Introduction to Patent Disclosure
Requirements for Genetic Resources and Associated Traditional Knowledge

IGC Special Session and Preparatory Committee of the Diplomatic Conference
Informal Information Session
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This presentation aims to provide Member States with a broad introduction to, first, patent applications in general and, second, patent applications for an invention based on genetic resources (GRs) and associated traditional knowledge (aTK). The presentation also introduces mainly Article 3 of the Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources (document WIPO/GRTKF/IC/SS/GE/23/2). The presentation is intended to support Member States and observers in their preparations for the IGC’s Special Session taking place from September 4 to 8, 2023. It was prepared by three technical experts identified by the WIPO Secretariat, and reviewed anonymously by several other experts.

Disclaimer: This presentation does not necessarily represent the views of WIPO or any of its Member States. It is not a substitute for legal advice. The presentation was prepared in late August 2023.
Part One: Patent Applications in General
  - Mr. Juan Rodrigo Pimentel Esquivel, Of Counsel, Arochi & Lindner SC, Mexico

Part Two: Examination of Patent Applications for an Invention Based on Genetic Resources and Traditional Knowledge Associated with Genetic Resources
  - Mr. Lutz Mailänder, Former Head of the Cooperation on Examination and Training Section, PCT International Cooperation Division, WIPO, Germany

  - Ms. Margo Bagley, Vice Dean and Asa Griggs Candler Professor of Law, Emory University School of Law, United States of America
Part One: Patent Applications in General

Mr. Juan Rodrigo Pimentel Esquivel, Of Counsel, Arochi & Lindner SC, Mexico
• A patent is an exclusive right granted for an invention, which is a **product, a process or a composition** that provides, in general, a new way of doing something, or offers a new technical solution to a problem.

• Not every invention deserves a patent right: **patentability requirements**. Inventions must be novel, inventive/non-obvious and useful in order to be patented.

• To get a patent, technical information about the invention must be **disclosed to the public** in a patent application - “sufficiency of disclosure” and “enablement”.
Territorial Rights

- Exclusive rights are only enforceable in the country or region in which a patent has been filed and granted, in accordance with the law of that country or región. There is not an “international” or “global” patent.

- The Patent Cooperation Treaty (PCT) assists applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions.
Patent Duration

The protection is granted for a limited period, generally 20 years as from the filing date of the application, subject to payment of maintenance fees.
Information Typically Contained in a Patent Publication (1/3)

- Title of invention
- Numbers: Priority, Application, Publication, Patent
- Dates: Priority, Filing, Publication, Issue
- Inventor / Assignee
- Technology fields (IPC)
- References Cited
- Abstract
### Specification

- **Background (Prior Art)**
- **Summary**
- **Detailed Description**
- **Examples**
- **Drawings**

(*optional)

#### BACKGROUND

The present invention relates to the use of an extract from snow algae, especially an extract from *Chlamydocapsa* sp (snow algae) in cosmetic and/or pharmaceutical products. More particularly, the invention relates to *Chlamydocapsa* sp (snow algae) in cosmetic and/or pharmaceutical products employed to guard against extrinsic aging of the skin caused by negative environmental exposure, for instance, UV radiation or air pollution, but also to guard against intrinsic aging of the skin as influenced by aging-specific gene expression levels. The invention relates furthermore to a method for producing extracts from snow algae, suitable for topical applications.

#### DETAILED DESCRIPTION

One method for producing a snow algae extract used in accordance with the invention is characterized by the steps:

- Culturing snow algae for example the strain *Chlamydocapsa* sp (CC1Cry 101-99, IBMT strain collection, deposited with the Culture Collection of Algae and Protozoa with the Scottish Marine Institute, OBAR, Argyll PA 37 1QA, United Kingdom, submitted on Feb. 10, 2012, and given accession number CCAP 9/3) in a tube reactor system in 2-phase culturing, harvesting being done in the 2nd phase (red phase);

#### SUMMARY

One object of the present invention is to provide a cosmetic and/or pharmaceutical product for protection, treatment and care of the skin. More particularly the object is to provide a cosmetic and/or pharmaceutical product to prevent or delay skin aging with which both intrinsic as well as extrinsic skin aging can be treated.

This object is achieved in accordance with the invention by an extract from snow algae, more particularly from *Chlamydocapsa* sp, contained in a cosmetic and/or pharmaceutical product, said extract being produced by a reproducible method employing 2-phase cryoculturing.

#### EXAMPLES

**Example 1**

Producing the Biomass

Producing the biomass was done in close cooperation with the IBMT Fraunhofer Institute in Berlin in two phases. During the first phase in production the snow algae were nurtured in a corresponding culturing medium (3N-BBM) with a pH of 5.5 and cultured at a temperature ranging from 4°C to 15°C; with a supply of CO₂. The time for the algae to double was approx. 1.3 days at a temperature of 14.5°C. On completion of the first production phase the snow algae were transferred to a nutrient-limited culturing medium to induce the transition into the red/stationary phase. Culturing in the 2nd phase of production was implemented with the same parameters as for the 1st phase. On completion of the 2nd phase the cell biomass was separated from the culturing medium and frozen at ~20°C.
Information Typically Contained in a Patent Publication (3/3)

Claims

“The Name of the Game is the Claims”

The invention claimed is:

1. A method for delaying skin aging comprising applying to the skin of a subject in need thereof a product comprising an effective amount of lysed *Chlamydocapsa* sp CCryo 101-99 snow algae.

2. A method for protecting skin against the loss of the barrier function induced by environmental exposure, comprising applying to the skin of a subject in need thereof a cosmetic composition comprising an effective amount of a snow algae extract wherein the snow algae extract is homogenized *Chlamydocapsa* sp CCryo 101-99 snow algae.

3. The method according to claim 1, wherein a Klotho anti-aging gene is activated.

4. The method according to claim 1, wherein genes for collagen production are activated.

5. The method according to claim 1, wherein gene expression of matrix metalloproteinases is reduced.
Part Two: Examination of Patent Applications for an Invention Based on Genetic Resources and Traditional Knowledge Associated with Genetic Resources

Mr. Lutz Mailänder, Former Head of the Cooperation on Examination and Training Section, PCT International Cooperation Division, WIPO, Germany
Conditions for Patentability

Formal and substantive patent examination must check

- Formal requirements (inventor names, ….)
- Novelty
- Inventive step (obviousness)
- Industrial applicability
- Unity of invention
- No case of exclusion/exemption
- Sufficient disclosure (knowledge sharing)
- Additions to initial disclosure after filing date
- Legal certainty of claims (clarity)
- Deposit of novel micro-organisms
- Disclosure of origin/source of genetic resources, and associated TK (PDR)

Example:
Samoa IP Act 2011
Section 7(2-4)
Section 5(1)
Section 8(1)
Section 4(3)(a-h)
Section 7(5)(a)
Section 8(3)
Section 7(6)(b)
no provision yet
Section 7(3) (g, h)
Example: Samoa IP Act 2011

10. Filing date and examination—

(2) Despite subsection (1), the Registrar must accord the filing date only when the application fee is paid and the requirements of section 7(2) to (4) are met.

7. Application for a patent—

(3) An application must contain the following:

(g) a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere;

(h) a statement disclosing the source and geographical origin of any biological material used for the invention;
Patent Examination

Examination of formal requirements
- For any application after filing
  - Basic requirements for allocating filing date (applicant, description, request; …)
  - Further formal requirements (inventor names, authorizations, claims, abstract, ….)
- Does not require technical expertise (obvious defects)

Substantive examination
- If requested or if obligatory (subject to national law)
- Of **claimed** subject matter, for example, with regard to prior art
- Requires prior art search + technical expertise
- Work-sharing opportunities for foreign applications by using foreign work-products (prior art search reports, opinions, ..) if claimed subject matter is similar
Proposed PDR in 'Article 3'

Claimed invention = invention as defined by independent claims

ARTICLE 3
DISCLOSURE REQUIREMENT

3.1 Where the **claimed invention** in a patent application is [*materially/directly*] based on GRs, each Contracting Party shall require applicants to disclose:

- (a) the country of origin of the GRs, or,
- (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the GRs.
Independent claims define the invention by citing all features necessary to solve the technical problem
- Dependent claims specify only additional features of various embodiments

Therefore:
- If independent claims refer to specific genetic resources/material, then:
  - the invention is likely to be (materially/directly) based on use of such genetic resources/material.

If an applicant files independent claims referring to specific genetic resources/material, then the applicant implicitly states that the invention is (materially/directly) based on such material.

If IP law stipulates PDR in such case, then an examiner can easily infer that an appropriate disclosure/declaration should be included in the application if any independent claim of the application refers to specific genetic resources/material (missing PDR is an obvious defect).
Patent Examination (continued)

Formality examination

Any independent claim refers to genetic resources?

YES

Disclosure of origin or declaration included in application?

YES

Substantive examination

NO

Applicant complies with invitation to correct obvious defect?

YES

Substantive examination

NO

NO

Rejection of application/
Application deemed to be withdrawn
Samples of Main Claims Referring to a Specific GR

**US8206721B2**
- 1. A method for delaying skin aging comprising applying to the skin of a subject in need thereof a product comprising an effective amount of lysed *Chlamydocapsa sp CCryo 101-99 snow algae*.

**EP2538917B1**
- 1. Use of a composition comprising an extract of *Dionaea muscipula* in cosmetic treatment of the skin, especially skin changes due to accelerated or chronological aging e.g. wrinkles, loss of firmness and elasticity, and increased pigmentation. (*Dionaea muscipula* is the scientific Latin name for the Venus Flytrap plant).

**EP2346948B1**
- 1. A method of manufacturing a pH-stable blue colorant comprising:
  A. Peeling off a *Genipa americana* fruit from its skin, wherein said fruit without skin is *Genipa americana* fruit pulp;
  B. Obtaining raw liquid juice from *Genipa americana* fruit pulp;
  C. Mixing the raw liquid juice with between 0.2 grams and 1.6 grams of glycine per 100 millilitres of raw liquid juice; and,
  D. Warming the raw liquid juice mixed with glycine to a temperature between 40 °C and 80 °C for a period of time from 1 hour to 10 hours.

Ms. Margo Bagley, Vice Dean and Asa Griggs Candler Professor of Law, Emory University School of Law, United States of America
Aims of International Instrument (Objectives)

OBJECTIVES (ART. 1)
A. Enhance the **efficacy**, transparency and quality of the patent system re: GRs and ATK.

B. Prevent patents from being granted erroneously for inventions that are **not novel or inventive** re: GRs and Associated TK.

The term “**efficacy**” is used to make it clear that a disclosure requirement implemented at the national level should be **effective, practical, easily implementable** and not result in overly burdensome **transaction costs**.

The words “misappropriation” and “access and benefit-sharing” are not explicitly mentioned; however, enhancing transparency in patents **will** facilitate benefit-sharing and deter misappropriation of GRs and ATK.
Provisions of the Draft Text

Preamble
Art. 1 Objectives
Art. 2 List of Terms
Art. 3 Disclosure Requirement
Art. 4 Exceptions and Limitations
Art. 5 Non-Retroactivity
Art. 6 Sanctions and Remedies
Art. 7 Information Systems
Art. 8 Relationship with Other International Agreements
Art. 9 Review

