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**Datasheet for the decision  
of 9 May 2019**

**Case Number:** T 2186/14 - 3.2.02

**Application Number:** 06709559.6

**Publication Number:** 1984049

**IPC:** A61M15/08

**Language of the proceedings:** EN

**Title of invention:**  
NASAL ADMINISTRATION

**Applicant:**  
Optinose AS

**Headword:**

**Relevant legal provisions:**  
EPC Art. 84

**Keyword:**  
Claims - clarity (no)

**Decisions cited:**  
T 0068/85

**Catchword:**



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Case Number: T 2186/14 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 9 May 2019**

**Appellant:** Optinose AS  
(Applicant) Oslo Innovation Center  
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**Representative:** Boden, Keith McMurray  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 5 June 2014  
refusing European patent application No.  
06709559.6 pursuant to Article 97(2) EPC**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** S. Böttcher  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. The applicant lodged an appeal against the decision of the Examining Division to refuse European patent application No. 06709559.6 for lack of clarity of claim 1. The written decision was dispatched on 5 June 2014.
- II. Notice of appeal was received on 15 August 2014. The appeal fee was paid on 6 August 2014. The statement setting out the grounds of appeal was received on 6 October 2014.
- III. Oral proceedings took place on 9 May 2019.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the request filed during the oral proceedings.

- IV. Claim 1 of the request filed during the oral proceedings corresponds to claim 1 on which the impugned decision was based and reads as follows:

"A delivery device, characterized in that the delivery device is for delivering substance to the central nervous system (CNS) of a subject, and comprises: a nosepiece unit (17; 117) for insertion into a nasal airway of a subject and comprising an outlet unit (21; 121) which includes a nozzle (25; 125) for delivering substance into the nasal airway of the subject; and a substance supply unit (18; 118) which is operable to deliver a dose of substance to the nozzle (25; 125); wherein the delivery device is configured such that at least 30 % of the dose as initially deposited in the nasal airway is deposited in an upper posterior region of the nasal airway which is posterior of the nasal

valve and above the inferior meatus, and thereby provides a CNS effect which is significantly greater than that predicted from a counterpart blood plasma concentration of the substance."

- V. The arguments of the appellant which are relevant for the present decision may be summarised as follows:

The definition in claim 1 "such that at least 30 % of the dose as initially deposited in the nasal airway is deposited in an upper posterior region of the nasal airway which is posterior of the nasal valve and above the inferior meatus" represented a result to be achieved.

However, in the present case, such a definition was permissible within the meaning of Article 84 EPC since this aspect of the invention could not be further defined without unduly restricting the scope of the claim and since the result could be directly and positively verified by an observation of whether at least 30 % of the dose was deposited in an upper posterior region of the nasal airway which was posterior of the nasal valve and above the inferior meatus.

The present application described in example 2 (page 27, last paragraph, to page 32, third paragraph) a routine measurement of the deposition of a test solution. This method included the labelling of a substance, the administering of the substance by a conventional nasal spray system and by an administration system of the invention, imaging the respective deposition with a camera, measuring the nasal dimensions, and evaluating the acquired images. Hence, it was possible to verify by observation

whether, for any given administration device, at least 30 % of the dose was deposited in the upper posterior region of the nasal cavity.

The present case was comparable to the example relating to the ashtray case mentioned in the Guidelines for Examination (F-IV, 4.10) since it was not possible to define the administration system more precisely without unduly restricting the scope of the invention. The structural features given in the claim in combination with the desired result, which could be verified by routine measurements, would have been sufficiently clear for the person skilled in the art to put the invention into practice. According to decision T 68/85, also referred to in the above-mentioned passage of the Guidelines, the definition of the subject-matter of the claim by the desired result did not infringe Article 84 EPC in such a case.

It also would have been clear for the skilled person that the definition in claim 1 required that the device be properly used when performing the measurement of the deposition. If properly used, the results of the measurement were reproducible. Hence, the definition in claim 1 clearly delimited the claimed device.

## Reasons for the Decision

1. The appeal is admissible.
2. Subject-matter of the application

Claim 1 relates to a delivery device for delivering a substance into a nasal airway of a subject (Figure 2). The device comprises a nosepiece unit having an outlet unit with a nozzle and a substance supply unit. The delivery device is configured such that at least 30 % of the dose is deposited in an upper posterior region of the nasal airway.

3. Article 84 EPC
  - 3.1 Article 84 EPC requires that the claims define the matter for which protection is sought in a clear and concise manner and that the claims be supported by the description. These requirements ensure that the public is not left in any doubt as to the subject-matter covered by a claim.
  - 3.2 Claim 1 includes a functional feature, namely, that the delivery device is configured such that at least 30 % of the dose as initially deposited in the nasal airway is deposited in an upper posterior region of the nasal airway which is posterior of the nasal valve and above the inferior meatus.
  - 3.3 While, in general, a functional feature defining a technical result can be permissible in a claim, in the present case, the skilled person would have been left in doubt regarding how the feature "configured such that at least 30 % of the dose as initially deposited

in the nasal airway is deposited in an upper posterior region of the nasal airway" could be reduced to practice. In fact, the claim does not specify any structural technical feature of the delivery device which provides for the deposition of at least 30 % of the dose in the upper posterior region of the nasal airway.

