

Examiners' Report Pre-examination 2024

PART 1

Question 1

Zlatko has 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.

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

TRUE – filing fee has to be paid within one month from filing (R. 38(1) EPC; 16 April 2023 is Sunday, hence R. 134(1) EPC extended to Monday 17 April 2023)

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

FALSE – 12 months, 16 March 2024, Saturday, extended to next working day, 18 March 2024 (R. 134(1) EPC; Art. 87(1) EPC)

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.

TRUE – translation shall be filed within two months from filing (Art. 14(2) and R. 6(1) EPC, GL A-VII,1.1); if the translation is not filed in accordance with the period defined by Art. 14(2) and R. 6(1) EPC, there exists also a possibility to remedy a deficiency of filing the translation within the period, R. 57(a) and 58 EPC, GL A-VII 1.4; this period to remedy the deficiency is not the period for filing the translation;

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

FALSE – claims are to be filed within two months from invitation (R. 58 and R. 57(c) EPC).

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.

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.

TRUE – see R21(1) EPC, GL A-III, 5.5 no requirement to provide evidence in the EPC for the information provided according to R19 and R21(1) EPC

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

FALSE – see R21(1) EPC, GL A-III, 5.3 and 5.5: signature of applicant is sufficient for the rectification of the designation of the inventor

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

TRUE – GL A-III,5.5: rectification may also be requested after the proceedings before the EPO are terminated.

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

FALSE – Article 100 EPC does not provide such ground for filing an opposition.

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.

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

FALSE – Since the missing drawings are completely contained in the priority document, DE-AF, and were filed within two months of the date of filing, the date of filing shall remain the original date of filing (R. 56(2) and (3) EPC)

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

TRUE – Since the correct claims were filed within two months of the date of filing, the application shall be re-dated to the date on which the correct application documents were filed (R. 56a(3) EPC). EP-AF2 does not claim priority to DE-AF and therefore R. 56a(4) EPC does not apply.

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.

FALSE – EP-AF2 not the first filing of AF2 (see DE-AF) so the priority is invalid, Article 87(1) EPC

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

FALSE – If a second application is filed without claiming priority but within 12 months from the first application, a declaration of priority can be made within 16 months from the earliest priority date claimed (R. 52(2) EPC). Consider: 23 May 2022 + 16 months -> Saturday, 23 September 2023 (Rule 134(1) EPC)-> Monday 25 September 2023

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.

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

TRUE – The EPO has acted as the International Searching Authority. The EPO will invite the applicant to amend the description and claims in accordance with Rule 161(1) EPC soon after Euro-PCT-M enters the European phase. Any amendment or comment can be filed within six months of that communication. Substantive examination only starts after the expiry of the Rule 161 period, or if the remainder of the Rule 161 period is waived.

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.

TRUE – The applicant will be invited to pay further search fees in respect of inventions that were not searched by the EPO in the international phase (Rule 164(2)(a) EPC)

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.

FALSE – The present set of claims includes at present 35 claims, and therefore claims fees are due in accordance with Rule 162(1) EPC: however, the legal consequence of not paying claims fees for some claims is that these claims shall be deemed to be abandoned (Rule 162 (4) EPC) – and anyway, this is not the deadline for paying claims fees.

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.

FALSE – The application is not deemed to be withdrawn, if the applicant fails to comment by 15 March 2024, since the applicant may do so within the period set in accordance with Rule 161(1) EPC.

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.

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

TRUE – the deadline for filing an opposition is 9 months of the publication of the mention of the grant, i.e. 4 May 2024 (Article 99 EPC) which is a Saturday, extended to Monday, 6 May 2024. The opposition fee can still be paid within the opposition term (R. 77(1) EPC)

5.2 Lack of clarity is a ground for opposition.

FALSE – lack of clarity is not a ground for opposition (Article 100 EPC).

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

TRUE – The Opposition Division may consider other grounds of opposition which have not been invoked by the opponent of its own motion (R. 81(1) EPC).

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

FALSE – explicit in Article 115 EPC, last sentence.

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.

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

TRUE – explicit in Article 109(1) EPC.

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

TRUE – Overlooking a request for oral proceedings (Article 116(1) EPC) is a substantial procedural violation (Article 113(1) EPC, GL E-XII, 7.3). Therefore the appeal fee shall be reimbursed in full (R. 103(1)(a) EPC).

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.

FALSE – The Board of Appeal will communicate the fact that the address is missing to the appellant and shall invite him to remedy the deficiencies noted within a period to be specified (R. 99(1)(a) EPC and R. 101(2) EPC).

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

FALSE – the statement setting out the grounds of appeal shall be filed within four months of notification of the decision (Article 108 EPC).

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.

7.1 PA-1 forms part of the state of the art against EP-M2 under Article 54(3) EPC.
FALSE – PA-1 is not prior art under Article 54(3) EPC because it is not a European patent application, see 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.
TRUE and FALSE are accepted as correct answers – G1/15 GL F-VI, 1.5; claim 1 is only partially entitled to priority, i.e. for the part disclosed by EP-M1; for this disclosed part EP-M1-A1 does not form part of the state of the art according to Article 54(3) EPC (Article 89 EPC); EP-M1-A1 is not prior art according to Article 54(3) EPC for the subject-matter of claim 1 in its entirety;

7.3 PA-1 is novelty-destroying for the subject-matter of claim 1 of EP-M2 under Article 54(2) EPC.
FALSE – G1/15, GL F-VI, 1.5 claim 1 enjoys partial priority in respect of copper and zinc, PA-1 is not prior art since it was published after EP-M2 filing date.

7.4 PA-1 is novelty-destroying for the subject-matter of claim 2 of EP-M2 under Article 54(2) EPC.
TRUE – claim 2 does not enjoy the priority of EP-M1, and PA-1 discloses a fork made of copper with a hollow handle; copper is a metal. Therefore, PA-1 discloses the subject-matter of claim 2 of EP-M2.

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.

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

TRUE – Under the EPC, opponents are not entitled to a reduction of the opposition fee, see Rule 6(3) and (4) EPC.

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

FALSE – Natural persons having their residence within a Contracting State having a language other than English, French or German as an official language (such as Martha), may file documents which have to be filed within a time limit (in this case a notice of opposition) in an official language of that State (in this case Polish) (Article 14(4) EPC). A translation must be filed within one month of filing the notice of opposition, Rule 6(2) EPC, that is on 28 March 2024 [28 February 2024 + 1 month (Rule 131(4) EPC)], or by the end of the opposition period (16 March 2024 [16 June 2023 + 9 months = Saturday 16 March 2024 -> Monday 18 March 2024), whichever is later (R. 6(2) EPC)

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.

TRUE – Any party to oral proceedings before the EPO may use one of the other official languages of the EPO, on condition that such party gives notice to the EPO at least one month before the date laid down for such oral proceedings (Rule 4(1) EPC, first sentence). The European Patent Office shall, if necessary, provide at its own expense interpretation into the language of the proceedings, or, where appropriate, into its other official languages, unless such interpretation is the responsibility of one of the parties (R. 4(5) EPC). Alternatively, the party may make provision for interpreting into the language of the proceedings, English (Rule 4(1) EPC, second-to-last sentence).

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

TRUE – any party may use an official language of a Contracting State, if the party provides for interpretation into the language of the proceedings (Rule 4(1) EPC, second-to-last sentence).

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.

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

TRUE – Article 11(1)(iii)(c) and Rule 20(1)(b) PCT.

The receiving Office shall accord as the international filing date the date of receipt of the international application, provided that that Office has found that, at the time of receipt, the international application contains the name of the applicant indicated in a way which allows the identity of the applicant to be established, even if the name is misspelled.

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.

FALSE – Art. 153, Rule 159 EPC: In respect of an international application for which the EPO is a designated or elected Office, the applicant shall perform the acts for entry into the European phase within thirty-one months from the date of filing of the application.

Filing date: 20/09/2021 + 31m [R. 159(1) EPC, Rule 131(4) EPC] => Saturday 20/04/2024
=> R. 134(1) EPC extended to Monday 22 April 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.

FALSE – Rule 132(2) EPC refers to periods specified by the European Patent Office, which may be extended upon request, if done so before the expiry of such periods. The 31 months period defined in Rule 159 is a fixed period specified by the EPC, which may not be extended.

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

TRUE – The Applicant may request further processing of the European patent application (Art. 121(1) EPC) with reference to the EP regional phase entry. The further processing shall be requested within 2 months from the notification of Communication of Loss of Rights under R. 112 (1) EPC (Rule 135(1) EPC). Such Communication will be sent to the Applicant after the expiration of the 31 months period of Rule 159 EPC, that is after 22 April 2024. Therefore, on 19 June 2024, the two months period for replying to the Communication of course is still running, and it will be possible to validly requesting further processing for performing the requirements for the entry into the EP regional phase (Art. 121(1), (2) EPC).

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.

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

TRUE – There are no nationality or residence restrictions for filing a European patent application with the EPO, Article 58 EPC.

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

TRUE – The EPO is the receiving Office competent for applicant Christina, who has her residence within one of the Contracting States (Germany), Article 151 EPC, Rule 157(1) EPC and Rule 19.1(a) PCT. If there are two (or more) applicants, the requirements of Rule 19.1 PCT regarding where to file are satisfied if the international application is filed with the competent receiving office of at least one of the applicants, Rule 19.2(i) PCT.

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

TRUE – A PCT application can be validly filed before the International Bureau (IB) whatever the nationality or residence of the applicant, Rule 19.1(iii) and Rule 19.2 (ii) PCT.

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.

TRUE – Only the IB can record the residence change upon the applicant's request, Rule 92bis.1.(a) (i)PCT.

PART 3

Question 11

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

TRUE – see paragraph [006] disclosing an electronic cigarette (100) comprising a liquid container (130, an atomiser (120) in connection with the liquid container (130), a short-range communication component (170) and a controller (140). Vapour production is activated (push button in paragraph [006]). The scope of claim I.1 is formulated with an “or” clause that broadens such scope to cover either of the alternatives.

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

FALSE – The second embodiment of the application covers only the use of fingerprints (paragraph [008]), not the use of scheduling.

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

TRUE – Vapour production can be activated with a pushbutton or a pressure sensor in the third embodiment (paragraph [009]) as a particular form of activation, 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.

FALSE – The fourth embodiment is the combination of the second embodiment (no scheduling, paragraph [008]) with the third one. The second embodiment of the application covers only the use of fingerprints (paragraph [008]), not the use of scheduling.

Question 12

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

TRUE – Such information is read by the short-range communication component 12 in D1, paragraph [004], which can prevent two cases of unauthorized use of disposable cartridges, refilled cartridges or cartridges with non-authorized identifiers

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

FALSE – D1 discloses an electronic cigarette (“electronic cigarette”, paragraph [002]) comprising a liquid container (“disposable cartridge 20”, paragraph [002]), an atomiser (“controller 15 connected to ... an atomiser”, paragraph [002]) in connection with the liquid container, communication component (“communication component 12”, paragraph [002]), and a controller (“controller 15”, paragraph [002]) for activating vapour production of the electronic cigarette (“Upon authenticating the identifier 23, the controller 15 sends a signal to the atomiser to enable vapour production”, paragraph [004]).

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

TRUE – D1 does not disclose scheduling.

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

TRUE – Paragraph [002] of D1 discloses an electronic cigarette provided with such components of liquid solutions, directed to comply with health regulations in paragraph [003].

Question 13

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

FALSE – D2 does not refer to any health risk.

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.

FALSE – D2 discloses a range of 5-7 mg/ml between the end points (0-20 mg/ml in paragraph [013] of the application), therefore this range is not novel (Guidelines G-VI, 8).

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

FALSE – D2 does not disclose reading information with a communication component from an RFID tag, but from a printed label.

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

TRUE – D2 discloses further chemical substances (“chemical substances like nicotine, propylene glycol, vegetable glycerine and banana flavouring”) which are combined with banana flavouring (paragraph [004]), in particular with a recipe with 5-7 mg/ml.

Question 14

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

TRUE – basis in paragraph [006]

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

FALSE – The fingerprint sensor is an alternative to the push button (paragraph [008]). In addition, claim II.2 lacks the features disclosed in combination with the fingerprint sensor 210 in paragraph [008].

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

FALSE – The application as filed does not directly and unambiguously disclose that the short-range communication signal allows the activation of vapour production, for instance without a controller. Paragraph [007] discloses that the controller allows or prevents the activation of vapour production.

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

FALSE – Claim II.4. lacks the features disclosed in combination with the pressure sensor and it is broader than the disclosure of paragraph [009]: that the pressure difference is created by the user inhaling through the mouthpiece (110).

Question 15

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

FALSE – D1 see paragraph [004], in which the controller prevents vapour production if the identifier of the RFID tag is deemed invalid after reading.

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

TRUE – no disclosure in the prior art about an electronic cigarette that delivers therapeutical drugs as part of the smoking experience.

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

FALSE – devices delivering therapy do not fall under the exception to patentability pursuant to Article 53 (c) EPC concerning methods for therapy, that does not extend to products.

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.

TRUE – D1 would be chosen as closest prior art, in view that it discloses all of the features of the claim including electronic verification of the liquid container apart from detecting a pressure difference when inhaling. The French version of claim III.3 using “courte durée” instead of “courte portée” does not impact the answer.

The effect of this differentiating feature is to allow the activation of the vapour production of the electronic cigarette in a convenient way to the user.

D1 does not disclose any detection of pressure differences to allow the activation the vapour production. Therefore, D1 neither discloses nor hints towards the solution claimed.

D2 is not concerned with detecting pressure differences or allowing the activation of vapour production with an electrical power supply. The person skilled in the art would not use D2 to achieve the effect sought. Therefore, it also involves an inventive step over D1 even if combined with D2.

PART 4

Question 16

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

FALSE – there is no disclosure in the application of any effect of Product X as antifungal (or antiparasitic). According to the description (paragraph [08]) the skilled person would require a research program based on trial and error to achieve such effects, which is indicative of lack of sufficient disclosure (GL F-III.3).

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

FALSE – there is no disclosure in the application of any effect as antifungal or antiparasitic. According to the description (paragraph [08]) the skilled person would require a research program based on trial and error to achieve such effects, which is indicative of lack of sufficient disclosure (GL F-III.3). The claim is not sufficiently disclosed over the “whole area claimed”, GL F-III.1.

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

TRUE – see table 1 and paragraph [01], [07] and [09] and [10], disclosing experimental data supporting the antibiotic effect of the use of product X.

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.

FALSE – The EPO would issue a Rule 62a EPC communication in such case.

Question 17

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

TRUE – Article 53(c) EPC and GL G-II, 4.2.1.2

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

FALSE – said claim is only limited to the treatment as an antiviral, the types of viruses are only optional because the term “more particular” is used, GL F-IV, 4.9.

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.

TRUE – The description on paragraph [12] provides basis to amend the claim compliant to Article 123(2) EPC to a range of at least 3 days. Such an amended claim covers also applying Product X for 7 days.

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

FALSE –The effect of the invention is reached without a nasal spray, see table 1 and paragraph [12], GL F-IV.4.5.2. The administration as a nasal spray improves the effect, see table 1 and paragraph [13] of the application and is declared as being not essential.

Question 18

18.1 The subject-matter of claim I.1 is not novel over D1.

FALSE – None of the prior art documents discloses the usage of Product X as an antiviral, an antibiotic, an antifungal or an antiparasitic, second medical use – Article 54(5) EPC, GL G-VI.7.1).

18.2 The subject-matter of claim I.5 is not novel over D1.

TRUE – because claim I.5 does not refer to a second medical use, Article 54(5) EPC does not apply. GL G-VI, 6.1.2. In addition, D1 explicitly discloses endpoint of 50 mg/kg bodyweight per day and endpoint of 6 months of overlapping ranges, GL G-VI, 8(iii).

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

TRUE and FALSE are accepted as correct answers – Category of claim I.7 might be interpreted as being unclear because dependent claims I.7 does not repeat “product X for use ...”, see GL G-VI, 7.1.5. If claim I.7 is interpreted as being directed to the product per se, the term “is administered as nasal spray” could be interpreted as not limiting the product X which is disclosed by D2. If claim I.7 is interpreted as a second medical use claim, the steps of administration as nasal spray would be limiting and, thus, novel over D2. Since the answer depends on the above interpretation, points are awarded for both answers.

18.4 The subject-matter of claim I.1 is not novel over D3.

TRUE – D3 discloses antibiotic treatment of product X referring to the Lyme disease, which is a bacterial infection, as made explicit in D3.

Question 19

19.1 The subject-matter of claim I.1 involves an inventive step over D3 alone.

FALSE – D3 discloses that Product X has an antibiotic effect and, thus, the subject-matter of claim I.1 is even not novel over D3.

19.2 For the following statement, assume that D1 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 D1 is that there is no hint in any one of documents D1, D2 and D3 that Product X has an antiviral effect.

TRUE and FALSE are accepted as correct answers – Category of claim I.3 might be interpreted as being unclear because dependent claims I.3 does not repeat “product X for use ...”, see GL G-VI, 7.1.5. If claim I.3, despite the reference to “the treatment” is interpreted as being directed to the product per se, the term “wherein the treatment is antiviral, more particularly a treatment against rhinovirus, influenza virus or coronavirus” could be interpreted as not limiting the product X, the subject-matter of claim I.3 would not be novel and, thus, not inventive over the prior art. If claim I.3 is interpreted as a second medical use claim (because it refers to “the treatment”, the subject-matter would be novel and inventive over the prior art because none of the documents D1, D2 or D3 discloses or hints an antiviral effect. Since the answer depends on the above interpretation, points are awarded for both answers.

19.3 The subject-matter of claim I.6 is novel over D1.

FALSE – because claims I.5 and I.6 do not refer to a second medical use, Article 54(5) EPC does not apply, GL G-VI, 6.1.2.

However, **TRUE and FALSE are accepted as correct answers.** Category of claim I.6 might be interpreted as being unclear because dependent claim I.6 does not define “product X for use ...” see GL G-VI, 7.1.5.

19.4 The difference of the subject-matter of claim I.8 over D3 as closest prior art may be regarded as not providing a technical effect.

TRUE and FALSE are accepted as correct answers – Category of claim I.8 might be interpreted as being unclear because dependent claims I.8 does not repeat “product X for use ...”, see GL G-VI, 7.1.5. If it is interpreted as a product claim, there is no difference providing a technical effect. If it is interpreted as a product claims with a medical use, the technical effect would be a higher suppression factor, see table 1, paragraph [13].

Question 20

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

FALSE – Only three specific examples of RNA viruses disclosed in the application (paragraph [10]). Claim II.2 defines an unallowable intermediate generalization GL H-V.3.2.1; there is no disclosure of the general group of RNA viruses.

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

FALSE – The subrange of 5-30 mg/kg is not disclosed and not directly and unambiguously derivable from the application as filed.

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

TRUE and FALSE are accepted as correct answers – For the English and French versions, the answer is True. Paragraph [11] provides basis to directly and unambiguously derive the subject-matter. For the German version, the answer depends on how the last sentence of paragraph [11] is interpreted.

20.4 The effect provided by the distinguishing features of the subject-matter of claim II.10 with respect to D3 is a synergistic effect.

TRUE – see description [11] disclosing a synergistic effect (GL G-VII.7): “we observed a suppression factor for streptococcal infection (bacterial infection) that was stronger than the sum of the individual effects of Product X and compound Z”.



EN

EUROPEAN QUALIFYING EXAMINATION 2024

Pre-examination

Documents for part 3

- | | | |
|---|--------------------------------|------------------|
| * | Description of the application | 2024/P3/EN/1-9 |
| * | Documents D1 and D2 | 2024/P3/EN/10-12 |

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

310: pressure sensor

510: secured electronic identification tag

Drawings of the application

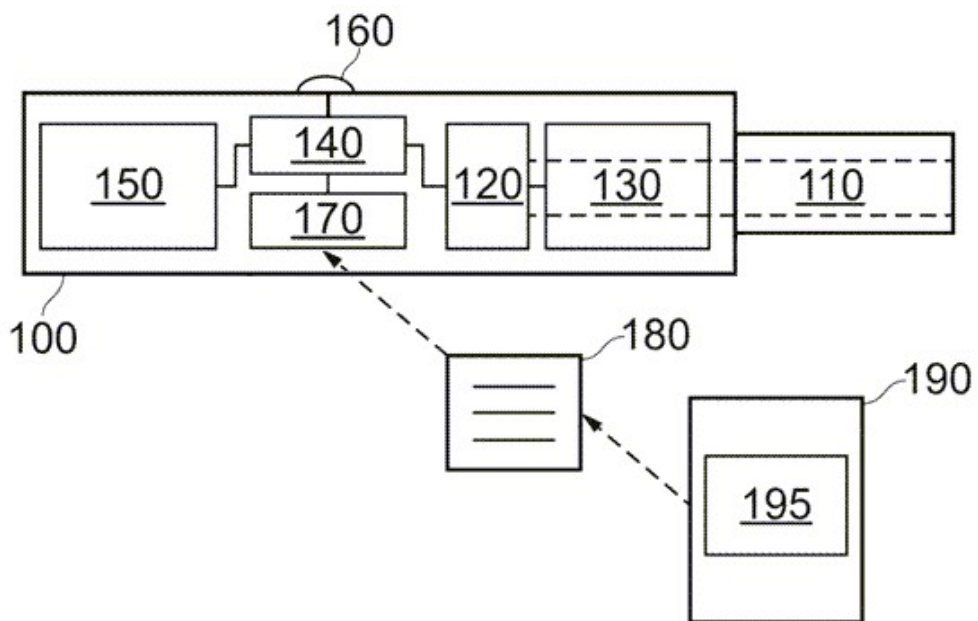


FIG. 1

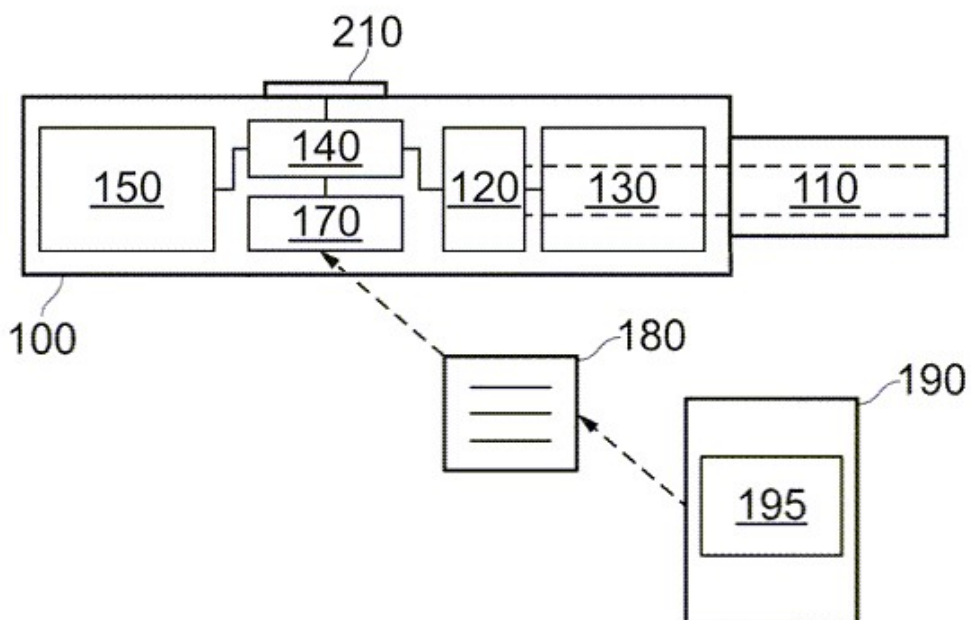


FIG. 2

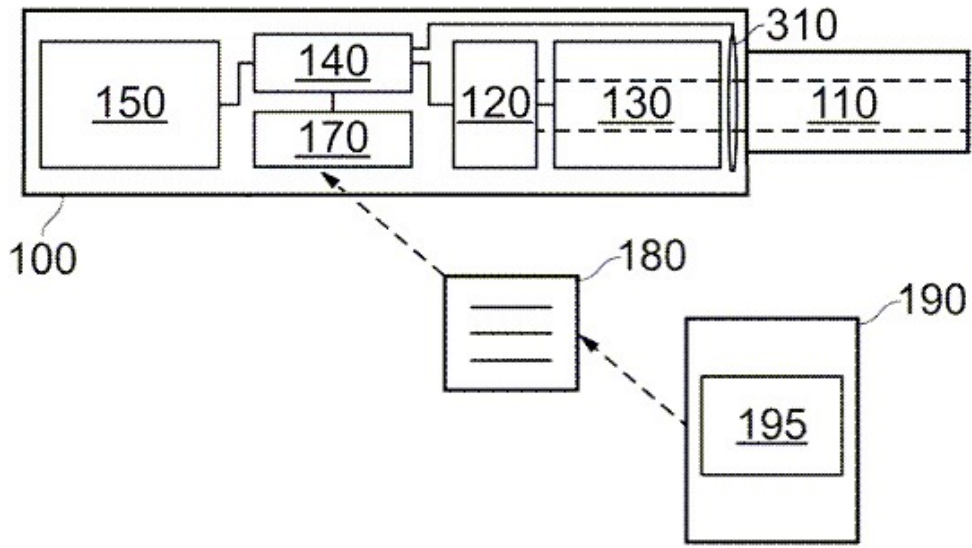


FIG. 3

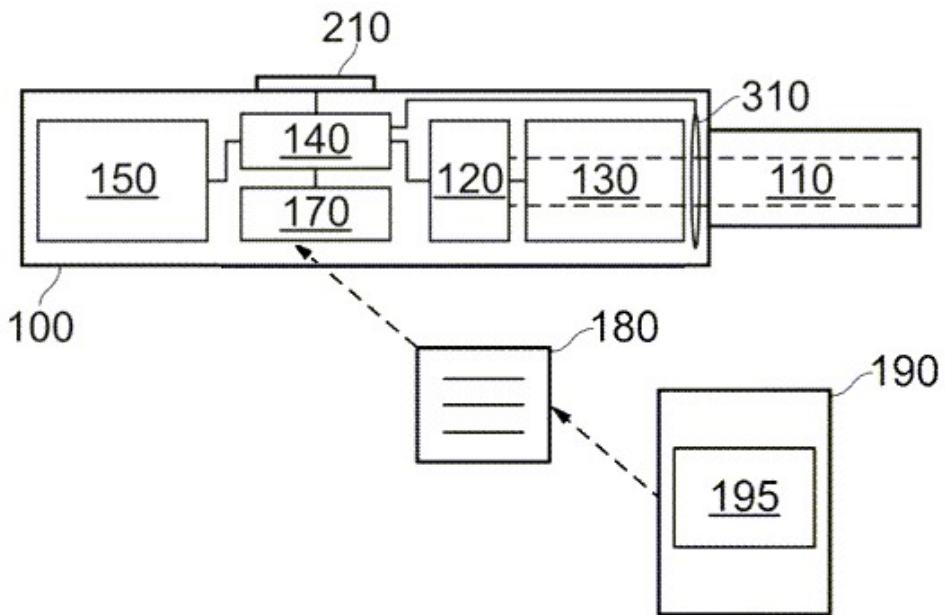


FIG. 4

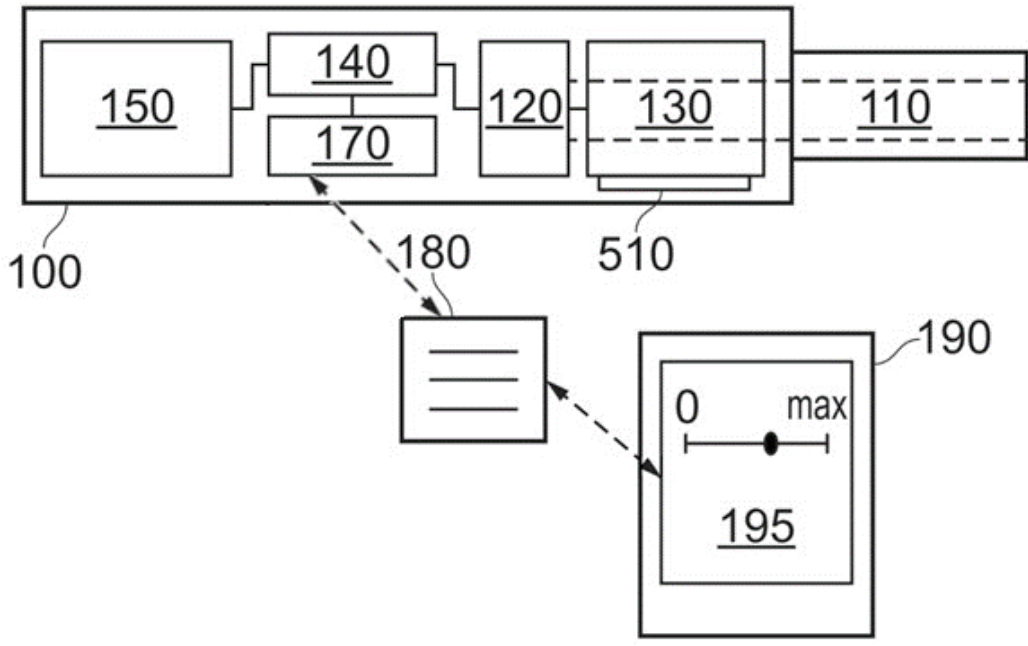


FIG. 5

Document D1, publication date 28 June 2023

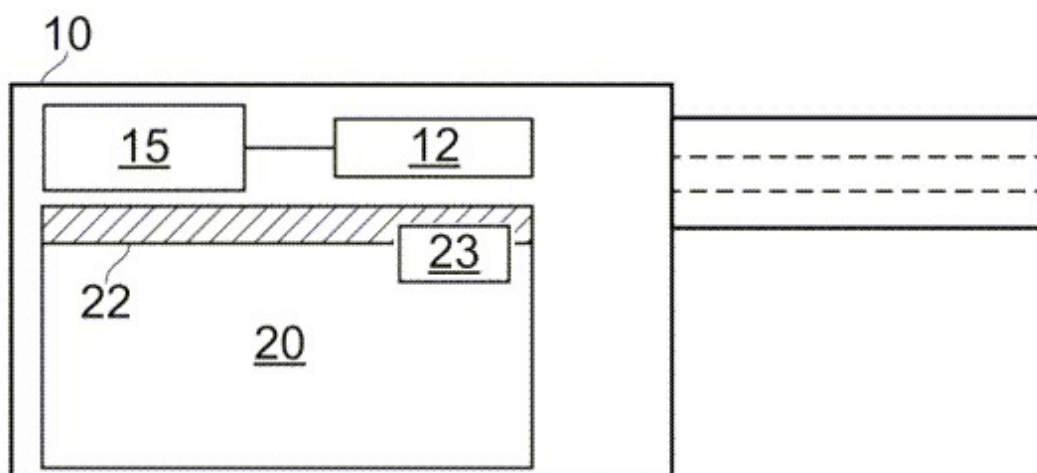
[001] There is a growing trend of counterfeit products on the electronic cigarette market, in particular liquid solutions for electronic cigarettes that are personalised by users who are unaware of the health risks posed by such liquid solutions. The use of counterfeit or personalised liquid solutions 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.



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.



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EUROPEAN QUALIFYING EXAMINATION 2024

Pre-examination

Documents for part 4

- | | | |
|---|--------------------------------|----------------|
| * | Description of the application | 2024/P4/EN/1-5 |
| * | Documents D1, D2 and D3 | 2024/P4/EN/6-8 |

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.

Assume that documents D1, D2 and D3 are prior art documents under Article 54(2) EPC.

Document D1

[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. D1 – Advertisement in *The Local Sun*, published on the 15 August 2019

Document D2

[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 D3

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.