

Date: February 16, 2012
Time: 17h38

Facilitators' Consolidated Document Relating to Intellectual Property and Genetic Resources

DRAFT OBJECTIVES AND PRINCIPLES RELATING TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Facilitators' comment on method on Draft Objectives and Principles Relating to Intellectual Property and Genetic Resources

The following objectives and principles reproduce the content of document IC/20/4 which was prepared at IGC 19 by the facilitators taking into account documents IC/19/6, IC/19/Af Gp and IC/19/LMC as well as interventions made in plenary at IGC 19.

The facilitators at IGC 20 considered document IC/20/4 as a suitable consolidation of all documents on the table regarding objectives and principles.

OBJECTIVE 1

Ensure [that] those accessing [and/or using] genetic resources [, their derivatives] and associated traditional knowledge [in particular applicants for intellectual property rights] comply with national law and [requirements¹ of the country providing² for prior informed consent, mutually agreed terms, fair and equitable] benefit-sharing [and disclosure of origin.]

PRINCIPLES OF OBJECTIVE 1

Principle 1

Recognize the wide variety of ownership arrangements pertaining to genetic resources [, their derivatives] and associated traditional knowledge, including the sovereign rights of States, the rights of indigenous peoples and local communities, as well as private property rights.

Principle 2

Ensure respect for the principle of self determination of indigenous peoples and local communities, including peoples partially or entirely under occupation and their rights over genetic resources and associated traditional knowledge, including the principles of prior informed consent, mutually agreed terms, and full and effective participation, noting the United Nations Declaration on the Rights of Indigenous Peoples.

¹ National law and requirements include customary norms.

² Country providing is the country of origin or that has acquired the genetic resources / with traditional knowledge in accordance with the CBD.

OBJECTIVE 2

Option 1

Prevent [intellectual property rights] [patents] involving the access and utilization of genetic resources, [their derivatives] and associated traditional knowledge from being granted [in bad faith]

- [in error for inventions that are not novel or inventive]
- [where there is no prior informed consent, mutually agreed terms and/or fair and equitable benefit-sharing, and disclosure of origin]
- or
- [or that was granted in violation of the inherent rights of the original owners]

Option 2

Ensure that no patents on life and life forms are granted for genetic resources and associated traditional knowledge.

PRINCIPLES OF OBJECTIVE 2

Principle 1

Patent applicants should not receive exclusive rights on inventions that are not new or inventive.

Principle 2

Option 1

The patent system should provide certainty of rights for legitimate users of genetic resources [and their derivatives] and associated traditional knowledge.

Option 2

The intellectual property system should provide certainty of rights for legitimate users and providers of genetic resources, their derivatives and/or associated traditional knowledge.

The intellectual property system must provide for mandatory disclosure requirements ensuring that the intellectual property offices become key checkpoints for disclosure and monitoring the utilization of genetic resources, their derivatives and/or associated traditional knowledge.

Administrative and/or judicial authorities shall have the right to (a) prevent the further processing of the intellectual property applications or (b) prevent the granting of intellectual property rights, as well as (c) revoke intellectual property rights subject [to judicial review] / to Article 32 of the TRIPS Agreement and render unenforceable intellectual property rights when the applicant has either failed to comply with the objectives and principles or provided false or fraudulent information.

Principle 3

Intellectual property rights applicants should not receive exclusive rights where free, prior and informed consent and fair and equitable benefit-sharing requirements for accessing and using genetic resources [and their derivatives] [and their associated traditional knowledge] have not been met [ensuring free prior informed consent and fair and equitable benefit-sharing for indigenous peoples and local communities].

Principle 4

Persons applying for intellectual property rights involving the use of genetic resources and/or associated traditional knowledge have a duty of good faith and candor to disclose in their applications all background information relating to the genetic resources and associated traditional knowledge, including the country of source or origin.

OBJECTIVE 3

Ensure that intellectual property [Patent] offices have appropriate information on genetic resources, [their derivatives] and associated traditional knowledge needed to make proper and informed decisions in granting intellectual property rights [patents]. [Such information shall include confirmation through the mandatory disclosure requirements that prior informed consent has been obtained and access has been granted on mutually agreed terms which can be made through an internationally recognized certificate of compliance.]

PRINCIPLES OF OBJECTIVE 3

Principle 1

Intellectual property [Patent] offices should [must] consider all relevant prior art [as far as known to the applicant] relating to genetic resources, [their derivatives] and associated traditional knowledge when assessing the eligibility for grant of intellectual property rights [a patent].

