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Datasheet for the decision of 11 February 2022

Case Number: T 0232/18 - 3.2.02

Application Number: 11779089.9

Publication Number: 2627386

IPC: A61M15/00, A61M15/08, B05B1/00

Language of the proceedings: EN

Title of invention:
NASAL SPRAY DEVICE

Patent Proprietor:
Ivax Pharmaceuticals Ireland
Teva Branded Pharmaceutical Products R & D, Inc.

Opponent:
FRKelly

Relevant legal provisions:
EPC Art. 100(a), 56

Keyword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0232/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 February 2022

Appellant: (Opponent)	FRKelly 27 Clyde Road Ballsbridge 4 Dublin (IE)
Representative:	FRKelly 27 Clyde Road Dublin D04 F838 (IE)
Respondent: (Patent Proprietor 1)	Ivax Pharmaceuticals Ireland Unit 301 Industrial Park Waterford (IE)
Respondent: (Patent Proprietor 2)	Teva Branded Pharmaceutical Products R & D, Inc. 425 Privet Rd Horsham, PA 19044 (US)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 15 November 2017 rejecting the opposition filed against European patent No. 2627386 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The appeal is directed against the decision of the Opposition Division rejecting the opposition against European patent No. 2627386.

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

The respondent (proprietor) requested that the appeal be dismissed.

III. Both parties requested oral proceedings on an auxiliary basis.

In a communication pursuant to Article 15(1) RPBA 2020 dated 28 October 2021 and annexed to the summons to oral proceedings, the Board informed the parties of its preliminary opinion that the appeal would likely be dismissed.

The appellant announced on 8 February 2022 that it would neither be attending nor be represented at the oral proceedings.

The Board then cancelled the oral proceedings.

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

"A nasal spray device (1) for the delivery of a pharmaceutical formulation to a nasal cavity in metered doses, the device comprising: a pressurised aerosol canister (3) including a vial (4) containing a

pharmaceutical formulation comprising an active ingredient, a propellant and, optionally, a co-solvent, the aerosol canister (3) further including a metering valve (6) having a valve stem (8); and an actuator (2) for the aerosol canister (3), the actuator (2) including a stem block (11) having a receptacle into which the valve stem (8) of metering valve (6) of the aerosol canister (3) is received and axially located and being displaceable relative to the vial (4) of the aerosol canister (3) to actuate the metering valve (6) of the aerosol canister (3), a sump (15) extending below the receptacle, the stem block (11) further defining a discharge orifice (19) for the pharmaceutical formulation and a transfer channel (13) through which a dispensed dose of the pharmaceutical formulation is able to pass from the sump (15) to the discharge orifice (19), wherein the actuator (2) further comprises a delivery outlet (12) for an aerosol plume, the discharge orifice (19) being arranged to direct the aerosol plume through the delivery outlet (12), characterised in that the device (1) is adapted to produce an aerosol plume for a dispensed dose having a spray force value no greater than 40 mN measured at a distance of 30 mm from the discharge orifice (19), wherein the discharge orifice (19) has a diameter of 0.15 to 0.65 mm and a length of 0.5 to 1.0 mm, and the transfer channel (13) has a length of 3 to 20 mm."

V. The following documents are relevant to the decision:

D1: WO 01/58508 A2
F2: Newman, "Principles of Metered-Dose Inhaler Design", Respir. Care 2005; 50(9), 1177-88

VI. The appellant's arguments, as far as they are relevant to the decision, can be summarised as follows:

Features distinguishing the subject-matter of claim 1 from the disclosure of D1

The feature "[a] nasal spray device" was disclosed in D1. The device of claim 1 did not comprise a nose piece, nor was a delivery outlet an essential feature required to achieve the claimed spray force. The feature should thus be interpreted as a spray device suitable for nasal delivery. D1 was directed to actuator nozzles for metered-dose inhalers, whether by nasal or by oral route. D1 did not make any reference to the actuator nozzles only being suitable for oral inhalers. D1 likewise disclosed inhalation devices for nasal applications on page 2, lines 14 to 24. The disclosure was thus not confined to the exemplified embodiment of an oral inhaler, but also applied to nasal inhalers. Moreover, the primary technical contribution of D1 resided in the actuator, which had no technical relationship with the mouthpiece disclosed in D1. The person skilled in the art would thus understand the teaching of D1 as also covering a spray device suitable for nasal delivery.

The feature "*a spray force value of no greater than 40 mN measured at a distance of 30 mm from the discharge orifice*" was likewise disclosed in D1. This was not a technical feature of the device of claim 1 but a result to be achieved which was an inevitable result of the operation of other technical features provided in the claim.

The only feature distinguishing the subject-matter of claim 1 from the disclosure of D1 was thus the transfer channel length having a length of 3 to 20 mm.

