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# Datasheet for the decision of 25 January 2021

Case Number: T 0642/16 - 3.2.02

07734890.2 Application Number:

Publication Number: 1996266

A61M15/08, A61F5/08 IPC:

Language of the proceedings: ΕN

#### Title of invention:

NASAL DELIVERY

#### Applicant:

Optinose AS

#### Headword:

#### Relevant legal provisions:

EPC Art. 54 EPC R. 103(1)(a)

#### Keyword:

Novelty - all requests (no) Reimbursement of appeal fee - (no)

#### Decisions cited:

# Catchword:



# Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0642/16 - 3.2.02

DECISION
of Technical Board of Appeal 3.2.02
of 25 January 2021

Appellant: Optinose AS

(Applicant) Oslo Innovation Center

Gaustadalléen 21 0349 Oslo (NO)

Representative: Boden, Keith McMurray

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 26 October 2015

refusing European patent application No. 07734890.2 pursuant to Article 97(2) EPC.

#### Composition of the Board:

Chairman M. Alvazzi Delfrate

Members: S. Böttcher

N. Obrovski

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### Summary of Facts and Submissions

I. The applicant appealed the decision of the examining division to refuse European patent application No. 07734890.2.

The examining division had considered that, in respect of the requests then on file, claim 1 of the main request and claim 1 of auxiliary requests 1 and 2 lacked clarity and novelty in view of D3 (WO-A-99/49984). Furthermore, the examining division had considered that the subject-matter of claim 1 of auxiliary request 3 lacked novelty.

- II. The appellant requested that the decision be set aside and a patent be granted on the basis of the main request or one of auxiliary requests 1 to 3 on which the examining division's decision was based. As an auxiliary request, the appellant requested that the case be remitted to the examining division for further prosecution and that the appeal fee be reimbursed due to a substantial procedural violation.
- III. In a phone call by the Board's registrar on 14 January 2021 the representative of the appellant was informed of the option to hold the oral proceedings by video conference in view of travel restrictions due to the Covid-19 pandemic. The representative declared that he did not intend to exercise this option, but did not request postponement of the oral proceedings either.
- IV. Oral proceedings were held before the Board on 25 January 2021. Nobody was present on behalf of the appellant who had been duly summoned to attend the oral proceedings.

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In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the oral proceedings were held without the appellant.

By their decision not to attend the oral proceedings, the appellant has chosen not to make any further submissions during such proceedings. They have thus to be treated as relying only on their written case.

V. Claim 1 of the main request and of auxiliary request 1 (which differs from the main request only by an amendment in claim 2) reads as follows:

"A nasal delivery device for delivering substance to a nasal cavity of a subject, the delivery device comprising:

a nosepiece unit including a nosepiece (220; 320; 420) for fitting to a nostril of a subject and a nozzle (245; 345; 445) through which substance is in use delivered to the respective nasal cavity; and a delivery unit (249; 349; 449) for delivering substance through the nozzle (245; 345; 445) of the nosepiece (220; 320; 420);

characterized in that at least a tip element (225; 325; 425) of the nosepiece (220; 320; 420) has a pre-defined shape and configuration, having an elongate lateral section, laterally in relation to the longitudinal axis of the nosepiece (22; 320; 420), which is substantially elliptical or substantially rectangular and has a longer dimension in a first direction (d1) than a second direction (d2) orthogonal to the first direction (d1), such that, when the nosepiece (220; 320; 420) is inserted in the nasal cavity of the subject, the longer dimension of the tip element (225; 325; 425) acts to engage lower and upper internal surfaces of the nasal

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cavity in relation to the sagittal plane and expand the same in the sagittal plane."

Claim 17 of the main request and of auxiliary request 1 reads as follows:

"A nosepiece for fitting to a nostril of a subject through which substance is delivered to a nasal cavity of the subject, characterized in that at least a tip element (225; 325; 425) of the nosepiece has a predefined shape and configuration, having an elongate lateral section, laterally in relation to the longitudinal axis of the nosepiece (220; 320; 420), which is substantially elliptical or substantially rectangular and has a longer dimension in a first direction (d1) than a second direction (d2) orthogonal to the first direction (d1), such that, when the nosepiece is inserted in the nasal cavity of the subject, the longer dimension of the tip element (225; 325; 425) acts to engage lower and upper internal surfaces of the nasal cavity in relation to the sagittal plane and expand the same in the sagittal plane."

VI. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the statement "laterally in relation to the longitudinal axis" has been replaced by "extending orthogonally in relation to the longitudinal axis".

Claim 17 of auxiliary request 2 corresponds to claim 17 of the main request.

VII. Claim 1 of auxiliary request 3 corresponds to claim 17 of the main request.

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VIII. The appellant's arguments put forward in the written proceedings can be summarized as follows:

Novelty

Contrary to the examining division's finding, the subject-matter of claim 1 of all requests did not lack novelty over D3.

The nosepiece as disclosed in D3 was adapted so as to not allow for insertion into a nasal cavity of a subject (page 11, lines 17 to 19). Therefore, D3 could not be held to disclose a nosepiece which was capable of insertion into a nasal cavity of a subject.

The subject-matter of claim 1 of all requests was clearly novel over D3.

