclosure of origin in IPR applications might simply regularise an existing customary practice to disclose the geographical origin of plants with limited distribution, and of associated traditional knowledge when describing compounds isolated from plant extracts.[100] However, where genetic resources are widely distributed the origin of such resources generally is not disclosed.

The tendency to disclose traditional knowledge in applications for patents is in all likelihood a consequence of requirements to disclose information regarding what is known as "prior art" in the description of a patent. Under the Patent Cooperation Treaty, for instance, the requirement is to include:

> ...the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and preferably cite the documents reflecting such art.[101]

Establishing requirements for disclosure of the geographic origin of genetic resources and the use of traditional knowledge may, therefore, not run contrary to TRIPS, but rather serve to formalise customary practice. However, it is unclear whether a failure to provide such information may be held to provide sufficient grounds for refusing to process a patent application, unless knowledge of the geographic origin and of the use of traditional knowledge are necessary for replicating the relevant invention.

4.4.2 "Reasonable Procedures"

Article 62 of TRIPS entitles national authorities to establish reasonable procedures, which must be met in order to process IPR applications. On the one hand, it has been argued that only those requirements that assist patent administrators to assess whether the substantive requirements of an application for a patent have been met, should be considered reasonable.[102] On the other hand, it is argued that requirements to provide evidence by way of disclosure of the existence of an agreement for the use of genetic resources and traditional knowledge are entirely reasonable, to the extent that they attempt to reconcile the objectives of the CBD with those of TRIPS,[103] protect the sovereign rights of countries over their resources, and protect ordre public by enforcing national access law.[104] It has also been suggested that, where countries require disclosure in order to promote compliance with national legislation in order to avoid costly legal disputes in international courts each time there is a case of wrongful appropriation, disclosure requirements are absolutely rational and indispensable.[105]

Determination of what may be 'reasonable' under TRIPS Article 62 may depend upon the scope of the disclosure requirement, which might range from disclosure of geographical origin to provision of documentary evidence of PIC. A decision on reasonableness may also depend upon the extent to which the subject matter of the IPR application is derived from the relevant genetic resource or traditional knowledge. It has been suggested that Article 62 is subjective in nature and therefore the reasonableness of any requirement for disclosure should be determined on a case–by–case basis.[106]

4.4.3 The "Doctrine of Unclean Hands"

As noted above, there are differing opinions regarding whether requiring disclosure of origin and legal provenance of genetic resources and traditional knowledge, in fact, conforms with TRIPS. However, there is one area of the debate on disclosure and its utility in IPR regimes about which there appears to be more widespread agreement. This relates to the principle that the holder of a patent, which has been obtained following an illegal act should not

be entitled to benefit from their illegal act, through exercise of the rights obtained in the grant of the IPR. This is generally referred to as the application of the "doctrine of unclean hands".

The doctrine of unclean hands, drawn from Anglo–Saxon law, holds that if an entity or individual has committed fraud in violation of national law, their rights to a patent will not include the derivative rights related to it, until the vices are corrected.[107] This would affect the ability of patent holders to sue infringers of their patents, as "...one must have clean hands to obtain relief from an equity court".[108]

Article 8.2 of TRIPS authorises WTO members to adopt appropriate measures to prevent the abuse of IPRs. It has been suggested, therefore, that patent owners might be prevented under "doctrine of unclean hands" (also known as the "fraudulent procurement doctrine" in US common law) from benefiting from patents, where there has been a breach of an obligation to disclose origin or legal provenance of genetic resources or traditional knowledge, and where the enforcement of patent rights illegitimately obtained would be considered abusive.[109]

4.4.4 Disclosure of Evidence of Prior Informed Consent

Analysis of legislative measures and communications to the TRIPS Council demonstrate the existence of an ideological divide between developed and developing countries with regard to the purpose behind establishing disclosure requirements. In European countries, disclosure has been treated as a formality, without substantive effect with regard to the processing or validity of patents and do not include any requirement to demonstrate PIC as a precondition for the granting of a patent. Under the Andean Community legislation, on the other hand, countries are empowered to require evidence of PIC as a condition for processing patent applications.

A number of potential problems associated with requiring PIC as a condition for granting patents has been set down in the Swiss communication to the TRIPs Council. These include:

- Patent authorities were not designed to carry out this task, and do not have the necessary legal and technical competence to determine the correctness of the evidence provided;
- Patent authorities would be burdened by the need to search for and have access to the national legislation of the country of origin and familiarise themselves with its provisions;
- It is questionable whether any such determination could be made with sufficient legal certainty.

One proposal for overcoming such impediments suggests the need for establishment of a standardised international system of 'certificates of origin' to act as evidence of PIC. Patent authorities would be entitled to accept a valid certificate of origin or of legal provenance as evidence of PIC, without any requirement to analyse the adequacy of the terms of any agreement or compliance with national ABS laws. Provision of a certificate of origin or of legal provenance precludes the need for disclosure of confidential contractual and other information unnecessary for the purposes of processing a patent application.

4.5 Evaluating Options

The WIPO Draft Study and the various proposals to the TRIPS council and other fora suggest a range of potential options for disclosure which are worthy or more in–depth investigation with regard to their practicality, functionality and cost, as well as that of measures which may facilitate their operation. The Bonn Guidelines have already called for analysis of the functionality, practicality, and cost of an international certificate of origin system. This issue will be discussed in further detail later in this report.

WIPO, in its Draft Stud,y has also suggested that the potential success of any system will relate to the degree of clarity and predictability of impact of any disclosure requirement, and thus its practical impact, this in turn is likely to depend on whether the requirement can be analysed or expressed in terms of patent law.[110] Review of the various disclosure proposals and their capacity to be expressed in such terms would be a practical follow–up by WIPO to their Draft Study, and would help to further inform the international debate on such issues.

4.6 The Role of Provider Countries in Disclosure of Origin Schemes

Any system requiring evidence of PIC as a condition for granting of patents must overcome the problem associated with the fact that most countries of origin and indigenous and local communities have no mechanisms for making decisions on access or providing PIC. The International Seed Federation has recently suggested that one of its principal objections to requirements for disclosure of PIC in patent applications process is that:

> Most countries have neither put in place a requirement for PIC with appropriate mechanisms for obtaining it, nor stated definitively that they will not require it. Demanding evidence of consent to access in these countries imposes the Intellectual Property protection applicant a condition that cannot be fulfilled.[111]

Developing countries wishing to promote adoption of an international requirement for disclosure of origin and of PIC must be prepared to establish their respective national ABS systems, and appoint competent national authorities capable of processing bioprospecting applications. Adoption of a global system requiring disclosure of origin may therefore act as an incentive for compliance by developing countries to develop national law and policy to meet their obligations to facilitate access under the CBD.

5 Measures to Address Infringements

Capacity to seek redress in the event of an infringement of legitimate interests of providers is dependent upon a number of factors including, most importantly, access to information regarding existence of rights, the breach of rights, the existence of judicial or administrative processes offering relief, or of alternative dispute resolution mechanisms, as well as of opportunities for obtaining legal representation, and of means for covering the costs of actions.

In many instances, access to justice even in the country of origin of resources may prove problematic. Once genetic resources and traditional knowledge have left the jurisdiction of the country of origin, difficulties may increase and capacity to protect national sovereign rights and those of indigenous and local communities will be dependent on obtaining "access to justice" in a foreign jurisdiction.

Effective justice involves a number of different steps. First there are issues of access to information, briefly discussed above, which are fundamental for identifying the existence of a cause of action, the manner for pursuing such an action and the location of the defendant etc. Second, there are a number of technical legal issues, which must be considered regarding the right to bring an action before a foreign court; this may involve issues such as the enforcement of foreign judgments, standing to sue in foreign jurisdictions, evidentiary standards, the burden of proof, and the like. Third, there are practical questions of access to justice including access to information, possibilities for bringing an action before the courts, etc, which even if the formal legal avenue for redress is available, may make it practically impossible for many providers to pursue an action. Even some developing country governments may find the costs and complexity of bringing an action against a major corporation or research institution in a foreign jurisdiction a serious impediment to seeking relief before the courts. This is certainly the case for indigenous peoples, developing country universities and research institutions, or public interest civil society groups.

5.1 Collaboration between Countries to Investigate Infringements

Many providers will often not be in a position to defend their rights in the event of a breach of an ABS agreement for the reasons outlined above, in particular due to lack of information, funds, access to courts, language difficulties and lack of legal representation. In order to be in a position to police and defend their rights they will require assistance from user countries. This issue is reflected in Bonn Guidelines, which calls for "[c]ooperation between Contracting Parties to address alleged infringements of access and benefit–sharing agreements".

Assistance may come in a range of guises including access to information, communication of patent applications, investigation of claimed breaches, provision of visas, recognition of standing, and provision of legal aid, amongst others. There is a need for more in–depth study of the ways and means by which developed countries could provide this kind of assistance to developing countries.

Establishment of an Ombudsman's Office or extension of the duties of existing ombudsman's offices is one possible and practical means for helping promote equity in ABS issues. An ombudsman might, amongst other responsibilities, be given power to monitor IP applications, respond to requests for information from countries of origin, indigenous peoples and local communities, collect information regarding claims, visit claimants where necessary in their own jurisdiction, facilitate provision of evidence by way of affidavit or audio/visual recording, take an action on behalf of a foreign claimant, and provide legal aid to a foreign claimant.[112] The Swedish Parliament first used the word "Ombudsman" in its modern sense when in 1809 it established the office of Justitie–Ombudsman, who was to function as a defender of the people in their dealings with government. Since then, similar offices have been established in over 100 countries worldwide, most of which are affiliated with the International Ombudsman Institute.[113]

The role of the ombudsman is to protect the people against violation of rights, abuse of powers, error, negligence, unfair decisions and maladministration in order to improve public administration and make the government's actions more open and the government and its servants more accountable to members of the public.[114] The ombudsman usually has the power to make an objective investigation into complaints from the public about the administration of government. Often the ombudsman may also have powers to initiate an investigation even if a complaint has not been registered.

To protect people's rights, the ombudsman is commonly authorised to investigate whether the administration of government is being performed contrary to law or unfairly; if an objective investigation uncovers improper administration, to make recommendations to eliminate the improper administrative conduct; and report on his activities in specific cases to the government and the complainant; and, if the recommendations made in a specific case have not been accepted by the government, to the Legislature. Most ombudsmen also make an annual report on their work to the legislature and the public in general.[115] In a number

of countries, the protection of human rights is one of the major purposes of the ombudsman office.[116] The office of ombudsman existing in a large number of countries may already provide opportunities for prosecuting actions to secure rights over genetic resources and traditional knowledge. It is conceivable that a claimant might seek to call upon the services of a national ombudsman based on a claim that failure to adopt measures by a user country in accordance with obligations arising under the CBD led to a failure to protect the claimants rights over genetic resources or traditional knowledge. Proposals for an ombudsman might include the development of an office for claimants at the Secretariat to the CBD.

Access to justice, in many cases, may require reliance on pro bono lawyers, or lawyers who are prepared to take a case based on receiving a percentage of the eventual damages, which may be awarded, sometimes known as 'contingency' or 'success fees'. In the US, for example, many law firms provide pro bono legal advice to those who cannot afford adequate legal representation. In a new development, an international network has been established to put needy clients in contact with pro bono public interest intellectual property lawyers.[117] This and other such initiatives may come to play an important role in helping communities and countries of origin seek justice in foreign jurisdictions.

5.2 Alternative Dispute Resolution

Many countries are parties to either or both of the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, and the Washington Convention on the Settlement of Investment Disputes between States and Nationals of Other States. Arbitration is generally less costly than litigation, as it is usually completed within a fixed time, and according to mutually agreed upon procedures. Furthermore, in arbitration proceedings it is not always necessary to have legal representation. There is also no risk of an award being granted against an indigenous or local community, for example, for the legal costs of the other party, something that could occur if an unsuccessful action is brought in the judicial court system.

The main drawback to arbitration is that it requires both parties to consent to the process. ABS contracts can specify that disputes will be resolved by arbitration, and may define who shall pay the costs of such arbitration. Under the terms of an agreement for the collection and use of traditional knowledge negotiated within the framework of the International Collaborative Biodiversity Group Program (ICBG) in Peru, the parties agreed to submit disputes to arbitration in New York under the rules of the American Arbitration Association. That agreement states "[s]ubject to NIH[118] approval, the ICBG Project shall undertake to pay reasonable costs of the collaborating [indigenous] organisations associated with the dispute".[119]

5.3 Enforcement of Foreign Judgments

As countries adopt ABS legislation, it is increasingly possible to imagine situations in which the courts of a country of origin may render judgments in favour of the state, a research institution, or an indigenous or local community, in an action relating to a contract or tort claim with respect to the use of genetic resources or traditional knowledge by a foreign user. In the event that the infringing party is not available within the country in which the judgment is obtained, it may be necessary to seek to enforce the judgment in a foreign jurisdiction.

In common law jurisdictions, such as the US and the United Kingdom, courts will look to various factors in determining whether a foreign judgment may be enforced, including procedural fairness, impartial justice between aliens and citizens, and an absence of factors that would show prejudice, fraud or some other reason for denying comity, such as concerns over public policy. Whether or not a judgment will be enforceable will depend upon analysis of the particular case with reference to relevant statutes and case–law precedents.

In civil law countries, on the other hand, courts are more concerned with reciprocity and enumerated rules for transnational enforcement of judgments. In Japan, for instance, a foreign court's judgment must not only meet due process considerations, it must not be contrary to public order or good morals in Japan, and there must be reciprocity between Japan and the nation from which the judgment came. However, as long as the aforementioned conditions are met, Japanese courts will generally enforce not only the monetary judgments of foreign jurisdictions, but also injunctions and declarations of legal relationship.

Civil law countries tend to be less willing, however, to enforce judgments for tort claims, in particular for what are seen as 'excessive' jury awards arising in the US system.[120] This has been a point of contention in the negotiation of the Hague Convention on the Recognition and Enforcement of Foreign Judgments, which has been under discussion since 1996 and involves more than 45 countries. If successfully concluded, The Hague Convention would establish a regime governing jurisdiction to sue defendants in tort and contract, and would improve predictability in the enforcement of the resulting judgments.[121] It is possible that such a Convention, if adopted, would offer expanded opportunities for countries of origin to secure enforcement of their judgments in the courts of other states that are party to the Convention.

Alternatively, it is possible that the provider can take legal action in the user country. Such an approach

may have various advantages. It avoids the difficulties relating to enforcement of foreign judgments, and it may offer opportunities for increased awards, in particular in tort actions brought in the US. The principal difficulties with this are the costs, the distance from the courts, problems of obtaining visas to process an action, awareness of the right to take an action, and of the potential means for advancing a case. Access to sound legal representation is important to provide litigants with an opportunity to promote successfully their case.

In summary, the opportunities to seek redress for breaches of rights over genetic resources and traditional knowledge already exist under tort and contract law in many developed country jurisdictions. Effective access to justice, in foreign jurisdictions, is subject to both technical/legal issues (such as rules on enforcement of foreign judgments, standing before the courts, evidentiary standards, and burden of proof) and practical issues (such as knowledge of rights and of the possibility of obtaining relief, legal representation, language, availability of visas, and costs).

There is, however, a need for further investigation and consideration of measures for promoting cooperation to address alleged infringements of ABS agreements. Possible measures include including investigation of claimed breaches; facilitating access to information on use of resources and knowledge; notification of patent applications; assisting service of court documents; identifying the location of defendants; flexibility of rules for accepting evidence by affidavit or audio/visual recordings; recognition of standing; provision of legal aid; provision of visas; and alternative, reduced–cost dispute resolution mechanisms, including arbitration. A practical measure to begin to address the technical and practical issues is the designation of an ombudsman to provide a point of contact for receipt of ABS claims, carry out preliminary investigation of alleged infringements of rights over genetic resources and traditional knowledge, and monitor breaches of contractual obligations.

5.4 Equity

Equity is a common law remedy developed as an extra judicial remedy exercised in olden days by the Chancellor to redress the injustices arising through strict application of the law. As a body of law, equity evolved over time through practice and precedent. For the purposes of implementation of the CBD's ABS provisions there is a clear need to identify what principles of equity should be applied. Considering the wide range of potential laws and policies that may be relevant to differing cases of bioprospecting relating to genetic resources and traditional knowledge, it may be desirable to seek to identify some general underlying principles of equity common to multiple legal systems. Sources of law and of principles of equity may be derived for instance from common law, civil law, Islamic law, Canon law, Talmudic law, etc, as well as from the customary law and practice of indigenous and local communities. Identification and recognition of such a body of principles could play an important role in facilitating dispute resolution.

5.5 Feasibility, Practicality, and Cost

There has to date been little research done on the issue of the respective practicality, feasibility and cost of proposals for establishment of disclosure requirements, whether mandatory or voluntary, and it is therefore too early to draw any conclusions regarding the relative merits of such systems vis–à–vis other user measures as a means to secure the CBD's objectives. In the event that a binding obligation to disclose origin is established this may imply significant costs and adoption of new legislation, including for instance amendment of the European Patent Directive, and may also require amendment of TRIPS,[122] though as seen above it has been argued that mandatory requirements may not under certain circumstances be in conflict with TRIPS. In all events such possibilities will need to be considered in the negotiation of alternatives at the international level.

One of the issues which will need to be considered in making such analysis is the actual extent to which IPR regimes are utilised for securing rights over products involving genetic resources and or traditional knowledge. It has been pointed out that many products utilising such resources are not the subject of IPR and this highlights the limitations of disclosure requirements to secure the wider aims of the CBD on ABS.[123] Notwithstanding such limitations it is apparent that some form of disclosure requirements is now seen by many countries as being a useful measure to assist in implementation of the CBD's ABS provisions.

Industry, on the other hand, has not adopted a common position on this issue,[124] although the international seed industry has stated that some form of voluntary mechanism may be acceptable. In order to move to a more informed debate on these issues, relevant research on the merits of the various alternative proposals should be carried out with due attention to their applicability and suitability for various different product sectors. It may also be worth considering whether some form of bloc exemptions may be established for specific product sectors such as for instance food and agriculture, where the multiplicity of inputs required for development of new plant varieties for instance might result in an impossible bureaucratic burden and inordinately raise the costs of doing business.

6 An International System for Documenting the Flow of Genetic Resources

Decision VI/24/C calls on the Secretariat to CBD to undertake further information gathering and analysis of the feasibility of an international 'certificate of origin' system as evidence of prior informed consent and mutually agreed terms. The term 'certificate of origin' was originally coined to define a standardised form to be issued as evidence of PIC for the purposes of assisting in the implementation of a system of disclosure of origin in patent applications.[125] It has now fallen into fairly common use to signify a standardised system of documentation for tracing the flow of genetic resources.[126]

Establishment of a standardised system for tracking and documenting flows of gentic resources would considerably facilitate both voluntary and mandatory measures discussed above. Customs officers, patent authorities, product approval agencies, and research funding institutions would be freed of any need to examine the substantive content of access agreements and genetic resources transactions. Their obligations might extend only to requiring evidence of origin, content and PIC, in the form of a standardised official document issued by the country of origin. As with CITES, there might be some difficulties with fraud, but establishment of a global internet–based information system—allowing cross–checks with source countries—could help combat fraud.

A globally recognised system of standardised gene flow documentation would, in short, harmonise procedures for identifying the existence of PIC; protect the confidentiality of contracts; reduce transaction costs; facilitate tracking of gene flows; promote increased trade in genetic resources; and provide an incentive for countries of origin to develop more flexible ABS rules and procedures.[127]

The documentation utilised in such a system might incorporate a standard permit of 'certificate of origin' including information concerning:

- particulars of the provider and user
- particulars of indigenous or local communities parties to the agreement; details of genetic resources or traditional knowledge
- details of the approved use which may be made of the resources
- details of any restrictions on use
- period of the agreement
- conditions relating to transfer of rights to third parties
- details of the issuing authority

In summary, it appears that in responding to the CBD mandate to consider and develop user measures—as well as the WSSD call for development of an international regime for genetic resources benefit–sharing—it will be important to consider the role which might be played by an standardised international system for documenting genetic resources flows.

Although widely used in discussions of ABS, the term 'certificate of origin' is not without problems and there have been suggestions that as it may prove impossible to identify the origin of genetic resources, it may be more appropriate to talk of a 'certificate of source'. This proposal is, however, also problematic as it would tend to support the position that the rights stem from the source not the country of origin a position, which may be at odds with the CBD. More recently, use has been made of the term 'certificates of legal provenance' in some countries, such as Mexico and Costa Rica, to designate documentation providing evidence that the laws of the country of origin or of other legal source have been complied with. This is an interesting and potentially sound proposal; it is, however, dependent upon agreement as to what amounts to legal provenance, something which is still ill–defined in many cases.

The nature of any particular system of documentation will depend upon the purpose it is intended to serve. There may also be a need to provide for different forms of documentation for different resources or depending upon the nature of the use. There is presently a lack of information regarding potential systems for tracing gene flows and for documenting PIC.

There is, therefore, a need for case studies from various different sectors including, for instance, agricultural resources such as those from the international genebanks in IPGRI, plant samples and the manner for their recording and transfer between botanical gardens, microbial resources such as those included in collections covered by the MOSAICC project, or medicinal plant flows. Analysis of this nature is required to investigate the practical feasibility and cost of establishing harmonised systems for tracing gene flows. Similarly, there is a need to examine the flow of traditional knowledge and the viability of establishing a system for documenting PIC related to access to traditional knowledge and for its use.

Conclusion

The investigations and analysis carried out for this study suggest that there is a wide range of feasible measures that users of genetic resources and associated traditional knowledge—and governments where such users are located—could take that would significantly strengthen implementation of the CBD's ABS provisions. While more research, analysis, and dialogue are obviously necessary, a few preliminary conclusions arise from the work carried out for this report. The executive summary details these.

This study has shown that many potential user measures may not, in fact, require the adoption of new legislation, or the development of complex new regimes. Rather, it suggests that modification of existing procedures for import controls, applications for intellectual property, and adjudication processes, coupled with strengthening and standardisation of voluntary measures, may go a long way towards redressing the perceived imbalance in ABS governance. However, in some cases, such as adoption of binding disclosure obligations, there may be requirements for the amendment of existing international legal obligations under TRIPS as well as of regional law such as the European Patent Directive.

In considering possible means to respond to the WSSD's call for negotiation of an international regime on benefit–sharing, within the framework of the CBD, parties may wish to consider potential mechanisms by which global governance of ABS may be advanced incrementally. The further development and implementation of the user measures proposed in this report is one such incremental step, which can enhance the sharing of responsibility between provider countries and countries in which users operate, to secure the CBD's objectives.

ABS regulation in both provider countries and user countries may be considered the basic building blocks of an international regime of ABS governance. What turns disparate national laws into a global regime are the threads which integrate these disparate elements thoroughly. One of those threads will no doubt be a system for documenting evidence of PIC. It is suggested that parties to CBD may wish to consider advancing development of such a system as a means to implement the Bonn Guidelines, and respond to the WSSD's call for negotiation of an international regime on benefit–sharing.

In adopting user measures, it will be important to promote measures which have the greatest possibility of helping to secure the CBD's ABS objectives without unduly hindering trade. It will be important, therefore, to avoid the establishment of mechanisms which raise transaction costs inordinately and establish time consuming and costly bureaucratic hurdles. User measures should not be adopted by countries for the sake of being seen to take action, but as effective mechanisms for complying with obligations and responsibilities to help impede the illegal and unapproved trade in genetic resources and traditional knowledge and the fair and equitable sharing of benefits. Most importantly, negotiators will need to consider the merits of promoting adoption of complex regimes for controlling or monitoring the flow of resources, in order to ensure that they do not have adverse effects on this flow of resources, which is so necessary for global food and health security and the development strategies of developing countries.

Endnotes

1 See Juma 1989., at p. 6.
2 Ibid at p. 38.
3 ten Kate and Laird 1999 give an estimate between US $500 and $800 billion for annual markets for various categories of product derived from genetic resources.
4 Ibid at p. 318.
5 Requirements of this nature have been included, for example, in Andean community Decision 391, establishing a common regime on Access to genetic resources, and national ABS legislation in the Philippines and Costa Rica's biodiversity law.
6 See Peruvian Law No. 27811, Law Introducing A Protection Regime For The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources, published in the Official Journal El Peruano on August 10, 2002.
7 See Dutfield 2000, for discussion of the neem and quinoa patents.
8 See, for instance, commentaries on biopiracy at: http://www.aidjharkhand.org/alert_gar.html, http://www.twnside.org.sg/title/iprharare.htm.
9 For discussion of international proposals for modification of IPR regimes, see Section V on Disclosure of Origin.
10 For discussion of existing ABS practices and useful bibliography, see Laird 2002 and ten Kate and Laird 1999.
11 See Downes 1993, Hendrickx 1994, and Tobin 1994, for some early discussions on proposals for user measures.
12 See paragraphs 1 and 2, Decision VI/24/C.
13 See paragraph 3, Decision VI/24/C.
14 The International Treaty includes a variety of obligations for parties in which genetic resources are used, including an obligation not to claim intellectual property rights (IPRs) over genetic resources provided through the multilateral system that the Treaty establishes, and an obligation to ensure that the terms of Material Transfer Agreements (MTAs) are implemented, even when the genetic material in question is subsequently transferred to a third party. The COP has stressed that the Bonn Guidelines are to be developed without prejudice to the Multilateral System envisioned by the International Treaty. Governments have already established an interim work programme for the Treaty, in which they will develop the Multilateral System and other key parts of the Treaty.
15 Pers. comm. Peter Schei, March 2003.
16 Pers. comm. Kent Ndozie, March 2003.
17 Pers comm. Seizo Sumida, 1 October 2003.
18 For further discussion of the role of contracts in ABS, see Tobin and Gollin in Laird. S. 2002, *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, Earthscan, London 2002, Chapters 9 and 10.
19 Convened in Kuala Lumpur in October 2002 by UNU-IAS and the United Nations Environment Programme (UNEP).
20 UNEP/CBD/ABS/EW-CB/1/INF/1, Appendix II, paragraph 2.
21 Pers. comm. Marcel Vernooij, March 2003
22 A survey carried out in 1999 of various user type industries, found that even though a high proportion of the companies and other organisations interviewed had heard of the CBD, many did not have a good understanding of the its scope, let alone their responsibilities as users. See ten Kate and Laird. 1999. *The Commercial Use of Biodiversity*. London: Earthscan Publications Ltd.
23 Pers. comm. Francois Pythoud, March 2003.
24 Pers. comm. Birthe Ivars, April 2003.
25 Pers. comm. Marcel Vernooij, March 2003.
26 ten Kate 1999, pp. 304–305.
27 Ibid at p. 303.
28 For detailed information on ABS policies developed by these and other research institutions, see Laird & Wynberg 2002.
29 For detailed information on the International Cooperative Biodiversity Groups (ICBG) program, see http://www.fic.nih.gov/programs/icbg.html. For a description and analysis of a number of ICBG–funded bioprospecting projects, see Rosenthal 1999.
30 ten Kate and Laird 1999.
31 Pers. comm. Lee Skillington, 4 November 2003.
32 Garcia 2001.
33 For a list of botanic gardens that have adopted the common principles on access to genetic resources and benefit–sharing, see http://www.rbgkew.org.uk/conservation/endorsements.html.
34 Full text and explanatory material on MOSAICC can be found at http://www.belspo.be/bccm/mosaicc/.
35 The full Japan Bioindustry Association Statement of Policy on Access to Genetic Resources and Benefit–Sharing is available at http://www.jba.or.jp/jbl/vol-16/8-5.html.
36 For a detailed discussion of professional codes of ethics and research guidelines related to genetic resources and traditional knowledge, see Laird and Posey 2002.
37 For example, the system of voluntary environmental standards developed by ISO, in particular, ISO 14020:1998, ISO 14021:1999, ISO 14024:1999, and ISO/TR 14025:2000.
38 Standards are succinct, specific statements describing various elements of the desired end–state. An ABS standard for users of genetic resources, for example, might state that "genetic resources shall only be accessed under mutually agreed terms embodied in a written, enforceable contract which fully complies with the applicable laws of the country of origin".
39 Best practices are a set of more detailed, complementary materials and examples that provide information and examples on how to meet a particular standard or set of standards. Thus, in our present example, the 'best practices' associated with this particular standard might elaborate the key elements of bioprospecting contracts, provide suggested model provisions, and suggest ways to ensure that the bargaining process is equitable and transparent. A standard must be uniform, whereas the methods utilised to achieve that standard will necessarily need to be as diverse and flexible as the range of actors and situations involved in genetic resources transactions.
40 Glowka 2001.
41 Ibid. at p. v.
42 Ibid. at p. 24.
43 See http://www.defra.gov.uk/animalh/illegali/plain_guide.pdf.
44 See Memorandum D19-1-1, Ottawa, 2 November 2000.
45 See http://www.inspection.gc.ca/english/plaveg/pr.otect/dir/d-02-02e.shtml.
46 See http://www.customs.gov.au/site.
47 See http://www.cdc.gov/od/ohs/biosfty/imprtper.htm.
48 See http://help.customs.gov/cgi–bin/customs.cfg/php/enduser/std.
49 See http://www.customs.ustreas.gov/xp/cgov/import/commercial_enforcement/ipr.xml.
50 These agreements include the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Montreal Protocol on Substances that Deplete the Ozone Layer, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Cartagena Protocol on Biosafety, and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.
51 See http://www.wcoomd.org/ie/index.html.
52 Ibid.
53 See http://www.cites.org/eng/disc/how.shtml.
54 See http://www.aphis.usda.gov/oa/pubs/ppqplant.html.
55 Lacey Act Amendments of 1981: 16 U.S.C. §§ 3371–3378, November 16, 1981, (as amended 1984 and 1988).
56 Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein. Official Journal L 061, 3/03/1997 P. 0001–0069.
57 Species listed on CITES Appendix III include "all species that any party identifies as being subject to regulation within its jurisdiction for the purpose of preventing or restricting exploitation, and as needing the cooperation of other parties in control of the trade".
58 The authors are grateful to Geoff Burton of Environment Australia for bringing this point to our attention.
59 Hendrickx et al. 1994.
60 See Tobin 1994, and Tobin 1997. The "Certificate of Origin"

proposal is based on three underlying principles: (a) controlling market use is most effectively achieved through use of a market tool; (b) requiring disclosure of origin and evidence of PIC transfers the burden of proof regarding rights to use genetic resources and traditional knowledge to the user; (c) the threat of loss of patent rights for failure to disclose the origin and PIC is an incentive to users to seek PIC at an earlier stage in the R & D process.

61 Bonn Guidelines, Section C, paragraph 1.

62 Bonn Guidelines, Section C, paragraph 2.

63 Andean Community, Decision 391 (1996). The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by–products or synthesised products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of this Decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

64 Andean Community Decision 486 (2000), Article 3.

65 Ibid, Article 26.

66 Ibid, Article 75.

67 Government of Peru, Supreme Decree 008-96-ITINCI (Implementing the Third Complementary Measure of Andean Community Decision 391).

68 Bill No. 93 of 2000, passed by the Indian Parliament in December 2002.

69 See Wells 1999 for detailed discussion of the development of Directive 98/44/EC.

70 See Doc. COM(97) 446 Final (august 19, 1997), Amendment 76 (1). See Wells 1999 Intellectual Property Rights and Genetic Resources: specification of origin on patent applications as a mechanism to facilitate benefit sharing under the Convention on Biological Diversity, June 1999, (unpublished manuscript) for discussion of the development of Directive 98/44/EC.

71 Recital 27. Directive 98/44/EC on the Legal Protection of Biotechnological Inventions.

72 See Straus (forthcoming).

73 Act 412, 31/5 2000 amended the Danish Patent Act.

74 This provison of ministerial regulation 1086 11/12 2000 replaced para 3 of the existing ministerial regulation on patents (Reg. 374 19/6 1998) (unofficial translation).

75 Pers. comm. Christian Prip, 10 Mar 2003.

76 See G van Overwalle 2002.

77 Pers. comm. Joseph Straus, Oct, 2003.

78 Section 166 of Norwegina Penal code, pers comm. Birthe Ivars, 30 June 2003.

79 Based on unofficial translation of legislative proposal (Ot.prp.nr.86 2202-2003), pers. comm. Birthe Ivars June 30, 2003.

80 IP/C/W/400.

81 Pers. comm. Lee Skillington, 4 November 2003.

82 See inter alia, documents IP/C/W/195, IP/C/W/228, IP/C/W/400, WT/GC/W/233, IP/C/M/32, and paragraph. 128, IP/C/M/33, paragraph 121.

83 See Decision IV/8, paragraph 3 and Annex; Decision V/26, paragraph A.15 (d); UNEP/CBD/COP/5/8: paragraph 127.

84 See TD/B/COM.1/EM.13/3, paragraph 17.

85 See SCP/3/10, WIPO/IP/GR/00/2, WIPO/IP/GR/00/4.

86 Commission on Intellectual Property Rights, 2002. Integrating Intellectual Property Rights and Development Policy. Report of the Commission on Intellectual Property Rights. London.

87 See, for example, IP/C/W/356

88 Communication by the European Communities and their Member States to the TRIPs Council on the Review of Article 27.33(b) of the TRIPs Agreement, and the Relationship Between the TRIPs Agreement and the Convention on biological diversity (CBD) and the Protection of Traditional Knowledge and Folklore. "A concept Paper", European Commission, directorate General for Trade, Brussels, 12 September 2002.

89 Ibid.

90 See GRAIN – Open letter to Pascal Lamy on TRIPS 27.3 (b) review, 27 Feb 2003, http://www.grain.org/publications/lamy.cfm

91 See IP/C/W/400.

92 Ibid.

93 See Straus (forthcoming).

94 See IP/C/W/400.

95 It is important to note that WIPO does not administer the TRIPS agreement.

96 WIPO/GRTKF/IC/5/10.

97 WIPO/GRTKF/IC/5/10, at page 71.

98 Decision VI/24 C. 3 (d).

99 Decision VI/24 C. 3 (e).

100 UNEP/CBD/COP/3/22, paragraph. 51. See also Sukhwani, A. Patents Using Biological Source Material, Spanish Patent and Trademark Office, Madrid.

101 Rule 5.1(a)(ii).

102 N Carvahlo 2000, p. 382.

103 The Doha WTO Ministerial Declaration has instructed the Council for TRIPS to examine this relationship with regard to the review of Article 27.3 (b) of TRIPS, Paragraph 19 states: We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

104 M Ruiz 2002.

105 CIEL 2002, p. 4.

106 Ibid.

107 CIEL 2002, p. 5.

108 Carvahlo 2000, p. 371.

109 Ibid, p. 396.

110 WIPO/GRTKF/IC/5/10, p 73.

111 International Seed Federation Position on Disclosure of Origin in Intellectual Property Protection Applications (adopted in June 2003 at the Annual Congress of the International Seed Federation in Bangalore, India) http://www.seedquest.com/News/releases/2003/august/6347.htm.

112 Examples of the services provided by Ombudsman include the European Ombudsman see http://www.euro–ombudsman.eu.int/guide/pdf/en/guide_en.pdf.

113 See http://www.comb.gov.au/.

114 See http://www.law.ualberta.ca/centres/ioi/eng/eng_home.html

115 For information on the International Ombudsman Institute see http://www.law.ualberta.ca/centres/ioi/history.htm

116 Ibid.

117 The group is called Public Interest Intellectual Property Advisors (PIIPA). See http://www.piipa.org.

118 National Institutes of Health of the United States of America.

119 As the ICBG Parties are no longer funded by NIH and it must be questioned who would pay the costs of arbitration if it were sought by the Aguarunas.

120 Murphy 2001.

121 Ibid.

122 Pers. comm. Lee Skillington, 4 November 2003.

123 Pers. comm. Susan Bragdon, 30 October 2003.

124 Pers. comm. Tom Jacob, 4 November 2003.

125 See Tobin 1994.

126 See statement from the COICA/UNDP Regional Meeting on Intellectual Property Rights and Biodiversity (Santa Cruz Declaration) September 1994 calling for an investigation of the potential role of certificates of origin to protect indigenous rights over traditional knowledge. For use of the term in a proposal of Elements for a Common Regime on Access to Genetic Resources for the Andean community, prepared by IUCN/ELC and SPDA, see Caillaux and Ruiz 1998. The term is also used in Costa Rica's Biodiversity Law, and the Department of Agriculture in Fiji has used a 'certificate of origin' form for evidencing approval for access to certain biological material. Certificates of origin are also issued for access to genetic resources by the Peruvian National Institute for Natural Resources (INRENA).

127 See Tobin 2000.

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