Inventive step over D1 combined with F2

The specific length of the transfer channel did not have a technical effect associated with it, so the objective technical problem was to provide an alternative spray device which was suitable for nasal delivery. Starting from D1 and faced with this problem, the person skilled in the art would consult F2 because it was concerned with metered-dose inhaler design. F2 taught that the aerosol particle size could be modified by changing the length of the actuator nozzle (page 1181, right-hand column, penultimate paragraph). The person skilled in the art would thus have modified the transfer chamber of D1 and arrived at the invention of claim 1 without exercising any inventive skill.

VII. The respondent's arguments, as far as they are relevant to the decision, can be summarised as follows:

Features distinguishing the subject-matter of claim 1 from the disclosure of D1

The person skilled in the art would not consider the devices having mouthpieces disclosed in D1 to be nasal spray devices. The devices of D1 were not even suitable for delivering a formulation to the nasal cavity in metered doses. Hence D1 did not disclose the feature "[a] nasal spray device for the delivery of a pharmaceutical formulation to a nasal cavity in metered doses".

The feature "*the device is adapted to produce an aerosol plume for a dispensed dose having a spray force value of no greater than 40 mN measured at a distance of 30 mm from the discharge orifice*" was not a result to be achieved but a functional feature. The contested

patent taught in paragraphs [0031] and [0052] that the spray force value could be provided by configuring the size and shape of the transfer channel and by reducing the outlet orifice diameter. There was no reason to believe that the ranges for the transfer channel length and the outlet orifice diameter defined in claim 1 would necessarily lead to the claimed spray force value, especially because claim 1 did not define the transfer channel diameter.

Inventive step over D1 combined with F2

Starting from D1, the objective technical problem was how to adapt the device of D1 for a further field of application. Neither D1 nor F2 was concerned with this problem. D1 instead was concerned with maximising the respirable fine-particle fraction for delivery to the lungs, thus teaching away from providing a device for delivering a formulation to the nasal cavity.

Reasons for the Decision

1. The invention

Metered-dose nasal spray devices are intended for the delivery of a pharmaceutical formulation to the nasal cavity over multiple usage cycles.

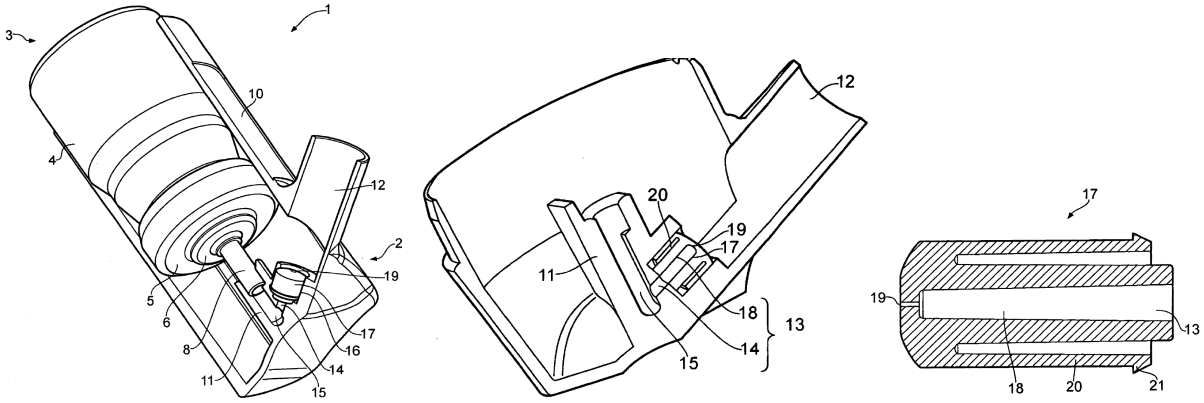
Spray devices having manually-operated pumps have some drawbacks relating to the difficulty for some users of achieving the required actuation force and to the variability in the delivered medicament dose. These drawbacks can be addressed using a pressurised aerosol canister. The aerosol canister has a vial containing the formulation including an active ingredient and a

propellant, and excipients such as co-solvents may be added to the active ingredient to facilitate dissolution or to stabilise the suspension.

While pressurised metered-dose inhalers have found broad market acceptance for devices intended for medicament inhalation via the mouth, the high level of co-solvents present in the nasal spray formulations produces an unpleasant sensation in the nasal cavity which is poorly tolerated by patients (paragraphs [0004]-[0006] of the patent specification).

The invention is based on the finding that even formulations containing high levels of co-solvents are well tolerated in a nasal spray formulation, provided that the nasal spray device used to deliver the formulation provides a "soft spray" having a spray force value of no greater than 40 mN measured at 30 mm from the discharge orifice (paragraphs [0010] and [0035] of the patent specification).

Accordingly, the invention provides a nasal spray device (1) comprising a pressurised aerosol canister (3) and an actuator (2) for the canister as defined by claim 1. The actuator (2) includes, *inter alia,* a delivery outlet (12) and a stem block (11) defining a transfer channel (13) and a discharge orifice (19). An example of a nasal spray device according to the invention is shown in Figures 1, 3 and 4 of the patent specification reproduced hereinafter.



