

National Group: BRAZIL

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**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:**

Yes, there is a legal requirement in Brazil 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. Details are given below in reply to the following questions.

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

As signatory of the CBD, Brazil established the main rules on access to genetic resources and associated traditional knowledge by the issuance of Provisional Measure (PM) 2186-16 of August 23, 2001. Just to clarify, we would like to inform that such Provisional Measure has a status of Law (Federal Statute).

Article 31 of PM 2186/16 sets forth that the granting of any industrial property right over a process or product obtained from genetic material is conditional on obtaining authorization for access from the competent entity, the Council to Manage Genetic Resources (*Conselho de Gestão do Patrimônio Genético* – CGEN), part of the Brazilian Federal Ministry of the Environment.

On November 10, 2006, the Brazilian Ministry of the Environment issued Resolution 23, regulating the way of proving satisfaction of the provision of Art. 31 of PM 2186-16, for purposes of granting patents of invention by the Brazilian Patent and Trademark Office (BPTO). The Resolution determines that the applicant for a patent involving access to a genetic resource or associated traditional knowledge gained as of December 30, 2000 and filed after the Resolution's publication date must declare to the BPTO that the formalities of PM 2186-16 have been satisfied and also must report to the BPTO the number and date of the corresponding Authorization for Access.

There are also Resolutions 207/09, 208/09 and 209/09 (the numbers after the slash mark indicate the year of issuance), issued by BPTO, which set the procedures for patent applications whose subject matter has been obtained from access to Brazilian genetic material or associated traditional knowledge.

Further according to these resolutions, BPTO may issue requirements during the technical examination of the patent application, as necessary to

regularize the application. If these are not met, the application will be shelved.

- 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?**

The Law requires that the number and date of the corresponding Authorization for accessing samples of material deemed to be part of the national genetic resources is declared to BPTO. If there is any doubt that the species used in the invention is considered part of the national genetic resources, it is advisable and prudent to submit a consultation to the CGEN, the entity responsible for granting that authorization. In any event, there are no administrative or judicial decisions yet on specific cases.

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

"Source" or "country of origin" or "country providing the resource": These concepts are not clearly defined in legislation, so there is room for various interpretations.

"Based on genetic resources/traditional knowledge" or "derived from biological resource and associated traditional knowledge": These concepts are also not clearly defined in legislation, so various interpretations are possible depending on the context.

Definitions according to Art. 7 of PM 2186-16:

I – Genetic resources: Information of genetic origin, contained in samples of all or part of a species of plant, fungus, microbe or animal, in the form of molecules and substances originating from the metabolism of living beings and extracts obtained from these organisms, either living or dead, found

under *in situ* conditions, including domesticated species or species maintained in collections *ex situ*, as long as gathered under *in situ* conditions within Brazilian territory, the continental shelf or exclusive economic zone.

II – Associated traditional knowledge: individual or collective information or practice of an indigenous or local community, with real or potential value, associated with a genetic resource.

- 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?**

It is limited to Brazilian genetic resources.

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

The process does not involve correcting or amending the text of the patent application, but rather complement the information about the authorization issued by the CGEN. This information (number and date of the authorization) must, in principle, be supplied in the application. If not, the applicant may complement the application to regularize this formality, by submitting the authorization voluntarily up to the completion of the technical examination, or in response to a requirement issued by BPTO. In the latter case, the time limit for compliance is 60 days, under penalty of shelving of the application, besides other penalties.

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

These documents are obligatory for issuance of the authorization for access to genetic material, which in turn is required for granting the patent application.

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

They are treated differently. Article 3 of PM 2186-16 states that human genetic resources are exempt from its provisions.

- 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?**

Yes, traditional knowledge is properly defined according to PM 2186-16, as indicated above. Further, the source of traditional knowledge is to be indicated only if it is connected to the 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.)?**

Yes, there are sanctions provided for noncompliance. According to BPTO Resolution 207/09, in case of failure to present the information on the origin of the genetic material or associated traditional knowledge, as well as the access authorization details (number and date), in response to an office action issued, the application can be shelved.

Also, according to Art. 30 of PM MP 2186/01-16, if the authorization has not been obtained, the IP rights will be canceled, besides other sanctions, summarized as follows: warning; fine, seizure of samples of genetic resources and instruments used in their collection or processing or the products obtained; suspension of sale of products derived from genetic resources or associated traditional knowledge; partial or complete interdiction or of activities or the intervention in the establishment; suspension of registration, patent, license or authorization; loss or restriction of tax incentives granted by the government; suspension of eligibility for subsidized financing from official development agencies; and prohibition to contract with the government, for up to five years.

Finally, Decree 5459/05 regulates Art. 30 of PM 2186-16, by establishing the procedures for applying the penalties and the amounts of the fines that may be assessed for conduct and activities injurious to national genetic resources or traditional knowledge. The fine can vary from R\$ 10 thousand to R\$ 50 thousand for infractions committed by companies or other legal entities.

- 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 date after which disclosure is mandatory is June 30, 2000, in view of the date of implementation of Articles 1, 8, letter "j", 10, letter "c", 15 and 16, items 3 and 4, 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.**

Members of the Brazilian group of AIPPI has a good experience with the application of the legal requirement as listed under 1) when filing patent applications in Brazil. However, considering the huge backlog the Brazilian PTO is facing, applications in the biotech area filed in 1999/2000 are now under examination, the reason why it is not possible to give further information regarding how the Brazilian PTO's Examiners will deal with this matter.

- 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.**

Unfortunately, there is no statistical data available in Brazil on the number of applications mentioning source and/or country of origin of genetic resources and/or traditional knowledge.

Further, considering the huge backlog the Brazilian PTO is facing, biotech inventions filed between in 1999 and 2000 are under examination now. Therefore, it is also not possible to even give an estimate of the number of such applications mentioning source and/or country of origin of genetic resources and/or traditional knowledge.

- 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 have been no decisions yet. The BPTO has issued requirements for regularization of patent applications in just a few cases, calling on the applicant to report whether or not the invention was developed from national genetic resources. If so, the applicants are supposed to declare the number and date of the authorization issued by the CGEN. There have been no decisions to date on such declarations.

- 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 *bill 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 bills.**