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Datasheet for the decision of 11 March 2024

Case Number: T 1056/21 - 3.2.02

Application Number: 09790635.8

Publication Number: 2326373

IPC: A61M11/06, A61M15/08, A61M31/00

Language of the proceedings: EN

Title of invention:
DEVICE FOR DELIVERING A MEDICAMENT

Patent Proprietor:
Xia, Tian

Opponent:
Gruber, Daniel

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
EPC R. 103(1)(a)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - added subject-matter (no)
Reimbursement of appeal fee - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1056/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 March 2024

Appellant: (Opponent)	Gruber, Daniel Freiherr-vom-Stein-Str. 5 10825 Berlin (DE)
Respondent: (Patent Proprietor)	Xia, Tian 2542 S. Lowe Chicago, IL 60616 (US)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 10 May 2021 rejecting the opposition filed against European patent No. 2326373 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	Y. Podbielski

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the opposition division to reject the opposition.

II. In a communication under Article 15(1) RPBA, dated 8 February 2024, the Board set out its preliminary opinion that the appeal was likely to be dismissed. Neither party made any written submissions thereafter.

III. Oral proceedings before the Board took place on 11 March 2024 in the presence of the respondent (patent proprietor).

The appellant (opponent), although duly summoned, did not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings were held without the appellant. By its decision not to attend the oral proceedings, the appellant has chosen not to make any further submissions during such proceedings. The appellant has thus to be treated as relying only on its written case.

IV. The appellant (opponent) requested in writing that the decision under appeal be set aside and that the patent be revoked. Furthermore, they requested reimbursement of the appeal fee because of a substantial procedural violation in the proceedings before the opposition division.

The respondent (patent proprietor) requested that the appeal be dismissed and the patent be maintained as granted (main request) or, if the decision was set aside, that the patent be maintained on the basis of

one of auxiliary requests 1-9 filed during the opposition proceedings. Furthermore they requested that the appellant's request for reimbursement of the appeal fee be rejected.

V. Claim 1 of the main request (patent as granted) reads as follows:

"A device for delivering a medicament to a patient in need thereof, the device comprising:
an injector (12) comprising a first end (29) configured to remain outside a patient's nasal passage and a second end (30) configured for entry into the patient's nasal passage; and
an introducer (18) configured for engagement into a nostril of the patient and comprising a passageway (48) in which the injector (12) is slidably received;
wherein the second end (30) of the injector (12) comprises one or a plurality of apertures (36) configured for dispersing a medicament superiorly and/or laterally and/or anteriorly towards the sphenopalatine ganglion when disposed within a nasal passage;
wherein the injector (12) comprises a tubular section (24) including a channel (22) that extends from the first end (29) to the one or plurality of apertures (36) at the second end (30) and that is configured to receive a medicament and to communicate the medicament to the one or plurality of apertures (36); and
wherein the injector (12) has a storage position within the passageway of the introducer before the introducer is engaged with the patient's nostril and is moveable within the passageway from the storage position to an engaging position in which the injector is extended outward from the introducer to allow the second end (30) of the injector to be situated medial and/or

posterior and/or inferior to a sphenopalatine ganglion of a patient when disposed within a nasal passage."

VI. The following documents are referred to in this decision:

D1 US 6 322 542 B1
D2 US 6 413 499 B1

VII. The arguments of the appellant may be summarized as follows:

Main request - Added subject-matter

Basis for granted claim 1 could not be found in the combination of original claims 20, 21, 24 and 28, paragraphs [0027] and [0029], and Figures 3 and 4 of the application as originally filed (WO 2010/014449).

Figure 4 was merely a schematic sketch and did not provide valid real information. Therefore, it was unjustified to take particular technical information from Figure 4.

Furthermore, the omission of some features from claim 21 resulted in an inadmissible intermediate generalisation.

Furthermore, the combination of the features of claims 28 and 24 was not originally disclosed, and the inclusion of the feature "tubular section" in claim 1 involved an unallowable intermediate generalisation due to the omission of the feature "cobra tube" mentioned in the first sentence of paragraph [0029] of the application as originally filed.

Therefore, claim 1 did not meet the requirements of Article 123(2) EPC.

Main request - sufficiency of disclosure

The functional features as defined in claim 1 did not enable the person skilled in the art (which would have to encompass a non-medically trained person) to design a device which was capable to deliver a drug to the sphenopalatine ganglion (SPG). Many essential parameters of the device (e.g. material, diameter, length, stiffness of the tube) remained undisclosed which would be required to practice the invention and find the accurate location of the SPG for the delivery of the drug as required.

Therefore, claim 1 did not comply with Article 83 EPC over the whole scope claimed.

Main request - novelty over D1

The feature "an introducer configured for engagement into a nostril of the patient" was at least inherently disclosed in D1 since both the end member 135 and/or the tubular member 151 shown in Figures 19 to 21 could be at least partially introduced into the nostril (Figures 19 to 21, column 8, lines 11 to 22).

Furthermore, the feature "a passageway in which the injector is slidably received" was disclosed in column 7, lines 1 to 9 and Figures 18 and 19 of D1, wherein the passageway extended from the small opening 137 via the longitudinal slot 143 to the elongate bore 147.

Hence, the subject-matter of claim 1 lacked novelty over D1.

Main request - inventive step starting from D1

The feature "an introducer configured for engagement into a nostril of the patient" was disclosed in D1 in Figures 19 to 21 (column 8, lines 19 to 22) and alternatively in Figure 1, (9) and (21). All the present invention of claim 1 had done was combining a feature of one design in D1 with the other.

The wetting of the hydrophilic coating of the tubular member (151) before insertion into the nose (column 8, lines 10 to 24) did not teach away from introducing the housing (105) into the nostril, but merely described the priming of the device before use and the introduction of tubular member (151). The common general knowledge would be motivation for the person skilled in the art to bring the end member (135) into contact with the nostril before and/or during delivery of the drug into the nose, resp., when moving the injector from the storage to the engaging position after priming the device.

Moreover, the person skilled in the art would combine the teaching of D1 and the disclosure of D2, particularly in Figure 6 showing an introducer (34) in the form of a spray nozzle (column 10, lines 41-47), which was designed for introduction into the nostril of the patient. The disclosure of D2 particularly dealt with methods how to administer a drug to the sphenopalatine ganglion (SPG) (column 14, lines 26-28) and would be considered by the person skilled in the art.

Thus, by combining the teaching of documents D1 and D2, the skilled person immediately arrived at the subject-

matter of claim 1.

Consequently, claim 1 as granted did not comply with the requirements of Article 56 EPC.

Request for reimbursement of the appeal fee

The appellant's right to be heard had been violated by the opposition division since they did not communicate during the oral proceedings that their understanding of the definition of the objective technical problem had changed.

The opposition division surprisingly identified further differences between D1 and the subject-matter of claim 1.

The opposition division did not comment on the highly relevant disclosure of Figure 1 of D1.

VIII. The arguments of the respondent may be summarized as follows:

Main request - added subject-matter

Basis for granted claim 1 could be found in the combination of original claims 20, 21, 24 and 28, paragraphs [0027] and [0029], as well as Figures 3 and 4 of the application as originally filed.

Although Figure 4 was a schematic sketch, the person skilled in the art would derive therefrom the information that the apertures of the injector were configured for dispersing a medicament towards the sphenopalatine ganglion (SPG) when disposed within the nasal passage.

Main request - sufficiency of disclosure

The person skilled in the art, reading paragraphs 24 to 30 and looking at Figures 1 to 4 of the patent, received sufficient information how to configure the injector and the introducer and how to use them in order to be able to dispense a medicament towards the sphenopalatine ganglion. Claim 1 and all the other claims of the Patent related to subject-matter which was sufficient in that they contained enough information for it to be reproduced by the skilled person without undue burden.

Main request - novelty in view of D1

D1 neither explicitly nor implicitly disclosed the feature "an introducer configured for engagement into a nostril of the patient" of claim 1.

D1 was completely silent about any part of the housing (105) coming into contact with the nostril of a patient. Further, it was not mentioned in D1 that the rounded end member 135 would be suitable to be inserted into the nostril.

Hence, the subject-matter of claim 1 was novel over D1.

Main request - inventive step starting from D1

The injector of the device of D1 needed to be provided in the extended position, prior to the device being used in the nasal cavity because the hydrophilic coating of the tubular member (151) had to be wetted before any insertion into the nose (column 8, lines 10-24). For this reason, the person skilled in the art

would not consider it obvious to use the housing (105) as an introducer configured for engagement into the nostril.

Furthermore, the person skilled in the art would not consider combining the teaching of D2 (or of the common nose spray devices) with D1. Such devices were very different and extensive modifications would be needed to add such an introducer to the device of D1.

Hence, the subject-matter of claim 1 involved an inventive step.

Request for reimbursement of the appeal fee

The appellant's request for the reimbursement of the appeal fee should be dismissed.

It could not be seen that there had been a substantial procedural violation.

Reasons for the Decision

1. Subject-matter of the patent

1.1 The patent relates to a device for delivering a medicament into the nostril of a patient, particularly a medicament for the management of pain associated with headaches, facial aches, and the like.

One method that has been employed for controlling the pain associated with headaches and facial aches is known as an SPG block. In this approach, anesthetic is applied to a sphenopalatine ganglion (SPG) of a

patient.

The sphenopalatine ganglion is a small bundle of nerves located deep behind the nose. These nerves process various types of pain from the face. Pain is lessened by blocking the pain signals from the sphenopalatine ganglion to the brain, reducing headaches and facial pain.

1.2 The device according to claim 1 of the main request (patent as granted) comprises an injector (12) and an introducer (18) (Figures 1 to 4 of the patent specification).

The injector has a tubular section including a channel that extends from a first end (29) to one or a plurality of apertures (36) at a second end (30). The channel is configured to receive a medicament and communicate it to the aperture(s). The aperture(s) is/ are configured for dispersing the medicament superiorly and/or laterally and/or anteriorly towards the sphenopalatine ganglion.

The introducer is configured for engagement into a nostril of the patient and comprises a passageway (48) in which the injector is slidably received to be moveable from a storage position (Figure 1) to an engaging position (Figure 4), in which the injector is extended outward from the introducer to allow the second end of the injector to be situated medial and/or posterior and/or inferior to the sphenopalatine ganglion when disposed within the nasal passage of a patient.

2. Main request - added subject-matter

2.1 Basis for granted claim 1 can be found in the combination of original claims 20, 21, 24 and 28, paragraphs [0027] and [0029], as well as Figures 3 and 4 of the application as originally filed (WO 2010/014449).

Original claim 24 as dependent on original claim 21 (and respectively on claim 20) defined the second end of the injector comprising one or a plurality of apertures configured for dispersing a medicament superiorly and/or laterally and/or anteriorly towards the sphenopalatine ganglion, but it did not explicitly define how the medicament arrives to the apertures. The skilled person would understand directly and unambiguously from the original wording of the claims, using his common general knowledge, that a lumen is needed in the injector, to allow the transport of the medicament to the second end of the injector and to the apertures.

Similarly, original claim 28 as dependent on original claim 21 (and respectively on claim 20) defined a channel extending from the first end to the second end and configured to receive a medicament. From this the skilled person understood directly and unambiguously, using his common general knowledge that at least one aperture is needed in order to allow the flow of the medicament from the channel towards the sphenopalatine configuration, when the injector is in the engaging position, as defined on the original claim 21.

Thus, the skilled person, using his common general knowledge, would understand directly and unambiguously that the features of claims 20, 21,24 and 28 can be combined, to allow dispersing the medicament.

2.2 Although Figure 4 is a schematic sketch, the person skilled in the art would derive therefrom the information that the apertures of the injector are configured for dispersing a medicament towards the sphenopalatine ganglion (SPG) when disposed within the nasal passage.

2.3 Contrary to the appellant, the Board considers that all the features of claim 21 have been introduced in claim 1 of the main request. The slight rewording ("preceding the engagement" to "before the introducer is engaged" and "pursuant to the engagement" to "when disposed within a nasal passage") does not add subject-matter as the teaching remains the same.

2.4 The objection relating to the omission of the wording "cobra tube" (disclosed in paragraph [0029] in connection with the tubular section) was raised for the first time on appeal, although it should have been submitted already in the opposition proceedings. Furthermore, the wording "cobra tube" relates to the tube extensibility. However, claim 1, defining the tubular section as part of the injector that can slide in the passageway, already comprises this technical feature. Hence no technical feature has been omitted. For these reasons this objection is not admitted into the proceedings.

2.5 Consequently, claim 1 does not comprise added subject-matter and meets the requirements of Article 123(2) EPC.

3. Main request - sufficiency of disclosure

3.1 The invention as defined in claim 1 is disclosed in paragraphs [0024] to [0030] and Figures 1 to 4 of the patent in a manner sufficiently complete to allow the person skilled in the art to perform the invention.

3.2 The wording "towards the sphenopalatine ganglion" (SPG) in claim 1 requires that the medicament is dispersed in the general direction of the SPG. Hence, contrary to the appellant's view, it is not required to find the accurate location of the SPG for the delivery of the medicament.

3.3 Hence, the requirements of Article 83 EPC are met.

4. Main request - novelty over D1

4.1 D1 discloses (Figures 18 to 21) a device for delivering a medicament to the SPG, the device comprising an injector (delivery means 103) that is movable within a passageway of a housing 105 between a storage position (Figure 21) and an engaging position (Figures 18 to 20) in which the injector is extended outward from the housing.

4.2 D1 does not disclose an introducer which is configured for engagement into a nostril of the patient. As explained at column 8, lines 10 to 35, it is only the delivery means 103 that is inserted into the nostril, after it has been moved to the extended position. D1 does not discuss why the end member (135) is represented as having round edges, nor does it provide any disclosure which would allow the person skilled in the art to understand implicitly that the housing (105) with its rounded end member (135) is an introducer configured for engagement into the nostril and that nothing else is intended by the shown configuration of

the end member.

4.3 Consequently, the subject-matter of claim 1 is novel in view of D1.

5. Main request - inventive step starting from D1

5.1 The Board agrees with the opposition division that the distinguishing feature is an introducer configured for engagement into a nostril of the patient.

Starting from D1, the objective technical problem is regarded as to provide an alternative device for delivering a medicament towards the SPG.

5.2 The person skilled in the art would not consider modifying the housing 105 of the device of D1 such that it is configured for engagement into the nostril. The injector of D1 needs to be moved into the extended position before insertion in order to wet the hydrophilic coating of the tubular member 151 (column 8, lines 10 to 24). After this priming step the injector remains in the extended position, and only the tubular member 151 is inserted into the nostril.

5.3 Moreover, in order to solve the problem of providing an alternative device for delivering a medicament towards the SPG, the person skilled in the art would not consider combining the teaching of Figure 6 of D2 with D1. Figure 6 of D2 discloses a nose spray device (also shown in Figure 2) for anesthetizing a portion or all of a patient's maxillary dental arch using a nasal delivered anesthetizing composition. Contrary to the appellant's view, this embodiment of D2 is not configured for delivering a medicament towards the SPG. The device includes a spray nozzle which is configured

to be inserted into the nostril and through which the liquid medicament is forced out upon squeezing the bottle.

Hence, if anything, D2 would teach the person skilled in the art to modify the part of the device of D1 which is inserted into the nostril and through which the medicament is dispensed, i.e. the delivery means 103. In any case, D2 does not prompt the person skilled in the art to change the end member 135 of the housing of D1 such that it is configured for engagement into the nostril.

5.4 Hence, the subject-matter of claim 1 involves an inventive step.

6. Request for reimbursement of the appeal fee

For the reasons set out in paragraphs 6.1-6.3 of the Board's communication of 8 February 2024, no substantial procedural violation occurred in the proceedings before the opposition division as alleged by the appellant. In addition, it is a condition for the refund of the appeal fee that the appeal is found to be allowable (Rule 103(1)(a) EPC).

Since the present appeal is not allowable, the request for reimbursement of the appeal fee is rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated