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Datasheet for the decision of 18 August 2025

Case Number: T 1492/23 - 3.2.07

17190469.1 Application Number:

Publication Number: 3281664

A61M15/08, A61M15/00 IPC:

Language of the proceedings: EN

Title of invention:

NASAL DELIVERY DEVICES

Patent Proprietor:

OPTINOSE, INC.

Opponent:

Beck Greener LLP

Headword:

Relevant legal provisions:

EPC Art. 56, 76(1), 83, 84, 123(2)

Keyword:

Inventive step - (yes)
Divisional application - added subject-matter (no)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Right to be heard - non-attendance at oral proceedings

Decisions cited:

G 0003/14

Catchword:



Beschwerdekammern Boards of Appeal

Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar GERMANY Tel. +49 (0)89 2399-0

Case Number: T 1492/23 - 3.2.07

DECISION
of Technical Board of Appeal 3.2.07
of 18 August 2025

Appellant:

(Opponent)

Beck Greener LLP

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London WC1V 6HR (GB)

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Respondent: OPTINOSE, INC.

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Representative: Boden, Keith McMurray

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on

 $6\ \mathrm{June}\ 2023$ concerning maintenance of the European Patent No. 3281664 in amended form.

Composition of the Board:

Chairwoman S. Watson
Members: V. Bevilacqua

S. Fernández de Córdoba

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Summary of Facts and Submissions

- The present appeal was filed by the opponent (appellant) against the decision of the opposition division to maintain European patent No. 3 281 664 in amended form according to auxiliary request 1 filed during oral proceedings before the opposition division.
- II. The following documents are referred to in the present decision:
 - D1: US 2011/0088690 A1
 - D2: "Hydraulics and Pneumatics. A technician's and engineer's guide", Parr, A., 1998, pages 90 to 96
 - D3: US 5,297,542
 - D4: WO 96/09085 A1
 - D6: Parent application as filed
 - D7: Dictionary extract: "whereby" and "wherein".
- III. The appellant (opponent) requested:
 - that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent (patent proprietor) requested:

- that the appeal be dismissed.
- IV. In preparation for oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA, in which it gave its preliminary opinion, according to which the appeal was to be dismissed.
- V. The appellant did not react to the above preliminary opinion in substance and informed the board, with submissions dated 4 August 2025 that they would not be

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represented at the oral proceedings.

- VI. Claim 1 as maintained according to the appealed decision (main request in appeal), with the feature numbering used in the appealed decision, reads as follows (amendments with respect to claim 1 of the application as originally filed are in bold, emphasis added by the board):
- 1.1 "A nasal delivery device for delivering substance to a nasal airway of a subject, comprising:
- 1.2 a nosepiece (117) for fitting to a nasal cavity of a subject;
- 1.3 a mouthpiece (119) into which the subject in use exhales;
- 1.4 a delivery unit (120), which comprises an actuation part (173) which is manually displaceable to actuate the delivery unit (120) to deliver substance from the nosepiece (119); and
- 1.5 a valve assembly (127) which is fluidly connected to the nosepiece (117) and the mouthpiece (119), wherein the valve assembly (127) comprises a body element (128) and a valve element (131) which is movably disposed to the body element (128) between closed and open configurations by manual displacement of the actuation part (173) of the delivery unit (120) to provide **for** an air flow through the nosepiece (117) simultaneously with delivery of substance; characterized in that:

the body element (128) includes

- 1.6 a valve seat (129) which defines a valve opening (130), and the valve element (131) comprises a seal (161) which is a resilient element and acts to close the valve opening (130) when the valve element (131) is in the closed position and
- 1.7 a support (163) which supports a central region of the

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- seal (161) so as to allow a peripheral region of the seal (161) to engage the valve seat (129) and the central region to be deflected relative to the peripheral region, thereby allowing for sudden release of the seal (161), and
- whereby the valve assembly (127), on opening of the valve element (131), provides for a burst of air flow, having a first, initial burst phase followed by a second, extended burst phase, wherein the second burst phase is of substantially greater duration than the first burst phase and the peak flow rate in the first burst phase is at least 10% greater than that of the average flow rate of the second burst phase in a period corresponding to ten times the duration of the period in which substance is delivered from the delivery unit (120)."
- VII. The lines of argument of the parties are dealt with in detail in the reasons for the decision.

Reasons for the Decision

- 1. Decision in writing, Article 12(8) RPBA
- 1.1 The board is able to decide the present case in written proceedings without holding oral proceedings in accordance with Article 12(8) RPBA and with Articles 113 and 116 EPC.
- 1.2 In reaction to the board's communication pursuant to Article 15(1) RPBA, the appellant wrote (letter of 4 August 2025):

"We are writing, on behalf of the Appellant (Opponent), to advise that the Appellant will no longer be - 4 - T 1492/23

represented at the oral proceedings currently scheduled for 18 September 2025.

The request for simultaneous interpretation dated 6 June 2025 is therefore withdrawn".

- 1.3 This statement is considered to be equivalent to a withdrawal of the appellant's request to hold oral proceedings before the board before a final decision on the appeal is issued (see Case Law of the Boards of Appeal, 11th edition 2025, identified as "CLB" in the following, III.C.5.3.2a)).
- 1.4 The appellant was informed of the board's negative preliminary assessment of the case with a communication under Article 15(1) RPBA which took the appellant's written submissions fully into account, and to which the appellant did not react in substance.

Thus, the grounds and evidence upon which the present decision is based were known to the appellant and have neither been commented on nor been further contested by the appellant.

Accordingly, the principle of the right to be heard (Article 113(1) EPC) has been observed since that provision only affords the opportunity to be heard, and the party's submissions have been fully taken into account (see CLB, III.B.2.8.3.b)).

1.5 In view of the fact that the case is ready for decision on the basis of the appellant's written submissions the board issues the present decision in written proceedings in accordance with Article 12(8) RPBA.

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- 2. Added subject-matter (Articles 76(1) and 123(2) EPC)
- The opposition division found (appealed decision, point II.12) that the ground of opposition of Article 100(c) EPC held against granted claim 1 because feature 1.8 was disclosed in the parent application specifically in the context of the second burst phase being "of substantially greater duration than the initial burst phase" (statement 19 of the present application as originally filed, original claim 19 of the earlier application), which is absent from granted claim 1.

This finding led to the rejection of the main request. The opposition division then proceeded to examine the auxiliary request, now main request, which included the omitted feature and was found to overcome this objection.

When discussing the present main request, the opposition division found that the amendment of "wherein" to "whereby" (see again statement 19 of the present application as originally filed, original claim 19 of the earlier application) did not add subjectmatter, as both terms conveyed the same meaning in context (decision, point II.16).

2.2 The appellant (statement of grounds, section 6) contested these findings, arguing as follows.

Claim 1 was amended during examination also by adding structural features of the valve assembly (features 1.6 and 1.7) and by linking these features to feature 1.8 using the term "whereby" instead of "wherein".

This last amendment introduced a cause-consequence relationship between the structural features of the

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valve assembly (features 1.6 and 1.7) and feature 1.8 which was neither present in the application as originally filed, contrary to Article 123(2) EPC, nor in D6 (parent application) contrary to Article 76(1) EPC.

In fact, neither the parent application nor the application as filed contained any disclosure that feature 1.8 specifically resulted from the structural features of the valve assembly (grounds of appeal, points 6.2-6.4).

2.3 The board is not convinced by the appellant's argument, based on document D7, that using "whereby" instead of "wherein" introduces additional information, which was not originally disclosed, because "whereby" implies a casual link which was not originally disclosed.

This is because, leaving aside the discussion on whether "wherein" and "whereby" convey, in the context of the claim, the same meaning (see the decision, point II.16), the board concurs with the respondent who argued that a casual link between valve structure and feature 1.8 is directly derivable from the original description (reply, point 15).

This is because the claimed valve structure (features 1.6 and 1.7) is described at pages 7 and 8 of both the application as filed and the parent application, in the context of the so-called "first embodiment", depicted in figures 1 to 7.

