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PATENT SYSTEM AND THE FIGHT AGAINST BIOPIRACY - THE PERUVIAN EXPERIENCE

Document submitted by Peru

1. In a note dated May 30, 2005, the Permanent Mission of Peru before the Offices of the United Nations and Other International Organizations in Geneva submitted a document to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee").

2. The above-mentioned note contained the following paragraph: "On this subject, the Permanent Mission of Peru wishes to request that the attached proposal, which contains material arising from Peru's experience in the fight against biopiracy, be circulated as a working document during the present session. It should be noted that this proposal was previously submitted to the Council for TRIPS of the World Trade Organization (WTO) in March 2005, as document IP/W/441, the Spanish version of which should be considered the original."

3. The submission is published in the form received in the Annex to this document.

4. The Committee is invited to take note of the contents of the Annex.

[Annex follows]

ANNEX

COMMUNICATION FROM PERU

The following communication, dated May 27, 2005, is being circulated at the request of the delegation of Peru. The present document was previously issued in WTO TRIPS Council as document IP/C/W/441, circulated on March 8, 2005.

PATENT SYSTEM AND THE FIGHT AGAINST BIOPIRACY THE PERUVIAN EXPERIENCE

I. INTRODUCTION

1. The current intellectual property system stems from a continuing process to foster trade and technological development. The protective scope of intellectual property legislation has thus gradually expanded with the recognition of new rights and subject-matter. We therefore believe that the traditional knowledge of indigenous peoples, as a significant sphere of human creativity, cannot be left out of the intellectual property system. Those peoples have a legitimate interest and an expectation of legal recognition that is no less significant than that which, at one time, warranted the recognition of new subjects of intellectual property protection (plant varieties, biological material, layout-designs of integrated circuits, software, databases, and so forth). National and international recognition of traditional knowledge is an issue of crucial importance to many developing countries, and especially Peru, whose geographical setting places it among the ten countries with the most extensive biodiversity in the world, which are also known as "mega-diverse countries" because of their range of ecosystems, species, genetic resources and indigenous cultures with valuable knowledge.

2. In this connection, the Peruvian Government advocates the extension of protection for intellectual property rights and seeks to stimulate innovation and the creation of intangible property of economic and commercial value throughout the country. Thus, after a number of years of work within the country, the Law establishing a protection regime for the collective knowledge of indigenous peoples derived from biological resources[1] was published in August 2002. The Law is the outcome of a process involving the participation of various public institutions, academic circles, NGOs, the business sector and the indigenous peoples themselves. However, we are well aware that ensuring protection at the domestic level is not sufficient, and we therefore consider that the international recognition of traditional knowledge as protectable intellectual property will give the beneficiaries legal standing to assert their rights in other countries.

3. On the other hand, we believe that, while the intellectual property system is not designed to protect the rights of the countries of origin of genetic resources, it may provide support for the system of access to genetic resources and contribute to its implementation through the establishment of the disclosure requirement, among others. This will benefit the

[1] Law No. 27811 published on 10 August 2002 in the Official Journal "El Peruano".

intellectual property system itself, by making it more fair and giving it greater legitimacy. It must be borne in mind that the legitimacy of the IP system is in dispute, and that will remain the case as long as bad patents continue to be granted and the system continues to be used to legitimize unjust and unfair situations.

4. Discussions on the relationship between the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Convention on Biological Diversity have been taking place in the Council for TRIPS since 1999. Both individually and in association with other countries such as Brazil, Ecuador, Venezuela, Cuba, the Dominican Republic, Thailand and India, among others, Peru has made various submissions[2] aimed at securing the insertion in the TRIPS Agreement of a provision requiring patent applicants for inventions that use biological resources and traditional knowledge to disclose the origin of those resources or that knowledge and to provide evidence that they have obtained proper prior informed consent and have complied with national legislation on the distribution of profits, all of which will help to reduce cases of bad patents and prevent biopiracy.

5. Peru has also developed concrete measures to reduce cases of bad patents and prevent bio-piracy. They include the following in particular:

II. ESTABLISHMENT OF THE WORKING GROUP TASKED BY THE NATIONAL INSTITUTE FOR THE DEFENCE OF COMPETITION AND INTELLECTUAL PROPERTY PROTECTION (HEREINAFTER INDECOPI) TO EXAMINE PATENTS GRANTED IN OTHER COUNTRIES AND INVENTIONS RELATING TO "MACA".

6. The Working Group was made up of persons from different government institutions and non-governmental organizations, such as the: Ministry of Foreign Relations, Ministry of Foreign Trade and Tourism, National Environmental Council, National Agricultural Research Institute (now the National Institute for Agricultural Research and Extension), Office of the First Lady of the Nation, International Potato Centre, Peruvian Institute for Medicinal Plants (now the Peruvian Institute for Natural Products), Peruvian Environmental Law Society and Probioandes (Pro Biodiversity of the Andes).

7. The Working Group drew up a report entitled "Patents referring to *Lepidium Meyenii* (maca): Responses of Peru", which was submitted by the Peruvian delegation at the fifth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.[3]

8. The report shows some of the problems that a country like Peru has to face upon identification of a pending patent application or patent grant whose subject matter concerns an invention obtained or developed from the use of a biological resource or traditional knowledge without securing the prior informed consent of the country of origin of the resource or the indigenous people owning rights in the knowledge, and without providing for any type of compensation to that country or indigenous people.

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[2] See documents WT/GC/W/362 of October 12, 1999, IP/C/W/246 of March 14, 2001, IP/C/W/356 of June 24, 2002, IP/C/W/403 of June 24, 2003, IP/C/W/420 of March 2, 2004, IP/C/W/429 of September 21, 2004, IP/C/W/438 of December 10, 2004.

[3] See document WIPO/GRTKF/IC/5/13.

III. ESTABLISHMENT OF THE NATIONAL COMMISSION FOR THE PROTECTION OF ACCESS TO PERUVIAN BIOLOGICAL DIVERSITY AND TO THE COLLECTIVE KNOWLEDGE OF THE INDIGENOUS PEOPLES

9. Law No. 28216 of 1 May 2004 established the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (hereinafter the National Anti-Biopiracy Commission).

10. The Commission, chaired and coordinated by INDECOPI, is made up of representatives of the following institutions: Ministry of Foreign Relations, Ministry of Foreign Trade and Tourism (MINCETUR), National Environmental Council (CONAM), Commission for the Promotion of Exports (PROMPEX), National Institute for Natural Resources (INRENA), National Institute for Agricultural Research and Extension (INIEA), International Potato Centre (CIP), National Centre for Intercultural Health (CENSI), National Commission of Andean, Amazonian and Afro-Peruvian Peoples (CONAPA), National Assembly of Governors (ANR), Peruvian Environmental Law Society (SPDA) (representing the NGOs), and Peruvian Institute for Natural Products (IPPN) (representing business associations).

11. The National Anti-Biopiracy Commission has the task of developing actions to identify, prevent and avoid acts of biopiracy with the aim of protecting the interests of the Peruvian State. Its main functions are to:

- Establish and maintain a register of biological resources and traditional knowledge;
- provide protection against acts of biopiracy;
- identify and follow up patent applications made or patents granted abroad that relate to Peruvian biological resources or collective knowledge of the indigenous peoples of Peru;
- make technical evaluations of the above-mentioned applications and patent grants;
- issue reports on the cases studied;
- lodge objections or institute actions for annulment concerning the above-mentioned patent applications or patent grants;
- establish information channels with the main intellectual property offices around the world;
- draw up proposals for the defence of Peru's interests in different forums.

12. The Commission held its first ordinary meeting in August 2004. To date, it has held six formal meetings. One of the activities agreed by the Commission has been the identification of potential cases of biopiracy involving Peruvian resources and the traditional knowledge of Peru's indigenous peoples. To that end, it has instituted a permanent search and monitoring system.

13. The National Anti-Biopiracy Commission considered it desirable to share the experience acquired in this first stage of the search for potential cases of biopiracy, inasmuch as this may contribute to an understanding of the problems faced by a country like Peru in the fight against biopiracy. To that end, and in order to enrich the ongoing debate within the TRIPS Council concerning the disclosure requirement, the results of the search effected on the websites of the main patent offices in the world (Japan, United States of America and Europe) are presented in respect of six resources of Peruvian origin identified as priority resources, together with a summary of the patent documents found, which have as their

subject-matter inventions related to those resources, and which may involve the use of traditional knowledge of the indigenous peoples of Peru.

14. This document is the fruit of efforts by the National Anti-Biopiracy Commission to identify possible cases of biopiracy as the subject-matter of a more rigorous and detailed analysis and of possible administrative or judicial proceedings. It is no more than the first step in the long and complex process starting with the search for potential cases of biopiracy and ending with the institution of actions against pending patent applications or patents obtained or developed from the use of a biological resource or traditional knowledge without the prior informed consent of the country of origin of the resource or of the indigenous people owning rights in the knowledge, and without providing for any type of compensation to that country or indigenous people.

15. It is hoped that this document will help serve the purpose of: (a) ascertaining how a mega-diverse country makes a serious attempt to address this phenomenon through its institutions; (b) understanding to some extent the methodology and standards used in the search for such patents, thereby helping other countries or regions which might wish to initiate similar efforts; (c) gaining knowledge of the large number of inventions referring to resources of Peruvian origin that might reflect cases of biopiracy (either because such resources have been obtained illegally, or because they involve the unauthorized use, without compensation, of traditional knowledge); and (d) demonstrating that a systematic and methodical search and analysis of "problem" patents can be undertaken.

16. It should be stressed that it is not our intention to assert that all pending patent applications or patent grants mentioned in the attached report do not deserve protection. What is presented is merely a set of pending patent applications or patent grants which have as their subject matter inventions apparently obtained or developed using biological resources of Peruvian origin and/or traditional knowledge of the indigenous peoples of Peru, for which reason it is necessary to check whether respect has been shown for the rights of Peru as the country of origin of the resources concerned and of the indigenous peoples of Peru as the owners of rights in the knowledge concerned.

17. The attached report sets out the results of the search for potential cases of biopiracy that was made using the databases accessible through the websites of the United States Patent and Trademark Office, the European Patent Office and the Japan Patent Office. The search for potential cases of biopiracy did not cover all resources of Peruvian origin considered as priority resources by the National Anti-Biopiracy Commission, but only the following: hercampuri, camu camu, yacon, caigua, sacha inchi and chancapiedra.

18. It should be noted that this report shows the results obtained during the first stage (*search for potential cases of biopiracy*). The first stage is to be followed by a second one (*identification of possible cases of biopiracy*), which will be the responsibility of Peruvian experts on the national resources covered by the search. The experts will analyse each of the cases included in the report and will propose cases requiring more detailed analysis to the Commission, thereby contributing to the collation of the results obtained at the first stage.

19. The National Anti-Biopiracy Commission will present the results obtained in the second stage to the TRIPS Council at its next meeting.

SEARCH FOR POSSIBLE CASES OF BIOPIRACY

I. SEARCH STRATEGY

The search was conducted on the basis of the scientific names and possible synonyms of the resources cited in the "List of resources to be included in the search for possible cases of biopiracy", drawn up by the National Anti-Biopiracy Commission.

II. DATABASES CONSULTED

The databases consulted for the purpose of conducting searches for possible cases of bio-piracy were the following:

1. Database of the United States Patent and Trademark Office (hereinafter US database)[4]

This database:

– Separates information relating to patents and patent applications, and separate searches were therefore conducted for:
  – Patents[5]
  – Patent applications[6]

– Permits a term search to be made in relation to the full text of the patent or patent application (abstract, claims and description).
– Permits the full text of the patent or patent application to be printed.

2. Database of the European Patent Office (hereinafter European database)[7]

This database:

– Permits a worldwide database search which includes patents and patent applications from about 70 countries and regions.
– Permits a term search to be made only in relation to the title or abstract of each document, thus limiting the search facility.
– Enables the full text of the patent or patent application to be printed.

3. Database of the Japan Patent Office (hereinafter Japanese database)[8, 9]

This database:

– Permits access to publications from 1976 onwards.

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4 Website of the US Patent and Trademark Office http://www.uspto.gov/
5 This database includes patents granted from 1976 onwards.
6 This database includes patent applications published from 2001 onwards.
7 Website of the European Patent Office http://ep.espacenet.com
8 Website of the Japan Patent Office http://www.jpo.go.jp
9 For searches in this database, the option "Patent Abstracts of Japan (PAJ)" was entered.

– Provides information on the legal status of publications from 1993 onwards.

– Permits a term search to be made only in relation to the title or abstract of each document, thus limiting the search facility.

– Facilitates access to a literal translation of the full text of the document from Japanese to English. However, this was not possible for documents published in 1992.

In order to print out claims relating to patents granted, "Patent & Utility Model Gazette DB" was entered, which enables the document to be accessed by means of its publication number.

III. SEARCHES

A search for the following resources was initiated:

– HERCAMPURI *Gentianella alborosea (Gilg) Fabris*
– CAMU– CAMU *Myrciaria dubia*
– YACON *Smallanthus sonchifolius*
– CAIGUA *Cyclanthera pedata L*
– SACHA INCHI *Plukenetia volubilis L*
– CHANCAPIEDRA *Phyllantus niruri*

The searches produced the results described below:

HERCAMPURI

Gentianella alborosea (Gilg) Fabris

Terms used in the search: *gentianella, hercampuri, hercampure, alborosea and gentiana.*

The scientific name for this resource is "*Gentianella alborosea*". However, a review of the Japanese database turned up references to the resource as "*Gentiana prostata*", "*Gentiana nitida*" and "*Gentiana alborosea*", so the term "gentiana" was included as a possible synonym.

US DATABASE

Searches using the terms gentianella, alborosea, hercampuri and hercampure produced no relevant results. On the other hand, a search for the term "Gentiana" brought up a list of references for the plant gentiana sp, gentiana extract and other species, notably: *Gentiana scabra, Gentiana triflora, Gentiana manshurica, Gentiana algida, Gentiana regescens, Gentiana macrophylla, Gentiana straminea, Gentiana crassicaulis, Gentiana dahurica* and, in particular, *Gentiana lutea*.

Particular mention should be made of application US 20040202638, published on 14 October 2004, claim 11 of which mentions the plant "Gentiana chancalagua" which the descriptive section refers to as a plant which grows in Peru.

EUROPEAN DATABASE

The search turned up two references to Japanese documents, for which no family of patents is cited.

JAPANESE DATABASE

The search turned up 11 references identified by their publication numbers:

<u>Preparations for external use</u>

1. 08-175963, published on 9 July 1996 and granted as patent No. 3224962 of 24 August 2001, concerning "Skin preparation for external use". Claim 1 refers to skin preparations for external use characterized by containing *hercampuri extract*.

2. 2000-063259, published on 29 February 2000, concerning "Lipolysis accelerating agent and skin preparation for external use for weight reduction". Claim 1 refers to a lipid decomposition accelerator characterized by consisting of an *extract of gentiana and/or hercampuri.*

3. 2000-336024, published on 5 December 2000, concerning "Cosmetic composition containing moisturizing plant extract". Claim 1 refers to a make-up base containing one or more extracts from uña de gato, hercampuri, quinoa, sangre de grado, cedrón, chanca piedra, pájaro bobo, balsamina, bordeaux, matico, manzanilla and muña. Claim 2 refers to a bath and claim 3 to a detergent.

