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**ANALYSIS OF OPTIONS FOR
IMPLEMENTING DISCLOSURE OF ORIGIN
REQUIREMENTS IN INTELLECTUAL
PROPERTY APPLICATIONS**

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



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

Joshua D. Sarnoff

Assistant Director, Glushko-Samuelsan Intellectual Property Law Clinic, and
Practitioner-in-Residence, Washington College of Law,
American University, Washington, DC

Carlos M. Correa

Director of the Centro de Estudios Interdisciplinarios de
Derecho Industrial y Económico (CEIDIE),
Faculty of Law and Social Sciences,
University of Buenos Aires, Buenos Aires

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Executive Summary

A. Background to the CBD invitation to UNCTAD

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 disclosure of the country of origin of genetic resources and of associated traditional knowledge in applications for intellectual property where the subject matter of the application concerns or makes use of such knowledge in its development. Since 2002, various proposals to facilitate or to mandate such “disclosure of origin” requirements within the world intellectual property law 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 analyse issues relating to implementation of disclosure of origin requirements in the intellectual property law system.

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.

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 discussions on the topics identified above. It builds upon prior analyses of these issues by the authors, by WIPO, by various countries, and in a growing body of literature.

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 defines the scope of the analysis and the terminology used therein. The discussion of terminology is important, both to assure a common understanding and to achieve clarity.

The introduction is followed by a five additional sections that address the topics identified by the CBD COP. Part II 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, as well as the choice of treaty regime in which to adopt disclosure requirements. Part III examines in greater depth the options relating to substantive and procedural triggers for disclosure requirements. Part IV addresses incentives for enforcement of disclosure obligations that are internal to the intellectual property law system. Part V discusses 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 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 VI analyses 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

The remainder of this executive summary provides a brief overview of the most significant issues and conclusions of the analysis. It briefly reviews the issues addressed and the conclusions of the introduction and of parts II to VI, with a view to facilitating an understanding of the detailed text.

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, in many others where intellectual property may be sought such requirements have yet to be adopted. Thus new international treaty provisions are required to assure worldwide implementation of disclosure of origin requirements.

Objections raised to mandating adoption of disclosure of origin 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, in providing greater certainty as to the validity of granted rights or privileges, and in reducing the need for revocation of improperly granted intellectual property;

- (b) May assist in identifying situations and facilitating 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 as a consequence 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 for 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 must provide authority to deny entitlements to apply for, own or enforce intellectual property. Similarly, they must provide authority to permit national intellectual property offices to delay processing of intellectual property applications or to consider such applications withdrawn when required information is not provided in a timely manner. 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 rectify disclosure failures should be provided, and remedies tailored to the scope and nature of the disclosure failures.

Scope of the analysis.

This analysis focuses on the concerns raised by the CBD with regard to disclosure of origin requirements in intellectual property applications. Although the Convention broadly concerns genetic resources, biological materials and biological diversity, the access and benefit-sharing requirements of Article 15 address only genetic resources. Accordingly, this analysis focuses on disclosure of origin requirements for 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's Article 8(j) directly addresses for purposes of equitable benefit-sharing only that body of traditional knowledge that is 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, this analysis focuses on traditional knowledge that is associated with genetic resources. Nevertheless, the principles discussed here may have relevance for biological materials other than genetic resources and for other forms of traditional knowledge that relate to the subject matter of intellectual property applications.

Terminology.

Many of the terms associated with disclosure of origin requirements relating to genetic resources and traditional knowledge have no standard definitions. Yet 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. In order to provide greater clarity, this analysis defines several key terms using definitions that 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 that possesses the relevant genetic resources in *in-situ* conditions, even if a country of origin is not the country where the genetic resources historically originated. There may be many countries of origin.
- (c) The **country providing genetic resources** means the country 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 either possess or 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 to ensure that the source or other relevant persons involved will receive an equitable share of benefits arising from the use of genetic resources. Authority is used here to define a legal condition, rather than to refer to a government entity (administrative or judicial) that determines whether access under specified conditions is permitted or prohibited.
- (f) **Legal provenance** means possession of or other 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 deriving benefits without equitable benefit-sharing.
- (i) **Traditional knowledge** means knowledge, innovations and practices of indigenous or local communities associated with genetic resources.
- (j) **Intellectual property applications** means applications relating to intangible subject matter that require some government 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 genetic resources and associated traditional knowledge under specified conditions and in the absence of misappropriation. Certificate of origin thus corresponds to common uses of the terms certificate of source and certificate of legal provenance. Monitoring may be needed to assure *ex-post* compliance with certificates of origin once they are issued.

Options for model provisions for disclosure of origin requirements

Principles relating to the recognition and enforcement of foreign laws may already 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

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