National Group: Ecuador

Independent Member:

Date: 2016-10-14

Questions

The Groups are invited to answer the following questions under their national laws:

1) Is there a legal requirement in your country that the source and/or country of origin of GRTK must be indicated in patent applications for inventions based on GRTK (***Disclosure Requirement***)?

No. However, if the origin of the genetic resources (or biological material) is any country from the Andean Community, special requirements of Andean Decisions 486 and 391 will apply.

Notwithstanding the above, there is currently a draft IP law very close to approval which will necessitate stating the source and/or country of origin of GRTK.

If yes, please: (i) indicate whether this legal requirement was introduced after 2010 or, if introduced prior to 2010, whether there have been substantial amendments since 2010; (ii) provide concise quotes of the corresponding text from the laws or regulations or a concise summary; and (iii) reply to the following questions a) to j).

(i) Andean Decision 486 (year: 2000) and 391 (year: 1996) are prior to 2010.

On October, 2011, the National Regulation on the Common Regime on Access to Genetic Resources was issued in accordance with the Decision of the Andean Community No. 391, which defines the complementary rules for the application of Decision 391.

(ii)

- Article 28 of Andean Decision 486:

(http://www.wipo.int/wipolex/en/text.jsp?file_id=223717)

28. The description of the invention shall be sufficiently clear and complete to be understood and for the invention to be carried out by a person skilled in the art. The description shall contain the name of the invention and the following information:

a) the technological sector to which the invention refers or in which it shall be applied;

b) prior technology known to the applicant that would help the invention to be understood and examined and references to previous documents and publications that discuss the technology involved;

c) a description of the invention in such a way that the technical problem and the solution provided by the invention may be understood, explaining the differences and possible advantages with respect to previous technology.

d) a brief description of the drawings if there are any;

e) a description of the best method known to the applicant for carrying out the invention, with the use of examples and references to the drawings if they are pertinent; and,

f) a statement as to how the invention meets the condition of being capable of industrial application, if this is not clear from the description or the nature of the invention itself.

There is no specific requirement about the disclosure of information on genetic resources.

- Article 26 of Andean Decision 486:

  (http://www.wipo.int/wipolex/en/text.jsp?file_id=223717)

  26. The application for a patent shall be filed with the competent national office and shall contain the following:

  (…)

  (h) where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin;

  (i) where applicable, a copy of the document accrediting the licensing or the authorization of the use of the traditional knowledge of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force

- Decision No. 391 Establishing the Common Regime on Access to Genetic Resources (http://www.wipo.int/wipolex/en/text.jsp?file_id=223610). Titles V-VII.

  Chapter III

  On the Access Contract

  32. The parties to the access contract are:

  (a) The State, represented by the Competent National Authority; and

  (b) The applicant requesting the access.

  The applicant must be legally empowered to make a contract in the Member Country in which it requests the access.

  33. The terms of the access contract must be in keeping with the provisions of this Decision and Member Country national legislation.

  34. The access contract shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products, the biological resources that contain them and the intangible component as applicable, in accordance with the corresponding contracts.

  35. When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.

  The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision.

  Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.

36. The Competent National Authority may enter into access contracts with universities, research centers or well-known researchers to support the execution of several projects, as provided for in this Decision and in keeping with the national legislation of each Member Country.

37. The ex-situ conservation centers or other institutions that perform activities involving access to genetic resources or their by-products and, if appropriate, the associated intangible component, should enter into access contracts with the Competent National Authority, pursuant to this Decision.

That Authority may likewise sign access contracts with third parties in regard to genetic resources of which the Member Country is the country of origin and which have been deposited at those centers, bearing in mind the rights and interests referred to in Article 34.

- National Regulation on the Common Regime on Access to Genetic Resources in accordance with the Decision of the Andean Community No. 391 (Executive Decree No. 905 of October 3, 2011 – hereinafter "the regulation")

  http://www.wipo.int/wipolex/en/details.jsp?id=11842

  This regulation applies to genetic resources of which Ecuador is the country of origin, their products, their associated intangible components, and to genetic resources of migratory species that for natural reasons are in its territory. It defines the official institutions participating in the management of genetic resources, and the access procedure to said resources and intangible components.

a) Is the Disclosure Requirement found in patent law (including utility model law, plant variety protection law or design law), general IP laws, in legislation implementing the CBD or the Nagoya Protocol, or any other (and if so, what) sources of law?

General IP laws and GRTK law.

b) What "triggers" the Disclosure Requirement, i.e. what relationship between the invention and the GRTK is required?

The products or processes for which a patent is sought must have been obtained or developed from genetic resources or products derived therefrom, or from traditional knowledge of the country.

c) Is it clear what the concepts 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" mean, and what information must be included in the patent application?

Yes, the law contains these definitions.

d) Is the Disclosure Requirement limited to GRTK of your country or is it applicable also to GRTK obtainable from other countries or geographical regions?

The requirement is of an access contract; the applicable regulations are for Ecuador and the Andean Community countries. Ecuador has signed the Convention of Biological Diversity but there are no specific procedures for GRTK of other countries.

Notwithstanding the above, there is currently a draft IP law very close to approval which will necessitate stating the source and/or country of origin of GRTK.

e) Is disclosure of PIC ("prior informed consent") and/or agreements on "fair and equitable benefit-sharing" required?

Yes.

f) Are human genetic resources treated differently or the same way as animal or plant genetic resources?

Human genetic resources are excluded from patentability.

g) Is "traditional knowledge" separately defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources or in general?

"Traditional knowledge" is separately defined. Among the requirements for a patent application, Andean Decision 486 provides:

(…)

i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations; …

h) Are there sanctions for non-compliance (e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.)? If yes, please briefly describe any applicable sanctions.

Andean Decision 391 states:

46. Any person performing access activities without the respective authorization shall be liable for punishment.

Also to be sanctioned is any person carrying out transactions with regard to by-products or synthesized products of such genetic resources or the associated intangible component, that is not protected by the corresponding contracts, signed in keeping with the provisions of Decision 391.

47. The Competent National Authority, pursuant to the procedure provided for in its own national legislation, may apply administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the infringer from applying for new access in cases of violation of this regime.

Those sanctions shall be applied without detriment to the suspension, cancellation of nullification of the access, the payment of compensation for such damages and losses as are incurred, including those caused to the biological diversity, and the civil and criminal sanctions that may possibly be in order.

Andean Decision 486 determines the following:

Article 75.- The competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, where:

(…)

g) when pertinent, the products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their byproducts originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material;

h) when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries; …

i) Is there any ability to amend the relevant text in the patent application after filing to address non-compliance?

Andean Decision 486 allows the amendment of the application provided the following conditions are met:

34. The applicant for a patent may request that his application be amended at any time during the processing thereof. The amendment may not involve any broadening of the protection that would have been accorded to the disclosure contained in the initial application.

The correction of any clerical error may be requested in the same way.

j) Is any Disclosure Requirement limited by reference to whether access occurred prior to a particular date, e.g. prior to the date of entry into force of the CBD?

No.

The following questions 2) to 14) deal with the effects of the Disclosure Requirement and aspects of the Nagoya Protocol, and the experiences of applicants (and representative of applicants) with those requirements. These questions should be answered by <u>all National and Regional Groups and Independent Members</u> to the extent applicable.

2) Please indicate your experience with the application of the Disclosure Requirement when filing and prosecuting patent applications in your country.

The recent practice of the IP Office in relation to claimed matter is to request supporting examples in the specification in order to demonstrate technical advantages, unexpected effects, or compliance with the industrial applicability requirement.

3) Please give statistical data on the number of patent applications mentioning source and/or country of origin of GRTK in your country. Is there a specific section of the patent register listing patents and patent applications comprising information on source or country of origin of GRTK? If such data are not available, please give an estimate of the number of such patents and patent applications and indicate the basis of the estimate.

There is no available information to estimate the number of such patents.

4) Please indicate whether administrative or judicial decisions on the application of the Disclosure Requirements is available. If yes, please provide a concise summary (or a link to an on-line version) of such decisions.

There are administrative decisions in which the previously mentioned criteria of the IP Office to request supporting examples for the complete scope of the claimed matter has been confirmed. Such decisions are not available on-line.

5) Please provide an estimate per patent application of the additional (a) time and (b) cost in legal fees associated with compliance with the Disclosure Requirement in your

country.

It is not possible to quantify additional time and fees in this regard due to the complexity of the application process and difficulties with isolating costs associated specifically with the disclosure requirement.

6) Please provide an estimate of the additional time and cost as described in question 5) associated with compliance with any foreign Disclosure Requirement.

Not applicable.

7) Has the Disclosure Requirement had an impact on patent valuation (either increasing or decreasing the perceived value of a patent) in your country?

No.

8) Has the Disclosure Requirement had any effect on R&D activities in your country, e.g., a change in the number of patent applications for inventions in biological technology fields, or an increase or decrease of such activities using biological materials such as plants, animals and microorganisms, etc. from either your country or other countries due to the ease or difficulty of obtaining PIC or MAT ("mutually agreed terms")?

The field of GRTK is rather new in relation to patent applications in Ecuador, local R&D activities that lead to patent applications are also limited.

9) Are you aware of any benefits or disadvantages, including for third parties, of the Disclosure Requirement in your country? For example, has the Disclosure Requirement improved patent examination, or led to the sharing of financial or other benefits?

No.

10) As a source country or country of origin, does your country have any legal system and/or administrative authorities or agency to provide any type of certificate to provide proof of the source and/or country of origin of GRTK? If yes, which ministry or authority is responsible? Please include also links to websites which would allow accessing information and contacting the responsible local authorities.

The Competent National Authority is the Environment Ministry.

http://www.ambiente.gob.ec/

11) The following questions relate specifically to the Nagoya Protocol.

a) If your country has not (yet) implemented the Nagoya Protocol, please indicate this.

Ecuador has not implemented the Nagoya Protocol yet. It is waiting the approval of the Congress.

b) The Nagoya protocol stipulates ABS ("access and benefit sharing"). In your country, is there any impact on intellectual property protection and/or enforcement if ABS is not satisfied?

It is a requirement of the access contract which in turn is necessary for requesting a patent application.

c) The Nagoya Protocol also stipulates PIC ("prior informed consent"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in PIC?

The access contract which necessitates PIC is required for a GRTK related application. Therefore, if there is no PIC, the patent application will be rejected.

When the access contract to genetic resources includes an intangible component relating to a genetic resource, the PIC for this component should be granted by the local communities to which the knowledge belongs ("the regulation", definitions)

d) The Nagoya Protocol also stipulates MAT ("mutually agreed terms"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in MAT?

These terms may be a component of the access contract. In case of non-compliance, the contract might be invalidated.

12) Academic research often involves GRTK. Are there any special regulations and/or measures for academics and/or academic institutions such as universities to protect and promote the protection and development of GRTK?

The National Environmental Authority may enter into access contracts with universities, research centers or well-known researchers, to support the execution of research projects and preservation of access to genetic resources (Andean Decision 391, article 42, "the regulation", article 39).

"Traditional medicine" may fall within GRTK. Information relating to traditional medicine is generally not found in the literature or in other written form in the public domain. Does your country permit patent or any other form of intellectual property protection in relation to traditional medicine? If yes, does your country have any specific legislation or examination practice for the protection of traditional medicine? Please include links to websites dealing with these practices or legislation, if appropriate.

Andean Decision 486 states:

Article 3.- The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.

One of the requirements of a patent application is the following (Andean Decision 486, article 26):

(…)

i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;

The Ecuadorian IP Office should coordinate actions in order to determine the existence of an intangible component associated to genetic resources ("the regulation", article 11).

In cases in which the access to genetic resources including an associated intangible component is requested, the applicant should file the plan for obtaining the consent of the local community for access to the intangible component. This plan should be heard and approved by the National Environment Agency, the Ecuadorian IP Office and other institutions ("the regulation", article 20).

The access contract should contain the agreement on the intangible component ("the regulation", article 30),

13) Have there been any authoritative studies in your country on the impact of the Nagoya Protocol? If yes, please provide author(s), title, and information where such studies can be found.

The Nagoya Protocol has been reviewed by the Congress but it is not approved yet. A summary of the analysis can be found through the following link:

http://www.asambleanacional.gob.ec/es/tramite-general-tratados-instrumentos-internacionales-agosto2009?created=&title=nagoya

Procedure

It would be most helpful if the National/Regional Groups / Independent Members would fill out the Questionnaire and send their answers to the General Secretariat of AIPPI (**StandingCommittees@aippi.org**) by **17 October 2016.**

For inquiries please contact: Konrad Becker, Chair of the Standing Committee on IP and Genetic Resources / Traditional Knowledge (konrad.becker@bluewin.ch), Maria Carmen de Souza Brito, the next Chair of the Standing Committee on IP and Genetic Resources / Traditional Knowledge (mcarmen@dannemann.com.br), and Catherine Mateu, Chair of the Standing Committee on TRIPS (c.mateu@armengaud-guerlain.com).