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D E C I S I O N
of 29 September 2004

Case Number: T 0046/02 - 3.2.2

Application Number: 96109925.6

Publication Number: 0734737

IPC: C12M 3/00

Language of the proceedings: EN

Title of invention:

Particle delivery of therapeutic powdered agents

Applicant:

PowderJect Research Limited

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 84, 123(2), 76(1)

Keyword:

"Added subject-matter (no), support by the description (yes)"

Decisions cited:

T 0873/94

Catchword:

-



Case Number: T 0046/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 29 September 2004

Appellant: PowderJect Research Limited
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 2 July 2001
refusing European application No. 96109925
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: S. S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 2 July 2001 to refuse European patent application No. 96 109 925.6. This application was divided out of the parent application 94 912 038.0 (WO-A-9 424 263).

The application was refused since the applicant disapproved the text in a communication under Rule 51(4) EPC, which was based on the third auxiliary request of the application. The examining division considered that at least claims 1 and 5 of the main request were objectionable under Article 123(2) EPC and the claims of the main request were also open to objection under Articles 83 and 84 EPC. The first and second auxiliary requests were also found to be unallowable under Articles 83 and 84 EPC, but the third auxiliary request was found to be allowable.

II. On 24 August 2001 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same date. On 9 November 2001 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 16 of the main request filed with the grounds of appeal, or alternatively, on the basis of claims according to first to sixth auxiliary requests filed with the grounds of appeal. Oral proceedings were requested if the main request was not allowed. However, the appellant did not wish for oral proceedings to be called if the Board intended to issue a decision

allowing the appeal in respect of the substantive objections and remit the case to the first instance so that the examination under Article 52(1) EPC could be carried out.

IV. Claim 1 of the main request reads as follows:

"A needleless syringe, which comprises a tubular nozzle (26), particles (32) of a powdered therapeutic agent, and energising means (10) which, on activation, deliver the particles through the nozzle at a velocity in the range of between 200 and 2,500, m/sec, in which the particles have a size predominantly in the range 10 to 250 μm and a density in the range of 0.1 to 25g/cm³."

Claim 2 to 16 are dependent on claim 1.

As will emerge from the following the claims of the auxiliary requests need not be discussed.

V. The appellant argued as follows:

The test for added subject-matter was whether the overall change in the content of the application, arising from the omission of references to "therapeutic" in claim 1, results in the skilled person being presented with information not directly and unambiguously derivable from the original application. The original application made references to non-therapeutic use, for example the delivery of contraceptives, and this was independent of the technical features of the syringe, so the application as a whole clearly taught the delivery of particles of a non-therapeutic agent.

Claim 1 was based on claim 38 of the original parent application, and claim 38 did not mention membranes. A membrane was described as a preferred method of containing the particles and for achieving a build-up of pressure, the person skilled in the art would know of other ways of doing this, for example the use of a mechanical valve which opened at a certain pressure. The membranes were not an essential feature, accordingly.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Articles 76(1) and 123(2) EPC*
 - 2.1 It is established case law of the EPO that a divisional application must satisfy the requirements of both Articles 76(1) and 123(2) EPC (see for example T 73/94; OJ 1997, 456), ie the present divisional application must not contain subject-matter which extends beyond the content of the parent application as filed, or the divisional application as filed, respectively. In the present case the description of the present application as filed is identical with the description of the parent application as filed. Therefore, if the present application finds support in the description of the original parent application, then both the Articles 76(1) and 123(2) EPC will be satisfied.

2.2 As set out in the opening parts of the application, the presently claimed needleless syringe is a development of the apparatus of WO-A-9 204 439 (cited in the description), which apparatus is for firing dense micro projectiles, made for example of tungsten or gold coated with genetic material, into target cells. The principle used in that apparatus is that particles are initially immobilised, e.g. electrostatically, on or upstream of a rupturable diaphragm, which is ruptured whereupon the particles are propelled by the gas flow from a tubular device.

The present inventors appreciated that the earlier technique could be modified to provide a non-invasive delivery system by means of a needleless syringe which fires light drug or other substance-containing particles in controlled doses into the intact skin. This is possible using particles of appropriate size entrained in supersonic gas flows (WO-A-9 424 263 page 2, line 34 to page 3, line 2).

2.3 The teaching of the original parent application is that not only dense particles, but also light substances such as drugs for therapy may be delivered by the syringe. The original parent application also teaches that substances other than drugs may be delivered. Thus, according to WO-A-9 424 263 page 2, lines 5 to 7, page 4, lines 12 to 15, and page 11, lines 12 to 14 the agent may be a contraceptive or a genetic material for the genetic transformation of cells.

2.4 The parent application as originally filed claimed different inventions, one of which is now the subject-matter of the present divisional application, whose

claim 1 corresponds to claim 38 of the original parent application and claim 13 of the original divisional application, which claim was supported by a statement of invention on page 5 of the original description. Another statement of invention, in the paragraph linking pages 1 and 2 of the original application, reflects the invention of claim 1 of that earlier application.

Thus, the application as originally filed described the different inventions generally in the opening parts of the description, together with the different agents that may be used. It is true that the above-cited passages of WO-A-9 424 263 describing the non-therapeutic uses follow the statement of invention corresponding to claim 1 of the original parent application, but it is clear that the nature of the agent which may be delivered by the syringe is independent of the structural features of the syringe, and each of the syringes claimed in the original application is capable of delivering the agent, regardless of its nature. This may be seen from original claim 41 according to which the agent may be delivered by either of the syringes defined in claim 1 or claim 38. Moreover, the non-therapeutic use mentioned on page 11 follows the description of and applies to both types of syringes described respectively on pages 1 and 2, and on page 5 and corresponding to claims 1 and 38, respectively, the latter being the syringe now claimed in the present application.

Therefore, both the parent and divisional applications as originally filed did disclose an invention comprising a syringe according to present claim 1 for a non-therapeutic use. The omission of "therapeutic use" in claim 1 is justified, accordingly, and the claim does not infringe either of Articles 76(1) and 123(2) EPC in this respect.

2.5 As regards the dependent claims the examining division criticised only claim 5 of the main request under Article 123(2) EPC, which claim has now been cancelled.

3. *Article 84 EPC*

3.1 WO-A-9 204 439 describes (page 2, lines 16 to 28) a system for firing dense particles into target cells, wherein a membrane closes a passage until ruptured on application of a predetermined pressure of gas from a reservoir, whereupon the particles are propelled by the gas flow from a tubular device. The particles may initially be immobilised on a rupturable diaphragm, which is ruptured when the gas flow commences, and which diaphragm may be the same as the rupturable membrane which ruptures to initiate the gas flow.

The present application as well as the parent and divisional applications as originally filed describe a membrane which ruptures upon application of a high pressure to generate a supersonic gas flow, and up to two diaphragms which immobilise the particles to be fired. Thus, the original parent application (WO-A-9 424 263) describes the rupturable membrane on page 6, line 10 onwards, and two diaphragms for immobilising the particles, on page 11, line 25 onwards.

- 3.2 As stated in point 2.2 above, the needleless syringe can fire light particles into the intact skin if the particles are entrained in a gas flow at supersonic velocities. The supersonic velocities may be achieved by building up the pressure behind a rupturable membrane until the membrane bursts. However, the person skilled in the art knows that other methods of providing a gas flow at supersonic velocities may be employed instead, for example by using a rapidly acting mechanical valve as described in WO-A-9 204 439, on page 3, lines 17 to 21. This paragraph of the prior document makes it clear that the use of a rupturable membrane is not the only way of producing the supersonic gas flow. The rupturable membrane is not, therefore, indispensable for the purposes of the present application.
- 3.3 As regards the means for introducing the particles to be fired into the gas stream, the paragraph linking pages 11 and 12 of the original application makes it clear that two diaphragms are the preferred means. The person skilled in the art would be able to devise other means for this purpose, for example the means suggested in WO-A-9 204 439 on page 2, lines 24 to 26. This paragraph makes it clear that, whereas the particles could be immobilised by a membrane, alternative means may be used for introducing the particles.
- 3.4 The present inventors were, therefore, aware that a rupturable membrane is not indispensable for producing a supersonic gas flow, and that a diaphragm(s) is not indispensable for introducing the particles to be fired into the gas stream. It is for these reasons that

original claim 38 of the parent application and claim 13 of the divisional application (which corresponds to present claim 1) and the corresponding statement of invention on page 5 of WO-A-9 424 263 define, as one of the inventions originally disclosed, a needleless syringe for delivering particles at near supersonic velocities and above, which does not comprise either a membrane or a diaphragm as an essential feature of the invention. Original claims 38 and 13 were, therefore, fairly supported by the description, as is present claim 1. The objection under Article 84 EPC is not justified, accordingly.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of claims 1 to 16 of the main request submitted with the grounds of appeal dated 9 November 2001.

The Registrar:

The Chairman

V. Commare

T. K. H. Kriner