National Group: US Group

Date: April 7, 2010

Questionnaire February 2010

Special Committees Q 94 – WTO/TRIPS and Q166 – Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

on the

Requirement of indicating the source and/or country of origin of genetic resources and traditional knowledge in patent applications

Introduction

The United States has not become a party to the Convention on Biological Diversity. No pending legislation exists that would alter that status. The answers of the US group are not substantively different from the answers submitted in July 2006.

Questions

1) *Is there a legal requirement in your country that the source and/or country of origin of biological/genetic resources and traditional knowledge must be indicated in patent applications for inventions based on such biological/genetic resources or traditional knowledge?*

No. In the United States, there is no requirement to disclose the source or origin of genetic resources or associated traditional knowledge (GR/TK), whether in relation to the access and benefit sharing goals of the Convention on Biological Diversity (CBD), or otherwise.

To the extent that there is any requirement to disclose information regarding a genetic resource, it arises only as a consequence of application of the generally-defined requirements of patentability, e.g., novelty, non-obviousness, written description, and enablement.

For example, information regarding a genetic resource may be necessary to meet the requirement for adequate disclosure under 35 U.S.C. §112, first paragraph if access to samples of the genetic resource is necessary to practice the claimed invention without undue experimentation, to demonstrate possession of the claimed invention, or to disclose the best mode known of practicing the invention at the time the application was filed. However, even in this case, there is no requirement to disclose the country of origin. There is only a requirement to provide access to the resource.

If the claimed invention does not require any information related to the genetic resource (including a genetic resource that may have been used somehow in the course of developing the invention) in order to meet the disclosure requirements of §112, no additional disclosure is needed. Thus, whether there is a need to disclose information regarding a genetic resource will depend on the particular facts and circumstances of each application.

An applicant may provide an adequate description of a genetic resource by a number of means. One would be to describe the physical characteristics of genetic resource by reference to objective, physical properties of the resource (e.g., structure, characteristics, etc). A second would be to provide a deposit of the genetic resource in a public depository, or refer to a prior deposit of the material. Finally, one could identify a location from which samples of the biological resource may be reliably obtained.

Thus, to the extent that any obligation exists under U.S. patent law standards to identify a location from which samples of the biological material can be obtained, that obligation can be satisfied by providing a description of any location from which samples of the genetic resource can be obtained. In most instances where access to samples of a disclosed biological material is necessary, that obligation can be most efficiently discharged by providing a deposit of the material in a recognized depository institution, such as the American Type Culture Collection (ATCC).

The U.S. patent law does not require a disclosure of the genetic or evolutionary “origin” of a genetic resource in any circumstance, as such information is not necessary to identify where one of skill could go to obtain a sample of the genetic resource. In other words, to

the extent that there is any “disclosure” obligation under the general U.S. patent law with regard to a genetic resource in a particular application, that obligation can be met by simply identifying any location from which a sample of the material can be obtained.

If yes, please quote the corresponding text from the law or regulations and reply to the following questions, if applicable:

No. There is no independent requirement for disclosure of source/origin of genetic resources or traditional knowledge. As such, there is no context in the U.S. system for this question.

a) *Are these regulations found in patent law, general IP laws or in legislation implementing the Convention on Biological Diversity?*

No, not relevant for the reasons previously stated.

b) *What "triggers" the disclosure requirement, i.e. how close must the relationship of the invention to the biological/genetic resource be to require disclosure?*

No, not relevant for the reasons previously stated.

c) *Is it clear what the concept of “source” or “country of origin” or "country providing the resource", and “based on genetic resource/traditional knowledge” or "derived from biological resource and associated traditional knowledge” means and what information must be included in the patent application?*

No. We are not aware of a consistent or coherent definition of “source,” “country of origin,” or “based on genetic resource/traditional knowledge.” None of these terms is explicitly defined in the Convention on Biological Diversity (CBD), especially with regard to informing patent applicants as to the type of information that must be supplied, when or how extensive such information must be set forth in a patent application. As noted above, these concepts of source/origin are not requirements of the U.S. law, so there are no corresponding definitions of the terms.

Under 35 U.S.C. §112, as explained above, an invention must be sufficiently described and enabled in the patent application. Section 112, however, is not concerned with or defined in reference to concepts of “source” or “origin.” These terms simply are not used in the U.S. patent law.

d) Is the disclosure requirement limited to biological/genetic resources or traditional knowledge of your country only or is it applicable also to biological/genetic resources or traditional knowledge obtained or obtainable from other countries and geographical areas?

No, not relevant for the reasons previously stated.

e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing?

No, not relevant for the reasons previously stated.

f) Is disclosure of "prior informed consent" and/or agreements on "fair and equitable benefit-sharing" required?

No. Disclosure of the existence of prior informed consent and/or agreements regarding benefit sharing are entirely irrelevant to the question of compliance with the disclosure requirements of §112, or other patentability criteria in the US system.

g) Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD?

As indicated above, disclosure concepts are not relevant to, nor are they found in, U.S. standards relating to adequacy of disclosures or other substantive patentability criteria.

h) Is traditional knowledge properly defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources (e.g. falling under the CBD) or in general?

As noted above, there are no requirements in the U.S. patent system pertaining to genetic resources or traditional knowledge. Accordingly, there is no definition in the U.S. patent law concerning "traditional knowledge." Information that may embody traditional knowledge, if publicly known in the US or published anywhere in the world prior to the effective filing date of the patent application, would be part of the prior art.

i) *Are sanctions foreseen for non-compliance (e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.)?*

No, not relevant for the reasons previously stated.

j) *Does the law/regulation indicate that access to a genetic/biological resource would not mandate a disclosure in the patent application, if such access had occurred prior to a particular date, e.g. prior to the date of entry into force of the CBD?*

No, not relevant for the reasons previously stated.

2) *Please indicate your* experience *with the application of the legal requirement as listed under 1) when filing and prosecuting patent applications in your country.*

No, not relevant for the reasons previously stated.

3) *Please give statistical data on the number of applications mentioning source and/or country of origin of genetic resources and/or traditional knowledge, following the legal requirement as listed under 1) in your country. If such data are not available, please give an estimate of the number of such applications.*

No such data is available for the reasons stated.

4) *Please indicate whether administrative or judicial decisions on the application of the legal requirement as listed under 1) are available. If yes, please provide the text of such decisions.*

There are no administrative or judicial decisions on the application of the legal requirement as listed under 1) because there is no legal requirement for mentioning source and/or country of genetic resources and/or traditional knowledge in the US.

5) *If there is no legal requirement of indicating the source and/or country of origin of genetic resources and/or traditional knowledge in patent applications for inventions based on such genetic resources or traditional knowledge in your country: Do you know of any project of law in your country dealing with the topic? If yes please provide the corresponding text and*

review it for the questions a) to i) as under 1). Please include also links to websites which would allow us to follow the progress on these projects of law.

No.

While the United States has been monitoring the proposals that have been made in a variety of fora to allow or mandate that national patent legislation require the declaration of the source of genetic resources and traditional knowledge in patent applications as well as demands for sharing of benefits from the commercialization of products utilizing them, the US government, with the strong support of US companies, has taken the position that these initiatives are unwise and unnecessary. There are no pending bills or discussions that would suggest that legislation will be introduced on these issues within the United States. It should also be noted that the United States is not a party to the Convention on Biological Diversity, and no pending legislation exists that would alter that status.