

THE PATENTS ACT, 1970

(AS AMENDED)

SECTION 15

IN THE MATTER OF APPLICATION FOR PATENT

APPLICATION No. **7127/DELNP/2011** dated 16/09/2011

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-----Applicant

Switzerland

Agent of The applicant:

LEX ORBIS

The Patent application No. **7127/DELNP/2011** dated **16/09/2011** filed by the above applicant. The said application was examined under sections 12 and 13 of the Patents Act, 1970 (as amended) and First Examination report was issued on 31/01/2018. In response to the First Examination Report, applicant's agent submitted its reply on 26/07/2018.

After considering the reply filed in response to the first examination report by the applicant's agent and the report of the examiner on such reply, it was observed that the said patent application was not in order for grant. Keeping in view the provisions of the Patents Act, 1970 (as amended) and with a view to provide natural justice to the applicant, a hearing was offered to the agent of the applicant dated 01/11/2019 (Hearing was shifted to 21/11/2019 after filing an adjournment motion by the applicant) along with the following objections which were found outstanding in the application:

Invention u/s 2(1)(j)

1. The prior art cited is:

D1: US2008241255 A1
(02/10/2008); D2: US4924883 A
(15/05/1990); D3: US5050621 A

(24/09/1991); D4: CN86102917 A
(11/11/1987);

Claims 1-20 lack inventive step under section 2(1)(j)(a) of the Indian Patents Act 1970, in the light of the document D1, D2 and D3, D4 cited above.

D1 the references in parentheses refer to the document D1) discloses device for delivering nicotine to a subject, the device comprising a housing, the housing comprising: a) an inlet and an outlet in communication with each other and adapted so that a gaseous carrier may pass into the housing through the inlet, through the housing and out of the housing through the outlet, the device comprising from inlet to outlet (para 37, 225, 227, figure 1): b) a first internal area in communication with the inlet, the first internal area comprising either a source of a compound for forming particles comprising nicotine, or a natural product nicotine source, (para 148-151, 227, 236, figure 4), c) a second internal area in communication with the first internal area, the second internal area comprising the source not selected for step b), and d) optionally, a third internal area in communication with the second internal area and the outlet (para 148-151, 227, figure 2).

Similarly D2 discloses same subject matter at claims 1, 2, 4-6, abstract, figures 1-3 and related paragraphs.

D2 and D3 fail to disclose that the natural product nicotine source includes tobacco and an alkaline substance which is however disclosed in D3 (claims 1-3, 5) and D4 (claims 1-9). Hence without prejudice, it would have been obvious to a person skilled in art to combine the teachings of D1 or D2 in D3 or D4 to arrive at the subject matter.

Non-Patentability u/s 3

1. 1. Claims 1-20 fall under the scope of section 3(i) of the Indian Patent Act 1970 as they claim a method and device for delivering nicotine to a person/animal which is a therapeutic substance, further the method claims disclose manner in which delivery of the therapeutic substance nicotine is to be made all of which constitutes a non patentable subject matter under the act as they are directed towards a method for treatment on human/animal body.

2. Claims 1-20 attracts section 3(b) and cannot be allowed

Sufficiency of Disclosure u/s 10 (4)

1. Differences, inventiveness and problems solved from the existing prior art is not provided properly. Proper background with references to the closest art should be provided. Citation/references to most related patent literature and non-patent literature shall be provided in the description.

Clarity and Conciseness

1. Characterizing clause should be clear. The claim should be in two part form for clear understanding of inventive features.

Other Requirement(s)

1. 1. Proof of right signed by inventors should be submitted in a prescribed manner & as per rule 10, section 6(1) and section 7(2) of the Patents Rules, 2003 (as amended).
2. Form 3 should be filed in a prescribed manner to comply the requirements of section 8(1) and 8(2) of IPA-1970.
3. You are required to provide breakup of fees in respect of additional claims and pages of the complete specification (including Form-2 as the 1st page of specification, Abstract and Drawings) in your response. In case you have not filed the adequate fees for the same U/R 7(2)(c), balance fees in respect of additional pages and/ or claims should be submitted immediately along with necessary petition and fees, failing which the instant application shall proceed U/S 142(3) of the Act.
4. GPA should be submitted in a prescribed manner
5. Amendment should be supported by the section 10(4), 57 and 59(1) of IPA-1970

2. Figures and illustrations shall be provided separately as drawings instead of between the description text as per section 10(2) of the Indian Patent Act 1970.

In response to the objection raised in the said hearing notice applicant has submitted the amended set of claim in the form of written submission dated 05/12/2019:

1. A device for delivering nicotine to a subject, the device comprising:

a housing, the housing comprising:

a) a first inlet, a second inlet and an outlet in communication with each other and adapted so that a first gaseous carrier may pass into the housing through the first inlet, through the housing and out of the housing through the outlet, and a second gaseous carrier may pass into the housing through the second inlet, through the housing and out of the housing through the outlet,

characterized in that, the device comprising:

b) a first internal area in communication with the first inlet, the first internal area comprising a source of a compound for forming particles comprising nicotine,

c) a second internal area in communication with the second inlet, the second internal area comprising a natural product nicotine source,

d) a third internal area in communication with the first and second internal areas and the outlet, wherein the

natural product nicotine source includes tobacco and an alkaline substance.

2. The device as claimed in any one of claims 1, wherein the source of nicotine is any natural materials having nicotine content, including plant materials and other natural sources.

3. The device as claimed in any one of claims 1-2, wherein the source of the compound for forming particles comprising nicotine comprises an adsorption element with the compound for forming particles comprising nicotine adsorbed thereon.

4. The device as claimed in any one of claims 1-3, wherein the alkaline substance is selected from the group consisting of calcium oxide, calcium hydroxide, sodium hydroxide, sodium bicarbonate, potassium hydroxide and potassium carbonate.

5. The device as claimed in any one of claims 1-4, further comprising a first reservoir in communication with the source of the compound for forming particles comprising nicotine, the first reservoir comprising the compound for forming particles comprising nicotine.

6. The device as claimed in any one of claims 1-5, wherein the source of the compound for forming particles comprising nicotine comprises a plurality of internal areas comprising two or more precursor compounds.

7. The device as claimed in claim 6, wherein the compound for forming particles comprising nicotine comprises ammonium chloride and the two or more precursor compounds include ammonia and hydrogen chloride.

8. The device as claimed in any one of claims 1-7, wherein the compound for forming particles comprising nicotine comprises an acid.

9. The device as claimed in claim 8, wherein the acid is an organic acid.

10. The device as claimed in claim 9, wherein the acid is a 2-Keto acid.

11. The device as claimed in claim 10, wherein the acid is selected from the group consisting of 3-Methyl-2-oxovaleric acid, Pyruvic acid, 2-Oxovaleric acid, 4- Methyl-2-oxo valeric acid, 3- Methyl-2-oxobutanoic acid, 2-Oxooctanoic acid and combinations thereof.

12. The device as claimed in any one of claims 1-11, wherein the housing simulates a tobacco product.

13. The device as claimed in any one of claims 1-12 comprising the third internal area, the third internal area optionally comprising a gaseous carrier turbulence element and/or an

Additional source
element.

14. The device as claimed in any one of claims 1-13, further comprising an internal area element in communication with the outlet optionally comprising a purifying agent.

15. The device as claimed in any one of claims 1-14, wherein the third internal area element comprises a flavouring agent.

16. The device as claimed in any one of claims 1-15, wherein the natural source nicotine source is heated.

17. The device as claimed in any one of claims 1-15, wherein the temperature of one or more of a) the natural product nicotine, b) the source of the compound for forming particles comprising nicotine, and/or c) the gaseous carrier is below 150 degrees C, preferably below 100 degrees C.

18. The device as claimed in any one of claims 1-17, wherein the natural product nicotine source has been treated to increase the release of volatile nicotine, from the natural product nicotine source, by one or more of the following:

- a) Minutizing the natural product nicotine source such as cutting, chopping or grinding;
- b) Raising the pH of the natural product nicotine source above neutral pH,
- c) Mixing or homogenization of the natural product nicotine source to produce a liquefied suspension, optionally clarified to remove some to all visible particulate matter;
- d) Supplementing the natural product nicotine source with nicotine base;
- e) Treating the natural product nicotine source with enzymes or detergents to break down the cellulose contained therein in order to render the nicotine more available for release through volatilization or other means;
- f) Using molecular sieves or other desiccants to reduce the water content of the natural product nicotine source in order to increase the relative concentration of nicotine; and/or

g) Using high salt content solution to extract

nicotine.

I now consider the cited documents viz. D1: US2008241255 A1 (02/10/2008); D2: US4924883 A (15/05/1990); D3: US5050621 A (24/09/1991); D4: CN86102917 A (11/11/1987); as mentioned in the said hearing notice.

In view of the cited documents' relevant teachings and Applicant's reasoned arguments regarding the said teachings, reference is now made to Hon'ble IPAB Order No.250/2012 dated 02/11/2012, where it is enunciated that "once the very subject-matter of the invention has been disclosed by the prior art..... the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work". It further opined that the said person "is not a person of exceptional skill and; knowledge.....He must, however, be prepared to display a reasonable degree of skill and common knowledge of the art in making trials...." Regarding obviousness, the observations are noteworthy, "When there is a design need or market pressure to solve a problem and (there) are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense...." The aforementioned IPAB order concludes that non-obviousness "demands that the claimed invention be sufficiently removed from the prior art", and that non-obvious enquiry is "a more aggressive sentry".

Further, in the F. Hoffmann-La Roche Ltd vs Cipla Ltd case (2012), the Honble Delhi High Court had observed that the obviousness test is what is laid down in Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444) and that "Such observations made in the foreign judgments are not the guiding factors in the true sense of the term as to what qualities that person skilled in the art should possess. The reading of the said qualities would mean qualifying the said statement and the test laid down by the Supreme Court." Hon'ble High Court further added "From the bare reading of the afore quoted observations of

Supreme Court, it is manifest that the Hon'ble Supreme Court has laid down the test for the purposes of ascertaining as to what constitutes an inventive step which is to be seen from the standpoint of technological advancement as well as obviousness to a person who is skilled in the art. **It is to be emphasized that what is required to be seen is that the invention should not be obvious to the person skilled in art.** These are exactly the wordings of New Patents Act, 2005 u/s Section 2(ja) as seen above. Therefore, the same cannot be read to mean that there has to exist other qualities in the said person like unimaginary nature of the person or any other kind of person having distinct qualities..... Normal and grammatical meaning of the said person who is skilled in art would presuppose that the said person would have the knowledge and the skill in the said field of art and will not be unknown to a particular field of art and it is from that angle one has to see that if the said document which is prior patent if placed in the hands of the said person skilled in art whether he will be able to work upon the same in the workshop and achieve the desired result leading to patent which is under challenge. If the answer comes in affirmative, then certainly the said invention under challenge is anticipated by the prior art or in other words, obvious to the person skilled in art as a mere workshop result and otherwise it is not. The said view propounded by Hon'ble Supreme Court in Biswanath Prasad (supra) holds the field till date and has been followed from time to time by this Court till recently without any variance..... Therefore, it is proper and legally warranted to apply the same very test for testing the patent; be it any kind of patent. It would be improper to import any further doctrinal approach by making the test modified or qualified what has been laid down by the Hon'ble Supreme Court in of Biswanath Prasad (supra).” In the view of the above, it is understood that the "person skilled in the art" is a competent craftsman or engineer as distinguished from a mere artisan. Hence, in the instant application the person skilled in the art aware of use of device having nicotine delivery functioning.

The argument given by applicant for the objection of the office letter dated 06/12/2019 is not convincing. In the light of the citations and the aforesaid IPAB order, I deduce the following

In the paragraph [0055], present subject matter acknowledges that a treatment **may improve the disease condition but** applicant is not sure about the improvement.

The body's own agent acetylcholine, acts over milliseconds to activate nicotinic receptors, whereas nicotine itself stimulates these receptors for hours. Nicotine locks on to one group of receptors that are normally targeted by the neurotransmitter acetylcholine. Nicotinic acetylcholine receptors are ion channels threaded through cell membranes. When activated, either by acetylcholine or by nicotine, they allow selected ions to flow across the cell membrane. The drug is reviled as the world's most addictive. The drug, of course, is nicotine. Higher doses are toxic, even lethal. Applicant fails to explain how to control the addiction effect of the nicotine which is hazardous to the health and therefore it cannot be allowed as per section 3(b) of IPA-1970.

Without prejudice to the above objection, applicant argument opinion about the form of nicotine that is being used in the cited documents D1 and D2 and in the present subject matter is different it's an inventive feature . In the present claimed subject matter, natural product nicotine source comprising a combination of both tobacco and an alkaline substance whereas in the cited it's not. Applicant's argument about the use of different form of nicotine is irrelevant since it does not disclose the difference of the result when natural source of nicotine being used. It only talks about that it can be easily acquired or stored but its form play insignificant role in the devices. Further, D3 uses a natural product nicotine source comprising tobacco. D1 discloses all the feature of the present subject matter. Applicant argument about the arrangement of D1 as series and present invention as parallel leaves no significant result differences between these two and it cannot be considered as inventiveness since its mere change of arrangement. Therefore, having the knowledge of D1 itself, the person skill in the art would be able to get the desired result without having any inventive step and it cannot be allowed as per section 2(1)(j) of IPA-1970.

The oral argument and the written submission of the agent of the applicant have been carefully considered. However without prejudice, although the hearing submissions have attempted to address the other requirements, yet the substantive requirement of the Patents Act, 1970 i.e. Section 2(1)(j) and 3(b) is not found

complied with. Hence, in view of the above and unmet requirements, this instant application is not found in order for grant.

Therefore, keeping in view the above facts, the submissions of the agents during hearing and subsequently through the written submission, as well as the outstanding official requirements, instant application no. **7127/DELNP/2011 dated 16/09/2011** does not comply with the requirements of The Patents Act, 1970 (as amended). I, therefore, hereby order that the grant of a patent for application no. **7127/DELNP/2011** is refused under the provisions of Section 15 of The Patents Act, 1970 (as amended)

This is to be noted that the aforesaid observations, and decision thereof, are based solely on the electronically uploaded documents to date.

Assistant Controller of Patents & Designs
Gopal Kumar

Date: 21/02/2020