Principle 2

[Intellectual property [Patent] applicants should disclose all background information of genetic resources, their derivatives and associated traditional knowledge relevant for determining the eligibility conditions.]

Principle 3

There is a need to recognize that some holders of traditional knowledge may not want their knowledge documented.

OBJECTIVE 4

Establish a coherent and mutually supportive [system] relationship between intellectual property rights involving the utilization of genetic resources, their [derivatives] and/or associated traditional knowledge and existing international and regional agreements and treaties, [including ensure consistency with international legal standards in the promotion and protection of the collective rights of indigenous peoples]

PRINCIPLES OF OBJECTIVE 4

Principle 1

Promote respect for and seek consistency with other international and regional instruments and processes.

Principle 2

Promote cooperation [awareness and information sharing] with relevant international and regional instruments and processes [and support, in particular, the implementation of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity.]

OBJECTIVE 5

Recognize and maintain the role of the intellectual property system in promoting innovation, transfer and dissemination of technology, to the mutual advantage of holders and users of genetic resources, their [derivatives] and associated traditional knowledge in a manner conducive to social and economic welfare [while]:

- [contributing to the protection of genetic resources, [their derivatives] and associated traditional knowledge.]
- [preventing the adverse effects of the intellectual property system on the indigenous peoples' customs, beliefs and rights with the aim of recognizing and protecting the rights of indigenous peoples to use, develop, create and protect their knowledge and innovation in relation to genetic resources.]

PRINCIPLES OF OBJECTIVE 5

Principle 1

Option 1

Maintain the incentives for innovation provided by the intellectual property system.

Option 2

Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and in the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and fair and equitable sharing of benefits arising from their use.

Principle 2

Promote certainty and clarity of intellectual property rights [, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and obligations with respect to the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and certainty and clarity for prior informed consent and fair and equitable benefit-sharing.

Protect creativity, reward investments and ensure prior informed consent and fair and equitable benefit-sharing with the knowledge holders.].

Principle 3

Protect creativity and reward investments made in developing a new invention.

Principle 4

Promote transparency and dissemination of information [, where not in contrast with public morality and/or ordre public,] by:

- [publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.
- [disclosing country of origin and publishing and disclosing technical information related to new inventions, where appropriate and where publicly available, so as to enrich the total body of technical knowledge accessible to the public.]
- [increase legal certainty and trust between users and providers of genetic resources and traditional knowledge through a mandatory disclosure of origin or source.]

OPTIONS FOR IMPLEMENTATION OF OBJECTIVES AND PRINCIPLES

Cluster A: Options on defensive protection of genetic resources

A.1 Inventory of Databases and information resources on GR

There are no proposals that concern an inventory of databases.

A.2 Information systems on GR for defensive protection

Option 1

Develop a database related to genetic resources and to traditional knowledge accessible by examiners worldwide in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge

A summary, which has been written in a language which every examiner can understand, be attached to documents written in indigenous languages

Each country to assess and compile the information concerning genetic resources and the related traditional knowledge under its own responsibility

An all-in-one consolidated system or multiple systems easily searchable with one click

Searchable databases should be in the possession of, and maintained by, each participating WIPO member states. The database will be composed of a WIPO portal site as well as databases of WIPO member states, which are linked to this portal site.

The WIPO portal site is only accessible to patent offices and other registered IP addresses.

Option 2

Collect traditional knowledge into databases.

There is a minimum standard to harmonize the structure and content of these databases.

WIPO administers a system to access the local, regional and national databases of traditional knowledge.

Option 3

Make available written and oral information regarding traditional knowledge associated with genetic resources, their derivatives for enabling search and examination of the intellectual property application including the details of the holder of the TK.

Put in place an adequate information dissemination system to enable an opportunity by relevant authorities from other contracting parties, indigenous and local communities or any other interested parties to submit information relevant to search and examination of an intellectual property application pending before national

intellectual property offices in order to better assess compliance with the eligibility criteria for the grant of intellectual property rights.

That the national intellectual property offices shall consider all relevant written and oral information relating to genetic resources, their derivatives and associated traditional knowledge, regardless of the language, from all countries when conducting search and examination for determining the eligibility criteria for granting of intellectual property rights.

A.3 Guidelines or recommendations on defensive protection

Option 1

That the national intellectual property offices shall develop appropriate and adequate guidelines for the purpose of conducting search and examination of intellectual property applications relating to genetic resource, their derivatives and associated traditional knowledge considering existing and additional information provided by the applicants, as well as accessible to the examiners.

Option 2

Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account the disclosure of the origin of genetic resources.

Use of available databases on genetic resources and/or associated traditional knowledge

Cluster B: Options on disclosure requirements

B.1 Mandatory disclosure

(Facilitators' Comments)

The comments from plenary discussion in IGC 20 present the divergent views of Member States on whether or not a mandatory disclosure requirement is appropriate or required.)

SUBJECT MATTER OF PROTECTION

Option 1

Protection shall extend to any utilization of genetic resources, its derivative and associated traditional knowledge.

For the purposes of this instrument:

- (a) "Associated Traditional knowledge" means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, that subsist in genetic resources.
- (b) "Derivative" means a biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity;

- (c) "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity
- (d) "Genetic Resources" are genetic material of actual or potential value;
- (e) Utilization of Genetic Resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, their derivatives and associated traditional knowledge including through the application of biotechnology.

Option 2

- (a) "Country of origin" is the country which possesses those genetic resources in in-situ conditions
- (b) "Country providing genetic resources" is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.
- (c) "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity
- (d) "Genetic resources" are genetic material of actual or potential value;
- (e) "Source" refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a research centre, gene bank or botanical garden.

Option 3

- (a) Associated traditional knowledge
- (b) Genetic resources
- (c) Derivatives
- (d) Internationally recognized certificate of compliance
- (e) Prior informed consent
- (f) Utilization

Option 4

The following terms are relevant to this proposal

- (a) "Genetic resources" as it is understood in the CBD and related instruments and the International Treaty on Plant Genetic Resources for Food and Agriculture
- (b) "Traditional knowledge related to genetic resources" as it is understood in the CBD and related instruments and the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) of the Food and Agriculture Organization (FAO). As a measure under patent law, the focus is on traditional knowledge that can give rise to a technical invention.
- (c) "Source" should be understood in its broadest sense possible.
 - (i) Primary sources, including in particular Contracting Parties providing genetic resources, the Multilateral System of FAO's International Treaty, indigenous and local communities; and
 - (ii) Secondary sources, including in particular ex situ collections and scientific literature.

BENEFITS / BENEFICIARIES OF THE PROPOSALS

Option 1

Measures for the protection of genetic resources, their derivatives and associated traditional knowledge shall be for the benefit of country of origin of genetic resources.

Parties shall respect the rights of indigenous and local communities in the traditional knowledge associated with genetic resources, their derivatives in accordance with the domestic legislation.

Option 2

A global and compulsory system creates a level playing field for industry and the commercial exploitation of patents, and also facilitates the possibilities under Article 15(7) of the CBD for the sharing of the benefits arising from the use of genetic resources.

Option 3

The proposal will ensure inventors and users using genetic resources and/or associated traditional knowledge comply with requirements for prior informed consent and fair and equitable benefit sharing

Prevent patents being granted in error and/or bad faith for inventions that are not novel or inventive in light of genetic resources and/or associated traditional knowledge

Prevent patents being granted where there is no prior informed consent, no fair and equitable benefit sharing, and disclosure requirements have not been met.

Provide certainty of rights for legitimate users and providers of genetic resources and/or associated TK

Recognise and maintain the role of the IP system in promoting innovation and transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare while also contributing to the protection of traditional knowledge, genetic resources and traditional cultural expressions.

Option 4

(a) Transparency: A requirement in national and international patent applications to disclose the source would increase transparency in access and benefit sharing with regard to genetic resources and traditional knowledge.

(b) Traceability: Disclosing the source in patent applications would allow the providers of genetic resources and traditional knowledge to keep track of the use of their resources or knowledge in research and development resulting in patentable inventions.

(c) **Technical prior art:** Disclosing the source of genetic resources and traditional knowledge in patent applications would assist patent examiners and judges in the establishment of prior art with regard to inventions that somehow relate to these resources or this knowledge, including use of databases of traditional knowledge that is prior art.

(d) **Mutual Trust:** The disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing. All of these stakeholders may be providers and/or users of genetic resources and traditional knowledge. Accordingly, disclosing the source would build mutual trust in the North – South – relationship. Moreover, it would strengthen the mutual supportiveness between the access and benefit sharing system and the patent system.