4. 2001-106619, published on 17 April 2001, concerning "Cosmetic composition". Claim 1 refers to a melanin generation inhibitor which comprises one or more *plant extracts from hercampuri, bal basuko and buranka*.

5. 2003-104848, published on 9 April 2003, concerning "Hair grower". Claim 1 refers to a hair restorer which contains an aromatase accelerator, while claim 2 specifies that this aromatase accelerator may be obtained, *inter alia*, from a *hercampuri extract.*

6. 2003-238432, published on 27 August 2003, concerning "Hyaluronic acid accumulation-accelerating agent". Claim 2 defines a composition which moisturizes the skin and prevents wrinkles. According to claim 1, this composition contains a hyaluronic acid accelerator, which in turn contains *hercampuri* and maca.

Extracts and references to foods

7. 10-245553, published on 14 September 1998, concerning "Antioxidant". Claim 1 refers to an antioxidant comprising an *extract of hercampuri* or of a gentian. The examples in the detailed description refer to creams.

8. 2002-275079, published on 25 September 2002, concerning "Composition for enhancing glutathione". According to the abstract, the problem to be solved is to provide a plant which enhances the action of glutathione. Claim 1 gives a list of plants, including hercampuri and maca. Claims 6 and 11 refer to a *liver function improvement* and a nutritional supplement, respectively.

9. 2002-316936, published on 31 October 2002, concerning "Antibacterial agent and anti- inflammatory agent". Claim 1 refers to an anti-microbial agent characterized by containing one or more extracts selected from huamansamana, hercampuri and canchalagua. The abstract explains that the extracts of huamansamana (*Jacaranda copaia*), hercampuri and canchalagua (*Sisyrinchium vaginatum*) have an excellent anti-inflammatory property for the skin. The detailed description indicates that hercampuri is widely distributed in the United States.

10. 2004-000172, published on 8 January 2004, concerning "Functional food product containing hercampure". The abstract states that the product inhibits blood pressure elevation and that it *inhibits bad cholesterol and increases good cholesterol.* Claim 1 refers to the aim of protecting a food that contains hercampure.

11. 2004-219101, published on 5 August 2004, concerning "Method for determining hercampure component". The abstract refers to a determination method for xanthone.

CAMU – CAMU

Myrciaria dubia

Terms used in the search: *myrciaria, camu, Eugenia, divaricata, marliera, rumberry, mirciaria, dubia, psidium, Psidium and dubium.*

The scientific name for this resource is "Myrciaria dubia". However, a review of the tropical plant database web page created by Raintree turned up references to the resource as "Eugenia divaricata", "Marliera" and "Rumberry", so these were included as search terms. In addition, Psidium dubium was used as a synonym.

UNITED STATES DATABASE

The search turned up two documents where the term myrciaria is used in the descriptive section:

– US 2003/0104076, published on 5 June 2003, concerning "Process for preparing dry extracts". The descriptive section (paragraph No. 0041) refers to the resource Myrciaria dubia among many others.

– US 2004/0161524, published on 19 August 2004, concerning "Process for producing a plant extract containing plant powder". The descriptive section (paragraph No. 0056) refers to the resource Myrciaria dubia among many others.

Although a continued search using the terms camu, dubia and Psidium dubium turned up further documents, these do not refer to the resource Myrciaria dubia.

EUROPEAN DATABASE

The search turned up references to Japanese documents, for which no family of patents is cited. Among the results obtained, mention should be made of document WO 2004/074304, published in Japanese on 2 September 2004, concerning "Compound, process for producing the same and use thereof". The English translation of the abstract refers to a compound originating in camu camu which is defined by its chemical structure.

JAPANESE DATABASE

The Japanese database search turned up 16 references identified by their publication numbers:

<u>Preparations for external use</u>

1. 09-221429, published on 26 August 1997 and granted on 23 May 2003 as patent No. 3431383, concerning "Melanogenesis suppressing agent". Claim 1 refers to a melanin inhibitor which contains an *extract of camu camu* obtained from a process of extraction using water, hydrophilic organic solvents or a mixture thereof.

2. 11-246336, published on 14 September 1999, concerning "Activated oxygen scavenger and skin beautifying cosmetic composition". Claim 2 refers to a make-up base containing an active oxygen elimination agent (antioxidant) which, according to claim 1, includes the plant camu camu among others.

3. 2000-327525, published on 28 November 2000, concerning "Skin preparation for external use". Claim 1 refers to a preparation for external use which contains an *extract of camu camu* and a cell activator.

4. 2000-327549, published on 28 November 2000, concerning "Cosmetic comprising extract of camu camu". Claim 1 refers to a make-up base characterized by comprising *camu camu fruit extract.*

5. 2000-327550, published on 28 November 2000, concerning "Skin preparation for external use". Claim 1 refers to a preparation for external use that contains an *extract of camu camu* and an antioxidant (active oxygen remover).

6. 2000-327552, published on 28 November 2000, concerning "Skin preparation for external use". Claim 1 refers to a preparation for external use which *contains an extract of camu camu* and a moisturiser.

7. 2000-327553, published on 28 November 2000, concerning "Skin preparation for external use". Claim 1 refers to a preparation for external use which contains a polyhydric alcohol, *a camu camu extract,* ascorbic acid and a placenta extract.

8. 2001-031558, published on 6 February 2001, concerning "Skin lotion". Claim 1 refers to a preparation for external use which contains (a) an *extract of camu camu* and (b) a whitening agent.

9. 2001-031580, published on 6 February 2001, concerning "Preparation for external use for skin". Claim 1 refers to a preparation for external use which contains (a) a *camu camu extract* and (b) an anti-inflammatory agent.

10. 2004-189698, published on 8 July 2004, concerning "Bleaching agent, antioxidant, collagenase inhibitor, hyaluronidase inhibitor, age resister, skin lotion, cosmetic and food". The claims refer to an *extract of camu camu seed* which produces these effects.

<u>Extracts and references to foods</u>

11. 09-140341, published on June 3, 1997, concerning "Dessert containing juice of Myrciaria dubia". Claim 1 refers to a dessert characterized by containing *camu camu juice*.

12. 09-140357, published on June 3, 1997, concerning "Improvement of taste and flavour of juice of fruit of Myrciaria dubia and beverage containing the juice". Claim 1 refers to a juice with improved flavour which comprises the *juice of the fruit,* an acidulant, sweeteners, essences, vitamins and minerals.

13. 09-140358, published on June 3, 1997, concerning "Preparation of juice of fruit of Myrciaria dubia, improved in flavour and taste". Claim 1 refers to *a fruit juice* with improved flavour due to treatment with polyvinylpirrolidone.

14. 09-215475, published on 19 August 1997, concerning “Preserves of fruit of Myrciaria dubia”. The abstract refers to food recipes containing sugar, pectin, water and the fruit of Myrciaria dubia.

15. 2000-342162, published on 12 December 2000, concerning “Bread-improving agent composition and production of breads”. Claim 1 refers to a bread-improving agent, one of the ingredients of which is *camu camu juice*.

16. 2004-135608, published on 13 May 2004, concerning “Method for producing breads”. Claim 1 refers to a bread produced on the basis of rice powder, alpha-amylase, fermented milk, a polysaccharide and wheat flour. Claim 4 states that *camu camu juice* is a component of the fermented milk.

YACON

Smallanthus sonchifolius

Terms used in the search: *yacon, llacon, smallanthus, smallantus, sonchifolius, sonchifolia* and *polymnia.*

The scientific name of this resource is *Smallanthus sonchifolius*. However, a review of the web page "Origen de las raíces andinas" (Origin of roots from the Andes) turned up references to the resource as *Polymnia sonchifolia*.

US DATABASE

A search of the US database brought up 15 documents with descriptive sections referring to the term 'yacon', although not as the preferred resource.

– Documents US6,596,332, US6,197,361 and US5,952,033, published on July 22, 2003, March 6, 2001 and September 14, 1999, respectively, refer to a "gelatinized cereal product containing oligosaccharide". Although the descriptive sections of the documents mention yacon (as a source of inulin) among a number of other plants, chicory is the preferred source.

– Document US6,569488, published on May 27, 2003, concerning "Processes for making novel inulin products" (also published as application US20020098272); document US6,419,978, published on July 16, 2002, concerning "Inulin fractions"; document US6,399,142, published on June 4, 2002, concerning "Liquid food products"; and document US20030207003, published on November 6, 2003, concerning "Sweetener compositions containing fractions of inulin", refer to products that contain inulin, and yacon, among other plants, is mentioned as a source of inulin in the descriptive sections of the documents. However, chicory is the preferred source.

– US6,093421, published on July 25, 2000, concerning "Maca and antler for augmenting testosterone levels". The descriptive section of the document states that yacon is grown in the Andes, as well as ahipa, arracacha and maca.

– US20030206981, published on November 6, 2003, concerning "Methods of using and compositions comprising cacao extract including dietary fiber". Yacon is mentioned in one of the comparative examples.

– US20040001898, published on January 1, 2004, concerning "Compositions and methods for detoxification and cancer prevention". Claim 1 refers to a composition comprising a plant that includes a source of dietary fibre and a phytochemical agent capable of inducing enzyme activity. Claim 5 mentions inulin. The descriptive section refers to yacon, among other plants, as a source of inulin. However, chicory and artichoke are preferred.

– US20040047896, published on March 11, 2004, concerning "Composition for improving age-related physiological deficits and increasing longevity". Yacon is mentioned in the descriptive section of the document.

– US20040161524, published on August 19, 2004, concerning "Process for producing a plant extract containing plant powder". Yacon, among many other plants, is mentioned in the descriptive section of the document. However, *Hydrangeae dulcis folium* is used in the examples.

– US20040208944, published on October 21, 2004, concerning "Compositions and methods against inflammatory processes". Claim 1 refers to a composition comprising a therapeutically effective plant, and although yacon is mentioned as forming part of the group of plant materials, chicory and artichoke are preferred.

– US20040219157, published on November 4, 2004, concerning "Composition comprising a prebiotic for decreasing inflammatory process and abnormal activation of non-specific immune parameters". Claim 1 defines a composition comprising a prebiotic, which, according to claim 3, comprises an oligosaccharide such as inulin. The descriptive section states that a plant material, including yacon, is the preferred prebiotic.

A search using the term 'polymnia' turned up document US6,399,124, published on June 4, 2002, concerning "Frozen dessert containing lactic acid bacteria". Claim 2 indicates that the dessert, as mentioned in claim 1, contains yacon (*Polymnia sonchifolia*). The other documents retrieved do not refer to the resource in question.

A search using the terms 'sonchifolius' and 'sonchifolia' turned up documents US20020192317, US20020022062 and US6,458,392, respectively published on December 19, 2002, February 21, 2002 and October 1, 2002, concerning "Preventive, alleviative or remedy for hypertension". Claim 1 in these documents refers to the use of a coffee bean extract. Yacon is not included in the claims and is only referred to in the descriptive sections as a possible additional component. This is also the case in US6,310,100.

A further search using the terms 'smallanthus', 'smallantus' and 'llacón' failed to turn up any documents.

EUROPEAN DATABASE

The European database search turned up references to Japanese documents for which no family of patents is cited. Documents RU2232188, KR2003064195, KR2001088568 and KR2001085077 were also retrieved. Although there were references to application WO9808527, published in Japanese on March 5, 1998, concerning "Yacon/oolong blend tea", the epoline database specifies that the application has been withdrawn.

JAPANESE DATABASE

The Japanese database search using the terms indicated in the table turned up 50 references identified by their publication numbers.

<u>Preparations for external use</u>

1. 2000-319120, published on November 21, 2000, concerning "Cosmetic composition including vegetable extract having moisture retaining property". Claim 1 refers to a make-up

base containing one or more extracts from plants such as yacon, aguaje, achira, algarrobo, huito, oca, olluco, kañihua, cupuazu, tarwi, maca, mashua and molle.

2. 2002-068953, published on March 8, 2002, concerning "Cosmetic composition". Claim 1 refers to a melanin inhibitor containing *yacon extract* and/or an extract from Citrus Junos.

3. 2002-205950, published on July 23, 2002, concerning "Elastase activity inhibitor and cosmetic composition". Claim 1 refers to an elastase inhibitor containing one or more plant extracts, including yacon. Claim 2 refers to a makeup base containing the inhibitor cited in claim 1.

Pharmaceutical applications

4. 03-227995, published on October 8, 1991, concerning "Production of fructo-oligosaccharide", refers to a *compound obtained from yacon juice*, with poor digestibility and low carcinogenicity, which improves the intestinal flora and reduces blood cholesterol.

5. 05-207900, published on August 20, 1993, concerning "Extraction of fructooligosaccharide from Polymnia sonchifolia", refers to a counter-current extraction using alkaline hot water with a pH of 9-11.

6. 07-061980, published on March 7, 1995, concerning "Antibacterial compound PSF-A, PSF-B, PSF-D, their production and antibacterial composition". The claims refer to compounds exhibiting a sesquiterpene lactone structure. Compounds A and B are known and compound D is new, but all are described as exhibiting novel antibacterial activity.

7. 2000-342228, published on December 12, 2000, concerning "Formulated tea of Smallanthus sonchifol with mulberry leaf", refers to the mixing of 1 part yacon tea with 0.3-3% per weight of mulberry leaves, which are effective in improving glucose tolerance. The tea can therefore be used in the treatment of diabetes (see also 2001-136939).

8. 2001-136939, published on May 22, 2001, concerning "Method for producing yacon tea containing mulberry leaf". Claim 1 refers to the mixing of yacon leaves and stems with mulberry leaves, shredded, steamed, dried and roasted.

9. 2001-299272, published on October 30, 2001, concerning "Lipase inhibitor". Claim 1 refers to a lipase inhibitor derived from a *terrestrial part of the yacon plant*, an extract from a terrestrial part and/or an active ingredient from a terrestrial part. The abstract explains that the crude drug or extract inhibits pancreatic lipase activity and therefore prevents lipid accumulation in the body. Under example 1 an aqueous extract is obtained from the leaves.

10. 2002-045157, published on February 12, 2002, concerning "Smallanthus sonchifolia-Acanthopanax senticosus Harms mixed tea". This tea is composed of yacon stems and leaves and *Acanthopanax* bark and leaves, and is used in the treatment of diabetes, hyperlipidemia and obesity.

11. 2003-128571, published on May 8, 2003, concerning "*Diabetic* medicine and health food". This is made from loquat leaves and an extract from at least one of a variety of plants, including yacon.

12. 2003-192603, published on July 9, 2003, concerning "Anti-cancer agent and healthy food". Claim 2 refers to an immune function-enhancing anticarcinogenic agent containing, *inter alia*, *yacon leaf extract*.

13. 2003-265151, published on September 24, 2003, concerning "Tea for health". The tea is composed of a mixture of 30 parts per weight of dried yacon leaves, 40 parts per weight of dried *Rubus suavissimus* leaves and 40 parts per weight of dried *Acanthopanax senticosus Harms* leaves. It is described as having anti-allergenic properties and is used in the treatment of diabetes mellitus and hyperlipidemia and in the prevention of obesity.

Plant analysis and propagation

14. 07-209248, published on August 11, 1995 and granted on September 18, 1996 as patent No. 2090596, concerning "Analysis of polyphenols". It refers to an analysis by means of an electrode, conducted on vegetable tissue (including yacon).

15. 06-292479, published on October 21, 1994, concerning "Proliferation of yacon". It refers to a method enabling the propagation of genetically stabilized yacon free of bacterial infection, using a growth inhibitor, gibberellin, etc., in a medium containing cytokinin and sucrose, in which the yacon plant is cultured.

Food products

16. 02-234648, published on September 17, 1990, concerning "Polynnia sonchifolia extract and polynnia sonchifolia juice". It refers to a juice (obtained after the removal of skin and pulp residues) that is heated at a temperature below boiling point and mixed with salt and an anti- discoloration agent. Any remaining hard residue is then removed and the juice is purified and sterilized.

17. 04-075569, published on March 10, 1992, concerning "Yacon and food and drink prepared therefrom". The yacon is heated with hot water, steamed, etc., at a temperature of 60-120ºC for 1-60 minutes, or preferably at 80-100ºC for 3-30 minutes. The processed product is then used to make a health food or beverage, dried powder or chips.

18. 04-104772, published on April 7, 1992, concerning "Food and drink and production thereof". The yacon is heat-treated through immersion in hot water, preferably at a temperature of 80-110ºC for 3-30 minutes, and then ground and treated with an enzyme (preferably cellulase or pectinase) to obtain the food product in question.

19. 04-248963, published on September 4, 1992, concerning "Preparation of agar cake", which is made according to the following procedure: (a) The yacon is peeled, sliced, boiled and drained; (b) separately, grated yacon is mixed with lemon juice and filtered to obtain yacon juice. The juice is then mixed with a sweetener (sugar) or honey, diluted with water, boiled, and agar is added. Finally, the yacon slices prepared according to (a) are incorporated into the liquid.

20. 04-248964, published on September 4, 1992, concerning "Preparation of 'yokan'-like agar ice cream", which is produced as follows: (a) The yacon is peeled, cut up into small pieces, mixed with sweetener, boiled over a slow fire and drained; (b) agar, lemon juice, sugar and honey are separately dissolved in hot water; (c) the yacon prepared according to (a)

is then added to the mixture, which is stirred while heating, after which the mixture is taken off the heat and left to cool down.

21. 04-248962, published on September 4, 1992, concerning "Preparation of jam". The yacon is treated with a vitamin C solution, finely grated, added with water, a sweetener (e.g. sugar), starch syrup, lemon juice and flavouring, and the mixture is stirred as it boils down to reach jam consistency.

22. 04-262747, published on September 18, 1992, concerning "Yacon jam". This refers to the preparation of a jam composed of yacon, lemon, fruit, sugar or Azuki bean (red bean).

23. 07-284382, published on October 31, 1995, concerning "Yacon strawberry". Claim 1 refers to a tea containing dried yacon in the form of powder or flakes.

24. 08-294379, published on November 12, 1996, concerning "Preparation of fermented yacon drink". This refers to a beverage prepared by adding milk or skimmed milk powder to (a) a liquid obtained through the fermentation of yacon juice with lactobacillus with a Brix of 10-15 degrees, and (b) yacon juice with a Brix of 10-15 degrees.

25. 08-308543, published on November 26, 1996, concerning "Drink preparation and its production". This refers to a beverage produced by: (a) Pressing the yacon to obtain juice and solids; (b) working the solids into a paste, using an enzyme (cellulase–pectinase); (c) blending the paste with the juice; and (d) adding ascorbic acid and fresh carrot juice.

26. 08-332046, published on December 17, 1996, concerning "Production of dried vegetable". This refers to a *vegetable that is vacuum-dried* after slicing into 5-15 mm sections.

27. 09-224624, published on September 2, 1997 and granted on March 17, 2000 as patent No. 3044337, concerning "Drinking preparation and production of the same". This refers to a beverage containing raw yacon and ascorbic acid or sodium ascorbate, which is produced by: (a) washing and heating the raw yacon to remove the pigment; (b) oxidizing and crushing the yacon to obtain a ground product; and (c) using ascorbic acid or sodium ascorbate to create the reaction that gives the vegetable drink its yellow or orange colour.

28. 10-028566, published on February 3, 1998, concerning "Production of yacon juice". The juice is obtained by subjecting yacon to the following process: (a) washing in water; (b) removal of the skin; (c) immersion in lemon water; (d) pressing and addition of lemon juice; (e) further pressing to extract the juice; (f) sterilization; and (g) bottling.

29. 10-218782, published on August 18, 1998, concerning "Food material from tuberous root part of yacon and its production". This refers to a powder made from the yacon root, which is produced by adjusting the pH of the juice extracted from the root to 6.5-9.5 and then drying the juice.

30. 10-298009, published on November 10, 1998, concerning "Aid for supplying nutrient to crop". Claim 1 refers to a crop supplement containing yacon-based vinegar.

31. 11-178505, published on July 6, 1999 and granted on January 11, 2002 as patent No. 3265471, concerning "long-term storage for tuberous root vegetables such as beet". According to the abstract, this refers to a process for stabilizing tuberous roots with a high

water content, such as beet and yacon. The process involves the following: (a) washing the root in water containing chlorine or hydrogen peroxide; (b) bleaching the root through immersion in a 1-2 per cent saline solution; (c) soaking the dried root in a saccharide solution for 2-24 hours; (d) removing the processed product from the solution and freezing it at a temperature of -20ºC.

32. 11-178536, published on July 6, 1999 and granted on June 21, 2002 as patent No. 3318864, concerning "Production of snack food of tuberous roots of beet or the like". According to the abstract, a beet or yacon snack is produced as follows: The beet or yacon root, whether chopped or whole, is pre-treated and immersed in a saccharide solution of 20-65 degrees Brix. It is then frozen or not as the case be may be, fried under reduced pressure, and dried.

33. 2000-157233, published on June 13, 2000, concerning "Squeezing of transparent concentrated juice from yacon juice without decomposing fructooligosaccharide". According to the abstract, the method consists of extracting the juice from the yacon, adding Vitamin C, subjecting the liquid to cold sterilization and removing the extract without the fructo-oligosaccharide undergoing decomposition.

34. 2000-316505, published on November 21, 2000 and granted on July 18, 2003 as patent No. 3451550 concerning "Quality-improving agent of noodle and noodle using the same". It refers to a water-soluble fructo-oligosaccharide obtained from the yacon root, a liquid obtained by separation from the root tuber, or a powder obtained from the water-soluble materials.

35. 2000-333642, published on December 5, 2000 and granted on July 18, 2003 as patent No. 3451545, concerning "Green crushed product of Polynnia sonchifolia and green juice of Polynnia sonchifolia". The green extract is obtained by removing the skin of the yacon, treating it with hot water to remove a blue pigment, crushing the treated plant, obtaining the green extract and again treating it thermally. Another method is to remove the skin, crush the yacon in air, leave it for a time, and then expose it to thermal treatment.

36. 2001-019664, published on January 23, 2001 and granted as patent No. 3039864, concerning "Tricaffeoylaldaric acid, its production and its use". Claim 1 refers to a formula defined in terms of its chemical structure. According to the abstract, the compound is an antioxidant for use in the food industry.

37. 2001-252038, published on September 18, 2001, concerning "Processed food made from yacon tuber as main raw material and method for producing the same". The abstract refers to a method of obtaining a food of stable colour (a juice) by mixing pulverized yacon tuber with other components such as fruits and vegetables.

38. 2002-101859, published on April 9, 2002, concerning "Yacon soybean milk drink". Claim 1 refers to a drink consisting of soybean milk, yacon juice and honey. According to claim 2, the yacon juice is obtained by pressing the yacon root and adding ascorbic acid or its salt.

39. 2002-119262, published on April 23, 2002, concerning "Method for producing yacon juice". The abstract explains that the method consists of contact-treating the yacon root with a heating medium to soften its surface, then removing the skin, heating and pressing in the

presence of an inert gas, squeezing out the juice, and heat-sterilizing it by means of conventional processes to obtain the yacon juice.

40. 2002-262816, published on September 17, 2002, concerning "Method for yacon processing". Claim 1 refers to a processing method, which involves freezing and vacuum-drying the yacon.

41. 2003-134996, published on May 13, 2003, concerning "Sake lees-pickled kimuchi", refers to a sake-based food product using yacon as a supplementary ingredient.

42. 2003-225050, published on August 12, 2003, concerning "Dried yacon and method of producing the same". Claim 1 refers to dessicated yacon characterized by containing surface aliphatic carboxylic acid and with a 3-13 per cent moisture content by weight. The detailed description refers to citric and ascorbic acids, and the abstract explains that the purpose is to obtain dried yacon that can be stored for long periods without deterioration and retain its natural taste.

43. 2003-231894, published on August 19, 2003, concerning "Citrus flavour deterioration inhibitor, citrus perfume, food and citral cyclization inhibitor". Claim 1 refers to a yacon extract that inhibits deterioration of the citrus flavour system.

44. 2003-235495, published on August 26, 2003, concerning "Method for producing food using yacon". Claim 1 refers to the process for manufacturing the food by treating the yacon with acidulated water in order to inhibit the activity of an oxidizing enzyme. The detailed description explains that the purpose is to prevent oxidization of the yacon's components, particularly the component known as Kraft oligosaccharide.

45. 2003-299460, published on October 21, 2003, concerning "Green yacon powder and method for producing the same". Claim 1 refers to a *green powder obtained by drying and then grinding the yacon leaves and stems.*

46. 2003-299466, published on October 21, 2003, concerning "Powdered drink and method for producing the same". Claim 1 refers to a powdered drink, characterized by a saccharide content consisting of the *dried powder of the yacon root*, containing about 20 per cent fructo-oligosaccharide by weight.

47. 2004-173664, published on June 24, 2004, concerning "Yacon processed food product soaked in sugar and compound confectionery using the same". Claim 1 refers to the process for obtaining the product, which involves first washing the yacon in cold water, then cutting and heat-treating it before infiltrating the product with sugar by soaking it in a sugar solution.

48. 2004-173684, published on June 24, 2004, concerning "Yacon tuber chip and method for production of the same". Claim 1 refers to the production process, which involves first washing the yacon in cold water, then boiling it to remove the bitter, astringent taste, cooling, slicing, treatment to prevent discoloration, then drying and baking the slices to obtain the chips.

49. 2004-194663, published on July 15, 2004, concerning "Functional food product". Claim 1 refers to a food product containing yacon powder and yoghurt powder, and which may also contain soybean meal. According to the abstract, the product helps to relieve constipation.

50. 2004-222703, published on August 12, 2004, concerning “Pickle of yacon and method for producing the same”. According to the abstract, the pickle is obtained from stems and leaves soaked in a pickling liquid at 5-10°C for 1-30 days.

CAIGUA

Cyclanthera pedata L.

Terms used in the search: *cyclanthera, ciclanthera, ciclantera, cyclantera, pedata, caigua, caihua, caygua, cayua, korila, achocha, achokcha, and wild cucumber.*

The scientific name of this resource is *Cyclanthera pedata*. However, a review of the Purdue University web page[10] yielded references to the resource as "caihua", "caygua", "cayua", "korila", "achocha", "achokcha" and "wild cucumber"; accordingly those terms were included in the search.

A search of the US database brought up a document in which the term "cyclanthera" is mentioned in the descriptive section:

– US 6,746,695, published on 8 June 2004, concerning "Pharmaceutical preparations of bioactive substances extracted from natural sources". Although the descriptive section mentions the *Cyclanthera* family among many others, the patent claims mention only the species "Kava root".

A search for the other terms in the US, European and Japanese databases turned up documents, but none relating to the species *Cyclanthera pedata,* although the documents refer to an author's name, to other plants (such as *Holothuroidea pedata, Viola pedata, Telphairia pedata, Adiantum pedatum L.*), and to the wild cucumber mosaic virus; consequently, they are not relevant.

[10] http://www.hort.purdue.edu/newcrop/SearchEngine.html

SACHA INCHI

Plukenetia volubilis L.

Terms used in the search: *Plukenetia, Pluquenetia, Plucenetia, volubilis, Sacha inchi, Sachainchi, Sacha inche, sachainche, sacha, Inca peanut, Inka peanut, fragariopsis and tetracapidium.*

The scientific name of this resource is *Plukenetia volubilis L*. However, a review of the Missouri Botanical Garden web page[11], turned up references to the resource as *Fragariopsis paxii Pittier*. The FAO Agricultural Services Bulletin web page[12] states that Sacha inchi is a plant that grows in tropical forests and that the main producers are in West Africa and Central and South America. The botanical synonym is *Tetracapidium conophorum*, and it is also known colloquially as "Inca peanut". Consequently, the latter two names were included as search terms.

The search in the United States database brought up the following:

– Eight hits for patents referring to inks. In these documents, although the term "plukenetia" is cited in the claims and the descriptive section, the reference is to plukenetia oil generally, without specifying the species used.

– Five applications for patents mention the term "plukenetia" in the claims and the descriptive section. Four of them refer to medicinal preparations in which, although the *Plukenetia* family is cited in a list of plant families that may possibly be used, the *Euphorbiaciae* family is cited as the preferred and appropriate source for putting the invention into practice. The fifth document refers to an ink that uses plukenetia oil, without specifying the species used.

Although a search for the term "volubilis" in the US, European and Japanese databases brought up documents, these do not refer to the resource *Plukenetia volubilis*, instead referring to *Cheiranthera volubilis, Dalbergia volubilis, Dregea volubilis, Streptomyces rochei var volubilis, Bowiea volubilis, Wattakaka volubilis, Bowica volubilis, Rhynchosia volubilis* and *Boviea volubilis*, and they are therefore not relevant.

A search in the US, European and Japanese databases using the term "sacha" yielded results that do not relate to the resource *Plukenetia volubilis*, referring instead to inventors' names, names of authors of publications, a plant, *Anthurium andreanum*, known as "Sacha", or to a brand of perfume, Sacha A 236,286; accordingly none of these is relevant.

A search using the term "Inca peanut" in the US, European and Japanese databases yielded documents which do not, however, relate to the resource *Plukenetia volubilis*.

A further search in the US, European and Japanese databases using the other terms listed yielded no documents.

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11 http://mobot.mobot.org/cgi-bin/search_vast?onda=N12802411

12 http://www.fao.org/docrep/X5043E/x5043E0a.htm

CHANCAPIEDRA (Shatterstone)

Phyllanthus niruri

Terms used in the search:*Phyllanthus, Phyllanthus niruri, niruri, Phyllanthus amarus, Chancapiedra, Chanca-piedra, Chanca piedra, Shatterstone, Quebra pedra and Phyllanthus lathyroides.*

The scientific name of the resource is "*Phyllanthus niruri*". The Tropilab Inc. website[13] refers to it, however, as *Phyllanthus amarus* & *niruri*, describing it as a plant found in Suriname and used in ayurvedic medicine, and adding that the species *P. amarus* and *P. niruri* are closely related. Therefore, although both terms have been included as search words, there is a need to ascertain whether they are synonyms or whether they refer to closely related species. The website also mentions that the species *Phyllanthus urinaria, debilis* and *fraternus* are closely related to the resource.

Furthermore, United States patent No. 6,136,316 states that *Phyllanthus* species are used in southern India as well as in China, the Philippines, Cuba, Nigeria, Guam, Africa, the Caribbean, Central America and South America.

An article in the MEDLINE[14] database explains that *Phyllanthus niruri* is a plant used in Brazilian folk medicine for the treatment of urolithiasis.

The database searches produced references to the species *Phyllanthus emblica*, but these were not considered to be relevant.

There is a need to establish whether the species *Phyllanthus urinaria*, *debilis* and *fraternus* are closely related to *Phyllanthus niruri*. Nevertheless, a search conducted using these names yielded only references to *Phyllanthus urinaria*, as follows:

US database

– US 5,073,545, published on December17, 1991, concerning "Agent containing an ellagic acid series compound for external application and use thereof".

– US 6,066,312, published on May 23, 2000, concerning "Topical composition for application to the skin containing an ellagic acid-based compound or salt thereof".

– US 6,080,401, published on June 27, 2000, concerning "Herbal and pharmaceutical drugs enhanced with probiotics".

– US 20040028643, published on February 12, 2004, concerning "Compositions for retarding skin ageing".

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13 Tropilab Inc. web page: http://www.tropilab.com/black-cat.html

14 http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12599017

European database

– KR 2003063308, published on July 28, 2003, concerning "Agent for treating type B hepatitis containing *Phyllanthus urinaria* and production thereof".

– KR 2000031308, published on June 5, 2000, concerning "*Phyllanthus urinaria* extract used for hepatitis therapy and production method thereof".

– CN 1238211, published on December 15, 1999, concerning "Yexiazhu tablet for treating hepatism".

– CN 1234741, published on November 10, 1999, concerning "Pharmaceutical composition for treatment of hepatitis B comprising extract of *Phyllanthus ussuriensis* and/or *Phyllanthus urinaria*".

– GB 2331460, published on May 26, 1999, concerning "Pharmaceutical composition for the treatment of hepatitis B comprising extract of *Phyllanthus ussuriensis* and/or *Phyllanthus urinaria*". Same patent family as WO 9807437.

– WO 0196589, published on December 20, 2001, concerning "Lignan compounds with antiproliferative properties".

Japanese database

2002-179581, published on June 26, 2002, concerning "Skin aging inhibitor".

Without prejudice to a subsequent check to establish whether *Phyllanthus niruri* and *Phyllanthus amarus* are synonyms or closely related species, the results of the search conducted using these two terms were as follows:

US DATABASE

The US database search yielded the following documents:

1. US 4,673,575, published on June 16, 1987, concerning "Composition, pharmaceutical preparation and method for treating viral hepatitis". Claim 1 refers to a method for treating viral hepatitis using a *Phyllanthus niruri* extract.

2. US 4,859,468, published on August 22, 1989, concerning "Compositions and method for decomposing adipose tissue". Claim 1 refers to an extract of *Piper angustifolium* and *Boldea fragrans*. The use of chancapiedra in a comparative trial is mentioned in the detailed description of the invention.

3. US 4,937,074, published on June 26, 1990, concerning "Method of treating retrovirus infection". Claim 1 refers to a treatment method involving the administration of a component of *Phyllanthus niruri* having endogenous reverse transcriptase inhibitory activity. Claim 11 states that this component is obtainable by *methanol or water extraction*. The descriptive section mentions that this plant is common to India and has been used in ayurvedic medicine.

4. US 5,529,778, published on June 25, 1996, concerning "Ayurvedic composition for the prophylaxis and treatment of AIDS, flu, TB and other immuno-deficiencies and the process for preparing the same". Claim 1 refers to a combination of plants, including *Phyllanthus niruri*.

5. US 6,136,316, published on October,24, 2000, concerning "Hepatoprotective compositions and composition for treatment of conditions related to hepatitis B and E infection". Claim 1 refers to a polyherbal composition, one of the components of which is *Phyllanthus amarus*.

6. US 6,218,183, published on April 17, 2001, concerning "Screening method for the identification of plants possessing anti-microbial activity and tolerance to abiotic stresses". Claim 1 refers to the steps involved in the screening method for the identification of such plants. The plants listed in the description of the invention include *Phyllanthus amarus*.

7. US 6,440,466, published on August 27, 2002, concerning "Composition for treating white spot syndrome virus (WSSV)-infected tiger shrimp (*Penaeus monodon*) and a process for preparation thereof". The descriptive section states that *Phyllanthus amarus* has antiviral properties. Claim 1, however, relates to other plants.

8. US 6,517,861, published on February 11, 2003, concerning "Composition of herbal biscuits for lactating mothers acting as dietary supplement and process for preparation thereof". The group of plants which can be used, as described in claim 4, includes *Phyllanthus amarus*. This patent was submitted as US Patent Application No. 20020136783.

9. US 6,589,570, published on July 8, 2003, concerning "Pharmaceutical formulation useful for the treatment of hepatitis B, hepatitis C and other viral infections of the liver and a process for its preparation". Claim 1 relates to three different *Phyllanthus amarus* extracts.

10. US 20020054921, published on May 9, 2002, concerning "Use of *Phyllanthus* components for the treatment or prophylaxis of infections triggered by flaviviridae". Claim 1 refers to the *use of one or more Phyllanthus components* and claim 6 specifies that these are derived from *Phyllanthus niruri*, *Phyllanthus amarus*, *Phyllanthus urinaria*, *inter alia*.

11. US 20020182227, published on December 5, 2002, concerning "Treatment of virus using chelator and antiviral agent". The detailed description of the invention states that the *antiviral agent can be prepared from Phyllanthus niruri*, *inter alia.*

12. US 20020182272, published on December 5, 2002, concerning "Methods of treatment of HIV-associated conditions". Claim 1 refers to the method using a chelator and an antiviral agent comprising a plant extract. Claim 10 states that this extract may be prepared from a number of plants, including *Phyllanthus niruri*.

13. US 20020187957, published on December 12, 2002, concerning "Time release reverse transcriptase inhibitors". Claim 1 relates to a composition which reduces the viral serum titer of a virus in an amount of at least 20 per cent over a period of at least six hours. Claim 4 states that the inhibitor compound comprises a plant extract and the list of the plants which can be used, as provided in the detailed description, includes *Phyllanthus niruri*.

14. US 20030068828, published on April 10, 2003, concerning "Novel method for chromatographic finger printing and standardization of single medicines and formulations". The detailed description mentions that *Phyllanthus niruri* was used in the work.

15. US 20030072822, published on April 17, 2003, concerning "Methods for treating disorders using plant extracts". Claim 1 relates to a method of modulating the blood glucose level of a mammal by administering an extract of Artemisia. The detailed description states that Artemisia may be combined with a second plant, such as *Phyllanthus niruri*.

16. US 20030083226, published on May 1, 2003, concerning "Composition having reverse transcriptase inhibitor activity". Claim 1 states that the active compound is found in plants and the list of possible plants given in the detailed description includes *Phyllanthus niruri*.

17. US 20030104076, published on June 5, 2003, concerning "Process for preparing dry extracts". The list of plants provided in the detailed description includes *Phyllanthus niruri*.

18. US 20040028754, published on February 12, 2004, concerning "Use of *Phyllanthus* component for the treatment or prophylaxis of infections triggered by flaviviridae ". Claim 1 refers to *the use of a Phyllanthus component*, while claim 6 mentions *Phyllanthus niruri, Phyllanthus amarus* and *Phyllanthus urinaria, inter alia*.

19. US 20040033275, published on February 19, 2004, concerning "Method for the production of *Phyllanthus* extracts". Claim 1 defines the extraction process, wherein: (a) *Phyllanthus* components are extracted with an ethanol/water mixture of 5-85% m/m to which a heavy-metal chelator is added; (b) the extract obtained is contacted and concentrated with (ba) Indian Sterculia gum at a concentration of 0.5-5% or (bb) one or more polymers and (c) the concentrated extract is dried. The application states that the use of *Phyllanthus amarus* is preferred.

20. US 20040161477, published on August 19, 2004, concerning "*Phyllanthus*-derived compounds for the prevention and/or treatment of disease associated with a retrovirus". Claim 1 refers to the use of a *Phyllanthus* extract and claim 16 specifies that this extract is obtained from *Phyllanthus amarus*.

21. US 20040197426, published on October 7, 2004, "Use of *Phyllanthus* constituents for treating or preventing infections caused by hepatitis". Claim 1 relates to the use, for the purpose of the treatment of infectious diseases caused by the hepatitis B virus, of a *Phyllanthus component*, derived, according to claim 6, from *Phyllanthus niruri, Phyllanthus amarus* and *Phyllanthus urinaria, inter alia*.

22. US 20040197889, published on October 7, 2004, "Recombinant expression of hhbv reverse transcriptase (rt)". Claim 11 refers to a method of screening for an HBV-RT (hepatitis B virus) inhibitor, which can be prepared from a plant such as *Phyllanthus amarus*.

EUROPEAN DATABASE

The following documents were retrieved:

1. IE 890994L, published on September 29, 1989, concerning "Compositions comprising a component of *Phyllanthus niruri*".

2. EP 0890360, published on January 13, 1999 and granted on 2 January 2003, concerning "A polyherbal pharmaceutical composition useful in the treatment of conditions associated with hepatitis E and hepatitis B virus infections". Claim 1 refers to a polyherbal composition of five plants, including *Phyllanthus amarus* Linn.

3. AU 4947700, published on October 9, 2000, concerning "An enriched fraction prepared from *Phyllanthus amarus* for the treatment of hepatitis and the preparation thereof". This patent is a member of same patent family as the application WO 0056347 (withdrawn on
4. 2 January 2002, according to the epoline database)[15]. Claim 1 refers to a process for the extraction of *Phyllanthus amarus* using (i) methanol and (ii) a methanol-water mixture.

5. DE 10014674, published on October 31, 2001, concerning "Extracting pure hepatoprotective agent phyllanthin in high yield from *Phyllanthus amarus*, by pulverizing and macerating dried leaves, percolating with organic solvent, defatting, chromatographing and crystallizing". The abstract refers to an extraction process. The full version of the patent is published in German and there is no patent family.

6. WO 03030635, published on April 17, 2003 (withdrawn on 24 November 2004), concerning "A herbal hepatoprotective and weight gain promoter and a process thereof". It refers to a polyherbal composition of four plants, including *Phyllanthus amarus*.

JAPANESE DATABASE

The search turned up the following documents:

Preparations for pharmaceutical use

1. 03-206044, published on September 9, 1991, concerning "Anti-retrovirus agent". It refers to a chemical compound defined by its chemical structure and obtained from an aqueous extract of *Phyllanthus niruri.*

2. 09-241176, published on September 16, 1997, concerning "Lipid metabolism improving and hepatic disorder suppressing agent". Claim 1 refers to a lipid metabolism-improving agent, the active ingredient of which is *quebra pedra (shatterstone) extract in an organic or aqueous solvent. Phyllanthus niruri* is mentioned in the abstract.

3. 2000-319188, published on November 21, 2000, concerning "Therapeutic agent for hyperlipemia". Claim 1 refers to an agent with blood lipid-improvement properties, the *active ingredient* of which is *Phyllanthus niruri*.

4. 2003-119117, published on April 23, 2003, concerning "Anticariogenic agent and composition for oral cavity". The abstract states that the anticariogenic agent can comprise a glucosyltransferase inhibitor extracted from a group of plants, including *Phyllanthus niruri*. No mention is, however, made of this species in the claims.

[15] http://register.epoline.org/espacenet/ep/en/srch-reg.htm

Preparations for cosmetic use

5. 05-070360, published on March 23, 1993 and granted on 13 April 2001 as patent No. 3177642, concerning "Androgenic hormone-resistant agent". The abstract refers to the extract of Japanese and Chinese plants and 14 types of *Peruvian* plants, as described in the claims and including hierba luisa (herb Louisa or lemon verbena), achicoria (chicory), matico, cardo santo (blessed thistle), *chancapiedra* (shatterstone), muña, uña del gato (cat's claw), kiwicha (love-lies-bleeding) and algarrobo (carob tree**).**

6. 08-012566, published on January 16, 1996, concerning "Inhibitor of tyrosinase activity". Claim 1 relates to a tyrosinase inhibitor comprising one or more extracts of (i) *chancapiedra* (shatterstone), (ii) matico and (iii) nettle.

7. 08-176004, published on July 9, 1996, concerning "Living body-aging preventive and composition for skin". Claim 1 refers to a *Phyllanthus niruri extract* with antioxidant activity.

8. 08-231352, published on September 10, 1996, concerning "Hair tonic". Claim 1 refers to a hair tonic comprising an extract of certain plants, including *Phyllanthus niruri* (referred to as Meniran). According to the legal status, this patent was withdrawn on 14 November 2001.

9. 09-087136, published on March 31, 1997, concerning "Dermal preparation for external use". Claim 2 refers to a skin preparation for external use containing an extract of *Phyllanthus niruri* (referred to as Meniram). The abstract states that the preparation acts as a melanogenesis inhibitor, tyrosinase inhibitor, protease inhibitor and elastase inhibitor. According to the legal status, this patent was withdrawn on 9 November 2001.

10. 10-130129, published on May 19, 1998, concerning "Hair dyeing composition". The abstract refers to a hair dye containing an oxidizable agent, an oxidizer and one or more kinds of plant extracts selected from *Ginkgo biloba*, *Phyllanthus niruri* and *Rosmarinus officinalis*.

11. 2000-336024, published on December 5, 2000, concerning "Cosmetic composition containing moisturizing plant extract". The abstract explains that the composition contains an extract of at least one of the following plants: uña del gato (cat's claw), hercampuri, quinoa, sangre de grado (dragon's blood), cedrón (herb Louisa or lemon verbena), *chancapiedra* (shatterstone), pajaro bobo, balsamina (balsam), boldo, matico, manzanilla (camomile) and muña.

12. 2001-261545, published on September 26, 2001, concerning "Skin care preparation for prevention of chapped skin". Claim 1 refers to a composition for external use containing an extract of *Phyllanthus niruri* or of other plants. According to the legal status, the application was withdrawn on 22 January 2002.

13. 2002-187843, published on July 5, 2002, concerning "Glucosyltransferase inhibitor". Claim 1 refers to a glucosyltransferase inhibitor comprising extracts of plants such as *chancapiedra* (shatterstone). The abstract explains that the inhibitor can be used to suppress the formation of dental plaque.

14. 2002-308750, published on October 23, 2002, concerning "Skin care preparation". Claim 1 refers to a preparation for external use characterized by containing fine particles

which serve as a UV filter, and possibly containing an *extract of Phyllanthus niruri* or of other plants (see claim 3).

[End of Annex and of document]