THE PATENTS (AMENDMENT) ACT, 2005

(15 of 2005)

(with effect from 1-1-2005)

&

THE PATENTS RULES, 2003

as amended by

THE PATENTS (AMENDMENT) RULES, 2014

(with effect from 28-02-2014)

In the matter of the provisions under The **Section 25(1)** of The Patents (Amendment) Act 2005 and The Patents Rules (Amendment) 2006

AND

In the matter of Patent Application Number **1556/KOL/2007** filed on 13th December 2006 by DEVELOPMENT CENTER FOR BIOTECHNOLOGY, A Taiwanese Company.

And

In the matter of Pre-Grant Opposition filed by way of Representation by COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH, Anusandhan Bhavan, 2, Rafi Marg, New Delhi - 110001

D E C I S I O N

DEVELOPMENT CENTER FOR BIOTECHNOLOGY, A Taiwanese Company having the address at No. 101, Lane 169, Kangning St., Xizhi City, Taipei County 221, Taiwan R.O.C., hereafter referred as 'the applicants' have filed a patent application for their invention titled as "A PHARMACEUTICAL COMPOSITION AND PROCESS THEREOF FOR THE PREPARATION OF PLANT EXTRACTS FOR TREATING SKIN DISORDERS AND ENHANCING HEALING OF WOUNDS" on 16th November 2007 which is provisionally numbered as 1556/KOL/2007. After completing the required formalities of the Act, the First Examination Report has been sent to the applicant on 29th March 2010 requesting the applicant

to meet the requirements of the Act within non-extendable time limit of 12 months from the date of dispatch of the said First Examination Report. The applicants had replied on 26th October 2010 wherein the last day for putting up the application in order for grant is 29th March 2011; a second examination report was issued to the applicant on 8th December 2010 for which a reply was filed on 11th February 2011 and requested for an early grant of the patent and requested for the personal hearing under the provisions of the Section 14 of the Act if the written submissions are felt for not meeting the requirements.

Under the provisions of the Section 25(1) of the Patents (Amendment) Act 2005, any person can file a Pre-grant Opposition by way of representation after the publication of the patent application at the expiry of 18 months from the date of filing the application for patent but within 6 months from the date of 18 month expiry publication or before the grant of patent. In the present instance Council of Scientific & Industrial Research [CSIR] have filed a Pre-grant Opposition by way of representation on **19th June 2012** within the stipulated time limit and hence the same has been taken on record. Under the provisions of the sub rule 3 of the Rule 55 of the Patents (Amendment) Rules 2003 the said representation has been forwarded to the applicant on 11th July 2013, intimating the applicant that if they desire, may file their statement and evidence, if any, within a non-extendable time limit of 3 months from the date of the notice. The applicant has filed the reply on 9th October 2013 which is within the stipulated period of 3 months and hence taken on record.

Having matured for hearing the hearing under the provisions of the Section 25(1) to read with the Section 15 of the Patents Act and Rule 55 of the Patents Rules the hearing was fixed and held on 24th September 2014.

CSIR is the general opponent in the field of Traditional Knowledge based patent applications and found to file the documents prepared by them under the programme of the preparation of Traditional Knowledge Digital Library [TKDL] to prevent the persons to claim patent right over the traditional knowledge. CSIR has an agreement with this office to share the TKDL for the purpose of search during prosecution of the filed patent applications and disposing them on merits. Being the opponent, in another similar case identified as 958/KOL/2008, intimation has been issued to CSIR to present before the undersigned during the hearing to present and argue their view for effective disposal of the said patent application. In reply through their letter with no reference number and dated 27th August 2014, signed by Dr. Archana Sharma, Project Leader, CSIR-TKDL, Unit, it is stated thus; **"As per practise, CSIR – TKDL, Unit has always submitted prior-art evidences available in TKDL with respect to patent applications filed on India's Traditional Knowledge at International Patent Office's but has never been a part of hearing process of Patent Offices. After submitting the prior art evidences we are of the view that decision is to be taken as per the wisdom and perception of the examiners and respective Patent Office**. **In view of the above, the Patent Office may proceed with the hearing and accordingly decision may be taken as per the Patent Law."** Hence there was no personal representative in any of the Pre-grant Opposition hearings. Present case is also not an exception of their view. Therefore the hearing has been conducted in the presence of the applicant representative only. In the following paragraphs the claims as filed and the first amended set of claims before filing the Pre-grant opposition followed by the final amended set of claims after filing the Pre-grant opposition are reproduced for understanding the scope and nature of the invention.

Claims as filed:

We Claim

1. A process for preparing Plectranthus amboinicus extracts comprising the step of:

   (a) Contacting dried Plectranthus amboinicus leaves with a leaf extracting solvent to obtain a Plectranthus amboinicus crude extract;
   (b) Concentrating the Plectranthus amboinicus crude extract; and
   (c) Separating the concentrated Plectranthus amboinicus crude extract by stirring separation method to obtain a Plectranthus amboinicus extract.
2. The process as claimed in claim 1, wherein the leaf extracting solvent comprises water or alcohol.
3. The process as claimed in claim 1 wherein the concentrated Plectranthus amboinicus crude extract is separated by a stirring separation method.
4. The process as claimed in claim 3, wherein the stirring separation method comprises the steps of:

   (a) Diluting the concentrated Plectranthus amboinicus crude extract with a high-polarity solvent;
   (b) Mixing the diluted Plectranthus amboinicus crude extract with an absorbing resin;
   (c) Stirring the absorbing resin with the diluted Plectranthus amboinicus crude extract;
   (d) After removing liquid portion, extracting the resin with the high-polarity solvent and collecting a first extract;
   (e) Extracting the resin with a sib-high-polarity solvent and collecting a second extract;
   (f) Extracting the resin with a medium-polarity-solvent and collecting the third extract; and
   (g) Extracting the resin with a low-polarity-solvent and collecting the fourth extract.
5. The process as claimed in claim 4, wherein the high polarity solvent comprises water, methanol, ethanol or mixtures thereof.
6. The process as claimed in claim 4, wherein the sub high polarity solvent has a polarity lower than that of high polarity solvent.
7. The process as claimed in claim 4, wherein the medium high polarity solvent has a polarity lower than that of sub-high-polar solvent.
8. The process as claimed in claim 4, wherein the low polarity solvent has a polarity lower than that of the medium polarity solvent.
9. A Plectranthus amboinicus extract prepared by the process as claimed in claim 3 containing one or more extracts selected from the first, second, third and fourth extracts.
10. The Plectranthus amboinicus extract as claimed in claim 8wherein the fourth extract has the following HPLC peaks of retention time:

Peak	Retention time (min)
1	5.5
2	9.6
3	20.0
4	22.5
5	23.5
6	24.8

7	27.7
8	27.8
9	28.6
10	2809
11	29.7
12	31.0
13	31.9
14	36.6
15	37.8

Wherein said HPLC is conducted in the following conditions:

Chromatographic Column: Phenomenex, 4.6 x 250 mm, Luna 5 micro silica(2)
Flow rate : 1.0 ml/min
Pressure Limit : 250 kgf/cm^2
Sample amount : 10 micro lit.
PDA condition : Sampling period : 0.64 sec
Wavelength range : 190-370 nm
Channel : 270, 320 nm
Elution Profile :

Mobile Phase	TIME IN MINUTES			
-	0	15	45	50
n-hexane	95%	85%	30%	95%
Ethyl acetate	5%	15%	70%	5%

11. A Plectranthus amboinicus crude extract prepared by step a) and/or b) of the process according to claim 1.
12. A pharmaceutical composition comprising a therapeutically effective amount of the Plectranthus amboinicus extract as claimed in claim 9 or 10 and optionally a pharmaceutically acceptable carrier, diluent or excipient.
13. The pharfmaceutical composition as claimed in claim 12 further comprising a therapeutically effective amount of Centella asiatica Urban extract.
14. The pharmaceutical composition as claimed in claim 13, wherein the Plectranthus amboinicus extract and the Centenella asiatica Urban extract have a weight ratio of about 1:60 to about 1:4
15. A pharmaceutical composition comprising a therapeutically effective amount of the Plectranthus amboinicus crude extract according to claim 11 and optionally a pharmaceutically acceptable carrier, diluent or excipient.
16. The pharmaceutical composition according to claim 15 further comprising a therapeutically effective amount of Centella asiatica Urban extract.
17. A wound dressing comprising a pharmaceutical composition as claimed in any one of claims 12 to 16.
18. A use of the pharmaceutical composition of any one of claims 10 to 12 in the manufacture of a medicament for treating skin disorder.
19. The use as claimed in claim 14 wherein the disorder is general trauma or bedsores.
20. The use as claimed in claim 14 wherein the skin disorder is wounds in a diabetic patient.

First Amended claims filed on 11th February 2011: [before filing the Pre-grant]

1. A process for preparing Plectranthus amboinicus extracts comprising the step of:

   (d) Contacting dried Plectranthus amboinicus leaves with a leaf extracting solvent to obtain a Plectranthus amboinicus crude extract;
   (e) Concentrating the Plectranthus amboinicus crude extract; and
   (f) Separating the concentrated Plectranthus amboinicus crude extract by stirring separation method to obtain a Plectranthus amboinicus extract.

2. The process as claimed in claim 1, wherein the leaf extracting solvent comprises water or alcohol.
3. The process as claimed in claim 1, wherein the stirring separation method comprises the steps of:

   (h) Diluting the concentrated Plectranthus amboinicus crude extract with a high-polarity solvent;
   (i) Mixing the diluted Plectranthus amboinicus crude extract with an absorbing resin;
   (j) Stirring the absorbing resin with the diluted Plectranthus amboinicus crude extract;
   (k) After removing liquid portion, extracting the resin with the high-polarity solvent and collecting a first extract;
   (l) Extracting the resin with a sib-high-polarity solvent and collecting a second extract;
   (m) Extracting the resin with a medium-polarity-solvent and collecting the third extract; and
   (n) Extracting the resin with a low-polarity-solvent and collecting the fourth extract.
4. The process as claimed in claim 3, wherein the high polarity solvent comprises water, methanol, ethanol or mixtures thereof.
5. The process as claimed in claim 3, wherein the sub high polarity solvent has a polarity lower than that of high polarity solvent.
6. The process as claimed in claim 3, wherein the medium high polarity solvent has a polarity lower than that of sub-high-polar solvent.
7. The process as claimed in claim 3, wherein the low polarity solvent has a polarity lower than that of the medium polarity solvent.
8. A Plectranthus amboinicus extract prepared by the process as claimed in claim 3 containing one or more extracts selected from the first, second, third and fourth extracts.
9. The Plectranthus amboinicus extract as claimed in claim 8wherein the fourth extract has the following HPLC peaks of retention time:

Peak	Retention time (min)
1	5.5
2	9.6
3	20.0
4	22.5
5	23.5
6	24.8
7	27.7
8	27.8
9	28.6
10	2809
11	29.7
12	31.0
13	31.9
14	36.6
15	37.8

Wherein said HPLC is conducted in the following conditions:

Chromatographic Column: Phenomenex, 4.6 x 250 mm, Luna 5 micro silica(2)
Flow rate : 1.0 ml/min
Pressure Limit : 250 kgf/cm^2
Sample amount : 10 micro lit.

PDA condition : Sampling period : 0.64 sec
Wavelength range : 190-370 nm
Channel : 270, 320 nm

Elution Profile :

Mobile Phase	TIME IN MINUTES			
-	0	15	45	50
n-hexane	95%	85%	30%	95%
Ethyl acetate	5%	15%	70%	5%

10. A pharmaceutical composition comprising a therapeutically effective amount of the Plectranthus amboinicus extract as claimed in claim 8or 9 and optionally acceptable carrier, diluent or excipient.
11. The pharfmaceutical composition as claimed in claim 10 further comprising a therapeutically effective amount of Centella asiatica Urban extract.
12. The pharmaceutical composition as claimed in claim 11, wherein the Plectranthus amboinicus extract and the Centenella asiatica Urban extract have a weight ratio of about 1:60 to about 1:4
13. A wound dressing comprising a pharmaceutical composition as claimed in any one of claims 10 to 12.
14. A use of the pharmaceutical composition of any one of claims 10 to 12 in the manufacture of a medicament for treating skin disorder.
15. The use as claimed in claim 14 wherein the disorder is general trauma or bedsores.
16. The use as claimed in claim 14 wherein the skin disorder is wounds in a diabetic patient.

FINAL AMENDED CLAIMS: [after filing the Pre-grant]

1. A process for preparing Plectranthus amboinicus extracts comprising the step of:

(g) Contacting dried Plectranthus amboinicus leaves with a leaf extracting solvent to obtain a Plectranthus amboinicus crude extract;
(h) Concentrating the Plectranthus amboinicus crude extract; and
(i) Separating the concentrated Plectranthus amboinicus crude extract by stirring separation method to obtain a Plectranthus amboinicus extract.

2. The process as claimed in claim 1, wherein the leaf extracting solvent comprises water or alcohol.
3. The process as claimed in claim 1, wherein the stirring separation method comprises the steps of:

(o) Diluting the concentrated Plectranthus amboinicus crude extract with a high-polarity solvent;
(p) Mixing the diluted Plectranthus amboinicus crude extract with an absorbing resin;
(q) Stirring the absorbing resin with the diluted Plectranthus amboinicus crude extract;
(r) After removing liquid portion, extracting the resin with the high-polarity solvent and collecting a first extract;
(s) Extracting the resin with a sib-high-polarity solvent and collecting a second extract;
(t) Extracting the resin with a medium-polarity-solvent and collecting the third extract; and
(u) Extracting the resin with a low-polarity-solvent and collecting the fourth extract.

4. The process as claimed in claim 3, wherein the high polarity solvent comprises water, methanol, ethanol or mixtures thereof.
5. The process as claimed in claim 3, wherein the sub high polarity solvent has a polarity lower than that of high polarity solvent wherein the sub-high polarity solvent is a

mixture of a high-polarity solvent defined in claim 4 with a solvent having lower polarity in a ratio (v:v) of about 30:70 to 70:30.

6. The process as claimed in claim 3, wherein the medium polarity solvent has a polarity lower than that of sub-high-polar solvent wherein the medium-polarity solvent is a mixture of a high-polarity solvent defined in claim 4 with a solvent having lower polarity in a ratio (v:v) of 30:70 to 5:95.
7. The process as claimed in claim 3, wherein the low polarity solvent has a polarity lower than that of the medium polarity solvent and wherein the low-polarity solvent is chloroform, isopropanol, acetone, ethyl acetate, a mixture of two or more of the preceding solvents, or a mixture of one or more of the preceding solvents with one or more solvents that have high polarity.
8. A Plectranthus amboinicus extract prepared by the process as claimed in claim 3 containing one or more extracts selected from the first, second, third and fourth extracts.
9. The Plectranthus amboinicus extract as claimed in claim 8wherein the fourth extract has the following HPLC peaks of retention time:

Peak	Retention time (min)
1	5.5
2	9.6
3	20.0
4	22.5
5	23.5
6	24.8
7	27.7
8	27.8
9	28.6
10	2809
11	29.7
12	31.0
13	31.9
14	36.6
15	37.8

Wherein said HPLC is conducted in the following conditions:

Chromatographic Column: Phenomenex, 4.6 x 250 mm, Luna 5 micro silica(2)
Flow rate : 1.0 ml/min
Pressure Limit : 250 kgf/cm^2
Sample amount : 10 micro lit.
PDA condition : Sampling period : 0.64 sec
Wavelength range : 190-370 nm
Channel : 270, 320 nm
Elution Profile :

Mobile Phase	TIME IN MINUTES			
-	0	15	45	50
n-hexane	95%	85%	30%	95%
Ethyl acetate	5%	15%	70%	5%

10. A pharmaceutical composition comprising a therapeutically effective amount of the Plectranthus amboinicus extract according to claim 8or 9 and optionally acceptable carrier, diluent or excipient wherein the therapeutically effective amount of the Plectranthus amboinicus extract 1 to 15% by weight.

11. The pharfmaceutical composition as claimed in claim 10 optionally comprising a therapeutically effective amount of Centella asiatica Urban extract.
12. The pharmaceutical composition as claimed in claim 11, wherein the Plectranthus amboinicus extract and the Centenella asiatica Urban extract have a weight ratio of about 1:60 to about 1:4
13. A wound dressing comprising a pharmaceutical composition as claimed in any one of claims 10 to 12.

DOCUMENTS AND ANNEX FILED BY THE OPPONENT;

The following are the 11 documents that are submitted by the opponent at the time of filing Pre-grant opposition in languages other than English for which the translations in English have been filed. The key points highlighted by the opponent in each document are stated hereunder in the order of their submission.

The first document, probably identified with the reference number as **RG2/683A**, refers to a therapeutic composition or formulation containing the active ingredients, that is, **Centella asiatica (Linn) Urban (Brahmi, Spade leaf, Indian penny wort).** The useful parts of the medicinal plants are crushed extracted with boiled water and filtered. This is called as **SAVARSA** which is **applied locally to treat Boils.**

The second document, probably identified with the reference number as **NA2/504A2**, again refers to a therapeutic composition or formulation containing the active ingredients, that is, **Centella asiatica (Linn) Urban (Brahmi, Spade leaf, Indian penny wort) .** It is stated here that a paste is prepared known as **ZIMMAAD** by powdering the fresh drugs with a liquid base for local application to heal **Septic Wounds**.

The third document, probably identified with the reference number as **RS/3318A**, once again, refers to a therapeutic single/compound formulation containing only one active ingredient, that is, **Centella asiatica (Linn) Urban (Brahmi, Spade leaf, Indian penny wort).** No process is described but it is stated that the said formulation is useful in the **treatment of Leprosy and other dermatoses, Anaemia / Hyperbillirubinaemia.**

The fourth document, probably identified with the reference number as **NA2/504G**, again refers to a therapeutic composition or formulation containing the active ingredients, that is, **Centella asiatica (Linn) Urban (Brahmi, Spade leaf, Indian penny wort)**. The therapeutic composition is prepared as **MATBOOKII** by soaking the drugs in water overnight. Then boil it till 2/3rd of water remain, strain it and use it for **the treatment of diseases of skin**.

The fifth document, probably identified with the reference number as **SSO2/407**, refers to a therapeutic single/compound formulation containing the active ingredients viz., Zingiber officinale Roscoe (Injii, Chukku)(garden Zinzer, Ginger), Glycyrrhiza glabra Linn. (Athimathuram, Athingam, Atti, Mathugam, Kundri vaer)(cultivated licorice), Myristica fragrance Houtt. (Jathikai, kulakkai, Vasuvassi, jathipathri)(Nutmeg tree), **Centella asiatica** (Linn), **Urban** (Yosanavalli, Saraswathy, Sandaki, Vallarai) (Spade leaf, Indian penny wort). It is stated that the composition of the above drugs is prepared as **KARKAM** which is a lump or paste of plant ingredient, metallo mineral ingredient ground well with or without using water or any other liquid. Ingredient available in fresh

form does not normally need any other liquid unless specified in the formulation. KARKAM which is **analgesic, restoring normal sensation administered either orally or locally.**

The sixth document, probably identified with the reference number as **AK11/2906**, refers to a therapeutic single/compound formulation, known as **Medhyavika Taila**, containing the active ingredients, Raphanus sativus Linn (radish), Datura metal Linn / Datura inoxia Mill / Datura stramonium Linn (Thornapple, Downy Datura), Helianthus annuus Linn (annual sunflower, common sunflower, sunflower, wild sunflower), Albizia lebbeck (Linn) Benth (lebbeck, raom tree, siris tree, soros-tree, woman's tongue, woman's-tongue tree), **Centella asiatica** (Linn), Urban, Sesamum indicum Linn(tila)(sesame). It is stated that the said formulation is prepared as TAILA SNEHAKALPANA / SNEHAKALPA – (MEDICATED OIL). Various kinds of preparations have been explained for the preparation of this medicated oil which is not reproduced herewith as it is not related to the present invention. In one of the preparations 16 ingredients are used which is not listed. **The said oil is used for Itching, Leprosy and other dermatoses**.

