

Informal summary:

First Draft Examination of Issues relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications

(referring to the draft text of January 31, 2005, available at <http://www.wipo.int/tk/en/genetic/proposals/index.html>)

This *informal summary* has been prepared at the suggestion of several participants at the third meeting of the CBD Ad Hoc Open-ended Working Group on Access and Benefit Sharing. It does not have official status and is only provided as an informal aid to analysing the materials on disclosure requirement that under development.

What's at issue? One objective of the Convention on Biological Diversity (CBD) is the equitable sharing of benefits from the use of genetic resources; the CBD also contains important provisions on respect for traditional knowledge (TK) related to biodiversity and equitable benefit sharing from the use of such knowledge. Various countries and stakeholders such as custodians of genetic resources and TK have expressed concern that intellectual property (IP) rights, particularly patents, have either been exerted over genetic resources and TK, or are granted on inventions that make use of genetic resources or TK without complying with CBD requirements on access and equitable benefit-sharing. This has led to a debate about whether, and if so how, the patent system can and should be reformed to increase the likelihood that a person using genetic resources and associated TK is complying with regulations on access and benefit-sharing. One particular concern has been that it is often in developed countries that genetic resources are used for technological and industrial advantage, and patents are mostly filed in those countries; whereas the bulk of the world's biodiversity and much of its TK resides in developing countries.

This debate has focussed on some specific proposals that international patent standards be amended to allow, or to require, patent authorities to impose conditions on patent applicants that relate to access to genetic resources and TK, and equitable sharing of benefits from their use. The proposed measures would vary in their scope and effect. Often termed 'disclosure requirements,' they focus on possible obligations for patent applicants to disclose information about genetic resources or TK used in a claimed invention. Some proposals would simply require patent applicants to disclose where they obtained genetic resources or TK they used in the invention. Others would be more rigorous, and require disclosure of the legal circumstances – such as whether genetic resources were obtained with prior informed consent, and whether arrangements had been concluded for equitable sharing of benefits. The legal implications of the proposals vary – some simply suggest that applicants be encouraged to make this information available, while others propose more rigorous effects, ranging from suspension or refusal of an application, invalidation of a patent, or transfer of ownership of the patent. Within the range of proposals, no one single model has emerged, and several have already been applied in some countries' national laws. Some countries and other stakeholders have questioned the value of any such measure, suggesting that alternative approaches are more appropriate to ensuring compliance with access and benefit-sharing regulations.

Context: WIPO has recently circulated an initial draft “Examination of Issues relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications” (the first draft examination, document WIPO/IP/GR/05/01). This represents one step in a series of WIPO activities on this topic in cooperation and dialogue with the CBD. It flows directly from an invitation from the Conference of Parties (COP) for WIPO to examine, and, where appropriate, address issues relating to access to genetic resources and disclosure requirements in intellectual property applications. Previous invitations to WIPO from the CBD led to the preparation of a technical study on this issue (WIPO publication, also available in six languages), and an array of complementary work on access and benefit-sharing issues. The CBD invitation recalls the need to ensure that the work is supportive of and does not run counter to the objectives of the CBD. The invitation also proposes that the CBD continue to provide further information to WIPO for its consideration “in the spirit of mutual supportiveness.”

What next? The WIPO General Assembly agreed on a timetable to respond to the most recent CBD invitation. This provides for a commenting period on this initial draft, followed by the preparation of a second draft, and a one-day meeting to consider the issues, before a further draft is put to the WIPO General Assembly in September. At that point, the Assembly would make a decision about transmitting this material to the CBD COP, in time for its next meeting in 2006. WIPO Member States and observers can submit comments on this initial draft up to the end of March 2005 – preferably to disclosure@wipo.int

Overview: The initial draft of the examination suggests that its status should be as a technical reference document only, and not an official position on the part of WIPO or its Member States. That said, the contents of the examination are drawn mostly from submissions by Member States, from the existing Technical Study, and from various proposals and laws of WIPO Member States. The examination is structured as follows:

Part I – An introduction, which sets out the context and background of the draft examination and the COP invitation that led to it, and sets this work in the context of continuing WIPO cooperation with the CBD.

Part II – An overview of existing proposals and mechanisms, which surveys a range of relevant legal provisions and proposals made at the international, regional and national levels. This includes a brief discussion of the state of play of relevant WIPO processes, including on the Patent Cooperation Treaty (PCT) and the work of the Standing Committee on Patent Law (SCP) on substantive patent harmonization.

Part III – Provides a technical and legal background, which simply summarizes the existing WIPO Technical Study and sets out a checklist of issues that is being used in discussions on these issues in the WTO TRIPS Council.

