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Datasheet for the decision of 16 April 2024

Case Number: T 2649/22 - 3.2.01

Application Number: 11820510.3

Publication Number: 2608686

IPC: A24F47/00, A61M15/06

Language of the proceedings: EN

Title of invention:
INHALATION DEVICE INCLUDING SUBSTANCE USAGE CONTROLS

Patent Proprietor:
JT International S.A.

Opponent:
Philip Morris Products S.A.

Headword:

Relevant legal provisions:
EPC 1973 Art. 52(1), 54, 56, 83, 123(2)
RPBA 2020 Art. 12(3), 12(5)

Keyword:
Novelty (yes)
Inventive Step (yes)
Amendments - Compliance with Art. 123(2) EPC (yes)
Sufficiency of disclosure (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2649/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 16 April 2024

Appellant: (Opponent)	Philip Morris Products S.A. Quai Jeanrenaud 3 2000 Neuchâtel (CH)
Representative:	Abitz & Partner Postfach 86 01 09 81628 München (DE)
Respondent: (Patent Proprietor)	JT International S.A. 8, rue Kazem Radjavi 1202 Geneva (CH)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 November 2022 concerning maintenance of the European Patent No. 2608686 in amended form.**

Composition of the Board:

Chairwoman	S. Fernández de Córdoba
Members:	V. Vinci
	S. Mangin

Summary of Facts and Submissions

I. The appeal filed by the appellant (opponent) is directed against the interlocutory decision of the opposition division to maintain the European patent No. 2 608 686 in amended form.

In its decision the opposition division held that the subject-matter of dependent claim 9 according to the main request filed on 28 July 2022 did not meet the requirements of Article 123(2) EPC and decided to maintain the patent according to the auxiliary request 0 filed during oral proceedings. In particular, the opposition division took the view that this amended auxiliary request complied with the requirements of Articles 83, 84 and 123(2) EPC and that the subject-matter of independent claims 1 and 9 was novel and involved an inventive step within the meaning of Articles 52(1), 54 and 56 EPC in view of the following prior art documents:

D3 : EP 2 468 118 A1
D6 : US 6 260 549 B1
D9 : WO 2008/01 6156 A1
D12: US 5 060 671
D18: US 2008/0017193 A1

The questions of the validity of priority claimed by D3 and whether this document represented a state of the art pursuant Article 54(3) EPC were raised by the parties. Documents D12 and D18 filed after expiry of the opposition period were admitted in the opposition proceedings.

II. With the communication according to Article 15(1) RPBA dated 3 January 2024, the Board informed the parties of its preliminary assessment of the case.

Oral proceedings pursuant to Article 116 EPC were held before the Board on 16 April 2024 by videoconference.

III. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed and hence that the decision to maintain the patent according to the first instance auxiliary request 0 be confirmed (main request) or, in the alternative, that the patent be maintained on the basis of one of the auxiliary requests 1, 2, 2A, 2B, 2B1, 2C, 2C1, 3, 3A, 3B, 3B1, 4, 4A, 4A1, 5, 5A, 5B, 5C, 5C1, 6, and 7 filed with the reply to the statement of grounds of appeal of the appellant (opponent).

IV. Independent apparatus claim 1 of the patent as maintained reads as follows (labelling of the features according to the decision):

F1 "*A smoke inhalation apparatus (100) comprising:*

F2 *a first cartridge (114) comprising*

F2-1 *a first release device (118) configured to*

F2-2 *release a variable amount of a first substance into a housing (112);*

F3 *a sensor (240, 291, 292, 293, 294, 295); and*

F4 *a controller (124, 224) configured to*

F4-1 *receive data from the sensor (240, 291, 292, 293, 294, 295);*
F4-2 *determine an amount of first substance released by the first cartridge (114) based on the data; and*

F4-3 *estimate a remaining amount of first substance in the first cartridge (114) based on the determined amount of first substance."*

Independent method claim 9 of the patent as maintained reads as follows:

"A method for providing smoke inhalation apparatus information comprising:

receiving data from a sensor (240, 291 , 292, 293, 294, 295);

determining an amount of a first substance released by a first cartridge (114) based on the data,

wherein the first cartridge (114) comprises a first release device (118) configured to release a variable amount of the first substance into a housing (112); and

estimating a remaining amount of first substance in the first cartridge (114) based on the determined amount of first substance."

Reasons for the Decision

Article 123 (2) EPC: Amendments

1. The patent as maintained meets the requirements of Article 123(2) EPC as correctly assessed by the opposition division in the decision under appeal.

1.1 The only amendment under discussion is the introduction in feature F2-2 of independent claims 1 and 9 of the additional information that the first release device is configured to release a *"variable amount"* of a first substance into a housing. It is uncontested that the release of a variable amount of the first substance by the release device is not verbatim disclosed in the application as originally filed. However, the opposition division took the view that this feature was directly and unambiguously derivable for a person skilled in the art reading the originally filed application as a whole and in particular from the information presented in paragraph [0021] stating that:

"*The first release device 118 can be configured to control or meter the amount or rate of first substance released from the first cartridge 114*" (emphasis added)

read in combination with the passages in paragraph [0041] of the WO publication stating that (see page 10, line 3 onwards)

"Different users have different usage habits: One person may prefer long hard puffs and another person may like short shallow puffs. A person having long hard puffs usually finishes a cigarette in a less number of puffs than the person having the short shallow puffs",

and that (see page 11, lines 3 to 8)

"For this reason, ... Another sensor such as a current sensor for the releasing means or the power source or a flow sensor with the air speed measurement can be applied to estimate the quantity of the substance use whenever the user draws the air through the device, and this information can be used along with the timer to calculate the more accurate amount of the substance use."

1.2 With their appeal the appellant (opponent) contested the finding of the opposition division in respect of Article 123(2) EPC and argued that the expression *"to control or meter"* in paragraph [0021] could also be read as meaning to *"set a limit on an intake amount of the substance per use."* This interpretation was allegedly supported by paragraph [0018], first sentence on page 4 of the application as filed. In the appellant's (opponent's) view, setting a limit on an intake amount of the substance per use was not the same as to provide a first release device configured to release a variable amount of substance as required by claim 1 as amended. It was also pointed out that paragraph [0021] contained 4 options (*"control or meter"* and *"amount or rate"*), this circumstance speaking against the conclusion of the opposition division that the contested amendment was directly and unambiguously derivable from this paragraph. Finally the appellant (opponent) submitted that controlling or metering the amount of first substance within the meaning of paragraph [0021] did not literally and technically equate the information introduced in claim 1 requiring a device *"configured to release a variable amount"*, i.e a device with particular structural limitations which achieved a release of a variable

amount of a first substance. The appellant (opponent) pointed out that paragraph [0042] disclosed the combination of structural features of the release device that according to the application as originally filed were required to obtain the claimed release of a variable amount, in particular a timer and a plurality of sensors. As these technical features which rendered the release device *"configured to"* release a variable amount were omitted in claim 1, the introduction of the mere general teaching in isolation that the device was configured to release a variable amount resulted in an unallowable intermediate generalisation of the specific embodiment on which the amendment at issue was allegedly based.

1.3 The arguments of the appellant (opponent) are not convincing for the following reasons:

The Board, in agreement with the opposition division and the respondent (patent proprietor), considers that the cited last sentence of paragraph [0021] as filed provides the person skilled in the art with a clear hint that the released amount can be varied during operation of the claimed inhalation apparatus to adapt it to different smoking habits of the users. If this was not the intention, i.e. if this amount was intended to remain constant, there would be no need to control or meter the amount of first substance released. This interpretation of the expression *"to control or meter"* in the sense of implying a variation of the amount of first substance released by the release device is supported by the cited statements in paragraph [0041] from which the person skilled in the art directly and unambiguously derives, irrespective of the technical features of the specific embodiment, the general teaching underlying the contested patent and now

clarified by the amendments introduced in feature F2-2 of claim 1 that the claimed smoke inhalation apparatus must be able to accommodate different usage habits regarding the length of the puffs taken whereby, to do so, the release device has to be configured (and controlled) in such a way to release larger amounts of first substance in the case of intakes with longer puffs and smaller amounts of first substance in the case of intakes with shorter puffs. In view of the above, the Board considers that - contrary the appellant's (opponent's) allegation - it is not necessary to introduce in claim 1 further technical features of the release device disclosed in paragraph [0042] as the timer and an additional sensor in order to comply with the requirements of Article 123(2) EPC. The same reasoning and conclusions apply to method claim 9 which contains the same amendment.

Article 83 EPC: Sufficiency of Disclosure

2. The patent as maintained meets the requirements of Article 83 EPC as correctly assessed by the opposition division in the decision under appeal.

2.1 This finding is contested by the appellant (opponent) with their appeal. At the oral proceedings the parties relied in this respect on the respective arguments presented in writing and did not make any further submissions. Consequently, the Board has no reason to deviate from the assessment of this alleged issue presented in its preliminary opinion which is herewith confirmed and reads as follows:

2.2 Irrespective of the admissibility issue raised by the respondent (patent proprietor) against this objection, the patent as maintained meets the requirements of

Article 83 EPC as stated in the decision under appeal. Under discussion is whether the patent provides sufficient information on how the release device must be designed such that it is *"configured to release a variable amount of first substance"* (see feature F2-2 of claim 1 and corresponding feature of claim 9). The Board shares the view of the opposition division and the respondent (patent proprietor) that the claimed functionality is achieved according to the contested patent by using the functionality of the timer (248) as described in paragraphs [0026] and [0027]. Contrary to the allegation of the appellant (opponent), the Board has no doubt that a person skilled in the art has no difficulties in controlling the variation of the amount of first substance released by the release device depending on the length of the puff by using the information provided by the intake sensor in combination with the information provided by the timer.

Articles 52(1) and 54 EPC: Novelty

3. The subject-matter of independent claims 1 and 9 of the patent as maintained is novel over the prior art within the meaning of Articles 52(1) and 54 EPC as correctly assessed by the opposition division in the decision under appeal.

3.1 The appellant (opponent) reiterates following lines of novelty attack based on D3, D6, D9, D12 and D18 which are however not convincing, and this irrespective of the questions raised by the respondent (patent proprietor) whether document D3 represents a state of the art pursuant to Article 54(3) EPC and of the disputed admissibility of the novelty attacks based on D3, D9 and D12.

Novelty over D3

3.2 Under discussion is whether the smoke inhalation apparatus disclosed in this prior art document comprises a release device configured to release a variable amount of a first substance in the housing of the apparatus according to feature F2-2 of claim 1.

3.3 The appellant (opponent) pointed out that as claim 1 did not contain any structural limitation for the release device, it was only required by the claim that the device was *"configured to"* and hence *"suitable for"* releasing a variable amount of substance. It their opinion the heater 119 of D3 was also suitable - when appropriately controlled by the controller 109 - to carry out the claimed functionality.

3.4 This reasoning cannot be followed:

The Board considers that the wording *"device configured to"* inherently implies that auch a device is inherently structured and controllable via an appropriate control software installed on and run by the controller in such a way to perform the specified functionality. As correctly held by the opposition division and the respondent (patent proprietor), there is no hint indicating that the release device of the smoke inhalation apparatus disclosed in this prior art document, namely the heater 119, is controlled by the controller 109 in such a way to release in operation a variable amount of substance. As convincingly argued by the opposition division and the respondent (patent proprietor), without any information as to how and when the heater 119 is deactivated after having been activated by the user's puff, i.e whether the heater is automatically deactivated after a predefined period of

time or alternatively only when no intake is longer sensed, it cannot be directly and unambiguously derived whether the release device of the known apparatus is configured to release a constant or a variable amount of first substance as it will be respectively the case according to the first or second alternative deactivation modes mentioned above. Furthermore, the possibility alleged by the appellant (opponent) that the heater after deactivation will not cool down immediately and will hence release a little additional amount of first substance for a certain period of time cannot be equate to a purposive configuration of the release device to release a variable amount. In addition it must be assumed that this theoretical additional amount of first substance which might be released until the heater has fully cooled down remains the same after each deactivation, thereby not resulting in any variable release. Finally, while the Board in principle agrees with the observation of the appellant (opponent) that a user taking a longer, harder puff would necessarily inhale more aerosolized liquid than a user taking a shorter, shallower puff, it cannot be definitely concluded that for this reason the release device of D3 is configured to release a variable amount depending on the length of the puff.

3.5 At the oral proceedings the appellant (opponent) argued that contrary to the view of the opposition division document D3 indeed provided in paragraph [0050] an indication on how/when the heater 119 was deactivated. It was explained that according to the embodiment described therein, the heater was deactivated when its temperature reached a predetermined threshold, this event indicating that the cartridge was nearly to be empty. The appellant (opponent) concluded that this situation resulted in a different amount of substance

to be released when the heater was deactivated during a puff due to overheating.

3.6 Irrespective of the admissibility of this allegedly new line of arguments which was contested by the respondent (patent proprietor), the reasoning of the appellant (opponent) is not convincing:

Firstly - as observed by the respondent (patent proprietor) - it is not unambiguously clear whether upon reaching the critical temperature the heater is deactivated immediately or only at the end of the puff. Only in the first case there is a variation of the amount release during the last puff compared with that associated the preceding puff. Furthermore, the Board takes the view that the cited passage merely discloses a safety measure which takes place only under particular circumstances, namely when the cartridge is depleted. However, there is no disclosure of a release device configured to purposively release, under normal operation conditions, a variable amount of substance.

3.7 These conclusions apply to the assessment of novelty of independent method claim 9 which recites the corresponding distinguishing method features.

Novelty over D9

3.8 The appellant (opponent) put forward that contrary to the assessment of the opposition division features F4-2 and F4-3 of claim 1 of the patent as maintained were directly and unambiguously derivable from the second embodiment of this prior art apparatus depicted in figures 8 and 9 and described on page 22, line 23 onwards. The appellant (opponent), after having extensively explained the functioning of this known

inhalation apparatus, pointed out that the only difference between the first embodiment shown in figures 4 to 6 and said second embodiment was that in the latter an optical sensors 41 and 42 instead of strain gauge 37 were used to determine the amount of a first substance released by the cartridge (7). Regarding in particular the disputed disclosure of feature F4-2, it was argued that at least an indirect determination of the amount of the first substance released by the first cartridge was derivable from the information presented on pages 28-30. This first delivery step was followed by a *"correction step"* required to ensure that the full dose of medicament was delivered. Regarding feature F4-3 it was argued that it was directly and unambiguously derivable from the teaching presented on page 28, line 10-24 and page 30, line 5 onwards.

3.9 The reasoning of the appellant (opponent) is not convincing:

The Board concurs with the opposition division and the respondent (patent proprietor) that according to the operation described on pages 28 and 30 referred to by the appellant (opponent), it is not an amount of first substance released by the first cartridge which is determined based on the data provided by the sensors (i.e the outputs of the optical sensors 41 and 42), as required by feature F4-2 of claim 1, but rather the time at which the predetermined amount of substance present between the first and second level is delivered (see Figures 9A and 9B). This determination is then used to calculate the medicine ejecting amount per unit time. Therefore, the approach adopted in D9 is conceptually different from that of the contested patent and is not considered to fall under the wording

of F4-2 which requires a determination of a quantity of substance released based on the data provided by the sensor and not of a time interval required for delivering a predetermined amount of substance as it is instead the case of the apparatus of D9. As a consequence, also feature F4-3, which presupposes the determination of said *"determined amount"* of first substance released, is not directly and unambiguously disclosed in this prior art document and this irrespective of the question raised by the respondent (patent proprietor) whether the stored *"medicine remaining amount"* mentioned on page 29, line 6-7 of D9 is indeed the remaining amount of first substance *"in the first cartridge"* recited in feature F4-3 of claim 1 as maintained as alleged by the appellant (opponent).

3.10 These conclusions apply to the assessment of novelty over D9 of independent method claim 9 which recites the corresponding distinguishing method features.

Novelty over D6, D12 and D18

3.11 At the oral proceedings the parties relied on the respective arguments presented in writing and did not make any further submission regarding these novelty attacks. Consequently, the Board has no reason to deviate from the positive assessment of novelty in respect of these prior art documents as presented in its preliminary opinion which is herewith confirmed and reads as follows:

Novelty over D6

3.12 The appellant (opponent) contested the view of the opposition division that document D6 did not directly and unambiguously disclose feature F2-2 of claim 1 and

the corresponding feature of claim 9. The appellant (opponent) referred to the passage in column 12, lines 31-36 of D6 teaching that *"Though not illustrated, conventional electronic circuitry, as would be known to one of ordinary skill in the art, are included in the embodiment described above that regulates the medication dosage by monitoring flow rate and time between start of inspiration."* It was argued that according to common understanding supported by the definition provided by the *"Merriam-Webster"* dictionary labelled as evidence D19 and submitted by the appellant (opponent) with the statement of grounds of appeal, the verb *"to regulate"* indicated the action of varying a certain parameter and thus, in the case of D6, the amount of first substance that it released as required by feature F2-2 of claim 1.

3.13 However, the Board shares the view of the opposition division and the respondent (patent proprietor) that the verb *"to regulate"* according to a further definition also provided by evidence D19 can also be understood in the context of the cited passage of D6 as meaning that the medication dosage is controlled in such a way to match a predetermined value, as it is normally required when a medicament is administered to a patient, and hence not necessarily that the dosage is varied. This interpretation is supported by the passage in column 9, lines 26-28 of D6 cited by the opposition division and the respondent (patent proprietor). The further argument of the appellant (opponent) who referred to the open- and closed-mouth intake techniques described in D6 is not convincing because, as correctly argued by the respondent (patent proprietor), the specific smoking technique applied is not detected by the known apparatus and therefore the activation of the apparatus and the consequent release

of the first substance is in any event independent on the technique adopted by the users when taking a puff.

Novelty over D12

3.14 The appellant (opponent) maintained that contrary to the assessment of the opposition division features F2-2 and F4-3 were directly and unambiguously disclosed in this prior art document. The respondent (patent proprietor) conversely alleged that beside features F2-2 and F4-3, D12 did not also directly and unambiguously disclose features F2 and F4-2 of claim 1. The same arguments were presented regarding the corresponding features of claim 9.

3.15 The Board follows the view of the opposition division and the respondent (patent proprietor) that irrespective of the assessment of the other features under discussion, D12 does not disclose neither a determination of an amount of first substance released based on data received from the controller/puff actuator 908 (feature F4-2) nor an estimation of a remaining amount of this substance based on said determined amount (feature F4-3). Therefore, at least for these reasons, document D12 is not prejudicial to novelty of the subject-matter of claims 1 and 9 of the patent as maintained. This conclusion which was presented in the preliminary assessment of the case provided in writing by the Board was not contested by the appellant (opponent) in the course of the further proceedings.

Novelty over D18

3.16 Regarding document D18, the Board shares the view of the opposition division and the respondent (patent

proprietor) that the apparatus described in this prior art document is meant to deliver a single and predetermined full dose of medicament when the protruding portion of the aerosol canister is depressed. The allegation of the appellant (opponent) that it would be in principle possible to partially depress the activation protrusion and hence to discharge a lower amount of medicament resulting in the claimed release of a variable amount of substance, is not directly and unambiguously supported by any statement of this prior art document. In this respect the Board agrees with the respondent (patent proprietor) that the cited passage in paragraph [0010] of D18 concerning the problem of avoiding *"partial release"* refers to the prior art cited in D18 and does not necessarily apply to the apparatus disclosed in D18. Therefore feature F2-2 of independent claim 1 and the corresponding feature of independent method claim 9 are not directly and unambiguously disclosed in D18.

Alleged non-uniform application of the concept of disclosure

4. In the statement of grounds of appeal the appellant alleged that a non-uniform concept of disclosure has been applied by the opposition division when assessing compliance with Article 123(2) EPC on one side and novelty over the cited prior art on the other side. No further submissions in this regard were made by the appellant (opponent) after the communication of the Board. The Board has thus no reason to deviate from the conclusion expressed in the preliminary opinion and thus concurs with the view of the respondent (patent proprietor) that this allegation is based on a partial reading of the reasoning provided in the decision and is therefore not justified.

Articles 52(1) and 56 EPC: Inventive Step

5. At the oral proceedings the parties expressly declared that they did not wish to make any further submissions regarding the issue of inventive step. Consequently, the Board has no reason to deviate from the assessment provided with its preliminary opinion which is herewith confirmed and reads as follows:

5.1 The Board ascertains that the appellant (opponent), after having duly substantiated lack of novelty over D3, D6, D9, D12 and D18, stated at the end of the relevant paragraphs VI.3.3 to VI.3.7 of the statement of grounds of appeal that the subject-matter of claims 1 and 9 of the main request lacked novelty over D3, D6, D9, D12 and D18 *"or at least inventive step "*. However, no logical and structurated chain of arguments supporting the alleged lack of inventive step was presented. By doing that the appellant (opponent) failed to meet the requirements of Article 12(3) RPBA requiring the appellant to clearly set out the reasons why the decision of the opposition division was incorrect and had thus to be reversed.

5.2 In view of this circumstance, the Board considers that the mere allegation of the appellant (opponent) that the subject-matter of independent claims 1 and 9 lacks an inventive step over the cited prior art is unsubstantiated and hence decides to disregard this objection pursuant to Article 12(5) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

H. Jenney S. Fernández de Córdoba

Decision electronically authenticated