EN

EUROPEAN QUALIFYING EXAMINATION 2024

Pre-examination

(INFORMAL VERSION
As extracted from Wiseflow and Examiner's report)

PART 1

Question 1

Zlatko filed a European patent application EP-Z in Croatian as a first filing with the European Patent Office on 16 March 2023. EP-Z does not contain any claims.

For each of statements 1.1–1.4, indicate whether the statement is true or false:

1.1 The period for paying the filing fee for EP-Z ended on 17 April 2023.

1.2 The period for filing an international patent application validly claiming priority from EP-Z ends on 16 March 2024.

1.3 The period for filing a translation of EP-Z into one of the official languages of the EPO ended on 16 May 2023.

1.4 The period for filing claims for EP-Z ended on 16 May 2023.

Question 2

Daniel Automotive SE filed a European patent application EP-D in June 2020. Claus is designated as the sole inventor. Last week, Daniel Automotive SE received a communication under Rule 71(3) EPC for EP-D. On 15 March 2024, an error is noted: the inventors of EP-D are actually Claus and Sabrina. Daniel Automotive SE now consults you for advice.

For each of statements 2.1–2.4, indicate whether the statement is true or false:

A valid element of your advice for correcting the error before the EPO is that ...

2.1 ... the applicant need not provide evidence that an error was made.

2.2 … if the request is filed by Daniel Automotive SE, the consent of Claus is required to rectify the designation of the inventor.

2.3 ... the designation of the inventor may be corrected after EP-D has been granted.

2.4 ... Sabrina may file an opposition based on the ground of not being mentioned as inventor.

Question 3

Anna-Frieda filed a German national patent application DE-AF in German on 23 May 2022 disclosing a first invention AF1 and a second invention AF2. On 24 April 2023, Anna- Frieda filed a first European patent application EP-AF1 covering the invention AF1 only and claiming priority from DE-AF. On the same day, 24 April 2023, she also filed a second European patent application EP-AF2 covering the invention AF2 only and without claiming any priority. Afterwards, Anna-Frieda noticed that no drawings had been filed for EP-AF1 and that the wrong claims had been erroneously filed for EP-AF2. On 2 May 2023, Anna- Frieda filed the missing drawings for EP-AF1, together with a certified copy of DE-AF, a letter correctly stating that the missing drawings are identical to those of DE-AF and a request to maintain the filing date of 24 April 2023. On 2 May 2023, Anna-Frieda submitted the correct claims for EP-AF2.

For each of statements 3.1–3.4, indicate whether the statement is true or false:

3.1 The filing date of EP-AF1 will be re-dated to 2 May 2023.

3.2 The filing date of EP-AF2 will be re-dated to 2 May 2023.

3.3 On 15 March 2024, Anna-Frieda can file a third EP patent application EP-AF3 validly claiming priority from EP-AF2 regarding the invention AF2.

3.4 The period for making the declaration of priority from DE-AF for EP-AF2 ends on 26 August 2024.

Question 4

Manuela filed international application PCT-M in September 2021 without claiming priority. PCT-M was searched by the EPO as International Searching Authority in February 2022. The International Searching Authority raised non-unity objections with respect to the subject-matter of the claims, considering claims 20 to 35 to relate to a separate invention with respect to claims 1 to 19. Manuela did not pay any additional fees. The International Searching Authority issued a partial search report covering claims 1 to 19. PCT-M entered the European phase on 15 March 2024 and is referred to in the following as Euro-PCT-M. No amendments have been filed.

For each of statements 4.1–4.4, indicate whether the statement is true or false:

4.1 Manuela will have an opportunity to amend the claims of Euro-PCT-M before substantive examination of Euro-PCT-M begins.

4.2 If in the application documents which are to serve as the basis of the substantive examination of Euro-PCT-M an invention is claimed that was not searched by the EPO as the International Searching Authority, Manuela will be invited to pay a further search fee in respect of this invention.

4.3 If Manuela does not pay claims fees by expiry of the period set by Rule 161 EPC, Euro-PCT-M will be deemed to be withdrawn.

4.4 If Manuela does not comment by 15 March 2024 on the written opinion of the International Searching Authority, Euro-PCT-M will be deemed to be withdrawn.

Question 5

Your client Pencilz has noticed that its biggest competitor Rulerz has a granted patent EP- R which covers important subject-matter for Pencilz. The mention of the grant of EP-R was published in the European Patent Bulletin on 4 August 2023. Pencilz asked you to file an opposition against EP-R and the notice of opposition was filed on 15 February 2024. No opposition fee was paid. EP-R was opposed on the following grounds: added subject-matter and lack of novelty. You also noticed some clarity issues with the granted claims of EP-R, which you also included in the statement of grounds filed with the notice of opposition.

For each of statements 5.1–5.4, indicate whether the statement is true or false:

5.1 On 15 March 2024, the opposition fee may still be paid.

5.2 Lack of clarity is a ground for opposition.

5.3 The Opposition Division may, of its own motion, examine EP-R for sufficiency of disclosure.

5.4 A third-party that has filed observations with the EPO concerning the patentability of EP-R is party to the opposition proceedings.

PART 2

Question 6

A European patent application is refused without holding oral proceedings for lack of novelty in a decision dated 1 February 2024. A request for oral proceedings filed by the applicant at an early stage in the examination procedure has been overlooked by the Examining Division. The applicant files an appeal with arguments explaining why the subject-matter claimed is novel over the prior art.

For each of statements 6.1–6.4, indicate whether the statement is true or false:

6.1 If the Examining Division considers the appeal to be admissible and well-founded, it shall rectify its decision.

6.2 The appeal fee is to be reimbursed in full because the applicant's request for oral proceedings has been overlooked.

6.3 If the notice of appeal does not contain the address of the appellant, and the address of the appellant is not given by today, 15 March 2024, the appeal will be rejected as inadmissible.

6.4 The statement setting out the grounds of appeal has to be filed within two months of filing the notice of appeal.

Question 7

On 1 June 2021, Matthieu filed a European patent application EP-M1 disclosing and claiming a fork made of copper or zinc. No other materials are mentioned and the kind of handle is not specified. On 1 June 2022, Matthieu filed a European patent application EP- M2 claiming priority from EP-M1 and disclosing and claiming a fork made of metal. The description of EP-M2 mentions that the metal can be copper, zinc, iron or any alloy of these metals. Claim 1 of EP-M2 claims a fork made of metal, claim 2 of EP-M2 claims a fork made of metal with a hollow handle. EP-M1 was published on 1 December 2022 as EP-M1-A1. A company brochure PA-1 published on 5 October 2021 discloses a fork made of copper with a hollow handle.

For each of statements 7.1–7.4, indicate whether the statement is true or false:

7.1 PA-1 forms part of the state of the art against EP-M2 under Article 54(3) EPC.

7.2 EP-M1-A1 forms part of the state of the art against the subject-matter of claim 1 of EP-M2 under Article 54(3) EPC.

7.3 PA-1 is novelty-destroying for the subject-matter of claim 1 of EP-M2 under Article 54(2) EPC.

7.4 PA-1 is novelty-destroying for the subject-matter of claim 2 of EP-M2 under Article 54(2) EPC.

Question 8

On 28 February 2024, Martha, a Polish national resident in Poland, filed with the EPO a reasoned notice of opposition against European patent EP-E in Polish. The mention of the grant of EP-E was published in the European Patent Bulletin on 16 June 2023. The language of the proceedings in the case of EP-E is English. In the notice of opposition, Martha requested oral proceedings.

For each of statements 8.1–8.4, indicate whether the statement is true or false:

8.1 Martha is not entitled to a reduction of the opposition fee.

8.2 Martha must file the translation of the notice of opposition at the latest on 18 March 2024.

8.3 If Martha requested in the notice of opposition to speak and listen in German during oral proceedings, the EPO would provide for interpretation.

8.4 Martha will be allowed to speak Polish during oral proceedings if she provides for interpretation into English.

Question 9

Sara, an Italian citizen living in Italy, filed an international application PCT-S1 in French with the EPO on 20 September 2021 without claiming priority. PCT-S1 documents as filed are: PCT request form designating all PCT contracting states, description, claims, drawings and abstract. After filing, Sara noticed that her name was misspelt on the PCT request form, but she could still be identified.

For each of statements 9.1–9.4, indicate whether the statement is true or false:

9.1 20 September 2021 is the international filing date of PCT-S1.

9.2 Without resorting to a legal remedy, the acts for entry into the EP regional phase shall be performed at the latest on 20 March 2024.

9.3 An extension of the time limit for performing the requirements for entry into the EP regional phase can be validly requested on 20 February 2024.

9.4 Further processing for performing the requirements for entry into the EP regional phase can be validly requested on 19 June 2024.

Question 10

Wolfgang intends to file the following patent applications:

(1) a European patent application EP-W;

(2) an international patent application PCT-WC.

PCT-WC will be jointly filed in the name of Wolfgang and Christina.

Christina lives in Berlin; Wolfgang lives in Uruguay and is of Uruguayan nationality. Uruguay is not a PCT member state.

For each of statements 10.1–10.4, indicate whether the statement is true or false:

10.1 Wolfgang may validly file EP-W with the EPO.

10.2 PCT-WC may be validly filed with the EPO as receiving Office.

10.3 PCT-WC can be validly filed with the International Bureau as receiving Office.

10.4 If Wolfgang moves to Berlin two months after validly filing PCT-WC, the International Bureau will, upon request, record the change of residence in relation to PCT-WC.

Part 3
Description of the application

Electronic cigarette, filing date: 15 March 2024

[001] The present invention relates to electronic cigarettes, in particular electronic cigarettes that do not produce tar.

[002] Traditional cigarettes consist primarily of tobacco leaves wrapped in cigarette paper. The user lights the tip of the cigarette to burn the tobacco and inhales the smoke through the unlit end. The combustion produces nicotine and other components, such as tar. Tobacco tar comprises several thousands of ingredients, many of which are carcinogenic.

[003] An advantage over traditional cigarettes is that electronic cigarettes do not produce tar. Electronic cigarettes provide nicotine to the user in an aerosol that simulates the smoke of a conventional cigarette, together with other substances that provide flavour.

[004] It is an object of the invention to create an electronic cigarette that does not have the health hazards of traditional cigarettes and is able to be personalised according to the taste preferences and needs of the user. The object of the invention is achieved by the subject-matter of the claims herein.

[005] Brief description of the drawings:
FIG. 1 schematically shows the cross-section of an electronic cigarette according to a first embodiment of the invention.
FIG. 2 schematically shows the cross-section of an electronic cigarette according to a second embodiment of the invention.
FIG. 3 schematically shows the cross-section of an electronic cigarette according to a third embodiment of the invention.
FIG. 4 schematically shows the cross-section of an electronic cigarette according to a fourth embodiment of the invention.
FIG. 5 schematically shows the cross-section of an electronic cigarette according to a fifth embodiment of the invention.

[006] The electronic cigarette 100 according to the first embodiment of FIG. 1 comprises a mouthpiece 110 through which the user draws vapour produced by an atomiser 120. The atomiser 120 is connected to a liquid container 130. The controller 140 is connected to each of the battery 150, atomiser 120, push-button 160 and communication component 170. When the controller 140 receives a signal caused by the user pressing the push-button 160, the controller 140 activates vapour production by supplying power from the battery 150 to the atomiser 120, wherein the atomiser transforms, by heating, the liquid held in the liquid container 130 into vapour to be inhaled by the user through the mouthpiece 110.

[007] The first embodiment may further comprise the following optional features: The communication component 170 may facilitate short-range radio communication between the electronic cigarette 100 and a software application 195 installed in a mobile phone 190, separate from the electronic cigarette 100. The communication component 170 may be a short-range communication component that in some embodiments reads radio frequency identifier (RFID) tags. The user may configure a time schedule for vapour production in the software application 195 including, for instance, maximum operation times of the electronic cigarette 100, such as times of the day in which the controller 140 allows or prevents the activation of vapour production. In addition, the controller 140 may establish compulsory pauses that deactivate or prevent activation of vapour production of the electronic cigarette after a designated amount of time used. The electronic cigarette 100 may receive a configuration file 180 with the time schedule via the communication component 170 from the mobile phone 190 to be read and implemented by the controller 140 for vapour production, as shown in FIG. 1. When activation of vapour production is prevented, as set in the time schedule, unauthorised use of the electronic cigarette 100 is prevented.

[008] However, it would also be possible for a child to use the electronic cigarette 100 when the time schedule allows vapour production. To prevent this problem, a second embodiment of the invention includes means for preventing unauthorised access as an alternative to the first embodiment. The electronic cigarette 100 in FIG. 2 includes a fingerprint sensor 210, which is connected to the controller 140. The fingerprint sensor 210 identifies key markers of the user's fingerprint, which are transmitted to the software application 195 in the mobile phone 190. The software application 195 configures access rights to the electronic cigarette 100 via the communication component 170. The user gives instructions to grant or deny access to the fingerprints read by the fingerprint sensor 210. The software application 195 sends a configuration file 180 with fingerprint details representing permissions designated to users to use the electronic cigarette 100. After receiving the configuration file 180, the electronic cigarette 100 is ready to verify fingerprints when a user touches the fingerprint sensor 210. As an alternative to the push-button 160 described above, the controller 140 verifies the fingerprints read by the fingerprint sensor 210 with the fingerprints stored in the configuration file 180. In this embodiment, the configuration file 180 only includes information received from the mobile phone 190 to verify one or more fingerprints to grant or deny user access and cannot contain any scheduling information. After verification of the user fingerprints as described above, the controller 140 of the electronic cigarette may activate or prevent activation of vapour production.

[009] In the third embodiment of the invention, a convenient way to activate vapour production of the electronic cigarette 100 is by the user inhaling air through the mouthpiece 110, represented in FIG 3. The push-button 160 in the first embodiment is replaced with a pressure sensor 310. When the controller 140 receives a signal from the pressure sensor 310 representing a pressure difference created by the user inhaling through the mouthpiece 110, it supplies power from the battery 150 to the atomiser 120, which transforms the liquid held in the liquid container 130 into vapour to be inhaled through the mouthpiece 110 to produce vapour.

[010] The operation of the fingerprint sensor 210 can be combined with activation of vapour production by inhalation in the fourth embodiment of the invention, represented in FIG. 4, by combining the second and third embodiments. When inhaling through the mouthpiece 110, a pressure difference is created in the region of the pressure sensor 310. Then the controller 140 additionally needs to verify a fingerprint in the fingerprint sensor 210 before supplying power to the atomiser 120 from the battery 150 to create vapour with the contents of the liquid container 130.

[011] The electronic cigarette 100 defined by the fifth embodiment provides nicotine dosage functionality via the communication component 170 by using the mobile phone 190. A software application 195 in the mobile phone 190 can control the dose of nicotine that will be supplied by the electronic cigarette 100, as exemplified in FIG. 5. This is particularly advantageous for adapting the vapour to the taste and needs of the user. When a user buys liquid to be vaporised and inhaled with a given nicotine concentration, for instance 20 mg/ml of nicotine, this information is introduced by the user in the software application 195 of the mobile phone 190.

[012] In addition, an authentication process allows the user to validate that the liquid used to produce vapour was produced by an official manufacturer. The communication component 170 reads an identifier stored in a secured electronic identification tag 510 on the liquid container 130. The secured electronic identification tag 510 may be an RFID tag. The electronic cigarette 100 transmits this identifier to the software application 195 of the mobile phone 190 to validate the liquid container 130 as being produced by an official manufacturer.

[013] The user interface displayed in the software application 195 of the mobile phone 190 provides a slide bar or a similar graphic element allowing the user to select a specific nicotine dose, ranging from 0 mg/ml to the maximum liquid concentration (for instance, the maximum liquid concentration is 20 mg/ml). This user selection of the nicotine dose is transmitted via the communication component 170 to the electronic cigarette 100 in the configuration file 180. The controller 140 can control the operation of the atomiser 120 so that a given amount of liquid is vaporised to achieve the dose specified in the configuration file 180.

[014] Further chemical substances in addition to flavouring may be added to the liquid.

[015] The electronic cigarette 100 can also be used to deliver a therapeutic drug to a patient with a medical condition. In particular, a pharmaceutically active substance capable of being delivered in an aqueous aerosol can be added to the liquid to be vaporised thus providing treatment of certain diseases. Such substances include therapeutic compounds, proteins, polysaccharides, lipids and nucleic acids. The therapeutic drug may be, for example, an antibiotic, fungicide, cough suppressant, heparin or a growth hormone.

Reference numbers:

100: electronic cigarette
110: mouthpiece
120: atomiser
130: liquid container
140: controller
150: battery
160: push-button
170: communication component
180: configuration file
190: mobile phone
195: software application

210: fingerprint sensor
10: pressure sensor
510: secured electronic identification tag

Drawings of the application

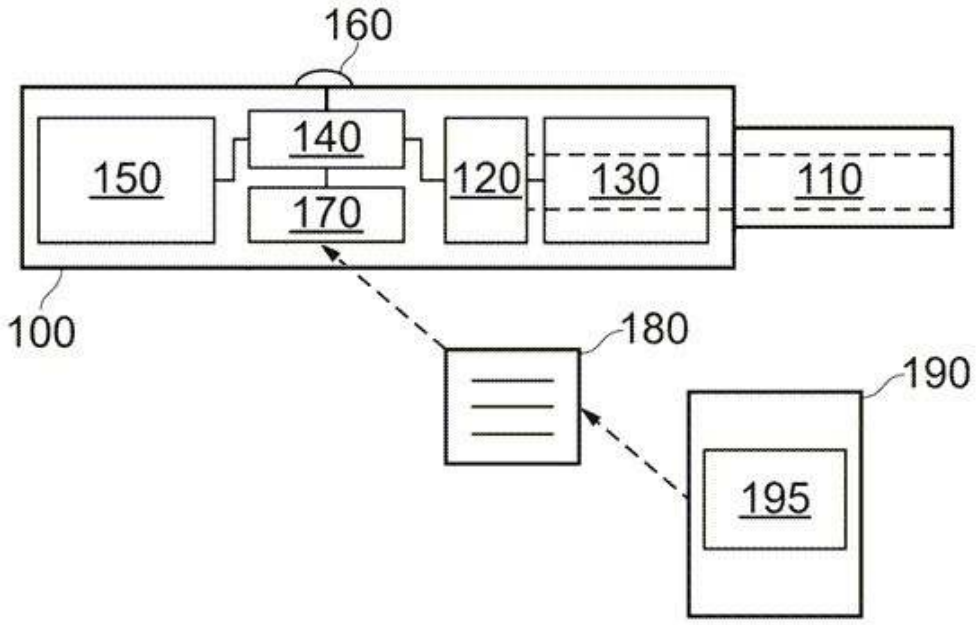


FIG. 1

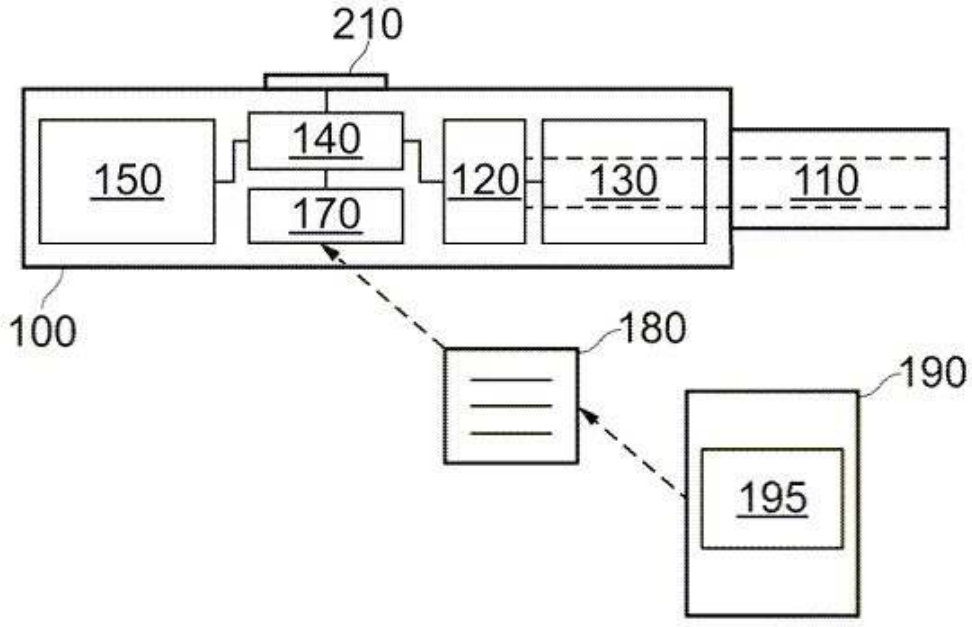


FIG. 2

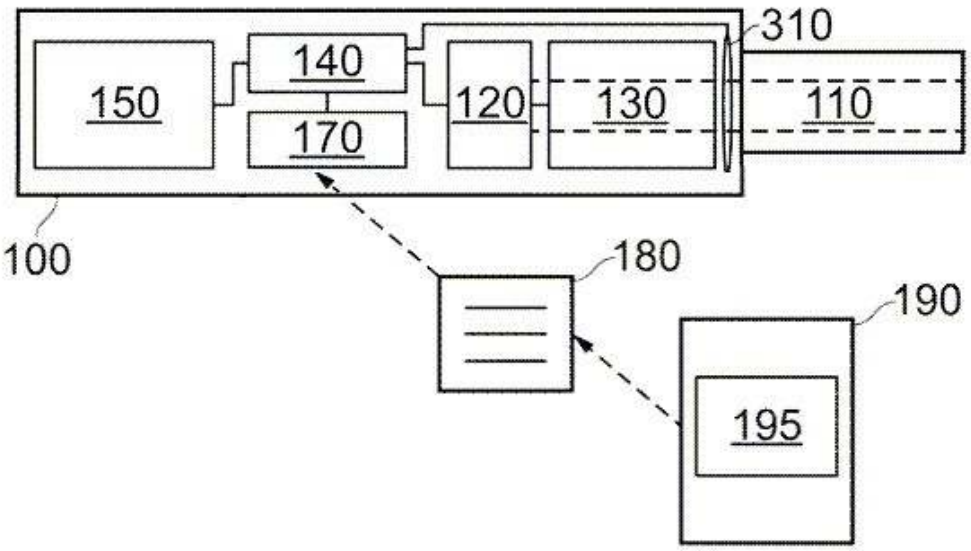

310
140
150
120
130
110
170
100
180
190
195

FIG. 3

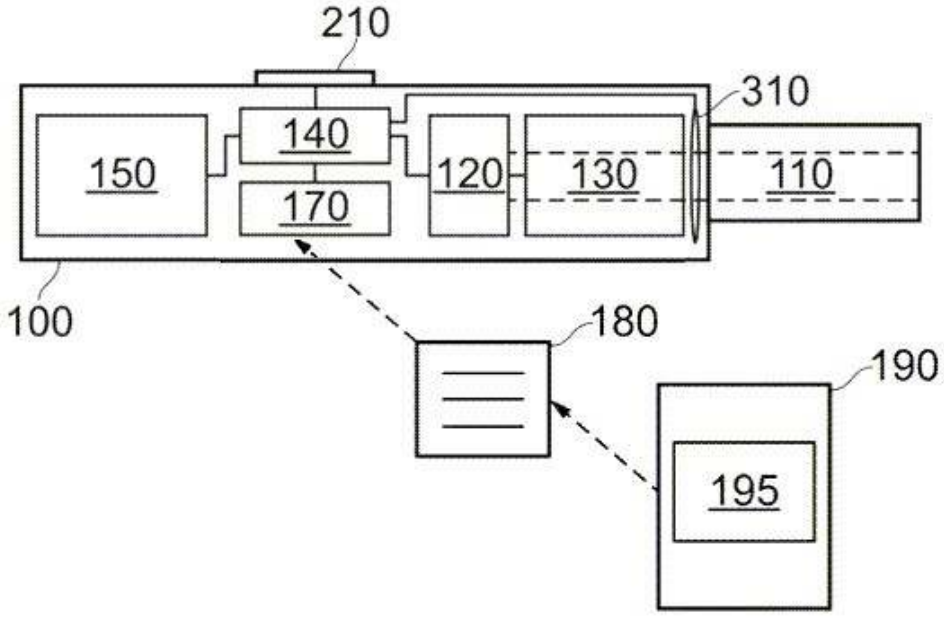

210
310
140
150
120
130
110
170
100
180
190
195

FIG. 4

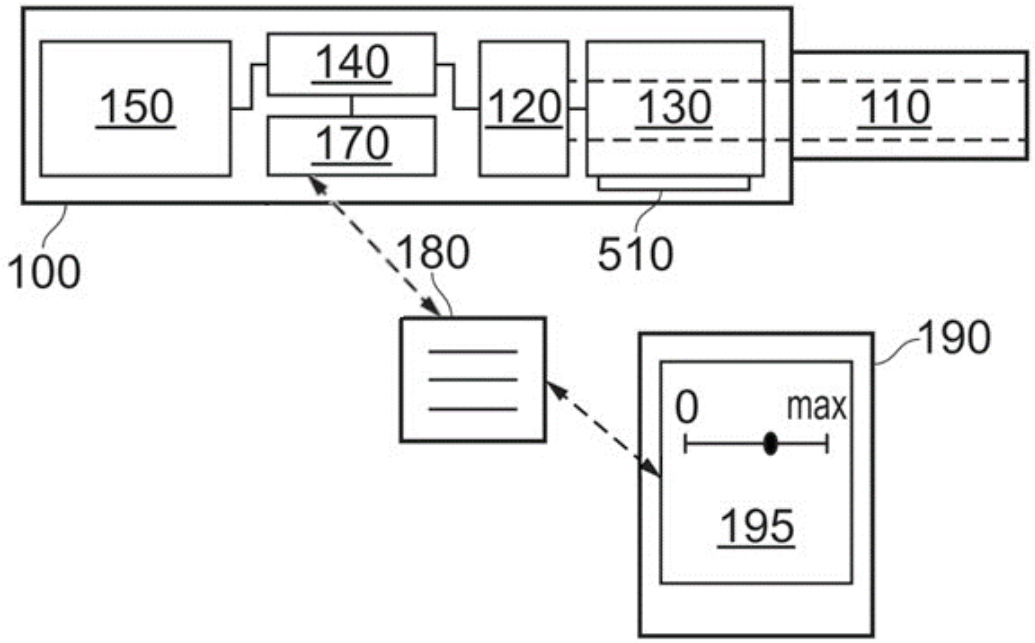


FIG. 5

Assume that claims I.1 and I.2 are the only claims filed with the client's patent application.

I.1 An electronic cigarette (100) comprising a liquid container (130), an atomiser (120) in connection with the liquid container (130), a communication component (170), and a controller (140) for activating or deactivating vapour production of the electronic cigarette (100).

I.2 The electronic cigarette of claim I.1, wherein a time schedule for the vapour production is received from a mobile phone (190) through the communication component (170).

Document D1, publication date 28 June 2023

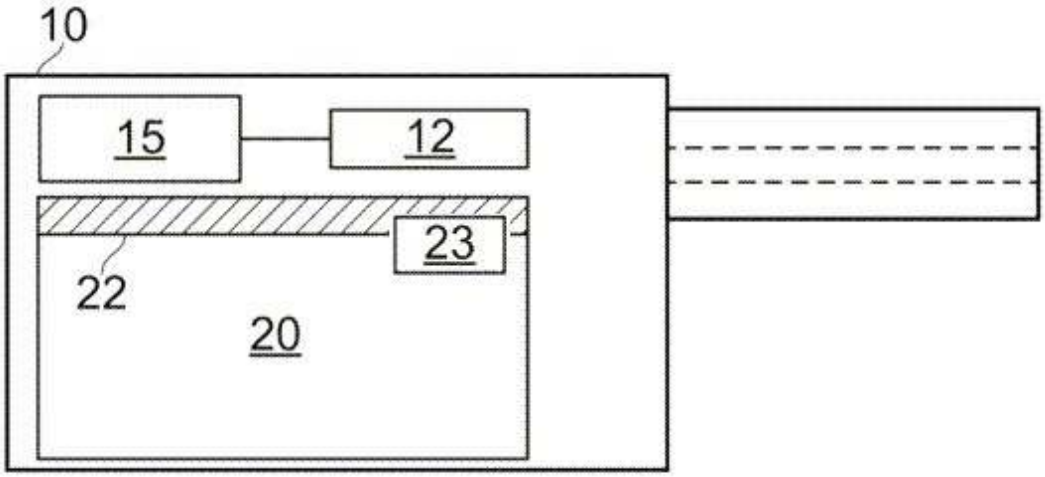
[001] There is a growing trend of counterfeit products on the electronic cigarette market, in particular liquid solutions for electronic cigarettes that are personalised by users who are unaware of the health risks posed by such liquid solutions. The use of counterfeit or personalised liquid solutions not authorised by the manufacturer of the electronic cigarette poses significant health and safety risks for consumers. It has been found that the use of flavourings in liquid solutions increases dramatically the health risk to consumers. There is also no expectation of any improvement or advantage when including flavourings to liquid solutions for electronic cigarettes. It is an object of the present invention to validate the authenticity of the liquid solution in an electronic cigarette and to restrict the use of liquid solutions so that the solutions used conform with health regulations and industry standards.

[002] The electronic cigarette in the figure comprises a body 10 with a cavity in which a disposable cartridge 20 with a liquid solution is inserted. The disposable cartridge 20 is identified with an RFID tag 22 that stores an identifier 23 to be read by a short-range communication component 12 in the electronic cigarette. A controller 15 is connected to the communication component 12, to a battery and to an atomiser (both not depicted).

[003] The nicotine content of the disposable cartridge is specified by the manufacturers in compliance with health regulations, ranging from 5 mg/ml to a maximum of 35 mg/ml to avoid health risks caused by high nicotine concentrations.

[004] Upon insertion of the disposable cartridge 20 into the cavity of the body 10, the short- range communication component 12 in the body of the electronic cigarette reads the RFID tag 22 and stores the identifier 23 in the memory of the controller 15 of the electronic cigarette. The controller 15 validates the identifier 23 as a valid identifier, for instance, by checking the identifier 23 against a list of valid identifiers stored in a read-only memory or against a set of validation rules. Upon validating the identifier 23, the controller 15 sends a signal to the atomiser to activate vapour production with the power supplied from the battery. If the identifier 23 is deemed invalid, the controller prevents activation of vapour production. Preferably, when the disposable cartridge 20 runs out of liquid, the identifier 23 is marked as a non-valid identifier to prevent the use of unauthorised refills if the disposable cartridge 20 is inserted again into the cavity of the body 10.

[005] The electronic cigarette reports usage data as registered by the controller 15 to a software application of a mobile phone. The software application obtains the usage data and can generate reports showing usage patterns, such as times of the day in which the electronic cigarette is used, or battery charge level.



Question 11

For each of statements 11.1–11.4, indicate whether the statement is true or false:

11.1 The electronic cigarette of the first embodiment of the application is covered by the scope of claim I.1.

11.2 The electronic cigarette of the second embodiment of the application is covered by the scope of claim I.2.

11.3 The electronic cigarette of the third embodiment of the application is covered by the scope of claim I.1.

11.4 The electronic cigarette of the fourth embodiment of the application is covered by the scope of claim I.2.

Question 12

For each of statements 12.1–12.4, indicate whether the statement is true or false:

12.1 The electronic cigarette in D1 reads information that can prevent the unauthorised use of disposable cartridges.

12.2 The subject-matter of claim I.1 is novel with respect to D1.

12.3 The subject-matter of claim I.2 is novel with respect to D1.

12.4 D1 discloses an electronic cigarette that provides a liquid solution to avoid the health risks caused by high nicotine concentrations.

Document D2, publication date 28 May 2022

[001] D2 is a brochure describing a mixing system for liquid solutions for electronic cigarettes (also known as e-liquids) that allows greater control and personalisation of the smoking experience.

[002] The mixing system consists of a mobile phone application (mobile app) and a kit with gloves, graduated syringes, chemical substances, such as nicotine and flavouring for the e-liquid, and a 100 ml beaker in which the e-liquid is prepared.

[003] The customer can use the mobile app to browse and select different flavourings and other components for the e-liquid. The customised e-liquid comprising said components and flavourings can then be purchased directly from the company behind the mobile app. Customers can even store their customised mixes on the mobile app, post them on social media and share the mixes with other mobile app users, who can rate and provide feedback on them. To facilitate the identification of every preparation of e-liquid, the mobile app provides a label identifying the mix that can be printed and attached to the cartridge or to the electronic cigarette. The label can be scanned using the camera of a mobile phone, which can identify the e-liquid and display information about it in the mobile app.

[004] D2 discloses a mix for an e-liquid comprising chemical substances, such as nicotine, propylene glycol, vegetable glycerine and banana flavouring. The nicotine content in the recipe is 5-7 mg/ml, which has been found ideal for combining with banana flavouring.

Question 13

This question relates to Document D2.

For each of statements 13.1–13.4, indicate whether the statement is true or false:

13.1 D2 discloses a mobile app to detect health risks caused by the mixture of components for a liquid solution for electronic cigarettes.

13.2 The range of nicotine values ranging from 0 mg/ml to 20 mg/ml disclosed in paragraph [013] of the application is novel over D2.

13.3 D2 discloses an electronic cigarette with a communication component configured to read information from an RFID tag to validate a liquid container.

13.4 D2 discloses a liquid solution that comprises further chemical substances in addition to flavouring.

Consider the introduction of the following amendments to the original claim I.1-I.2 during the examination proceedings.

Deleted passages are marked as "~~strikethrough~~," and added passages are underlined.

II.1~~I.1~~ An electronic cigarette (100) comprising a liquid container (130), an atomiser (120) in connection with the liquid container (130) and a mouthpiece (110) through which the user draws vapour produced by the atomiser (120), a battery (150), a push-button (160), a communication component (170), and a controller (140) ~~for activating or deactivating vapour production of the electronic cigarette (100)~~ being connected to each of the battery (150), the atomiser (120), the push-button (160), and the communication component (170),
wherein, when the controller (140) receives a signal caused by the user pressing the push-button, the controller activates vapour production by supplying power from the battery (150) to the atomiser (120),
wherein the atomiser transforms, by heating, the liquid held in the liquid container (130) into vapour to be inhaled by the user through the mouthpiece (110).

~~I.2 The electronic cigarette of claim I.1, wherein a time schedule for the vapour production is received from a mobile phone (190) through the communication component (170).~~

II.2 The electronic cigarette of claim II.1, wherein a fingerprint sensor (210) transmits identified key markers of the user's fingerprints to a software application in a mobile phone.

II.3 The electronic cigarette of claim II.1, wherein a short-range communication signal allows the activation of vapour production.

II.4 The electronic cigarette of claim II.1, wherein a pressure sensor (310) replaces the push-button (160) and the pressure sensor (310) sends a signal to the controller (140) representing a pressure difference for producing vapour.

Question 14

Considering the introduction of the amendments on the previous page to the original claims I.1-I.2 during the examination proceedings for each of statements 14.1–14.4, indicate whether the statement is true or false:

14.1 Claim II.1 meets the requirements of Article 123(2) EPC.

14.2 Claim II.2 meets the requirements of Article 123(2) EPC.

14.3 Claim II.3 meets the requirements of Article 123(2) EPC.

14.4 Claim II.4 meets the requirements of Article 123(2) EPC.

Assume that claims III.1-3 were originally filed

III.1 An electronic cigarette (100) comprising a liquid container (130) comprising a secured electronic identification tag (510), a communication component (170) for reading the secured electronic identification tag (510) and a controller (140) configured to allow or prevent activation of vapour production of the electronic cigarette (100) on the basis of authentication of the secured electronic identification tag (510) to validate the liquid container (130).

III.2 An electronic cigarette (100) comprising a liquid container (130) comprising a secured electronic identification tag (510), a short-range communication component (170) for reading the secured electronic identification tag (510) and a controller (140) configured to allow or prevent activation of vapour production of the electronic cigarette (100) on the basis of authentication of the secured electronic identification tag (510) to validate the liquid container (130), wherein the liquid container (130) contains smoking liquid comprising flavouring and a therapeutic drug.

III.3 A method of using an electronic cigarette (100) comprising a liquid container (130) comprising a secured electronic identification tag (510), a short-range communication component (170) for reading the secured electronic identification tag (510) and a controller (140) configured to allow or prevent activation of vapour production of the electronic cigarette (100), wherein the controller (140) supplies electric power for the vapour production upon detecting a pressure difference when inhaling from a mouthpiece in the electronic cigarette (100).

Question 15

Considering the disclosure of documents D1 and D2 and the claims on the previous page, for each of the statements 15.1–15.4, indicate whether the statement is true or false:

15.1 The subject-matter of claim III.1 is novel over D1.

15.2 The subject-matter of claim III.2 is novel over D1.

15.3 The subject-matter of claim III.2 is excluded from patentability.

15.4 The subject-matter of claim III.3 involves an inventive step in view of the disclosure of D1 as the closest prior art and D2.

Part 4

Description of the application

Title: Product X for use in treating infectious diseases

[001] The present invention relates to the use of Product X in treating infectious diseases that are caused by viruses, bacteria, fungi or parasites. The present invention relates also to the treatment of receptor-Y-dependent diseases.

[002] Product X is a small molecule compound that has been extensively described in research literature since the early 1990s. A well-known drug comprising Product X has been provided in tablet form in prior art for treating certain cardiac diseases.

[003] Antiparasitics are a class of medications which are used to treat parasitic diseases, such as those caused by helminths, amoeba, ectoparasites and protozoa, among others.

[004] Antifungals are a class of medications which are used to treat fungal diseases, e.g. mycosis, ringworm, cryptococcal meningitis and others.

[005] Antibiotics are a class of medications which are used to treat diseases caused by bacteria, such as borreliosis, listeria or streptococcal infections.

[006] Antivirals are a class of medications which are used to treat diseases caused by a virus infection. Examples for these viruses are influenza viruses, Epstein-Barr viruses, hepatitis viruses, coronaviruses, rhinoviruses and adenoviruses.

[007] According to an embodiment of the present invention, Product X is provided for use as an antiviral, an antibiotic, an antifungal or an antiparasitic. According to a preferred embodiment of the present invention, Product X is provided for use as an antiviral against rhinovirus, influenza virus or coronavirus.

[008] In the present invention, it was surprisingly found that Product X is effective in the treatment of viral and bacterial diseases by suppressing the viral and bacterial growth. Although it is not plausible at the moment, we also want to investigate whether an effect can be reached for treatment of other kinds of infectious disease. We are about to start a research programme wherein we will investigate whether there is an effect of Product X when used as an antifungal or antiparasitic. Such programme will require immense
trial-and-error tests.

[009] Table 1 shows the results of a test that we have performed. Product X was given in one of three different dosages in one of two forms, either in tablet form or as a nasal spray, to a number of human beings over a period of at least 10 days. The results show the measured antibiotic and antiviral effects. The suppression factor is well-known and well- defined in the art for skilled persons in infectious diseases. The suppression factor is categorised in no, low, medium, high and very high suppression of the viral load / bacterial load. An antiviral or antibiotic effect is achieved when the suppression factor is low, medium, high or very high.

Table 1 - Suppression factor of viral load / bacterial load

Dosage of Product X in mg/kg bodyweight per day	Form	Influenza virus (viral infection)	Coronavirus (viral infection)	Rhinovirus (viral infection)	Streptococcus (bacterial infection)
5	Tablet	Low	Low	Low	Low
10	Tablet	Medium	Medium	Medium	Medium
25	Tablet	High	High	High	Medium
5	Spray	Medium	Medium	Medium	Medium
10	Spray	High	High	High	Medium
25	Spray	Very high	Very high	Very high	High

[010] Table 1 shows that Product X has an enhanced antiviral and antibiotic effect (corresponding to an at least medium suppression factor) for dosages of 10 mg/kg bodyweight per day when given in tablet form and, at even lower dosages of 5 mg/kg bodyweight per day when given as nasal spray. The tests were performed for the streptococcus and for three different kinds of RNA viruses: influenza virus, coronavirus and rhinovirus. We have carried out further experiments (not shown) which demonstrate that the antibiotic effect is reached for any kind of bacteria.

[011] Table 1 also shows that Product X appears to have on average a weaker effect against a bacterial infection than against a viral infection because the suppression factor is lower. However, when we combined Product X with the known antibiotic compound Z in other tests (not shown), we observed a suppression factor for the streptococcal infection (bacterial infection) that was stronger than the sum of the individual effects of Product X and compound Z. In one embodiment, a composition comprising Product X and antibiotic compound Z is provided.

[012] It is expected that the adult human daily dosage should not exceed maximum 50 mg/kg bodyweight because a higher dosage provokes adverse effects, such as heart rhythm disturbances, as is widely described in the literature. There seems to be a saturation effect in that the suppression factor was not observed to further increase for dosages above around 20 mg/kg bodyweight per day. A noteworthy suppression of infection has been observed from 5 mg/kg bodyweight for at least three days onwards. Thus, a further embodiment of the invention is Product X for use as an antiviral, an antibiotic, an antifungal or an antiparasitic, wherein Product X is administered for at least three days, preferably for at least 10 days, in a dosage of 5-50 mg/kg bodyweight, preferably in a dosage of 10-50 mg/kg bodyweight.

[013] Suitable administration routes for therapeutic treatment include intravenous, intramuscular, nasal and oral administration. From the prior art and its known use as a cardiac medicament we know that oral administration of Product X is generally well tolerated and rarely produces minor side effects. Generally, oral administration in form of tablets has the advantage that the dosage can be set very exactly; moreover, tablets have a long shelf life of up to several years. However, we also developed an administration route in form of a nasal spray, which is particularly suitable for children who do not like to swallow tablets. Surprisingly, the suppression factor of the nasal spray was significantly higher compared to the oral administration route in form of tablets when administering equal doses, see table 1. Thus, a further embodiment of the invention is Product X administered as nasal spray. In extremely severe infectious conditions, an intravenous administration of Product X might be helpful in order to quickly suppress the viral and bacterial load respectively and further improve the patient's condition.

[014] According to the present invention, a further very interesting relationship has been identified. According to the test results of table 2, it seems that the severity of the infection in a patient is dependent on the activity level of receptor Y. Receptor Y is a specific membrane-bound tyrosine kinase receptor (TKR) belonging to TKR subfamily 2. Product X seems to act as an inhibitor of receptor Y. Thus, the present invention is also related to a Product X for use in a treatment by inhibiting receptor Y, see claim I.2. As receptor Y is yet largely unknown as a druggable target, we claim that Product X might be valuable even in other diseases in which receptor Y plays a decisive role. Consequently, Product X can
also be used to treat other pathological conditions where it has the function of inhibiting receptor Y. The activity level is categorised in no, low, medium, high and very high activity of receptor Y.

Table 2 (Covid infection) – Activity level (well-known parameter)

	Before infection	Day 5 after infection without treatment	Day 5 after infection (tablet treatment started on day 2 after infection)
Laboratory mouse without receptor Y	No	Low	Low
Laboratory mouse with level of receptor Y above regular level	No	Very high	Very high
Laboratory mouse with regular level of receptor Y	No	Medium	Low

[015] The examples are provided for the purpose of illustration only and the invention should in no way be construed as being limited thereby.

Claim set I filed together with the description:

I.1 Product X for use in a treatment as an antiviral, an antibiotic, an antifungal, or an antiparasitic.
I.2 Product X for use in a treatment by inhibiting receptor Y.
I.3 Product X according to claim I.1, wherein the treatment is antiviral, more particularly a treatment against rhinovirus, influenza virus, or coronavirus.
I.4 Product X according to claim I.1, wherein Product X is administered for at least 10 days in a dosage of 5-50 mg/kg bodyweight per day.
I.5 Product X, wherein Product X is administered for at least 10 days in a dosage of 5-50 mg/kg bodyweight per day.
I.6 Product X according to claim I.5, wherein Product X is administered for at least 10 days in a dosage of 25 mg/kg bodyweight per day.
I.7 Product X according to claim I.1, wherein Product X is administered as a nasal spray.
I.8 Product X according to claim I.1, wherein the treatment is an antibiotic and Product X is administered as a nasal spray.
I.9 A method for therapeutic treatment of a living human, wherein the treatment comprises administration of Product X.
I.10 The method according to claim I.9, wherein the treatment comprises intravenous administration.

Assume that documents D11, D12 and D13 are prior art documents under Article 54(2) EPC.

Document D11

[001] Product X is a well-known angiotensin II receptor blocker (ARB) that is used to treat high blood pressure, hypertension, left ventricular hypertrophy and heart failure. Angiotensin II is a hormone made by the human body and it tightens the muscles of blood vessels. Angiotensin II also contributes to salt and water retention in human bodies. Increased salt in the human body and tightened blood vessels may cause blood pressure to rise. High blood pressure harms blood vessels and should be avoided.

[002] Product X has the technical effect that when it is supplied to a human being it blocks the angiotensin II receptor and, thus, decreases the risk of death from a cardiac event. Side effects of Product X include: irregular heartbeat caused by high blood potassium levels, respiratory symptoms, leg swelling, high potassium levels and, in rare cases, liver failure. Particularly, as a result of the frequent adverse effects regarding heart rhythm disturbances, dosages over 50 mg/kg bodyweight per day are not allowed. However, when dosed equal to or below 50 mg/kg bodyweight per day the treatment is allowed for up to six months. D11 – Advertisement in *The Local Sun*, published on the 15 August 2019

Document D12

[001] Most tyrosine kinase receptors (TKRs) are single subunit receptors but some exist as multimeric complexes. The TKRs can be subdivided structurally into seven different subfamilies, each of the subfamilies consisting of many specific receptors. TKR subfamily 2 comprises the largest subfamily of – so far known – 23 members with many different specificities and a high structural variety. Many members of TKR subfamily 2 are not yet completely understood in terms of their biological function.

[002] Product class Z comprises Products A, B, C, D, ..., X. The method of production of Products A and B is fully described in our article published in 2021.

[003] Receptor W, a member of TKR subfamily 2, seems to be an interesting novel drug target in the field of infectious diseases. First binding test screens on receptor W show that Products A and B might have an inhibition effect of receptor W. As the binding mechanism is still not clear, we will try to determine the crystal structure of the receptor W in order to elucidate how Product A and Product B bind to receptor W.

[004] Product X, which is a well-known angiotensin II receptor blocker (ARB) that is used to treat high blood pressure, hypertension, left ventricular hypertrophy and heart failure, is a member of product class Z.

Document D13

The first-line standard of care treatment for adults with Lyme disease, which is a bacterial infection with Borrelia, is doxycycline. Other antibiotics that have activity against Borrelia include amoxicillin and Ceftin. Recent studies show that a treatment with the known cardiac medicament Product X in tablet form can also be helpful in reducing the Lyme disease symptoms, e.g. the reddening around the bite of the tick, and quick suppression of bacterial load. Thus, Product X might be a secondary treatment route, particularly, if there are multiple resistances against the first-line standard antibiotics, such as doxycycline.

Question 16

For each of the statements 16.1-16.4, indicate whether the statement is true or false

16.1 The usage of Product X as an antifungal is sufficiently disclosed by the application as filed.

16.2 The subject-matter of claim I.1 is sufficiently disclosed by the application as filed.

16.3 The usage of Product X as an antibiotic is sufficiently disclosed by the application as filed.

16.4 The EPO will issue a communication according to Rule 63 EPC because the claim set comprises a plurality of independent claims of the same category.

Question 17

For each of the statements 17.1-17.4, indicate whether the statement is true or false

17.1 Claim I.9 is excluded from patentability because it relates to a method which encompasses at least one therapeutic step.

17.2 Claim I.3 is limited to the treatment of rhinoviruses, influenza viruses and coronaviruses by Product X.

17.3 There is a basis in the application as filed, so that claim I.5 can be amended compliant to Article 123(2) EPC in a way that the resulting subject-matter also covers administering Product X for seven days.

17.4 The subject-matter of claim I.4 is unclear because the essential feature of administration via nasal spray is missing.

Question 18

For each of the statements 18.1-18.4, indicate whether the statement is true or false

18.1 The subject-matter of claim I.1 is not novel over D11.

18.2 The subject-matter of claim I.5 is not novel over D111.

18.3 The subject-matter of claim I.7 is not novel over D2.

18.4 The subject-matter of claim I.1 is not novel over D13.

Question 19

For each of the statements 19.1-19.4, indicate whether the statement is true or false

19.1 The subject-matter of claim I.1 involves an inventive step over D13 alone.

19.2 For the following statement, assume that D11 is regarded as the closest prior art to the subject-matter of claim I.3: A valid argument that the subject-matter of claim I.3 involves an inventive step over D11 is that there is no hint in any one of documents D11, D12 and D13 that Product X has an antiviral effect.

19.3 The subject-matter of claim I.6 is novel over D11.

19.4 The difference of the subject-matter of claim I.8 over D13 as closest prior art may be regarded as not providing a technical effect.

Claim Set II filed by the applicant during the examination proceedings

Deleted passages are marked as ~~strikethrough~~, added passages are underlined.

II.1~~I.1~~ Product X for use in a treatment as an antiviral~~, an antibiotic, an antifungal or an antiparasitic~~.

~~I.2 Product X for use in a treatment by inhibiting receptor Y.~~

11.2 Product X according to claim II.1, wherein the treatment is antiviral against RNA viruses.

II.3~~I.3~~Product X according to claim II.1~~I.1~~, wherein the treatment is ~~antiviral, more particularly~~ a treatment against rhinovirus, influenza virus, or coronavirus.

II.4~~I.4~~Product X according to claim II.1~~I.1~~, wherein Product X is administered for at least 10 days in a dosage of 5-50 mg/kg bodyweight per day.

II.5 Product X according to claim II.1, wherein Product X is administered for at least 10 days in a dosage of 5-30 mg/kg bodyweight per day.

II.6~~I.5~~Product X, wherein Product X is administered for at least 10 days in a dosage of 5-50 mg/kg bodyweight per day.

II.7~~I.6~~ Product X according to claim II.6~~I.5~~, wherein Product X is administered for at least 10 days in a dosage of 25 mg/kg bodyweight per day.

II.8~~I.7~~ Product X according to claim II.1~~I.1~~, wherein Product X is administered as a nasal spray.

II.9~~I.8~~ Product X according to claim II.1~~I.1~~, wherein the treatment is an antibiotic and Product X is administered as a nasal spray.

II.10 A composition comprising Product X and antibiotic compound Z.

~~I.9 A method for therapeutic treatment of a living human, wherein the treatment comprises administration of Product X.~~

~~I.10 The method according to claim I.9, wherein the treatment comprises intravenous administration.~~

Question 20

For each of the statements 20.1-20.4, indicate whether the statement is true or false

20.1 The subject-matter of claim II.2 complies with the requirements of Article 123(2) EPC.

20.2 The subject-matter of claim II.5 complies with the requirements of Article 123(2) EPC.

20.3 The subject-matter of claim II.10 complies with the requirements of Article 123(2) EPC.

20.4 The effect provided by the distinguishing features of the subject-matter of claim II.10 with respect to D13 is a synergistic effect.