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Datasheet for the decision of 21 September 2006

Case Number: T 1400/05 - 3.2.07

Application Number: 02750541.1

Publication Number: 1368253

IPC: B65D 83/14

Language of the proceedings: EN

Title of invention:
Inhaler with means for improving chemical stability of medicinal aerosol solution contained therein

Applicant:
CHIESI FARMACEUTICI S.p.A.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - (yes after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1400/05 - 3.2.07

D E C I S I O N
of the Technical Board of Appeal 3.2.07
of 21 September 2006

Appellant: CHIESI FARMACEUTICI S.p.A.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 23 June 2005 refusing European application No. 02750541.1 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: C. Holtz
Members: P. O'Reilly
H. Felgenhauer

Summary of Facts and Submissions

I. European application No. 02750541.1 was refused by the examining division.

The examining division held that the subject-matter of the independent claims did not involve an inventive step in view of D1 and the general knowledge of the skilled person.

II. The appellant (applicant) filed an appeal against the decision.

III. Oral proceedings were held before the Board on 21 September 2006.

IV. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of claims 1 to 8 according to the single request filed during the oral proceedings.

V. The independent claims of the single request read as follows:

"1. A medicinal aerosol solution formulation product with improved chemical stability, comprising a pressurized metered dose inhaler (10), comprising an aerosol canister (16) having a rim equipped with a metering valve (18) and rubbers used as valve gasket between the valve and the rim of the canister and containing a medicinal aerosol solution formulation containing a corticosteroid as an active ingredient subject to a degradation by means of peroxides and/or other leachables, a hydrofluorocarbon propellant, a co-

solvent and optionally a low-volatility component, wherein part or all of the internal surfaces of said inhaler (10) consists of stainless steel, anodized aluminium or are lined with an inert organic coating, characterized in that the canister (16) has a rolled neck (40) or full rollover rim (46) to avoid damage and compression of the surface of the rubbers used as valve gaskets and in that the valve (18) is washed before crimping of the valve upon the canister (16) with ethanol."

"8. Process for making a chemically stable medicinal aerosol solution formulation product, comprising a pressurized metered dose inhaler (10), by filling an aerosol solution formulation into a canister (16) having a rim of a pressurized metered dose inhaler (10) equipped with a metering valve (18) and rubbers used as valve gaskets between the valve and the rim of the canister (16), the inhaler (10) consisting of stainless steel, anodized aluminium or being lined with an inert organic coating, the valve (18) being washed with ethanol before crimping of the valve upon the canister (16), the aerosol solution formulation comprising a corticosteroid as an active ingredient subject to a degradation by means of peroxides or other leachables, wherein the canister (16) has a rolled neck (40) or full rollover rim (46) to avoid damage and compression of the surface of the rubbers used as valve gaskets."

VI. The documents cited in the present decision are the following:

D1: WO-A-00/78286
D2: EP-A-1 052 190
D3: US-A-4 271 875

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

The subject-matter of claims 1 and 8 of the single request involves an inventive step. D1 is the closest prior art document. The problem to be solved starting from D1 is to prevent degradation of a medicinal aerosol formulation containing a corticosteroid. D1 was concerned with preventing degradation due to the formation of metal oxides on the interior surfaces of metal canisters. The solution to this problem was to coat these interior surfaces. There is no indication in D1 of a further problem of degradation. The skilled person therefore had no reason to modify the aerosol product disclosed in D1. The inventors of the present application were the first persons to recognise that there was a further problem. It was also the inventors who first recognised that the origin of the problem was the leaching of peroxides from the gasket. The inventors proposed the solution of washing the gasket with ethanol to which there was no hint in the prior art. Furthermore, the inventors were the first to recognise that there was a further problem due to damage or compression of the gasket by the end of the cut-end canister used in D1. The solution to this further problem of providing a rolled neck or full rollover rim was not therefore obvious to the skilled

person. Although this form of neck or rim is known *per se* in the prior art there is no suggestion that it could solve the problem of degradation of a medicinal aerosol formulation containing a corticosteroid.

D2 discloses that the neck of the container may be rolled inwards or outwards in connection with the problem that the profile of the neck has to engage with the mounting means. There is no indication to use containers with rolled necks to improve the chemical stability of an aerosol solution formulation contained therein.

D3 is concerned with fast pressure filling and providing a tight seal for the gasket. Although D3 mentions that sharp edges should be avoided this is mentioned in the context of preventing leakage, not in the context of avoiding minor damage. The problem of stability of a solution contained therein is not mentioned at all in D3.

Reasons for the Decision

1. *Amendments*

1.1 Claim 1 as amended according to the single request is a combination of claims 1, 2, 5, 6, 7, 11 and 13 as originally filed together with a feature taken from the description.

1.2 The originally filed dependent claims 2 and 5 were each directly dependent upon claim 1 and were directed to the features of the canister (16) having a rolled neck

and full rollover rim respectively and may therefore be incorporated into claim 1 as alternative features. Originally filed claims 6, 7, 11 and 13 were each dependent on all the preceding claims so that no new combination of features arises in combining the features of these claims together with the features of claims 2 and 5 in claim 1.

1.3 The feature that the rolled neck or full rollover rim are "to avoid damage and compression of the surface of the rubbers" may be derived from the application description on page 10, lines 4 to 7, page 13, lines 8 to 10 and page 19, line 12 to 17, wherein it is explained that the purpose of the shape of the rim or neck is to avoid damage and compression of the surface of the rubbers, such as occurs in the prior art products.

2. *Novelty*

2.1 The examining division implicitly considered that the subject-matter of the independent claims was novel since in dealing with inventive step it found a difference to the disclosure of the closest prior art document D1. The Board also has satisfied itself that this is the case for the independent claims of the single request before the Board. In particular, the characterising features of the independent product claim 1 and the corresponding features in the independent process claim 8 are not disclosed in D1.

3. *Inventive step*

3.1 The closest prior art is represented by D1 which discloses a medicinal formulation product comprising the features of the preamble of claim 1.

3.2 The objective problem to be solved by the features of claim 1 is to provide a product in which the chemical stability of an aerosol solution formulation containing a corticosteroid is enhanced (cf. application description page 10, lines 8 to 9).

3.3 The solution to the problem is that the canister (16) has a rolled neck (40) or full rollover rim (46) to avoid damage and compression of the surface of the rubbers used as valve gaskets and that the valve (18) is washed before crimping of the valve upon the canister (16) with ethanol.

3.4 D1 concerns an aerosol product which can contain a formulation including a corticosteroid (cf. page 1, lines 8 to 11). The document is directed to the problem of chemical degradation of the corticosteroid when stored in a metal container due to the formation of metal oxides on the interior surface of the container (cf. page 3, lines 8 to 12). The solution to this problem as proposed in D1 is to utilize a non-metal interior surface (cf. page 3, lines 14 to 16). This non-metal interior surface is achieved by providing a coating layer over as much of the surface as is feasible (cf. page 6, lines 18 to 20). Furthermore, a gasket is used which also helps to prevent contact of the formulation with metal components (cf. page 6,

lines 25 to 26). The gasket is thus part of the internal layer covering the metal surface.

3.5 According to the application in suit however there still remained a degradation problem with the corticosteroid whose origin was not known at its priority date (cf. page 8, lines 20 to page 9, line 3). In accordance with the application in suit this problem is solved by washing the gasket with ethanol as set out in the characterising portion of claim 1. As explained in examples 1, 2 and 3 in the description of the application this washing of the gasket reduced the chemical degradation of a formulation containing a corticosteroid as shown by the differences in tables 1 and 2 which concern the gasket not washed with ethanol and washed with ethanol respectively.

Although the washing with ethanol partially solved the problem of degradation of the corticosteroid in that it reduced the degradation there still remained degradation when the product was stored in an inverted position as shown by table 3. Therefore a second problem arises from the partial solution of the general problem which is to further reduce the degradation of the formulation containing a corticosteroid. This remaining problem was believed to be caused by the leaching of peroxides from the gasket rubber (cf. page 18, lines 13 to 16). The prior art contains no hint to such a problem since although washing with ethanol is known per se there is no indication that an ethanol washed valve had been used in conjunction with a cut-end canister. The origin of this remaining problem was recognised in the application in suit to be due to damage or compression of rubber gasket because

of the form of the canister rim which is known as a cut-off rim due to its being formed by cutting of metal to form the rim (cf. page 10, lines 6 to 8 and page 13, lines 2 to 7).

In view of the absence of an indication in the prior art of the problem and the absence in the prior art of an ethanol washed valve being used in conjunction with a cut-end canister there was no indication to the skilled person to look to the rims of the canister for the origin of the problem. Consequently, there was no reason for the skilled person to modify the rims so as to have the form specified in the characterising portion of claim 1.

3.6 D2 discloses a canister with a rolled neck (cf. figures 1 to 3) and D3 discloses a canister with a full rollover rim (cf. figure 8). However, the purpose of these forms of the canister rim is not explained in these documents. Part of the purpose of these features apparently is to provide a form such that a valve stem can be attached and exert a pressure onto the gasket to ensure that the gasket can fulfil its function of preventing leakage. There is no indication that these features may perform other functions.

3.7 D3, in column 5, lines 16 to 20, indicates that the container should have no sharp edges which could cut the gasket. However, this statement is made in the context of causing leakage of the gasket. Such damage would therefore be major such as to cause a failure of the gasket. In accordance with claim 1 there should be a rolled neck or full rollover rim which avoids damage or compression of the surface. This means that any

damage is avoided, not just major damage. D3, in the cited passage, does not therefore give a hint to the particular form of the rim of the canister that is specified in claim 1.

3.8 Independent process claim 8 of the single request contains features corresponding to those of the characterising portion of product claim 1. The provision of these features in a process is not obvious for the same reasons as explained above with respect to the product claim 1.

3.9 Therefore, the subject-matter of claims 1 and 8 of the single request involves an inventive step in the sense of Article 56 EPC.

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 with the order to grant a patent with the following documents:

Claims:	1 to 8 as filed during the oral proceedings;
Description:	pages 2 to 8, 12, and 16 to 20 as originally filed, and pages 1, 9, 10, 11, 13 to 15, and 21 as filed during the oral proceedings;
Drawings:	figures 1A, 1B as originally filed, and figures 2 and 3 as filed during the oral proceedings.

The Registrar: Chair:

G. Nachtigall C. Holtz