


SEMINAR ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Geneva, May 26 and 27, 2016

**Disclosure requirements
relating to Genetic Resources
and Associated Traditional
Knowledge**



Disclosure requirements relating to Genetic Resources and Associated Traditional Knowledge

Currently RO Patent Office's approach on disclosure requirements relating to genetic GR and associated TK based on relevant provisions in the RO Patent legislation

NO MANDATORY DISCLOSURE OF ORIGIN UNDER RO PATENT LEGISLATION

- Indication of the geographical origin on the voluntary basis
 - provisions concerning biotechnological inventions in Ro patent legislation since 2008
 - dedicated chapter of the Implementing Regulations of the Romanian Patent Law 64/1991, republished, transposing Directive 98/44/EC on biotechnological inventions
 - for the RO patent applications and patents concerning biotechnological inventions, the relevant provisions of the patent legislation shall be applied and interpreted in accordance with the provisions of Chapter III of Implementing Regulations of the Patent Law
- Directive 98/44/EC shall be used as a supplementary means of interpretation
 - to ensure that the recitals preceding the provisions of the Directive are also taken into account and to promote a uniform interpretation of the relevant provisions.

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

- Recital 27 of Directive 98/44/EC lays down that:
 - if an invention is based on biological material of plant or animal origin, or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.
- Recital 27 of EU Directive 98/44/EC has to be regarded as being an encouragement to mention the geographical origin of biological material in the patent application, along the line indicated by Article 16(5) of the Convention on Biological Diversity
- Romania is part of the CBD since 15 November 1994.

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

NO *STRINGENT* OBLIGATION ON THE APPLICANT TO ACKNOWLEDGE PRIOR ART KNOWN TO HIM

- the legal situation with respect to GR and associated TK at this moment is in line with the general principles under the RO Patent Legislation

- while applicants are encouraged to provide information on prior art related to the claimed invention, there is no stringent obligation on applicants to acknowledge all prior art known to them, and

- the burden to find the relevant prior art for challenging novelty or inventive step is in principle on the RO Patent Office

Disclosing Requirements relating to Genetic Resources and Associated Traditional Knowledge

Implementing Regulations of RO Patent Law provides with regard to the description that:

- the description shall "indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, for the search report and examination of the patent application.
- *when the state of the art includes also TK, they shall be clearly indicated in the description, including their source , if known*
- there is no sanction if the applicant holds back part of his prior art knowledge.

However, Patent Office is entitled by Patent Law to ask the applicant all the clarifications and documents considered needed with regard to identity of the applicant or of an inventor or to the fulfill the patentability conditions, implicitly the invention disclosure requirements.

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

NO REQUIREMENT REGARDING *PRIOR INFORMED CONSENT*

- Romanian patent law does not contain, at the moment any requirement with respect to genetic resources and associated traditional knowledge to give evidence of compliance with the applicable legal requirements in the providing country, especially prior informed consent requirements.

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

While there are no mandatory disclosure requirements under the RO Patent legislation, the concerns to prevent acquisition of patent rights over GR and associated TK by parties other than their customary custodians, are addressed in the following ways:

PRIOR ART CONCEPT

The concept of absolute novelty adopted under RO law:

An invention is considered to be new if it does not form part of the state of the art.

- state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the RO patent application.
- no restrictions to the geographical location or the language or manner in which the relevant information was made available to the public; also, no age limit is stipulated for the documents or other sources of the information.

Same concept of prior art which applies to the inventive step requirement and any disclosure, including through use, at any time anywhere in the world, may be sufficient to challenge the inventive step of an application.

It should be noted that, just as in other fields of technology, patents can be granted if an application demonstrates significant improvements and inventiveness compared to the prior art.

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

- **Access of examiners to prior art information on GR and associated TK is a huge challenge, as associated TK tends not to be documented, or if it is, it is unlikely to be easily accessible to a patent examiner**
- **Patent examiners in RO Patent Office perform search documentations using especially :**
 - **EPOQUE (EPO QUERy service) containing dedicated database)**
 - **Espacenet (useful tool: IPC Classification A61K 36/...)**
 - **Periodicals, Revues, Books etc**
 - **dedicated sites on Internet**
- **Third parties can submit observations and relevant information and documentation in all pending examination proceedings**

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

- Romania has an important tradition in phytotherapy and use of medicinal plants
 - more than 3600 of plant varieties with therapeutic properties grow in Romania, 400 of them having a great officinal value
- Patent applications filed by Romanian applicants (companies or private inventors) rarely indicate the geographical origin or the traditional knowledge
 - merely because the inventions are based on biological materials originating from Romania and
 - disclosure requirement is on voluntary bases

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

Considerations on some of the issues to be tackled at the IGC30

Based on our practical experiences we consider that :

1. **Disclosure Requirements relating to GR and associated TK should be addressed to patents only**
 - the full disclosure of invention is the basic principle of patent law
 - GR have the potential of being translated into substantial commercial benefits via patent protection
2. **Disclosure relating to GR should be mandatory not voluntary**
 - a mandatory requirement has to be seen from at least 4 perspectives :
 - of patent applicant
 - of GR owner
 - of Patent Office (patent examiner)
 - of third party
 - disclosure on mandatory bases brings more consistency, transparency, uniformity and coherency
 - if it is on voluntary basis the disclosure relating to GR is nothing more than a symbolic appeal to the patent applicant's moral sincerity

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

- 3. Subject matter of disclosure would be the country of origin or if unknown the source of the specific GR to which the inventor has had physical access**
- 4. The disclosure of country of origin or the source of GR when the claimed invention directly based on subject matter is to be included within the condition of full disclosure of invention (disclosure be sufficient so that a person of ordinary skill could reproduce the invention);**
 - the disclosure of TK associated with GR can be considered as important information with regard to state of the art**
- 5. In order to improve and update the Abstract national or international Data Bases regarding GR and associated TK, the information resulted from the disclosure requirements, at least with regard to the country of origin or source, should be introduced by the applicant in the Abstract filed with the patent application**

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

Thank you for your attention !