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Datasheet for the decision of 29 January 2007

Case Number: T 1320/04 - 3.2.02

Application Number: 96902379.5

Publication Number: 0809521

IPC: A61M 5/307

Language of the proceedings: EN

Title of invention:
Trans-mucosal particle delivery

Applicant:
PowderJect Research Limited

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 56

Keyword:
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1320/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 29 January 2007

Appellant: PowderJect Research Limited
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 7 July 2004 refusing European application No. 96902379.5 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Noel
M. Vogel

Summary of Facts and Submissions

I. European patent application No 96 902 379.5 was refused by the examining division on 7 July 2004 on the ground that the claimed subject-matter lacked inventive step under Article 56 EPC vis à vis the prior art documents:

D1: WO-A-94/24263, and
D2: US-A-5049125.

II. The appellant (applicant) lodged an appeal against this decision by notice of appeal received on 18 August 2004 and paid the appeal fee on the same day. A statement of grounds was filed on 5 November 2004, along with amended sets of claims according to a main and five auxiliary requests.

III. In response to communications of the Board sent on 3 November 2006 and 21 December 2006, respectively, the appellant submitted by letter dated 20 December 2006 a new set of amended claims 1 to 28.

IV. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for grant of a patent on the basis of these claims.

V. Independent claims 1 and 7 read as follows:

"1. A needleless syringe comprising an elongate tubular nozzle (7), an upstream end of which is, or is arranged to be, connected to a source (3) of gaseous pressure; means (9,18) for suddenly releasing the gas to create a supersonic condition within the nozzle; and

a source (8,21) of particles (P) of a powdered therapeutic agent which are arranged to be propelled from the downstream end of the nozzle upon the gas release, wherein the supersonic condition is a supersonic gas flow in which the particles are entrained; **characterised** in that the nozzle has a bend (11) a part way along its length and that the part (12) of the nozzle downstream of the bend (11) is narrower than the part (10) upstream of the bend so that the gas flow is accelerated to supersonic speed only after the gas has travelled around the bend."

"7. A needleless syringe comprising an elongate tubular nozzle, an upstream end of which is, or is arranged to be, connected to a source (3) of gaseous pressure; means (18) for suddenly releasing the gas to create a supersonic condition within the nozzle; and a source (21) of particles (P) of a powdered therapeutic agent which are arranged to be propelled from the downstream end of the nozzle upon the gas release; **characterised** in that the nozzle has a bend a part way along its length and that the part of the nozzle downstream of the bend is provided with a diaphragm (20), which is movable outwardly from an inverted first position, in which it presents outwardly of the nozzle a cavity containing the particles, to a second position, the arrangement being such that a supersonic shockwave, providing the supersonic condition in the nozzle, is arranged to move the diaphragm outwardly from its first position to its second position to catapult the particles outwardly."

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The subject-matter of independent claim 1, which corresponds to the embodiment illustrated in Fig. 1 of the present application, is formed by a combination of features taken from claims 1, 4 and 5 as originally filed.

Claims 2 to 6 are identical to original claims 3, 6, 7, 8, respectively.

The subject-matter of independent claim 7, which corresponds to the embodiments illustrated in Fig. 2 to 6, is formed by a combination of features taken from claims 1 and 9 as originally filed. Additionally, the feature according to which "the part of the nozzle downstream of the bend is provided with a diaphragm (20)" is unambiguously derivable from the drawing, in particular from Fig. 2 to 4 of the application as filed.

Claim 8 is supported by the application as filed on page 7, lines 22 to 27 and illustrated by Fig.2 and 3.

Claim 10 is a combination of features drawn from claim 9 as originally filed.

Claims 9 and 11 to 28 are identical to original claims 3 and 10 to 27, respectively.

Consequently, the amendments made to the claims do not extend their subject-matter beyond the content of the application as filed, in accordance with the requirements of Article 123(2) EPC.

3. *Inventive step*

3.1 The closest state of the art, also cited as starting point in the application as filed, is represented by document D1. It discloses (see in particular Fig. 1 and 8) a needleless syringe for particle delivery comprising an elongated tubular nozzle, the upstream end of which being arranged to be connected to a source of gaseous pressure and means for suddenly releasing the gas to create a supersonic condition within the nozzle. A source of particles of a powdered therapeutic agent, contained within a capsule introduced into the body of the syringe, is arranged to be propelled from the downstream end of the nozzle upon the gas release, wherein the supersonic condition is a supersonic gas flow in which the particles are entrained.

In D1 the supersonic gas flow is produced by a gaseous pressure sufficient to burst the membranes of the capsule, whereby to generate a shock wave for entraining the particles at supersonic velocity, depending further on the nozzle geometry. Preferably, the nozzle has a convergent/divergent portion (venturi) for accelerating the gas flow and producing the supersonic shock wave at the throat of the nozzle.

However, the syringe disclosed in D1 is formed of a straight nozzle portion terminating in an outlet directed in the axial direction of the nozzle, which

turned out to be inappropriate for the delivery of particles into the palate or other relatively inaccessible sites within the mouth of a patient.

3.2 With respect to the disclosure of D1 the objective problem upon which the present application is based is to provide a needleless syringe that enables injections into soft tissues of relatively inaccessible sites of body organs such as mucosa within the mouth of a patient while at the same time maintaining adequate and efficient target penetration of the particles propelled at a supersonic velocity.

The principle solution to this problem consists in providing the nozzle with a bend and means within the nozzle for producing a shock wave and adequate expulsion of the particles in the gas flow propelled at a supersonic velocity while still accommodating the bend. The present application provides two embodiments in order to propel the particles at said supersonic velocity.

According to the first embodiment illustrated in Fig. 1 of the present application and covered by the subject-matter of independent claim 1, the flow of gas in which the particles are entrained is accelerated to supersonic speed by means of a narrower part (convergent) of the nozzle placed downstream of, i.e. after the bend. In this way the gas flow is accelerated only after the gas has travelled around the bend as it passes through and out of the nozzle, such that the bend does not cause unacceptable deceleration, attrition or breaking up of the particles.

According to the second embodiment illustrated in Fig. 2 to 6 and covered by the subject-matter of independent claim 7, the source of particles (capsule) is placed in that part of the nozzle situated downstream of the bend, which is provided with a bistable diaphragm. The abrupt inversion of the diaphragm, which is required to catapult the particles outwardly, is caused by a shock wave generated upstream of the diaphragm.

3.3 Neither of the solutions claimed in independent claims 1 and 7 is disclosed nor suggested by the state of the art.

In D1, as already mentioned, the nozzle has a straight portion which does not allow for attaining inaccessible body cavities.

Document D2 discloses (see Fig. 2a) a needleless injection instrument provided with an injection nozzle for dental applications having a head portion 5 bent at right angle for facilitating the access to the dental mucosa of a patient.

However, this instrument is designed to produce a jet of liquid under pressure, i.e. a substantially incompressible fluid, for which the phenomenon of supersonic velocity does not arise and the problem underlying the present application is not addressed. Thus, the techniques applied in D2 are inconsistent with those performed in the present application and this document does not suggest the specific features of claims 1 and 7.

3.4 It results therefrom that the subject-matter of independent claims 1 and 7 and of the claims which depend thereon involves an inventive step over the state of the art.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of claims 1 to 28 filed with the letter of 20 December 2006 after adaptation of the description to the independent claims 1 and 7.

The Registrar: The Chairman:

V. Commare T. Kriner