Part IV – Provides information on the five specific issues that the COP invitation raise, namely (a) model provisions; (b) trigger mechanisms; (c) incentives; (d) treaty implications; and (e) implications of certification. This part draws mainly on the submissions by Member States, the material set out above, the Technical Study and several other studies.

Contents: The initial draft examination is just that – an initial draft, more a framework for development of the document. Given the process set up to comment on and further develop the text, there are likely to be significant changes in its structure and content. Even so, the initial draft attempts to provide a summary of the main points under each item to assist in discussion. A further summary of this material is briefly provided here – with the caution that this do not attempt to express the full range of views and approaches that are relevant, and should not be treated as official or comprehensive.

On terminology: the examination notes that the term “disclosure requirements” is frequently used to express legal mechanisms that go beyond the simple disclosure of information as such, and can have substantial implications for example affecting the eligibility of a patent for protection, and the entitlement of an applicant to apply for, hold or enforce a patent.

On subject matter: The examination also points to the potential implications of different terms, such as genetic resources, as against biological material or resources, and traditional knowledge, as against TK relevant to the conservation of biological diversity. ‘Genetic resources’ and ‘biological materials’ are defined in the CBD – to avoid prejudging the scope of disclosure requirements, the study uses the abbreviation ‘GBMR’ to refer to all possible categories. ‘Traditional knowledge’ doesn’t have a set international definition, so the study refers to a definition currently under consideration by the WIPO IGC. Article 8(j) of the CBD refers to certain biodiversity-related knowledge, knowledge, innovations and practices of indigenous and local communities.

On *options for model provisions*, the examination covers the form or status of model provisions, and ways of classifying possible content of such provisions.

The form or status could include provisions for practical guidance, non-binding recommendations, provisions that serve to illustrate the range of options available for national legislation, provisions that serve to illustrate the range of options available for international debate, policy coordination or textual negotiations, or draft provisions intended to serve as the basis for coordination and negotiation on a future binding legal instrument or provisions within a revised international legal instrument. Other options could depend on the purpose of the model provisions. A key concern is that the development or promulgation of any model provisions should not prejudice the position or interests of Member States.

The content of the options could be classified according to the nature of mechanism, the subject matter of disclosure, the required linkage with claimed or patented invention (or substantive trigger), the procedural trigger for disclosure requirement, the legal principle forming the basis of the requirement, the nature of the obligation on the applicant, the consequences of failure to comply and incentives to comply, and the means of implementing, verifying or monitoring the requirement. The following table was developed to illustrate some of these options. This table aims to summarize information and is not intended to interpret, limit or promote any particular mechanism.

On possible *substantive triggers* for disclosure (i.e. the required link to a genetic resource that would trigger a requirement), some draw on or adapt existing patent law principles:

(a) access to the GBMR is necessary to carry out or replicate the invention as claimed; (b) access to the GBMR is necessary to implement the preferred embodiment of the invention or other example given in the description of the patent; (c) the TK is prior art, known to the applicant, which is relevant to the assessment of whether the invention as claimed is novel and not obvious; (d) TK was provided by a TK holder and is directly used in developing the invention, to the extent that the TK holder is a potential co-inventor; (e) the circumstances of access to the GBMR or TK are sufficient to establish a claim of ownership or entitlement to apply for a patent.

Other substantive linkages go beyond existing patent law principles: (a) the invention makes immediate use of the genetic resource, that is, it depends on the specific properties of the resource (in particular, the functional units of heredity and the actual or potential value that define it as a genetic resource); (b) the GBMR or TK were used in the course of research that led to the invention, and were essential to deriving the invention; (c) the GBMR or TK were used in the course of research leading to the invention, but were only incidental to the attainment of the invention; (d) the GBMR or TK forms part of the claimed invention; (e) the GBMR or TK was a necessary prerequisite for the development of the invention; (f) the GBMR or TK was used to facilitate the development of the invention; (g) the GBMR or TK was necessary background material for the development of the invention; (h) the research leading to the invention, the attainment of the invention itself, or the act of filing the patent application, falls within the scope of an obligation incurred under a national biodiversity law or other access legislation, or under a specific access permit, licence, agreement or contract.

The *procedural trigger* creating an obligation for disclosure may in theory include: (a) initial filing of the application (a minimum documentation requirement); (b) a specific deadline after filing the application; (c) formal examination of the application; (d) substantive examination; (e) prior to grant or sealing of the patent; (f) during patent opposition or revocation proceedings (including counterclaims during enforcement proceedings); or (g) when the patent right is asserted or enforced.

On incentive measures, the examination notes that incentives may be legal, economic, social and moral, and may be positive, negative or perverse. The behaviour that may be encouraged by incentives included

- conservation and sustainable use of genetic resources, and conservation of TK
- equitable sharing of benefits
- obtaining prior informed consent
- confidence in equitable basis for sharing TK or GBMR
- greater cooperation and partnership with custodians of TK and GBMR
- innovation related to conservation and sustainable use
- compliance with laws or contractual obligations in country of origin
- conformity with guidelines or other standards
- incentives to disclose new information to the public.

Positive incentives could include the following:

- benefits an applicant obtains from greater legal security concerning the legitimacy of the application and granted patent

- enhanced and less burdensome avenues for further cooperation and access
- enhanced basis for dealing with the patented technology
- reduced fees
- recognition that an invention is biodiversity-friendly
- benefits from a positive public perception concerning the use of the GBMR or

TK

Negative incentives could include:

- fines, imprisonment or criminal penalties for false declarations
- refusal or invalidation of patent, or incapacity to enforce patent rights
- full or partial transfer of ownership of patent
- applicant's original use of GBMR or TK would infringe the patent once ownership transferred

"Perverse" or undesirable incentives could include:

- discouraging disclosure of invention through patent system, favouring use of trade secrets
- discouraging sustainable use of GR
- invalidation leading to more widespread use of invention by third parties, without equitable benefit-sharing with provider
- costs of legal unpredictability or uncertainty
- disclosure of exact origin prejudicial to conservation of rare but valuable species
- disclosure of secret or sacred TK that is constrained by customary law or confidentiality constraints

On *implications for WIPO-administered treaties*, the examination reviews the Paris Convention (provisions concerning the right of the inventor to be mentioned as such in a patent, the independence of patents and national treatment); and the PCT and PLT (provisions concerning documentation and formal requirements, potentially also concerning requirements for evidence of entitlement to apply; no effect on substantive conditions of patentability). It also notes that there are current relevant proposals concerning the SPLT and revisions to the PCT Regulations.

On IP-related issues concerning certification of genetic resources, the examination recalls that the COP decision identified a specific role for the Working Group on Access and Benefit-Sharing in providing information on this issue in particular. It notes that certification (e.g. proposed international certificate of origin/source/legal provenance) may be relevant in:

- establishing factual or legal circumstances of access to the GBMR or TK;
- providing prima facie evidence for national authorities that relevant laws of a foreign jurisdiction have been complied with within that distinct jurisdiction
- providing information for monitoring purposes

- complying with any obligation to provide evidence or documentation relating to the obtaining of GBMR or TK

Other issues relating to certification also include:

- substantive or formality requirements relating to certification
- “enablement” or other procedures relating to the disclosure of inventions which involve the use of certain GBMR, where documentation provides information on the deposit of microorganisms or GBMR more generally.

ILLUSTRATIVE TABLE OF OPTIONS FOR DISCLOSURE AND RELATED MECHANISMS*

Nature of mechanism	Subject matter	Linkage with invention	Legal basis	Nature of obligation	Consequences of failure	Implementation
Acknowledgement of inventorship	Traditional knowledge	Part or entirety of the claimed inventive concept	Entitlement to apply derived from actual inventor(s); Paris Convention obligation to identify inventor	If TK holder contributes to claimed inventive concept, requirement to disclose identity. Possible requirement to identify TK holder as co-applicant/co-owner, or as sole applicant/owner.	Application may be refused	Office may request further information in the event prima facie doubt exists re identity of inventor Administrative or judicial proceedings for opposition, revocation or full/partial transfer of patent to TK holder
Declaration of TK as relevant prior art	Traditional knowledge that meets legal criteria for prior art [and that is known to applicant]	Relevant to the patentability of the claimed invention (e.g. novelty and inventiveness/non-obviousness)	Patentability of invention includes novelty and inventive step (or non-obviousness). Obligation to inform office of known relevant information.	Applicant is obliged to disclose all known prior art relevant to patentability of claimed invention, including traditional knowledge.	“Fraud on the office” or similar offence; sanctions for inequitable behaviour; Failure to disclose known TK may render patent unenforceable.	Failure to disclose may become apparent during examination or enforcement of patent, or in opposition or revocation proceedings
Definition of prior art	Traditional knowledge	TK explicitly designated as prior art that vitiates novelty and/or non-obviousness	Clarification of existing law of patentable inventions	Invention must be novel and non-obvious	Claims may be narrowed, refused or revoked.	Relevant to examination, opposition or revocation proceedings.
Definition of patentable invention	Traditional knowledge and/or GBMR	Invention cannot consist of existing TK or certain GBMR	Law defining scope of patentable subject matter	Claimed invention must fall within permitted subject matter	Claims may be narrowed, refused or revoked.	Relevant to examination, opposition or revocation proceedings.

* PLEASE NOTE: This table is to illustrate mechanisms that have been discussed or proposed. It is not intended to suggest, interpret or promote any particular mechanism, nor to limit choices available. It does not imply that any specific choice is consistent or otherwise with treaty obligations.

Sources: Member State submissions and responses to WIPO/GRTKF/IC/Q.3, Technical Study, and measures in Part II above.

Nature of mechanism	Subject matter	Linkage with invention	Legal basis	Nature of obligation	Consequences of failure	Implementation
Specific disclosure of TK or GBMR, or related ABS-compliance measure	<p>(i) TK (ii) TK associated with GR (iii) genetic resources (iv) biological resources and/or (v) biological material</p> <p>Where (i) source/origin of TK/GR is already known to applicant; or (ii) applicant can determine its source/origin through reasonable effort; or (iii) TK/GR is not subject to any such qualification]</p> <p>TK/GR may be in public domain [or may be hitherto undisclosed]</p>	<p>Invention (i) directly based on TK/GBMR (ii) [essentially] derived from TK or GBMR (iii) uses biological material (iv) makes immediate use of GR (depends on its specific properties) (v) resulted from research using GBMR or TK, which were</p> <ul style="list-style-type: none"> - essential/necessary - incidental - necessary <p>to deriving the invention (vi) partly or entirely comprises TK/GBMR</p> <p>or there is an obligation or responsibility under ABS law, regulation, permit, licence or agreement relating to TK or GBMR that covers</p> <ul style="list-style-type: none"> (i) the research or related activities that lead to the invention, or (ii) the attainment of the invention, or (iii) the act of filing for patent on the invention. 	<p>Compliance with ABS laws in the country of origin, with the terms of an ABS licence or permit, or with specific contractual obligations to provider of GBMR or TK.</p> <p>Ownership rights established on the basis of an ABS law or specific ABS agreement.</p> <p>Expanded conception of patent law disclosure principles.</p> <p>Principles governing equitable behaviour.</p>	<p>Patent applicant is obliged to:</p> <ul style="list-style-type: none"> (i) disclose the origin or source of the GBMR or TK (ii) provide a declaration, evidence or certification of prior informed consent relating to access (iii) provide a declaration, evidence or certification of an agreement to share benefits, or of actual sharing of benefits and/or used in invention are legitimately sources (v) ensure applicant has derived proper title from the inventor and third party interests (e.g. provider of TK or GBMR) are reflected in identification of applicant. 	<ul style="list-style-type: none"> (i) Application considered incomplete upon filing without required declaration or documentation (ii) Application rejected during formality examination (with/without procedure for rectifying) (iii) Application rejected during substantive examination (with/without procedure for rectifying) (iv) Patent not granted or sealed until/unless required material is provided (v) Patent opposed or revoked if required material is lacking. (vi) Patent ownership transferred in whole/in part to beneficiary of ABS law or agreement. (vii) Patent is not enforceable on basis of equity. 	<ul style="list-style-type: none"> (i) routine step during formal/substantive examination (ii) grounds for opposition, revocation, or unenforceability of patent (iii) basis for claim of assignment or transfer of patent in whole or part to ABS beneficiary.

Nature of mechanism	Subject matter	Linkage with invention	Legal basis	Nature of obligation	Consequences of failure	Implementation
Obligation outside patent law to disclose details of access/use, or to cede/share ownership	GBMR and/or TK provided under an ABS or related law, or within the terms of a specific ABS agreement.	Defined by obligations under the ABS or related law, or the specific ABS agreement.	ABS or related law in country of origin Contract obligation in country of origin, to be recognized in patenting country.	Obligation to disclose TK or GMRM Obligation to include ABS beneficiary as applicant or co-applicant	Breach of obligation under law or contract Transfer of ownership in whole or part.	Counterclaim during patent enforcement Challenge by interested party
Deposit of microorganisms or biological material	Microorganisms, or biological material	Relevant to patent procedure (e.g. invention cannot be fully disclosed or enabled without access to microorganism or biological material)	Obligation to disclose invention under basic patent law principles cannot be fulfilled without deposit of actual sample. Budapest Treaty arrangements for international recognition of deposit.	Disclosure of actual sample; Provision of certification regarding deposit to patent authorities.	Patent may be found inadequately disclosed, resulting in	Certification provided during patent procedure.