The seventh document, probably identified with the reference number **GP02/848**, refers to a therapeutic single/compound formulation, containing 38 different herbs [names not reproduced but does not contain Plectranthus amboinicus] along with Cow Milk (Pasu, Komaadhaa) and specified weights and volumes of the ingredients have been disclosed for the said therapeutic single/compound formulation preparation. One among them is **Centella asiatica** used as a juice whose quantity is mentioned as 1.3 litres of the formulation. **The said formulation is used in the treatment of Carbuncle / Furuncle (Pilavai, Vipuruthi, Pudai).**

The eighth document, probably identified with the reference number **VK5/1197,** refers to a therapeutic composition or formulation containing a total number of 30 ingredients, the listed names is not reproduced here,[does not contain Plectranthus amboinicus] wherein only **Centella asiatica** is marked by the opponent is added by the weight of 12 gram of the total weight of the composition. The preparation method is described on the addition of all the 30 ingredients that includes water. **Once again the method of preparation is not required to be considered for the purpose of this opposition because the opponent stresses on the use of the Centella asiatica for skin related disorders.** This particular composition is stated to be useful for the treatment of various diseases but only the highlighted portions are reproduced herein which are **Gout, Urticaria / Allergic rashes, 18 types of Leprosy and other dermatoses, Ulcer/wound, Eruptions, Dry and weeping eczema, Itching, In whole body**.

The ninth document, probably identified with the reference number **GR02/57**, refers to a therapeutic composition or formulation containing a total number of 20 ingredients, the listed names is not reproduced here,[does not contain Plectranthus amboinicus] wherein only **Centella asiatica** is marked by the opponent is added by the volume of 0.65 litres of the total weight of the composition. **Once again the method of preparation is not required to be considered for the purpose of this opposition because the opponent stresses on the use of the Centella asiatica for skin related disorders.** This particular composition is stated to be useful for the treatment of various diseases but only the highlighted portions are reproduced herein which are **Itching** and **Scabies**.

The tenth document, probably identified with the reference number **GR02/34,** refers to a therapeutic single/compound formulation containing a total number of 12 ingredients, the listed names is not reproduced here,[does not contain Plectranthus amboinicus] wherein only **Centella**

asiatica is marked by the opponent is added by the weight of 350 gram of the total weight of the composition. The preparation is known as **CHOORNAM** and it is a fine powder mixture. This particular composition is stated to be useful for the treatment of various diseases but only the highlighted portions are reproduced herein which are **Diabetes mellitus and Ulcer / Wound.**

The eleventh document, probably identified with the reference number **AM05/2148,** refers to a therapeutic single/compound formulation containing a total number of 17 ingredients, the listed names is not reproduced here,[does not contain Plectranthus amboinicus] wherein only **Centella asiatica** is marked by the opponent is added by the weight of 350 gram of the total weight of the composition. The preparation is known as NEI which is a category of medicine that is prepared by boiling the substances with ghee. This particular composition is stated to be useful for the treatment of various diseases but only the highlighted portions are reproduced herein which are **Ulcer / Wound Healing, Leprosy, Itching, Scabies.**

The opponents in their filed Annex-I have stated that TKDL is a collaborative project between CSIR, Ministry of Science and Technology and Department of AYUSH of Ministry of Health and Family Welfare and being implemented in CSIR. TKDL acts as a tool which breaks the language and format barriers of available 148 printed text books on Indian System of Medicine i.e Ayurveda, Unani, Siddha and Yoga, and makes the ancient knowledge available in languages and format understandable to Patent Examiners. It is therefore, apparent that the formulations that are transcribed and presented in this digital library are not just some herbal recipes or tips that were known to our ancestors through hit and trial method but are methodical, scientific procedures of treating various disorders. They, in fact, illustrate the principles laid down by ancient scholars about the use of drugs in various possible disorders.

Further it is stated in the same annex which is reproduced as hereunder:

The following features of Indian systems of traditional medicine may elucidate the above:

- The list of drugs mentioned under each classification is meant only to provide examples.
- There can be variation in the botanical description of a drug with respect to habitat and environment in which it has been grown or collected and may show variations with respect to morphological characteristics. However, the pharmacology and the clinical efficacy of the drug may be the same as described originally.
- Some synonyms of the same drug are given for correct identification of the same drug. However, not all synonyms are used. Hence mere use of drugs with their synonyms does not form an invention.
- Moreover, on the basis of rules for designing the combinations of drugs as laid down in Indian systems of Medicine, a large number of other combinations of the drugs described here can still be made, keeping in view the nature of constituent drugs and the requirement of the disease as well as the diseased. Hence, mere addition or deletion of constituents from drug combinations described, or mixing of two or more of singly described drugs having similar actions, or mere change of dosage form of these drugs or combinations does not form innovation and cannot be considered for grant of positive rights (Patents).
- The pharmaceutical processes that are described for the preparation of dosage form are subject to variation from the standard in terms of concentration and potency of the end

product, to suit the severity of disease as well as the diseased which is clearly evident from the variations observed in different formulations of the same dosage form.

- The dosage and duration of therapy are also subject to variation and are highly specific to the person and disease. Therefore, mere variation in these with relation to any formulation cannot qualify for the invention. Since, the selection of drug and dosage forms is mainly made on the basis of the nature and severity of the disease, diagnosis is made on the basis of intricately woven parameters designed and described in Indian systems of Medicine. A new indication added to the formulation merely in terms of its modern name also does not form valid claim for novelty to acquire intellectual property rights in the form of patents.
- This access to TKDL to patent offices will hopefully facilitate the prevention of grant of wrong patents.
- The references cited in the case enclosed, exists in TKDL database along with the images of the original texts and their publication information.