These features are said to

"be particularly effective in the present application where it is desired to achieve a sudden, initial burst

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of airflow" (see page 8, last paragraph).

Feature 1.8 also belongs to the embodiment of figure 8, mentioned in the originally filed description on page 10.

A skilled reader would therefore derive that this specific first embodiment relates to one exemplary device in which it is the same valve structure described in pages 7 and 8 which also provides for a second burst phase being of substantially greater duration than the first burst phase.

Therefore claim 1 of the main request does not extend beyond the content of the application as filed (Article 123(2) EPC) or the parent application (Article 76(1) EPC).

- 3. Clarity (Article 84 EPC)
- 3.1 The opposition division found that the amendments made to claim 1 did not introduce any lack of clarity (decision, II.18).
- 3.2 The appellant contests these findings in section 4 of the statement setting out the grounds of appeal, identifying a lack of clarity in relation to the determination of the average flow rate.
- 3.3 The board considers that these arguments of the appellant are not convincing.

The alleged lack of clarity regarding the determination of the average flow rate already existed in the granted claim, where the starting point and duration of the second burst phase were also not specified.

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According to G 3/14, the requirements of Article 84 EPC are only to be examined in an amended patent to the extent that the amendments introduce the non-compliance.

- 4. Sufficiency of disclosure (Article 83 EPC)
- 4.1 The opposition division found that the requirements of sufficiency of disclosure (Article 83 EPC) were satisfied (decision, II.10).
- 4.2 The appellant gave reasons why these findings of the opposition division are not correct and should be set aside (statement of grounds of appeal, section 5).
- 4.3 The board disagrees and considers that the objection of the appellant as formulated in the statement setting out the grounds of appeal rather concerns clarity (of the granted claim) than sufficiency of disclosure.

According to established case law (CLB II.C.8.2.2.a)), questions about whether a skilled person is operating within the claimed scope relate to the definition of the scope of protection (Article 84 EPC) and not to sufficiency of disclosure (Article 83 EPC). The patent provides enough information through examples and figures for the skilled person to carry out the invention, even if some parameters may vary during use.

- 5. Inventive step (Article 56 EPC)
- 5.1 The opposition division acknowledged inventive step of claim 1 of the main request starting from document D1 (decision, II.20).

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- 5.2 The appellant gave reasons why these findings of the opposition division were not correct and should be set aside (statement of grounds of appeal, section 7), arguing in particular that
 - the claimed flow characteristics could be achieved in D1 through appropriate operation and
 - using resilient materials for valve seals was a conventional measure.
- 5.3 The board considers that the respondent's arguments on inventive step are more convincing than those of the appellant, for the following reasons.

The appellant's assertion that the flow characteristics could be achieved in D1 through appropriate operation overlooks the fact that the claimed device achieves these characteristics through its structural configuration, independent of user operation.

Following the appealed decision's approach, the objective technical problem should be formulated as how to provide a more sudden delivery of the substance in a nasal delivery device (decision, point 20.2.1).

While D2 may show that poppet valves were generally known alternatives to sliding valves, neither D2 nor the other cited documents (D3, D4) disclose or suggest a valve assembly that would solve this objective technical problem in the claimed manner, particularly through the combination of:

- -a resilient seal
- -a support for the central region allowing peripheral engagement with the valve seat
- -the specific configuration enabling deflection of the central region relative to the peripheral region for sudden release.

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The appellant's argument that using resilient materials for valve seals was conventional (statement of grounds of appeal, point 7.23) oversimplifies the invention by considering this feature in isolation. The invention lies in the specific configuration of the resilient seal with its supported central region that provides the solution to the objective technical problem of achieving more sudden substance delivery.

Therefore, even accepting that poppet valves were known alternatives to sliding valves, the specific valve assembly claimed would not have been obvious to the skilled person seeking to solve the objective technical problem of providing a more sudden delivery.

The findings of the appealed decision according to which the subject-matter of claim 1 involves an inventive step (Article 56 EPC) are therefore also correct.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



G. Nachtigall

S. Watson

Decision electronically authenticated