



National Group: The Egyptian National Group

Contributors: Mrs. Hoda A. Serageldine and Mr. Samir Hamza

Date: March 09th, 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

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:

Art. 13 of Law No. 82/2002 for the Protection of Intellectual Property Rights specifies in its relevant part:

“If the patent application is related to an invention comprising botanical or animal biological materials, traditional knowledge in connection with medicine, environment, agriculture, industry, crafts, heritage or folklore the inventor shall establish that he has obtained such knowledge from its source in a legitimate way”.

In addition, Art. 3.3 of the Executive Regulations of Law 82/2002 repeat the same provisions. However, it adds to it that the applicant has to submit documentation evidencing that he has obtained such knowledge from its source through a legitimate way in accordance with the laws of the Arab Republic of Egypt.

Furthermore, the standard application form for a patent application includes in case of biotechnology an undertaking to submit within a period of **4** months the information regarding the source(s) of any botanical or animal biological materials, traditional knowledge in connection with medicine, environment, agriculture, industry, crafts, heritage or folklore.

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

These regulations are found in the general IP Laws.

- 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?**

There is no clear definition in the above mentioned legislations of how close the relationship of the invention should be to the biological/ genetic resource 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?**

The concept of "source" or "country of origin" and "based on genetic resource/traditional knowledge" are not clearly explained or defined in the above mentioned articles of the law. The Executive Regulation as well do not define the "documentation" or information to be submitted with the patent application to prove that the applicant has obtained such knowledge from its source through a legitimate way in accordance with the laws of the Arab Republic of Egypt..

- 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?**

The disclosure requirement is not limited to biological/genetic resources or traditional knowledge of our country , it is also applicable to biological/genetic resources or traditional knowledge obtained from other countries and geographical areas

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

There are ways to complement / amend a patent application within 4 months from filing and/or before examination.

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

There are no specific reference in the IP Law and Regulations to disclosure of “prior informed consent” and/or agreements on “sharing of benefits”.

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

Human genetic resources are not patentable at all according to **Article 2** of law 82/2002 for the Protection of Intellectual Property.

<Quote>

Patents shall not be granted for:

- (1) Inventions whose exploitation is likely to be contrary to public order or morality, or prejudicial to the environment, human, animal or plant life and health.
- (2) Discoveries, scientific theories, mathematical methods, programs and schemes.
- (3) Diagnostic, therapeutic and surgical methods for humans and animals.
- (4) Plants and animals, regardless of their rarity or peculiarity, and essentially biological processes for the production of plants or animals, other than microorganisms, non-biological and microbiological processes for the production of plants or animals.
- (5) Organs, tissues, live cells, natural biological substances, nuclear acid and genome

<Unquote>

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?

Traditional knowledge is not defined. The source of traditional knowledge should be indicated in general and not only if it is connected to genetic resources.

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.)?

The patent application will be cancelled for non-compliance with the provisions of art. 3.3 of the Executive Regulations.

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?

The requirement for disclosure of genetic resources in a patent application was only available after the issuance of the IP Law No: 82 /2002 that came into force on June 2002 .

Egypt acceded to the Convention on Biodiversity (CBD) by virtue of Presidential Decree No. 54 for the year 1994.

According to the Egyptian Constitution, any international treaty which is signed by the Government of Egypt and ratified by the Egyptian Parliament becomes part of national legislation from the date of its publication in the Official Gazette. Thus, there is no need for specific legislations and the provisions of the Rio Convention will apply as an Egyptian legislation from that date onwards with no retroactive effect.

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.

From our experience since 2002 to date the application of the legal requirement as regards the disclosure of the source for biological/ genetic resources has only been a **formal requirement**. (i. e.) There is no follow-up on this matter after the patent application has been duly filled and submitted.

To the best of our knowledge, no **data bank** has been created to collect all this important information and no case for the invalidation of a patent on the grounds of non compliance with the requirement of indicating the source and/or country of origin of genetic resources and traditional knowledge in patent applications.

Furthermore, no amendments have been introduced in Law No. 82/2002 to establish a requirement for disclosure of “ prior informed consent” or agreements on “ sharing of benefits”

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.

Not available to date.

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.

Not available to date.

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.

Not available to date.