The opponent in their statement has stated that **the following claims are included in the third party observation. The referred claims are from 11 to 16 of the first amended claims**. The said claims are;

"11. The pharfmaceutical composition as claimed in claim 10 further comprising a therapeutically effective amount of Centella asiatica Urban extract.

12. The pharmaceutical composition as claimed in claim 11, wherein the Plectranthus amboinicus extract and the Centenella asiatica Urban extract have a weight ratio of about 1:60 to about 1:4

13. A wound dressing comprising a pharmaceutical composition as claimed in any one of claims 10 to 12.

14. A use of the pharmaceutical composition of any one of claims 10 to 12 in the manufacture of a medicament for treating skin disorder.

15. The use as claimed in claim 14 wherein the disorder is general trauma or bedsores.

16. The use as claimed in claim 14 wherein the skin disorder is wounds in a diabetic patient."

Though the opponent has stated that the above claims are "INCLUDED" no arguments have been made against the remaining claims. Hence it is not possible to conclude against the remaining claims under the opponent's perspective under this pre grant opposition.

Arguments by the applicant against the contents of the documents filed by the opponent:

The agent for the applicant with reference to Patents Rule 61(2) that states that "Where a specification or other document in a language other than English is referred to in the notice, statement or evidence, an attested translation thereof, in duplicate, in English shall be furnished along with such notice, statement or evidence, as the case may be", has argued that the opponent herein has merely thrown a few documents from TKDL without providing verified translation and hence the translated documents as filed are null and void, consequently shall not be considered to be taken on record. Hence it was requested to proceed with the application as if the opposition has not been filed.

Though the agent for the applicant is correct in the above said argument his view cannot be considered for the reason that despite the legal requirement objection the applicant did not attempt to prove that the translations are wrong. Secondly an authorized translator is required to translate the documents which are in other than English language under a declaration that he/she is an authorized translator and should be well conversant with the language other than English and English language as well. The next question is who authorizes such translators? It shall be the Government. CSIR is mainly funded by the Ministry of Science and Technology, it operates as an autonomous body registered under the Registration of Societies Act of 1860 and the chairman of which is the Prime Minister of India. Further CSIR-TKDL as stated by them in their annex has an agreement with this office to share the TKDL for the purpose of search during prosecution of the filed patent applications and disposing them on merits. Therefore translations filed by them are deemed authenticated by the Government itself. Further this office solely depends on the said TKDL source for search purpose in deciding whether the applicant is indeed claiming any Traditional Knowledge and patent applications are scrutinised under the provisions of the Section 3(p) of the Patents Act. Hence it is concluded that translations as filed herein for the opposition are correct beyond doubt and taken on record for the consideration of disposal of this case.

It was argued that the present opposition is very loosely drafted and the purported statement does not even set out the grounds of opposition which is the basic requirement of a contested proceeding. It was pointed out that in a contested proceeding the grounds ought to be pleaded and proved. In case there is lack of pleading such grounds cannot be considered and the proceeding ought to be outright rejected. To emphasize the contention the attention was drawn to the following decisions from Intellectual Property Appellate Board [IPAB].

1. **IPAB order No. 262 of 2013 – Paragraph 5:**
   It reads thus "Here we would like to impress upon the applicant counsel that bald assertions in pleadings and filing of documents is not sufficient in patent in revocation if the ground under Section 64(1)(d) [Not an Invention], 64(1)(e) [Anticipation] and 64(1)(f) [Obviousness] are taken. Plain reading of these provisions suggests that opening words 'that the invention so far as claimed in any claim' requires the comparison of the prior art documents with the claimed invention to establish these grounds. The onus of establishing the relevance of document lies on the applicant. Counsel's argument cannot substitute pleadings."
   The agent for the applicant has stated that in the instant case the opponent instead of even referring to the specified grounds under Section 25(1) has only mentioned 'traditional knowledge on the issue of novelty and inventive step concerning Section 3(p) and Section 2(1)(j) respective of Indian Patents Act.' Has thrown some documents and has not shown how the said documents are relevant for the claims of the present application.
2. **IPAB order No. 262 of 2013 – Paragraphs 34, 36, 49, 51 and 52:**
   These paragraphs of the IPAB order deals with non-compliance of Section 8 [intimation of foreign filing particulars to be filed during prosecution by the applicant till the grant of patent]. The above order states that "the applicant seeking revocation under Section 8 may think that it is enough if he just types the password S.8 not complied with and the IPAB will do the rest. The IPAB will do no such thing. He will have to say that these are the foreign office actions that were not filed with the office. In this case the affidavit filed by the applicant merely lists the documents that were downloaded without giving any pleadings. We do not think that this is sufficient. The facts have to be pleaded and the applicant must

state how the particular undisclosed application was for the same or substantially the same invention. It is also not enough to just file the documents along with the affidavit. For this reason we hold that violation of Section 8 has not been proved by the applicant and this ground is rejected."

The agent for the applicant has therefore stated that arguments, if any, on the compliance of Section 8 is simpler than the pleadings to be made for non-establishing the novelty and inventive step. The IPAB has rejected the ground under Section 8 for not pleading the case therefore under the similar lines the present opposition ought to be rejected for not making any pleadings by the opponent on how the filed documents prove that there is no novelty and inventive step of the claims in dispute.

Further it was argued that the opponent has stated to have objected for the claims 11 to 16. The claims 14, 15 and 16 were deleted during the prosecution as the said claims are "use" claims and do not fall within the scope of the Section 2(1)(j) of the Patents Act. The remaining claims 11 to 13 needs to be defended. Claim 11 is a dependent claim on the previous claim. No opposition has been filed with respect to claim numbers 1 to 10 of the instant application. Entire opposition documents refers to Centella asiatica Urban which is an optional feature of the present invention.

It was pointed out that admittedly the extract of P. amboinicus is known though not for wound healing. Also admittedly, Centella asiatica Urban is known and its use for wound healing for treatment of burns etc., is also known. Thus admittedly no invention is claimed in either Plectranthus amboinicus or Centella asiatica. It is mentioned in page 3 of the specification that extract of Plectranthus amboinicus is known. However, the method of extracting is cumbersome and time consuming. Moreover, large quantity is not available. Accordingly, the present invention as mentioned in page 4 of the specification provides stirring method to replace the traditional column chromatography for mass production of extract of Plectranthus amboinicus. Moreover, composition of such extract provides better effects rather than the extract prepared by column chromatography. The specification also provides demonstration (Example 6) of better effectiveness of composition comprising Plectranthus amboinicus and Centella asiatica over composition comprising other known wound healing drugs including Centella asiatica alone. Also the Plectranthus amboinicus alone prepared by the method of present invention and formed into composition provides better wound healing efficacy than composition of Centella asiatica alone, as demonstrated in Example 7.

It was further argued that the documents filed by the opponent only show the use of Centella asiatica either alone or in combination with other plant extracts but extract of Plectranthus amboinicus is not at all shown. Therefore the claims are novel over these documents. Further as there is no hint of use of extract of Plectranthus amboinicus from those citations, the person skilled in the art could never be motivated to such combination and to extract of Plectranthus amboinicus as extracted by the process of the present invention. In view of this it was prayed to acknowledge the presence of Inventive Step of the alleged invention.

Further it was argued that the composition with both the extract of Plectranthus amboinicus and Centella asiatica as in claim 11 where the extract of Plectranthus amboinicus is prepared by prior art method of present invention is better than composition having Plectranthus amboinicus and Centella asiatica where Plectranthus amboinicus is prepared by prior art method. Thus both the compositions with single and both the extracts are within the purview of the present invention.

Hence it was requested to allow the claims 11 and 12. Claim 13 is an independent claim wherein the wound dressing comprising the extract of the present invention and since it comes under the definition of "invention" as defined in Section 2(1)(ja) should be allowed.

ANALYSIS

Section 25(1) of the Patents Act deals with the grounds of the opposition on which the opposition is to be filed and argued. These grounds are applicable for both Pre-grant and Post-grant oppositions. In the instant opposition the opponent has relied upon lack of novelty and lack of inventive step. The Section 25(1)(b) to (d) deals with novelty and the Section 25 (1)(e) refers to inventive step. Section 25(1)(b) refers to loss of novelty if there is a PRIOR PUBLICATION of the subject matter of a claim under dispute before the date of priority. Section 25(1)(c) refers to loss of novelty of a claim if there is a PRIOR CLAIM which has the earliest priority in contrast with the claim in dispute but is published after the priority date of the claim in dispute. Section 25(1)(d) refers to loss of novelty of a claim in dispute if the subject matter of the said claim was PUBLICLY KNOWN OR PUBLICLY USED in India before the priority date of that claim. The same are the guidelines for understanding the provisions of the Section 2(1)(j) of the Patents Act for the assessment of Novelty of a claim during prosecution. Similarly Section 25(1)(e) refers to loss of Inventive Step of a claim if the subject matter of that claim is OBVIOUS AND CLEARLY DOES NOT INVOLVE INVENTIVE STEP, having regard to the matter published as mentioned in clause 25(1)(b) or having regard to what was used in India before the priority date of the claim. "Inventive Step" has been defined in Section 2(1)(ja) that states that inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

Though the opponent has not mentioned the relevant portions of the Section 25 undoubtedly the opponent refers to lack of Novelty and Obviousness under the Section 2 of the Patents Act. Hence the opposition is considered as sufficiently explained the grounds of opposition which are within the scope of the grounds of opposition as laid in the Section 25(1) of the Indian Patents Act.

Agreeing to the submissions made by the agent for the applicant that there are no pleadings except the statement made by the opponent that the claims, and claims 11 to 16 in particular, lack novelty and inventive e step in lieu of the evidences attached with the statement it is difficult to think on the lines of the opponent to conclude, if any, under the opponent's lens.

Despite the hindrance as stated above the evidences filed by the opponent are examined and an attempt has been made to scrutinize the invention in dispute under the purview of the law. Though the agent of the applicant has stated that there is no comparison and pleading by claim wise against any claim either has been published or claimed prior to the priority date of the present invention, novelty assessment of the latest filed claims has been made thus;

a) Claims 1 to 7 are process claims wherein the Plectranthus amboinicus extract is prepared. Claims 1 to 3 refers to methodology of the process wherein stirring separation technique is stressed upon. The remaining claims 4 to 7 are considered as dependent claims thereon. No document of the opponent refers to Plectranthus amboinicus or to its extract or to any process of extraction or to any use or new use of Plectranthus amboinicus extract. Further it appears from the statement of the opponent that mainly the claims 11 to 16 are included for

a third party observation which in other words the opponent is trying to oppose the use of Centella asiatica extract and its use for any skin disorder. CSIR-TKDL source is the source for this office to search for the existence of Traditional Knowledge in the prosecution of the patent applications. CSIR-TKDL has exhaustive data over which perhaps entire world depends. This office could not retrieve any data related to the extract of Plectranthus amboinicus as claimed herein. While filing opposition it is not correct to conclude that the opponent is not aware about the first 10 claims of the present specification. In the absence of any documental evidence about the extract of Plectranthus amboinicus prepared by stirring method and its use for wound healing Novelty of the first 10 claims has to be acknowledged.

The statement made by the opponent in the annex that a large number of combinations can be made with Centella asiatica other than the combinations as disclosed in the filed documents does not go well because the use of Plectranthus amboinicus for treating any skin disorder is not known and why such combination will be prepared is not clear. To assess the novelty according to the law the subject matter of the claim 11 either should have been either published prior to the priority date or should have been prior claimed or should have been in public domain before the priority date of the present application. Since the opponent is silent on these aspects the combination of Plectranthus amboinicus and Cetella asiatica as claimed in claim 11 is considered as Novel. The claim 12 is a dependent claim on claim 11 which defines the specific ration of the two constituents also considered as Novel. The subject matter of claim 13 is an independent claim, claiming a product that is a "wound dressing" that comprises either the extract of Plectranthus amboinicus or the combined extracts of Plectranthus amboinicus and Centella asiatica. Hence this claim is also Novel. Therefore all the claims that is 1 to 13 are considered as Novel.

b) The applicant in page 3 of the specification has acknowledged about the existence of the extract of Plectranthus amboinicus. It was stated that the US patent application US 2006/0099283 A1 refers to the leaf juice of Plectranthus amboinicus wherein the said juice is obtained by grinding and removing the different fragments by centrifugal filter devices. The other process of extracting the leaf juice of Plectranthus amboinicus has been described in USSN 11/605,178 wherein the extraction was carried out by column chromatography. The problems identified by the inventor are that the known methods are time consuming and do not yield larger quantities of the active. Hence the present process that is stirring separation. Now the question to understand the inventiveness of a claim is to understand whether there is any teaching that solid-liquid separation [stirring separation] is superior to column chromatography or centrifugal separation in general and for extracting the leaf juice of Plectranthus amboinicus, in particular. There is no mention about this by the opponent. In page 9 of the disclosure the applicant has stated that the process according to the invention is about five times faster than the column chromatographic separation method. Example 1 of the specification explains the preparation of Plectranthus amboinicus extracts by stirring separation method that is the process of the present invention wherein the yield of the active is shown as 0.94%. Example 2 of the specification explains the preparation of Plectranthus amboinicus extracts by column chromatography separation method that is the process of the prior art wherein the yield of the active is shown as 0.67%. Thus the applicant

has established the technical advancement as compared to the existing knowledge and hence for satisfying the requirement of the Section 2(1)(ja) of the Patents Act, thus the "Inventive Step" is established. A person skilled in the art is expected to study the prior art(s) that are available before him and may combine as trial and error method to solve the problem. The solution thus obtained passes the novelty test but fails in inventive step because no inputs are made by the said person ordinarily skilled in the art. No citation filed by the opponent refers to Plectranthus amboinicus lest to any process of extraction of it. Further no citation refers to the combination of Plectranthus amboinicus and Centella asiatica nor any guidance to prepare such combination. In addition, the use of Plectranthus amboinicus is known for treating cancer and or tumour. The new use of Plectranthus amboinicus either alone or in combination with Centella asiatica for wound healing is not known according to the present disclosure. In the absence of such direction the alleged invention both for the preparation and the combination cannot be concluded on the lack of inventive step when read with the provisions as laid in the Section 25(1)(d) of the Patents Act. It is further agreed with the argument made by the applicant that mere statement without pleadings cannot justify the objection raised therein.

c) Since the opponent is silent on the subject matter of the claims 1 to 10 it is to conclude that the subject matter of the said claims is novel and inventive in nature. With respect to claim 11 the addition of the extract of Centella asiatica is an optional feature. Further Examples as provided in examples 6 and 7 wherein examples refers to wound closure percentages wherein CT_{50} values are provided indicating time required for 50% of wound closure and in the case of claimed composition it is shown as 7.65 days which is lower than any other test materials. Further it is shown that the exclusive Centella asiatica extract is shown to exhibit CT_{50} value as 10.3 days. Hence the effectiveness of the composition has been proved through the disclosure. It has not been disputed by the opponent. Therefore even though the addition of Centella asiatica has been claimed as an optional feature the said composition is considered to be novel and inventive.

CONCLUSION

The opponent has objected to lack of novelty and inventive step but could not prove it. The opponent, understandably, has mainly objected for Centella asiatica which is not the main inventive concept. The opponent did not make any reference to the extract of Plectranthus amboinicus nor to its method of preparation and nor to a combination nor to its use for skin disorders. Therefore it is concluded that opponent has failed to prove the lack of novelty and inventive step of the claims on record. Therefore it has been decided to grant the patent right to the applicant.

Patent right is hereby granted to the applicant.

Dated 30th October 2014

(T.V.MADHUSUDHAN)
Deputy Controller of Patents and Designs.