- 3.4 Furthermore, the Board holds that the deposition of the substance depends not only on the configuration of the device but also on factors which do not relate to the delivery device. The amount of substance deposited in a specific region of the nose depends, for instance, on the anatomy of the patient, on the type of substance and how it is delivered (e.g. liquid aerosol, dry powder, liquid jet...), and on how the device is used, i.e. at which angle or how far the nosepiece is inserted into the nose.

Hence, there is no direct and unique link between the device and the claimed result. Therefore, the functional definition cannot be used to define the subject-matter covered by the claim.

- 3.5 The appellant considered the definition in terms of the result to be achieved to be allowable because the result could be easily verified by an observation. It referred to example 2 of the description of the present application which disclosed a routine measurement of the deposition (page 27, last paragraph, to page 32, third paragraph). With the method described in this example, it would have been possible for the skilled person to verify whether any given administration device would fall under the scope of the claim or not.

The Board observes that example 2 relates to a study



comparing the deposition achieved by a conventional nasal spray administration system with that achieved by a delivery device according to the invention. To evaluate the deposition, a labelled test solution was administered to some patients, and the nasal cavity was imaged by a camera. The deposition as obtained by the two administration systems is illustrated in Figures 12(a) and 12(b), respectively. As shown in table II, with the device according to the invention, 32 % of the dose is deposited in the upper posterior region of the nasal cavity, whereas the conventional device only provides for a deposition of 11 % in that region.

However, in this example, a specific test setting was employed, e.g. the aerosol was administered with the subjects sitting in the upright position (page 28, last paragraph, to page 29, first paragraph). There is no reason to believe that with a different test setting, e.g. the subjects leaning forward or backward during the administration, or with a different test solution, equal results would be achieved with the same device. Hence, since the desired result is influenced by factors not related to the claimed device, it is not possible to define the device by this result.

- 3.6 The appellant argued that it would have been clear to the skilled person that the device had to be used properly, e.g. properly inserted into the nose, and that if the device was used properly, the deposition did not depend on how it was used.

The Board does not concur with this view. Even among the ways of normal use of a nasal administration device there is a certain degree of freedom for how the device is used. This unavoidably has an impact on the result. For instance, for the amount of the deposition in a

certain region of the nasal cavity, it surely matters how far the device is inserted into the nose and under which angle. In other words, it is inevitable that different results will be achieved from using the same device in a different (but still proper) way.

Furthermore, the deposition also depends on the anatomy of the subject, e.g. whether a child or an adult.

3.7 The appellant referred to the case underlying decision T 68/85 and to the ashtray example, both mentioned in the Guidelines for Examination (F-IV, 4.10).

Decision T 68/85 states that the claimed features may be expressed in structural or functional terms, the latter if, from an objective point of view, the features cannot otherwise be defined more precisely without unduly restricting the scope of the claim, and if the functional features provide instructions which would have been sufficiently clear for the skilled person to reduce them to practice without undue burden. However, this decision also found that an applicant cannot simply define a technical feature as it wishes. Rather, the objectively most precise form must be chosen (T 68/85, Reasons, 8.4.2).

The Board agrees with the appellant that the extent of protection should not be unduly limited. Nevertheless, the claim must clearly define the subject-matter for which protection is sought, and it must be possible to determine from the definition of the subject-matter whether any given device falls under the scope of the claim. In the Board's view, this is not the case for claim 1, as explained above.

The example referred to by the appellant concerns an

ashtray in which a smouldering cigarette end is automatically extinguished due to the shape and relative dimensions of the ashtray. The latter may vary considerably in a manner difficult to define whilst still providing the desired effect. As long as a claim specifies the construction and shape of the ashtray as clearly as possible, it may define the relative dimensions by reference to the result to be achieved, provided that the specification includes adequate directions to enable the reader to determine the required dimensions by routine test procedures.

In this example, it is clear which structural features have to be appropriately designed to achieve the desired effect. The relative dimensions of the ashtray may vary but will always be such that a cigarette is automatically extinguished.

However, in the present case, the specific structural features which have to be appropriately designed are not clear from the wording of the claim. The only structural features included in the claim are a nosepiece unit comprising a nozzle and a substance supply unit. Apart from this, no indication is given as to how the device has to be configured so as to provide for the deposition of at least 30 % of the dose in the upper posterior region of the nasal airway.

3.8 In conclusion, claim 1 does not meet the provisions of Article 84 EPC.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated