

**CONVENTION ON
BIOLOGICAL
DIVERSITY**Distr.
GENERALUNEP/CBD/COP/8/INF/25
9 February 2006

ENGLISH ONLY

**CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY**

Eighth meeting

Item 17 of the provisional agenda*

Curitiba, Brazil, 20-31 March 2006

**ANALYSIS OF OPTIONS FOR IMPLEMENTING DISCLOSURE OF ORIGIN
REQUIREMENTS IN INTELLECTUAL PROPERTY APPLICATIONS -
SUBMISSION BY UNCTAD**

The Conference of the Parties, at its seventh meeting, in decision VII/19 E, paragraph 9, invited UNCTAD to examine a number of issues related to disclosure of origin requirements in intellectual property applications and to prepare a report for submission to the ongoing process of work of the Convention on Biological Diversity.

The Executive Secretary is pleased to circulate an analytical study entitled “Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications”, by Joshua Sarnoff and Carlos Correa, which was commissioned by the UNCTAD Secretariat in response to the invitation by the Conference of the Parties. The paper was written by the authors in their personal capacities as experts in the field, and does not necessarily represent the views of the UNCTAD Secretariat. It is intended to make an in-depth, practical and substantive contribution to policy dialogue and consensus-building on the topics considered.

The paper was previously distributed as an information document for the fourth meeting of the Open-ended Working Group on Access and Benefit-Sharing (UNEP/WG-ABS/4/INF/2). It is being circulated in the form and the language in which it was received by the Convention Secretariat.

* UNEP/CBD/COP/8/1.

Analysis of Options for Implementing Disclosure of Origin Requirements In Intellectual Property Applications

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A contribution to UNCTAD's response to the invitation of the Seventh
Conference of the Parties of the Convention on Biological Diversity*

* The views in this document are solely those of the authors and do not necessarily reflect the views of UNCTAD.
This document has been issued without formal editing.

Executive Summary

A. Background on the CBD Invitation to UNCTAD

1. In 2002, the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) at its Sixth Meeting adopted the Bonn Guidelines to address access to genetic resources and fair and equitable benefit sharing arising from use of those resources. In the Bonn Guidelines, the CBD COP invited Parties and governments to encourage the disclosure of the country of origin of genetic resources and of associated traditional knowledge that relate to the subject matter of intellectual property applications. Since 2002, various proposals to facilitate or to mandate such “disclosure of origin” requirements within the world intellectual property system have been submitted by countries to intergovernmental organizations, notably the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). In 2004, at its Seventh Meeting, the CBD COP in Decision VII/19 invited WIPO and the United Nations Conference on Trade and Development (UNCTAD) to analyze issues relating to implementation of disclosure of origin requirements in the intellectual property law system.

2. Specifically, the CBD COP identified for analysis five distinct topics relating to disclosure of origin requirements. These are:

- Options for model provisions on proposed disclosure requirements;
- Practical options for intellectual property application procedures with regard to the triggers of disclosure requirements;
- Options for incentive measures for applicants;
- Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties; and
- Intellectual property-related issues raised by proposed international certificates of origin/source/legal provenance

3. This analysis has been commissioned by the UNCTAD secretariat as a contribution to its response to the CBD COP’s invitation. However, the views in this document are solely those of the authors and do not necessarily reflect the views of UNCTAD or the authors’ institutions. The analysis is intended to make a thorough, practical, and substantive contribution to the analysis of the topics identified above. The analysis builds upon and extends prior analyses of these issues by the authors, by WIPO, by various countries, and in a growing body of literature.

4. The analysis begins with an Introduction, which provides additional background on the CBD COP invitation, identifies the need for and features of an international system of mandatory disclosure of origin requirements, and clarifies the limits of the analysis and the terminology used therein. The discussion of terminology is important, both to assure a common understanding and to achieve clarity.

5. The Introduction is followed by five sections addressing the topics identified by the CBD COP. Part I discusses the basic choices for “model provisions,” focusing on an international regime of mandatory disclosure requirements, triggers for disclosure requirements and the consequences of disclosure failures, and the choice of treaty regime in which to adopt disclosure requirements. Part II addresses in greater depth the options relating to substantive and procedural triggers for disclosure requirements. Part III addresses in greater depth incentives relating to enforcement consequences that are internal to the intellectual property law system. Part IV addresses practical issues in implementing disclosure of origin requirements within existing WIPO-administered treaties, focusing on WIPO patent law treaties. These practical considerations apply beyond the specific context of patent applications and have relevance for other intellectual property law treaty regimes, such as the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), the Union for the Protection of New Varieties of Plants (UPOV), and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Finally, Part V analyzes intellectual property law issues raised by international certificates of origin when such certificates are used to effectuate disclosure of origin requirements.

B. Summary of Principal Findings

6. This rest of this Executive Summary provides a brief overview of the most significant issues and conclusions of the analysis. The Executive Summary briefly reviews the issues addressed and conclusions of the Introduction and Parts I through V. Accordingly, the Executive Summary should be considered to provide only an introduction that facilitates understanding of the detailed text.

7. **Introduction.**

- **There is a need for an international system of mandatory disclosure of origin requirements.** An international system of mandatory disclosure of origin requirements is needed to prevent misappropriation of genetic resources and associated traditional knowledge, to promote compliance with CBD access and benefit sharing requirements, and to prevent misuse of the intellectual property system. As recognized by the Bonn Guidelines, disclosure of origin requirements for intellectual property applications are an important element of the CBD access and benefit sharing regime, reflecting the interconnection of the CBD regime with the international intellectual property law system. Although national legislation imposing disclosure of origin requirements already exists in some countries, disclosure of origin requirements have yet to be adopted in many countries where intellectual property may be sought. New international treaty provisions are required to assure worldwide effectuation of disclosure of origin requirements.

- Objections that have been raised to mandating adoption of disclosure of requirements through new international treaty provisions either do not stand up to analysis or do not outweigh the benefits to be obtained. Specifically, disclosure of origin requirements:
 - (a) may be useful in improving substantive examinations and in assuring the integrity of determinations under traditional intellectual property legal requirements, providing greater certainty regarding the validity of granted rights or privileges and reducing the need for revocation of improperly granted intellectual property;
 - (b) may assist in identifying situations and may facilitate corrective actions where intellectual property is improperly granted or where access to genetic resources and associated traditional knowledge has been obtained without concluding contracts establishing prior informed consent and equitable benefit sharing;
 - (c) are necessary to prevent misappropriation of commercial benefits that are improperly obtained directly from the acts of applying for, owning, or transferring intellectual property;
 - (d) may help to make more coherent existing and future national laws regarding misappropriation that affect the validity of intellectual property or the entitlement to own or retain benefits from intellectual property; and
 - (e) may reduce uncertainties of and make more transparent an international system of national access and benefit sharing and intellectual property laws.

- **Suggested outline of an international system of mandatory disclosure of origin requirements.** To be effective in deterring violations of access and benefit sharing requirements and in preventing misappropriation, disclosure of origin requirements may need to result in the denial of entitlements to apply for, own, or enforce intellectual property. Similarly, disclosure of origin requirements may need to permit national intellectual property offices to delay processing of intellectual property applications or to consider such applications withdrawn when required information is not timely provided. Disclosures of origin should be required at the earliest stage of intellectual property applications, and should obligate applicants to disclose:
 - (a) the source of genetic resources and associated traditional knowledge;
 - (b) the country providing genetic resources and associated traditional knowledge;
 - (c) available documentary information regarding compliance with access and benefit sharing requirements, and
 - (d) information known to the applicant (following a specified level of effort for inquiry) regarding persons involved in the subject matter

of the application and the country of origin of genetic resources and associated traditional knowledge.

These disclosures should be based on a broad set of substantive triggers that relate the subject matter of the application to the genetic resources and associated traditional knowledge. Required disclosures should be reviewed at the international and national stages of application proceedings for completeness and for formal compliance with specified procedures, but should not ordinarily be reviewed for substantive validity or legality (unless such review already is required). In contrast, substantive reviews of disclosures should occur principally in a judicial action, or in a pre-grant or post-grant administrative challenge proceeding. In the absence of bad faith, opportunities to cure disclosure failures should be provided and remedies should be tailored to the scope and nature of the disclosure failures.

- **Limits of the analysis.** This analysis focuses on the concerns raised by the CBD in regard to disclosure of origin requirements for intellectual property applications. Although the CBD broadly relates to genetic resources, biological materials, and biological diversity, the CBD access and benefit sharing requirements in Article 15 address only genetic resources. Accordingly, the analysis focuses on disclosure of origin requirements relating to genetic resources, and explores a wide variety of substantive and procedural relationships between the genetic resources and the subject matter of intellectual property applications. Similarly, the CBD in Article 8(j) directly addresses for purposes of equitable benefit sharing only traditional knowledge relevant for the conservation and sustainable use of biological diversity. Traditional knowledge, innovation, and practices, however, encompass a much wider array of information. As has the CBD COP, the analysis focuses on traditional knowledge that is associated with genetic resources. Nevertheless, the principles discussed in this analysis may have relevance to biological materials other than genetic resources and to other forms of traditional knowledge that relate to the subject matter of intellectual property applications.
- **Terminology.** No standard definitions exist for many of the terms associated with disclosure of origin requirements relating to genetic resources and traditional knowledge. The scope of and burdens in complying with required disclosures will depend on the definitions of relevant terms and how they relate to the various substantive and procedural triggers adopted. To provide greater clarity, the analysis defines the following terms, which are derived from or supplement those adopted by the CBD.

- (a) **“Genetic resources”** means “genetic material of actual or potential value,” *i.e.*, valuable “material of plant, animal, microbial or other origin containing functional units of heredity.”
- (b) The **“country of origin”** means the country or countries in which the genetic resources are possessed in *in-situ* conditions, even if a country of origin is not the country where the genetic resources historically originated.
- (c) The **“country providing genetic resources”** means the country or countries from which genetic resources relevant to an intellectual property application have been supplied.
- (d) The **“source”** of genetic resources means the person or entity directly providing access to genetic resources. A source may possess or may lack authority to provide access under specified conditions of use and of equitable benefit sharing.
- (e) **“Authority”** refers to the ability of the source to legally provide access on specified conditions of use and to establish conditions that assure the source or other relevant persons involved will receive an equitable share of benefits. Authority is used here to define a legal condition, rather than to refer to a governmental entity (administrative or judicial) that determines whether access under specified conditions is permitted or prohibited. Where the source possesses authority, the person or entity receiving genetic resources will possess the legal provenance to use the resources under the specified conditions of access and benefit sharing.
- (f) **“Legal provenance”** means access to genetic resources for use under specified conditions, pursuant to authority.
- (g) **“Biopiracy”** means obtaining access to genetic resources without authority.
- (h) **“Misappropriation”** means using genetic resources in violation of access conditions or to derive benefits without equitable benefit sharing.
- (i) **“Traditional knowledge”** means knowledge, innovations, and practices of indigenous or local communities that is associated with genetic resources. Similar meanings to those for genetic resources apply to the “source,” “country of origin,” “country providing associated traditional knowledge,” and “authority” of the source.
- (j) **“Intellectual property applications”** means applications relating to intangible subject matter that require some governmental action (such as registration or examination) before rights or privileges will vest.
- (k) The **“applicant”** for intellectual property means any and all persons entitled or required to apply for the relevant intellectual property.
- (l) **“Persons involved”** means all persons who were involved in the development of the subject matter of or the application for

intellectual property, or whose involvement may have a bearing on the entitlement of the applicant to apply for or receive benefits of intellectual property.

- (m) **“Certificate of origin”** means a document issued by a competent entity that identifies the source of genetic resources and associated traditional knowledge, attests to the authority of the source to provide access under specified conditions of use, and attests to *ex ante* compliance with applicable benefit sharing requirements. Certificates of origin thus differ from declarations (typically under oath) made by applicants for intellectual property, and from other common uses of the term to denote certificates that identify the country of origin. By certifying authority to use genetic resources and associated traditional knowledge, certificates of origin document the legal provenance of the recipient to use genetic resources and associated traditional knowledge under the specified conditions and in the absence of misappropriation. Certificates of origin thus correspond to common uses of the terms certificates of source and certificates of legal provenance. Monitoring may be needed to assure *ex post* compliance with certificates of origin once they are issued.

8. Options for Model Provisions for Disclosure of Origin Requirements.

- **Principles relating to the recognition and enforcement of foreign laws already may impose mandatory disclosure of origin requirements.** Disclosure of origin requirements already exist under the national laws of many countries, and contracts for access and benefit sharing may impose requirements to make such disclosures in intellectual property applications wherever filed, even when not required by such national laws. Mandatory disclosure requirements thus already exist, to the extent that national disclosure of origin laws and contracts requiring such disclosures are recognized and enforced in the various jurisdictions where intellectual property is sought. However, the principles governing recognition and enforcement of national disclosure of origin requirements (including choice of law and jurisdictional principles) are not well established or understood. New international treaty provisions may help to make the recognition and enforcement of such national laws and contractual provisions regarding disclosure of origin requirements more coherent.
- **Disclosure of origin requirements are consistent with international intellectual property treaties.** Prior analyses have established that most of the proposed forms of national disclosure of origin requirements are consistent with WIPO-administered patent law treaties, as well as with the TRIPS Agreement and with the UPOV Convention. In particular, existing intellectual property law treaties do not preclude disclosure of origin requirements, as they relate to substantive entitlements to apply for and to

own intellectual property. Permissible consequences of failing to comply with disclosure of origin requirements may include refusing to grant intellectual property rights or privileges or invalidation of intellectual property when required information was accidentally or intentionally omitted and when false or fraudulent documentation was submitted. Therefore, proposals to facilitate such disclosures that seek, for example, to amend the Rules of the Patent Cooperation Treaty (PCT) may not be needed.

- **Mandatory disclosure of origin requirements are needed and may provide greater coherence to the international system.** As noted by many developing countries, although mandatory disclosure of origin requirements exist pursuant to the national legislation of some countries, good reasons exist to adopt new international treaty provisions requiring mandatory disclosure of origin obligations. Without mandatory obligations, national disclosure of origin requirements may not be recognized and enforced by other countries in which intellectual property is applied for, and information provided pursuant to such requirements may not be employed to prevent improper issuance of intellectual property. In contrast, mandatory disclosure of origin requirements will provide numerous benefits for both the CBD regime and intellectual property law system, including providing greater coherence to recognition and enforcement of existing disclosure of origin obligations. In addition to the benefits listed above, mandatory requirements: may improve determinations of inventorship or other relationship to the subject matter, thereby assisting in the identification of persons involved who should participate in equitable benefit sharing; may facilitate abilities to use the subject matter of the intellectual property; may promote compliance with access and benefit sharing legislation; and may help to track commercialization of intellectual property so as to promote more effective benefit sharing.
- **Numerous options for mandatory disclosure of origin requirements and compliance consequences must be evaluated.** Disclosure of origin obligations must be evaluated in regard to the nature and timing of the information to be disclosed and evaluated, and the consequent administrative burdens and costs associated with providing and reviewing disclosed information. Issues to be considered include:
 - (a) the substantive and procedural triggers for information to be provided and evaluated, including specifying the relevant relationships between genetic resources and associated traditional knowledge and the subject matter of intellectual property at the international and national stage of application procedures, in pre-grant and post-grant administrative challenges, and in judicial proceedings;

- (b) the form, prescribed formats, and timing of the information and documentation to be submitted, and whether and when it should be supplemented or corrected, including disclosures of information only, disclosures accompanied by declarations of applicants, disclosures accompanied by documentary information regarding access and benefit sharing, and disclosures accompanied by international certificates of origin;
 - (c) the degree to which information and documentation is reviewed for sufficiency and validity, including completeness, substantive adequacy of information, accuracy of declarations and documents, and validity of international certificates of origin; and
 - (d) the degree to which disclosure failures of varying types should be sanctioned, including: leaving decisions to the discretion of contracting states; relying on sanctions that do not affect the validity or ownership of intellectual property; imposing civil liability or criminal penalties; using unfair competition or other legal regimes in addition to the intellectual property system; imposing administrative fines or criminal penalties for omissions or false or fraudulent statements; requiring revocation or invalidation of intellectual property; requiring full or partial transfer of rights or privileges; and requiring return of unjustified benefits.
- **The TRIPS Agreement is the most appropriate treaty regime in which to adopt mandatory disclosure of origin requirements.** Careful attention needs to be provided to the choice of treaty regime in which to mandate disclosure of origin requirements, so as to assure that the obligations will apply to all intellectual property for which applications are made and so that there will be continuing coordination between CBD obligations and the intellectual property law system. Particularly in light of the broad membership in the WTO and its existing dispute resolution procedures, the TRIPS Agreement is the most appropriate treaty regime in which to include mandatory disclosure of origin requirements.

9. **Practical options for intellectual property application procedures.**

- **Substantive triggers.** Substantive triggers for disclosures of origin must define the relationships between genetic resources and associated traditional knowledge and applications for intellectual property that require disclosures of origin in various procedural contexts. Substantive triggers should reflect the purposes to be accomplished by disclosure obligations. Disclosures of origin may assist in making determinations: within the intellectual property system; regarding entitlements to apply for and own intellectual property and to receive an equitable share of benefits under other laws; and of compliance with CBD access and benefit sharing legislation and contracts. Substantive triggers will need to be broad (*i.e.*,

will need to address many types of inputs into the process of discovery of and application for the subject matter, as well as of its use) to assure the proper recognition and enforcement of entitlements to apply for and own intellectual property and to assure that benefit sharing is equitable. Mandatory disclosure obligations also must specify the types of information to be disclosed, such as disclosures of information only, disclosures accompanied by declarations of applicants, and disclosures accompanied by documentary information. Different disclosure obligations may apply to various substantive and procedural triggers.

- Substantive triggers may address.
 - (a) the relation of the source of genetic resources and associated traditional knowledge to the subject matter of the intellectual property application (*e.g.*, by forming part of the subject matter, by use during its development, by use as a necessary prerequisite or to facilitate development, by use as necessary background, and by forming part of the prior art);
 - (b) the relation of the source to the applicant for intellectual property, under intellectual property and other laws;
 - (c) the relation of the applicant to persons involved;
 - (d) disclosure of the country of origin; and
 - (e) disclosure of documentary information regarding compliance with prior informed consent for access and equitable benefit sharing requirements.

- Mandatory disclosure obligations also may need to specify the manner in which applicants must provide required information. Options for disclosures may include:
 - (a) presenting information on standardized forms using standardized terms;
 - (b) addressing specified mandatory contents;
 - (c) describing specified levels of effort and documenting investigations performed;
 - (d) reaching a specified set of conclusions and explaining the bases therefore; and
 - (e) providing indications of levels of confidence.

- **Procedural triggers.** Procedural triggers for disclosures of origin must define the opportunities for required disclosures and evaluations, the format in which information is to be submitted, and the types of evaluations that are to be made. Procedural triggers may be imposed by national access and benefit sharing legislation, by contracts, and by new treaty requirements. In specifying mandatory procedural triggers, consideration must be given not only to evaluations that are made by

international and national intellectual property offices, but also to other uses to which required disclosures may be put during and after the application process. Application disclosure requirements thus may include information that may not be evaluated during the application process. Consideration also must be given to whether and when to require or to permit applicants or owners to supplement or to correct disclosures during or after the application process.

- Opportunities for required disclosures and evaluations may include:
 - (a) the international stage of application processing (in a coordinated international system of national intellectual property application procedures);
 - (b) the national stage of application processing;
 - (c) pre-grant and post-grant administrative challenge proceedings; and
 - (d) judicial proceedings.
- Options for evaluations of disclosed information may include determining:
 - (a) completeness;
 - (b) conformity to standardized forms and formats;
 - (c) accuracy of factual information;
 - (d) substantive validity of conclusions reached;
 - (e) conformity to declarations and documentary information; and
 - (f) substantive legality of access and benefit sharing.

10. **Options for incentive measures for applicants.**

- Different types of incentive measures exist to induce compliance with mandatory disclosure of origin requirements. These include various types of sanctions and positive incentives that do not have a sanctioning effect.
- A wide range of sanctions exist to address the failure of applicants to make required disclosures of origin. Sanctions for disclosure failures may be mandatory or facultative, and may apply directly within or external to the intellectual property law system. Options for direct or indirect mandatory sanctions or facultative sanctions may include:
 - (a) curable or incurable, temporary or permanent bars to processing of applications;
 - (b) administrative fines, civil liability, or criminal penalties;
 - (c) termination or full or partial transfer of entitlements to apply for or own intellectual property;
 - (d) curable or incurable, temporary or permanent, full or partial unenforceability, revocation, narrowing of the subject matter, or invalidation of granted intellectual property rights and privileges;

- (e) return or transfer of benefits received from intellectual property;
and
- (f) enforcement of existing or new obligations to provide for equitable benefit sharing.

- Incentive measures regarding disclosures of origins must provide an effective deterrent to non-compliance and must assure that the intellectual property system is not misused to further inequitable conduct. Incentive measures also should minimize burdens on applicants that might generate perverse results and should provide flexibility to respond to a wide variety of disclosure failures. Sanctions may be applied sequentially or in combination, rather than as exclusive alternatives.

11. **Implications for WIPO-administered treaties.**

- Although most of the proposed forms of disclosure of origin requirements are legally compatible with existing WIPO-administered treaties, those treaties were not adopted with disclosure of origin requirements in mind. Moreover, even if some forms of mandatory disclosure of origin obligations were deemed incompatible with existing WIPO-administered treaty provisions, the disclosure of origin obligations (as later-enacted treaty obligations) would take precedence for parties to both sets of treaties. Nevertheless, the rules, forms, and procedures adopted pursuant to WIPO-administered treaties may need to be changed in order to more effectively implement mandatory disclosure of origin obligations.
- Analysis of the PCT regime identifies a number of issues to be addressed in effectuating disclosure of origin requirements within the international system of intellectual property applications. These include:
 - (a) revising rules, forms, and administrative instructions to address the types of information to be supplied, including use of standardized formats and wording for the provision of information;
 - (b) adopting procedures (including the use of electronic documents) for duplicating, evaluating, and transmitting the different types of information supplied, considering the costs involved and the uses to which the information will be put;
 - (c) revising the fees charged to applicants to reflect the type of information submitted and the costs incurred in processing and evaluating the information at the international and national stages of application procedures; and
 - (d) addressing the timing and need for translation of required information and documentation.

12. **Intellectual property-related issues for international certificates of origin.**

- International certificates of origin not only may assist in tracing flows of genetic resources and associated traditional knowledge, but also attest to the legal provenance to provide access to such resources and knowledge under specified conditions for their use. Thus, certificates of origin could

assist in demonstrating compliance with CBD access and benefit sharing requirements and in complying with mandatory disclosure of origin requirements. However, the use of certificates of origin raises the same considerations previously discussed regarding substantive and procedural triggers for disclosure, evaluations of submitted information, and consequences for disclosure failures. In addition, the use of certificates of origin raises additional issues regarding *ex ante* verification of information by certifying entities, the consequences of errors of certification, *ex post* tracking of certified information to assure its continuing validity, and misuse of certificates by persons to whom they are issued and others. Determining what entities have authority to issue certificates also may raise complex considerations.

- Like other types of certification documents, international certificates of origin may be issued erroneously, falsified, or put to improper uses. Consideration must be given to what standards should apply to issuing certifications, whether to mandate or to facilitate use of certificates of origin in satisfying disclosure of origin requirements, how to address errors of certification and improper uses of certificates, and what consequences should attach to false, deceptive, or confusing uses of certificates. Additional consideration must be given to whether and how ownership of certificates of origin may be transferred.

13. **Conclusion.**

- In summary, there is a need for new international treaty provisions that would mandate disclosures of origin requirements in regard to applications for intellectual property. The most appropriate treaty regime to adopt such requirements is the TRIPS Agreement. Numerous benefits would be provided by disclosure of origin requirements, although care should be taken to minimize the administrative costs and burdens of implementation. The treaty provisions will need to specify the substantive and procedural triggers for making required disclosures, the types and timing of evaluations to be performed with disclosed information, the mandatory or facultative consequences of various types of disclosure failures, and whether to mandate or facilitate use of international certificates of origin in making required disclosures. Although disclosure of origin requirements are consistent with existing intellectual property treaties, such requirements may be facilitated by revising existing rules, forms, and procedures implementing those treaties.
- Additional research and evaluation would help to inform policy choices regarding the contents of mandatory disclosure of origin requirements to be included in new international treaty provisions. In particular, additional analysis would be beneficial regarding: the relationship of existing national laws governing misappropriation to entitlements to apply for and

own intellectual property; and the recognition and enforcement of national access and benefit sharing laws and contractual provisions imposing disclosure of origin requirements and their relation to the intellectual property law system.

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Introduction

14. This analysis has been commissioned by the United Nations Conference on Trade and Development (UNCTAD) secretariat in order to respond to an invitation from the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) in Decision VII/19, adopted at the Seventh Meeting of the COP in 2004.¹ The views in this document are solely those of the authors and do not necessarily reflect the views of UNCTAD or the authors' institutions.

A. Background on the CBD Invitation to UNCTAD

15. **The CBD, Bonn Guidelines, WIPO Technical Study, and Decision VII/19.** Paragraph 15.5 of the CBD subjects access to genetic resources to the prior informed consent of the Party providing genetic resources. Paragraphs 15.4 and 15.7 of the CBD subjects any granted access to genetic resources to mutually agreed terms and requires Parties to take measures to share in a fair and equitable way with the Party providing genetic resources the results of research and development and the benefits resulting from commercialization and other uses. Paragraph 8(j) of the CBD encourages respect for and preservation of traditional knowledge, and the equitable sharing of benefits in regard to utilization of traditional knowledge that is relevant for the conservation and sustainable use of biological diversity. These requirements for prior informed consent and mutually agreed terms in regard to providing access to genetic resources and for equitable benefit sharing in regard to genetic resources and traditional knowledge are generically referred to as “access and benefit sharing” requirements.

16. In 2002, the sixth COP of the CBD adopted voluntary guidelines (the Bonn Guidelines) to address access to genetic resources and fair and equitable benefit sharing arising from use of those resources.² In the Bonn Guidelines, the CBD COP invited Parties and governments to encourage applicants for intellectual property to disclose the country of origin of genetic resources and the origin of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles (traditional knowledge), when the subject matter of the application concerns or makes use of genetic resources or traditional knowledge in its development.³ Such disclosure requirements are generically referred to as “disclosure of origin” requirements. When adopting the Bonn Guidelines, the CBD COP contemplated that disclosure of origin requirements would contribute to tracking compliance with prior informed consent

¹ See UNEP/CBD/COP/7/21, Decision VII-19, *Access and benefit-sharing as related to genetic resources (Article 15)* (2004), available at www.biodiv.org/doc/decisions/COP-07-21-part2-en.pdf.

² See UNEP/CBD/COP/6/20, Decision VI-24, *Access and Benefit Sharing as Related to Genetic Resources, A. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of Their Utilization* (2002), ¶ 3 & Annex, available at <http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf>.

³ *Id.*, VI-24.C. *Role of intellectual property rights in the implementation of access and benefit-sharing arrangements*, ¶¶ 1, 2.

and the mutually agreed terms (including provisions for equitable sharing of the benefits of research and commercialization) on which access to those resources was granted.⁴

17. In the Bonn Guidelines, the CBD COP also urged consideration of measures aimed at preventing the misappropriation of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources. Specifically, in the Bonn Guidelines the CBD COP suggested measures to support compliance with access and benefit sharing requirements, including disclosures of origin of genetic resources and traditional knowledge, measures to prevent use of genetic resources obtained without prior informed consent, and measures discouraging unfair trade practices.⁵ The CBD COP also: suggested that national governments monitor applications for intellectual property relating to the material supplied; recognized that verification of compliance with access and benefit sharing requirements may involve systems of voluntary certification; and authorized Parties to adopt appropriate, effective, and proportional measures for violations of national requirements implementing the CBD.⁶

18. The CBD COP invited the World Intellectual Property Organization (WIPO) to submit for the Seventh Meeting an analysis of disclosure of origin requirements in patent applications and consistency with WIPO-administered treaties.⁷ Specifically, the CBD COP requested analysis relating to the disclosure of:

- (a) genetic resources used in developing claimed inventions;
- (b) the country of origin of such genetic resources;
- (c) associated traditional knowledge used in such development;
- (d) the source of such associated traditional knowledge; and
- (e) evidence of prior informed consent.⁸

WIPO responded by submitting a detailed “Technical Study” of disclosure of origin issues.⁹ The Technical Study analyzed various disclosure of origin requirements in patent applications,¹⁰ with regard to the WIPO-administered Paris Convention for the

⁴ See *id.*, ¶ 1.

⁵ See *id.*, VI-24 A., Annex, ¶¶ 16(d)(ii), (iii) & (vi).

⁶ See *id.*, VI-24.A., Annex, ¶¶ 55, 58, 61. Such measures also would help to accomplish the United Nations’ Millennium Development Goals, specifically Goal 7 (to ensure environmental sustainability) and Goal 8 (to develop a global partnership for development). See *UN Millennium Development Goals*, available at <http://www.un.org/millenniumgoals/>; United Nations General Assembly, A/Res/55/2, *United Nations Millennium Declaration* (2000), available at <http://www.un.org/millennium/declaration/ares552e.pdf>; United Nations General Assembly, A/56/326, *Road map towards the implementation of the United Nations Millennium Declaration: Report of the Secretary-General*, at 33-34 (2001) (adopting a goal to press for full implementation of the CBD), available at <http://www.un.org/documents/ga/docs/56/a56326.pdf>.

⁷ See UNEP/CBD/COP/6/20, Decision VI-24 C, ¶ 4.

⁸ See *id.*

⁹ See WIPO WO/GA/30/7 Add.1, *Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge* (2003), in UNEP/CBD/COP/7/INF/17, available at <http://www.biodiv.org/doc/meetings/cop/cop-07/information/cop-07-inf-17-en.pdf>.

¹⁰ See UNEP/CBD/COP/7/INF/17, ¶¶ 161-81.

Protection of Intellectual Property (Paris Convention),¹¹ Patent Law Treaty (PLT),¹² and Patent Cooperation Treaty (PCT),¹³ as well as with regard to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).¹⁴

19. In Decision VII/19, the CBD COP sought to further existing efforts to develop an international regime to effectively implement access and benefit sharing and disclosure of origin requirements. Decision VII/19 directs two CBD Working Groups to elaborate and to negotiate an international regime on access to genetic resources and benefit-sharing, with the aim of adopting international instruments to effectively implement the relevant CBD provisions. Of particular relevance here, the CBD COP recognized the need for further analysis of issues identified in the WIPO Technical Study and elsewhere regarding disclosure of origin requirements and international certificates of origin/source/legal provenance, which are generically referred to as “certificates of origin.” The CBD COP thus invited WIPO and UNCTAD to identify and to analyze issues raised by disclosure of origin requirements and certificates of origin, including five sets of specific issues.¹⁵ The text of the invitation identifying these sets of issues is provided below.

¹¹ Concluded Mar. 20, 1883 at Paris, effective 1884, as revised through July 14, 1967 at Stockholm and as amended Sept. 28, 1979 at Stockholm, available at <http://www.wipo.int/clea/docs/en/wo/wo020en.htm>

¹² Concluded June 1, 2000 at Geneva, effective Apr. 28, 2005, available at http://www.wipo.int/documents/en/document/pt_dc/doc/pt_dc47.doc.

¹³ Concluded June 19, 1970 at Washington, as amended Sept. 28, 1979 and modified Feb. 3, 1984 and Oct. 3, 2001, effective Apr. 1, 2002, available at <http://www.wipo.int/pct/en/texts/pdf/pct.pdf>.

¹⁴ Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, concluded Apr. 15, 1994, effective Jan. 1, 1995, available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

¹⁵ CBD COP 7, Decision VII-19, ¶¶ 7-9.

CBD Decision VII/19 Request and Invitation

7. *Requests* the Ad hoc Open-ended Working Group on Access and Benefit-Sharing to identify issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights, including those raised by a proposed international certificate of origin/source/legal provenance, and transmit the results of this examination to the World Intellectual Property Organization and other relevant forums;

8. *Invites* the World Intellectual Property Organization to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the Convention on Biological Diversity, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:

- (a) Options for model provisions on proposed disclosure requirements;
 - (b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
 - (c) Options for incentive measures for applicants;
 - (d) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties;
 - (e) Intellectual property-related issues raised by proposed international certificate of origin/source/legal provenance;
- and regularly provide reports to the Convention on Biological Diversity on its work, in particular on actions or steps proposed to address the above issues, in order for the Convention on Biological Diversity to provide additional information to the World Intellectual Property Organization for its consideration in the spirit of mutual supportiveness;

9. *Invites* the United Nations Conference on Trade and Development and other relevant international organisations to examine the issues in, and related to, the matters specified in paragraphs 7 and 8 in a manner supportive of the objectives of the Convention on Biological Diversity and prepare a report for submission to the on-going process of the work of the Convention on Biological Diversity on access and benefit sharing;

20. In January of 2005, WIPO published a first draft analysis responsive to the CBD COP's invitation in Decision VII/19.¹⁶ In May of 2005, following receipt of comments on the first draft, WIPO published a second draft analysis on these issues (the WIPO Examination).¹⁷ The WIPO Examination contains useful discussions of the identified issues (building on the earlier Technical Study), and summarizes the various country submissions to WIPO for purposes of developing its response to the CBD COP's invitation. Additional analyses and discussion of options to implement disclosure of origin requirements and certificates of origin have been developed for and by other intergovernmental organizations, *e.g.*, the WTO, the United Nations Environment

¹⁶ See WIPO/IP/GR/05/01, *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications: First Draft* (2005), available at http://www.wipo.int/tk/en/genetic/proposals/first_draft_examination_cbd_invitation.pdf.

¹⁷ See WIPO/IP/GR/05/03, *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications: Second Draft* (2005), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_gr_05/wipo_ip_gr_05_3.pdf.

Programme (UNEP), and UNCTAD.¹⁸ Groups of countries, nongovernmental organizations, and academics also have provided detailed suggestions regarding elements of an international disclosure of origin requirements regime. For example, various developing countries have proposed that the TRIPS Agreement be amended to require applicants for patents to disclose the source and country of origin of genetic resources and associated traditional knowledge used in inventions relating to biological materials or traditional knowledge, along with documentary information regarding legal access and required benefit sharing.¹⁹ This analysis builds upon the prior analyses.

21. In accordance with the CBD invitation, this analysis is organized in five sections. Part I addresses options for model provisions on disclosure of origin requirements that could be mandated by new international treaty provisions. Part II addresses practical options relating to the procedural and substantive triggers for disclosure of origin requirements. Part III addresses incentive measures for such requirements, focusing in particular on enforcement mechanisms within the intellectual property law system. Part IV addresses implications for the functioning of disclosure requirements within WIPO-administered patent law treaties. Prior work of the authors and WIPO, briefly summarized in Part I,²⁰ has demonstrated that most of the relevant forms of disclosure of origin requirements (including refusal to grant intellectual property or sanctions that include invalidation or unenforceability) are fully consistent with existing WIPO patent law treaties, with the TRIPS Agreement, with the Union for the Protection of New

¹⁸ See, e.g., WTO, *Article 27.3b, traditional knowledge, biodiversity* (secretariat document listing relevant submissions through 2004), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm; Anil K. Gupta, *WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Traditional Knowledge* (2004) (WIPO-UNEP Study), available at http://www.wipo.int/tk/en/publications/769e_unep_tk.pdf; United Nations University, Institute of Advanced Studies (UNU-IAS), *User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity* (2d ed. 2003) (UNU-IAS Report), available at <http://www.ias.unu.edu/news/details.cfm/articleID/458>; UNCTAD TD/B/Com.1/EM.13/3, *Report of the Expert Meeting on Systems and National Experiences for the Protection of Traditional Knowledge, Innovations, and Practices* (2000) (UNCTAD Expert Meeting Summary), available at http://www.unctad.org/fr/docs/c1em13d3_fr.pdf. See generally

http://r0.unctad.org/trade_env/test1/meetings/tk2.htm and http://r0.unctad.org/trade_env/test1/meetings/delhi.htm (papers and reports from UNCTAD Workshops in February 2004 with the Commonwealth Secretariat and in April 2002 with the Government of India).

¹⁹ See, e.g., WTO IP/C/W/356, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, Submission of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia, and Zimbabwe (2002), ¶ 10; WTO IP/C/W/403, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, Submission of Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela (2003), ¶ 1; WTO IP/C/W/404, *Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, Joint Communication from the African Group (2003), at 5-6 (all available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm).

²⁰ See, e.g., Joshua D. Sarnoff, Memorandum for Public Interest Intellectual Property Advisors (PIIPA), *Compatibility With Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing*, at 31-37, 51 (Sarnoff, *Consistency*), available at <http://www.piipa.org/library.asp>; WIPO Technical Study, ¶¶ 148, 153, 175, 183.

Varieties of Plants (UPOV),²¹ and with the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).²² Accordingly, Part IV does not repeat the legal analysis but rather focuses on practical aspects of implementation of disclosure of origin requirements within the relevant treaty regimes. Part IV analyzes the PCT and the PLT to illustrate issues at the international stage of application processing in a coordinated international system of national intellectual property application procedures, and at the national stage of application processing. Finally, Part V analyzes intellectual property law issues raised by international certificates of origin. Before addressing the specific issues identified by the CBD, however, this analysis discusses the need for an international system of mandatory disclosure of origin requirements and, to provide greater clarity, defines relevant terminology and identifies limits of the analysis.

B. Mandatory Disclosure of Origin Requirements

22. **There is a need for an international system of mandatory disclosure of origin requirements.** For reasons stated elsewhere by developing countries and in a growing body of literature, an international system of mandatory disclosure of origin requirements is needed to prevent misappropriation, to promote compliance with CBD access and benefit sharing requirements, and to prevent misuse of the intellectual property system.²³ As recognized by the Bonn Guidelines,²⁴ disclosure of origin requirements for intellectual property applications are an important element of the CBD access and benefit sharing regime, reflecting the interconnection of the CBD regime with the international intellectual property law system.²⁵ Intellectual property applicants should not be rewarded with rights or privileges that convey commercial benefits, when the subject matter of the applications was obtained or derived from genetic resources or traditional knowledge acquired in violation of CBD prior informed consent requirements and

²¹ Concluded Dec. 2, 1961 at Paris, entered into force Aug. 10, 1968, as revised at Geneva Nov. 10, 1972, Oct. 23, 1978, and Mar. 19, 1991 (entered into force Apr. 1998), available at <http://www.upov.int/en/publications/conventions/index.html>.

²² Concluded Nov. 3, 2001 at Rome, entered into force June 29, 2004, available at <http://www.fao.org/ag/cgrfa/itpgr.htm#text>.

²³ See, e.g., TRIPS Council Meeting, 14 June 2005, Agenda Items C-E, Statement By India, at 2 (2005) (Indian TRIPS Council Statement) (noting “transboundary implications” of commercial exploitation of erroneously granted patents contrary to CBD objectives); WTO IP/C/W/447, *Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore*, Communication from Peru, at 2 (2005) (suggesting establishment of an international obligation under the TRIPS Agreement “and another binding international instrument”), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm; Carlos M. Correa, *Establishing a Disclosure of Origin Requirement in the TRIPS Agreement*, Quaker United Nations Organization (QUNO), Occasional Paper No. 12, at 2-3 (2003) (Correa, *Disclosure*), available at <http://www.iprsonline.org/resources/trips.htm>; The Center for International Environmental Law, *CBD Request to WIPO on the Interrelation of Access to Genetic Resources and Disclosure Requirements: Observations from the Center for International Environmental Law (CIEL) on the First Draft of the WIPO Examination of the Issues*, at ¶¶ 22-26 (2005) (CIEL Comments), available at http://www.ciel.org/Publications/WIPO_CBD%20Request_1Apr05.pdf.

²⁴ See UNEP/CBD/COP/6/20, Decision VI-24.C., ¶¶ 1, 2.

²⁵ See, e.g., CBD Art. 16.5 (obligating Parties to cooperate “to ensure that [intellectual property] rights are supportive of and do not run counter to” CBD objectives).

conditions of access for genetic resources. Similarly, intellectual property owners should not retain such commercial benefits in violation of CBD benefit sharing requirements.

23. Disclosure of origin requirements could fulfill important traditional functions within the intellectual property system.²⁶ Specifically, disclosure of origin requirements may: improve the substantive examination of patents and other subject matter for which rights or privileges are sought; enhance determinations of inventorship and other entitlements to apply for intellectual property; and facilitate or permit use of the subject matter. The United States, however, has taken the position that erroneously granted patents “are the rare exception rather than the rule,” and thus that disclosure of origin requirements are not needed to assist such traditional determinations in regard to patents.²⁷ The factual basis for this assertion is not apparent and has been called into question by the United States Federal Trade Commission and in other analyses of the United States patent system.²⁸ As a result, numerous measures to revise the United States Patent Act to remedy perceived, widespread issuance of erroneously granted patents are under consideration.²⁹ Thus, even if not *required* to assure the proper application of intellectual property laws, disclosure of origin requirements certainly may assist in making the relevant determinations and thereby enhancing the integrity of the intellectual property system.³⁰

24. In addition, disclosure of origin requirements may promote compliance with CBD access and benefit sharing legislation (by, *inter alia*, reducing opportunities and incentives for misappropriation) and may assist in tracking the commercial exploitation of genetic resources and traditional knowledge for purposes of equitable benefit sharing. The United States, however, has taken the position that a contract-based access and benefit sharing regime requiring disclosures of commercial application of genetic resources or traditional knowledge “provides a more effective means” of monitoring CBD access and benefit sharing objectives, particularly as commercial benefits may be obtained from use of genetic resources or traditional knowledge without inventing subject

²⁶ See, e.g., Correa, *Disclosure*, at 2-3.

²⁷ WTO IP/C/W/449, *Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, Communication by the United States, at 2 (2005), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

²⁸ See, e.g., Indian TRIPS Council Statement at 2; U.S. Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Executive Summary, at 4-13 (2003) (noting concern over questionable patents and recommending adoption of an opposition system, elimination of the strong presumption of patent validity, revision of the obviousness standard, and increases in Patent Office funding), available at <http://www.ftc.gov/opa/2003/10/cpreport.htm>; National Research Council, National Academy of Sciences, *A Patent System for the 21st Century*, at 61-62 (2004) (noting beliefs of legal scholars that changes in patentability standards have resulted in issuance of patents on obvious inventions and expressing concern about the U.S. Patent Office’s application of those standards), available at <http://www.nap.edu/html/patentsystem/>.

²⁹ See, e.g., H.R. 2795, Patent Reform Act of 2005, available at <http://thomas.loc.gov/>; H.R. 2791, United States Patent and Trademark Fee Modernization Act of 2005, available at <http://thomas.loc.gov/>.

³⁰ See, e.g., Indian TRIPS Council Statement, at 4; WTO IP/C/W/443, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Technical Observations on Issues Raised in a Communication by the United States (IP/C/W/434)*, Submission from Brazil and India, ¶¶ 12, 17 (2005), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

matter that qualifies for patent protection.³¹ However, a contractual system would not address improper commercialization through issuance of erroneously granted patents or other intellectual property,³² and it is unclear how such a system would assure CBD objectives in the absence of concluded contracts.³³

25. Even if intellectual property is properly granted under applicable intellectual property laws, such rights or privileges may convey commercial value before they are used to obtain commercial benefits by excluding commercial competition or maintaining commercial monopoly market power. For example, commercial benefits may result from raising stock prices or through the sale of intellectual property as an asset.³⁴ Denying or invalidating intellectual property obtained in violation of CBD access and benefit sharing principles thus may be *necessary* to prevent misappropriation of genetic resources or traditional knowledge that results in commercial benefits obtained directly from acquiring, owning, or transferring intellectual property rights or privileges.

26. Various national laws prevent such misappropriation by limiting the conditions that define the validity of intellectual property or entitlements to own or to retain benefits deriving from intellectual property.³⁵ This is true even when the relevant genetic resources or traditional knowledge have been misappropriated from countries that have not established national access and benefit sharing legal regimes under the CBD.³⁶ For example, trade secrecy laws in the United States might prohibit applications for patents, when access to genetic resources or traditional knowledge was obtained in another country without appropriate authority, even though no national legislation regarding conditions for access and benefit sharing had been adopted in the other country.³⁷

27. The United States, however, has raised concerns that new disclosure of origin requirements “would *cause* the additional uncertainty that may lead to invalidation” of intellectual property.³⁸ Rather than cause uncertainty, new international treaty provisions addressing disclosure of origin requirements may help to make more coherent existing

³¹ See WTO IP/C/W/449, ¶¶ 18, 22.

³² See, e.g., Indian TRIPS Council Statement, at 2; *id.* at 3 (noting the need to employ costly revocation proceedings to limit use of erroneously granted patents).

³³ See, e.g., WTO IP/C/W/446, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore and Review of Implementation of the TRIPS Agreement under Article 71.1*, Communication from Switzerland at 3 (2005), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm

³⁴ See, e.g., *id.* at 3; Clarissa Long, *Patent Signals*, 69 U. Chi. L. Rev. 625, 625–28 (2002) (discussing various valuable market-information functions served by obtaining patents); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 Minn. L. Rev. 697, 707-10 (2001) (explaining how exclusionary rights facilitate social ordering and bargaining).

³⁵ See, e.g., WTO IP/C/W/447 (citing the Second Supplementary Provision of Andean Community Decision 391, which provides that “Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources ... obtained or developed through an access activity that does not comply with ... this Decision,” and providing authority to request nullification and other actions in countries that have conferred rights or granted “protective title documents”).

³⁶ See, e.g., *id.*, ¶ 23 (noting the absence of national legislation in the majority of member countries).

³⁷ See, e.g., Restatement (3d) of Unfair Competition, §§ 39, 40 (1995) (defining trade secrets and misappropriation under state laws).

³⁸ WTO IP/C/W/449, ¶ 25.

and future national laws regarding misappropriation, including their recognition and enforcement in other countries. At least such an instrument may make more transparent and predictable existing uncertainties already present in regard to national access and benefit sharing and intellectual property laws applicable to transboundary resource and information flows.³⁹ The relationships between national laws addressing misappropriation and intellectual property have not been adequately studied. Additional analysis of national laws addressing the relationship between misappropriation of genetic resources or traditional knowledge, and their effect on the validity of or entitlement to own or retain benefits from intellectual property would significantly assist future discussions of disclosure of origin requirements.⁴⁰

28. This analysis thus focuses on the need for and significant features of new international treaty provisions that would mandate requirements for disclosures of origin in regard to genetic resources and associated traditional knowledge. As noted in a recent multi-country submission to the WTO, contractual arrangements alone cannot ensure monitoring and enforcement of CBD requirements in third countries. Rather, obligatory and enforceable requirements are needed to address the broad range of intellectual property applications that relate to genetic resources and associated traditional knowledge.⁴¹ The appropriate controls may be accomplished by requiring disclosures of origin that include information on prior informed consent and of equitable benefit sharing in patent and other intellectual property applications.⁴² Although the Bonn Guidelines invited governments to encourage applicants to disclose the country of origin based on broad substantive triggers relating genetic resources and associated traditional knowledge to intellectual property applications,⁴³ and although national legislation imposing disclosure of origin requirements already exists in some countries, disclosure of origin requirements have yet to be adopted in many countries where intellectual property may

³⁹ See, e.g., WTO IP/C/W/443, ¶ 9 (an “internationally established and enforced [disclosure of origin] system” would promote “transparency and predictability [that] cannot be established through a fragmented nation-to-nation system”).

⁴⁰ Cf. WTO IP/C/W/446, at 2, 3 (requesting clarification of the circumstances that would warrant revoking patents or requiring full or partial transfer of rights in inventions, and how benefit sharing would be determined to be equitable).

⁴¹ See WTO IP/C/W/441 Rev.1, Article 27.3(B), *Relationship Between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore*, Submission of Peru (2005), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm (identifying numerous applications for patents made in regard to subject matter apparently obtained or developed using biological resources of Peruvian origin and/or traditional knowledge of indigenous Peruvian peoples without securing the prior informed consent of Peru or of those indigenous peoples). See also Marko Berglund, *The Protection of Traditional Knowledge Related to Genetic Resources: The case for a modified patent application procedure*, 2 SCRIPT-ed 108, 120 (2005) (discussing the need for “a concerted, global approach incorporating internationally enforceable minimum standards” to protect traditional knowledge associated with genetic resources “which originates in a third country”) (Berglund, *TK Protection*), available at <http://www.law.ed.ac.uk/ahrb/script-ed/vol2-2/TK.asp>.

⁴² See, e.g., WTO IP/C/W/438, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the Obligation to Disclose Evidence of Prior Informed Consent Under the Relevant National Regime*, Submission of Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, and Venezuela, ¶ 7, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

⁴³ See UNEP/CBD/COP/6/20, Decision VI-24.C., ¶¶ 1, 2.

be sought. New international treaty provisions are required to assure worldwide effectuation of disclosure of origin requirements.⁴⁴

29. **Suggested outline of an international system of mandatory disclosure of origin requirements.** The following principles may provide the outline for more detailed consideration of the contents of mandatory disclosure obligations. These mandatory obligations could be included in new international treaty provisions that would also specify the relationship of required disclosures to mandatory and facultative sanctions. To be effective in deterring violations of access and benefit sharing requirements and in preventing misappropriation, disclosure of origin requirements may need to result in denial of the entitlement to apply for, own, or enforce intellectual property, and to permit delays in the processing of applications or to consider applications withdrawn if required information is not provided initially or in a timely fashion after a request. In order to assure the availability of information on which the integrity of the requisite intellectual property law determinations are to be made, mandatory disclosure of origin requirements should be imposed at the international stage of any application procedures, where relevant, and otherwise at the national stage of application procedures. These requirements should obligate applicants to disclose the source of genetic resources and associated traditional knowledge, the country providing genetic resources, available documentary information regarding compliance with access and benefit sharing requirements, and (following a specified level of effort for inquiry) information known to the applicant regarding persons involved and the country of origin of genetic resources and associated traditional knowledge. Required disclosures should be based on a broad set of substantive triggers that relate the subject matter of the application to the genetic resources and associated traditional knowledge.

30. Required disclosures of origin should be reviewed at the international and national stages of application proceedings for completeness and for formal compliance with specified procedures, but should not ordinarily be reviewed for substantive validity or legality (unless such review already is required under intellectual property laws or other laws relating to the validity of the subject matter of the application and entitlements to apply for and own the intellectual property). Rather, substantive reviews of such disclosures should occur principally in a judicial action, or in a pre-grant or post-grant administrative challenge proceeding in which an initial showing is made demonstrating the lack of compliance with disclosure requirements or with other legal requirements that would affect validity of or entitlements to apply for or own intellectual property.

31. Opportunities should be provided to cure failures to disclose required information at the international and national stages of application procedures, in the absence of

⁴⁴ See, e.g., Graeme B. Dinwoodie, UNCTAD Commonwealth Secretariat Workshop, *Elements of National Sui Generis Systems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework: Towards an International Framework for the Protection of Traditional Knowledge*, at 1 (2004) (Dinwoodie, *International Framework*) (noting that “international initiatives are essential, given the need to adopt similar provisions in different jurisdictions or to recognize foreign requirements across jurisdictions), 2004 draft available at [http://r0.unctad.org/trade_env/test1/meetings/tk2/UCNTAD%20Paper\(0129\).pdf](http://r0.unctad.org/trade_env/test1/meetings/tk2/UCNTAD%20Paper(0129).pdf).

indications of bad faith or a showing that any required inquiries were not performed. Opportunities for cure should be more limited following the grant of intellectual property.

32. Remedies for disclosure failures should, where possible and where appropriate, transfer full or partial ownership of intellectual property or impose benefit sharing conditions in preference to invalidating the intellectual property at issue. Remedies also should be tailored, where possible and in the absence of bad faith, to the scope and nature of the disclosure failure.⁴⁵

C. Terminology and Limits of the Analysis

33. In order to evaluate options for disclosure of origin requirements, it is necessary to determine what actions and materials are to be addressed. A detailed discussion of mandatory obligations for disclosure of origin requirements and of substantive and procedural “triggers” for disclosure is provided in Parts I and II. However, to assure that the analysis proceeds with a common understanding, it is necessary to clarify the terminology to be used.⁴⁶ The analysis adopts terminology from the CBD, supplementing that terminology as necessary. Some of the definitions adopted differ from those used in prior analyses or country submissions regarding disclosure of origin and certificate of origin issues.

34. **“Genetic resources”** are defined in Article 2 of the CBD as “genetic material of actual or potential value,” and “genetic material” is defined as “any material of plant, animal, microbial or other origin containing functional units of heredity.” In contrast, “biological resources” are defined to “include[] genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.” Thus, genetic resources are a subset of genetic material, which in turn are a subset of biological resources, which are a subset of all biological materials. Although disclosure of origin issues thus could address a broader category of biological materials,⁴⁷ the focus of this analysis is on “genetic resources.”

35. **“Country of origin of genetic resources.”** Article 2 of the CBD defines the “country of origin of genetic resources” as “the country which possesses those genetic resources in *in-situ* conditions.” “*In-situ* conditions” is defined to mean “conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.” A country of origin thus is any country where such resources are now located in *in-situ* conditions, whether or not that country is where the resources

⁴⁵ See, e.g., WIPO Technical Study, ¶155 (describing the “general trend” of existing sanctions provisions under national laws as “a tendency for the consequences of failure to comply to correspond to the nature of the information that is not supplied”).

⁴⁶ See, e.g., WTO IP/C/W/446, at 2-3 (requesting clarification of terms used in various developing country submissions).

⁴⁷ See, e.g., WTO IP/C/W/443, ¶ 13 (discussing disclosures of origin in regard to “biological material and/or associated traditional knowledge”).

historically originated. Further, there may be more than one country of origin for any particular genetic resource.

36. **“Country providing genetic resources.”** The access and benefit sharing requirements of the CBD do not apply to the “country of origin,” but rather apply based on the “country providing genetic resources.” Article 2 of the CBD defines the country providing genetic resources as “the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.” Article 15.5 requires any access to genetic resources in a Contracting Party providing genetic resources to be subject to the prior informed consent of that Party, unless it determines otherwise. Similarly, Article 15.7 requires Contracting Parties to adopt “legislative, administrative, or policy” 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 utilization of genetic resources with the Contracting Party providing such resources.” However, Article 15.3 provides that “the genetic resources being provided by a Contracting Party ... are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.”

37. Significantly, genetic resources may be supplied from a country providing genetic resources that is not a country of origin of those resources. This is particularly likely to occur in regard to *ex-situ* genetic resources that are maintained in various world-wide collections. Unless the subject matter of an intellectual property application requires repeated inputs of the same genetic resource in its development, however, only one country is likely to be the country providing that specific resource. In contrast, the subject matter may require the input of many different genetic resources, supplied from different countries.

38. **Considerations relating to disclosure of the country of origin and the country providing genetic resources.** Because CBD Article 15’s mandatory access and benefit sharing requirements relate directly to the “country providing genetic resources,” disclosures of origin requirements that are tied to the CBD Article 15 requirements may not necessarily disclose the country of origin of the genetic resources in question. Determining the country (or countries) of origin may be a complex undertaking for genetic resources obtained from countries that are not themselves a country of origin (for instance, when supplied by gene banks, botanical gardens, or other sources that conserve biological materials in *ex-situ* conditions). It may be particularly difficult to determine the country of origin of plant varieties that have acquired distinctive characteristics in different countries.⁴⁸ Disclosures of origin requirements for genetic resources that relate to the multilateral access and benefit-sharing system of the ITPGRFA (in cases where intellectual property in such materials may be sought⁴⁹) may be addressed, where

⁴⁸ See, e.g., Correa, *Disclosure*, at 5.

⁴⁹ The ITPGRFA prohibits applications for intellectual property on PGRFA in the form they are received from the multilateral system, but does not clearly prohibit applications when the subject matter is derived from or used such resources in its development. See ITPGRFA, Art. 12.3(d) (“Recipients shall not claim

appropriate, through information that the relevant Plant Genetic Resources for Food and Agriculture (PGRFA) have been obtained from the Multilateral System, under the standard Material Transfer Agreement to be adopted by the Governing Body of the Treaty.⁵⁰ Further, if disclosure of origin requirements are tied to access and benefit sharing requirements of the CBD, disclosures in intellectual property applications may not necessarily be required when genetic resources are provided from countries that are not Parties to the CBD, or when the subject matter does not relate to genetic resources. In such cases, mandating disclosure of origin requirements in intellectual property applications would extend beyond CBD considerations, but would still be relevant in other contexts, such as in the WTO.

39. Requiring applicants for intellectual property to disclose the country of origin may force them to search for or to generate information that may not be readily available and that may be difficult to obtain or produce. To avoid such burdens, requirements could be limited to disclosing only the country providing genetic resources, which information should be readily known. Alternatively, requirements for disclosing the country of origin could be limited to knowledge already in the possession of applicants. Between these two positions, applicants could be required to exert a specified level of effort to search for or generate country of origin information.

40. In some cases, traditional intellectual property laws may already require the disclosure of the country of origin in applications, even if applicants must search for or generate the required information. For example, disclosure of the country of origin may be required to enable the public to practice an invention for which a patent is sought.⁵¹ In addition, national access and benefit sharing laws of the country providing genetic resources or of the country of application (or contracts pursuant to such laws imposing the terms and conditions of access and benefit sharing) may require the disclosure of the country of origin in any international or national intellectual property application.⁵² New international treaty provisions that required applicants to disclose the country of origin in intellectual property applications would not impose any additional burdens on applicants in such cases. Rather, such treaty provisions might facilitate disclosures that already are required under intellectual property laws, and would lead to the removal of obstacles to disclosures under national laws when required by other countries' laws or contractual provisions. The analysis thus focuses on disclosure of origin requirements that are not already mandated by intellectual property laws, national access and benefit-sharing laws and/or contracts signed pursuant to such laws.

any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System”).

⁵⁰ See ITPGRFA, Art. 12.4.

⁵¹ The WIPO Technical Study provides useful discussions (which are not repeated here) of obligations to disclose the country of origin under intellectual property laws, and summarizes some national or regional laws requiring such disclosure as part of legislation implementing CBD access and benefit sharing requirements. See WIPO Technical Study, ¶¶ 39-87.

⁵² See *id.* Cf. Indian TRIPS Council Statement, at 3 (discussing United States proposal for a “national contract-based system with an ‘international outlook’”).

41. **“Source” of genetic resources.** The CBD does not define the “source” of genetic resources, or of associated traditional knowledge (discussed below). Although the Preamble to the CBD reaffirms that “States have sovereign rights over their own biological resources,” genetic resources may be owned by private persons or entities, which may have rights to control access to and uses of owned genetic resources. The CBD access and benefit sharing requirements thus must address not only the Contracting Party providing such resources or materials, but also national legislation defining ownership and use rights to control conditions of access and benefit sharing. As recognized by the WIPO Technical Study, “[t]here may be a specific legal framework for access to genetic resources, or access may be regulated indirectly through laws concerning rights attached to land ownership or leasehold, through the conditions that apply to access to and exploitation of State-owned land and resources, or through the effect of the law of contract. Government agencies and access providers have used contracts (such as material transfer agreements), licenses and permits, to establish and enforce the conditions of access to genetic resources and associated [traditional knowledge].”⁵³ Further, various levels of governmental approval may be required in order to provide access or to establish conditions for equitable benefit sharing.⁵⁴

42. A “source” of genetic resources may be defined as any person or entity (whether private or governmental) directly providing access to genetic resources that relates in any relevant way to the subject matter of intellectual property applications. Because more than one genetic resource may relate to that subject matter, there may be more than one source of genetic resources that may need to be disclosed in any given application for intellectual property. A source may possess or may lack the authority to provide access (based on the applicable legal requirements) under specified conditions of use and equitable benefit sharing.

43. **“Authority” to provide access and to establish conditions for an equitable share of benefits.** It is often difficult to determine who has the legal authority to provide access to genetic resources and to establish conditions for equitable benefit sharing deriving from such access. Whether any person or entity possesses such authority will depend upon national laws and norms of the country providing resources (and in some cases may trigger international laws relating to peoples of different nations),⁵⁵ including legal relationships regarding indigenous or local communities.⁵⁶ In order for an

⁵³ WIPO Technical Study, ¶ 15.

⁵⁴ See, e.g., *id.*, ¶¶ 16-19.

⁵⁵ See, e.g., Brendan Tobin, *Certificates of Origin: A role for IPR regimes in securing prior informed consent*, in *Access to Genetic Resources. Strategies for Benefit Sharing*, at 4 (ACTS Press, Nairobi, 1997) (Tobin, *Certificates*), available at <http://www.ias.unu.edu/research/details.cfm/ArticleID/520>.

⁵⁶ See, e.g., WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore E:\6-12.doc, *Preliminary Submission by Assembly of First Nations (AFN), Call of the Earth, Aboriginal and Torres Strait Islanders Commission (ATSIC), Foundation for Aboriginal and Islander Research Action (FAIRA), Canadian Biodiversity Network, Coordinating Body of the Indigenous Organizations of the Amazon Basin (COICA), Hokotehi Moriori Trust, Rekohu, Aotearoa (New Zealand), Indigenous Peoples Caucus of the Creators Rights Alliance, the Kaska Dena Council, the Saami Council and the International Indian Treaty Council: Objectives, principles and elements of an international instrument, or instruments, on intellectual property in relation to genetic resources and on the protection of traditional knowledge and traditional cultural expressions*, at 2 (2003) (noting the

international system of disclosure of origin requirements to assist in assuring compliance with access and benefit sharing requirements, however, the issue of authority must be addressed.

44. Authority reflects the application of all laws and required determinations by all relevant governmental entities (administrative and judicial) that are competent to authorize the source to provide access and to determine the legality of the conditions established for access and for equitable benefit sharing (including laws defining misappropriation). Authority also reflects the application of laws regarding public or private ownership and use of the resources in question. “Authority” thus may be understood as a legal condition of public or private entities, rather than solely as a governmental entity that is competent to determine whether the source has authority. In some cases, governmental entities may be sources that possess authority to provide access to genetic resources. In other cases, governmental entities may need to approve private persons (or other government entities) to provide access. Authority to provide access to genetic resources may require the approval of more than one individual, community, or private or governmental entity. Persons who or entities that receive genetic resources from a source with authority and comply with specified conditions of access and benefit sharing possess the legal provenance to use those resources according to the authorized conditions.⁵⁷

45. **“Legal provenance”** means access to genetic resources for use under specified conditions, pursuant to legal authority. The term “legal provenance” is frequently employed in regard to certificates of legal provenance, which would document and attest to the provision of genetic resources from a source with authority.⁵⁸ As used in that context, legal provenance may reflect application of and compliance with the law of “the country of origin or of other legal source,” and is “ill-defined in many cases.”⁵⁹

“general element” of national treatment and mutual recognition of indigenous customary laws and national legislation), available at http://www.wipo.int/tk/en/igc/ngo/afn_igc6.pdf; UNCTAD/DITC/TED/10, *Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions*, at 83, 217-18 (Sophia Twarog & Promila Kapoor, eds., 2004) (discussing recommendation of indigenous groups for strengthening customary laws of indigenous peoples in regard to traditional knowledge and the constitutional status and rights of indigenous peoples of Bolivia), available at http://p166.unctad.org/file.php/12/ditcted10_en.pdf. See generally Angela R. Riley, “Straight Stealing”: *Towards an Indigenous System of Cultural Property Protection*, 80 Wash. L. Rev. 69, 86-91 118-23 (2005) (discussing conflicts of approach between indigenous and national legal regimes, and limits to indigenous groups’ legal jurisdiction, in regard to cultural property issues).

⁵⁷ See, e.g., WTO IP/C/W/447, at 1 n.1 (pointing out that “the concept of legal provenance presupposes the existence of prior informed consent (PIC) and of fair and equitable benefit sharing”).

⁵⁸ See, e.g., David Cunningham, Brendan Tobin & Kazuo Watanabe, UNU-IAS, *Tracking genetic resources and international access and benefit sharing governance: The role of certificates of origin*, at 3 (2004) (*Tracking genetic resources*) (“A certificate of legal provenance would document evidence that the resources had been obtained from a legally entitled provider. In the face of continuing uncertainties regarding legal rights over resources and absent a binding international regime on ABS, legal provenance would fall to be decided by the laws of the country where the resources were sourced, potentially providing an opportunity for circumvention of the rights of countries of origin.”), available at http://www.ias.unu.edu/binaries2/Certificates_of_origin_backgr_paper.doc.

⁵⁹ UNU-IAS Report, at 38.

46. **“Biopiracy” and “misappropriation.”** There are no authoritative definitions for the term “biopiracy”. Biopiracy may be defined as the effect of obtaining access to genetic resources without appropriate authority.⁶⁰ It also may be defined more broadly to involve unauthorized commercialization resulting from access, derivation of unjustified benefits, or failure to provide for equitable benefit sharing.⁶¹ In contrast, misappropriation has legal significance in many jurisdictions that includes the concept of taking the value of the intellectual or other property through use.⁶² Accordingly, misappropriation may be defined as the consequence of biopiracy, of violating authorized conditions of access, or of using the genetic resources to derive unjustified or inequitably shared benefits.⁶³ Misappropriation may be remedied by many different legal doctrines, including but not limited to those relating to unfair competition, trade secrecy, and unjust enrichment.⁶⁴

47. **“Traditional knowledge.”** Article 8(j) of the CBD requires, “as far as possible and as appropriate” that a Contracting Party “subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the

⁶⁰ See, e.g., Stephen Smith, *International Expert Workshop on Access to Genetic Resources and Benefit Sharing: Access to Genetic Resources and Intellectual Property Rights: What is Biopiracy?*, at 1 (2004) (treating biopiracy as unauthorized use of biological resources or traditional knowledge, unequal shares of benefits, or patenting without respect to substantive patent law criteria), available at <http://www.canmexworkshop.com/documents/papers/I.3d.1.pdf>; Graham Dutfield, *International Expert Workshop on Access to Genetic Resources and Benefit Sharing: What is Biopiracy?*, at 2 (2004) (treating biopiracy as “theft, misappropriation of, or unfair free riding” or “unauthorized and uncompensated collection for commercial ends”), available at <http://www.canmexworkshop.com/documents/papers/I.3.pdf>.

⁶¹ See, e.g., Carlos M. Correa, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries*, South Centre, § VI, Conclusions (2002), available at <http://www.southcentre.org/publications/traditionalmedicine/traditionalmedicine.pdf>.

⁶² See, e.g., Restatement of Unfair Competition (3d), Ch. Four, § 38 (American Law Institute 1995) (discussing appropriation of another’s “intangible trade values” under United States law); *id.*, § 44 (discussing injunctions to prohibit the appropriation of trade secrets for unauthorized uses). Cf. WTO IP/C/W/434, *Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, Communication from the United States (2004), ¶ 8 (limiting misappropriation to “improper collection and/or use,” without addressing use to obtain intellectual property), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

⁶³ Cf. WTO IP/C/W/443, ¶ 12 (describing misappropriation as use in developing the subject matter of applications and of applying for intellectual property without obtaining prior informed consent or providing for equitable benefit sharing); WIPO/GRTKF/IC/7/5, *Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles*, Annex I, ¶ B.2. (2004) (defining as an act of misappropriation any “acquisition or appropriation of traditional knowledge by unfair or illicit means”), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_5-annex1.pdf.

⁶⁴ See, e.g., Paris Convention Art. 10bis; TRIPS Agreement Arts. 22.2(b), 39.1; Restatement of Unfair Competition (3d), Ch. Four, §§ 38, 44 (United States law); *Cases, Materials and Texts on Unjustified Enrichment* at 524-30, 544-48 (Hart Publishing, Oxford, United Kingdom 2003) (discussing restitutionary claims and disgorgement or royalty remedies for tortious or delictual behavior and for breach of contract under United Kingdom common law and German civil law); *Ultra-Precision Mfg. Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1377-82 (Fed. Cir. 2005) (discussing unjust enrichment claims – based on implied in law contractual provisions, breaches of confidential relationship, misappropriation of trade secrets, or conferral of an incremental benefit other than accessing information in the public domain – that are not preempted by United States patent law).

approval and involvement of the holders of such knowledge, innovations, and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations, and practices.” However, Article 2 of the CBD does not define “traditional knowledge, innovations, and practices.” Traditional knowledge can serve several functions, and thus may take many forms.⁶⁵ The WIPO secretariat has proposed to define traditional knowledge, in relevant part, as “the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations.”⁶⁶

48. The language of Article 8(j) suggests that traditional knowledge must be “relevant for the conservation and sustainable use of biological diversity” in order to be subject to CBD requirements for equitable benefit sharing.⁶⁷ Article 2 of the CBD defines “biological diversity” (to which Article 8(j) refers) as variability among living organisms from all sources including ... ecological complexes of which they are part.” Biological diversity thus is broader than and different from genetic resources, to which the obligations of Article 15 apply. Biological diversity also is broader than the Article 2 definition of biological resources. The relationship of traditional knowledge to biological diversity thus may be broader than the relationship of traditional knowledge to genetic resources, genetic material, or biological material.

49. Article 8(j), however, does not impose any clear-cut mandate for national measures for prior informed consent for access to traditional knowledge. Rather, Article 8(j) promotes the wider application of traditional knowledge with approval and involvement of the relevant indigenous/local communities and encourages equitable benefit sharing. Thus, the CBD does not appear to regard the respect or preservation of traditional knowledge as an end in itself.⁶⁸ Nevertheless, the CBD COP has sought to develop guidelines and mechanisms for prior informed consent and for equitable benefit sharing of benefits arising from the use of traditional knowledge,⁶⁹ and has encouraged consideration of “a process and set of requirements governing prior informed consent, mutually agreed terms and equitable sharing of benefits with respect to traditional

⁶⁵ See, e.g., WIPO-UNEP Study, at 26 (identifying semiotic, institutional, configurational, utilitarian, situational, and religious/spiritual forms of traditional knowledge).

⁶⁶ WIPO/GTRKF/IC/8/5, *The Protection of Traditional Knowledge: Revised Objectives and Principles*, Annex, at 20 (2005), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_5.doc.

⁶⁷ See, e.g., UNEP/CBD/TKBD/1/2, *Traditional Knowledge and Biological Diversity*, ¶ 30 (1997), available at <http://www.biodiv.org/doc/meetings/tk/wstkbd-01/official/wstkbd-01-02-en.pdf> (noting the connections between genetic resources and traditional knowledge warrant implementing Article 8(j) in conjunction with Article 15).

⁶⁸ See, e.g., Carlos M. Correa, *Update on International Developments Relating to the Intellectual Property Protection of Traditional Knowledge Including Traditional Medicine*, South Centre, Trade-Related Agenda, Development, and Equity Working Paper 18, at 2 (2004), available at <http://www.southcentre.org/publications/workingpapers/paper18/wp18.pdf>.

⁶⁹ See, e.g., UNEP/CBD/COP/5/23, Decision V/16, Annex, *Programme of Work on the Implementation of Article 8(j) and Related Provisions of the Convention on Biological Diversity*, Element 4, Task 7 (2000), available at <http://www.biodiv.org/doc/decisions/COP-05-dec-en.pdf>.

knowledge, innovations, and practices associated with genetic resources and relevant for the conservation and sustainable use of biological diversity.”⁷⁰ Similarly, all of the submissions to the TRIPS Council regarding disclosure of origin obligations in the CBD context suggest including traditional knowledge associated with biological materials or genetic resources.⁷¹

50. Accordingly, “traditional knowledge” may be defined for this analysis as any form of knowledge resulting from intellectual activity of indigenous or local communities, part of traditional knowledge systems, or embodying traditional lifestyles of indigenous or local communities that is associated with genetic resources and that leads to the development of, is incorporated in, is used with, or is otherwise relevant to the subject matter of intellectual property applications. Similar meanings to those for genetic resources apply to the “source,” “country of origin,” “country providing associated traditional knowledge,” and “authority” of the source. The CBD COP invited WIPO to examine “the disclosure of origin of relevant traditional knowledge in intellectual property applications,” invited Parties and government to encourage such disclosures “where the subject matter of the application concerns or makes use of such knowledge in its development,” and urged Parties and governments to examine CBD provisions “with respect to prior informed consent and mutually agreed terms where traditional knowledge is used in its original form or in the development of new products and/or new applications.”⁷² The principles developed in this analysis, however, may be relevant to a broader range of traditional knowledge that relates to the subject matter of intellectual property applications.⁷³ In particular, the principles may have relevance to efforts to develop a *sui generis* system of protection and equitable benefit sharing for traditional knowledge.

51. Requirements for disclosures of the origin of traditional knowledge associated with genetic resources may assist in ensuring prior informed consent and equitable benefit sharing with regard to both the traditional knowledge and the associated genetic resources. Similarly, disclosure of origin requirements may assist in preventing misappropriation of traditional knowledge associated with genetic resources. For example, the draft provisions for the protection of traditional knowledge considered by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore would require measures to protect against

⁷⁰ See UNEP/CBD/COP/7/21, Decision VII/16, *Article 8(j) and related provisions, H. Development of elements of sui generis systems for the protection of traditional knowledge, innovations, and practices*, Annex, Some Potential Elements to be Considered in the Development of *Sui Generis* Systems for the Protection of Traditional Knowledge, Innovations, and Practices of Indigenous and Local Communities, ¶ 5 (2004), available at <http://www.biodiv.org/doc/decisions/COP-07-dec-en.pdf>.

⁷¹ *Id.* at 12.

⁷² See, e.g., UNEP/CBD/COP/6/20, Decision VI/10, ¶¶ 31, 46, 47 (2002), available at <http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf>.

⁷³ For example, traditional knowledge might lead to inventions that would help to preserve biological diversity, but would not use genetic resources in developing the invention, as components of the invention, or when using the invention.

misappropriation by acquisition, appropriation, or utilization of traditional knowledge by unfair or illegal means.⁷⁴

52. As with disclosures relating directly to genetic resources, disclosure of origin requirements may address the country of origin of the traditional knowledge, the country providing traditional knowledge, the source of traditional knowledge, and the authority of the source to provide access to traditional knowledge on specified conditions of use and equitable benefit sharing. Disclosure of the country of origin may require applicants to search for or to generate relevant information. Establishing whether the source possesses authority to provide access on the specified conditions may require complex determinations. As recognized by Article 8(j) of the CBD, traditional knowledge is located in “indigenous and local communities.” But such communities may have customary laws and norms that govern ownership and use rights that differ from and are in addition to those established by national legislation.⁷⁵ Authority to provide access to traditional knowledge within such communities may be heterogeneously dispersed among community members.⁷⁶ Such communities also may extend across national boundaries, raising complex issues regarding the legal relations of nations to the different members of those communities. Moreover, because knowledge may be readily communicated and transmitted, traditional knowledge may be more easily transferred than associated genetic resources by the source to a recipient in a different country.

53. **“Intellectual property applications.”** There are many different forms of intellectual property that vest only after some form of application and review procedure. For example, intellectual property may vest based on registration that requires governmental review only to record or issue relevant documents, or based on detailed examination of the substantive validity and compliance with formalities of the contents of applications. Disclosure of origin requirements applicable to intellectual property applications thus must address a wide variety of application and review procedures. “Intellectual property applications” may be defined as applications that require some degree of governmental registration or examination before the relevant rights or privileges vest. Although the primary focus of this analysis is on patents and plant breeders’ rights, intellectual property applications also may be required for utility models, petty patents, trademarks, industrial designs, and *sui generis* protections requiring registration or examination.⁷⁷ In contrast, some forms of intellectual property vest without the requirement to file applications, based on status or conduct in relation to the subject matter of the rights or privileges. Because the CBD invitation was limited to consideration of disclosure of origin requirements in regard to intellectual property

⁷⁴ See WIPO/GRTKF/IC/8/5, ¶¶ 1-2.

⁷⁵ See, e.g., Robert J.L. Lettington and Kent Nnadozie, *A Review of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore at WIPO*, South Centre, Trade-Related Agenda, Development, and Equity Occasional Papers 12, ¶ 24 (2003), available at <http://www.southcentre.org/publications/occasional/paper12/paper12.pdf>.

⁷⁶ See, e.g., WIPO-UNEP Study, at 27, 40 (noting the lack of homogeneity of interests of the members of many local communities and that not all prevalent community knowledge is communal or traditional in nature).

⁷⁷ See, e.g., WIPO Technical Study, ¶ 73.

applications, this analysis does not address such intellectual property, although many of the principles of the analysis also may apply to such intellectual property.

54. **“Applicant” for intellectual property.** Intellectual property often is sought by applicants who did not themselves develop the subject matter of the application. For example, applications for patents may be filed (often by or with the assistance of an attorney or agent) on behalf of inventors, assignees of inventors in the inventors’ names, or assignees in their own names. National patent laws may require applicants to disclose the names of and information regarding each person who is considered an inventor of the subject matter or has some other basis (such as assignment) for the entitlement to apply. The failure to disclose the requisite information may result in substantive invalidity of the patent.⁷⁸ The TRIPS Agreement and other treaties addressing patents, plant breeders’ rights, and other intellectual property did not harmonize national laws regarding ownership of intellectual property or the relation of creative entities to substantive entitlements to apply for intellectual property.⁷⁹ In the *Havana* case, the WTO Appellate Body unequivocally affirmed the holding of the dispute resolution panel that the TRIPS Agreement does not regulate the issue of ownership of trademarks, leaving entirely to national legislation the conditions regarding who is entitled to apply for and own intellectual property.⁸⁰ Accordingly, the “applicant” for intellectual property is defined for this analysis as all persons and entities entitled or required to apply for or to register an interest in intellectual property, under the national law of the country where such rights or privileges are sought.⁸¹

55. **“Persons involved” in intellectual property applications.** Sources of genetic resources and associated traditional knowledge and persons or entities obtaining access directly from those sources may not necessarily qualify as inventors or applicants under national intellectual property laws.⁸² In such cases, additional disclosures may be needed to identify those persons or entities and their relationship to the subject matter of the application. For this analysis, “persons involved” in applications are defined as all persons who were involved in the development of the subject matter of or the application for the intellectual property or whose involvement may have a bearing on the entitlement of the applicant to apply for and receive benefits of intellectual property. Persons

⁷⁸ See, e.g., WIPO Technical Study, ¶ 50 (citing European Patent Convention Art. 81), ¶ 51.

⁷⁹ See, e.g., Sarnoff, *Consistency*, at 35 & nn.173 & 174 (citing WTO WT/DS176/AB/R, *United States – Section 211 Omnibus Appropriations Act of 1998*, Report of the Appellate Body, ¶ 189 (2002) (*Havana* WTO AB Report), available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/176ABR.doc>; WIPO Technical Study, ¶ 177; and CBD UNEP/CBD/WG-ABS/2/INF/2, *Measures, Including Consideration of their Feasibility, Practicality and Costs, to Support Compliance With Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on Which Access Was Granted in Contracting Parties With Users of Such Resources Under Their Jurisdiction, Disclosure of origin and prior informed consent for applications of intellectual property rights based on genetic resources: a technical study of implementation issues*, ¶ 3.1.43 (2003) (CBD Consultant Report), available at <http://www.biodiv.org/doc/meetings/abs/abswg-02/information/abswg-02-inf-02-en.pdf>).

⁸⁰ See *Havana* WTO AB Report at ¶¶ 155-65, 189.

⁸¹ See WIPO Technical Study, ¶¶ 74-79 (discussing registration of different forms of ownership interests in the subject matter of intellectual property applications or of the issued rights or privileges).

⁸² See *id.*, ¶ 52 (discussing differences under United Kingdom law between inventive and non-inventive contributions, e.g., directions for research leading to inventions).

involved in applications thus may have a direct or remote relationship to the applicant or to the source of genetic resources and associated traditional knowledge. The definition of persons involved is more expansive than, for example, the definition of “individuals associated with the filing or prosecution” of a patent application required to supply to the U.S. Patent Office known “information material to patentability.”⁸³

56. **“Certificate of origin.”** The CBD inquiry refers to the “proposed international certificate of origin/source/legal provenance.” Although the CBD does not define certificates of origin, certificates of source, or certificates of legal provenance, these concepts were developed in the context of intergovernmental and regional efforts to implement the CBD.⁸⁴ Some prior analyses have discussed “voluntary” or third-party certification schemes, where individuals or entities may certify conformity to various types of standards in a unitary or progressive (step-by-step) fashion, or have suggested that certificates of origin could be issued by owners of the genetic resources or traditional knowledge.⁸⁵ In contrast, this analysis conceives of international certificates of origin as documents issued by a competent entity that assures the integrity of the contents of the certification.⁸⁶ A certificate of origin also may, but need not, contain a sworn declaration of a source or of a recipient of genetic resources or associated traditional knowledge. Thus, certificates of origin differ from certifications or declarations that may be required of or made by applicants when seeking intellectual property.

57. An international “certificate of origin” may be defined for this analysis as a document issued by a competent entity, which identifies the source, attests to the authority of the source to provide the relevant resources and knowledge for specified conditions of use, and attests to the compliance with equitable benefit sharing requirements (pursuant to contractual arrangements or other mechanisms). This definition varies from some other formulations of certificates of origin, source, and legal provenance.⁸⁷ In particular, “certificate of origin” differs from common use of the term

⁸³ See, e.g., 37 C.F.R. § 1.56(c)(3) (under United States law, “[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application.”).

⁸⁴ See, e.g., UNEP/CBD/WG-ABS/3/INF/5, Brendan Tobin, David Cunningham & Kazuo Watanabe, UNU-IAS, *The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Preliminary Results of Comparative Analyses of Tracking Materials in Biological Resource Centres and of Proposals for a Certification Scheme*, at 8 (2004), available at <http://www.biodiv.org/doc/meeting.aspx?mtg=ABSWG-03&tab=1>; Tobin, *Certificates*, at 7 & n.16; UNU-IAS Report, at 38.

⁸⁵ See, e.g., UNU-IAS Report, at 23; Rodrigo de la Cruz, *Informal Notes: Vision of Indigenous Peoples in the context of the decisions pertaining Access to Genetic Resources and Benefit Sharing (ABS) and Article 8j; An Analysis of the Impacts of CBD/COP Decisions with respect to WIPO’s IGC mandate*, at 8 (2004), available at http://www.iucn.org/themes/pbia/themes/trade/final_cruz_EN.pdf.

⁸⁶ See, e.g., *id.* at 38 (discussing “standardized official document[s] issued by the country of origin”). Consistency with the WTO Sanitary and Phytosanitary Agreement and the Technical Barriers to Trade Agreement is not addressed by this analysis, but may need to be investigated. See *id.* at 24. Further, we do not mean to prejudge issues regarding the political relationships of indigenous or local communities to the countries in which they are located. Cf. Tobin, *Certificates*, at 3 & n.3 (noting that Article 8(j) fails to explicitly recognize indigenous and local community property rights).

⁸⁷ See, e.g., UNEP/CBD/WG-ABS/3/INF/5, at 10 (noting that certificates of origin would be granted by the national authority of the country of origin, rather than the country providing genetic resources, and that

to denote a certificate that identifies the country of origin, although such information may also be included. Because certificates of origin must identify the authority of the source, they also document the legal provenance of the recipient to make use of genetic resources and associated traditional knowledge, in the absence of misappropriation. “Certificate of origin” thus corresponds more closely to common uses of the terms certificates of source and certificates of legal provenance.⁸⁸ Monitoring may be needed to assure *ex post* compliance with conditions of access and equitable benefit sharing once a certificate of origin is issued. The analysis in Part V focuses on use of international certificates of origin in regard to disclosure of origin requirements.

certificates of legal provenance could be issued by non-governmental entities in countries other than the country of origin).

⁸⁸ See, e.g., UNU-IAS Report, at 38; *Tracking genetic resources*, at 3.

I. Model Provisions for Disclosure Requirements

58. In general terms, three different sets of issues exist for adopting model provisions of an international regime to implement disclosure of origin requirements. The first set of issues relates to whether to impose disclosure of origin requirements as mandatory treaty obligations or just to facilitate such disclosures within the existing intellectual property law system. The second set of issues relates to the nature of the disclosure obligations and the mandatory or facultative consequences to be prescribed for failures of applicants or parties to comply with requirements or obligations. The third set of issues relates to the treaty regime in which to locate the obligations. Because the nature of the disclosure obligations and the consequences of disclosure failures overlap with the second and third set of issues posed for analysis by the CBD COP, these issues are more comprehensively addressed in Parts II and III.

A. Mandatory or Facilitated Disclosure of Origin Obligations

59. **Foreign recognition of existing mandatory disclosure of origin obligations.** As noted in numerous submissions to WIPO and to the WTO, various national laws already require applicants for intellectual property to disclose the source and country of origin of genetic resources and associated traditional knowledge and relevant documentary information regarding compliance with access and benefit sharing requirements.⁸⁹ Similarly, contracts providing for compliance with access and benefit sharing requirements and adopted under national laws implementing CBD obligations also may require such disclosures (including copies of the contracts), even when the national laws do not.⁹⁰ In theory, national laws and contracts may mandate such

⁸⁹ See, e.g., WIPO/GRTKF/IC/Q.3, *Questionnaire on Various Requirements for Disclosure Relating to Genetic Resources and Traditional Knowledge in Patent Applications*, Part I, Annex (2005) (compiling country submissions in response to WIPO Question 3, regarding specific requirements to disclose the source and geographic origin of genetic resources or traditional knowledge and evidence of compliance with access requirements), available at <http://www.wipo.int/tk/en/consultations/questionnaires/ic-q3/responses.pdf>; WIPO Examination, at 23-26 (summarizing various regional and national measures); WTO IP/C/W/368, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made* (2002) (citing the submissions in IP/C/W/310 (Australia), IP/C/W/198 (India), IP/C/W/296 (Peru), and IP/C/W/341 (United States)), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. See also Correa, *Disclosure*, at 3-4 (summarizing provisions of Costa Rica, India, the Andean Group, and Brazil, and discussing the European Directive on Biotechnological Inventions, No. 96/9/EC of March 11, 1996, and Belgian Patent Act 1984, Art. 49(1)(1), which encourage such disclosures and may prohibit exploitation if contrary to *ordre public* and morality).

⁹⁰ For example, WTO IP/C/W/368 at ¶¶ 21, 26 (citing WTO IP/C/W/257 (United States), WTO IP/C/M/29, ¶ 155 (Japan), WTO IP/C/M/30, ¶ 171 (Korea), WTO IP/C/M/29, ¶ 174 (Thailand), WTO IP/C/M/30, ¶ 177 (United States)), discusses national legislation to require contracts for access and benefit sharing that would require detailed elaboration of access and use conditions, including provisions for judicial jurisdiction, and which might include requirements to disclose such contracts (as documentation of prior informed consent) or additional evidence of compliance with contractual terms (for benefit sharing) in intellectual property applications. Similarly, such contracts may require other disclosures of source and the country of origin (including in required descriptions of the subject matter).

disclosures of origin in intellectual property applications filed in foreign jurisdictions.⁹¹ If recognized and enforced in foreign jurisdictions, these legal and contractual requirements already impose an international system of mandatory disclosure of origin obligations.⁹²

60. National or contractual requirements for disclosures of origin in foreign intellectual property applications, however, are not uniform in scope and may potentially conflict with intellectual property and other laws in the foreign jurisdictions. Complex legal rules regarding conflict of laws and legislative and judicial jurisdiction may sometimes preclude such national requirements from being effectuated.⁹³ Not only are determinations regarding recognition and enforcement unpredictable, but also they increase the burdens and costs of enforcing such requirements. As noted in a recent WTO submission suggesting amendment of the TRIPS Agreement to require mandatory disclosure of origin requirements, “it would be more cost-effective” to establish an internationally accepted solution ... to prevent biopiracy than to divert national resources to expensive judicial processes for the revocation of patents that include illegal genetic resources. ... Developing countries, in particular, do not have the resources to follow each and every patent issued outside their territories on the use of their resources.”⁹⁴ Similarly, indigenous and local communities typically lack the resources to effectively enforce patents and other rights relating to genetic resources and traditional knowledge.⁹⁵ New international treaty provisions imposing mandatory disclosure of origin obligations would reduce uncertainties regarding recognition and enforcement of such national disclosure requirements in foreign intellectual property applications, and would thereby reduce the burdens and costs of preventing and remedying biopiracy and misappropriation. Additional analysis of the recognition and enforcement of existing national access and benefit sharing laws and contractual provisions imposing disclosure of origin requirements, and their relation to intellectual property laws, would significantly assist future discussions of disclosure of origin requirements.

61. **Treaty consistency of existing disclosure obligations.** Prior analyses have demonstrated that most forms of national disclosure of origin requirements for domestic and foreign patent applications (including requirements under existing national laws) are consistent with WIPO- and WTO-administered intellectual property law treaties,⁹⁶ including the TRIPS Agreement, the PCT and the PLT. Such consistent requirements may preclude the grant of rights or privileges absent timely submission of required documentation, or may invalidate intellectual property if requisite information or documents were accidentally or intentionally omitted or if false or fraudulent information

⁹¹ By comparison, the Indian Biological Diversity Act, 2002, Article 6(1) prohibits applications for intellectual property in any form “in or outside India” for inventions based on biological resources “obtained from India” without the prior approval of the Indian National Biodiversity Authority.

⁹² See, e.g., UNU-IAS Report, at 36-37 (discussing recognition issues relating to enforcement of foreign judgments).

⁹³ See, e.g., Sarnoff, *Consistency*, at 3 n.10, 19, 20 & n.91; WIPO Technical Study, ¶¶ 117-21, 156-60.

⁹⁴ WTO IP/C/W/356, ¶ 12.

⁹⁵ See, e.g., Berglund, *TK Protection*, at 110.

⁹⁶ See, e.g., Sarnoff, *Consistency*, at 31-37, 51; WIPO Technical Study, ¶¶ 148, 153, 175, 183.

or documents were submitted.⁹⁷ One potential inconsistency with existing patent law treaties would arise if an inadequate disclosure resulted in the denial of an effective filing date for an application as of its initial submission, if the application otherwise met specified requirements. However, these treaty requirements may not supersede additional requirements for the further processing of applications, and may easily be avoided simply by according a filing date before additional consequences ensue (such as abandonment or refusal to process the application).⁹⁸ Another potential inconsistency would arise absent adequate opportunities for prior comment and for judicial review of any invalidation of rights or privileges.⁹⁹ The prior analyses were premised in part on the fact that existing international intellectual property law treaties have not sought to regulate national laws that determine entitlements to apply for or own intellectual property. Thus, parties to those treaties remain free to limit substantive entitlements to apply for or to own intellectual property, as well as to condition such entitlements on disclosure obligations and to sanction disclosure failures.¹⁰⁰ The relevant substance of the prior analyses is summarized briefly below.

62. The PCT does not prohibit national disclosure of origin requirements at the national stage of processing international PCT applications, regardless of whether these requirements are considered to be “formal” or “substantive.”¹⁰¹ Nor does the PLT prohibit such requirements for national applications filed through the PCT system or initially in national patent offices.¹⁰² Although PCT Article 27(1) and PLT Article 6(1) limit the ability to require compliance with additional requirements relating to the “form and contents” of applications, these requirements do not apply to disclosure of origin

⁹⁷ See Sarnoff, *Consistency*, at 37-53. Although UPOV has suggested that disclosure obligations that would deny or invalidate plant breeders rights conflict with the UPOV Convention, UPOV did not directly address the issue of entitlement to apply for such rights, but rather treated such requirements “as an additional condition of protection.” See WTO IP/C/W/347/Add.3, *Review of the Provisions of Article 27.3, Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore, Information from Intergovernmental Organizations, Addendum, International Union for the Protection of New Varieties of Plants (UPOV)*, ¶ 20, available at http://docsonline.wto.org/gen_home.asp?language=1&=1.

⁹⁸ See Sarnoff, *Consistency*, at 45-49 (discussing PCT Art. 11(1) and PLT Art. 5(1)).

⁹⁹ See *id.* at 41-42, 45-46, 49-51.

¹⁰⁰ See *id.* at 35-37. See also *Havana* WTO AB Report, ¶¶ 155-65, 189.

¹⁰¹ See Sarnoff, *Consistency*, at 46-49 (discussing PCT Arts. 3(2), (4), 14, 26, and 27(1)). Cf. WIPO Technical Study, ¶¶ 132-35, 6 (discussing differences among treaty requirements applicable to substantive and formality requirements); WIPO Examination, ¶ 73 (discussing substantive and formality requirements and distinguishing both from ownership requirements), ¶¶ 168-72, 176-80 (discussing treaty requirements in regard to substantive and formality requirements); WTO IP/C/W/433, *Further Observations By Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, ¶¶ 4-8 (2004) (discussing formal requirements, substantive requirements, and formal requirements strongly linked to substance, concluding that disclosures or origin are formal requirements, and urging amendment of PCT rules to authorize requirements for such disclosures), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. Neither the PCT nor the PLT clearly distinguishes substantive rules from formalities.

¹⁰² See Sarnoff, *Consistency*, at 49-51 (discussing PLT Art. 6(1) and Art. 10(1), which incorporates Art. 6(1) by reference).

requirements as substantive conditions of entitlement.¹⁰³ Both the PCT and the PLT expressly state that they do not regulate substantive patentability rules, and permit the imposition of requirements for additional documentation in that regard.¹⁰⁴ But even if disclosure of origin requirements were to constitute prohibited formalities, the PCT would not preclude imposing disclosure obligations at the national stage. Further, there were only ten countries Party to the PLT as of April 2005.¹⁰⁵ Countries with disclosure of origin requirements either would not ratify the PLT or the PLT might be amended to permit such disclosure requirements. Additional discussion of implementation within the PCT and PLT treaty regimes is provided in Part IV below.

63. The TRIPS Agreement does not prohibit countries from imposing additional substantive conditions of entitlement and requirements for applicants to demonstrate their entitlement to apply for or own intellectual property. Article 29.1 of the TRIPS Agreement specifies mandatory and facultative patent application disclosure requirements. But Article 29.1 does not preclude countries from imposing additional disclosure requirements for national applications, particularly when effectuating substantive conditions of entitlement.¹⁰⁶ Nor do the TRIPS Agreement, the PCT, or the PLT prohibit countries from refusing to grant or from invalidating patents or plant breeders' rights when substantive criteria for entitlement have not been met or when required disclosures have not been provided.¹⁰⁷

64. Assuming for analysis that disclosure of origin requirements were to constitute formalities, Article 62.1 of the TRIPS Agreement expressly authorizes members to impose "reasonable procedures and formalities" for acquisition and maintenance of intellectual property (such as copyright formalities and evidence of use for registered marks). Thus, disclosure of origin requirements would need to be evaluated for reasonableness under Article 62.1. Requirements to disclose the source, the country providing genetic resources and associated traditional knowledge, the country of origin, persons involved, and documentary information regarding access and benefit sharing may entail varying degrees of burden for applicants. If properly tailored to minimize unnecessary burdens, disclosure of origin requirements should be considered "reasonable." In contrast, requirements for intellectual property application offices to evaluate such disclosures of origin may entail significant administrative burdens, particularly if national application offices are required to assess compliance with access

¹⁰³ See *id.* at 47-50 (citing, *inter alia*, PCT Arts. 27(1), (2), 27(3), 27(5), PLT Art. 6(1), and WIPO SCP/6/5, *Study on the Interface Between the SPLT, the PLT, and the PCT* (2001), available at http://www.wipo.int/scp/en/documents/session_6/pdf/scp6_5.pdf).

¹⁰⁴ See WIPO Technical Study, ¶¶ 165, 169-71, 175 (citing TRIPS Art. 29.2, PLT Art. 2(2), and WIPO SCP/6/5).

¹⁰⁵ These are Croatia, Denmark, Estonia, Kyrgyzstan, Nigeria, Republic of Moldova, Romania, Slovakia, Slovenia, and Ukraine.

¹⁰⁶ See, e.g., Sarnoff, *Consistency*, at 40-41; WTO IP/C/W/383, *Review of Article 27.3(B) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore*, Communication from the European Communities and Their Member States, at ¶ 48 (2002) (noting that Article 29.1 permits additional disclosure requirements that do not relate to substantive patent validity criteria), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

¹⁰⁷ See Sarnoff, *Consistency*, at 37-41, 50-51.

and benefit sharing requirements imposed by different countries' laws or by contracts.¹⁰⁸ However, Article 62.1 would not prohibit such requirements, as Article 62.1 does not regulate the reasonableness of administrative procedures *per se*.¹⁰⁹

65. **The Swiss proposal to facilitate disclosure obligations.** Because it views PCT Article 27(1) and PLT Article 6(1) to preclude disclosure of origin requirements for PCT international and national stage and for PLT national applications, Switzerland has proposed to amend the PCT to expressly authorize disclosure of origin requirements for national applications. The PCT amendments would apply to the PLT for national and regional applications, as PLT Article 6(1) incorporates by reference PCT requirements relating to the form and contents of an international application.¹¹⁰ The Swiss proposal would not mandate national disclosure of origin requirements. Rather, it would authorize PCT and PLT parties to impose disclosure of origin requirements at the national stage of application processing and would permit (but would not require) applicants to include such disclosures at the international stage of PCT applications. If such disclosures are voluntarily included at the international stage, the PCT would require receiving offices to publish them.¹¹¹ The Swiss proposal would apply only to declaring the “source” of genetic resources, which is defined broadly to include both the source (as defined for this analysis) and the country providing genetic resources or traditional knowledge. The Swiss proposal would not require disclosure of more than the “primary source” (but would permit disclosure of additional sources if known), and would define the primary source as the country providing genetic resources or traditional knowledge.¹¹² The proposal would not require disclosure unless the invention that is the subject of the patent application was “directly based” on genetic resources or traditional knowledge.¹¹³ Thus, the Swiss proposal would adopt a very narrow substantive trigger for requiring disclosures of origin in patent applications.

66. The Swiss proposal, however, would not authorize applicants to declare the source of genetic resources or traditional knowledge unless the declaration was relevant to the national application of at least one designated country. Of potentially greater

¹⁰⁸ See, e.g., Correa, *Disclosure*, at 9.

¹⁰⁹ See Daniel Gervais, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* at 330 (2d ed. Sweet & Maxwell 2003).

¹¹⁰ See WIPO Technical Study, ¶ 168 (citing WIPO/SCP/6/5).

¹¹¹ See WTO IP/C/W/433; WTO IP/C/W/423, *Additional Comments By Switzerland on its Proposals Submitted to WIPO Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, Communication from Switzerland (2004), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm; WTO IP/C/W/400/Rev.1, *Article 27.3(b), the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, Communication from Switzerland (2003), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm; WIPO Examination, ¶¶ 52-54 (summarizing the Swiss Proposal, citing PCT/R/WG/4/13; PCT/R/WG/5/11 Rev; PCT/R/WG/6/11; PCT/R/W/7/7).

¹¹² See WTO IP/C/W/433, ¶¶ 11-13 (discussing proposed PCT Rules 4.17(vi) & 51bis.1(g)); WTO IP/C/W/423, ¶¶ 21-23.

¹¹³ See WTO IP/C/W/423, ¶¶ 27-28 (noting that “directly based” in proposed PCT Rule 51bis.1(g) requires the invention to “make immediate use of the genetic resource” and for the inventor to have had sufficient contact with the genetic resource or the traditional knowledge to identify properties that were relevant for the invention).

significance, the Swiss proposal would *prevent* designated countries from requiring applicants to provide additional documentation regarding the disclosure of source in national patent applications, absent reasonable doubt as to the veracity of the declaration made in the prescribed form (which would be adopted by amendment of the Administrative Instructions).¹¹⁴ Designated offices could request applicants to cure defective declarations (where reasonable doubt exists) or missing declarations, and could refuse the application or consider it withdrawn after at least two months from notice. But the failure to comply with disclosure obligations would not provide grounds for revocation of issued patents (under PLT Article 10(1) if applicable), unless the failure reflected fraudulent intention.¹¹⁵ The Swiss proposal thus might preclude nations from imposing more substantial disclosure of origin requirements on national-stage PCT applications and on national applications subject to the PLT. It would thereby prohibit requirements to disclose additional sources and the country of origin, as well as documentary information regarding compliance with CBD access and benefit sharing requirements.¹¹⁶ If adopted, countries currently requiring such disclosures at the national stage would have to change their laws in order to conform to the PCT or the PLT.

67. **Mandatory disclosure of origin obligations.** Authority currently exists for countries to require disclosures of origin in patent applications. Authority also exists for countries to deny intellectual property during the application process if a failure to make required disclosures is recognized, and to invalidate intellectual property if required disclosures were not made or were improperly made. None of the existing intellectual property law treaties, however, mandates that parties impose disclosure of origin requirements on intellectual property applicants. Nor do these treaties obligate parties to impose any specific consequences for failures to comply with national disclosure of origin requirements, or to recognize and enforce other countries' access and benefit sharing laws and contracts requiring applicants to make such disclosures.¹¹⁷ Thus, although disclosure of origin requirements may be imposed at the national level, there is

¹¹⁴ See WTO IP/C/W/433, Annex (Comment to Proposed PCT Rule 4.17(vi), Proposed PCT Rule 51bis.2(d) and Comment); WTO IP/C/W/423, ¶ 25.

¹¹⁵ See WTO IP/C/W/423, ¶¶ 25-26 (discussing proposed revisions to PCT Rule 51bis.3(a) to reference proposed PCT Rule 51bis.1(g)).

¹¹⁶ See WTO IP/C/W/400/Rev.1, ¶¶ 12-20 (discussing Swiss' views that requirements to disclose evidence of compliance with CBD access and benefit sharing obligations should not be included in facultative PCT and PLT disclosure provisions, and that requiring such disclosures would be contrary to Art. 62.1 of the TRIPS Agreement). To the extent that such disclosures are needed to comply with substantive patent law requirements (such as enablement), additional disclosures may be necessary and relevant information may be incorporated into the written specification of the invention in the application. The Swiss Proposal does not address whether additional disclosure obligations may be compelled of applicants for intellectual property through requirements of national access and benefit sharing laws of different countries. If such disclosures were considered "voluntary," they would not trigger the restrictions of proposed PCT Article 51bis.3(a). It is also unclear whether receiving offices would transmit any such additional documents to designated offices if submitted by applicants. Complex issues also arise if national access and benefit sharing laws were to require invalidation of the right to seek or own patents in other countries if such additional disclosures were not made or were falsely or fraudulently made. See Sarnoff, *Consistency*, at 46.

¹¹⁷ CBD Article 15.2, however, requires Parties not to impose "restrictions that run counter to the objectives" of the Conventions. CBD Article 5 requires Parties to cooperate with other Parties on "matters of mutual interest." CBD Article 16.5 obligates Parties to cooperate "to ensure that [intellectual property] rights are supportive of and do not run counter to" CBD objectives.

no coherent international system in place to assure that disclosure of origin requirements are effectuated on a world-wide basis. Although concerns have been raised that adoption of proposed mandatory disclosure of origin requirements “would lead to significant uncertainties,”¹¹⁸ these concerns are misplaced. Such uncertainties already exist, and they cannot be resolved without an agreed solution through new international treaty provisions or other agreements directly addressing disclosure of origin requirements.

68. Some developed countries and many developing countries have identified the need for a mandatory international system to address disclosure of origin issues.¹¹⁹ As noted by several developing countries, most of the proposals to improve patent examination in regard to genetic resources and traditional knowledge (so as to deter biopiracy and to prevent misappropriation) are unlikely to address the full scope of prior art. Further, to the extent they are voluntary measures, those proposals would “provide no guarantee” that information on the source and country of origin will be considered, so as to prevent improper issuance of patents.¹²⁰ Enforcement mechanisms external to the intellectual property law system or reliance on contractual measures are inadequate, because there is no obligation to legislate for such measures or to enforce such contracts. Such contracts also are unlikely to be entered unless they are obligatory and enforceable.¹²¹ In contrast, mandatory disclosures in intellectual property applications would continue to be useful after the application stage, and would reduce the need for costly administrative or judicial challenges to the validity of the patent or the entitlement of the applicant or owner. Developing countries in particular lack adequate resources to undertake such challenges on a world-wide scale.¹²²

69. Numerous benefits have been identified for both the CBD regime and the intellectual property law system from adopting mandatory disclosure obligations. These include: improving substantive examination of applications; providing greater certainty regarding the validity of granted rights and privileges; reducing the need for revocation of improperly granted intellectual property; improving identification of possible cases of

¹¹⁸ WTO IP/C/W/449, at 2.

¹¹⁹ See, e.g., Carlos M. Correa, *The Politics and Practicalities of a Disclosure of Origin Obligation*, QUNO, Occasional Paper No. 16, at 2-3 (2005) (Correa, *Politics*); South Centre and CIEL, *IP Quarterly Update, Fourth Quarter 2004: Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, ¶¶ 23-24 (2004) (South Centre/CIEL Update) (discussing the New Delhi Ministerial Declaration of the Group of Like Minded Megadiverse Countries); WTO IP/C/W/383, ¶¶ 50-56 (acknowledging the “merits” of addressing disclosure issues through a mandatory international system but opposing additional formal or substantive patentability criteria); WIPO, *Member State Proposals and Suggestions Regarding the Invitation to WIPO from the Conference of the Parties to the Convention on Biological Diversity on Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications (Provisional Compilation)*, at 10 (2005) (WIPO Compilation), Submission of Brazil; *id.* at 18, Submission of Ghana; *id.* at 59, Submission of the African Group; *id.* at 61, Submission of the Andean Community.

¹²⁰ WTO IP/C/W/429/Rev.1 & Add.1-Add.3, *Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention*, Submission of Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, and Venezuela (2004), ¶¶ 3-4. available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

¹²¹ See, e.g., WTO IP/C/W/438, ¶ 7; WTO IP/C/W/443, ¶ 8.

¹²² See WTO IP/C/W/429 Rev.1 & Add.1-Add.3, ¶ 5.

misappropriation; facilitating actions to challenge the validity of wrongly issued intellectual property; improving determinations of inventorship or other relationship to the subject matter, thereby assisting identification of persons involved who should participate in equitable benefit sharing; facilitating abilities to use the subject matter of the intellectual property; promoting compliance with access and benefit sharing legislation; and tracking commercialization to promote more effective benefit sharing.¹²³ Of course, disclosure obligations should only be seen as one of many elements of an international system to prevent biopiracy and misappropriation.¹²⁴

70. Objections to disclosure of origin requirements have been raised based on concerns that such requirements will not necessarily prevent misappropriation (even if misappropriation is understood only by reference to lack of authority to grant access and lack of prior informed consent for access).¹²⁵ Additional objections are based on concerns that invalidation of intellectual property will not necessarily assure and may prevent equitable benefit sharing.¹²⁶ In response, it has been noted that disclosure of origin requirements seek not to replace but to supplement other methods for enforcing prior informed consent and benefit sharing regimes.¹²⁷ Thus, such objections appear to be premised on the controversial view that such measures are unduly burdensome to applicants and administrative offices and unduly costly to other interests (such as the certainty of patent validity) when compared to the benefits to be obtained.¹²⁸ Such objections also do not take account of the need to monitor intellectual property once validly granted under applicable intellectual property legal requirements (and the associated costs of doing so), so as to deter and remedy misappropriation (*e.g.*, by violating contractual conditions under which rights or privileges were to be obtained or equitable benefits were to be shared).¹²⁹ Nor do these objections take account of the need to prevent misuse of the intellectual property system itself.¹³⁰ Objections that disclosure of origin requirements would not prevent misappropriation when applications for

¹²³ See, *e.g.*, Correa, *Disclosure*, at 2-3; Correa, *Politics*, at 3

¹²⁴ See, *e.g.*, WTO IP/C/W/442, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the Obligation to Disclose Evidence of Benefit-Sharing Under the Relevant National Regime*, Submission from Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru, and Thailand, ¶ 5 (2005), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm; Correa, *Politics*, at 3-4.

¹²⁵ See, *e.g.*, WTO IP/C/W/434, ¶ 7 (“only contractual obligations ... can ensure that prior informed consent is achieved”); WIPO Compilation, at 45, Submission of United States.

¹²⁶ See, *e.g.*, WTO IP/C/W/434, ¶¶ 9-11; WIPO Compilation, at 45-46, Submission of United States.

¹²⁷ See, *e.g.*, WTO IP/C/W/403, ¶¶ 5-8; WTO IP/C/W/442, ¶ 5; South Centre/CIEL Update, ¶ 24.

¹²⁸ See *e.g.*, WTO IP/C/W/434, ¶¶ 14-16. See also *id.*, ¶ 25 (arguing that disclosures would be too burdensome for the patent system and that effective enforcement should be limited to direct civil and criminal enforcement of access and benefit sharing laws). Cf. WTO IP/C/W/442, ¶¶ 6-8 (disputing the burdens and articulating the need for an international framework for protection); WTO IP/C/W/443, ¶ 4 (noting existing uncertainties to facilitated access resulting from the lack of international disclosure of origin rules); *id.*, ¶ 10 (noting that properly tailored legal consequences of disclosure failures may deter persons acting in bad faith); *id.*, ¶¶ 19-22 (disputing that administrative burdens would be substantial and noting that examiners would not be required to determine *validity* of prior informed consent or *adequacy* of benefit sharing).

¹²⁹ See WTO IP/C/W/443, ¶ 13.

¹³⁰ See CIEL Comments, ¶¶ 23-25.

intellectual property are not filed¹³¹ are similarly misplaced. Such objections do, however, imply the need for effective international measures that directly protect against improper access and misappropriation of genetic resources and traditional knowledge.¹³²

71. It bears noting that many countries are still in the process of enacting legislation to effectuate CBD access and benefit sharing requirements. Determining compliance with CBD prior informed consent and equitable benefit sharing principles in such situations may be a complex undertaking. Such determinations may need to take account of legal principles that have not been reduced to legislation and may raise complex issues that have not been previously addressed or adequately resolved. For example, authorized access may depend on common law or traditional rules of property, as well as on inchoate sovereign interests over their resources and on complex principles of international law.¹³³ Equitable benefit sharing may need to be determined in the absence of contractual or other agreements reflecting mutually approved terms.¹³⁴ Additional analysis of CBD access and benefit sharing obligations and of disclosure of origin requirements in such circumstances would be helpful.

72. For the reasons articulated above, this analysis concludes that mandatory international obligations to impose disclosure of origin requirements are both necessary and appropriate. Such obligations should be adopted within an appropriate intellectual property law treaty regime. The treaty provisions should address what disclosures should be required, whether to recognize and apply access and benefit sharing requirements of countries providing genetic resources and associated traditional knowledge, and how international and national intellectual property application offices and national judiciaries should evaluate the adequacy of such disclosures. The treaty also may need to address whether to recognize and enforce contracts that require disclosures that differ from or add to the mandatory treaty obligations or national laws.

B. Specification of Mandatory Disclosure Obligations and Consequences

73. The investigatory burdens and costs to applicants of providing disclosures of origin and documentary information regarding access and benefit sharing, as well as the administrative burdens and costs of evaluating such information, should be limited to what is necessary to attain the intended objectives of the disclosure obligations.¹³⁵ Various options are explored below in regard to the scope of the disclosures and the administrative burdens they may entail. Unless and until new international treaty provisions are adopted, the scope of required disclosures and consequences of disclosure

¹³¹ See WTO IP/C/W/443, ¶ 16.

¹³² See *id.*, ¶ 6.

¹³³ See, e.g., CBD Preamble (affirming sovereign rights over their resources); WTO IP/C/W/442 (suggesting that declarations of authorized access could be provided in the absence of a national access and benefit sharing regime).

¹³⁴ See, e.g., WTO IP/C/442, ¶ 11 (suggesting that equitable benefit sharing may be provided if it “fully respects the prevalent laws, regulations and practices of the country of origin”).

¹³⁵ See, e.g., Correa, *Disclosure*, at 9; WTO IP/C/W/434, ¶ 15; WIPO Compilation, at 25, Submission of Japan; WIPO Compilation at 47, 50, Submission of United States.

failures will vary across countries.¹³⁶ Similarly, the failure to disclose required information may result in different legal consequences, such as punitive sanctions and/or invalidation of granted rights or privileges. Objections have been made to mandating invalidation of intellectual property for disclosure failures, as the absence of intellectual property might in some circumstances jeopardize or prevent commercialization that could lead to appropriate benefit sharing.¹³⁷ However, some flexibility in the mandatory obligations may be warranted so as to permit the consequences of disclosure failures to be tailored to the circumstances. The goals of such tailoring would be, where appropriate, to encourage the cure of unintentional disclosure errors and to permit the transfer (rather than invalidation) of intellectual property or the return of unjustly obtained benefits in cases of fraudulent conduct, unauthorized access, or inequitable benefit sharing.¹³⁸

74. Because these issues overlap with the discussion of procedural triggers in Part II and with the discussion of incentive measures in Part III, analysis in this section is limited to an overview of various administrative and post-administrative options.

75. **Disclosures in application submissions and their evaluation.** In order to promote compliance with CBD access and benefit sharing requirements, disclosure of origin obligations must provide useful information, but should not impose undue costs and burdens on applicants or administrative offices. Significantly, information contained in intellectual property applications may be put to use after the application process, *e.g.*, in administrative or judicial proceedings to invalidate improperly granted intellectual property or to seek remedies for misappropriation. Requiring applicants to disclose information on the source of and country providing genetic resources and associated traditional knowledge, the authority of the source, the country of origin, and compliance with access and benefit sharing requirements not only may help to assure proper entitlements to apply for and own intellectual property, but also may assist compliance with CBD access and benefit sharing requirements even when such information is not evaluated in the application context.¹³⁹ When specifying what disclosure of origin

¹³⁶ *See, e.g.*, WTO IP/C/W/447, at 9 (discussing the Third Supplementary Provision of Andean Community Decision 391, which obliges Member Countries to require applicants to disclose the registration number and a copy of the contract providing access to genetic resources “as a pre-requisite to granting the respective right” and requires establishment of an information exchange system between national authorities granting access and national intellectual property offices; also discussing Andean Community Decision 486, Arts. 26(h)&(i) and 75(g)&(h), which require disclosure of copies of contracts for access to genetic resources and documents certifying the license or authorization to use traditional knowledge, and requiring patents to be declared void if the applicant has failed to submit these copies); *id.* at 11-12 (summarizing significant features of existing requirements of various nations to disclose evidence or certificates of origin and to prohibit intellectual property where access was not legal).

¹³⁷ *See, e.g.*, WIPO Compilation, at 42, 46, Submission of United States; *id.*, at 56, Submission of European Communities; WTO IP/C/W/383, ¶ 55.

¹³⁸ *See, e.g.*, Indian TRIPS Council Statement, at 3 (noting a purpose to prevent monopolies on biological material or traditional knowledge when they are not warranted); Sarnoff, *Consistency*, at 52-53.

¹³⁹ For example, documentary information regarding benefit sharing may be reviewed not only for technical compliance with benefit sharing legislation of the country providing genetic resources, but also to assure that the “shares of benefits that accrued ... was equitable and fair in the circumstances.” WTO IP/C/W/443, ¶ 3. Such documentary information is likely to extend beyond contractual provisions

requirements to mandate by treaty, consideration should be given to what information must be disclosed during the application process, what evaluations should be made of the information, what other uses the information may be put, and whether and when information should be supplemented or corrected.

76. There are several contexts in which information provided by mandatory disclosure of origin requirements may be evaluated. These include:

- international applications;
- national applications;
- pre-grant administrative oppositions or other challenges;
- post-grant administrative reexamination, interference, revocation, opposition, or other challenges; and
- judicial proceedings (including enforcement actions and separate legal actions addressing validity, ownership, or misappropriation).

77. There are also numerous options regarding what information and documentation must be disclosed by applicants, and whether and when it should be supplemented or corrected at later times. These include:

- disclosures of information only (which may be required in prescribed forms or contents);
- disclosures of information accompanied by various declarations by applicants (*e.g.*, declarations of adequate investigation, declarations of the accuracy of submitted information, and declarations of compliance with access and benefit sharing requirements);
- disclosures of information accompanied by documentary information regarding access and benefit sharing (*e.g.*, submission of contracts providing conditions for access and benefit sharing; evidence of compliance with contractual requirements, etc.); and
- disclosures of information accompanied by international certificates of origin.

Obviously, these different options may be combined in various ways, and the information may be put to different uses in different contexts. Requiring information to be provided at entry to the international stage (if any) or the national stage of the application process would assure that such information (if transmitted and retained) would be available for consideration at later stages. So long as transmission of the information does not impose significant burdens, analysis can focus on whether it would be useful to provide the information at earlier stages (*e.g.*, requiring submission at the international stage to assure

providing for access and benefit-sharing, may not be fully available for review during the application process, and if available may not be reviewed for substantive fairness within the application process without imposing significant burdens on that process. *See, e.g.*, WTO IP/C/W/442, ¶ 9-10 (discussing benefit sharing information available before and after application).

efficient transmission to multiple national stage application offices), even if the information is evaluated only at later stages.

78. Further, there are numerous options regarding the scope of evaluations for information submitted pursuant to mandatory disclosure obligations. These include:

- evaluations for completeness of submitted information, declarations, and documents;
- evaluations for substantive adequacy of disclosed information;
- evaluations of relevance and accuracy of declarations;
- evaluations of relevance and accuracy of documentary information regarding access and benefit sharing; and
- evaluations of validity of international certificates of origin.

Different evaluations may occur in different procedural contexts.

79. Demonstrations of entitlement to apply for or to own intellectual property (*e.g.*, recorded assignment documents) are rarely scrutinized by national intellectual property offices for their substantive validity, unless those documents (and thus the right to apply for or to own intellectual property) are suspect or are otherwise challenged in a pre-grant or post-grant administrative proceeding.¹⁴⁰ Nevertheless, such documents are routinely required to be filed and reference is required to be made to those documents in intellectual property applications.¹⁴¹

80. **Consequences of disclosure failures, fraudulent conduct, lack of authority, and inequitable benefit sharing.** Various options have been proposed for the consequences of providing incomplete, incorrect, or fraudulent disclosures of origin. These options include:

- leaving sanctions decisions to contracting states (including recognition and enforcement of other states' laws, where applicable)¹⁴²;

¹⁴⁰ *See, e.g.*, 37 C.F.R. § 1.48(g) (under United States law, the U.S. Patent and Trademark Office (US PTO) may require additional information as needed to correct inventorship); 37 C.F.R. § 3.73(b) (United States law requiring documentation of assignee ownership "to the satisfaction of the Director" of the US PTO, including relevant chain of title information). *See also* 37 C.F.R. §§ 1.171, 1.175, 1.324, 1.634 (United States law addressing correction of inventorship in reissue applications, issued patents, and interferences).

¹⁴¹ *See, e.g.*, 35 U.S.C. § 261, ¶ 4 (United States law requiring recording of assignments, grants, or conveyances of patents to be valid against subsequent purchasers); 37 C.F.R. § 1.76(b)(1) (United States law requiring for voluntary application data sheets inclusion of information demonstrating authority of assignees to apply for patents, pursuant to 37 C.F.R. § 1.46, which authorizes issuance of patents to assignees); 37 C.F.R. § 3.11(a) (United States law providing for recording of assignments and other documents affecting title to applications, patents, or registrations); 37 C.F.R. § 3.21 (United States law requiring registered assignments to cross-reference related applications); 37 C.F.R. § 3.56 (United States law treating conditional assignments as absolute unless withdrawn, because the Office does not evaluate or determine whether conditions have been met).

¹⁴² *See, e.g.*, WIPO Compilation, at 56, Submission of the European Communities.

- relying on “effective, proportionate and dissuasive [external] sanctions,” without affecting the validity or ownership of intellectual property (so as to provide greater certainty regarding validity and ownership)¹⁴³;
- imposing civil liability or criminal penalties for violation of contractual obligations¹⁴⁴;
- using unfair competition rules and other legal regimes to address violations of access and benefit sharing requirements¹⁴⁵;
- addressing the failure to provide required information or the submission of false or fraudulent statements or documents through administrative fines or criminal penalties internal or external to the intellectual property system (depending on the effect of the information on the applications)¹⁴⁶;
- requiring evaluations of various forms of disclosure and refusing to process applications or to grant rights or privileges where required information is not submitted (potentially subject to opportunities for cure) or where information is falsely or fraudulently submitted¹⁴⁷;
- requiring revocation or invalidation of intellectual property rights and privileges following determinations that various forms of required information were not submitted (potentially subject to opportunities for cure) or where information was falsely or fraudulently submitted¹⁴⁸;
- requiring full or partial transfer of rights or privileges in the subject matter of intellectual property, so as to promote fair and equitable benefit sharing¹⁴⁹; and
- requiring the return of any unjustified benefits conferred in violation of access and benefit sharing requirements.¹⁵⁰

These options for mandatory disclosure obligations are not mutually exclusive, and there may be reasons for multiple options to be available so as to assure adequate deterrence, enforcement, and compensation.

81. **Conflict of laws and jurisdictional rules.** Mandatory disclosures of origin obligations will assist in effectuating a number of existing legal regimes, such as laws implementing CBD access and benefit sharing requirements and specifying the consequences of failure to comply with those requirements; laws addressing entitlements to apply for intellectual property; and laws relating to misappropriation and to the return of unjustified benefits. In the absence of mandatory disclosure of origin obligations specified by new international treaty provisions, these and other laws will continue to

¹⁴³ WIPO Compilation, at 56, Submission of the European Communities. *See also* WTO IP/C/W/434, ¶ 3 (viewing “with the utmost caution” proposals that “would add uncertainties in patent rights”); *id.*, ¶ 14 (sanctions that include invalidation “would create a ‘cloud’ of uncertainty over the patent right”).

¹⁴⁴ *See, e.g.*, WTO IP/C/W/434, ¶ 26; WIPO Compilation, at 50, Submission of the United States; Correa, *Politics*, at 8-9 (summarizing the positions of a US PTO presentation).

¹⁴⁵ *See, e.g.*, WTO IP/C/W/434, ¶ 11.

¹⁴⁶ *See, e.g.*, WTO IP/C/W/442, ¶¶ 13, 14.

¹⁴⁷ *See, e.g., id.*, ¶¶ 13.

¹⁴⁸ *See, e.g., id.* ¶ 14.

¹⁴⁹ *See, e.g., id.*

¹⁵⁰ *See, e.g.*, CIEL Comments, at ¶ 24.

apply and to impose the various consequences listed above. New international treaty provisions addressing mandatory sanctions thus may assist in clarifying the applicable legal framework and in establishing more uniform conditions for recognition and enforcement of the various sets of potentially applicable legal requirements.¹⁵¹

Alternatively, an international agreement could assure that national disclosure of origin requirements take precedence over national intellectual property laws that otherwise might preclude recognition and enforcement of disclosure of origin requirements.¹⁵²

Mandatory disclosure of origin obligations thus may help to make the international system of national laws requiring disclosures of origin more coherent.

82. Consideration also should be given to imposing mandatory provisions regarding jurisdiction and recognition and enforcement of judgments (such as mutual recognition, application of mandatory rules, and jurisdiction that cannot be declined)¹⁵³ or less strict obligations to adjudicate disputes (such as *forum non-conveniens* principles that would permit national agencies and courts to decline jurisdiction)¹⁵⁴ regarding compliance with national access and benefit sharing laws and with mandatory, treaty-based or additional disclosure obligations. Similarly, consideration should be given to whether and under what conditions to refer compliance issues to an appropriate intergovernmental organization or to the courts or agencies of other countries (*e.g.*, for definitive interpretations of CBD access and benefit sharing requirements or of CBD implementing

¹⁵¹ See, *e.g.*, Graeme B. Dinwoodie, *Conflicts and International Litigation: The Role of International Norms, in Intellectual Property in the Conflict of Laws* 202, 206 (Basedow, Drexl, Kur & Metzger, eds., 2005) (Dinwoodie, *Conflicts*) (discussing ways that substantive treaty law may affect or constitute choice of law rules and may affect harmonization); WIPO Technical Study, ¶ 157 (discussing choice of law and recognition of judgment issues).

¹⁵² See, *e.g.*, WIPO/GRTKF/IC/8/6, *Practical Means of Giving Effect to the International Dimensions of the Committee's Work*, ¶¶ 27-29 (2005) (discussing *jus cogens* and other means to assure national effect to international obligations), available at

http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_6.doc.

¹⁵³ See, *e.g.*, Peter Drahos, UNCTAD Commonwealth Secretariat Workshop, *Elements of National Sui Generis Systems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework: Towards an International Framework for the Protection of Traditional Group Knowledge and Practice*, at 27-28 (2004) (discussing mutual recognition principles) (Drahos, *International Framework*), available at http://r0.unctad.org/trade_env/test1/meetings/tk2/drahos.draft.doc; Convention on the law applicable to contractual obligations, Concluded June 19, 1980 at Rome, Art. 7(1) (Rome I Convention) (authorizing application of mandatory rules of law of other countries “with which the situation has a close connection” for contractual disputes), available at http://www.rome-convention.org/instruments/i_conv_cons_en.htm; Dinwoodie, *Conflicts*, at 202 (discussing universal jurisdiction); European Union, *Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters*, O.J. L 12/1 (Jan. 16, 2001) (adopting complex rules for when courts have jurisdiction and must recognize and enforce judgments rendered in other jurisdictions), available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_012/l_01220010116en00010023.pdf.

¹⁵⁴ See, *e.g.*, United States Dept. of State, *The Doctrine of Forum Non Conveniens in the United States* (2001) (noting that the *forum nonconveniens* doctrine in United States law permits courts to decline jurisdiction where the forum is inconvenient and adequate alternative forums exist), available at http://www.state.gov/www/global/legal_affairs/us_annex-c.html; *Altman v. Republic of Austria*, 317 F.3d 954, 972 (9th Cir. 2002) (noting that the *forum nonconveniens* doctrine authorizes district courts in the United States to decline to exercise jurisdiction based on the convenience of the parties and the interests of justice, subject only to abuse of discretion review), *aff'd on other grounds*, 541 U.S. 677 (2004).

legislation of the country providing genetic resources and associated traditional knowledge).¹⁵⁵

83. Finally, mandatory disclosure of origin treaty provisions will likely need to be translated into domestic legislation and administrative rules, because such obligations may need to be phrased in general terms and because some national legal systems do not permit adoption of self-implementing treaty provisions. An obvious principle for drafting such treaty provisions is that the language of mandatory disclosure of origin obligations should be made as clear as possible, so as to avoid disputes regarding their meaning and to facilitate their translation into national laws and rules. Further, attention should be given in the text to how failures by Parties to fully implement those requirements should be addressed. Dispute resolution provisions already exist within the TRIPS Agreement, which appears to provide the most appropriate regime in which to locate mandatory disclosure of origin obligations.

C. Choice of Treaty Regime To Implement Mandatory Disclosure Obligations

84. Numerous countries have suggested amending the TRIPS Agreement's patent provisions (specifically TRIPS Article 29) to impose mandatory disclosure of origin obligations.¹⁵⁶ Applying such disclosure obligations only in the context of patents, however, would not affect other intellectual property applications whose subject matter implicates CBD access and benefit sharing requirements.¹⁵⁷ Of particular relevance, such a limitation would not apply mandatory disclosure obligations to the subject matter of plant breeders' rights, if such rights are not provided by patents but rather by plant breeders' certificates under the UPOV Convention (as is permitted by Article 27.3(b) of the TRIPS Agreement). To the extent that plant breeders' rights are addressed by the UPOV Convention, both the 1978 and 1991 texts of the UPOV Convention might need to be amended to assure mandatory disclosure of origin obligations in applications for plant breeders' rights. However, there are many fewer parties to the UPOV Conventions than

¹⁵⁵ See, e.g., *Handelskwekerij G.J. Bier B.V. v. Mines de Potasse d'Alsace S.A.*, Case 21/76, [1976] E.C.R. 1735, 1745 (referring from a national appellate court to the European Court of Justice a question of interpretation under the European Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters, art. 2, done at Brussels, Sept. 27, 1968, 33 O.J. Eur. Comm. (C189/1) 1 (July 28, 1990)); Dinwoodie, *International Framework*, at 14-15 (discussing concerns over judicial competence that might "counsel in favor of input from courts in countries with developed bodies of traditional knowledge law," noting concerns of developed countries over deference to foreign institutions in the contexts of negotiation of the Hague Convention on Jurisdiction, Recognition, and Enforcement of Foreign Judgments in Civil and Commercial Matters, Work.Do. No. 110E (Revised) (27 April 2004), available at www.hcch.net/doc/jdgm_wd110_e.pdf), and suggesting use of international institutions to determine compliance issues). Cf. 28 U.S.C. §§ 1781, 1782 (United States law discussing authority to receive letters rogatory and to compel assistance to foreign and international tribunals); European Convention on Transfer of Proceedings in Criminal Matters, opened for signature May 15, 1972, entered into force March 30, 1978 (delineating principles for transfer to courts with concurrent jurisdiction).

¹⁵⁶ See, e.g., WTO IP/C/W/356, § 10 (proposing to amend TRIPS patent provisions); WTO IP/C/W/403, § 1 (same); WTO IP/C/W/404, at 6 (proposing to amend Art. 29).

¹⁵⁷ Again, application of disclosure of origin requirements to utility models, petty patents, trademarks, industrial designs, and other *sui generis* protections is not addressed here, but is implicated by the analysis.

to the TRIPS Agreement. If such obligations were included only within the UPOV Conventions, they would not apply directly to countries who are not members to the UPOV Conventions.

85. Without regard to the political economy of the choice of treaty regime,¹⁵⁸ it appears most appropriate to locate mandatory disclosure of origin obligations in the TRIPS Agreement (without limiting those obligations to patent applications). Reasons for locating new treaty provisions for disclosure of origin requirements in the TRIPS Agreement include: the large membership of the WTO; the recognized expertise of the WTO in regard to intellectual property issues; the comprehensive approach of the TRIPS Agreement to the intellectual property system; the obligation of the WTO to address the relationship of the TRIPS Agreement to the CBD pursuant to Paragraph 19 of the Doha Declaration¹⁵⁹; the provision in the TRIPS Agreement for a review procedure¹⁶⁰; and the existence of the WTO's binding mechanism for dispute resolution to address violations of requirements.¹⁶¹ Because the WTO does not implement many intellectual property law treaties, however, appropriate measures would need to be included in the TRIPS Agreement to assure the application of new mandatory disclosure of origin treaty provisions to other intellectual property treaty regimes.¹⁶² Those regimes might then need to be amended to effectively incorporate the relevant obligations to be effectuated.¹⁶³ Provision also might be adopted to assure a continuing role for the CBD to provide assistance and coordination in developing and implementing disclosure of origin requirements.

86. In contrast, including new mandatory disclosure of origin treaty provisions in the CBD would more readily provide for linkage and continuing coordination of disclosure of origin obligations to CBD access and benefit sharing requirements. The CBD secretariat also has substantial technical expertise regarding genetic resources and associated traditional knowledge that would relate to the subject matter of intellectual property applications, as well as substantial legal expertise regarding the CBD and

¹⁵⁸ See, e.g., Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and International Intellectual Property Lawmaking*, 29 Yale J. Int. L. 1 (2004); Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 Loyola of L.A. Law Rev. 323 (2004).

¹⁵⁹ See WTO WT/MIN(01)/DEC/1, at ¶ 19 (2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf.

¹⁶⁰ See TRIPS Agreement, Art. 71.1.

¹⁶¹ See WTO IP/C/W/447, at 13 (the TRIPS review process and binding mandates “makes this the ideal forum for incorporating requirements concerning disclosure of origin and legal provenance in the text of the TRIPS Agreement”). See generally WTO, Annex II, Understanding on rules and procedures governing the settlement of disputes, of the Marrakesh Agreement Establishing the World Trade Organization, concluded Apr. 15, 1994, effective Jan. 1, 1995, available at http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm.

¹⁶² See, e.g., TRIPS Agreement, Arts. 2, 27.3(b) (requiring compliance with specific provisions of the Paris Convention, and limiting effects of the Agreement on existing obligations under other Conventions; requiring protection for plants under patent requirements regulated by the TRIPS Agreement or under the UPOV Convention or a *sui generis* protection system).

¹⁶³ Under the Vienna Convention, later-enacted treaties control in the event of conflict. See Vienna Convention on the Law of Treaties, May 23, 1969, Arts. 31(2) & (3), 1155 U.N.T.S. 331 (Vienna Convention). Thus, it may not be necessary to amend those treaties to permit effectuation, but coordination and any necessary amendment would be preferable.

national access and benefit sharing requirements. Nevertheless, the CBD would be a less appropriate location than the TRIPS Agreement for such new treaty provisions. Locating such provisions within the CBD regime would not incorporate disclosure requirements directly into the intellectual property law system, and thus would complicate efforts to assure that disclosure obligations are adopted within intellectual property treaty regimes. Further, disclosure of origin obligations mandated within the CBD would not directly apply to the intellectual property systems of countries that are not Parties to the CBD,¹⁶⁴ but which may be parties to the TRIPS Agreement. The CBD COP also could make a contribution to possible negotiations on the contents of disclosure obligations to be adopted within the TRIPS Agreement, within the context either of ongoing review of the TRIPS Agreement and WTO Doha Round negotiations or of CBD COP efforts to develop international treaty provisions further addressing access and benefit sharing requirements.

87. Given the comprehensive nature of the TRIPS Agreement and other relevant features of the WTO regime, WIPO would not appear to be the most appropriate choice of forum for developing new international treaty provisions to effectuate disclosure of origin requirements. The TRIPS Agreement is part of a set of WTO agreements that address not only intellectual property but other concerns, and thus may more readily integrate CBD access and benefit sharing considerations with the intellectual property law system. In contrast, WIPO has a narrower focus on the intellectual property legal system. Although WIPO possesses a wealth of expertise regarding intellectual property concerns and regarding the mechanics of intellectual property applications and their processing, it lacks relevant expertise relating to biological diversity and to issues of access and benefit sharing.¹⁶⁵ Further, although the Paris Convention addresses a broad range of intellectual property subject matter,¹⁶⁶ it does not generally establish comprehensive minimum standards as does the TRIPS Agreement and does not relate its requirements to other intellectual property treaty regimes. New treaty provisions adopted within a WIPO-administered treaty context, moreover, would be subject to voluntary ratification and would not take advantage of the dispute settlement mechanism that the WTO provides.

¹⁶⁴ Notably, although the United States is a signatory to the CBD, it has not ratified the Convention. *See* Parties to the Convention on Biological Diversity/Cartagena Protocol on Biosafety, available at <http://www.biodiv.org/world/parties.asp>.

¹⁶⁵ *See* CIEL Comments, ¶¶ 5-8.

¹⁶⁶ *See, e.g.*, Paris Convention Arts. 4-11.

II. Options For Application Procedure Triggers

88. Disclosure of origin obligations may require submission of different types of information that may be subjected to different kinds of evaluations during and after the process of applying for intellectual property. The analysis below first identifies how genetic resources and associated traditional knowledge may substantively relate to the subject matter of intellectual property applications, the types of evaluations that may be performed, and the types of information that may be submitted. The analysis then discusses the different procedural triggers for submitting and evaluating disclosure of origin information, and briefly describes options for the consequences of disclosure failures.

A. Substantive Triggers

89. One of the most basic issues for disclosure of origin obligations is when the subject matter of applications is sufficiently related to genetic resources and associated traditional knowledge that the disclosure of relevant information will be required.¹⁶⁷ Prior analyses have noted that evaluations pursuant to traditional patent law doctrines – such as understanding the scope of claimed subject matter, determining whether it constitutes prohibited subject matter, evaluating the adequacy of written description and enablement, examining prior art, and assessing inventorship and entitlement to apply for or own patents – already may require applicants to disclose the source and country of origin of genetic resources and traditional knowledge, as well as some persons involved in developing the subject matter.¹⁶⁸ Deposits of source materials or other biological materials also may be required.¹⁶⁹ Material transfer agreement contracts also may specify the relationship between source materials and “derivatives,” and such relationships may in some cases impose ownership or disclosure obligations that extend beyond traditional patent law doctrines such as inventorship.¹⁷⁰ The relationships of genetic resources and associated traditional knowledge to the subject matter of applications under traditional patent law doctrines thus cannot be reduced to simple formulations.¹⁷¹

90. Numerous proposals have been suggested to require disclosures of origin in regard to genetic resources, under various conditions when such information is *not* already specifically required under national patent laws. For example:

¹⁶⁷ See, e.g., WTO IP/C/W/429 Rev. 1, ¶ 7.

¹⁶⁸ See, e.g., WTO IP/C/W/429 Rev. 1, ¶¶ 4-6, 8; WIPO Technical Study, ¶¶ 32-52, 57-64.

¹⁶⁹ See, e.g., WIPO Technical Study, ¶¶ 32(a), 102-05; Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), concluded Apr. 28, 1977, effective Aug. 19, 1980, amended Sept. 26, 1980, effective May 24, 1984, available at http://www.wipo.int/treaties/en/registration/budapest/pdf/trtdocs_wo002.pdf. See also WIPO Compilation, Submission of Japan, at 23-24 (noting that disclosures cannot substitute for deposits).

¹⁷⁰ See, e.g., WIPO Technical Study, ¶¶ 107-09.

¹⁷¹ See, e.g., *id.*, ¶¶ 92-109, 112-14.

- the Bonn Guidelines suggest such disclosures when “the subject matter of the application concerns or makes use of genetic resources [or traditional knowledge] in its development”¹⁷²;
- the Swiss proposal would require disclosures only when the subject matter of the patent application is “directly based” on genetic resources or traditional knowledge, by making immediate use of the genetic resources and by having sufficient contact with the traditional knowledge to identify relevant properties¹⁷³; and
- various national or regional laws, such as those of the Andean Community, require extensive disclosures (including contracts for access and documentary information regarding legal provenance to provide access to traditional knowledge) based on much broader relationships to the subject matter of the applications (*e.g.*, for products or processes that are developed or obtained from genetic resources or traditional knowledge).¹⁷⁴

Consideration must therefore be given to the purposes to be accomplished by disclosure requirements and the benefits or burdens such disclosures would provide or impose.

1. Substantive Triggers and the Purposes of Disclosure Requirements.

91. The appropriate linkage for disclosure of origin requirements of genetic resources and associated traditional knowledge to the subject matter of an intellectual property application will depend on the reasons for making the disclosures and on the types of information to be disclosed and evaluated.¹⁷⁵ Broader reasons for making disclosures entail correspondingly broader substantive relations between the subject matter and the applicant on one hand and the kinds of information that may become relevant for disclosure on the other. The following paragraphs provide a non-comprehensive list of determinations that provide reasons for requiring disclosures of origin, which gives an indication of the breadth of information that may be relevant. In general, the applicant should already know at the time the application is filed what genetic resources and

¹⁷² UNEP/CBD/COP/6/20 Decision VI/24, Annex, C. *Role of intellectual property rights in the implementation of access and benefit sharing arrangements*, ¶¶ 1, 2.

¹⁷³ See WTO IP/C/W/423, ¶¶ 27-28.

¹⁷⁴ See Andean Communities, Decision 486, *Common Intellectual Property Regime*, Concluded Sept. 14, 2000 at Lima, Arts. 26(h) & (i), available at <http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm>. See also Andean Community, Decision 391, *Common Regime on Access to Genetic Resources*, Concluded July 2, 1996 at Caracas, Complementary Provisions, Second, (prohibiting recognition of intellectual property obtained in violation of access requirements, and authorizing member countries to request nullification of granted rights or privileges), available at <http://www.comunidadandina.org/ingles/treaties/dec/d391e.htm>.

¹⁷⁵ Various countries have implicitly identified these purposes as the underlying premises to be explored for disclosure of origin obligations, asking how such requirements would help in various contexts, *e.g.*, improving examination, ensuring a “harmonious relationship” between the CBD and the TRIPS Agreement, and achieving the objectives of the CBD. WTO IP/C/W/420 & Add.1, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD): Checklist of Issues*, Submission of Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand, and Venezuela, II., ¶¶ 1-3 (2004), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

associated traditional knowledge are involved, and the sources and countries providing such resources and knowledge.¹⁷⁶ In contrast, the applicant may not necessarily know all persons involved, the country of origin, what authority the source possessed to transfer the resources, materials, or knowledge under the applicable conditions, and whether use of the resources, materials, or knowledge leading to or incorporated in the subject matter of the application conforms to applicable legal requirements. Such determinations sometimes may require legal judgments that the applicant cannot itself perform, such as judicial determinations of unfair competition or unjust enrichment. In such cases, disclosures of information nevertheless may facilitate the identification of the persons involved, the country of origin and the authority of the source, and may also facilitate required legal determinations.

92. Determinations relating directly to intellectual property laws. Because national intellectual property laws differ, existing requirements for disclosures of origin in intellectual property applications also differ. In regard to patents, genetic resources and associated traditional knowledge typically are required to be disclosed to the extent they constitute known prior art relevant to examination or when required to enable those skilled in the art to practice the claimed subject matter. In some jurisdictions, national patent laws also require applicants to disclose their status as inventors¹⁷⁷ and to disclose the source of genetic resources and associated traditional knowledge if the source is a joint inventor or holds a sufficient interest to be treated as an applicant or owner. Further, national patent laws may impose requirements for applicants and owners to share the commercial benefits of the invention with persons involved.¹⁷⁸ The applicant also may disclose the country of origin when identifying the sources and countries providing genetic resources and associated traditional knowledge, inventors, co-applicants and co-owners, and other persons involved. In contrast, the applicant may not know or be required to disclose whether the source had authority to transfer genetic resources and associated traditional knowledge, whether benefits have been equitably shared, or the identity of the original source and country providing resources or knowledge where improvements are made to derivatives of the original resources. However, disclosures may be required even though the subject matter is not “directly based” on such inputs, as the scope of information relevant to substantive validity and entitlement determinations may extend beyond what the applicant did with the inputs.¹⁷⁹

¹⁷⁶ Two notable exceptions are when the subject matter was developed without the applicant realizing that such resources, materials, or knowledge were used in or otherwise related to the development, or when the applicant has not fully characterized those aspects of the resources, materials, or knowledge of which use was made.

¹⁷⁷ In many jurisdictions, applicants must file in the name of the inventor. Under the Paris Convention, the inventor is entitled (but not required) to be identified. *See* Paris Convention, Art. 4^{ter}.

¹⁷⁸ For example, Japanese Patent Law Art. 35 requires the provision of reasonable remuneration to inventors who transfer their rights or otherwise enable their employers to obtain patents on their inventions.

¹⁷⁹ *See, e.g.*, WIPO Technical Study, ¶¶ 98-100 (describing various uses of inputs in relation to the subject matter of applications).

93. Because intellectual property laws do not exhaust the laws governing ownership interests or rights to equitable benefit sharing (including the law of contracts¹⁸⁰), the category of determinations relating to intellectual property laws is not self-contained. National intellectual property laws may require applicants to provide declarations and supporting documentation regarding their entitlements to apply for and own intellectual property, and can also require supporting documentation regarding declared information (at least to the extent that the national office “may reasonably doubt the veracity” of the applicant’s declaration).¹⁸¹ Accordingly, disclosures of origin required by intellectual property laws may include by reference disclosures required by laws governing entitlements and equity.

94. **Determination of entitlements and equity under other laws.** Numerous laws, including those defining misappropriation and unjustified enrichment, define who may qualify as an applicant for or owner of intellectual property and who may possess beneficial interests in intellectual property that would require equitable benefit sharing. Various submissions have noted the need for disclosures of origin to assist in deterring, identifying, and remedying misappropriation, in preventing misuse of the intellectual property system to advance and to provide benefits to inequitable conduct, and in assuring equitable sharing of the commercial benefits of genetic resources and associated traditional knowledge.¹⁸² Accordingly, laws addressing entitlements and equity may require disclosure of the authority of the source to provide access to genetic resources and associated traditional knowledge for the uses leading to the subject matter of the intellectual property, documentary information regarding equitable benefit sharing, or identification of the original source and country of origin in the case of derivatives. The failure to disclose such information also may affect the validity or enforceability of intellectual property. For example, the failure to disclose unauthorized acquisition of genetic resources and associated traditional knowledge might qualify as inequitable conduct or unclean hands, which would prevent enforcement of patents.¹⁸³ Such legal and equitable concerns may apply even in the absence of bad faith, *e.g.*, where a source unknowingly lacked authority to provide access to those inputs.¹⁸⁴

¹⁸⁰ See, *e.g.*, WIPO Technical Study, ¶¶ 74-79 (discussing licenses and material transfer agreements containing shared ownership requirements for derived subject matter, and varying consequences of failures to record ownership interests in regard to transfers and enforceability of intellectual property).

¹⁸¹ WIPO Technical Study, ¶ 177 (*quoting* PCT Rule 51bis.2(a)&(b)).

¹⁸² See, *e.g.*, WTO IP/C/W/443, ¶ 3; CIEL Comments, ¶ 25 & n.54, ¶ 26 & n.55.

¹⁸³ See, *e.g.*, *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 809-10, 815, 819-20 (1945) (case under United States law upholding the dismissal of an action to enforce patents that were obtained based on fraudulent statements in an interference regarding the date of invention – and probably also involved incorrect inventorship); *Seismograph Service Corp. v. Offshore Raydist*, 135 F. Supp. 342, 347-48, 353-56 (E.D. La. 1955) (case under United States law invalidating on prior art grounds a patent that was based on misappropriated information and possible false inventorship, and suggesting that an equitable remedy of a royalty free license would have been appropriate had the patent been valid), *aff’d in pertinent part*, 263 F.2d 5, 22 (5th Cir. 1959).

¹⁸⁴ Many *ex-situ* repositories and depositories exist for genetic resources and biological materials. Although ITPGRFA Art. 12.3(d) prohibits intellectual property or other rights or privileges that would restrict access to materials obtained through the multilateral system in the form received, the ITPGRFA may not prevent application of equitable principles to derivatives for which intellectual property may be sought.

95. **Determination of compliance with CBD legislation and contracts.** Legislation implementing CBD access and benefit sharing obligations, and contracts adopted pursuant to such legislation or to effectuate access and benefit sharing requirements, also may require disclosures of origin. Disclosing the source, country providing genetic resources and associated traditional knowledge, and country of origin may assist countries and indigenous or traditional communities to identify unauthorized access or use and inequitable benefit sharing. Such disclosures may be particularly helpful in the absence of CBD-implementing legislation in the country providing genetic resources and associated traditional knowledge or in the absence of contracts establishing conditions for access and equitable benefit sharing.¹⁸⁵ Conversely, CBD-implementing legislation or contracts entered in the country providing genetic resources and associated traditional knowledge or the country of application could require disclosures of any relevant information. Such disclosure requirements raise recognition and enforcement issues.¹⁸⁶

96. **Other motivations for requiring disclosures.** Various other motivations have been identified for requiring disclosures of origin, which would suggest different substantive triggers and the submission of different types of information. For example, disclosure of the source, the country providing genetic resources and associated traditional knowledge, and the country of origin may provide a more predictable environment for governments, investors, traditional communities, and researchers to enter into transfers of such resources or knowledge.¹⁸⁷ Further, prior informed consent for access and equitable benefit sharing principles are not limited to genetic resources and associated traditional knowledge regulated by the CBD. Accordingly, mandatory disclosure of origin requirements could extend beyond the CBD context.

2. Types of Information To Be Disclosed.

97. The level of effort involved in developing and submitting various types of information in many cases may not be significant if such information already is known by the applicant. Relevant information may need to be known in order to ground the applicant's belief in its entitlement to apply for and to own the relevant intellectual property. Known information may be required to be presented by intellectual property laws, although it may not be required in a format that would distinctly identify it as a disclosure of origin.¹⁸⁸

98. For each of the substantive relationships that might trigger disclosures, there are at least three non-exclusive categories of information that could be disclosed. These are:

¹⁸⁵ See, e.g., WTO IP/C/W/368, ¶ 24 (citing IP/C/M/32, ¶ 128 and IP/C/M/28, ¶ 158).

¹⁸⁶ For example, Colombia has proposed that the text of Swiss proposal to amend the PCT refer to national law applied by any Member State, rather than to the designated Office, to assure that the disclosure obligation is mandatory in all PCT members even when the country of origin is not designated by the applicant. See WIPO Compilation, Submission of Colombia, at 15.

¹⁸⁷ See, e.g., WTO IP/C/W/368, ¶ 24 (citing WTO IP/C/W/228).

¹⁸⁸ See, e.g., WTO IP/C/W/429 Rev. 1, ¶¶ 9-10 (noting the need to “cull out” relevant information from that “usually collected and recorded in the process of invention”).

- submission of the required information only;
- submission of the required information along with a declaration by the applicant, which may address adequacy of any required investigation, accuracy of any disclosed information, or compliance with applicable access and benefit sharing requirements; and
- submission of the required information along with supporting documents.

In addition, required information may be submitted along with an international certificate of origin issued by a competent entity attesting to compliance with authorization and benefit sharing requirements.¹⁸⁹ Issues relating to certificates of origin are discussed in Part V below.

99. For each of the categories of information to be disclosed, disclosure of origin requirements may require disclosure of specified contents and the use of specified formats. These include:

- presenting information on standardized forms using standardized terms;
- addressing specified mandatory contents;
- describing specified levels of effort and documenting investigations performed;
- reaching a specified set of conclusions and explaining the bases therefore; and
- providing indications of levels of confidence.

100. **Disclosure of information only and level of effort.** Mandatory disclosure obligations may readily require applicants to disclose relevant information already known to the applicant,¹⁹⁰ similar to existing patent laws that require disclosure of known, relevant information.¹⁹¹ For some types of disclosures of origin, however, it may be necessary to specify the level of effort to be imposed on the applicant to identify and disclose the relevant information. For example, the applicant should normally know the source and country providing genetic resources and associated traditional knowledge, and ought to know the authority of the source to provide access on the specified conditions of use (or at least should have good reason to believe in that authority, when legal judgments are required that the applicant is not qualified to make). However, the applicant may not necessarily know the country of origin, persons involved, and the original country of origin for improvements to derived genetic resources. Mandatory disclosure obligations thus may need to specify the amount of investigation required of applicants to obtain such information, based on the uses to which that information may be put during or after application.

¹⁸⁹ See Correa, *Disclosure*, at 9.

¹⁹⁰ See, e.g., Correa, *Disclosure*, at 6.

¹⁹¹ See, e.g., 37 C.F.R. § 1.56(a) & (c) (United States law requiring disclosure of all known information material to patentability known by a variety of persons involved in applying for patents).

101. **Declarations of applicants.** Sworn oaths or declarations by applicants for intellectual property may be a useful addition to the disclosure of information only, particularly to the extent that the applicant should know that it has obtained and used the relevant genetic resources and associated traditional knowledge with authority and has provided or arranged for equitable benefit sharing. Similarly, applicants should know whether and to what extent they have made investigations to identify information and to determine that the information is correct and complete. However, such declarations may be difficult to provide in the absence of clear rules identifying the level of effort required or of transparent standards for determining prior informed consent for access and equitable benefit-sharing. Such declarations may not be possible when they require legal judgments that the applicant is not qualified to make. Declarations also may impose substantial burdens on applicants to verify the accuracy of information on which the declarations are based. Nevertheless, declarations could prove useful as a preventative measure to assure conformity to applicable requirements and as a deterrent to unauthorized conduct, particularly to the extent that fraudulent declarations may result in significant civil or criminal sanctions.

102. **Documentary information.** Documentary information also may be a useful addition to the disclosure of information only or to such disclosure supplemented by declarations. Various countries have suggested including in mandatory disclosure of origin requirements evidence of compliance with access and benefit sharing requirements (including submission of contracts for access and benefit sharing).¹⁹² However, complete documentation regarding compliance with equitable benefit sharing obligations may be impossible to provide, as such obligations may extend to future commercial benefits that the application for intellectual property is intended to provide. Documentary information regarding entitlements to apply for, own, or receive benefits from intellectual property and regarding compliance with laws implementing CBD access and benefit sharing requirements also may involve complex legal determinations that intellectual property application offices are not well suited to make. As a result, application offices would not readily be able to evaluate such documentary information, although evaluation may already be required to determine the substantive validity of or entitlements to apply for or own intellectual property.¹⁹³

103. **Trade secrecy of disclosed information.** Trade secrecy concerns may be triggered by disclosures, to the extent that the information is not itself part of the subject matter of the intellectual property application and is not required to be disclosed under the relevant intellectual property laws. Such concerns potentially could be addressed by

¹⁹² See, e.g., WTO IP/C/W/356, ¶ 10; WTO IP/C/W/403, ¶ 1; WTO IP/C/W/404, at 5-6.

¹⁹³ See, e.g., WTO IP/C/W/433, ¶¶ 21-22 (noting that proposals to include such evidence have not argued for substantive evaluation of the documents by national patent offices, absent challenge to the validity of a patent in a pre-grant or post-grant opposition or revocation proceeding); Correa, *Disclosure*, at 9 (noting the lack of technical preparation for national intellectual property offices to assess such requirements of foreign laws).

subjecting such information to protection from public disclosure upon an adequate showing of trade secret status.¹⁹⁴

3. **Relationships Establishing Substantive Triggers.**

104. Disclosed information may relate to many different types of substantive evaluations that are relevant to determinations during and after the process of applying for intellectual property. Substantive triggers may include those:

- relating the source to the subject matter of the application;
- relating the source to the applicant.
- relating the applicant to persons involved;
- disclosing the country of origin; and
- disclosing documentary information regarding compliance with access (including prior informed consent) and benefit sharing requirements.

Consideration must be given to whether and to what extent to require information relating to these different substantive triggers.

105. **Relation of the source to the subject matter.** The source of genetic resources and associated traditional knowledge may relate to the subject matter of intellectual property applications in a variety of ways. These may include:

- forming part of the subject matter for which intellectual property rights or privileges are sought (including as a required disclosure to enable others to use or replicate the subject matter);
- use during the process of developing the subject matter;
- use as a necessary pre-requisite to develop the subject matter;
- use to facilitate development of the subject matter;
- use as necessary background material or information for development of the subject matter; and
- forming part of the prior art relevant for examination of the application.¹⁹⁵

The importance of the genetic resources and associated traditional knowledge to the subject matter also may vary, ranging from essential (*e.g.*, as a component of the subject matter or integral to its development) to marginal (*e.g.*, as providing prior art disclosures of how others had failed to develop the subject matter, without suggesting the subject matter).

¹⁹⁴ See, *e.g.*, 40 C.F.R. Part 350 (United States law requiring assertion and documentation of claims to trade secrecy status of information submitted in regard to emergency planning information disclosure requirements).

¹⁹⁵ See, *e.g.*, WTO IP/C/W/429 Rev.1, ¶ 8; WTO IP/C/W/404, at 6; WIPO Technical Study, ¶¶ 92-101; WIPO Examination, ¶ 83.

106. Determining whether and what disclosures to require in all of these situations should depend not only on whether such information is required under traditional intellectual property law principles, but also on the additional purposes to be accomplished and on the importance of the input to the subject matter. A broad approach to triggering disclosure of such information should be adopted, because it may be difficult to determine by generic category and in advance what types of relationship to the subject matter will exist, and how that relationship may affect entitlements to apply for or own the intellectual property sought. The applicant should normally possess information regarding the source of genetic resources and associated traditional knowledge.¹⁹⁶ Little effort would be required to submit such information or declarations of the source, or documents identifying the source already in the applicants' possession. In contrast, the potential use of such information may be substantial.

107. Where information regarding the source is known, information regarding the country providing the genetic resources and associated traditional knowledge also should be known. A broad approach to triggering disclosure of such information also should be adopted. Disclosure of the country providing genetic resources and associated traditional knowledge is critical to assuring that applicable access and equitable benefit sharing requirements have been complied with under the laws of countries implementing the CBD. In contrast, more complicated evaluations are needed regarding the benefits and burdens of disclosing additional information regarding the country of origin, persons involved, and authority to use the genetic resources and associated traditional knowledge.

108. So-called negative declarations may help to assure that the applicant has performed an adequate investigation before concluding that genetic resources and traditional knowledge were not involved in the development of the subject matter, and thus that no additional disclosures of origin are required. Similarly, positive declarations may help to assure the integrity of submitted information and documents regarding the source, the country providing genetic resources and associated traditional knowledge, the country of origin, persons involved, and legal authority for access and benefit sharing. Documentary information regarding the source or country providing genetic resources and associated traditional knowledge may be unnecessary if declarations are required, although such documentation may help to prevent or to detect fraudulent declarations.

109. **Relation of the source to the applicant.** Both intellectual property laws and other laws define the relationship of the source to the applicant. Applicants in some jurisdictions are routinely required to disclose their relationship to the subject matter, *e.g.*, as an inventor, as an assignee, or as another person having a beneficial interest. An applicant normally should know these relationships in order to ground its belief in its entitlement to apply for or own the intellectual property. In contrast, it may be more

¹⁹⁶ Brazil has proposed the disclosure of information on the source and (subject to reasonable efforts) the country of origin "even where the use was only incidental ... if the disclosure were relevant" for substantive patentability, to understand or use the invention, or for inventorship or entitlement determinations. WIPO Compilation, Submission of Brazil, at 11. Even if substantial effort is required, such information may need to be obtained and disclosed in order for the application office to determine whether it is or is not relevant.

difficult to know of persons involved who may possess a beneficial interest in the subject matter of the application, and in some cases entitlement issues may require legal judgments that the applicant is not authorized to make. In such cases, it may nevertheless be useful for the applicant to identify the issues that give rise to uncertainties.

110. Accordingly, a broad approach to triggering disclosures of relevant information also should be adopted in regard to the relation of the source to the applicant.¹⁹⁷ Much of the information should be readily available to the applicant, and thus should not require substantial effort to disclose. This is true even though such disclosures may not normally be reviewed by national intellectual property offices (except when they are facially insufficient or when they are subjected to a third-party challenge).

111. Declarations of applicants also may be appropriate in regard to the relation of the source to the applicant. For example, inventors of patentable subject matter (and assignees in the event the inventor is deceased or unwilling) are routinely required to sign oaths or declarations of inventorship of the subject matter for which patents are claimed.¹⁹⁸ Such declarations could be appropriately limited in the event of legal uncertainty, *e.g.*, by statements such as “to the extent of applicant’s knowledge” or “subject to a contrary legal determination.” Submission of documentary information regarding the relation of the source to the applicant may be more appropriate in this context, as such information may already be required to be submitted under intellectual property laws and may be required to be generated to comply with CBD access and benefit sharing legislation.

112. **Relation of the applicant to persons involved.** It may be difficult to determine what other persons may be involved in the application and to determine the relationship of those persons to the applicant. Information regarding persons involved may not be readily available to the applicant. For example, the source or the country providing genetic resources and associated traditional knowledge may owe equitable benefit sharing obligations to indigenous or local communities living in different countries. Confirming the existence and scope of such obligations would likely require legal judgments that applicants are not qualified to make, even if applicants possessed the relevant information. Investigating such issues could involve significant expenditures of time and resources, without leading to definitive conclusions.

113. Accordingly, careful evaluation should be made regarding whether the potential existence of persons involved should trigger mandatory disclosure of origin obligations. To the extent such information already is known to the applicant, disclosure may more readily be required. Disclosure of such information will help to assure that persons involved will know of the applicant and application. Thus, consideration also should be

¹⁹⁷ In the rare case where the source is unknown, disclosure of the genetic resources and associated traditional knowledge could be made along with a statement that the source is unknown. *Cf.* WIPO Compilation, Submission of Colombia, at 14 (discussing declarations that the origin is unknown).

¹⁹⁸ *See, e.g.*, 35 U.S.C. §§ 115, 117, 118 (United States law requiring oath or declaration, authorizing filing in the event of death, and authorizing filing by assignees of unwilling inventors along with documents proving the relevant facts).

given to mandating a specified level of effort to identify persons involved, so as to better assure appropriate access and benefit sharing. The investigatory burden should not be so great as to discourage the use of genetic resources and associated traditional knowledge, which would defeat the purpose of facilitated access and benefit sharing.¹⁹⁹

114. Requirements for disclosure or investigation of persons involved should not “create uncertainties” in regard to the application process or generate unnecessary additional litigation.²⁰⁰ Such uncertainties already may exist if there are persons involved who possess interests in the application or in equitable benefit sharing that the applicant has not recognized. It is the fact that persons are involved, and not the disclosure of their relationship *per se*, that may call into question the validity of the intellectual property or the entitlement of the applicant. Disclosure of information relating to persons involved thus may help to identify and to resolve such existing uncertainties. Because abusive use of challenge procedures or litigation can be dealt with adequately, the fear of such abuses does not provide a reason to reject disclosures of origin relating to persons involved.

115. Consideration also should be given to requiring declarations by applicants identifying known persons involved, specifying a level of effort to investigate whether persons are involved, and to provide negative declarations that no other persons are involved. Performing exhaustive searches may be unduly burdensome. Although applicants may not be able to specify the relationship of persons involved that require legal judgments that applicants are not qualified to make, applicants may identify those issues and thus may assist identification and resolution of existing uncertainties. Documentary information might be required to demonstrate the relationship of persons involved to the applicant, particularly when required to demonstrate compliance with CBD access and benefit sharing requirements.

116. **Disclosure of the country of origin.** Disclosure of the country of origin also may involve complex determinations and may require extensive investigations to obtain information that applicants may not routinely possess. For example, it may be difficult to identify the country of origin of plant varieties, particularly as plant varieties may acquire distinctive characteristics in different countries.²⁰¹ Similarly, it may be difficult to

¹⁹⁹ See, e.g., WIPO Compilation, Submission of Japan, at 25.

²⁰⁰ See, e.g., WIPO Compilation, Submission of United States, at 42, 47, 50. The contractual approach suggested by the United States (including disclosures to “appropriate authorities” regarding applications of genetic resources or traditional knowledge), *see id.* at 48-49, does not remove any such uncertainties. Rather, contracts only add to the types of relevant information that must be evaluated in regard to whether applicants are entitled to seek intellectual property and whether they specify additional terms for access and equitable benefit sharing. Further, contracts may require that the contracts and other information be disclosed in intellectual property applications.

²⁰¹ See Correa, *Disclosure*, at 5. In the case of plant genetic resources for food and agriculture obtained from the Multilateral System set forth by the ITPGRFA, the benefits are multilaterally shared. See ITPGRFA, Art. 13. Hence, it might suffice for disclosure obligations to provide an indication that the relevant plant genetic resources have been obtained from the multilateral system under the standard Material Transfer Agreement, so long as the purpose and conditions of access were limited solely to the utilization and conservation of the resources for research, breeding and training for food and agriculture, not including chemical, pharmaceutical and/or other non food/feed industrial uses. See ITPGRFA, Arr. 12.3(a).

identify traditional knowledge that constitutes prior art,²⁰² and thus to identify the country of origin when such knowledge formed part of the background to the invention. Because of concerns over sovereign rights and for other reasons, some countries have suggested that a duty to investigate the country of origin is warranted.²⁰³

117. Accordingly, careful evaluation should be made regarding whether to require disclosures of the country of origin. Such information should likely be disclosed to the extent it is already known by applicants, and consideration should be given to imposing investigatory obligations to identify countries of origin. This will help to notify countries of origin of the use of the resources and of the application for intellectual property when they are not the country providing the genetic resources and associated traditional knowledge.

118. Careful evaluation also should be made regarding whether to require declarations by applicants of the country of origin and that required investigations were made, or negative declarations that no unidentified country of origin is involved. Documentary information relating to the country of origin or to the level of effort of the declaration also might be required, and could assist in assuring the validity of the information and the integrity of the declarations.

119. **Disclosure of documentary information regarding access and benefit sharing.** Applicants should normally possess information regarding and documents (including contracts) demonstrating their compliance with prior informed consent for access and equitable benefit sharing obligations imposed by the CBD and by national legislation implementing the CBD. Absent such information and documents, applicants may be in violation of the relevant laws. Accordingly, a broad approach to triggering disclosure of such information and documents should be required, at least for information already in the applicant's possession.²⁰⁴ In some cases, applicants may lack documentary information, such as when countries have not adopted legislation to implement CBD requirements. However, applicants risk biopiracy and misappropriation when they are not qualified to make legal judgments that the source has authority to provide the genetic resources and associated traditional knowledge for uses leading to intellectual property applications or that benefit sharing arrangements will be equitable. Requirements to disclose information and documents regarding access and benefit sharing thus would help to identify such cases and the issues they raise. Such disclosures would strengthen incentives that applicants already possess to investigate the authority of the source to provide access on specified conditions and the equity of benefit sharing arrangements.

120. Documentary information regarding access and benefit sharing, moreover, will normally relate directly to entitlements to apply for and own intellectual property or to impose obligations to restrict use or to share commercial benefits. Such information and

²⁰² See, e.g., WIPO Compilation, Submission of Belize, at 8.

²⁰³ See, e.g., WIPO Compilation, Submission of Colombia, at 15 (noting that declarations that the origin of a genetic resource is unknown "would not suffice for fully satisfying the disclosure requirement").

²⁰⁴ See, e.g., WIPO Compilation, Submission of Brazil, at 12 (suggesting declarations of source and country of origin accompanied by relevant evidence of access and benefit sharing).

documents may not routinely be reviewed by national intellectual property offices, except when they are facially insufficient or when they are subjected to a third-party challenge.

121. Declarations by applicants also may be appropriate in regard to compliance with access and benefit sharing requirements. Applicants should know the legal status of their use of genetic resources and associated traditional knowledge, and of the retention of benefits deriving from that use. Thus, any investigatory burdens associated with making such declarations should be justified. Such declarations also may assist in assuring the integrity of disclosed information and documents, as well as compliance with CBD-implementing legislation, as false or fraudulent declarations typically may invoke substantial liability or civil or criminal penalties. To the extent that access and benefit sharing requirements are not clear, however, providing declarations may be difficult for applicants. Thus, requirements for declarations might need to identify legal determinations that the applicant in good faith has sought but has been unable to resolve.

B. Procedural Triggers

122. Requirements for disclosures of origin may be triggered at various times, so as to be of use at different procedural stages during and after application for intellectual property. Procedural triggers must define the opportunities for required disclosures and evaluations, the format in which information is to be submitted, and the types of evaluations that are to be made. Procedural triggers may be imposed by national access and benefit sharing legislation, by contracts, and by new treaty requirements. Various non-exclusive procedural triggers exist for requiring disclosures of origin. Salient times during and after application for intellectual property to require such disclosures include:

- the international stage of application processing (in a coordinated international system of national intellectual property application procedures);
- the national stage of application processing;
- pre-grant and post-grant administrative challenge proceedings; and
- judicial proceedings.

For each of the triggers, it is important to consider: the form, prescribed formats, and timing for submission of any required disclosures; whether and to what extent the disclosed information may be evaluated at the time of the disclosure or at a later stage; and whether and when to require or to permit applicants or owners to supplement or to correct disclosures during or after the application process.

123. To the extent that form, prescribed formats, timing, and supplementation are evaluated at any of the relevant times, it also becomes necessary to consider the consequences that should attend failures to conform to procedural requirements. A brief discussion of the consequences of disclosure failures is provided in regard to procedural triggers, and a more extensive analysis is provided in Part III.

1. CBD-Related Sources of Disclosure Requirements.

124. **CBD implementing legislation-imposed disclosure requirements.** As noted in the WIPO Technical Study, disclosure of origin requirements in intellectual property applications may “have [their] roots in the laws and regulations of the source country that relevantly govern access and benefit-sharing.”²⁰⁵ These laws and regulations thus may become an integral part of the intellectual property system to the extent they require disclosures to (and evaluations by) national application offices or other entities within the intellectual property system. For example, national access and benefit sharing legislation not only could require disclosures regarding genetic resources and associated traditional knowledge to be made to competent access and benefit sharing authorities of the country providing genetic resources and associated traditional knowledge,²⁰⁶ but also such laws (if recognized and enforced in other countries) may require disclosures to be made in all jurisdictions where applications for intellectual property are filed that relate in relevant substantive ways to such resources and knowledge.

125. National access and benefit sharing laws could impose the same types of procedural triggers for disclosures of origin as could be imposed pursuant to mandatory obligations under new international treaty provisions. These include disclosures made at the time of filing or during the processing of international or national applications, during pre-grant or post-grant challenge proceedings, or during various forms of judicial proceedings. Thus, procedural triggers imposed pursuant to national access and benefit sharing laws are not discussed separately below, but rather are subsumed within the general discussion of procedural triggers.

126. **Access and benefit sharing contract-imposed disclosure requirements.** Provisions of contracts entered into pursuant to national access and benefit sharing laws also may require disclosures of origin to competent access and benefit sharing authorities and in intellectual property applications throughout the world.²⁰⁷ The existence of such contractual disclosure obligations raises “complex question[s] of private international law.”²⁰⁸ Because such contracts could impose the same procedural triggers for disclosures of origin relating to intellectual property applications as national access and benefit sharing laws or as mandatory treaty requirements, they are not discussed separately below.

2. Procedural Triggers for Disclosures.

²⁰⁵ WIPO Technical Study, ¶116.

²⁰⁶ See, e.g., WTO IP/C/W/400 Rev.1, ¶ 11 (discussing potential reference of disclosures of origin in PCT applications to a list of “competent government agencies”).

²⁰⁷ See WIPO Technical Study, ¶ 107 (noting that contracts may result from standard material transfer agreements stipulated by law or regulations implementing CBD requirements). A discussion of various issues to be addressed in contracts is provided in WIPO/GRTKF/IC/7/9, *Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing* (2004), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_9.pdf. For example, contractual terms to be negotiated by parties include who will decide whether to apply for what types of intellectual property. See *id.*, Annex, ¶ 33.

²⁰⁸ WIPO Technical Study, ¶118. See also *id.*, ¶¶ 108, 129.

127. **International stage disclosure requirements.** Various countries have suggested that disclosures of origin should be made at some point during the international phase of patent applications filed under the PCT.²⁰⁹ The PCT establishes a coordinated international system of national application filing procedures. Under the PCT, applicants for patents may file a single, initial application in one country that designates multiple countries in which patents may ultimately be sought. Applicants thereby obtain the benefit of the international filing date when they ultimately prosecute patent applications in regional or national patent offices around the world.²¹⁰ These suggestions (which can be broadened to address the international stage of any coordinated international system of national intellectual property application procedures) have the advantage of assuring that disclosures of origin would be transferred to all national offices of countries in which intellectual property is applied for through the international system. However, these suggestions do not provide detailed discussions of options for required disclosures at the international stage, for evaluations that might be performed at that stage, or for the consequences that should attend to disclosure failures.²¹¹

128. Disclosures of origin at the international stage could include the same categories of information (*i.e.*, disclosures of information only, disclosures with declarations by the applicant, and disclosures with documentary information) pursuant to the same substantive triggers discussed above. Although the legal consequences of treating these required information disclosures as “formal” or “substantive” may vary under existing international intellectual property law treaties, this distinction is not particularly helpful in regard to specifying alternatives for inclusion as mandatory treaty obligations.²¹² More relevant questions relate to the timing, contents, and format of the disclosures, the level of effort required, the nature of any required evaluations at the international stage, and whether any failures to conform to disclosure requirements will have curable or incurable mandatory or facultative consequences.

²⁰⁹ See, e.g., WIPO Examination, ¶ 52 (discussing the Swiss proposal of WTO IP/C/W/433, WTO IP/C/W/423, and WTO IP/C/W/400/Rev.1, which would authorize but not require disclosure at the time of filing an international application “or later during the international phase”); WIPO Examination, at 58, Box, Summary of triggers for disclosure requirements; *Procedural options* (noting procedural triggers include initial filing, specific deadlines after filing, formal or substantive examinations, prior to grant or sealing of patents, during opposition or revocation proceedings, or when patents are asserted or enforced); WTO IP/C/W/442, ¶ 9 (discussing provision of evidence of benefit sharing “at the time of applying for the grant of a patent”).

²¹⁰ See, e.g., PCT Art. 3 (international application); PCT Art. 11 (filing date); PCT Art. 20 (communication of international application to designated offices).

²¹¹ In the case of the Swiss Proposal to amend the PCT, if disclosures of origin are required by the national law of a designated Office, PCT Rule 51bis.3(a) would require the designated Office to provide an invitation to supply any missing disclosure at the beginning of the national phase, within a specified time limit of not less than two months from the invitation. See WTO IP/C/W/423, ¶ 25. Further, PCT Rule 26ter provides for correction or addition to declarations before publication, and for the receiving Office or the International Bureau to invite applicants to correct declarations under PCT Rule 4.17 if “not worded as required” or (for inventorship) if “not signed as required.” See WTO IP/C/W/433, at 10 (reprinting Rule 26ter and noting the ability of applicants to provide or correct declarations at the international stage).

²¹² See, e.g., WIPO Technical Study, ¶¶ 132-35.

129. Disclosures may be required initially upon filing of applications or at other stages of international intellectual property application procedures. Because many disclosures of origin will directly relate to entitlements to apply for intellectual property, they should be required at filing. However, opportunities should be provided (in the absence of bad faith or fraudulent intent) to cure disclosure failures and to supplement initial disclosures.

130. Different options exist for whether and how evaluations of disclosed information are to be performed at the international stage. Evaluating disclosures or origin at the international stage may be efficient if it would result in termination of application processing, which would avoid duplicative evaluations in multiple national application offices. In contrast, international stage evaluations may be inefficient if evaluations will inevitably be duplicated at the national stage.

131. Consideration also needs to be given to the competence of international intellectual property application offices to make various types of evaluations. For example, disclosures of origin might be evaluated at the international stage for substantive compliance by applicants with national access and benefit sharing legislation of the country providing genetic resources and associated traditional knowledge. International application offices may be poorly qualified to perform such evaluations, which may require the intervention of authorities of the countries providing the genetic resources and associated traditional knowledge. The outcome of such determinations, however, should not vary with the receiving office in which the international application is filed or the with the national intellectual property application offices that are designated. Although international application offices may be better suited to evaluate disclosures of origin that relate to entitlements to apply for the subject matter, entitlement determinations may vary depending on the laws of designated countries in which intellectual property is sought. Evaluations of patentability conducted at the international stage for PCT applications²¹³ typically apply harmonized and restrictive substantive evaluation criteria that may differ from national patent laws and thus are preliminary in nature.

132. International stage evaluations could review disclosures of origin for:

- completeness;
- conformity to standardized forms;
- accuracy of the factual information presented;
- substantive validity of conclusions reached;
- conformity of the disclosed information to any declarations by applicants and documents presented;
- substantive legality of access and benefit sharing.

²¹³ See, e.g., PCT Art. 18 (international preliminary search report); PCT Art. 33 (international preliminary examination report); PCT Rule 43bis (written opinion of the international search authority).

Rules may need to be developed to address burdens of proof and standards for rebuttal in any such evaluations.²¹⁴

133. The degree of administrative burden of international stage evaluations increases substantially if evaluations are required of the factual accuracy of information, the substantive validity of conclusions reached, or the legality of access and benefit sharing. However, some such evaluations may already be required within the intellectual property law system to the extent that disclosed information may call into question entitlements to apply for intellectual property or the substantive validity of the application.²¹⁵ Whether or not evaluations are performed at the international stage, the information submitted at the international stage may need to be transmitted to multiple national application offices. Disclosures at the international stage thus impose costs on applicants and additional administrative burdens on the international stage application offices.

134. Consideration also needs to be given to whether to impose mandatory or facultative consequences for disclosure failures, or to leave sanctions decisions wholly to the discretion of countries in which international applications are filed. Various consequences could attend to the failure to provide complete, conforming, accurate, or valid disclosures, initially or following any opportunities provided for curing inadequacies. The most basic consequence could be to delay processing unless or until complete, conforming, accurate, or valid information is provided.²¹⁶ However, additional consequences might be imposed when disclosures are found to be inadequate. Additional consequences may include abandonment of applications (thereby terminating rights of priority), transfer of rights to prosecute applications, abandonment of entitlements to apply for or to own the intellectual property, and administrative fines, civil liability or criminal penalties. These consequences may vary depending on consideration of factors such as the good faith and diligence of applicants, administrative burdens of performing repeated evaluations of corrected or supplemented information, costs of additional evaluations and delays in processing and whether such costs may be offset by applicant fees, and other factors.²¹⁷

135. Various consequences may also apply to already-issued intellectual property if disclosures are found to be inadequate after the international stage. Whether to impose

²¹⁴ See, e.g., WIPO Technical Study, ¶ 137 (discussing *prima facie* showings in regard to burdens of proof); WIPO Examination, ¶ 87 (discussing burdens of proof in evaluating adequacy of disclosures).

²¹⁵ See, e.g., PCT, Arts. 33, 34 (discussing substantive evaluations and procedures for international preliminary examination).

²¹⁶ See, e.g., WTO IP/C/W/442, ¶ 12 (suggesting that applications “would not be processed any further” absent disclosure of required information, and could be accompanied by imposing time limits for making the required disclosures, following which the application “could be deemed withdrawn”); WIPO Compilation, at 56, Submission of European Communities (suggesting that the required disclosures be made in response to a standard application form, and that failure or refusal to disclose should trigger the opportunity “to remedy the omission within a certain time fixed under” applicable law and that the application “shall not be further processed” in the even of continuing failures).

²¹⁷ See, e.g., WIPO Examination, ¶¶ 87-88 (discussing good faith and fraudulent intent in regard to disclosure failures). Cf. 35 U.S.C. § 41 (United States law addressing extension of time and petition fees); 35 U.S.C. § 133 (United States law limiting response time to six months except on a showing that delay was unavoidable); 35 U.S.C. § 151 (United States law limiting issue fee payments to three months).

such consequences may depend on similar factors to those described above. The consequences of disclosure failures in this context may include:

- substantive invalidation of the intellectual property;
- terminating or transferring ownership of the intellectual property;
- imposing administrative fines, civil liability, or criminal penalties (including for violations of relevant access and benefit sharing legal and contractual requirements) within or external to the intellectual property system; and
- requiring return of any unjustified benefits conferred as a result of disclosure failures or in violation of access and benefit sharing requirements.

136. Further discussion of these consequences is provided in Part III. However, it is useful to note here that international application offices may not necessarily possess administrative subpoena power or other compulsory process to require applicants to provide information or to testify, so as to determine good faith or fraudulent intention.²¹⁸ Similarly, such offices may not be authorized by national laws or constitutional provisions to impose punitive fines, civil liability, or criminal penalties.

137. Because of the administrative burdens of performing evaluations other than for completeness or consistency, and notwithstanding the potential to avoid duplicative determinations at the national stage in multiple jurisdictions, it seems unwarranted to require review of disclosures of origin at the international stage for factual accuracy or for substantive validity. Intellectual property examiners at the international stage are unlikely to possess training in applying access and benefit sharing requirements or contractual provisions under the laws of foreign jurisdictions. Nevertheless, the international office should be authorized to require applicants to supplement with additional information and documents any initial disclosures that appear to be inadequate, inaccurate, or invalid, or when disclosed information appears insufficient to support conclusions reached or to demonstrate entitlements and substantive validity.

138. **National stage disclosure requirements.** As at the international stage, at least three different categories of information relating to different substantive triggers may be disclosed at the national stage of the application process (*i.e.*, disclosures of information only, disclosures with declarations by the applicant, and disclosures with documentary information). Similarly, these disclosures could be presented using specified formats (*e.g.*, standardized forms, mandatory contents, described levels of effort, specified conclusions, and indicated levels of confidence) and may be cured or supplemented over time. To the extent that disclosures are required at the international stage, supplemental disclosures may occur upon entry into the national stage or thereafter.

²¹⁸ *Cf.* 35 U.S.C. § 24 (United States law authorizing district courts to issue subpoenas to compel testimony relating to contested patent cases in the US PTO).

139. Evaluations at the national stage may be more extensive than, may duplicate, or may rely to some extent upon evaluations performed at the international stage. Similar types of evaluations of disclosed information may be performed (*e.g.*, for completeness, conformity to prescribed formats, factual accuracy, substantive validity of conclusions, conformity to declarations, and substantive legality). As at the international stage, because of the administrative burdens and lack of training to make determinations regarding national access and benefit sharing requirements or contractual requirements under the laws of foreign jurisdictions, it seems unwarranted to require review of disclosures of origin for factual accuracy or for substantive validity during initial application processing. However, national application offices are more likely to use such disclosed information to make determinations regarding substantive entitlements and substantive validity of applications under relevant intellectual property law standards.

140. Various mandatory or facultative consequences also could attend to failures at the national stage to provide complete, conforming, accurate, or valid disclosures. In addition to delaying processing of applications, following notice and an opportunity to cure in the absence of bad faith or fraudulent intent,²¹⁹ additional consequences may include abandonment of applications or abandonment of entitlements to apply for or to own the intellectual property. Following issuance of intellectual property, consequences may include substantive invalidation, terminating or transferring ownership, imposing fines, liability, or penalties, and requiring return of any unjustified benefits.

141. **Pre-grant and post-grant administrative challenges.** Pre-grant and post-grant administrative challenges normally address either the entitlement to apply for or own the intellectual property or the substantive validity of the issued intellectual property. Unlike during the initial application process, pre-grant and post-grant administrative reexamination, interference, revocation, or opposition proceedings may involve more substantial administrative procedures and may provide for the participation of interested third parties.²²⁰ Such proceedings therefore may be more appropriate for conducting more extensive evaluations of the factual accuracy of and validity of conclusions regarding disclosures of origin. Depending upon when such proceedings are available, they may be considered efficient and low-cost alternatives to judicial resolution of intellectual property application or ownership disputes.²²¹ The availability and procedures for such challenges, however, vary across jurisdictions.

²¹⁹ *See, e.g.*, WIPO Compilation, Submission of Colombia, at 15 (suggesting that the “competent national office” should notify the applicant and avoid continuing to “other phases of the application procedure” until the requisite disclosure is made).

²²⁰ *See, e.g.*, 35 U.S.C. §§ 311-18 (United States law specifying *inter partes* reexamination procedures); 35 U.S.C. § 135 (United States law specifying interference procedures); European Patent Convention (EPC), Arts. 99-105 (specifying opposition procedures). *Cf.* 35 U.S.C. §§ 301-07 (United States law specifying *ex parte* reexaminations, subject to the same procedures as initial examination after a determination that sufficient cause exists and after the filing of an initial statement and reply).

²²¹ *See, e.g.*, EPC Art. 99(1) (limiting oppositions to filing within nine months after publication of notice of grant); U.S. Patent and Trademark Office, *21st Century Strategic Plan, Action Paper 40: Post-Grant Review of Patent Claims* (2003) (noting that post-grant review under United States law provides accused infringers and patent holders with an alternative forum to district court litigation of patent validity issues”), available at <http://www.uspto.gov/web/offices/com/strat21/action/sr2.htm>.

142. Mandatory or facultative evaluations of disclosures of origin in pre-grant or post-grant challenge proceedings are unlikely to be limited to reviews for completeness and for conformity to prescribed formats, because of the inherent potential for such challenges to link disclosures of origin to substantive entitlements or to the validity of applications or granted intellectual property. In such challenges, national offices thus may be required to evaluate information regarding authority of the source to provide access to genetic resources and associated traditional knowledge and of the applicant to provide for equitable benefit sharing under actual conditions of use. Where pre-grant and post-grant challenges do not relate to disclosures of origin, however, it may not be warranted for national offices to evaluate the disclosed information for factual accuracy or validity of conclusions.

143. Given that pre-grant and post-grant administrative challenges to intellectual property are typically conducted when prior information and evaluations have been called into question, different types of or additional disclosures of origin may be required, and different substantive triggers may be adopted. Similarly, correction or supplementation of earlier disclosures and submission of documentary information relating to earlier disclosures is more likely to be requested or required. Evaluation of such additional disclosures within the context of the administrative proceeding may be efficient, limiting the need for subsequent or duplicative judicial actions to determine relevant issues.

144. The same types of mandatory or facultative consequences could attend to disclosure failures discovered at the pre-grant or post-grant administrative challenge stage. However, because such challenges involve more extensive procedures and may be adversarial, additional burden of proof rules and presumptions may need to be specified. Unlike during *ex parte* administrative proceedings, international or national application offices may need to adjudicate competing evidentiary presentations of opposing parties.²²² Further, pre-grant and post-grant challenge procedures raise the potential for formal and informal discovery mechanisms, which may assist in addressing information gaps in regard to the various disclosure issues to be evaluated. In such proceedings, national application offices may or may not possess administrative subpoena powers.

145. **Judicial proceedings.** Disclosures of origin may be required and evaluations of disclosed information may occur in judicial proceedings raising challenges to patent validity (e.g., in infringement or declaratory judgment actions). Disclosures also may be required and evaluations may occur in other judicial actions that relate to the subject matter, the applicant, the persons involved, the country of origin, and conformity with access and benefit sharing requirements. The range of issues to be addressed in such judicial proceedings thus may be broader than in the context of application procedures or pre-grant and post-grant administrative challenges.

²²² Cf. WIPO Technical Study, ¶ 137 (noting the potential for different burden of proof rules in litigation).

146. Judicial systems also differ in regard to their reliance on adversarial or inquisitorial procedures to reach determinations.²²³ These differences may affect not only how much information and documentation is requested, but also who may participate and what type of information discovery may be obtained. Participants in judicial proceedings may include applicants for or owners of intellectual property, accused infringers, persons involved who may claim various entitlements and other interested third parties. Different rules regarding burdens of proof and presumptions in regard to disclosures of origin may be appropriate for judicial proceedings. In contrast to international or national stage examination or administrative challenges, moreover, judicial systems typically possess subpoena powers and other compulsory process authority to require testimony and the production of documents that may be needed to make determinations and to assess good faith and fraudulent intention.²²⁴

147. Judicial proceedings thus are better suited to reviewing the full variety of issues raised by disclosures of origin. In particular, judges may more readily require disclosure of (and parties to judicial proceedings may more readily seek to discover) information relevant to compliance with earlier-stage disclosure requirements, contractual provisions, access legislation, and equitable principles for determining ownership entitlements and benefit sharing. Judges also are better suited to reviewing and evaluating access and benefit sharing legislation of foreign countries and contractual provisions.

148. As with international and national application stages and administrative challenges, mandatory disclosures in judicial proceedings could take various forms and could relate to different substantive triggers. In the judicial context, there may be less need to require prescribed forms or formats for presenting information or to disclose the level of confidence in regard to various conclusions. In contrast, there may be greater need to evaluate the level of effort previously expended in investigations and to document the basis for conclusions reached, so as to assess good faith, as earlier disclosures and conclusions are more likely to be called into question. Judicial proceedings also are more likely to include persons involved who were not previously identified, and thus to address considerations of misappropriation and unjustified enrichment.

149. The same types of mandatory or facultative consequences could attend to disclosure failures at the judicial proceeding stage, including for determinations that earlier disclosures were inadequate, false, or fraudulent, or based on inadequate investigatory efforts. However, deferring all evaluations of disclosures of origin until the judicial stage may not adequately protect the interests of countries of origin or of persons involved. Developing countries in particular may lack adequate resources to effectively monitor and enforce violations of access and benefit sharing requirements in

²²³ See, e.g., Law Reform Commission of Western Australia, *Review of the Criminal and Civil Justice System: Final Report*, Ch. 6, The Adversarial System of Civil Litigation, ¶ 6.2 (2000) (noting distinctions between inquisitorial and adversarial approaches), available at <http://www.lrc.justice.wa.gov.au/RevCCJS-p92/finalreport/finalreporhtml/ch6adverscivil.html>.

²²⁴ See, e.g., Fed. R. Civ. P. 45(a)(1)(C) (authorizing United States district courts to issue subpoenas to compel testimony or the production of documents).

multiple jurisdictions following the grant of intellectual property.²²⁵ Earlier administrative evaluations of disclosures of origin could reduce the need for later judicial proceedings, or could permit countries of origin or persons involved to bring appropriate judicial actions at earlier times to transfer ownership, to invalidate intellectual property, or to establish entitlements at earlier stages of application procedures or at lower cost.

150. Because of the wide variety of judicial proceedings that might be brought that could trigger disclosure of origin requirements, careful evaluation is needed to determine what disclosure of origin obligations should be triggered at the judicial proceeding stage, and what mandatory or facultative evaluations should be required of such disclosures. For example, it may not be sufficient in judicial actions that dispute validity or ownership (even in inquisitorial judicial systems) to rely on the parties to identify and to litigate issues regarding equitable sharing of benefits with countries of origin and persons involved. It may therefore be appropriate to adopt mandatory provisions authorizing persons involved to intervene and to participate as full parties in such proceedings.²²⁶ This would permit persons involved to raise additional issues and to seek to obtain an equitable share of any benefits that are conferred through such an infringement action.²²⁷ Similarly, it may be necessary to mandate new legal claims (rights of action)²²⁸ and jurisdiction over such claims to allow persons involved or countries of origin to assure that there is a forum in which they may obtain appropriate relief.

²²⁵ See, e.g., WTO IP/C/W/356, ¶ 12.

²²⁶ Cf. Fed. R. Civ. P. 24(a) & (b) (describing requirements under United States law for mandatory and facultative intervention).

²²⁷ For example, the person involved might seek to impose a constructive trust over any damages award, by proving a right to an equitable share of the benefits of commercialization of genetic resources and associated traditional knowledge that was acquired from the person involved.

²²⁸ Cf. *Cort v. Ash*, 422 U.S. 66, 78 (1975) (identifying four requirements for implying private rights of action under United States laws); *Middlesex County Sewerage Authority v. National Sea Clammers Assoc.*, 453 U.S. 1, 20 (1981) (describing under United States laws conditions for limiting recourse to a statutory private right of action, based on remedial scheme provided in a different statute).

III. Incentive Measures for Applicants

A. Types of Incentive Measures

151. Incentive measures relating to compliance with mandatory disclosure of origin obligations may come in different forms. These may include direct mandatory sanctions, indirect mandatory sanctions, facultative sanctions, and positive incentives.²²⁹

152. **Direct mandatory sanctions** have mandatory consequences that directly affect the intellectual property law system as a result of disclosure of origin requirements. These consequences may include:

- curable or incurable, temporary or permanent bars to processing of applications;
- administrative fines, civil liability, and criminal liability imposed within the intellectual property law system;
- termination or full or partial transfer of entitlements to apply for or own intellectual property;
- curable or incurable, temporary or permanent, full or partial unenforceability, revocation, narrowing of the subject matter, or invalidation of granted intellectual property rights and privileges;
- return or transfer²³⁰ of benefits received from intellectual property; and
- enforcement of existing or new obligations to provide for equitable benefit sharing.

Direct mandatory sanctions provide strong “negative” incentives to comply with disclosure requirements. Such sanctions may apply as a consequence of existing intellectual property and other laws, but could be mandated directly by treaty when specifying disclosure of origin requirements.

153. **Indirect mandatory sanctions** have mandatory consequences external to the intellectual property law system, but which supplement the consequences of those requirements. For example, indirect mandatory sanctions may include: administrative fines, civil liability, or criminal sanctions that are imposed separately from the intellectual property law system and in addition to any effects that failures to comply with disclosure

²²⁹ Cf. Michael A. Gollin, WTO Public Symposium, ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on *Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement on the Road to Hong Kong, Feasibility of National Disclosure of Origin Requirements*, ¶ 1 (2005) (discussing and adopting different definitions for “direct,” “indirect,” and “voluntary/permissive” requirements), available at http://www.iprsonline.org/ictsd/docs/DOO3_Gollin.pdf.

²³⁰ In addition to disgorgement remedies based on unjustified enrichment, some jurisdictions provide duties to account on co-owners of intellectual property. See, e.g., H.R. Rep. No. 1476, 94th Cong., 2d Sess. 121 (1976) (recognizing the judicially developed duty to account in United States copyright law). Cf. 35 U.S.C. § 262 (United States law specifying there is no duty of joint owners of patents to account to each other).

of origin requirements may have on inventorship, entitlements to apply for or own intellectual property, or substantive validity of intellectual property.

154. **Facultative sanctions** authorize but do not mandate consequences within or external to the intellectual property legal system that supplement or duplicate existing consequences that may apply as the result of intellectual property and other legal requirements. Facultative sanctions may include the same types of measures as direct or indirect mandatory sanctions.

155. **Positive incentives** are measures to encourage disclosures that do not have mandatory or facultative sanctioning effects. Positive incentives may include reduced filing fees for providing specified disclosures of origin in applications for intellectual property, as well as reputational or moral benefits of responsible conduct and equitable benefit sharing.²³¹

156. The choice of mandatory or facultative sanctions in regard to disclosures of origin may be the most controversial issue to be resolved in developing an international agreement. Some countries vigorously oppose any mandatory or facultative sanctions that would affect entitlements to apply for or own intellectual property or that would invalidate granted rights or privileges,²³² even though disclosure failures and false or fraudulent submissions already may have such consequences under existing intellectual property and other laws.²³³ Other countries seek to apply as direct sanctions only existing sanctions under intellectual property laws, e.g., authorizing revocation or invalidation of patents only in the case of fraudulent intention, as provided by PLT Article 10(1).²³⁴ Yet other countries would impose a wide variety of mandatory or facultative sanctions, “the

²³¹ See, e.g., WIPO Examination, ¶ 159 (discussing submission of Japan regarding “‘sense of responsibility and conduct fair and equitable benefit sharing’”). See also *id.*, Box following ¶ 164, Summary of incentives (discussing additional positive incentives); WIPO Compilation, at 43, Submission of United States (discussing patents as incentives for disclosure of new, useful, and unobvious information); WIPO-UNEP Study, at 39-40 (discussing incentives to conserve biological diversity and to prevent knowledge erosion). Although the WIPO Examination discusses “[b]ehavior that may be encouraged by incentives,” reflecting objectives of the CBD (and other values such as compliance with applicable laws) and “[p]erverse’ or undesirable incentives,” these so-called incentives are better classified as desirable effects or undesirable behavior that may result from adoption of various options). WIPO Examination, Box following ¶ 164.

²³² See, e.g., WIPO Compilation, at 56, Submission of European Communities; WTO IP/C/W/434, ¶ 2.

²³³ See, e.g., WIPO Examination, ¶¶ 79, 89; Correa, *Disclosure*, at 10 (noting the inequitable conduct doctrine under United States patent law).

²³⁴ See, e.g., WTO IP/C/W/400 Rev. 1, ¶ 29; WTO IP/C/W/423, at 3; Felix Addor, WTO Public Symposium, ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on *Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement on the Road to Hong Kong: Switzerland’s Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications and Switzerland’s Views on the Declaration of Evidence of Prior Informed Consent and Benefit Sharing in Patent Applications*, at 4, 5 (2005) (discussing the Swiss Proposal, which would limit sanctions to those under PLT Art. 10(1) and would require submission and evaluation of documentary information regarding access and benefit sharing only to and by “government agencies competent to receive information”), available at http://www.iprsonline.org/ictsd/docs/DOO6_Addor.pdf.

nature of which will depend on whether one is dealing with a formal or substantive component of the disclosure and on whether it is at the level of pre- or post-grant.”²³⁵

B. Considerations for Sanction Provisions

157. Sanctions for disclosure failures may be based on different substantive and procedural triggers relating the subject matter of or the applicant for intellectual property to the source, the country providing genetic resources and associated traditional knowledge, the country of origin, and access and benefit sharing legislative requirements. Careful evaluation of the options is needed, given the many potential sanctions and the substantial disputes regarding whether particular sanctions are appropriate as mandatory or facultative requirements. Consideration thus should be given to the following issues:

- sanctions must provide an effective deterrent to non-compliance with CBD access and benefit sharing requirements and should assure that the intellectual property is not granted inappropriately and that the intellectual property system is not misused to further inequitable conduct²³⁶;
- the burdens imposed in assuring conformity to disclosure requirements and the potential fear of sanctions should not deter facilitated access to genetic resources and associated traditional knowledge where access and equitable benefit sharing should occur²³⁷; and
- flexibility should be provided to tailor the sanctions to the conduct involved (either by leaving their application to the discretion of Contracting States²³⁸ or by specifying requirements or principles for applying flexibility), so as to assure the sanctions are appropriate and do not result in adverse consequences.²³⁹

158. When considering what sanction obligations to adopt in regard to disclosures of origin, it is important to note that sanctions may be applied sequentially or in combination, rather than as exclusive alternatives. Decisions to impose sanctions thus may need to take into account not only to the type of sanctions that are appropriate in relation to the conduct but also whether previously imposed sanctions may logically or practically preclude or render particular additional sanctions inappropriate. This is particularly true of sanctions that already exist under national intellectual property laws, which might preclude application of more lenient sanctions. To the extent that particular sanctions might conflict with existing patent law treaties, mandatory sanctions obligation

²³⁵ WTO IP/C/W/443, ¶ 10. *See also* WTO IP/C/W/429/Rev. 1 & Add.1-Add.3, ¶¶ 11-14 WIPO Examination, ¶155 (summarizing Submission of Brazil); WIPO Compilation, at 16, Submission of Colombia (also noting reduction of application processing time).

²³⁶ *See, e.g.*, WTO IP/C/W/429/Rev.1 & Add.1-Add.3, ¶¶ 3-6; WTO IP/C/W/442, ¶¶ 5-8; WIPO Examination, ¶ 164 (summarizing Submission of CIEL).

²³⁷ WTO IP/C/W/434, ¶¶ 15, 25-27; WTO IP/C/W/429/Rev.1 & Add.1-Add.3, ¶¶ 9-10; WTO IP/C/W/443, ¶¶ 10-12, 18-23.

²³⁸ *See, e.g.*, WIPO Compilation, at 56, Submission of European Communities.

²³⁹ *See, e.g., id.* (discussing “effective, proportionate, and dissuasive sanctions outside the field of patent law”).

might supersede those treaty requirements.²⁴⁰ Mandatory sanctions obligations also may make more coherent the existing international system requiring recognition and enforcement of national laws that would impose various sanctions on disclosure of origin failures.

²⁴⁰ See Vienna Convention, Arts. 31(2) & (3). For example, mandatory sanctions obligations might require withdrawal and resubmission of applications or invalidation of the right to apply for the subject matter, even though the applicant had otherwise provided sufficient disclosures to obtain a filing date under PLT Art. 5(1) or PCT Art. 11(1).

IV. Functioning of Disclosure Requirements Under World Intellectual Property Organization Treaties

159. Most of the proposed forms of disclosure of origin requirements are legally compatible with existing WIPO treaties dealing with patent law (as well as with the TRIPS Agreement and with the UPOV Convention).²⁴¹ Even if some forms of mandatory disclosure obligations were incompatible with an existing WIPO-administered treaty provision, such obligations (as later-enacted treaty provisions) would supersede the WIPO-administered treaty provisions for parties to both sets of treaty requirements. Alternatively, the WIPO-administered treaties could be amended to be consistent with these obligations. This analysis does not repeat the earlier legal analyses, but rather focuses on procedures within the WIPO-administered intellectual property law treaty system for processing applications, focusing on patent law requirements. In doing so, the analysis identifies various issues that may need to be addressed in any new international treaty provisions imposing mandatory disclosure of origin requirements.

160. Although existing international treaties would legally permit the imposition of required disclosure of origin requirements at the national stage, they may not facilitate the receipt and transmission of any required or voluntarily disclosed information from international “receiving” intellectual property application offices to national “designated” offices. Receiving and designated offices may not be prepared to carry out mandatory disclosure obligations effectively or efficiently without the development of additional administrative rules, procedures, and forms. Such rules, procedures, and forms may need to address reproduction, publication, and transmission of declarations and of supporting evidentiary documentation. Both international and national application offices also may need authority to impose appropriate fees to cover the costs and administrative expenses relating to processing such information. Additional complexities arise in regard to electronic filing and processing of disclosures. Rules, procedures, and forms also must address language of documents, linguistic abilities of officials, and translation concerns. Finally, consideration must be given to the development of necessary administrative expertise, particularly if substantive evaluations of disclosed information are to be performed during the application process.

A. Rules, Forms and Processing of Information at the International Stage

161. The basic premise of the PCT system is the creation of a consistent set of international procedures for the administration of patent applications, which permits the filing of a single application in a receiving office having simultaneous effect for filing priority purposes in multiple designated countries.²⁴² Although receiving offices are authorized to require applicants to supplement disclosures that appear to be facially

²⁴¹ See generally Sarnoff, *Consistency*. Additional discussions of specific provisions of the Paris Convention, the PLT, and the PCT, focusing on their formal or substantive character, are provided in the WIPO Examination, ¶¶ 172-90.

²⁴² See, e.g., WIPO Technical Study, ¶¶ 172-73.

invalid or inadequate,²⁴³ they do not routinely evaluate the substantive adequacy of disclosed information.²⁴⁴ Following preliminary reviews in the receiving office, applications may be subjected to various preliminary substantive reviews (*e.g.*, for preliminary searches and preliminary examinations²⁴⁵) in the receiving office or other appropriate application offices. Although the PCT system now requires preliminary reports on patentability,²⁴⁶ the reports (and voluntarily requested preliminary examinations) are not binding on designated national application offices. The principle function thus served by the international system is the receipt, processing, and transfer of the application information and preliminary analyses to the designated national offices.

162. **Rules and forms.** At the international stage, disclosures must be provided through a standardized application Request form that references the PCT Administrative Instructions, which in turn mandate the use of “standardized wording” for completing the Request form.²⁴⁷ The PCT Rules direct the international receiving office to delete information contained in the Request form that is not authorized under the Rules or is not expressly permitted to be voluntarily disclosed under the Administrative Instructions.²⁴⁸ Additional PCT Rules address specific forms of information relating to genetic resources, such as references to deposits of biological materials or to listing of nucleotide or amino acid sequences.²⁴⁹

163. The PCT Rules authorize designated national offices to require additional disclosures at the national stage of application processing that relate to: (i) inventorship; (ii) entitlements to apply; (iii) entitlements to claim priority to earlier applications; (iv) oaths or declarations of inventors; (v) documents relating to “non-prejudicial” (public) disclosures under national laws; (vi) confirming signatures of additional applicants; and (vii) missing information regarding applicants.²⁵⁰ As recognized by the Swiss Proposal, the PCT Rules limit the authority of national offices to require additional formal (but not substantive) disclosures to those made at the international stage in regard to inventorship

²⁴³ Under PCT Rule 26ter.2, the receiving office or the International Bureau “may” invite applicants to correct declarations under Rule 4.17 if the office or Bureau “finds” they are not worded or signed as required by the Administrative Instructions, but the Rules do not mandate review for such defects.

