The Design of the TKDL: Mapping out the Technical and Legal Specificities

V K Gupta, Senior Advisor and Director, TKDL, Council of Scientific and Industrial Research, Rafi Marg, New Delhi; E-mail: vkg@csir.res.in

International Conference on “Utilization of the Traditional Knowledge Digital Library (TKDL) as a Model for the Protection of Traditional Knowledge”

New Delhi, India, March 22 to 24, 2011

Case-I EP1747786

European Patent Office

Bibliographic data

<table>
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<tr>
<th>Publication number: EP1747786 (A2)</th>
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<tr>
<td>Publication date: 2007-01-31</td>
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<tr>
<td>Inventor(s): PAULO ROMERO ABEL GUSTAVO [VE], ROJAS URDANETA JANETH ELISABETH [VE]</td>
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<td>Applicant(s): FERDI EUGRUPGROUP ELEGH</td>
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<td>Classification: A61K36/42; A61K36/61; A61K36/752; A61P17/00</td>
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<td>Application number: EP20060115343; 20060724</td>
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<td>Priority number(s): EP20060115342; 20060725</td>
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Natural product in cream with anti-vitiligo therapeutic properties

Also published as: EP1747786 (A3)

Cited documents:
- US2002102957A1
- FR2222038A1
- WO2004019723A1
- WO2004019723A1
- X000079810A
- X018001083A

View INPADOC patent family
View list of citing documents
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**Natural product in cream with anti-vitiligo therapeutic properties**

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<th>Bibliographic data</th>
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<th>Mosaics</th>
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**Claims of EP 1749786 (A2)**

1. Natural product based on vegetal ingredients with anti-vitiligo therapeutic properties to be employed in the white patches of depigmentation present in the skin with vitiligo and to regenerate the melanocyte, which is dysfunctional during the disease. It shows the following composition:

- Watery extract of Pimienta racemosa 1:1
- Watery extract of Cucumis melo 1:2
- 100 ml. Watery extract of Citrus aurantifolia
- 100 mg Coenzyme Q-10
- 100 mg Pyridoxine Chlorhydrate

*and other related claims from 2 to 7*
Dear Sir,

This is in reference to 'Third Party Observation' under Article 115 of the EPC concerning the patentability of the invention on the issue of 'Novelty' of the claim.

The patent application titled 'Natural product in cream with anti-vitilligo therapeutic properties' with publication no: EP1747786 (Inventor(s): PALEO ROMERO ABEL GUSTAVO [VE], ROJAS URDANETA JANETH ELISABETH [VE]), may kindly be referred to wherein the usefulness of extract of the Cucumis melo for the treatment of leucoderma / vitilligo through local application has been claimed to be novel. However, in Traditional Knowledge Digital Library (TKDL) there are several references where Cucumis melo has been used for the treatment of leucoderma / vitilligo through local application, since long. Hence, there does not seem to be any novelty or inventive step involved in the claims made in the above referred patent application.

In view of the above, Third Party Observation along with existing relevant prior art in printed books of Ayurveda, Unani and Siddha, is being enclosed for kind consideration.

Please also find enclosed herewith a brief write up on the TKDL as Annex-I for kind information. It may not be out of place to mention that TKDL Access Agreement with European Patent Office was concluded in February 2009. TKDL has been found to be a useful tool for establishing prior art by EPO examiners as mentioned in Press release by EPO (copy enclosed, Annex-II). The Third party observation filed herewith consists of prior art in the languages Sanskrit, Hindi, Tamil, Urdu, Arabic and Persian and translation of the same in English- one of the official languages of EPO and also terminology conversion in respect of names of plants and diseases (details enclosed as Annex-III).

With regards,

Yours sincerely,

(V K Gupta)

End: As above.

European Patent Office
Postfach 5818
2280 HV Rijswijk
Netherlands
Tel: 431/4170 340 2040
Third Party Observation under Art. 115 of EPC

A. Details of Application
This is with reference to the Patent Application (no. 06015343.4) with publication number EP1747786, published on 2007-01-31

Title: Natural product in cream with anti-vitiligo therapeutic properties

Inventor(s): PALEO ROMERO ABEL GUSTAVO [VE]
ROJAS UROJETA JANETH ELISABETH [VE]

Applicant(s): PERDIX EUROGROUP S L [ES]

Priority: VE20050001492

B. Claims
The following claims are included in the third party observation:
1. Natural product based on vegetal ingredients with anti-vitiligo therapeutic properties to be employed in the white patches of depigmentation present in the skin with vitiligo and to regenerate the melanocyte, which is dysfunctional during the disease. It shows the following composition: Watery extract of Pinicola racemosa 1:1 Watery extract of Cucumis melo 1:2 100 ml. Watery extract of Citrus aurantifolia 100 mg Coenzyme Q-10 100 mg Pyridoxine Chlorhydrate

C. Statement of Grounds
The observation against the patent application EP1747786 (A2), relates to the novelty (Art 54, 56 of EPC) based on the references cited below:

D. Prior art

Documents & References
1. Quraqaboothead Najib-al-Ghaniji by Mohd. Najmul Ghani Khan, Munshi Naval
Kishore, Lucknow Ed. 2nd 1956, Pg 511
F.ID: NAH32382
Form name: Zimaad-e-Karsana

F.ID:AN22069
Form name: Zimaad E Matar Barae Bars

F.ID:FA110202
Form name: Zimaad-e-Karsana

F.ID:JA6709G
Form name: Zimaad E Matar Barae Bars

F.ID:JA77160E
Form name: Tila Bara-e- Amraz-e-Jild

The Exhibit 1: (pg. no. 04-05) refers to a formulation containing Cucumis Melo along with two other ingredients used for the treatment of leucoderma / vitiligo through local application.

The Exhibit 2: (pg. no. 06-07) refers to a formulation containing Cucumis Melo along with two other ingredients used for the treatment of leucoderma / vitiligo through local application.

The Exhibit 3: (pg. no. 08-09) refers to a formulation containing Cucumis Melo along with two other ingredients used for the treatment of leucoderma / vitiligo through local application.

The Exhibit 4: (pg. no. 10-11) refers to a formulation containing Cucumis Melo along with two other ingredients used for the treatment of leucoderma / vitiligo through local application.

The Exhibit 5: (pg. no. 12-13) refers to a formulation containing Cucumis Melo along with two other ingredients used for the treatment of leucoderma / vitiligo through local application.
The alleged patent application EP1747786 claims the usefulness of extract of *Cucumis melo* for the treatment of leucoderma / vitiligo. However *Cucumis Melo* has been known for its anti vitiligo property through local application in the Indian system of medicine, since long, as is evident from the exhibits cited from the books namely Quaraabaadeen Najm-al-Ghani by Mohd. Najmul Ghani Khan (Unani, Exhibit 1: pg. no. 04-05), Khazaain-al-Advia, by Mohd. Najmul Ghani Khan (Unani, Exhibit 2: pg. no. 06-07), Muheet Azam by Mohd. Azam Khan (Unani, Exhibit 3: pg. no. 08-09), Khazaain-al-Advia, by Mohd. Najmul Ghani Khan, (Unani, Exhibit 4: pg. no. 10-11) and Muheet Azam by Mohd. Azam Khan (Unani, Exhibit 5: pg. no. 12-13).

In addition to the aforesaid references, some other references also exist in TKDL, wherein *Cucumis Melo* has been used in combination with few other ingredients for the treatment of leucoderma / vitiligo.

The use of *Cucumis Melo* for the treatment of leucoderma / vitiligo as claimed in the said application EP1747786 (A2), is not novel as per the cited prior art and does not involve any inventive step, therefore can not qualify for the grant of patent rights.

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**Ground of Opposition:**

- **Claims:** Cucumis melo for treatment of leucoderma / vitiligo

- **Prior art:** 3 Unani texts describe the use
  - Quaraabaadeen Najm-al-Ghani by Mohd. Najmul Ghani Khan (20th Century AD)
  - Khazaain-al-Advia, by Mohd. Najmul Ghani Khan (20th Century AD)
  - Muheet Azam by Mohd. Azam Khan (19th century AD)
Substantive examination is to be resumed (see Guidelines G-VI, 14.5).

The Examiners have become aware of new prior art (Third Party Observation under Article 123(4) EPC).

The application claims the usefulness of a combination of five constituents for the treatment of vitiligo, one of these constituents being a 1:2 w/w extract of Cucumis melo containing catalase and superoxide dismutase.

However, Cucumis melo has been known for its anti-vitiligo property through local application in the Indian system of medicine, since long, as is evident e.g. from the Exhibits 1-5 (TKDL abstracts) as cited in the Third Party Observation under Art. 115 EPC.

This, even more, as the other ingredients of the combination, such as coenzyme Q10 or pyridoxine chlorhydrate, have also been used already in the therapeutic field of skin diseases e.g. as cutaneous antioxidants, see for instance D 1, D 3, D 4, D 5, D 6.

Therefore, Applicant is asked to provide evidence for a surprising, i.e. superior effect of the claimed combination product versus the already known products comprising the single ingredients. If there is no such evidence, then the Examiner reserves the right to refuse the application under Article 97 (2) EPC.

2) The above mentioned objections should be overcome by suitable amendment or explanation. In the case where new claims are filed, they should be accompanied by carefully adapted pages of the description (Rule 42 (1) EPC).

All outstanding issues will be discussed during oral proceedings.

If, however, the objections cannot be overcome by the Applicant, a refusal of the application (Art. 97 (2) EPC) has to be reckoned with at the end of the oral proceedings.
Neem Patent Case - EP436257 at European patent Office (EPO)

- Date of Grant: 4 August 1994
- Date of Opposition: 14 June 1995
- Date of Final Rejection: 8 March 2005
- No. of documents submitted by Applicant during opposition: 47
- No. of documents submitted by the Opposing Party: 45
- No. of oral hearings after Opposition: 20
- Average time between hearings: 3 to 4 months
- No. of Lawyers/Examiners in each hearing: 8
METHOD OF TREATMENT OR MANAGEMENT OF STRESS

The EPO does not accept any responsibility for the accuracy of data and information originating from other authorities than the EPO; in particular, the EPO does not guarantee that they are complete, up-to-date or fit for specific purposes.

Claims not available for EP 1906980 (A2)

Claims of corresponding document WO 2007014334 (A2)

What is claimed is:

1. A method for treating or managing stress disorders, comprising the step of administering to a mammal a therapeutically effective amount of a composition comprising: a) a [Virolene® trademark] plant extract, and b) a pharmaceutically, veterinary or nutritionally acceptable carrier(s).

2. The method according to claim 1, wherein the disorder is selected from the group consisting of anxiety-induced stress, operation-induced stress, stress-induced disease, hypnic change-induced stress, posttraumatic stress, induced stress, convulsion-induced stress, and adrenocortical-induced stress.

and other related claims from 3 to 30
Dear Sir,

This is in reference to ‘Third Party Observation’ under Article 115 of the EPC concerning the patentability of the invention on the issue of ‘Novelty’ of the claim.

Patent Application no. EP1905980 titled ‘Method of treatment or management of stress’ (Inventors: Ghoshal Shibnath [IN]), may kindly be referred to wherein treatment of anxiety induced stress, depression induced stress, sleep deprivation induced stress, thermic change induced stress, gastric ulcer induced stress, convulsion induced stress and adrenocortical induced stress with Withania somnifera has been claimed to as novel. But, in Traditional Knowledge Digital Library (TKDL) several references are there, where Withania somnifera is used for treatment of depression, insomnia, gastritis, gastric ulcer and convulsions, since long. Hence, there does not seem to be any novelty or inventive step involved in the claims made in the above referred patent application.

In view of the above, Third Party Observation along with relevant prior art existing in printed books of Ayurveda, Unani and Siddha, is being enclosed for kind consideration.

With regards,

Yours sincerely,

(V.K. Gupta)

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A. Details of Application

This is with reference to the Patent Application (no. WO 2007/014334) with publication number EP1905980, published on 01.02.2007.

Title: Method of treatment or management of stress
Inventor: Ghoshal Shibnath [IN]
Applicants: Natron Inc. [US]
Priority: 60/702,947, 27 July 2005 US
11/493,185, 26 July 2006 US

B. Claims

All claims of the application are included in the third party observation including the following:

1. A method for treating or managing stress disorders, comprising the step of: administering to a mammal a therapeutically effective amount of a composition comprising:
   a) Withania somnifera plant extract; and
   b) a pharmaceutically, veterinary or nutritionally acceptable carrier(s).
2. The method according to claim 1, wherein the disorder is selected from the group consisting of: anxiety induced stress, depression induced stress, sleep deprivation induced stress, thermic change induced stress, gastric ulcer induced stress, convulsion induced stress, and adrenocortical induced stress.
3. The method according to claim 4, wherein said composition is in the form of a tablet, syrup, elixir or capsule.
C. Statement of Grounds

The observation against the patent application no EP1906980 relates to the novelty (Art. 54 of EPC) based on the references cited below:

D. Prior art

Documents & References

   F.I.D.: RG12/1226
   Form name: Aswagandhadigntam

   F.I.D.: ak11/4074
   Form Name: Asvagnadhi Yoga

   F.I.D.: NA2/108X
   Form Name: Rochan-e-Asgandh

   F.I.D.: RG12/1062
   Form name: Aswagandhadi Curna

   F.I.D.: MH3/116
   Form Name: Asgand

6. Athmarakshaamirtham by Kandasamy Mudalair, Pub: Ilakkana Achagam, Chennai (1879), pp 465,466
   F.I.D.: AMOS/1004
   Form name: Parangi Chooranam - 7

7. Therayar Karisel (I.N.A.), by Therayar, pp 75
   F.I.D.: SP01/75
   Form name: Aswanganthathy Chooranum

   F.I.D.: AM05/1839
   Form Name: Vaayu Thratchiku Mezhugu

   F.I.D.: NA2/108V
   Form name: Safoof-e-Asgandhi

10. Agasthiar Vaiithiam 600 by Agasthiyar, Thamarai noolakam, 1st edn, 2003
    Page 39, 40
    F. ID: PD04/54
    Form name: Amukkara Karpam

    F. ID: RS21/767
    Form name: Phalasava
Third Party Observation

F.I.D. : MA3/828
Form name: Kushta Gau Danti

F.I.D. : SK03/201
Form name: Aavaari Nei

F.I.D. : AM05/1674
Form name: Mega Neerizivukku Ilagam -2

15. Vaithya Chinthamani by Yugi, Pub: Palani Thandayuthapani Devasthanam publications, Directorate of Indian systems of Medicine, Chennai. (Edn: 2nd, 1976) Page 286
F.I.D. : SP02/547
Form name: Theeya Naatra Iya Noikku Mezhugu

Exhibit 1 (pg.no. 8-10) and Exhibit 2 (pg.no. 11-12) refer to formulations wherein Withania somnifera is used as a single ingredient for the treatment of insomnia through oral administration.

Exhibit 3 (pg.no. 13-15) refers to a formulation wherein Withania somnifera has been mentioned as a memory enhancer through oral administration.

Exhibit 4 (pg.no. 16-18) contains reference of a formulation containing Withania somnifera along with one more ingredient used for the treatment of insomnia, weakness of heart, heart beat (palpitation) through oral administration.

Exhibit 5 (pg.no. 19-21) refers to the use of Withania somnifera as a single ingredient in the treatment of gastritis and as a general, uterine, renal and nerve tonic through oral administration.

Exhibit 6 (pg.no. 22-24) refers to the use of Withania somnifera, along with three other ingredients through oral administration for the treatment of hyperacidity, gastric ulcer and anaemia.

Exhibit 7 (pg.no. 25-27) contains reference of a formulation containing Withania somnifera along with seven other ingredients through oral administration used for the treatment of gastric ulcer and anaemia.

Exhibit 8 (pg.no. 28-31) contains reference of a formulation containing Withania somnifera, along with few other ingredients used through oral administration for the treatment of gastric ulcer.

Exhibit 9 (pg.no. 32-33) contains reference of a formulation containing Withania somnifera along with two more ingredients through oral administration used for the treatment of restlessness and depression.

Exhibit 10 (pg.no. 34-37) contains reference of a formulation containing Withania somnifera and also as a single ingredient through oral administration used for the treatment of gastric ulcer and anaemia.

Exhibit 11 (pg.no. 38-41) contains reference of a formulation containing Withania somnifera, along with few other ingredients used through oral administration for the treatment of insomnia.

Exhibit 12 (pg.no. 42-44) contains reference of a formulation containing Withania somnifera along with two more ingredients used for the treatment of convulsion through oral administration.

Exhibit 13 (pg.no. 45-47) contains reference of a formulation containing Withania somnifera, along with few other ingredients used through oral administration for the treatment of diabetes mellitus.
Comparison of Patent Application with Prior Art

The patent application EP1906980 claims to use the plant extract of *Withania somnifera* through oral administration for the treatment of anxiety induced stress, depression induced stress, sleep deprivation induced stress, thermic change induced stress, gastric ulcer induced stress, convulsion induced stress and adrenocortical induced stress. The effect of the composition on stress has been ascertained by clinically studying the subjective and objective features of stressed patients. These are nothing but symptoms and conditions which arise when a person is stressed. A whole lot of stress associated symptoms and changes are claimed to be mitigated by the use of said composition.

The prior art cited shows that *Withania somnifera* is frequently and effectively used through oral administration in the treatment of depression, insomnia, gastritis, gastric ulcer and convulsions which are defined as the causative factors of stress in the patent application.

The patent application EP1906980 further claims that use of *Withania somnifera* provides relief in palpitation, perspiration, increased blood pressure and improves haemoglobin level which have been stated as conditions resulting from stress. Again, the prior art quoted from the books Ayurveda Sarasamgrahah (Ayurveda, Exhibit 1: pg.no. 8-10), Vangasena by Vangasena (Ayurveda, Exhibit 2: pg.no. 11-12), Khazhaain- al-Advia by Mohd. Najmul Ghani Khan (Unani, Exhibit 3: pg.no. 13-16), Ayurveda Sarasamgrahah (Ayurveda, Exhibit 4: pg.no. 16-18), Muheet Azam by Mohd. Azam (Unani, Exhibit 5: pg.no. 19-21) Athmarakshaamirtham by Kandasamy Mudaliar (Siddha, Exhibit 6: pg.no. 22-24), Therayar Karisal by Therayar (Siddha, Exhibit 7: pg.no. 25-27) Athmarakshaamirtham by Kandasamy Mudaliar (Siddha, Exhibit 8: pg.no. 28-31), Khazaain-al-Advia by Mohd. Najmul Ghani Khan (Unani, Exhibit 9: pg.no. 32-33), Agathiar Vaithiam 600 by Agasthiyar (Siddha, Exhibit 10: pg.no. 34-37), Rasatantrasarah Evam Siddhaprayogasamgrahah (Ayurveda Exhibit11: pg.no. 38-41), Bayaaz-e-Kabir by Kabiruddin (Unani, Exhibit 12: pg.no. 42-44), Chikithsa Rathna Deepam by Kannusamy Pillai (Siddha, Exhibit 13: pg.no. 45-47), Athmarakshaamirtham by Kandasamy Mudaliar (Siddha, Exhibit 14: pg.no. 48-50), Valthya Chinthamani by Yugi (Siddha, Exhibit 15: pg.no. 51-54), also mentions use of *Withania somnifera* in the treatment of palpitation, excessive perspiration, diabetes mellitus and anaemia. The use of *Withania somnifera* as a general, uterine, renal and nervous tonic is also well known in ancient literature.

The use of *Withania somnifera* in the management of stress conditions mentioned in the claims of EP1906980 is not novel and there is no inventive step and its use in similar and related conditions has been prevalent and well known in the Indian systems of medicine (Ayurveda, Unani and Siddha).
Comparison of Claims with Prior Art

Ground of Opposition:

- Claims: Withania somnifera for management of stress and related disorders
- Prior art: 3 Ayurveda, 3 Unani and 5 Siddha texts describe the use
  - Vangasena by Vangasena (12th Century AD)
  - Ayurveda Sarasamgrahah (20th Century AD)
  - Rasatantrasarah Evam Siddhaprayogasamgrahah (20th Century AD)
  - Khazhaain- al-Advia by Mohd. Najmul Ghani Khan (20th Century AD)
  - Muheet Azam by Mohd. Azam (19th century AD)
  - Bayaaaz-e-Kabir by Kabiruddin (20th Century AD)
  - Athmarakshaamirtham by Kandasamy Mudalir (20th Century AD)
  - Therayar Karisal by Therayar (10th -15th Century AD)
  - Agathiwar Vaithiam 600 by Agasthiwar (700 AD – 1000 AD)
  - Chikithsa Rathna Deepam by Kannusamy Pillai (19th Century AD)
  - Vaithya Chinthamani by Yugi (10th -15th Century AD)

Examiner’s Report

The examination is being carried out on the following application documents:

Description, Pages
1-50 as published

Claims, Numbers
1:30 filed with entry into the regional phase before the EPO

1. The present application refers to the use of a Withania somnifera plant extract for the preparation of a composition for treating or managing stress disorders.

2. Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure:

D1: US-B1-6 713 092
3. **Novelty; Article 54 EPC.**

3.1 The document D1 discloses high purity *Withania somnifera* extracts comprising withanolide glycosides, oligosaccharides and withanolide aglycones (Abstract). Said extracts have application as adaptogen or anti-stress agent (column 4, line 45 to column 7, line 35). The compositions of D1 can be in the form of lotions (examples 1, 3, 4 and 5), creams (example 2), tablets and capsules (examples 6, 7, 8, 9 and 10), beverages (example 11).

3.10 The document D10 is an entry of the Traditional Knowledge Digital Library which refers to a composition comprising *Withania somnifera* root powder, a product of sugarcane and clarified butter. This composition is useful for the treatment of insomnia.

The Search Authority considers that the *Withania somnifera* extract used in this composition will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since these compounds are naturally present in *Withania somnifera* roots.

Insomnia is considered to be a chronic stress disorder. Clarified butter is considered to comprise fatty acids and vitamins.

In the light of this document, the subject-matter of claims 1-4, 6-7, 10-11, 13-17, 20-26, 28 and 29 cannot be considered as novel (Article 54 EPC).

3.11 The document D11 is an entry of the Traditional Knowledge Digital Library which discloses a therapeutic composition for the treatment of insomnia which comprises a root extract from *Withania somnifera* and a root extract from *Argyenia nervosa* (a plant extract). Said composition can be administered together with milk or water and is thus considered to fulfil the definition of a beverage.
The Search Authority considers that the Withania somnifera extract used in this composition will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since this compounds are naturally present in Withania somnifera roots. Insomnia is considered to be a chronic stress disorder.

In the light of D11, the subject-matter of claims 1-4, 6-11, 13-17, 20-26, 28 and 29 cannot be considered as novel in the sense of Article 54 EPC.

3.12 Documents D12, D13 and D16 are entries of the Traditional Knowledge Digital Library which disclose therapeutic compositions comprising a Withania somnifera root extract together with other plant extracts for the treatment of gastric ulcers or acute gastritis. The composition is in the form of a powder.

The Search Authority considers that the Withania somnifera extract used in these compositions will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since these compounds are naturally present in Withania somnifera roots. Gastric ulcers are considered to be chronic stress disorders.

Therefore, the subject-matter of claims 1-4, 6-7, 11-17, 20-26, 28 and 29 cannot be considered as novel (Article 54 EPC).

3.13 The document D14 is an entry of the Traditional Knowledge Digital Library which discloses a therapeutic composition for the treatment of gastric ulcers and acute gastritis comprising numerous plant extracts. One of these extracts is a Withania somnifera root extract. The composition further comprises garlic extracts. The composition is waxy.

The Search Authority considers that the Withania somnifera extract used in this composition will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since these compounds are naturally present in Withania somnifera roots. Gastric ulcers are considered to be chronic stress disorders.

Therefore, the subject-matter of claims 1-4, 6-7, 11-17 and 20-30 cannot be considered as novel (Article 54 EPC).

3.14 The document D15 is an entry of the Traditional Knowledge Digital Library which discloses a therapeutic composition for the treatment of restlessness and depression comprising Withania somnifera bark, leaf, flower, fruit and root extracts, Terminalia bellerica root extract and a sugar cane product. The composition is formulated as a powder.

The Search Authority considers that the Withania somnifera extract used in this composition will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since this compounds are naturally present in Withania somnifera roots. Restlessness and depression are considered to be chronic stress disorders.

Therefore, the subject-matter of claims 1-4, 6-7, 10-11, 13-17, 20-26, 28 and 29 cannot be considered as novel over the teaching of D15 (Article 54 EPC).

3.15 The document D17 is an entry of the Traditional Knowledge Digital Library which discloses a therapeutic composition for the treatment of hyperacidity and insomnia comprising numerous plant extracts including a Withania somnifera root extract. The composition is in the form of a fermented alcoholic product and fulfills the definition of a beverage or elixir.

The Search Authority considers that the Withania somnifera extract used in this composition will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since these compounds are naturally present in Withania somnifera roots. Hyperacidity and insomnia are considered to be chronic stress disorders.

Therefore, the subject-matter of claims 1-11, 13-17, 20-26, 28 and 29 cannot be considered as novel over the teaching of D17 (Article 54 EPC).
Examiner’s Report in Favour of TKDL

• The Search Authority considers that the Withania somnifera extract used in this composition will comprise withanolide glycosides, oligosaccharides and withanolide aglycones since these compounds are naturally present in withania somnifera roots.

• Insomnia, gastric ulcers, restlessness, depression and hyperacidity are considered chronic stress disorders. Therefore the subject matter of claims could not be considered as novel over the teaching of TKDL Exhibits.

Withdrawal of Application

For any questions about this communication: Tel: +39 02/340 46 00

Minoja, Fabrizio
Blanchetti Bracco Minoja Srl.
Via Pirlo 63
20129 Milano
ITALIE

Rule 25-03-2010

Noting of loss of rights pursuant to Rule 112(1) EPC

The European patent application [insert number] is deemed to be withdrawn because the requirements of the Patent Convention and/or of the Rules have not been met. The application was filed [insert date] and entered the European phase on [insert date].

Means of redress

Request for a decision (R. 112(2) EPC)

If the applicant considers that the finding of the European Patent Office is inaccurate, he may, within a (non-extendable) period of two months after notification of this communication, apply in writing for a decision. Any such request cannot only lead to the finding being reversed if this does not actually correspond to the factual or legal situation.
Comparative Table between TK & Modern Knowledge

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<th>TK</th>
<th>Modern Knowledge</th>
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<td>Public Domain</td>
<td>✓✓✓✓</td>
<td>X</td>
</tr>
<tr>
<td>Publicly available</td>
<td>✓✓✓✓</td>
<td>✓✓✓</td>
</tr>
<tr>
<td>Manner of creation</td>
<td>Lab of Life</td>
<td>Lab of Bricks &amp; Mortar</td>
</tr>
<tr>
<td>Misappropriation</td>
<td>✓✓✓✓</td>
<td>X</td>
</tr>
<tr>
<td>IP protection TCE</td>
<td>Traditional (No)</td>
<td>Contemporary (Yes)</td>
</tr>
<tr>
<td>IPRs</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Traditional Knowledge

- Local and not Widely Understood
- Unstructured in Nature
- Language & Access Barrier exist
- Not amenable to digitization available
  Search Engines can not retrieve TK

Oral or Codified

- Disclosed or undisclosed

Misappropriation

Innovative Capacity & Wealth creation
Nature & Complexities of TK/Biodiversity Documentation Projects

- Identification & Involvement of holder(s), confidence & trust
- Ownership & practical model on sharing of the benefits
- Unequal partnership & Alliance
- Technological and Societal Barriers
- Customary laws, abuse & morality
- Safeguarding vs encouragement of misappropriation
- Disclosed vs undisclosed TK
- Standard & Format

Databases/ Registries

**Functionalities**
- Different Vocabularies
- Information exchange
- Capacity Building
- Stake holders identification & participation
- Decentralized functioning
**Traditional Knowledge**

- **Databases for Public or Private Use**
  - No legal right
  - Defensive option
  - Manner of collection protected under copyrights
  - Need of maintaining balance while making it opens
  - Rights of communities are to be protected
  - Access & Control would need be with TK holders

**TK Databases and Registers**

- Compile databases for public domains TK
  - Accessible
  - Defensive protection
- Establish registers for non public domain TK
  - National Sui-Gnen Legal frame work
  - TK Holder/registrant should be open to License the use of TK
- TK registers would grant legal right to the registrant
  - Need national laws to setup registries
  - Registrants asserts a claim
  - Need be notified to public
  - Register does not grant right rather it records the existence of rights
TKDL software with its associated Classification System i.e., TKRC converts Sanskrit Slokas. It may be noted that the software does not do transliteration rather it does smart translation, where data abstracted is converted into several languages by using Unicode Meta data methodology. Software also converts traditional terminology into modern terminology, for example kumari to Aloe vera, Mussorika to small pox etc.
Relationship between Traditional & Modern System of Medicine

Basis
Objective, aims & methodology
Diagnosis methodology & identification of symptoms
Drug (substance) & its components

Conclusions: It is feasible & practical to develop a Classification tools on TK/TCE etc.

TKRC Classification Symbol

Section A – Ayurveda; Class 01 – Pharmaceutical Preparations Sub-Class B – Based on Animals; Group 1/00 – Based on Animals & their Products; Sub-group 1/21 - Milk
### Stages of Formal Acceptance of Traditional Knowledge Classifications

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb 2001</td>
<td>India submitted a proposal for inclusion of traditional knowledge at International Patent Classification Union.</td>
</tr>
<tr>
<td>Feb 2002</td>
<td>Task force of five nations constituted by WIPO recommended creation of subclass in A61 linking Traditional Knowledge Resource Classification developed by India with International Patent Classification.</td>
</tr>
<tr>
<td>Oct 2004</td>
<td>Deliberations on IPC-TKRC Concordance list of the new main group A61K 36/00.</td>
</tr>
</tbody>
</table>
Classification/Standards Setting up of TK Databases/Registries

Classification

Database/Registries Schema

Directories/ Schemes & Meta data

Technical Proposals on Databases and Registries of Traditional Knowledge and Biological /Genetic Resources

Common TK Data Fields

Standards
Common TK Data Fields

- ST-9, common data elements
  - Application Detail
  - IPC
  - Prior Art
  - Abstract or claim
- Biological specific elements
  - Distribution of biological elements
  - Access conditions
  - Arrangement with stakeholders
  - Biological Information Details
  - Keywords
  - Utility
  - Bibliographic references
  - Language

Standards

Metadata gives details about data, and is stored in a repository containing detailed description of each data element. Metadata repository permits application of some data management principles independent to its location.

XML encodes a description of document in DTP. Permits structured and unstructured information. XML process has the intelligence in processing.

Image & Audio visual format

- Monochrome: TIFF/Group IV
- Colour: GIF/JPEG
- Multimedia: MPEG
**SECTION**
(Whole body of knowledge is divided in eight sections)

- **Section Symbol**: each section is designated by capital letters A to H.
- **Section Title**: broad indication of the contents of the section.
- **Section Contents**: title is followed by the summary of the titles of its main subdivisions.

---

**Example**

<table>
<thead>
<tr>
<th>Section</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A</td>
<td>Human Necessities</td>
</tr>
<tr>
<td>Section B</td>
<td>Performing Operations;</td>
</tr>
<tr>
<td></td>
<td>Transporting</td>
</tr>
<tr>
<td>Section C</td>
<td>Chemistry; Metallurgy</td>
</tr>
<tr>
<td>Section D</td>
<td>Textiles; Paper</td>
</tr>
<tr>
<td>Section E</td>
<td>Fixed Constructions</td>
</tr>
<tr>
<td>Section F</td>
<td>Mechanical Engineering; Lighting;</td>
</tr>
<tr>
<td></td>
<td>Heating; Weapons; Blasting</td>
</tr>
<tr>
<td>Section G</td>
<td>Physics</td>
</tr>
<tr>
<td>Section H</td>
<td>Electricity</td>
</tr>
</tbody>
</table>
Subsection

- Within section, informative heading forms subsections. *Subsections are title without symbol*
- Example:
- Section A : Human Necessities
  — covering the subject matter under:
  - Subsections : Agriculture; Foodstuffs; Tobacco; Personal of Domestic; Articles; Health; Amusement

Classes

- Each section is subdivided into Classes
  - *Class Symbol*: section symbol followed by a two digit number
  - *Class Title*: title gives an indication of the contents of the class
  - *Class Index*: gives an informative summary giving a broad survey of the contents of the class.
Example

Subsection: Agriculture
Class A 01: Agriculture; Forestry; Animal Husbandry; Hunting; Trapping; Fishing

Subsection: Foodstuffs; Tobacco
Class A 21: Baking; Edible Doughs
Class A 22: Butchering; Meat Treatment; Processing; Poultry or Fish
Class A 23: Foods or Foodstuffs; Their Treatment, Not covered by other classes

Subclasses

- Each class has one or more subclass
  - Subclass Symbol: class symbol followed by a capital letter
  - Subclass Title: indicates as precisely as possible the content of the subclass
  - Subclass Index: It is merely an informative summary giving a broad survey of the content of the subclass
Examples

Class A 47—Furniture; Domestic Articles or Appliances; Coffee Mills; Spice Mills; Suction Cleaners; General.
Subclass A 47 B — Tables; Desks; Office furniture; Cabi Drawers; General details of furniture
Subclass A 47 C — Chairs; Sofas; Beds
Subclass A 47 D — Furniture specially adapted for Children
Subclass A 47 F — Special furniture, fittings, or accessory shops, storehouses, bars, restaurants etc.

Groups/Main Groups

- Each subclass is further divided in Groups/Main groups
  - Group Symbol: subclass symbol followed by one-to three digit number, oblique stroke and then number 00.
  - Group Title: defines a field of subject matter considered to be useful for search purposes
  - Example:
    - C01B17/00 — Sulfur; compounds thereof.
    - B01B1/00 — Boiling apparatus for physical or chemical purposes
Subgroup

Groups/Main groups are further divided into subgroups to make more precise the subject matter of the invention.

- **Subgroup Symbol**: Subclass symbol followed by one-to-three digit no. of its main group, the oblique stroke and then no. of at least two digits other than 00. *Any third or subsequent digit after the oblique is to be understood as decimal subdivision of the digit preceding it.*

- **Subgroup Title**: it defines a field of subject matter within the scope of its main group. It is further preceded by one or more dots indicating the hierarchical position of that subgroup.

Basis

<table>
<thead>
<tr>
<th>Activity</th>
<th>Traditional medicine</th>
<th>Modern medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical view</td>
<td>Philosopho scientific</td>
<td>Scientific</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Comprehensive</td>
<td>Analytical</td>
</tr>
<tr>
<td>Clinical distinction</td>
<td>Wholeness</td>
<td>Local or systemic</td>
</tr>
</tbody>
</table>
Objectives, Aims and Methodology

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Natural</th>
<th>Chemical derivatives of natural/synthetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study method</td>
<td>Human experience</td>
<td>Clinical trials/lab tests</td>
</tr>
<tr>
<td>Maintenance of health</td>
<td>Promotion &amp; Prevention</td>
<td>Vaccination &amp; Sanitary</td>
</tr>
<tr>
<td>Treatment</td>
<td>Individualized</td>
<td>Standardized</td>
</tr>
<tr>
<td>Treatment Aim</td>
<td>Cure of disease</td>
<td>Symptom relief</td>
</tr>
<tr>
<td>Treatment View</td>
<td>Natural</td>
<td>Invasive</td>
</tr>
</tbody>
</table>

Despite of above difference of outlook, both the systems have many things in common

Diagnostic Methodology and Identification

<table>
<thead>
<tr>
<th>Disease</th>
<th>Symptoms in TM (Ayurveda)</th>
<th>Symptoms in Modern Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>Rise in body temperature, malaise/bodyache, loss of/diminished perspiration</td>
<td>An elevation of body temperature above the normal range (Oral temperature 98.6°F; 37°C) along with associated symptoms</td>
</tr>
<tr>
<td>Gout</td>
<td>Disease starts from base of toe or thumb, with swelling and severe pricking pain</td>
<td>Acute mono or polyarticular pain...The pain becomes progressively more severe and is often described as throbbing, crushing or excruciating...The meta tarsophalangeal joint of the great toe is involved most frequently</td>
</tr>
</tbody>
</table>
### Drugs (Substance) and its components

<table>
<thead>
<tr>
<th>Drug</th>
<th>TM</th>
<th>MM</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Psoralia corylifolia</em> Linn.</td>
<td>Seeds used in leucoderma</td>
<td>Chemical compound psoralin extracted from seeds used in leucoderma</td>
</tr>
<tr>
<td><em>Colchicum luteum</em> Baker</td>
<td>Used in treatment of gout</td>
<td>Colchicines extracted from plant is useful for treatment of gout</td>
</tr>
<tr>
<td><em>Commiphora mukul</em> Hook ex Stocks</td>
<td>Exudates used in treatment of obesity</td>
<td>Guggulosterone extracted from the exudates is useful in the treatment of hyperlipidaemia</td>
</tr>
</tbody>
</table>

### Section A – Ayurveda

**Class**
- 01 – Pharmaceutical Preparations (*Kalpana*)
- 02 – Personal Hygiene Preparations
- 03 – Dietary (*food/food stuff or Beverages*)
- 04 – Biocides, Fumigatives (*Dhupana, krmighna*)

**Section A Class 01 – Pharmaceutical Preparations (*Kalpana*)**

**Sub-Class**
- 01A Based on *Auddhida* (Plants)
- 01B Based on *Jangama* (Animals)
- 01C Based on *Parthiva* (Minerals)
- 01D Characterised by *Roga* (Diseases)
- 01E Characterised by *Karma* (Action)
- 01F Mode of Administration
- 01G Miscellaneous

**Sub-Class: A01A – Pharmaceutical Preparations (*Kalpana*) Based on *Auddhida* (Plants)**

- Group: A01A
  - 1/00 Whole medicinal plant
  - 2/00 Parts of medicinal plant used
  - 3/00 Characterised by Physical form