

**National Group:** [P.R.CHINA]

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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? 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?

[In Third-amended Patent Law of China, Article 26\(5\) reads:](#)

[Both direct source and original source of genetic resources that the achievement of invention is relied on should be disclosed in the application documents.](#)

- 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?

Under the new Patent Law, "an invention achieved relying on genetic resources" refers to an invention the achievement of which utilizes the genetic function of genetic resources, and in more details, means that genetic function units are isolated, analyzed, treated and so on, so as to complete the invention and realize the value of the genetic resources.

More specifically, the term "genetic resources" refers to materials of human, animal, plant or microbial origin containing genetic function unit and having actual or potential values. Such materials are further interpreted to mean carriers of genetic function units, including not only the whole organism but also some parts of an organism, such as organs, tissues, blood, humor, cells, genomes, genes, DNA or RNA fragments, etc. The term "genetic function unit" refers to a gene or a DNA or RNA fragment with genetic function of an organism. The term "genetic function" refers to the capability of an organism to pass down a trait or characteristic to its offspring through propagation or to replicate the whole organism.

- 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?

According to Guidelines for Examination 2010, said "Direct Source" of said genetic resource refers to the immediate upstream source for obtaining said genetic resource, and information of time, place, and measures for obtaining said genetic resources as well as name of provider should be disclosed in the application documents.

According to Guidelines for Examination 2010, said "Original Source" of said genetic resource refers to collection place in the original environment of the living body that said genetic resource belongs to. While said living body is growing naturally, said original environment is environment it naturally grows; and while said living body is incubated or domesticated, said original environment is environment where specific trait or characters is formed.

- 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 limitation to the source is specifically stipulated in the Article 26(5) of Patent Law. According to our understanding, genetic resources that obtained from either China or other countries/geographical areas should be disclosed as long as it is relied on for the achievement of invention.

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

The applicant may voluntarily disclose said source by filing and submitting the Registration Form for Disclosing the Sources of Genetic Resource(s) at any time during the whole prosecution of the application (e.g., when filing an application in China or entering Chinese national phase) on its own initiative, or wait until receiving a notification from the Chinese Patent Office requesting the FORM during examination stage.

However, so far we have no information/indication but wait for examination practice of SIPO whether said corresponding text in the FORM could be corrected or amended after filing.

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

In Article 5(2) of Patent Law, it only stipulated that patent right should not be granted when obtaining and/or utilizing genetic resources violates the law and/or administrative regulation. However, it implies that Prior Informed Consent and/or agreements on Fair and Equitable Benefit-sharing is still required as long as relevant Law or regulations for obtaining/utilizing said genetic resource is stipulated or required.

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

N/A

- 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?

N/A

- 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.)?

Non-compliance of Article 5(2) of new Patent Law, the patent could be either rejected during substantive examination or invalidated after issuance.

Failing to meet requirement of disclosing source of genetic resources could only be rejected during substantive examination, which is not a reason for invalidating a patent under current Law.

- 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?

N/A

**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.

Due to the fact that new Patent Law comes into force since last October, most of patent applications that the new stipulation is applicable have not entered into substantive examination stage up to now. Therefore, we have to wait and see the real effect on patent filing and prosecution at present.

Currently, our client is recommended not to file the FORM at the time of filing and wait until receiving a notification from the Chinese Patent Office requesting the same during examination stage.

**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.

Actually, no statistical data from SIPO is available at present. According to our understanding, less than one hundred applicants had filled and submitted the FORM when filing or national phase entering of his patent application before SIPO.

**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.

N/A

**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.

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