²⁴⁴ *Cf.* WIPO Examination, ¶¶ 170-71 (discussing formal review of disclosure adequacy at the international stage for purposes of obtaining a filing date, and later substantive review for patentability).

²⁴⁵ *See* PCT Arts. 17, 18, 34, 35.

²⁴⁶ *See* PCT Rules 44bis, 70 (as in force from April 1, 2005) (establishing an enhanced international search and preliminary examination system, requiring mandatory “international preliminary reports on patentability,” whether or not an applicant requests a preliminary examination), available at http://www.wipo.int/pct/en/texts/pdf/pct_regs.pdf.

²⁴⁷ *See* WIPO PCT/RO/101, Notes to the Request Form, at 3 (April 2005) (referencing WIPO PCT/AI/2, PCT Administrative Instructions §§ 211-15 (as in force Feb. 12, 2004), available at <http://www.wipo.int/pct/en/texts/pdf/ai.pdf>); *id.* (noting that where the “standardized wordings are not applicable,” declarations should not be made on the PCT authorized form but rather should be supplied only at the national stage).

²⁴⁸ *See* PCT Rule 4.18(a) & (b).

²⁴⁹ *See* PCT Rules 13bis.1, 13bis.2, and 13ter; WIPO Technical Study, ¶ 178.

²⁵⁰ *See* PCT Rules 4.17, 51bis.1(a).

and entitlement to apply, unless there is reasonable doubt as to the veracity of the earlier disclosures at the international stage.²⁵¹

164. The types of information that may be supplied at the international stage pursuant to disclosures of origin requirements is likely to vary significantly from the types of information that were contemplated when creating the PCT Rules, Administrative Instructions, and Request form. Thus, any new international treaty provisions mandating disclosure of origin requirements may need to address amendment of the rules implementing various intellectual property treaties and the creation of appropriate forms and instructions to assure that required information may be included in, transmitted with, and published as part of applications for intellectual property. Mandating the types of information and documents to be published at the international stage (in full, partial, or summary form) will help to assure that countries of origin and persons involved receive adequate notice of relevant applications at the earliest time.

165. **Processing of information and fees.** Specific PCT Rules also address the preparation and recording of the contents of applications and accompanying disclosures, and transmission of such information for various purposes to different international application offices (such as the International Bureau and the International Search Authority).²⁵² These purposes may include publication and provision of references to additional disclosures that are provided in the application, the International Search Report, and preliminary amendments to the claims.²⁵³ Additional Rules address further transmission of information (including opinions and examination reports)²⁵⁴ to applicants and to various international and national application offices (including Designated Offices for national stage processing).²⁵⁵

166. As with the PCT Rules addressing information content and forms, the PCT Rules addressing information processing procedures were established with specific types of information in mind. Mandatory disclosure of origin obligations may require submission at the international stage of different kinds of information than are required by existing application procedures. Such information will need to be transmitted to various application offices and may be published. Careful consideration thus should be given to the types of information management procedures that will best facilitate transmission of disclosed information for recording, evaluation, and public notice purposes, without generating undue administrative burdens and costs.

167. The costs of information processing may be substantially reduced through use of electronic documents and electronic transmission. The PCT Rules thus permit electronic

²⁵¹ See PCT Rule 51bis.2(a). As discussed elsewhere, PCT Art. 27(3) (from which Rule 51bis.2 purports to derive its authority) should not be understood to prohibit additional disclosure requirements relating to substantive entitlements to apply for patents at the national stage. See Sarnoff, *Consistency*, at 48. Rule changes may be needed, however, to assure that such information can be required to be processed at the international stage and transmitted to the national stage.

²⁵² See PCT Rules 22, 23.

²⁵³ See PCT Rules 43, 46, 48.2.

²⁵⁴ See PCT Rules 43bis, 44, 44bis, 62, 70.

²⁵⁵ See PCT Rules 47, 71, 73, 93bis.1.

filing, processing, and transmission of applications and associated documents.²⁵⁶ However, various countries may not be prepared to manage electronic submissions or transmissions,²⁵⁷ and many applicants may lack the ability to create or to transmit electronic documents. Additional concerns may arise in regard to: creating, assuring the legibility, preserving, and assuring the integrity of electronic records or documents²⁵⁸; assuring that information follows common formats and that electronic information management systems are interoperable and secure²⁵⁹; and certifying the authenticity of electronic records or documents.²⁶⁰

168. Current PCT Rules for fees²⁶¹ also were established with specific types of information in mind. Accordingly, fees may need to be adjusted to take into account the different types of disclosure of origin information that will need to be processed. Consideration should be given to assuring that such fees are not prohibitive for applicants.

169. **Language concerns.** Specific PCT Rules govern the requirements for submission of applications in various languages,²⁶² and specify when translations of information contained in applications or produced during evaluation of applications may be required.²⁶³ Issues relating to the language of submitted information and the need for translations may occur with greater frequency for disclosures of origin than for other types of disclosures in intellectual property applications. Access to genetic resources and associated traditional knowledge may be provided from countries that either may not be the countries where the patentable subject matter is developed or may not be the countries in which international or national applications are originally filed and subsequently prosecuted. Sources providing access to genetic resources and traditional knowledge may provide information and documents in languages (including indigenous languages and local dialects) different from the official language of the country providing such resources and knowledge. Information and documents and CBD access and benefit sharing legislation from such countries thus may reflect languages different from the official language of the international receiving office or designated offices.

170. Careful consideration therefore should be given to the languages in which intellectual property applicants must submit required disclosures of origin and documentary information regarding compliance with access and benefit sharing, and to the need for and timing of translations of such information and documents. Applicable requirements should reflect the types of mandatory or facultative evaluations of such information that are to be performed at various stages of international application processing.

²⁵⁶ See PCT Rule 89bis.1(a), 89ter; WIPO PCT/AI/2, §§ 701-13.

²⁵⁷ See PCT Rules 89bis.1(d), 89bis.3.

²⁵⁸ See, e.g., WIPO PCT/AI/2, §§ 706, 708.

²⁵⁹ See, e.g., WIPO PCT/AI/2, §§ 703, 710, Appendix F.

²⁶⁰ See, e.g., WIPO PCT/AI/2, §§ 710(a)(iv), 711(b).

²⁶¹ See, e.g., PCT Rules 14-16, 19.4(b), 21(c), 26bis.2(c), 31.1(b), 40.1, 40.2, 48.4, 49.1, 57, 58, 58bis, 68.2, 68.3, and 91(f).

²⁶² See PCT Rule 12.1.

²⁶³ See, e.g., PCT Rules 12.3, 12.4, 45, 48.3, 55.1, 55.2, 62bis.1, 72, 74, 76.

B. Rules, Forms and Processing of Information at the National Stage

171. As with international stage applications, mandatory disclosure obligations will need to address the rules, forms, procedures, and fees at the national stage of processing applications for intellectual property, in light of the types of evaluations to be performed. However, such national stage procedures and evaluations may vary dramatically among different countries, given the wide range of practices and legal requirements that exist for different types of intellectual property applications. Additional documentation or the use of forms different from those employed at the international stage may be required at the national stage.²⁶⁴ Translation of information and documents also is more likely to be required at the national stage,²⁶⁵ and different fee structures will apply given the different types of information required to be submitted and the different types of evaluations that are performed at the national stage.²⁶⁶

172. Unlike at the international stage, national application offices may be *required* to evaluate the factual accuracy, validity, and authenticity of various disclosures, declarations, and documents (at least where the information facially appears to relate to substantive validity of the application or facially calls into question the entitlement to apply for intellectual property). Different considerations thus may be involved in regard to retaining, processing, and transmitting disclosures of origin and accompanying documentation at the national stage.

173. **Rules, forms, processing, and fees.** Neither the PCT nor the PLT prohibit disclosure of origin requirements at the national stage of processing PCT applications or for national applications in PLT jurisdictions. Depending on the degree to which mandatory disclosure of origin obligations harmonize national application disclosure requirements, different types of information may be required to be submitted at the national application stage using varying forms and formats and pursuant to varying procedures. Consideration therefore should be given to the degree to which disclosure requirements can and should be made consistent, so as to minimize information processing burdens on applicants. Particularly where regional application processing may exist,²⁶⁷ or where national application offices rely on prior evaluations and decisions by other countries' application offices,²⁶⁸ such consistent procedures may greatly

²⁶⁴ See, e.g., PCT Rule 51bis; PLT Arts. 6(2)(a) & 6(6). See also PLT Art. 2(2) (limiting the Treaty from restricting any party from "prescribing such requirements of the applicable substantive law relating to patents as it desires").

²⁶⁵ See, e.g., PLT Art. 6(3).

²⁶⁶ See, e.g., PLT Art. 6(4).

²⁶⁷ See, e.g., Protocol on Patents and Industrial Designs Within the Framework of the African Regional Industrial Property Organization (ARIPO), concluded at Harare (Zimbabwe) Dec. 10, 1982, as amended Dec. 11, 1987, Apr. 27, 1994, Nov. 28, 1997, May 26, 1998, Nov. 26, 1999, and Nov. 30, 2001, §§ 3(3)-3(7).

²⁶⁸ See, e.g., Patents, How to apply for grant of patents in the Hong Kong SAR? (2005) (noting that Hong Kong SAR registers patents granted by the State Intellectual Property Office of the Peoples Republic of China, the European Patent Office for patents designating the United Kingdom, and the United Kingdom Patent Office), available at http://www.ipd.gov.hk/eng/intellectual_property/patents/how_to_apply.htm#p3.

facilitate the submission and evaluation of required disclosures of origin and documentary information regarding access and benefit sharing.

174. Consistent requirements and forms may be particularly useful to minimize processing burdens and costs for applicants who file in multiple jurisdictions. As noted by others in the context of certificates of origin, common procedures and standardized electronic (paperless) systems and databases that can be adapted for local purposes are to be preferred, because of the reduction of the need to perform different types of evaluations under differing legal regimes and because of the high costs of maintaining and tracking non-electronic information.²⁶⁹

175. **Language concerns.** Translation issues may be particularly complex in regard to national stage evaluations of disclosures of origin. Disclosures of origin at the international stage are unlikely to be made in multiple languages, but may need to be translated so as to be understood and evaluated at the national stage in all of the various countries for which intellectual property is sought. Similarly, documents relating to access and benefit sharing requirements may, of necessity, be drafted in multiple languages. Whether translations are required will depend on the types of evaluations to be made of information disclosures, declarations, and documents. Where translations are required, significant costs may be entailed and the potential for translation errors will be raised. Thus, careful consideration should be given to how disclosure of origin requirements might facilitate national stage evaluations in various languages.

²⁶⁹ See, e.g., UNEP/CBD/WG-ABS/3/INF/5, at 62, 64-65, 66. Of course, a substantial investment of resources may be required to develop and adopt those systems.

V. Intellectual Property Issues Raised By International Certificates of Origin

176. International certificates of origin were conceived of in the context of registering genetic resources and traditional knowledge and of tracking their transboundary flows.²⁷⁰ As understood here, international certificates of origin are documents issued by entities competent to provide certifications regarding the authority of the source of genetic resources and associated traditional knowledge to provide access on specified conditions, and regarding the existence of *ex ante* benefit sharing requirements, that are compliant with the CBD and with relevant laws and equitable principles of the country providing such resources or knowledge.²⁷¹ International certificates of origin thus provide documentation of the legal provenance of the recipient to use the genetic resources and associated traditional knowledge under the identified conditions of access and benefit sharing. As a result, international certificates of origin may provide highly relevant information regarding the types of disclosures of origin that may be required of intellectual property applicants.

177. Numerous issues are raised by mandatory or facultative disclosures of international certificates of origin in intellectual property applications. International certificates of origin may assist applicants to make required disclosures of origin regarding compliance with access and benefit sharing requirements of the country providing genetic resources and associated traditional knowledge. The value of certificates of origin in this context will depend on the types of information contained in the certificates, and how certifications would be verified and tracked to assure integrity of their continuing application to the genetic resources and associated traditional knowledge that are relevant to the application for intellectual property.²⁷² As with other disclosures of origin, use of certificates of origin could impose significant burdens of analysis, investigation, and evaluation for applicants, certification entities, and intellectual property offices, particularly if it is necessary to track *ex post* compliance with benefit sharing requirements identified in certificates of origin. These considerations, however, do not

²⁷⁰ See, e.g., UNEP/CBD/WG-ABS/3/INF/5, at 52 (discussing certificates to “trace the flow of genetic resources”); *id.* at 54 (discussing certificates to monitor “transboundary movement of genetic resources and potentially traditional knowledge”); WIPO Compilation, at 41, Submission of Turkey (noting the registration of genetic resources in Turkey and supporting an international certification system to register all genetic resources).

²⁷¹ See, e.g., UNEP/CBD/WG-ABS/3/2, *Analysis of Existing National, Regional and International Legal Instruments Relating to Access and Benefit-Sharing and Experience Gained in Their Implementation, Including Identification of Gaps*, ¶¶ 62, 67, 89 & n.33, 91 & n.43 (2004) (discussing a draft Central American regional agreement that would require competent entities to issue certificates of origin establishing the legality of access to genetic resources and traditional knowledge and would require intellectual property authorities to require presentation of the certificate before registering products or processes that “may involve the use” of genetic resources and traditional knowledge; also discussing Philippine and Costa Rican certification requirements), available at <http://www.biodiv.org/doc/meetings/abs/abswg-03/official/abswg-03-02-en.pdf>. Cf. WIPO Examination, ¶ 204 (noting questions of legal and practical capability of administrative and legal authorities in one jurisdiction to determine conformity with laws and regulations in other jurisdictions).

²⁷² See, e.g., UNEP/CBD/WG-ABS/3/INF/5, at 17-18.(citing UNU-IAS Report).

differ significantly from the discussions provided above regarding substantive and procedural triggers, and thus are not repeated below. Instead, the analysis focuses on how certificates of origin may interact with existing intellectual property law requirements, and identifies additional intellectual property law issues (deriving from the context of trademark and unfair competition law) that are raised by certificates of origin.

A. Subject Matter of the Certification and the Certification Standard

178. Certificates of origin not only may help to track flows of genetic resources and associated traditional knowledge, they also provide a certification of authority to provide access to the relevant genetic resources and associated traditional knowledge on specified conditions of use and *ex ante* benefit sharing. Certificates of origin thus may require applicants and certification entities to evaluate the genetic resources and associated traditional knowledge used at very early stages in developing the subject matter of intellectual property applications, or that are used as necessary background information for such development. To assure the integrity and relevance of certificates of origin, certification entities also must verify that the uses to which genetic resources and associated traditional knowledge have been put conform to the authorized conditions.²⁷³ The certification standard thus must address the level of confidence required for various determinations before certificates of origin will be issued.

179. Certifying authorized access and equitable benefit sharing may require extremely complex evaluations. For example, certification may require determinations of how the source acquired the resources under the national laws of multiple jurisdictions, and potentially may require determinations of international legal claims of sovereignty over genetic resources made by different countries. Certificates of origin also may certify additional information relevant to determinations of authorized access and of equitable benefit sharing, thereby facilitating additional disclosures of origin in intellectual property applications. For example, certification entities may perform or may require certificate applicants to conduct investigations to identify countries of origin and persons involved.²⁷⁴ Careful consideration therefore should be given to the types of information to be certified, the levels of investigatory effort and of confidence required by the certification standard in regard to such information, and the burdens and costs of providing certifications. As with disclosures of origin, the nature of the certifications in regard to intellectual property applications should depend on the types of evaluations to be performed and the uses to which the certificates of origin will be put.

²⁷³ See, e.g., UNEP/CBD/WG-ABS/3/INF/5, at 55 (discussing use of certificates to demonstrate both the origin and the right to use resources for specific purposes).

²⁷⁴ See, e.g., UNEP/CBD/WG-ABS/3/5, *Analysis of Measures to Ensure Compliance with Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on which Access Was Granted, and of Other Approaches, Including an International Certificate of Origin/Source/Legal Provenance*, ¶ 96 (2004) (noting difficulties of identifying the country of *in-situ* origin of genetic resources), available at <http://www.biodiv.org/doc/meetings/abs/abswg-03/official/abswg-03-05-en.pdf>.

180. Consideration also should be given to the consequences of certification errors made by competent entities, and to misuse of certificates by persons to whom they were issued. For example, where an applicant for intellectual property obtained a certificate of origin based on false representations to the certifying body, the applicant might (depending on the laws and equitable principles involved) lose the right to apply for or own the intellectual property, might be found to have engaged in inequitable conduct that would render the intellectual property invalid or unenforceable, or might be required to transfer ownership or commercial benefits that have been or will be obtained.

B. Ex-Ante Verification and Ex-Post Tracking of Certifications

181. Others have noted the complexities involved in verifying that certificates of origin correspond to the genetic resources being certified, initially and at later times, particularly in regard to derivative genetic materials.²⁷⁵ These concerns have particular relevance to certificates of origin relied upon to document compliance with access and benefit sharing requirements when applying for intellectual property. Certificates of origin thus may need to provide traceability of the genetic resources and associated traditional knowledge in question from the source providing such inputs through and including development of the subject matter of the intellectual property application and any granted rights and privileges.²⁷⁶ Without such traceability, it may be difficult to determine whether disclosures of certificates of origin are required and to verify that the certifications correspond in the relevant ways disclosed to the subject matter of the application.

182. To assure integrity of authorized access and equitable benefit sharing under specified conditions of use, it may be necessary to trace genetic resources and associated traditional knowledge not only from the source to the subject matter of and applicant for the relevant intellectual property, but also to additional uses to which such resources and knowledge may be put (and for which intellectual property applications may not necessarily be sought). For example, genetic resources may lead to the development of subject matter by the applicant, which in turn may lead to the development of additional subject matter by other persons or entities who are not subject to contractual provisions for equitable benefit sharing. Alternatively, the applicant may use genetic resources not

²⁷⁵ See, e.g., WIPO Examination, ¶ 203 (quoting from UNEP/CBD/WG-ABS/3/5, at 18); UNEP/CBD/WG-ABS/3/5, ¶ 94 (discussing “check points” for verifying certificates); UNEP/CBD/WG-ABS/3/7, Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing on the Work of Its Third Meeting, Annex I, at 29 (2005) (discussing, in the context of additional elements and options for an international regime on access and benefit sharing, internationally recognized certificates of legal provenance of genetic resources that employ standardized codes that accompany biological materials and are “passed to all extracts, derivatives, or information”), available at <http://www.biodiv.org/doc/meetings/abs/abswg-03/official/abswg-03-07-en.pdf>; Tom Dedeurwaerdere (CPDR), Sélim Louafi (IDDRI), Carmen Richerzhagen (UNU/IAS), Brendan Tobin (UNU/IAS), *2nd Paris Roundtable on ABS Governance: Roundtable on Practicality, Feasibility and Cost of Certificates of Origin: Workshop Summary*, at 2, 4 (2004) (CPDR/Idri/UNU-IAS Summary) (discussing change in materials covered by certificates due to “processing, breeding and refinement” and whether certification would address the “gene, sample, species, or batch”), available at <http://www.iddri.org/iddri/telecharge/biodiv/workshop-abs.pdf>.

²⁷⁶ See, e.g., Carmen Richerzhagen, United Nations University Institute of Advanced Studies, *Are certificates of origin feasible?, Part 1* (2004) (discussing for certificates of origin the “3 T’s: traceability, transparency, and tractability”), available at <http://www.ias.unu.edu/research/details.cfm/articleID/601>.

only to develop the subjective matter of intellectual property applications, but also additional subject matter for which intellectual property applications are not filed (*e.g.*, trade secrets) that provides unjustified and inequitable commercial benefits.

183. Consideration also should be given to how international certificates of origin relate to the actual *ex post* provision of equitable benefit sharing based on certification of *ex ante* arrangements for such benefit sharing. This is particularly relevant in the context of intellectual property applications, as the premise of such applications is the grant of exclusive rights or privileges that may subsequently result in commercial benefits. Tracing certificates of origin to subsequent conduct, however, may entail substantial levels of effort, administrative burdens, and costs.

C. Authority to Certify

184. As noted by others, prior informed consent and mutually agreed terms for access and benefit sharing may involve, among other things, “research permits, collecting permits, export, and import permits. In most countries, different offices, even different ministries, have the responsibilities for some or all of these permissions. Research on lands managed by local and indigenous communities or on their biodiversity knowledge can require additional agreements (not formal permits, *per se*).”²⁷⁷ Accordingly, obtaining certificates of origin may require interacting with different levels of government and multiple agencies or ministries within each level of government.

185. Certificate of origin may need to differentiate among the types of certifications provided (and the entities authorized to provide them), based on when genetic resources and associated traditional knowledge were acquired. For example, it has been proposed to distinguish between access obtained before the CBD (and its recognition of sovereign rights over genetic resources) and access obtained before and after adoption of CBD access and benefit sharing legislation in the country providing genetic resources.²⁷⁸ This is particularly relevant in regard to *ex-situ* collections and materials provided under the multilateral facilitated access system of the ITPGRFA.²⁷⁹ Additional consideration is needed of how certificates of origin would assist disclosures of origin and demonstrations of compliance with access and benefit sharing requirements in such situations.

²⁷⁷ UNEP/CBD/WG-ABS/3/INF/5, at 27.

²⁷⁸ *See, e.g.*, CPDR/Iddri/UNU-IAS Summary, at 3.

²⁷⁹ Although facilitated access is subject to strict conditions under material transfer agreements that apply to subsequent transfers and either provide for benefit sharing to an international fund or encourage such benefit sharing where products are made available for further breeding, access is supposed to be provided expeditiously “without the need to track individual accessions.” *See* ITPGRFA, Arts. 12.3(b), 12.4, 13.2b(i)&d(ii). Further, although recipients are not supposed to claim intellectual property or other rights or privileges in accessed materials “in the form received,” ITPGRFA, Art. 12.3(d), significant disputes exist regarding application of this provision to isolated and purified genetic sequences. *See, e.g.*, FAO Legal Papers Online #31, *Intellectual Property Rights in Plant Varieties: an Overview with Options for National Governments*, at § 4.3.2.4, available at <http://www.fao.org/Legal/Prs-OL/lpo31.pdf>. Thus, benefits: may flow to the international fund without regard to the country of origin; may not be required to be shared under the ITPGRFA; and may involve materials with a disputed relationship to ITPGRFA restrictions on seeking intellectual property.

186. Particularly given the complexities of determining certification authority and of making appropriate certifications, careful consideration should be given to whether to impose mandatory or facultative requirements to obtain and to disclose certificates of origin in order to meet disclosure of origin obligations. Such evaluations will depend, in part, on the robustness and comprehensiveness of the certificate of origin system and on the degree to which certificates of origin generate the types of information required to be submitted by mandatory disclosure of origin obligations and useful in evaluations within or relevant to the intellectual property system.

D. Confusion, False Certifications, Errors, and Related Concerns

187. International certificates of origin, like other certification documents issued by competent government entities, may be put to numerous commercial uses, in addition to obtaining access to genetic resources and associated traditional knowledge and demonstrating prior informed consent and equitable benefit sharing so as to obtain intellectual property. For example, certification marks and labeling relating to certificates of origin may be useful in promoting commercial recognition of the subject matter of intellectual property and in obtaining benefits for countries and indigenous or local communities exercising rights over genetic resources and associated traditional knowledge. Such uses raise difficult questions regarding what authenticity standards are to be applied.²⁸⁰

188. Certificates of origin also may be subject to false, deceptive, and confusing uses.²⁸¹ As with consumer confusion regarding the “origin, sponsorship, or approval” of goods or services in trademark law,²⁸² relevant persons (including officials in intellectual property offices) may be confused as to the referents of certificates of origin and the authority of the certificate holder to use the certified genetic resources and associated traditional knowledge. Confusion also may result if certificates of origin fail to identify the country of origin and other persons involved, to the extent that such identification may be required to demonstrate the legitimacy of access or equitable benefit sharing. Similarly, confusion may result when multiple countries issue certificates of origin that are in conflict regarding claims of authority to use genetic resources or in regard to the equity of benefit sharing arrangements.

²⁸⁰ See, e.g., Drahos, *International Framework*, at 32-34 (discussing failures to accommodate needs of all indigenous groups and to fund administration of the Indigenous Label of Authenticity and Collaboration Mark adopted by the National Indigenous Arts Advocacy Association of Australia in 1999).

²⁸¹ Cf. Sergio Escudero, *International Protection of Geographical Indications and Developing Countries*, South Centre, Trade-Related Agenda, Development, and Equity Working Paper 10, at 9 (2001) (discussing the Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods of 1891, Art. 1(1) (as revised), requiring seizure of goods bearing a false or deceptive indication of geographical origin), available at <http://www.southcentre.org/publications/workingpapers/paper10/wp10.pdf>; 15 U.S.C. § 1125(a)(1)(B) (United States law prohibiting false designations of origin or misleading designations of fact that misrepresent in commercial advertising the geographic origin of goods, services, or commercial activities)

²⁸² 15 U.S.C. § 1125(a)(1)(A). See 15 U.S.C. § 1114(a) (United States law addressing infringement of registered marks).

189. Concerns regarding the integrity of certificates of origin arise precisely because certifications are valuable to commercial relations and may provide unjustified commercial benefits when they are falsified, contain errors, or are used in a confusing manner. Applicants for certificates of origin may falsify information submitted to certification entities, in order to obtain improper certifications for use in intellectual property applications. Applicants for intellectual property also may falsify certificates of origin themselves.²⁸³ Falsification or other improper uses of certificates of origin may result in improper issuance of intellectual property and other public and private harms, whether or not access to genetic resources and traditional knowledge was authorized and equitable benefit sharing is provided. Even when all parties are acting in good faith, certificates of origin may contain errors.

190. Consideration should be given to assuring the integrity of certificates of origin, to correcting errors of certification, and to deterring, identifying, and punishing false statements and falsified certificates. Existing laws may impose mandatory or facultative consequences within and external to the intellectual property system for errors in certificates of origin that are relied on for disclosures in intellectual property applications. For example, a certificate of origin that failed to name the correct source may result in the failure to name a joint inventor of the subject matter of the intellectual property application. Later discovery of the error might entail any of the following remedies under existing intellectual property laws: correction of inventorship; transfer of ownership; invalidation or unenforceability of the intellectual property; and return or transfer of benefits. Additional consequences within or external to the intellectual property law system might be imposed, including administrative fines, civil liability, and criminal penalties and imposing additional benefit sharing obligations. Flexibility may be needed to differentiate the consequences various types of such certification errors.

191. Finally, consideration should be given to whether and how ownership of certificates of origin can be transferred. For example, in the United States, trademarks cannot be assigned separately from the goodwill that the trademarks signify.²⁸⁴ Certificates of origin may need to apply to and be transferred with the relevant genetic resources and associated traditional knowledge.²⁸⁵ It may not make sense to permit the transfer of ownership in certificates of origin separately from the relevant genetic resources and associated traditional knowledge.

²⁸³ See, e.g., CPDR/Iddri/UNU-IAS Summary, at 2 (discussing authorized signatures/seals, special paper or stamps, electronic systems, and security issues).

²⁸⁴ See, e.g., Thomas J. McCarthy, *Trademarks and Unfair Competition*, § 18.2 (2005) (citing U.S. cases).

²⁸⁵ See, e.g., UNEP/CBD/WG-ABS/3/7, at 29 (discussing passing certification codes to extracts, derivatives, and knowledge); UNEP/CBD/WG-ABS/3/INF/5, at 46 Fig. 4 (providing flow diagram of material entering and leaving biological resource centers).

Conclusion

192. In summary, there is a need for new international treaty provisions that would mandate disclosures of origin requirements in regard to applications for intellectual property. The most appropriate treaty regime to adopt such requirements is the TRIPS Agreement. Numerous benefits would be provided by disclosure of origin requirements, although care should be taken to minimize the administrative costs and burdens of implementation. The treaty provisions will need to specify the substantive and procedural triggers for making required disclosures, the types and timing of evaluations to be performed with disclosed information, the mandatory or facultative consequences of various types of disclosure failures, and whether to mandate or facilitate use of international certificates of origin in making required disclosures. Although disclosure of origin requirements are consistent with existing intellectual property treaties, such requirements may be facilitated by revising existing rules, forms, and procedures implementing those treaties.

193. Additional research and evaluation regarding the following issues would help to inform policy choices regarding the contents of mandatory disclosure of origin requirements:

- existing national laws addressing the relationship between misappropriation of genetic resources or traditional knowledge, and their effect on the validity of or entitlement to own or retain benefits from intellectual property; and
- applicable legal principles for the recognition and enforcement of existing national access and benefit sharing laws and contractual provisions imposing disclosure of origin requirements, and their relation to intellectual property laws.
