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*Exp/SG
19/4/12*

1565/CHE/2006

Date: 2nd April, 2012

To,
The Controller of Patents, Designs and Trademarks,
Boudhik Sampada Bhavan,
S.M. Road, Antop Hill,
Mumbai-400037

2012/17341

*Pregrant
Oppn*

**Subject: Reply to Pre-Grant Opposition for Application
No.1565/CHE/2006.**

Ref: Mumbai Patent Office Diary No. 6507

Sir,

We have received a representation for Pre-Grant opposition from Mumbai patent Office filed by TKDL, CSIR.

We are filing, a Reply Statement in support of our Application No. 1565/CHE/2006 titled "Eugenia jambolana plant extracts for the treatment of diabetes and the extraction process thereof". Kindly find attached the Reply Statement along with this cover letter.

Sincerely,

Dr. Mohini Suryawanshi,
Registered Indian Patent Agent (IN/PA/2023)
Avesthagen Ltd.

✓ Copy to:
Intellectual Intellectual Property Office,
Chennai

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BEFORE THE CONTROLLER OF PATENTS

MUMBAI

In the matter of Section 25(1) of The Patents Act, 1920- 80,
as amended upto the Patents (Amendment) Act 2005

And

In the matter of The Patents Rules, 2005

And

IN THE MATTER of Patent Application **1565/CHE/2006** filed on
30.08.2006 by **Avesthagen Limited**, Bangalore, India

.....Applicant

And

IN THE MATTER of **PRE-GRANT OPPOSITION** by **Council of Scientific
and Industrial Research (CSIR)**, New Delhi, India

.....Opponent

REPLY STATEMENT TO PRE-GRANT OPPOSITION U/S 25(1)

We, **Avesthagen Limited**, an Indian Company registered under the provisions of The Companies Act, 1956, with its Office at "Discoverer" 9th Floor, Unit 3, International Tech Park, Whitefield Road, Bangalore 560066, Karnataka, India (hereinafter referred to as "**Applicant**") had filed Application No. 1565/CHE/2006 titled "**EUGENIA JAMBOLANA PLANT EXTRACTS FOR THE TREATMENT OF DIABETES AND THE EXTRACTION PROCESS THEREOF**" dated 30 August, 2006 with the Chennai Patent Office and also subsequently followed the other requirement prescribed under the Patent Act, 1920- 80 (as amended from time to time) - w.r.t. filing the request for examination on 30 August, 2010. The Applicant is now waiting for First Examination report from the Indian Patent Office, Chennai.

Council of Scientific and Industrial Research (CSIR), New Delhi, (hereinafter referred to as "**Opponent**") has filed pre-grant opposition for above mentioned application on 6th January, 2012, wherein Opponent objected our said application on the basis of its relation to traditional knowledge and hence, it exhibits lack of Novelty and lack of Inventive Step as per Section 3(p) and Section 2(1(j) respectively, of Indian Patents Act, 1920- 80. Opponent also produced five relevant prior art documents which are in different languages viz. Urdu, Persian, Marathi and Tamil. These existing prior art documents are present in printed books of Unani, Ayurveda and Siddha and such references are included in Traditional Knowledge Digital Library (TKDL) maintained by Opponent. In these prior art documents, Eugenia jambolana (synonym-Syzygium cuminii) extracts are used in various forms of treatment of diabetes mellitus through oral route in the Indian system of medicine since long time. Along with these 5 prior art

documents, the Opponent also claiming other references exist in TKDL wherein, *Eugenia jambolana* (synonym-*Syzygium cuminii* Linn.) have been used alone or in combination with few other ingredients for the treatment of Diabetes Mellitus. Therefore, Opponent is of the opinion that usefulness of *Eugenia jambolana* extracts for its hypoglycemic activity claimed in said application is not a novel feature and it does not involve any inventive step as per Section 3(p) and Section 2(1(j) respectively, of Indian Patents Act, 1970. So, it is not fulfilling the criteria of patentability of invention based on Traditional knowledge under section 3(p).

Initially, the Applicant respectfully acknowledges TKDL for its traditional knowledge database, traditional knowledge of Ayurveda, Unani and Siddha, the references from which are somewhere relevant to said application and also would like to mention that Applicant is ready to make necessary amendments in the specification/claims to the satisfaction of the Controller of Patents as directed by the Learned Controller of Patents at the end of this Pre-grant Opposition decision.

The Applicant also likes to provide references of Ayurveda, Unani and Siddha in the specification of said application as well as in this reply as below:

- Anonymous (1999). **The Ayurvedic Pharmacopoeia of India** Part-I and Volume-II 1st edition. Ministry of Health and Family Welfare, Govt. of India, New Delhi. 57-60
- Kiritikar KR, Basu BD. **Indian medicinal plants**. Dehradun: International Book Distributors; 1987; p. 1052-1054.
- Sastri BN. **Wealth of India**. New Delhi: C.S.I.R. Publications; 1954

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The Opponent has objected claims-1, 4, 10, 12, 13, 14, 15 on the basis of lack of novelty and lack of inventive step. With due attention to these objections related to claims and in view of these objections, the Applicant would like to address the objections raised by the Opponent w.r.t. said application as below:

OBJECTION 1: Lack of Novelty and Lack of Inventive Step

The Applicant would humbly likes to mention that the instant application relates to a method of developing and screening extracts from Eugenia seed using various cell assays for the treatment of hypoglycemic activity, composition prepared from such Eugenia seed extract and use of Eugenia plant extract for treatment of Diabetes Mellites.

In the instant application, the Applicant has come up with a **novel method** of developing and screening extract from Eugenia seed using various cell assay methods, **a novel composition** which is prepared from Eugenia seed extract

Claim 1: A method of treating or preventing diabetes by administering to a mammal a therapeutically effective non-toxic amount of an extract derived from the plant Eugenia characterized of hypoglycemic activity.

The Applicant humbly likes to admit that as per Indian Patents Act, 1970 under Section 3(i), "a process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products" is non-patentable and the Applicant is ready to amend or delete claim 1 accordingly as per the directions of learned Controller.

Claim 4: A method according to claim any of the preceding claims wherein, the plant extracts are extracted from leaves, seeds, roots, stems, flowers, or various combinations thereof but preferably the seed of the plant.

Claim 10: Use of the Eugenia plant extract according to at least one of the claims 1 to 9 as a medicament.

Claim 12: Use of the Eugenia plant extract according to at least one of the claims 1 to 9 for the production of a medicament with hypoglycemic activity.

Claim 13: A Composition comprising one or more plant extracts that are capable of delaying the onset and/or management of diabetes derived from the plant belonging to the plant sp. Eugenia.

In view of claims **4, 10, 12, 13:** All prior art documents and references produced by the Opponent describes a therapeutic single/ compound formulation consisting of **useful parts** of Eugenia jambolana (Syzygium cuminii), here different parts of the plant are mentioned like **seed, stem, bark, fruit, ripe fruit, flower etc.** and this formulation is said to be useful for the treatment of Diabetes mellitus.

Though the useful parts of Eugenia jambolana (Syzygium cuminii), mentioned in the prior art are seed, stem, bark, fruit, ripe fruit, flower etc. and the composition or formulation is found to be useful for the treatment of Diabetes mellitus since ancient time which is already a traditional knowledge, and the Applicant is using traditionally known Eugenia seed which is having anti-diabetic properties for its experiments, **the novelty of said application lies in preparation of Eugenia seed extract in variety of solvents and analysing effective solvent concentration as 20- 80% Ethanol for such preparation which has not been described in cited prior art documents and**

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references (For claim 2, 3, 4, and rest of the claims and specification, the Applicant would like to amend and restrict the scope of the invention in specification-description and claims by keeping only **Eugenia seed** as a plant material and Seed extract concentration as 20-80% instead of 70% since we have working examples for such concentraion).

Further study of Eugenia 20- 80% Ethanol seed extract showed higher insulin mimetic and higher insulin sensitization activity. Both these higher insulin mimetic and higher insulin sensitization activities have been checked using 3T3 L-1 adipocyte cell lines and C2C12 myocyte cell lines. So, the novelty of the application is use of traditionally known Eugenia seed extract for the treatment of Diabetes Mellitus but at specific concentration prepared from specific solvent that is 20- 80% alcohol Eugenia seed extract, and such solvent specific seed extract for studying insulin mimetic and higher insulin sensitization activities using two particular cell lines 3T3 L-1 adipocyte cell lines and C2C12 myocyte cell lines in relation to treatment of Diabetes Mellitus.

Here, the Applicant submits that in said application a method of extraction of Eugenia seed extract has been claimed in Claim 2, and claim 4 is a dependent claim of independent claim 2, wherein claim 2 clearly describes the method of extraction of Eugenia seed extract using different solvents viz. an aqueous, an ethanolic, an organic solvent or a combination thereof, thereby providing one or more Eugenia seed extracts possessing hypoglycemic activity. Claim 2 also includes analysis of these obtained Eugenia seed extract for free radical scavenging potential, total polyphenols content, alpha-glucosidase inhibition potential and insulin mimetic and insulin sensitization activity using two specific cell lines to confirm its use for the treatment of Diabetes Milletus.

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It becomes evident from above clarification that the Applicant is using traditionally known Eugenia seed effective for showing anti-diabetic property or possessing hypoglycemic activity, but by using such seed the Applicant is claiming a better and substantially effective ethanolic seed extract and composition made out of such claimed method which is useful for the treatment of Diabetes Mellitus. So, it would be erroneous to say that such invention lacks novelty.

The inventive step of said application lies in further efficacy screening of 20- 80% ethanol Eugenia seed extract using streptozotocin induced Sprague dawley rats for hypoglycemic activity.

The Applicant humbly acknowledges the traditional knowledge digital library (TKDL) in case of claims 4, 10, 12 and 13 and would definitely make necessary changes in claims in accordance with Indian Patents Act, 1970 to meet the patentability criteria.

Claim 14: A composition comprising one or more plant extracts, wherein the administration of the therapeutic composition can be formulated as pharmaceutical or naturopathic formulation such as phytoceuticals or nutraceuticals, for oral, topical, rectal, parenteral administration or for administration by inhalation or spary.

The prior art documents and references produced by the Opponent (all 5 prior arts) shows use of Eugenia jambolana plant parts for the treatment of Diabetes Mellitus when taken orally. It appears from these documents that **oral administration** is recommended in the past but the Applicant also claims other types of administration of composition (along with said oral administration) as an inventive step and for purpose of novelty the Applicant acknowledges the traditional knowledge of Ayurveda, Unani and Siddha.

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Claim 15: A composition comprising one or more plant extracts, wherein the pharmaceutical or naturopathic formulations may be in a form suitable for oral use, for example, as tablets, troches, lozenges, aqueous or oily suspensions, dispersible powders or granules, emulsion hard or soft capsules, or syrups or elixirs.

The prior art documents and references produced by the Opponent insist on the **oral administration** of the composition for the treatment of Diabetes Mellitus and claim 15 includes oral administration as one of the form of formulations in addition to other forms of formulations mentioned in claim 15. So, it becomes inventive step over prior art and for purpose of novelty the Applicant acknowledges the traditional knowledge of Ayurveda, Unani and Siddha.

In case of **claim 14 and 15**, and in view of submitted prior art documents by the Opponent, the Applicant would like to assure to the learned Controller that the Applicant will make all necessary amendments in these claims and specification as per the directions of the Controller.

Firstly, the Applicant affirms that to overcome the objection of "**LACK OF NOVELTY**" under as per Section 3(p) on the basis of relevancy of said application with the traditional knowledge, the Applicant acknowledges the traditional knowledge of Ayurveda, Unani and Siddha. The Applicant also agrees to amend **wherever necessary** claims of said application on the basis of novel method claimed in Claim 2 of the specification of said application. Furthermore, the applicant would like to amend **wherever necessary** claims and specification wherever necessary according to the description of a novel method, composition, use with reference to specific standardised method parameters, solvents, specific cell lines used and various effective concentrations of Eugenia 20-80% ethanolic seed extract etc. which is already detailed out in specification of said

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application without changing the scope of the invention which is acceptable under Indian Patents Act, 1970 under Section 57, 59 and Rule-81, 82 as the Controller thinks fit.

Secondly, to overcome the objection of "LACK OF INVENTIVE STEP" related to all objected claims, the Applicant would like to amend **wherever necessary** claims according to the **INVENTIVE STEP** mentioned in the specification, wherein screening of Eugenia 20- 80% Ethanol for studying insulin mimetic and higher insulin sensitization activities using two particular cell lines 3T3 L-1 adipocyte cell lines and C2C12 myocyte cell lines in relation to treatment of Diabetes Mellitus. Furthermore, the inventive step of said application is also strengthened when further efficacy screening of 20- 80% ethanolic Eugenia seed extract using streptozotocin induced Sprague dawley rats for hypoglycemic activity has been carried out with amazing results. Accordingly, the Applicant would amend **wherever necessary** claims by mentioning particular standardized parameters, values, cell lines, effective composition produced from a novel claimed method etc. in claims to make them more limited and specific as described above thereby incorporating inventive step feature in claims by sticking to the scope of the invention which is acceptable under Indian Patents Act, 1970 under Section 57, 59 and Rule-81, 82 as the Controller thinks fit.

The Applicant craves leave to amend, alter or add to all or any of the claims or specification as below:

1. By acknowledging traditional knowledge in the specification of said application;
2. By reaffirming that the claims will be amended as per section-59 of the Indian Patents Act-1970 and no amendment will be done, the effect of which would be that the claims after amendment would claim or disclose any

matter which was not in substance disclosed before amendment.

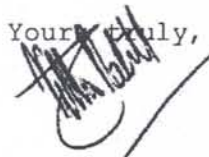
Relief Sought:

The Applicant humbly submits that it has been conclusively established on each clarification provided that said application does not lack novelty and inventive step on the basis of traditional knowledge. The Applicant prays for the following relief:

1. Leave to amend, alter, add to whenever necessary or any of the claims or specification;
2. The objections raised by the Opponent are dismissed;
3. The application be ordered to proceed for grant of patent;
4. Such relief(s) as the Controller may deem fit.

Dated: 2nd April, 2012

Your Truly,



Dr. Viloo Morawala Patell
CMD & FOUNDER
Avesthagen Limited