2. Inventive step in view of D1 and F2

2.1 It is common ground that D1 does not disclose the feature "the transfer channel length has a length of 3 to 20 mm".

2.2 Claim 1 does not define a device *suitable for* nasal delivery, but a "nasal spray device for the delivery of a pharmaceutical formulation to a nasal cavity in metered doses".

The only example of an inhaler including the nozzle taught by D1 is an inhaler adapted for oral delivery (mouthpiece 26 in Fig. 5 and on page 12, line 12). D1 does not disclose the dimensions of the mouthpiece and in particular does not disclose its dimensions being suitable for the nostril(s). A mouthpiece which does not fit within the nostrils would deliver at most a part of the metered dose within the nasal cavity. Hence the inhaler of D1 can neither be regarded as a "nasal spray device" nor as suitable "for delivery of a pharmaceutical formulation to a nasal cavity in metered doses".

It is correct that page 2, lines 14 to 27 of D1, in the background of the invention, also refers to inhalation

devices which can target the nasal passages. However, D1 does not disclose any nasal spray device using the actuator nozzle later presented as being the invention in D1. This holds true irrespective of whether the actuator nozzle and the mouthpiece in the embodiment of Figure 5 of D1 have any technical relationship.

It follows that D1 does not disclose the feature "[a] nasal spray device for delivery of a pharmaceutical formulation to a nasal cavity in metered doses".

2.3 The feature "*the device is adapted to produce an aerosol plume for a dispensed dose having a spray force value of no greater than 40 mN measured at a distance of 30 mm from the discharge orifice*" is a functional feature restricting the device of claim 1. The feature is not explicitly disclosed in D1.

While other features defined in claim 1 do indeed have an impact on the spray force value, there is no reason to assume that the other features of claim 1 will inevitably result in the claimed force. As submitted by the respondent, the patent specification discloses in paragraphs [0031] and [0052] that the spray force depends to a large degree on the shape and size of the stem block insert / transfer channel, whereas claim 1 only specifies the length of the transfer channel but not its geometry.

Hence, even if D1 were to disclose a device with all the other features of claim 1, the claimed spray force value could not be regarded as being inherent in the device of D1. Therefore the feature *"the device is adapted to produce an aerosol plume for a dispensed dose having a spray force value of no greater than 40 mN measured at a distance of 30 mm from the*

discharge orifice" further distinguishes the subject-matter of claim 1 from the disclosure of D1.

2.4 The distinguishing features indicated above allow nasal delivery of a pharmaceutical formulation (see paragraphs [0006] and [0010] of the patent specification).

The problem submitted by the appellant, namely the provision of an alternative spray device suitable for nasal delivery, is not appropriate because it is based on the wrong premise, that D1 discloses a nasal spray device for the delivery of a pharmaceutical formulation to a nasal cavity in metered doses (see point 2.2 above).

The problem solved can instead be regarded as how to adapt the inhaler of D1 to a further field of application.

2.5 D1 discloses that "*the ability to deliver drugs to a target area is largely dependent on the size of the medicament particle, its velocity and settling properties*" (page 2, lines 17 to 19). D1 further teaches on page 2, lines 19 to 26 that particles of six microns or less, referred to as "particles of respirable size", are well adapted for delivery to the lung (alveolar region, bronchioles and bronchi), whereas particles with a size range greater than 6 microns are suitable for delivery to the laryngeal region, throat or nasal passages.

D1 is concerned with providing a nozzle which maximises the fraction of particles of respirable size, while at the same time reducing deposition of drug/material in the throat and in the device/inhaler (see page 2, line

25 - page 3, line 15; page 3, lines 22 to 23; page 5, lines 4 to 9; page 6, lines 3 to 7). Hence the nozzle of D1 is taught as being advantageous for delivery to the lungs but disadvantageous for delivery to the nasal passages.

2.6 F2 deals with principles of metered-dose inhaler design. F2 neither mentions nasal delivery nor a nasal spray device. Rather, F2 refers at several locations to a mouthpiece and to delivery through the mouth (see e.g. Table 1, 4th line from the bottom). There is no suggestion in F2 of using any other medication delivery route.

2.7 In conclusion, neither D1 nor F2 provides any incentive to undertake any specific modification for providing a nasal spray device for delivering a pharmaceutical medication to a nasal cavity.

It follows that the subject-matter of claim 1 is not obvious starting from the device of D1 in view of the disclosure of F2.

3. The only objection raised in appeal proceedings does not prejudice maintenance of the patent as granted. There is thus no reason to set aside the Opposition Division's decision rejecting the opposition. Accordingly, the appeal is to be dismissed.

4. The Board considers, in accordance with established case law (see Case Law of the Boards of Appeal, 9th edition 2019, III.C.4.3.2), the appellant's submission that it would neither attend nor be represented at the oral proceedings to be equivalent to a withdrawal of the appellant's request for oral proceedings since the

appellant unequivocally expressed that it only wished to rely on its submissions made in writing.

The respondent's main request, on the other hand, was that the appeal be dismissed. Therefore the decision can be rendered in writing without holding oral proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated