(12) STANDARD PATENT (11) Application No. **AU 2015254999 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Flavoured nicotine powder inhaler

(51) International Patent Classification(s)
A24F 47/00 (2006.01)

(21) Application No: **2015254999** (22) Date of Filing: **2015.04.23**

(87) WIPO No: **WO15/166350**

(30) Priority Data

(31) Number	(32) Date	(33) Country
61/984,968	**2014.04.28**	**US**
14166210.6	**2014.04.28**	**EP**

(43) Publication Date: **2015.11.05**
(44) Accepted Journal Date: **2019.08.01**

(71) Applicant(s)
Philip Morris Products S.A.

(72) Inventor(s)
Zinovik, Ihar Nikolaevich;Zuber, Gerard

(74) Agent / Attorney
Spruson & Ferguson, GPO Box 3898, Sydney, NSW, 2001, AU

(56) Related Art
US 20110220106 A1
US 20060147389 A1

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 November 2015 (05.11.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/166350 A3

(51) International Patent Classification:
A24F 47/00 (2006.01)

(21) International Application Number:
PCT/IB2015/001283

(22) International Filing Date:
23 April 2015 (23.04.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/984,968 28 April 2014 (28.04.2014) US
14166210.6 28 April 2014 (28.04.2014) EP

(71) Applicant: **PHILIP MORRIS PRODUCTS S.A.** [CH/CH]; Quai Jeanrenaud 3, CH-2000 Neuchâtel (CH).

(72) Inventors: **ZINOVIK, Ihar, Nikolaevich**; Rue Du Chasselas 20a, CH-2034 Peseux (CH). **ZUBER, Gerard**; Route Du Chalet a Gobet 2, CH-1055 Froideville (CH).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
21 January 2016

(54) Title: FLAVOURED NICOTINE POWDER INHALER

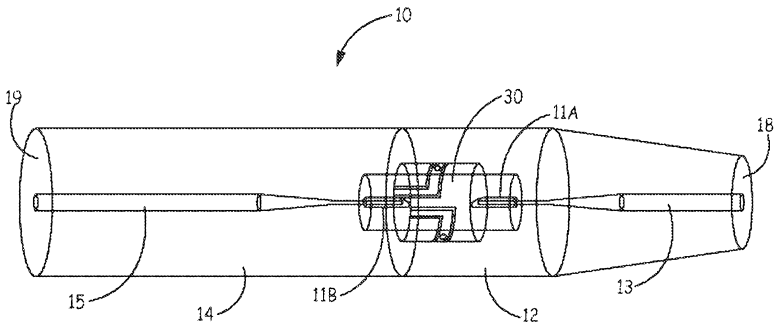

FIG. 3

(57) Abstract: This disclosure relates to flavoured nicotine powder inhalers where the nicotine powder is delivered at air flow rates that mimic a smoking regime.

WO 2015/166350 A3

FLAVOURED NICOTINE POWDER INHALER

This disclosure relates to flavoured nicotine powder inhalers, where the flavoured nicotine powder is delivered at low air flow rates.

Dry powder inhalers (DPI) are known and are used to treat respiratory diseases by delivering a dry powder comprising a pharmaceutical, in aerosol form through inhalation to the patients' airways. For delivery deep into the lungs, particles in the range of 1 to 5 micrometers are required. In pharmaceutical dry powders, the active pharmaceutical ingredient (API) is agglomerated on the surface of larger carrier particles, e.g. lactose, and DPI's therefore operate complex mechanisms to ensure such agglomerates disperse, break up or disaggregate before the API can be inhaled deep into the lungs. Pharmaceutical dry powders containing lactose as a carrier are typically in the range of 20 to 100 micrometers. Existing DPI's for example first "grind" or de-agglomerate the dry powder or impact the larger particles of the dry powder to result in the aforementioned particle size range.

DPI's rely on the force of the patients' inhalation to entrain the powder from the device to subsequently break-up the powder into particles that are small enough to enter the lungs. Sufficiently high inhalation rates are required to ascertain correct dosing and complete disaggregation of the powder. Typically a large amount of API remains attached on the surface of the carrier and is deposited in the upper airways due to incomplete de-aggregation of the powder. Inhalation rates of existing DPI's are usually in the range of 40-120 liters/min (L/min). Existing DPI's are therefore only suitable for delivering dry powders to users in a manner that is different from the inhalation rate associated with smoking articles.

It would be desirable to provide a flavoured nicotine powder inhaler that can deliver flavoured nicotine powder to a user at inhalation or air flow rates that are within conventional smoking regime inhalation or air flow rates. It would be desirable to provide a flavoured nicotine powder inhaler that is a similar size and configuration as a conventional cigarette. It would be desirable to provide a flavoured nicotine powder inhaler that can provide a metered dose of flavoured nicotine and an optional simultaneous delivery of a second active ingredient.

Flavoured nicotine powder inhalers of the invention described herein can be utilized to deliver flavoured nicotine to a user at inhalation or air flow rates that are close to or within conventional smoking regime inhalation or air flow rates. The flavoured nicotine powder

inhalers can provide a predictable and metered dose of flavoured nicotine or other optional active ingredients. Flavoured nicotine powder inhalers of the invention described herein have a similar size and configuration as a conventional cigarette and have a simple configuration.

As described herein, a flavoured nicotine powder inhaler includes a body extending between a mouthpiece and a distal end portion and an airflow channel extends along the body of the inhaler. A nicotine powder receptacle along the airflow channel holds a dose of nicotine powder. A flavour delivery element is in fluid communication with the airflow channel. The dose of nicotine powder can be inhaled into lungs of a user at an inhalation rate of less than about 5 L/min or preferable less than about 2 L/min. Preferably the dose of nicotine powder is a nicotine salt contained in a capsule that can be pierced by the inhaler.

Various aspects of the flavoured nicotine powder inhalers described herein may have one or more advantages relative to standard dry powder inhalers. For example, the flavoured nicotine powder inhalers deliver the dry powder nicotine and the flavour particles at inhalation or air flow rates that are within conventional smoking regime inhalation or air flow rates and inhalation manner. This allows users with even compromised or impaired breathing conditions to successfully deliver the dry powder nicotine and flavourant. The flavoured nicotine powder inhalers described herein have a simplified configuration that allows the user to predetermine the metered dose of dry powder nicotine and flavourant. The dry powder nicotine can be in series or in parallel flow relation with the flavour delivery element. The flavourant can be a dry powder or a liquid flavourant. Additional advantages of one or more aspects flavour delivery system described herein will be evident to those of skill in the art upon reading and understanding the present disclosure.

The term “nicotine” refers to nicotine and nicotine derivatives such as nicotine salts.

The term “flavourant” or “flavour” refers to organoleptic compounds, compositions, or materials that alter the taste or aroma characteristics of nicotine during consumption or inhalation thereof.

The present disclosure provides flavoured nicotine powder inhalers for inhaling dry powder nicotine and flavourant. The flavoured nicotine powder inhalers include a body extending between a mouthpiece portion and a distal end portion. An airflow channel extends between the mouthpiece portion and a distal end portion and a nicotine powder receptacle. The

nicotine powder receptacle is disposed along the airflow channel and is configured to receive a dose of nicotine powder. A flavour delivery element is in fluid communication with the airflow channel. The dose of nicotine powder can be inhaled into lungs of a user at an inhalation rate of less than about 5 L/min or less than about 2 L/min which mimics the inhalation flow rate utilized for a conventional smoking regime. The flavourant is delivered to the mouth of the user simultaneously as the nicotine particles are inhaled. The flavoured nicotine powder inhalers described herein are "passive" devices that utilize only the inhalation air flow created by the lungs of a user to create air flow though the body of the flavoured nicotine powder inhaler.

The airflow path or airflow channel through the body of the inhaler is a simple path or channel. In many embodiments the airflow path or airflow channel through the body of the inhaler is parallel to a longitudinal axis of the inhaler and is linearly extending along an entire length of the inhaler body. In some embodiments the inhaler includes two or three co-extensive airflow channels. One, two or all three of the airflow channels can include a capsule receptacle. In some embodiments the one or more airflow paths or airflow channels includes a swirl generator element that is configured to induce a rotational movement of the airflow moving through the body of the inhaler. The swirl generator element can discharge into an outlet channel that can be a larger volume than the one or more individual airflow paths or airflow channels.

The nicotine powder receptacle and the flavour delivery element are configured and arranged to provide the nicotine powder and the flavourant simultaneously. In some embodiments the flavourant is a dry powder mixed with the nicotine powder in a capsule, for example. In other embodiments the flavourant is separated from the nicotine powder before inhalation or mixing within the airflow channels of the inhaler. In some of these embodiments the flavourant and the nicotine powder are in serial flow arrangement and disposed within a single flow channel and the flavourant or flavour delivery element is either upstream or downstream of the nicotine powder or nicotine powder receptacle. In other embodiments the flavourant and the nicotine powder are in parallel flow arrangement and disposed within a pair of flow channels where the flavourant and the nicotine powder combine to form a mixture downstream of both the nicotine powder receptacle and the flavour delivery element.

The nicotine powder receptacle can receive a capsule of nicotine powder. The capsule can contain a predetermined amount or dose of nicotine powder and optional flavourant. In

many embodiments the capsule can contain enough nicotine powder to provide at least 2 inhalations or "puffs" of nicotine powder, or at least about 5 inhalations or "puffs" of nicotine powder, or at least about 10 inhalations or "puffs" of nicotine powder. In many embodiments the capsule can contain enough nicotine powder to provide from about 5 to 50 inhalations or "puffs" of nicotine powder, or from about 10 to 30 inhalations or "puffs" of nicotine powder. Each inhalation or "puff" of nicotine powder can deliver from about 0.5 mg to about 3 mg of nicotine powder to the lungs of the user or from about 1 mg to about 2 mg of nicotine powder to the lungs of the user or about 1 mg of nicotine powder to the lungs of the user.

In many embodiments the capsule holds or contains at least about 5 mg of nicotine powder or at least about 10 mg of nicotine powder. In many embodiments the capsule holds or contains less than about 30 mg of nicotine powder or less than about 25 mg of nicotine powder, or less than 20 mg of nicotine powder. In many embodiments the capsule holds or contains from about 5 mg to about 30 mg of nicotine powder or from about 10 mg to about 20 mg of nicotine powder.

In embodiments that include the flavourant blended or combined with the nicotine powder within the capsule, the flavourant is present in an amount that provides the desired flavour to each inhalation or "puff" delivered to the user.

The capsule can be formed of an airtight material that can be pierced or punctured by the inhaler. The capsule can formed of a metallic or polymeric material that serves to keep contaminates out of the capsule but can be pierced or punctured by the inhaler during use.

The inhaler can include a piercing element or pair of opposing piercing elements that are configured to pierce the capsule of nicotine powder. The piercing element or pair of opposing piercing elements fluidly connect the airflow channel with the dose of nicotine powder. The piercing element or pair of opposing piercing elements can engage with the capsule of nicotine powder upon loading the capsule of nicotine powder into the nicotine powder receptacle or upon demand by an actuator on the body of the inhaler.

In many embodiments the nicotine powder is a pharmaceutically acceptable nicotine salt or nicotine salt hydrate. Useful nicotine salts or nicotine salt hydrates include nicotine bitartrate, nicotine salicylate, nicotine fumarate, nicotine mono-pyruvate, nicotine glutamate or nicotine hydrochloride, for example. The compound combining with nicotine to form the salt or salt

hydrate can be chosen based on its pharmacological effect. For example: nicotine salicylate can be administered for fever relief, as an anti-inflammatory or painkiller; nicotine fumarate can be administered to treat multiple sclerosis; and nicotine mono-pyruvate can be administered for treating chronic obstructive pulmonary disease (COPD) or for weight loss.

The nicotine powder can have any useful size distribution for inhalation delivery into the lungs of a user. In many embodiments at least about 90 wt% of the nicotine powder has a particle size of about 10 micrometers or less, preferably about 7 micrometers or less. The nicotine powder preferably has a mean average diameter size range from about 0.1 to about 10 micrometers, more preferably from about 1 to about 7 micrometers, even more preferably from about 2 to 6 about micrometers.

Conventional formulations for dry powder inhalation typically contain carrier particles that serve to increase the fluidization of the active particles since the active particles are typically too small to be influenced by the airflow though the inhaler. The carrier particles thus were utilized to improve the dose uniformity by acting as a diluent or bulking agent in a formulation. However, the nicotine powder described herein can be carrier-free. Being carrier-free allows the nicotine powder and to be inhaled and delivered to the user's lungs at inhalation or airflow rates that are similar to typical smoking regime inhalation or airflow rates. In addition, since the nicotine powder is carrier-free, the airflow path of the inhaler can have simple geometry or a simple configuration.

The nicotine powder described herein can be a surface modified nicotine salt where the nicotine salt particle is a coated particle. One preferred coating material is L-leucine. These carrier-free nicotine powders are described and are available from Teicos Pharma Inc., Espoo, Finland. One particularly useful nicotine powder is an L-luecine coated nicotine bitartrate.

Flavourants or flavours can be provided as liquid or solid flavours (at room temperature of about 22 degrees centigrade and one atmosphere pressure) and can include flavour formulations, flavour-containing materials and flavour precursors. The flavourant may include one or more natural flavourants, one or more synthetic flavourants, or a combination of natural and synthetic flavourants.

Flavourants or flavours refer to a variety of flavour materials of natural or synthetic origin. They include single compounds and mixtures. Preferably the flavour or flavourant has flavour

properties that enhance the experience of the nicotine powder inhaler to, for example, provide an experience similar to that resulting from smoking a combustible smoking article. For example, the flavour or flavourant can enhance flavour properties such as mouth fullness and complexity. Complexity is generally known as the overall balance of the flavour being richer without dominating single sensory attributes. Mouth fullness is described as perception of richness and volume in the mouth and throat of the consumer.

Suitable flavours and aromas include, but are not limited to, any natural or synthetic flavour or aroma, such as tobacco, smoke, menthol, mint (such as peppermint and spearmint), chocolate, licorice, citrus and other fruit flavours, gamma octalactone, vanillin, ethyl vanillin, breath freshener flavours, spice flavours such as cinnamon, methyl salicylate, linalool, bergamot oil, geranium oil, lemon oil, and ginger oil, and the like.

Other suitable flavours and aromas may include flavour compounds selected from the group consisting of an acid, an alcohol, an ester, an aldehyde, a ketone, a pyrazine, combinations or blends thereof and the like. Suitable flavour compounds may be selected, for example, from the group consisting of phenylacetic acid, solanone, megastigmatrienone, 2-heptanone, benzylalcohol, cis-3-hexenyl acetate, valeric acid, valeric aldehyde, ester, terpene, sesquiterpene, nootkatone, maltol, damascenone, pyrazine, lactone, anethole, iso-s valeric acid, combinations thereof, and the like.

Further specific examples of flavours may be found in the current literature, for example, in Perfume and Flavour Chemicals, 1969, by S. Arctander, Montclair N.J. (USA); Fenaroli's Handbook of Flavour Ingredients, CRC Press or Synthetic Food Adjuncts by M.B. Jacobs, van Nostrand Co., Inc.. They are well-known to the person skilled in the art of flavouring, i.e. of imparting an odor or taste to a product.

In some embodiments, the flavourant is a high potency flavourant, and is typically used at levels that would result in less than 200 parts per million in inhalation air flow. Examples of such flavourants are key tobacco aroma compounds such as beta-damascenone, 2-ethyl-3,5-dimethylpyrazine, phenylacetaldehyde, guaiacol, and furaneol. Other flavourants can only be sensed by humans at higher concentration levels. These flavourants, which are referred to herein as the low potency flavourants, are typically used at levels that results in orders of magnitude higher amounts of flavourant released into the inhalation air. Suitable low potency flavourants include, but are not limited to, natural or synthetic menthol, peppermint, spearmint,

coffee, tea, spices (such as cinnamon, clove and ginger), cocoa, vanilla, fruit flavours, chocolate, eucalyptus, geranium, eugenol and linalool.

The flavour delivery element can be in the form of a capsule containing the flavourant. The capsule can be ruptured by mechanical force such as being squeezed or crushed by a use's fingers or other mechanical means activated by the user. The flavourant within the flavour capsule is preferably a liquid flavourant. The flavour capsule can be disposed upstream of the nicotine powder receptacle, but it is preferably downstream of the nicotine powder receptacle. The flavour capsule can be disposed in a filter element.

The flavour delivery element can be a thread element impregnated by flavourant. Preferably the flavourant in these embodiments is menthol. The thread can be disposed in a filter element that is preferably upstream of the nicotine powder receptacle.

The filter element containing the flavour delivery element can be formed of filtering material such as conventional cellulose acetate filtering material. The filtering material can be a plug of filtering material wrapped in paper or plug wrap. The filtering material can be upstream or downstream of the flavour delivery element, preferably the filtering material is disposed both upstream or downstream of the flavour delivery element. In some embodiments the flavour delivery element extends through the filtering material.

A second active agent or ingredient can be delivered along with the flavoured nicotine powder. The second active agent or ingredient can be mixed with the nicotine in the capsule or separate from the nicotine in its own capsule. The second active agent or ingredient can be fluidized with the flavoured nicotine powder and inhaled by a user.

This second active agent or ingredient can be any active pharmaceutical material. In many embodiments the second active agent or ingredient can be combined with the nicotine powder and flavourant described herein by blending the materials during inhalation. The nicotine powder, flavourant and the second active agent or ingredient can be blended in the same capsule or provided in series in a single air flow channel in the DPI or provided in parallel in separate flow channels of the DPI. The second active agent or ingredient can have a similar mean average diameter size range as the nicotine powder described above.

The flavoured nicotine powder inhaler is less complex and has a simplified powder storage and airflow path as compared to existing DPIs, and does not need a carrier ingredient, such as lactose, as described above. Therefore the complex mechanisms to dissociate/disaggregate a pharmaceutical dry powder is not required in the described flavoured nicotine inhaler and therefore the described nicotine inhaler operates under low airflow. The inhaler does not require the typical high inhalation rates of conventional DPIs to deliver the dry nicotine powders described above deep into the lungs.

The flavoured nicotine inhaler according to this invention operates using a flow rate of less than about 5 L/min or less than about 3 L/min or less than about 2 L/min or about 1.6 L/min. In many embodiments the flow rate is in a range from about 1 L/min to about 3 L/min or from about 1.5 L/min to about 2.5 L/min. In preferred embodiments the inhalation rate or flow rate is similar to that of Health Canada smoking regime, that is about 1.6 L/min. In contrast, a conventional DPI operates at a flow rate of about 40-120 L/min and often requires an energy source or propellant to promote air flow to achieve this air flow rate.

The flavoured nicotine inhaler described herein can be used by a consumer like smoking a conventional cigarette or vaping an electronic cigarette. Such smoking or vaping is characterized by two steps: a first step during which a small volume containing the full amount of nicotine desired by the consumer is drawn into the mouth cavity, followed by a second step during which this small volume comprising the aerosol comprising the desired amount of nicotine is further diluted by fresh air and drawn deeper into the lungs. Both steps are controlled by the consumer. During the first inhalation step the consumer can determine the amount of nicotine to be inhaled. During the second step, the consumer can determine the volume for diluting the first volume to be drawn deeper into the lungs, maximizing the concentration of active agent delivered to the airway epithelial surface. This smoking mechanism is sometimes called “puff-inhale-exhale”.

All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein.

The terms “upstream” and “downstream” refer to relative positions of elements of the inhaler described in relation to the direction of inhalation air flow as it is drawn through the body of the inhaler from a distal end portion to the mouthpiece portion.

As used herein, the singular forms “a”, “an”, and “the” encompass embodiments having plural referents, unless the content clearly dictates otherwise.

As used herein, “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. The term “and/or” means one or all of the listed elements or a combination of any two or more of the listed elements.

As used herein, “have”, “having”, “include”, “including”, “comprise”, “comprising” or the like are used in their open ended sense, and generally mean “including, but not limited to”. It will be understood that “consisting essentially of”, “consisting of”, and the like are subsumed in “comprising,” and the like.

The words “preferred” and “preferably” refer to embodiments of the invention that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the disclosure, including the claims.

FIG.s 1-11 are schematic diagrams of illustrative flavoured nicotine powder inhalers **10**. **FIG.s 3-7** are shown with transparent bodies for ease of illustration of the flow channels and internal elements. The schematic drawings are not necessarily to scale and are presented for purposes of illustration and not limitation. The drawings depict one or more aspects described in this disclosure. However, it will be understood that other aspects not depicted in the drawing fall within the scope and spirit of this disclosure.

Referring now to **FIG. 1** and **FIG. 2**, the flavoured nicotine powder inhalers **10** include a mouthpiece portion **12** and a distal end portion **14** and a nicotine capsule **20** disposed between them. Piercing elements **11A** and **11B** are configured to pierce the capsule **20** and fluidly connect the airflow channel **13** of the mouthpiece portion **12** with the airflow channel **15** of the distal end portion **14**. The airflow channel extends linearly along a length of the nicotine powder inhaler **10**. **FIG. 2** further illustrates the capsule **20** within a receptacle **25** that can be re-usable. A flavour delivery element can be upstream, downstream or within the capsule **20**.

FIG. 3 and **FIG. 4** illustrate flavoured nicotine powder inhalers **10** having a single linear airflow channel **13**, **15**. Piercing elements **11A** and **11B** extend into a nicotine powder

receptacle **30** and are configured to pierce the nicotine powder capsule and fluidly connect the airflow channel **13** of the mouthpiece portion **12** with the airflow channel **15** of the distal end portion **14**. The airflow channel extends linearly along a length of the nicotine powder inhaler **10** from a proximal mouthpiece end **18** to a distal end **19**. The mouthpiece portion **12** can connect with the distal end portion **14** via a bayonet-type connection. In **FIG. 3** the mouthpiece portion **12** is not symmetrical with the distal end portion **14**. In In **FIG. 4** the mouthpiece portion **12** is symmetrical with the distal end portion **14**. A flavour delivery element can be disposed along the airflow channel **13**, **15** and can be pierced with the piercing elements **11A** and **11B** or separate set of piercing elements, not illustrated.

FIG. 5 and **FIG. 6** is a further illustrative flavoured nicotine powder inhaler **10** having multiple airflow channels **15**. **FIG. 6** is a view of **FIG. 5** taken along lines **6-6**. This embodiment includes three airflow channels **15** and a first, second and third powder receptacles **30, 32** and **33** respectively. A nicotine powder capsule and flavour capsule can be received in at least one of the powder receptacles **30, 32** and **33**. In some embodiments, a second active agent can be received in at least one of the powder receptacles **30, 32** and **33**. The three flow channels **15** fluidly connect to an outlet channel **40** via a swirl generator **50** configured to induce rotation movement in the airflow. The airflow channels **15** extend linearly along a length of the flavoured nicotine powder inhaler **10** from a proximal mouthpiece end **18** to a distal end **19**. A ventilation element **70** can be disposed along an airflow channels **15** to provide dilution air, as desired.

FIG. 7 is a further illustrative flavoured nicotine powder inhaler **10**. This embodiment includes three airflow channels **15A, 15B** and **15C** and first, second and third powder receptacles **30, 32** and **33** respectively. A nicotine powder capsule and flavour capsule can be received in at least one of the powder receptacles **30, 32** and **33**. In some embodiments, a second active agent can be received in at least one of the powder receptacles **30, 32** and **33**. The three flow channels **15** fluidly connect to an outlet channel **40** via a swirl generator **50** configured to induce rotation movement in the airflow. The airflow channels **15A, 15B** extend linearly along a length of the flavoured nicotine powder inhaler **10** from a proximal mouthpiece end **18** to a distal end **19**. In some embodiments an airflow loop element **60** is disposed along an airflow channels **15C**.

FIG.s 8-11 illustrate schematic diagrams of flavoured inhalers **10**. **FIG. 8** shows a flavoured nicotine inhaler **10** having a single flow path and a single capsule **120** containing both

2015254999 15 Mar 2019

the powdered nicotine and flavourant, preferably a powdered flavourant. The air flow path includes an upstream portion **15** and a downstream portion **13**.

FIG. 9 shows a flavoured nicotine inhaler **10** having a single flow path and a nicotine capsule **20** containing powdered nicotine in serial flow arrangement with the flavourant capsule **100**, preferably a powdered flavourant. In some embodiments the flavourant capsule **100** contains a liquid flavourant. In many of these embodiments the flavourant capsule **100** can be ruptured by a user to release the liquid flavourant, as described above. The liquid flavourant is preferably downstream of the nicotine capsule **20.** The air flow path includes an upstream portion **15** and a downstream portion **13**.

FIG. 10 shows a flavoured nicotine inhaler **10** having a parallel flow path and a nicotine capsule **20** containing powdered nicotine in parallel flow arrangement with the flavourant capsule **100**, preferably a powdered flavourant. In some embodiments the flavourant capsule **100** contains a liquid flavourant. The flavourant capsule **100** can be pierced as described above for the nicotine capsule **20.** The air flow path includes an upstream portion **15** and a downstream portion **13**.

FIG. 11 shows a flavoured nicotine inhaler **10** having a single flow path and a nicotine capsule **20** containing powdered nicotine in serial flow arrangement with the flavour delivery element **130**. The flavour delivery element **130** can be a filter element having a thread impregnated with flavourant, preferably liquid flavourant. The nicotine capsule **20** is preferably downstream of the filter element providing the flavourant**.** The air flow path includes an upstream portion **15** and a downstream portion **13**.

In this specification, the terms “comprise”, “comprises”, “comprising” or similar terms are intended to mean a non-exclusive inclusion, such that a system, method or apparatus that comprises a list of elements does not include those elements solely, but may well include other elements not listed.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that the prior art forms part of the common general knowledge.

CLAIMS:

1. A nicotine powder inhaler comprising:
a body extending between a mouthpiece portion and a distal end portion;
an airflow channel extending between the mouthpiece portion and the distal end portion parallel to a longitudinal axis of the inhaler;
a nicotine powder receptacle disposed along the airflow channel and comprising a dose of flavourant and a dose of nicotine powder comprising nicotine salt and;

a swirl generator element constructed to induce rotational movement in the airflow;
wherein the dose of nicotine powder can be inhaled into lungs of a user at an inhalation rate of less than about 5 L/min.

2. A nicotine powder inhaler according to any one of the preceding claims, wherein the dose of flavourant comprises powdered flavourant.

3. A nicotine powder inhaler according to any one of the preceding claims, wherein the dose of flavourant comprises liquid flavourant.

4. A nicotine powder inhaler according to any one of the preceding claims, wherein the nicotine powder receptacle is configured to receive a capsule containing nicotine powder comprising nicotine salt.

5. A nicotine powder inhaler according to claim 4, wherein the capsule further contains the dose of flavourant comprising powdered flavourant.

6. A nicotine powder inhaler according to any one of the preceding claims, wherein the dose of flavourant comprises a crushable capsule that can be ruptured by a user to release flavourant.

7. A nicotine powder inhaler according to any one of the preceding claims, further comprising a filter element upstream of the nicotine powder receptacle and the dose of flavourant is disposed within the filter element.

8. A nicotine powder inhaler according to claim 7, wherein the dose of flavourant is a thread impregnated with menthol.

9. A nicotine powder inhaler according to any one of the preceding claims, further comprising dose of a second active agent.

10. A method of inhaling flavoured nicotine into lungs of a user:
inhaling air through the flavoured nicotine power inhaler according to any one of claims 1 to 9 at a flow rate of less than about 2 L/min to deliver flavoured powder nicotine into lungs of a user.

11. A nicotine powder inhaler according to claim 1, wherein the dose of flavourant is selected from tobacco, smoke, menthol, mint, chocolate, licorice, citrus and other fruit flavours, gamma octalactone, vanillin, ethyl vanillin, breath freshener flavours, cinnamon, methyl salicylate, linalool, bergamot oil, geranium oil, lemon oil, and ginger oil.

12. A nicotine powder inhaler according to claim 1, wherein the dose of flavourant comprises menthol.

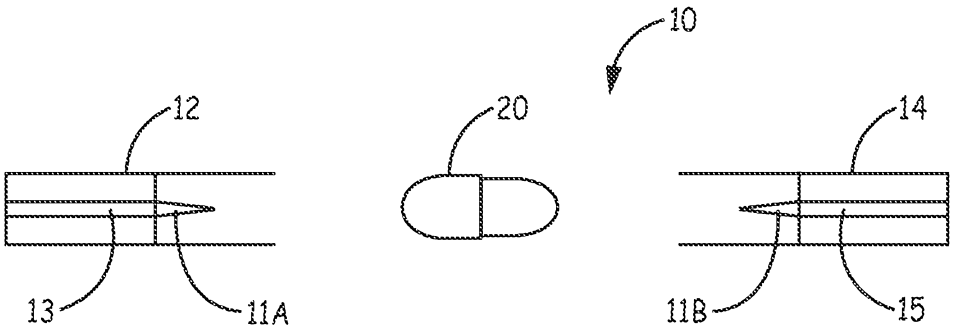

FIG. 1

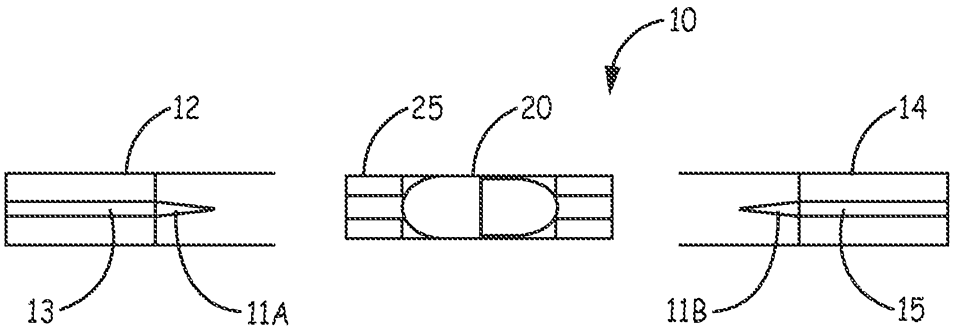

FIG. 2

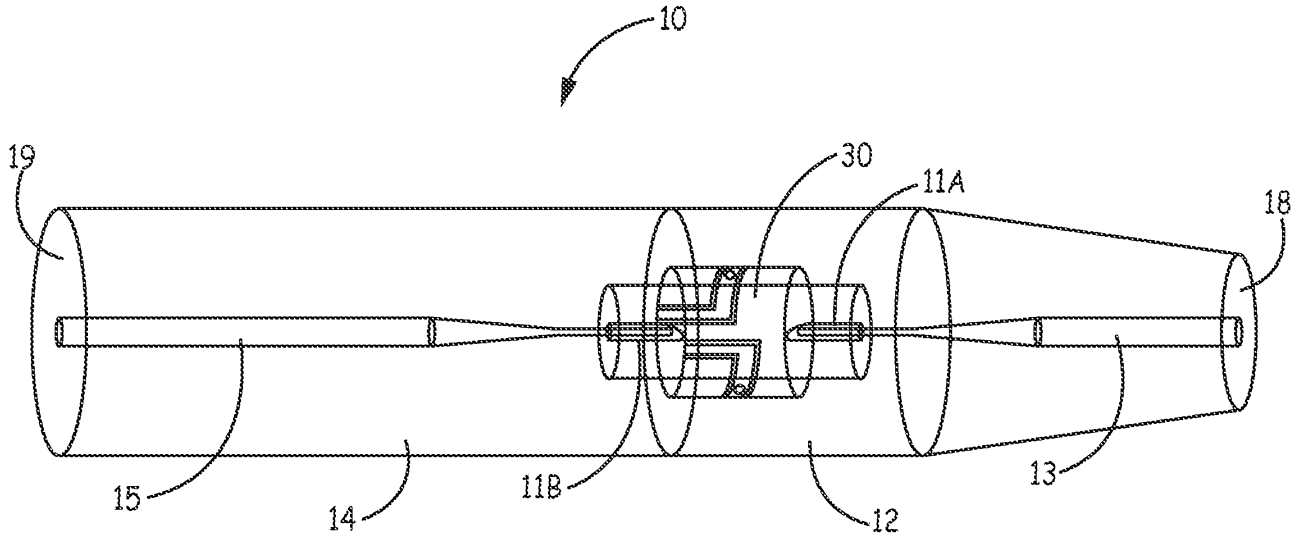

FIG. 3

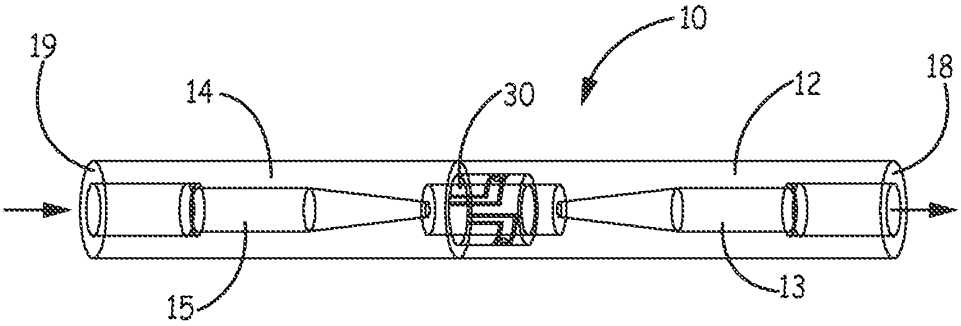

FIG. 4

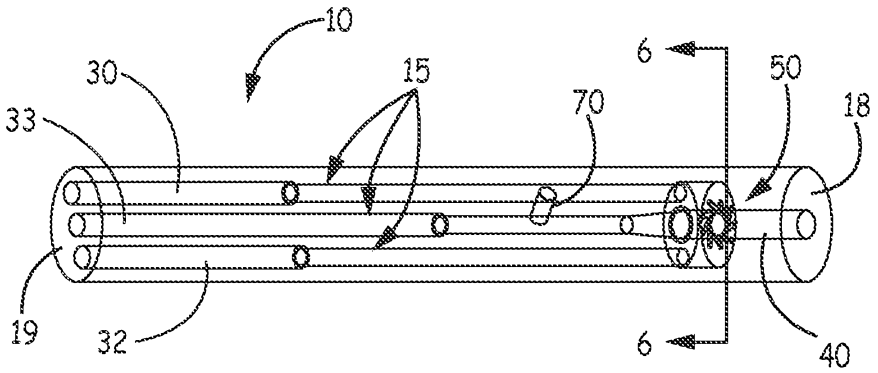

FIG. 5

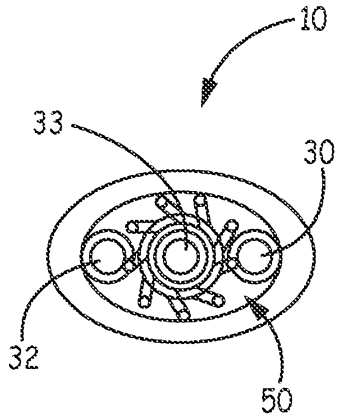

FIG. 6

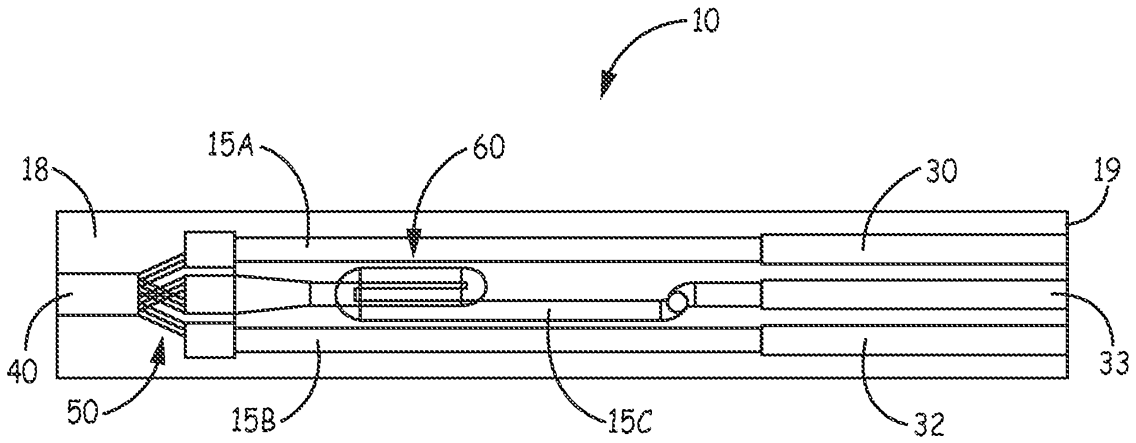

FIG. 7

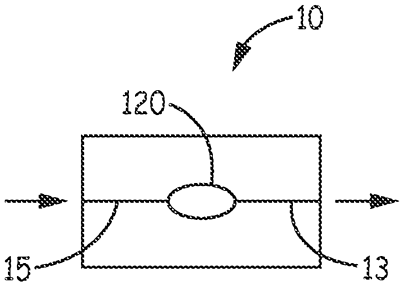

FIG. 8

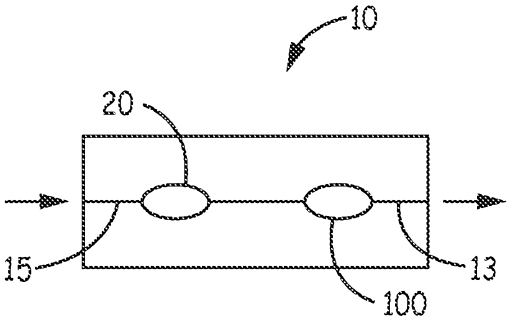

FIG. 9

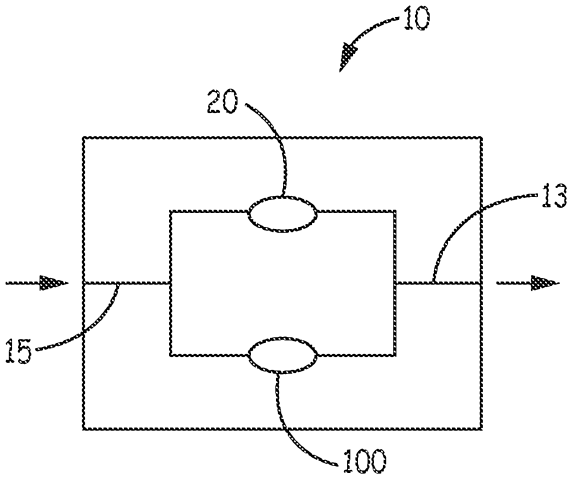

FIG. 10

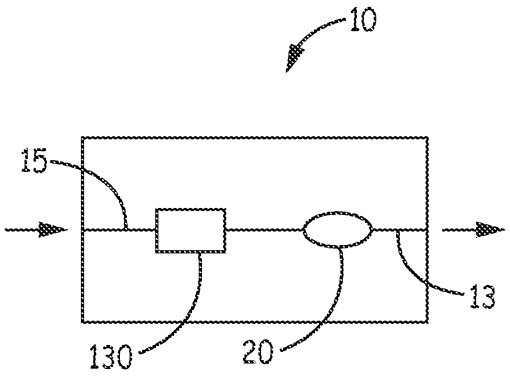

FIG. 11