Request for remittal and reimbursement of the appeal fee

The applicant's right to be heard had been infringed, since the reason in the decision for refusing auxiliary request 3 had not been raised before during the proceedings.

Claim 1 of auxiliary request 3 corresponded to claim 17 of the main request, in respect of which no objection had been made by the examining division. Hence, the applicant had expected that there was no remaining objection to claim 1 of auxiliary request 3.

In the impugned decision the examining division had held, for the first time, that the subject-matter of claim 1 of auxiliary request 3 was not novel over D3.

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The examining division referred to original claim 130 as basis for claim 1 of auxiliary request 3. Since claim 130 had been objected under Article 54 EPC, the applicant should apparently have expected an objection to claim 1 of auxiliary request 3. However, claim 1 of auxiliary request 3 had been significantly amended compared to original claim 130.

As a result, the applicant had been caught unawares by the decision, which was based on a reason on which they did not have the opportunity to comment. This procedural violation justified the remittal of the case to the examining division, with reimbursement of the appeal fee.

#### Reasons for the Decision

1. The subject-matter of the application

The present claims relate to a nosepiece (220) of a nasal delivery device for delivering a substance to a nasal cavity of a subject and to a nasal delivery device comprising a delivery unit (249) and a nosepiece unit including such a nosepiece (220) (third embodiment shown in Figures 14 to 16).

The nosepiece has a tip element (225) having a substantially elliptical or rectangular cross-section, such that, when the nosepiece is inserted in the nasal cavity, the longer dimension of the tip element acts to engage lower and upper internal surfaces of the nasal

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cavity and expand the same in the sagittal plane (description page 39, 2nd paragraph, Figure 19).

2. Main request - claims 1 and 17 - novelty

The examining division held that claim 1 of the main request lacked novelty over D3 = WO 99/49984.

It is noted that claim 1 of the main request is worded like an independent claim, without reference to any other claim. However, claim 1, relating to a nasal delivery device comprising a nosepiece, includes all features of claim 17, relating to the nosepiece as defined in claim 1. Claim 1 must therefore be regarded as a dependent claim.

D3 discloses a nasal delivery device (Figures 2 and 3) comprising a nosepiece unit including a nosepiece (5) which is designed to fit against a user's nostril opening without being inserted substantially into the nostril (page 11, lines 17 to 19). As can be seen from the figures, the tip element of the nosepiece has a pre-defined shape and configuration, having a substantially elliptical cross-section (and thus, implicitly, a longer dimension in a first direction than a second, orthogonal direction).

In use, the nosepiece of the device is placed in contact with the nostril opening (page 10, lines 28 to 30). If pressure is applied by the user, there may be some flaring of the nostril (page 10, lines 30 to 33).

In the Board's view, a flaring of the nostril can only be achieved in that the nosepiece is in fact inserted to a certain amount into the nostril, such that the longer dimension of the tip element engages lower and - 7 - T 0642/16

upper internal surfaces of the nasal cavity and expands the same in the sagittal plane.

The Board agrees with the examining division that the nosepiece of D3 is capable of being inserted into the nostrils, although this is not the intended use. It depends solely on the dimensions of the nostrils whether and how far the nosepiece can be inserted and whether the longer dimension of the tip element engages the interior surface of the nostril. In this regard, the Board does not concur with the appellant's arguments.

Hence, the subject-matter of claim 17 lacks novelty over D3.

Since the nasal delivery device of D3 also comprises a nozzle and a delivery unit for delivering substance though the nozzle, the subject-matter of claim 1 lacks novelty, too.

3. Auxiliary claim requests - novelty

Claims 1 and 17 of auxiliary request 1 are identical to claims 1 and 17 of the main request. Claim 17 of auxiliary request 2 and claim 1 of auxiliary request 3 are identical to claim 17 of the main request. Hence, none of these requests are allowable.

4. Auxiliary request for remittal and reimbursement of the appeal fee

According to Rule 103(1)(a) EPC the appeal fee shall be reimbursed in full where the Board of Appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural

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violation.

As mentioned above, claim 1 of auxiliary request 3 is identical to claim 17 of the main request, which is an independent claim and relates to the nosepiece included in claim 1 as part of the nasal delivery device. Hence, claim 1 of the main request includes all the features of claim 17 and is, in fact, a dependent claim (Rule 43(4) EPC).

The lack of novelty of a dependent claim implies the lack of novelty of the associated independent claim. Hence, by raising an objection against claim 1 of the main request in their annex to the summons to oral proceedings, which were not attended by the applicant, the examining division implicitly raised the corresponding novelty objection also against claim 17 of the main request.

Therefore, since the appellant was aware of the objection against dependent claim 1 of the main request, they could not be caught by surprise by the very same objection against independent claim 17 of the main request (to which claim 1 of auxiliary request 3 corresponds).

In the Board's view, the examining division did not violate the applicant's right to be heard by refusing auxiliary request 3, and no substantial procedural violation occurred in this respect.

Moreover, since the appeal is not directed as a main request to the grant of a patent on the basis of auxiliary request 3, there is no causal link between the alleged substantial procedural violation and the filing of the appeal. Hence, even if the alleged - 9 - T 0642/16

substantial procedural violation were acknowledged, the reimbursement of the appeal fee would not be equitable.

# Order

# For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated