



100140

北京市金融大街 27 号投资广场 A 座 10 层 永新专利商标代理有限公司
过晓东 (010-63611666)

Issuing Date:

Application No. or Publication No.201480025499.X

Issue No.:

Application or Patentee: Ur Laboratories Ltd.

Title of Invention: Nicotine Salt Formulations for Aerosol Devices and Methods Thereof

The Third Office Action

1. The examiner has already received the observation submitted by the applicant on 2018-5-2, based on this, the examiner continues the substantive examination for aforesaid application for a patent for invention.

In accordance with the reexamination decision of the Patent Reexamination Board of the State Intellectual Property Office on _____ - _____ - _____, _____ the examiner continues the substantive examination for aforesaid application for a patent for invention.

2. Upon examination, the amendment submitted by the applicant on _____ shall not be accepted for not in conformity with Rule 51.3 of the Implementing Regulations of the Patent Law.

3. Continuation of the examination is performed on the basis of the following applicant documents:

Amended application documents attached to the aforesaid observation.

Application documents to which the last Office Action is directed and replacement sheets of the amended application documents attached to the aforesaid observation.

Application documents to which the last Office Action is directed.

Application documents confirmed by the aforesaid reexamination decision.

4. This Office Action does not refer to any new reference documents.

The following reference documents are cited in this Office Action(the serial number(s) of which is numbered as before, and it will be used in follow-on examination) :

No.	Document number or Document title	publication date (or application date of the conflicting
6	US 2006/0018840A1	20060126

5. Conclusive opinions of the examination:



About the description:

The application falls into the scope of subject matter which is nonpatentable according to Article 5 of the Patent Law.

The description fails to comply with the provisions of Article 26.3 of the Patent Law.

The description fails to comply with the provisions of Article 33 of the Patent Law.

The drafting of the description fails to comply with Rule 17 of the Implementing Regulations of the Patent Law.

About the claims:

The claim(s) _____ fail(s) to comply with the provisions of Article 2.2 of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Article 9.1 of the Patent Law.

The claim(s) _____ fail(s) to comply with the novelty requested by Article 22.2 of the Patent Law.

The claim(s) 1-34 fail(s) to comply with the inventive steps requested by Article 22.3 of the Patent Law.

The claim(s) _____ fail(s) to comply with the applicability requested by Article 22.4 of the Patent Law.

The claim(s) _____ fail(s) into the scope of subject matter which is nonpatentable according to Article 25 of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Article 26.4 of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Article 31.1 of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Article 33 of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Rule 19 of the Implementing Regulations of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Rule 20 of the Implementing Regulations of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Rule 21 of the Implementing Regulations of the Patent Law.

The claim(s) _____ fail(s) to comply with the provisions of Rule 22 of the Implementing Regulations of the Patent Law.

The application fails to comply with the provisions of Article 26.5 of the Patent Law or Rule 26 of its Implementing Regulations.

The application fails to comply with the provisions of Article 20.1 of the Patent Law.

The divisional application fails to comply with the provisions of Rule 43.1 of the Implementing Regulations of the Patent Law.

The detailed analyses of the above conclusive opinions refer to the text of this Office Action.

6. On the basis of the conclusive opinions, the examiner suggests:

The applicant should amend the application documents according to the text of this Office Action.



The applicant should state the reasons why the patent application should be granted in the observation, and amend the part which fails to comply with the provisions according to this Office Action; otherwise the patent application should not be granted.

The substantive content that might be granted can not be found in the application, if the applicant does not state the reasons or the stated reasons are not sufficient, the application shall be rejected.

7. The applicant should pay attention to the followings statements:

(1) In accordance with Article 37 of the Patent Law, the applicant should submit the written opinion within two months from the date of receipt of this Office Action. If, without any justified reason, the time limit for reply is not met, the application shall be deemed to have been withdrawn.

(2) The amendment of the application document by the applicant should be in conformity with Article 33 of the Patent Law, and it should not exceed the scope specified in the initial description and claims. Meanwhile, the amendment of the application document by applicant should be in conformity with Rule 51.3 of the Implementing Regulations of the Patent Law, and in accordance with this Office Action.

(3) The written opinion and/or amendment document of the applicant should be sent by mail or submitted directly to the Receiving Division of the Patent Office of the State Intellectual Property Office, otherwise it will be considered to have no legal effect.

(4) Without appointment, the applicant and/or the agent should not come to the Patent Office of the State Intellectual Property Office to have an interview with the examiner.

8. The text of this Office Action has 6 pages, and the attachments are as follows:

The total number of copies of the reference documents cited is _____ copies and _____ pages.

Name of the Examiner: 刘欢

Tel: 022-
84867341

Examination Department: 专利审查协作天津中心
光电技术发明审查部



The Third Office Action

Application

Number:201480025499X

The Applicant filed an Opinion Statement and an amended Application Document on May 2, 2018 and the Examiner, after reading the above document, proceeds with the examination of the present document and sets forth the following Examining Options.

In one, claims 1-34 are devoid of the inventive step specified in clause 22, clause 3 of the patent law.

1. Claim 1 claims a method of delivering nicotine to a user. Comparative document 1 (CN1541577A), which is the closest prior art, discloses a non-flammable e-spray cigarette and discloses in particular (cf. Page 1 penultimate paragraph-page 2, paragraph 2, page 3, paragraph 7-page 4, paragraph 3, page 6, paragraphs 5-9; figures 1-6) The following technical summary: The present invention relates to a non-flammable e-spray cigarette with smoking cessation and cigarette replacement. The cigarette comprising a mouthpiece-shaped ensemble consisting of a housing, a battery, a high frequency generator, a nicotine reservoir and container, control circuitry, a display screen, an airflow sensor, a human contact sensor, a piezoelectric ultrasonic atomizer, a high temperature vaporization nozzle, and accessories; nicotine solutions for nebulization are composed of nicotine, propylene glycol, glycerol, organic acids, antioxidants, fragrances, water, ethanol; wherein nicotine is present in an amount of from 0.1% to 6%, propylene glycol is present in an amount of from 80% to 90%, organic acid is present in an amount of from 0.2% to 20%, and the balance is glycerol, a fragrance, an antioxidant, water and ethanol; the basic principle of this spray cigarette is that when the mouthpiece is placed on the mouth, the resistance sensor 19 activates the control circuit board 8, the control circuit board respectively outputs two drive voltages, one powers the electric heating element of the high temperature vaporization nozzle 17, and two activates the micropump 11 (structure see Fig. 6) to pump the liquid storage from the liquid storage container 13 into the nozzle 17, the nicotine solution is vaporized on the electric heating element of the nozzle into high temperature vapor that is ejected towards the open end, and the ejected vapor expands in the atmosphere to condense into a fine mist of smoke-like droplets. The role of the ultrasonic piezo sheet 20 attached to the nozzle tube is to vaporize the large droplets in the high pressure unsteady hot gas stream in sufficient contact with the heating element, two to break-up atomize the droplets directly in the nozzle tube, and three to solve the problem of explosion of the liquid above the boiling point. The combined atomization results in aerosol droplet diameters between 0.2 and 3 um. Fog droplets of this size are more readily absorbed into the alveoli and the air flow sensor 18 is sensitive to the dilute air flow entering the air inlet 16 when a "puff" action occurs and its sensing signal is input into the control circuit to shut off power to the micropump and heater after a time delay. The red light emitting diode 3 flashes in each puff and the flashing signal is given a 1.2 second sawtooth signal by the



control circuit, giving the flashing a gradual change in brightness to simulate the change in brightness of the combustion flash of smoke.

As such, Comparative Document 1 discloses heating a nicotine liquid formulation in an electronic cigarette to produce an inhalable aerosol, wherein the nicotine liquid formulation comprises nicotine and an organic acid in a biologically acceptable liquid carrier, and inhalation of said aerosol by said user.

The solution claimed in claim 1 is distinguished by the fact that the amount of organic acid contained in said aerosol is sufficient to increase the heart rate of said user after said inhalation relative to the absence of said organic acid compared to the technical content disclosed in comparative document 1. Based on the distinguishing technical features described above, the technical problem actually solved by claim 1 is how to increase the heart rate of the user.

For the above distinguishing technical features, Comparative Document 6 (US2006/0018840 A1) discloses an aerosolized formulation containing nicotine, and specifically discloses (see paragraphs 10-15, 23-24, 33-95 of the specification; Figures 1A-3C) the following technical contents: the present invention aims to provide a safe and effective way of delivering nicotine, hopefully in a way that mimics the delivery of nicotine in cigarettes; free nicotine may be combined with an organic acid to form a nicotine salt; the results achieved show that nicotine with the addition of organic acids has a more desirable MMAD size compared to free nicotine, and can lead to lower throat deposition and higher intake, whereas higher nicotine intake necessarily leads to an increase in heart rate. See e.g. Organic Chemistry, Chen Gold Bead, et al., Beijing Polytechnic University Press, pages 251-252, August 2011. The technical content disclosed above in Comparative Document 6 has the same role as it has in Claim 1 to solve the technical problem, all by increasing the heart rate by an organic acid nicotine salt, that is to say that Comparative Document 6 gives a corresponding technical implication. In addition, Comparative Document 6 also discloses that Example 4 demonstrates that about 1.2: 1 acid: nicotine is able to convert most of the nicotine to nicotine salt, resulting in higher nicotine inhalation. This content also gives insight to adjust the amount of organic acid to obtain the best aerosol effect.

It follows that it is obvious to a person skilled in the art that the technical solution claimed in claim 1 is obtained on the basis of Comparative Document 1 in combination with Comparative Document 6. Accordingly, the claimed subject matter of Claim 1 has no outstanding material features and significant advancements, and is devoid of the inventive step set forth in Article 22, Section 3 of the Patent law.

2. Claims 2-8 all further define Claim 1, which further defines the type of organic acid, whereas Comparative 6



discloses (see paragraphs 33, 42 of the specification) the following technical contents: organic acid means an acid composed of molecules containing organic groups, such as lactic acid and propionic acid, which contain ionizable-COOH groups; alternative organic acids include, but are not limited to, the following carboxylic or dicarboxylic acids: formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, gluconic acid, saccharic acid, malic acid. Comparative document 4 (CN102933199A) discloses pharmaceutical compositions containing nicotine and specifically discloses (see claim 13; description paragraphs 11-13, 23-24): Exemplary pharmaceutically acceptable nicotine salts include nicotine salts of tartrate, chloride, sulfate, perchlorate, ascorbate, fumarate, citrate, malate, lactate, aspartate, salicylate, tosylate, succinate, pyruvate, and the like; nicotine salt hydrate and the like; other organic acids that can form salts with nicotine include formic acid, acetic acid, propionic acid, isobutyric acid, butyric acid, a-methylbutyric acid, isovaleric acid, b-methylvaleric acid, caproic acid, 2-furoic acid, phenylacetic acid, heptanoic acid, octanoic acid, nonanoic acid, oxalic acid, malonic acid, and glycolic acid, and other fatty acids having a carbon chain of up to about 20 carbon atoms. The compositions of the invention also include a levulinate moiety. The role of the technical content disclosed above in the comparative documents 6, 4 is the same as that in the claims 2-8 for solving the technical problem, both of the type of acid providing the nicotine salt, that is to say, the comparative documents 6, 4 give the respective technical implications.

It follows that the combination of Comp 6 on the basis of Comp 1 or Comp 6, 4 on the basis of Comp 1 results in the technical solutions claimed in claims 2-8, which are obvious to the person skilled in the art. Thus, the claimed subject matter of claims 2-8 has no outstanding material features and significant advancements, without the inventive step set forth in Article 22, Section 3 of the Patent law.

3. Claims 9-10 are dependent claims that further define the type of liquid carrier, whereas Comp 1 discloses (see page 4, paragraph 1 of the specification) the following technical content: The nicotine solution for nebulization consists of nicotine, propylene glycol, glycerol (glycerol), organic acids, antioxidants, fragrances, water, ethanol. The undisclosed 1, 3-propanediol is reasonably selectable by those skilled in the art according to the nature of the actual nicotine and acid. Accordingly, to the extent that a claim to which it is dependent is not inventive, neither is such dependent claim capable of the inventive step specified in clause 22, clause 3 of the patent law.

4. Claims 11-15 are dependent claims that further define the nicotine concentration ratio, whereas Comp 1



discloses (see page 4, paragraph 1 of the specification) the following technical content: The nicotine solution used for nebulization consists of nicotine, propylene glycol, glycerol (i.e. Glycerol), organic acids, antioxidants, fragrances, water, ethanol. Wherein nicotine is present in an amount of from 0.1% to 6%, propylene glycol is present in an amount of from 80% to 90%, organic acid is present in an amount of from 0.2% to 20%, and the balance is glycerol, fragrance, antioxidant, water and ethanol. Whereas the nicotine concentration is determinable according to the nicotine salt actually used, the liquid formulation content and the electronic cigarette operating conditions. Accordingly, to the extent that a claim to which it is dependent is not inventive, neither is such dependent claim capable of the inventive step specified in clause 22, clause 3 of the patent law.

5. Claim 16 further defines any one of claims 1 to 15, whereas Comparative Document 1 discloses (see page 4, paragraph 1 of the specification) the following technical content: A nicotine solution for nebulization is composed of nicotine, propylene glycol, glycerol, organic acids, antioxidants, fragrances, water, ethanol. It follows that additional technical features of claim 48 have been disclosed by Comparative Document 1. Accordingly, to the extent that a claim to which it is dependent is not inventive, neither is such dependent claim capable of the inventive step specified in clause 22, clause 3 of the patent law.

6. Any one of claims 1 to 16 is further defined by claim 17 and Comparative 4 discloses (see claim 13; description paragraphs 13, 39-40): said pharmaceutical composition comprising: a nicotine source selected from the group consisting of nicotine in free base form, a nicotine salt other than nicotine levulinate, a resin complex of nicotine, and mixtures thereof, and a levulinate moiety selected from levulinic acid, nicotine levulinate, an alkali or alkaline earth metal salt of levulinic acid, an alkyl ester of levulinic acid, and mixtures thereof. Typically, the compositions of the invention comprise at least one other form of nicotine salt compound in addition to nicotine levulinate, in other words, the compositions of the invention comprising a nicotine active ingredient source typically consist of at least 2 nicotine forms, one of which is the form of nicotine levulinate. Such as nicotine free base in combination with nicotine levulinate, nicotine salts of two organic acids (e.g., a nicotine levulinate/nicotine tartrate mixture or a nicotine levulinate/nicotine bitartrate mixture). The technical content disclosed above in Comparative Document 4 has the same role as it has in Claim 17 to solve the technical problem, all providing a mixture of various nicotine salts, that is to say, Comparative Document 4 gives an implication to apply the technical content described above to Comparative Document 1 to solve the technical problem thereof. Accordingly, in order to increase the range of use and effectiveness of nicotine, those skilled in the art are motivated to add one or more additional organic acids



in the nicotine salt liquid formulation. Accordingly, to the extent that a claim to which it is dependent is not inventive, neither is such dependent claim capable of the inventive step specified in clause 22, clause 3 of the patent law.

7. Claim 18 claims a liquid formulation of nicotine in an electronic cigarette. Comparative document 1 (CN1541577A), which is the closest prior art, discloses (cf. Page 1 penultimate paragraph-page 2 paragraph 2, page 3 paragraph 7-page 4 paragraph 3, page 6, paragraphs 5-9; figures 1-6) the following technical content: The present invention relates to a non-flammable e-spray cigarette with smoking cessation and cigarette replacement. The cigarette comprising a mouthpiece-shaped ensemble consisting of a housing, a battery, a high frequency generator, a nicotine reservoir and container, control circuitry, a display screen, an airflow sensor, a human contact sensor, a piezoelectric ultrasonic atomizer, a high temperature vaporization nozzle, and accessories; nicotine solutions for nebulization are composed of nicotine, propylene glycol, glycerol, organic acids, antioxidants, fragrances, water, ethanol; wherein nicotine is present in an amount of from 0.1% to 6%, propylene glycol is present in an amount of from 80% to 90%, organic acid is present in an amount of from 0.2% to 20%, and the balance is glycerol, a fragrance, an antioxidant, water and ethanol; the basic principle of this spray cigarette is that when the mouthpiece is placed on the mouth, the resistance sensor 19 activates the control circuit board 8, the control circuit board respectively outputs two drive voltages, one powers the electric heating element of the high temperature vaporization nozzle 17, and two activates the micropump 11 (structure see Fig. 6) to pump the liquid storage from the liquid storage container 13 into the nozzle 17, the nicotine solution is vaporized on the electric heating element of the nozzle into high temperature vapor that is ejected towards the open end, and the ejected vapor expands in the atmosphere to condense into a fine mist of smoke-like droplets. The role of the ultrasonic piezo sheet 20 attached to the nozzle tube is to vaporize the large droplets in the high pressure unsteady hot gas stream in sufficient contact with the heating element, two to break-up atomize the droplets directly in the nozzle tube, and three to solve the problem of explosion of the liquid above the boiling point. The combined atomization results in aerosol droplet diameters between 0.2 and 3 μm . Fog droplets of this size are more readily absorbed into the alveoli and the air flow sensor 18 is sensitive to the dilute air flow entering the air inlet 16 when a "puff" action occurs and its sensing signal is input into the control circuit to shut off power to the micropump and heater after a time delay. The red light emitting diode 3 flashes in each puff and the flashing signal is given a 1.2 second sawtooth signal by the control circuit, giving the flashing a gradual change in brightness to simulate the change in brightness of the combustion flash of smoke.

As such, Comparative Document 1 discloses a nicotine liquid formulation in an electronic cigarette, the



nicotine liquid formulation comprising nicotine and an organic acid, the nicotine liquid formulation being for generating an inhalable aerosol when heated in an electronic cigarette.

The solution claimed in claim 18 compared to that disclosed in Comparative Document 1 is characterized by the fact that the amount of organic acid contained in said aerosol is sufficient to increase the heart rate of a user after inhalation by said user relative to the absence of said organic acid. Based on the distinguishing technical features described above, the technical problem actually solved by claim 18 is how to increase the heart rate of the user.

For the above distinguishing technical features, comparative document 6 (US2006/0018840 A1) discloses (see paragraphs 10-15, 23-24, 33-95 of the specification; Figures 1A-3C) the following technical contents: the present invention aims to provide a safe and effective way of delivering nicotine, hopefully in a way that mimics the delivery of nicotine in cigarettes; free nicotine may be combined with an organic acid to form a nicotine salt; the results achieved show that nicotine with the addition of organic acids has a more desirable MMAD size compared to free nicotine, and can lead to lower throat deposition and higher intake, whereas higher nicotine intake necessarily leads to an increase in heart rate. See e.g. Organic Chemistry, Chen Gold Bead, et al., Beijing Polytechnic University Press, pages 251-252, August 2011. The technical content disclosed above in Comparative Document 6 has the same role as it has in Claim 18 to solve the technical problem, all by increasing the heart rate by an organic acid nicotine salt, that is to say that Comparative Document 6 gives a corresponding technical implication. In addition, Comparative Document 6 also discloses that Example 4 demonstrates that about 1.2: 1 acid: nicotine is able to convert most of the nicotine to nicotine salt, resulting in higher nicotine inhalation. This content also gives insight to adjust the amount of organic acid to obtain the best aerosol effect.

It follows that it is obvious to a person skilled in the art that the technical solution claimed in claim 18 is obtained on the basis of Comparative Document 1 in combination with Comparative Document 6. Accordingly, the claimed subject matter of Claim 18 has no outstanding material features and significant advancements, and is devoid of the inventive step specified in Article 22, Section 3 of the Patent law.

8. Additional technical features of claims 19-25 are the same as those of claims 2-8, for review see the review of claims 2-8.

9. Additional technical features of claims 26-27 are the same as those of claims 9-10, for review see the review of claims 9-10.



10. Additional technical features of claims 28-32 are the same as those of claims 11-15, for reviews of which see the reviews of claims 9-10.

11. Additional features of claim 33 are the same as in claim 16, for review see claim 16.

12. Additional features of claim 34 are the same as in claim 17, for review of which see claim 17.

Two. Answer to Statement of Applicants' Opinion

Since this response is a modification and response made to the overrun proposed by the second review opinion, nothing involved in the solution by the reviewer needs to respond to the applicant.

For the above reasons, the present application has no patentable prospect. If Applicant is unable to propose a sufficient reason to suggest that the application is inventive, within the answering date set forth in this written description, the application will be dismissed.

Examiner phone 022-84867341; on-duty phone 022-84868569 (referred to instead);

In case of issues that cannot be addressed by opinion statements or phone discussions, feedback can be made through the public mailbox tjscfk@sipo.gov.cn, writing the application number and contact phone. Please note that the opinion statements and/or amendments fed back through this mailbox are not legally valid and cannot replace formal replies.