SCOPE OF PROTECTION

Option 1

Contracting parties shall provide in their national intellectual property legislation the following in the event that the subject-matter of an application involves genetic resources, their derivatives and associated traditional knowledge:

- (a) **Mandatory disclosure of information in the intellectual property application, of the following:**
 - (i) Country of origin and source of genetic resources, their derivatives and associated traditional knowledge;
 - (ii) Prior informed consent, either by the certificate of origin or by any other document issued in accordance with the domestic law of country of origin. In case the country of origin is not identifiable even after making reasonable efforts, certificate of evidence issued in accordance with the domestic law of country providing;
 - (iii) Evidence of benefit sharing under mutually agreed terms entered with the beneficiaries as define in Article 2 in accordance with their domestic legislation;
 - (iv) Make available written and oral information regarding traditional knowledge associated with genetic resources, their derivatives for enabling search and examination of the intellectual property application including the details of the holder of the TK.
- (b) Put in place an adequate information dissemination system to enable an opportunity by relevant authorities from other contracting parties, indigenous and local communities or any other interested parties to submit information relevant to search and examination of an intellectual property application pending before national intellectual property offices in order to better assess compliance with the eligibility criteria for the grant of intellectual property rights.
- (c) That the intellectual property offices while examining the intellectual property application ascertain whether the applicant has comply with the mandatory disclosure requirements as per clause 1(a) of this Article and take necessary measures as mandated in this instrument in case of non compliance.
- (d) No intellectual property rights shall be granted to genetic resources that naturally occur in situ and ex situ.
- (e) That the national intellectual property offices shall:

- (i) Consider all relevant written and oral information relating to genetic resources, their derivatives and associated traditional knowledge, regardless of the language, from all countries when conducting search and examination for determining the eligibility criteria for granting of intellectual property rights.
- (ii) Develop appropriate and adequate guidelines for the purpose of conducting search and examination of intellectual property applications relating to genetic resource, their derivatives and associated traditional knowledge considering existing and additional information provided by the applicants, as well as accessible to the examiners.

Contracting Parties shall appoint national intellectual property offices as a checkpoint for disclosure of the country of origin and source of genetic resources, their derivatives and associated traditional knowledge and for their monitoring.

Option 2

Contracting parties should implement in a legally binding and universal manner the following in the event that a patent applicant used genetic resources in the claimed invention and

- (i) The invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource; and
- (ii) The inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention; or
- (iii) If the applicant is aware that the invention is directly based on traditional knowledge associated with genetic resources, that is, the inventor must consciously derive the invention from this knowledge:
 - (a) Mandatory disclosure of information in the patent application of the following:
 - (i) The country of origin, or if not known, the source of the specific genetic resource to which the inventor has had physical access and which is still known to him.

Option 3

The patent system must provide for a mandatory disclosure requirement ensuring that the IP Offices becomes a key checkpoint for disclosure and monitoring the utilization of genetic resources and/or associated TK (in line with Article 13 of the CBD Nagoya Protocol)

With a view to amending the PCT and PLT to reflect a mandatory disclosure requirement of the origin of the genetic resource, incorporation of the "internationally recognized certificate of compliance" as stipulated in the Nagoya Protocol and any other submission that may be tabled by member countries.

The information should include measures to ensure that prior informed consent has been obtained through a mandatory disclosure requirement and an internationally recognised certificate of compliance.

Option 4

Patent applicants must declare the primary source to fulfill the requirement, if they have information about this primary source at hand, whereas a secondary source may only be declared if patent applicants have no information at hand about the primary source.

- (a) The invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource; and
- (b) The inventor must have had physical access to this resource, that is, its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the invention.

Amend the PCT Regulations to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. The proposals thus leave it up to the national legislator to decide whether such a requirement is to be introduced in the national patent legislation.

PROPOSAL ON COMPLEMENTARY MEASURES

Option 1

Contracting Parties may facilitate access to information, including information made available in databases, relating to genetic resources, their derivatives and associated traditional knowledge with the intellectual property offices of Contracting Parties to this instrument.

Contracting Parties shall ensure that:

- (a) Confidentiality of such information provided to the intellectual property offices as stated in clause 1.1. is maintained by the such offices and the applicants who have access to such information, in accordance with domestic legislation or contractual obligation;
- (b) Any violation of the same shall be considered as an act of unfair competition and a violation of contractual obligations or an infringement of the protection provided in this instrument and be subjected to sanction as provided in this instrument.

Option 2

A simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

Option 3

Promotion of cooperation with relevant international and regional instruments and processes.

Promoting transparency and dissemination of information by disclosing country of origin and publishing and disclosing technical information related to new inventions,

where appropriate and where publicly available, so as to enrich the total body of technical knowledge accessible to the public.

Option 4

Establish a publicly available list of government agencies competent to receive information about patent applications containing a declaration of the source of genetic resources and/or traditional knowledge. Patent offices receiving patent applications containing such declaration could inform the competent government agency that the respective State is declared as the source. WIPO could, in close collaboration with the CBD, consider the possible establishment of such a list of competent government agencies.

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

Option 1

Contracting Parties shall establish a coherent system and promote mutually supportive relationship between intellectual property rights involving the utilization of genetic resources, their derivatives and associated traditional knowledge and existing international agreements and treaties.

Contracting Parties shall support, in particular, the implementation of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity.

Option 2

In order to achieve such a binding disclosure requirement, amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and, as the case may be, regional agreements.

A simple notification procedure should be introduced to be followed by the patent offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

Option 3

Respect for and consistency with other international and regional instruments and processes.

The work of the IGC should not prejudice the work pursued in other fora.

Promotion of cooperation with relevant international and regional instruments and processes.

Option 4

Enable the Contracting Parties of relevant international agreements, including the CBD, the International Treaty of FAO, the PCT, the PLT and the TRIPS Agreement, to fulfill their respective obligations.

INTERNATIONAL COOPERATION

Relevant WIPO bodies to encourage Patent Cooperation Treaty members to develop a set of guidelines for the search and examination by the international search and examination authorities under Patent Cooperation Treaty including additional information arising from the disclosure requirement as provided in this instrument.

TRANSBOUNDARY COOPERATION

In instances where traditional knowledge is located in territories of different Contracting Parties, those Contracting Parties shall co-operate by taking measures that are supportive of and do not run counter to the objectives of this instrument.

SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS

Option 1

Contracting Parties shall ensure, in accordance with their legal systems, adequate criminal, civil and administrative enforcement procedures and dispute resolution mechanisms are available under their laws against the willful infringement of the protection provided genetic resources, their derivatives and associated traditional knowledge under this instrument.

Contracting Parties shall provide that administrative and/or judicial authorities have the right to:

- (a) Prevent the further processing of the intellectual property applications;
- (b) Prevent the granting of intellectual property rights;
- (c) Revoke intellectual property rights; and
- (d) Render unenforceable intellectual property rights when the applicant has either failed to comply with the obligations of mandatory disclosure requirements as provided in this instrument or provided false or fraudulent information.

Where a dispute arises in relation to mutually agreed terms between users, beneficiaries and providers of genetic resources, their derivatives and associated traditional knowledge each Party may be entitled to refer the issue to an alternative dispute resolution mechanism recognized by domestic legislation.

Option 2

Where it is proved that the patent applicant has disclosed incorrect or incomplete information, effective, proportionate and dissuasive sanctions outside the field of patent law should be imposed on the patent applicant or holder. If the applicant provides supplementary information during the processing of the application, the submission of this supplementary information should not affect the further processing of the application. For reasons of legal certainty, the submission of incorrect or incomplete information should not have any effect on the validity of the granted patent or on its enforceability against patent infringers.

It must be left to the individual Contracting State to determine the character and the level of these sanctions, in accordance with domestic legal practices and respecting general principles of law. Both within WIPO as in other international fora means could be discussed to develop such sanctions.

Option 3

Administration and/or judicial authorities shall have the right to prevent (a) the further processing of an application or (b) the granting of a patent as well as (c) to revoke, subject to Article 32 of the TRIPS Agreement, or render unenforceable a patent when the applicant has either failed to comply with these objectives and principles or provided false or fraudulent information.

Option 4

The sanctions currently allowed for under the PCT and the PLT should apply to failure to declare the source or wrongful declaration of the source of genetic resources and traditional knowledge in patent applications.

If the patent applicant does not comply with this invitation within the set time limit, the designated Office may refuse the application or consider it withdrawn on the grounds of this non-compliance.

Furthermore, if it is discovered after the granting of a patent that the applicant failed to declare the source or submitted false information, such failure to comply with the requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention (Article 10 PLT). However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed.

TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

Relevant WIPO bodies shall develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO shall provide technical assistance, cooperation, capacity building and financial support for developing countries in particular the least developed countries to implement the obligations under this instrument.

- B.2 *Further examination of issues relating to disclosure requirements*
- B.3 *Guidelines or recommendations on disclosure*
- B.4 *Alternative mechanisms*

The table of proposals used by the facilitators is as an Annex to this document and was previously distributed to the plenary.

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