

National Group: AIPPI Malaysian Chapter

Contributors: Zaraihan Shaari

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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

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?

CURRENTLY THERE IS NO SUCH LEGAL REQUIREMENT IN MALAYSIA.

- 2) If yes, please quote the corresponding text from the law or regulations and reply to the following questions, if applicable:
 - a) Are these regulations found in patent law, general IP laws or in legislation implementing the Convention on Biological Diversity?
 - 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?
 - 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?

- 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?
- e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing?
- f) Is disclosure of “prior informed consent” and/or agreements on “fair and equitable benefit-sharing” required?
- g) Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD?
- 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?
- 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.)?
- 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?

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.

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.

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.

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.

A BILL ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING IS BEING DRAFTED IN MALAYSIA. THIS IS CURRENTLY UNDER THE PURVIEW OF THE MALAYSIAN MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT (www.nre.gov.my).

Procedure

It would be most helpful if the National Groups would fill out the Questionnaire and send in their answers to the General Secretariat of AIPPI by **12 March 2010** to:

f.martin@aippi.org

Please use a separate sheet for indicating your answers or include the answer in the present text at the end of each question.

For inquiries, please contact any of the chairs of Q94 and Q166:

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