Administrative Clauses
[bracketed]
Art. 10 General Principles on Implementation
Art. 11 Assembly
Art. 12 International Bureau
Art. 13 Eligibility to Become a Party
Art. 14 Revisions
Art. 15 Signature
Art. 16 Entry Into Force
Art. 17
Art. 18 Reservations
Disclosure Requirement – Genetic Resources

ART 3.1
Where the **claimed invention** in a patent application is **materially/directly** based on **genetic resources (GRs)**, each Contracting Party shall require applicants to disclose:

(a) the country of origin of the GRs, or,
(b) in cases where the information in (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the GRs.
ART 3.2
Where the **claimed invention** in a patent application is **[materially/directly] based on** ATK, each Contracting Party shall require applicants to disclose:

(a) the indigenous peoples or local community that provided the ATK, or,
(b) in cases where the information in (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the ATK
TERMS (ART. 2)

**Genetic resources, Genetic material, Country of origin, and In situ conditions**, have been taken directly from the Convention on Biological Diversity.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" means genetic material of actual or potential value.

The Text proposes not to define traditional knowledge in this instrument as it is still under discussion under a different track at the IGC.

The Text thus proposes that the term TK be left to national interpretation.
Definitions

TERMS (ART. 2)

“Materially/directly based on” means that the GRs and/or ATK must have “been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the GRs and/or Associated TK.”

This aims to specify the close relationship between the claimed invention and the GRs and/or ATK triggering disclosure.
Examples where GR Origin/Source Disclosure would be required
Invention comprises using neem seed oil extract as a fungicide

GRs mentioned in claims and description; claimed invention appears to depend on the specific features of the genetic resource
GRs mentioned in claims and description; claimed invention appears to depend on the specific features of the genetic resource; Origin suggested

Neem seeds consist of two parts, a shell that does not contain oil or insecticidal activity and the kernel which contains oil and azadirachtin. However, the composition of seeds collected from throughout the world varies considerably as shown in Table A. In particular we have found that oil derived from neem trees with high azadirachtin concentration is both insecticidal and fungicidal.

<table>
<thead>
<tr>
<th>Seeds Source</th>
<th>% Kernel in Seed</th>
<th>% Volatile</th>
<th>Content Oil %</th>
<th>AZAD mg/gak*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senegal (Pout)</td>
<td>54</td>
<td>7</td>
<td>22</td>
<td>6.6</td>
</tr>
<tr>
<td>India (Funjah)</td>
<td>55</td>
<td>5.8</td>
<td>30</td>
<td>1.6</td>
</tr>
<tr>
<td>Togo (Atikame)</td>
<td>57</td>
<td>7.3</td>
<td>27</td>
<td>4.5</td>
</tr>
<tr>
<td>Haiti (Arcahe)</td>
<td>51</td>
<td>12.0</td>
<td>19</td>
<td>2.7</td>
</tr>
<tr>
<td>Ghana (BawK)</td>
<td>57</td>
<td>6.4</td>
<td>14</td>
<td>3.9</td>
</tr>
</tbody>
</table>

*gak = gram seed kernel

Eighty (80) kgs of dried defruited neem seeds from Africa were ground in a cutting mill to about 10 mesh.

We claim:

1. A method of protecting a surface from fungi comprising contacting the surface to be protected with a fungicide having a fungicidally effective amount of a non-polar, hydrophobic solvent extracted neem oil which has less than 1 weight percent of azadirachtin, and which has been treated to remove the non-polar solvent, wherein the non-polar, hydrophobic solvent has neem oil solubility and substantially no azadirachtin and water solubility.
Example where Associated TK might need to be disclosed

1. A method of manufacturing a colorant comprising:
   A. Peeling off a *Genipa americana* fruit from its skin, wherein said skin is discarded, and wherein said fruit without skin is *Genipa americana* fruit pulp;
   B. Obtaining raw liquid juice from the *Genipa americana* fruit pulp;
   C. Mixing the raw liquid juice with glycine; and,
   D. Warming up the raw liquid juice mixed with glycine for a determined period of time.

*Invention is a method of making a blue colorant from the juice of the fruit pulp of a plant.*
Example where Associated TK might need to be disclosed

Disclosure mentions the name of the fruit in the language of a particular tribe

[0051] For purpose of the present invention, the term “Genipa americana” includes all the following:
[0052] Gardenia genipa Sw.
[0053] Genipa americana, var. caruto fo. grandifolia
[0054] Genipa excelsa
[0055] Genipa americana var. Carnuto
[0056] Genipa barbata
[0057] Genipa pubescens DC.
[0058] Genipa humilis
[0059] Genipa caruto
[0060] Genipa grandifolia
[0061] Genipa oblongifolia

[0062] Similarly, for purpose of this invention, the term “Genipa americana” also includes as equivalent any of the following popular synonym names:
[0063] Irayol (Guatemala);
[0064] Maluco (Mexico);
[0065] Guaitil (Costa Rica);
[0066] (VEN) Caruto;
[0067] Caruto, Jagua (Colombia);
[0068] Quipará o Quepará (native language of tribe étnia emberá);
Examples where GR Origin/Source Disclosure NOT required
GRs mentioned in patent, but no GR disclosure requirement is triggered.

Invention is a novel process for producing a low fat or high protein nut paste while retaining good flavor and texture. Contains more nut solids (defatted) than regular nut butters.
Patent description mentions several GRs; but claims do not. The GRs are not necessary or material to the development of the claimed invention, and the claimed invention does not depend on the specific properties of those GRs (i.e. it is a novel process that can be used with any of a wide variety of nut pastes).

The process of the present invention utilizes a nut paste, preferably peanut paste, as a starting material. While this invention will be generally described in terms of peanuts and peanut paste, it should be readily apparent that other materials such as almonds, pecans, walnuts, cashews, filberts, macadamia nuts, brazilians, sunflower seeds, sesame seeds, pumpkin seeds and soybeans could be used to form the nut paste utilized in the process of the present invention. The term “nut” as used herein encompasses these nuts and seeds. Mixtures of these nuts and oil seeds can also be used.

What is claimed is:

1. A process for preparing a low fat nut spread having desirable fluidity, texture, and flavor, which process comprises the steps of:
   a) depositing nut paste in a mixing tank;
   b) mixing the solid ingredients into the nut paste to form a mixture having a viscosity exceeding 30 poise and from about 25% to about 42% total fat, and passing the mixture through a high shear mixer;
   c) adjusting the mixture so that it has a temperature as it exits a homogenizer in step (d) of less than about 240°F;
   d) pumping the mixture through a homogenizer at a pressure ranging from about 9,000 to about 14,500 psig;
   e) pumping the mixture through a colloid mill; and
   f) pumping the mixture through a versator and a scraped wall heat exchanger to provide a nut spread having a distribution such that at least 50% of the solids have a particle size of less than 18 microns, at least 90% of the solids in the nut spread have a particle size of less than about 60 microns, and up to about 73% of the solids in the nut spread have a particle size of less than about 13.0 microns, and further having a Casson plastic viscosity of from about 8 to about 17 poise; and a yield value of less than about 300 dynes per square centimeter.
Patent description mentions several GRs; but claims do not. The GRs are not *necessary or material* to the development of the claimed invention, and the claimed invention (*process claims and product claims*) does not depend on the specific properties of those GRs (i.e., it is a *novel process* that can be used with any of a wide variety of nut pastes and a *novel nut spread* that can be made from a wide variety of nuts).

15. A low fat bimodal nut spread which has desirable fluidity, texture and flavor and which comprises:
   a) from about 50% to about 90% of a nut paste;
   b) from about 13% to about 50% of solid ingredients;
   c) from 0% to about 3% stabilizer;
   d) from 0% to about 3% emulsifier; and
   e) from 0% to about 8% flavorant;
wherein the nut butter or nut spread has i) a Casson plastic viscosity ranging from about 8 to about 17 poise; ii) a yield value of less about 300 dynes per square centimeter; iii) from about 25% to about 42% total fat; and iv) a bimodal particle size distribution such that from about 80% to about 87% of the water insoluble solids comprising the nut butter or spread have a particle size less than about 21.6 microns, from about 75% to about 83% of the water insoluble solids comprising the nut butter or spread have a particle size of less than about 16.7 microns, from about 65% to about 73% of the water insoluble solids comprising the nut spread have a particle size of less than about 13.0 microns, from about 55% to about 60% of the water insoluble solids comprising the nut butter or spread have a particle size of less than about 10.1 microns, from about 43% to about 50% of the water insoluble solids comprising the nut butter or spread have a particle size of less than about 7.9 microns and from about 25% to about 30% of the water insoluble solids comprising the nut butter or spread have a particle size of less than about 6.2 microns.

What is claimed is:

1. A process for preparing a low fat nut spread having desirable fluidity, texture, and flavor, which process comprises the steps of:
   a) depositing nut paste in a mixing tank;
   b) mixing the solid ingredients into the nut paste to form a mixture having a viscosity exceeding 30 poise and from about 25% to about 42% total fat, and passing the mixture through a high shear mixer;
   c) adjusting the mixture so that it has a temperature as it exits a homogenizer in step (d) of less than about 240°F;
   d) pumping the mixture through a homogenizer at a pressure ranging from about 9,000 to about 14,500 psig;
   e) pumping the mixture through a colloid mill; and
   f) pumping the mixture through a versator and a scraped wall heat exchanger to provide a nut spread having a distribution such that at least 50% of the solids have a particle size of less than 18 microns, at least 90% of the solids in the nut spread have a particle size of less than about 60 microns, and up to about 73% of the solids in the nut spread have a particle size of less than about 13.0 microns, and further having a Casson plastic viscosity of from about 8 to about 17 poise, and a yield value of less than about 300 dynes per square centimeter.
Invention is an article of bedding (a comforter), with differing filler materials in different zones to create particular performance features, in particular, specialized zones of warmth.
Patent description mentions several GRs; but the claims do not. The GRs are not necessary or material to the development of the claimed invention, and the claimed invention does not depend on the specific properties of those GRs (i.e. it is a novel process that can be used with any of a wide variety of filler materials).

The filler of the present invention can be wool, cotton, silk, batting, microfiber, synthetic and natural fibers, wadding and similar standard filling materials. Those skilled in the art would appreciate that premium filler materials can include variations and variants of the standard filler than has been specially modified or constructed for the purposes of improved comfort, heat retention or functionality. For instance, premium filler is envisioned but not limited to memory foam, visco-elastic materials, natural feathering and products, as well as similar textile materials.

I claim:
I. A bedding article comprising:
a top material sheet,
a bottom material sheet,
wherein the top sheet and the bottom sheet are joined so as to produce a plurality of enclosed cells;
wherein at least a portion of the enclosed cells are filled with a premium bedding material and the remaining portion of the cells is filled with a standard bedding material and each cell is configured to prevent the migration of bedding material from one cell to another;
wherein contents of the enclosed cells alternate between cells filled with a standard bedding material type and cells filled with a premium bedding material type such that at least one cell filled with a standard bedding material type is interposed between two cells filled with a premium bedding material type.

The patent disclosure requirement will be a measure to indirectly support implementation of the CBD and Nagoya Protocol by enhancing the efficacy, transparency and quality of the patent system re: GRs and ATK.

It is also likely to aid in preventing patents from being granted erroneously for inventions that are not novel or inventive re: GRs and ATK.
Key Resources

Disclosure Requirements Table and other resources available at https://www.wipo.int/diplomatic-conferences/en/genetic-resources/index.html
Q&A Session