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**Datasheet for the decision
of 16 June 2011**

Case Number: T 1309/10 - 3.2.07

Application Number: 01202061.6

Publication Number: 1157749

IPC: B65D 83/14

Language of the proceedings: EN

Title of invention:

Process for preparing a metered dose inhaler

Patent Proprietor:

GlaxoSmithKline LLC

Opponent:

3M Innovative Properties Company

Headword:

-

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Inventive step (all requests - no)"

Decisions cited:

T 1532/09, T 0366/89, T 1191/05, T 1176/05

Catchword:

-



Case Number: T 1309/10 - 3.2.07

D E C I S I O N
of the Technical Board of Appeal 3.2.07
of 16 June 2011

Appellant:
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 19 April 2010
revoking European patent No. 1157749 pursuant
to Article 101(2) EPC.

Composition of the Board:

Chairman: H. Meinders
Members: H. Hahn
E. Dufrasne

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the Opposition Division to revoke the European patent EP-B-1 157 749 for lack of inventive step. It requested to set aside the impugned decision and to maintain the patent on the basis of the main request or, alternatively, on the basis of the first or second auxiliary request, all requests as filed together with the grounds of appeal dated 27 August 2010. In case that the Board should consider a decision other than according to the aforementioned requests, oral proceedings were initially requested.

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

II. The following documents of the opposition proceedings are cited in the present decision:

- D2 = EP-A-0 642 992
- D3 = Ullmann's Encyclopedia of Industrial Chemistry, 5th edition, Vol. A18, VCH Verlagsgesellschaft mbH, Weinheim, Germany (1991), pages 380-382 and 536
- D5 = "Principle of Adhesion of Fluoropolymer Coatings to Substrates", K. Batzar, Advances in Organic Coatings Science and Technology Series 13 (1991), pages 463-471
- D9 = Drug Delivery to the Respiratory Tract, Eds. D. Ganderon and T. Jones (1987); copy of book cover and Chapter 9 "The Formulation and evaluation of pressurized metered-dose inhalers" G. W. Hallworth

- D10 = Pharmacopoeial Forum, "Establishing More Meaningful Specifications and Tests for Metered-Dose Pressurized Inhalers Formulated as Suspensions" Haywood et al., May-June 1989, page 5193
- D11 = Aerosols in Medicine, Principles, Diagnosis and Therapy, F. Moren, M.T. Newhouse and M.B. Dolovich, publ. Elsevier (1985), page 272
- D12 = Pharmacy International "Aerosols for Inhalation Therapy" W.F. Kirk (June 1986) Vol. 7 no.6, pages 150-154 (Reprint)
- D13 = The pharmaceutical Journal "Continuing Education - Drug Delivery (3) Inhalation Therapy" C. Livingstone (October 8, 1988), pages 476-478
- D14 = US-A-2 707 930
- D15a = "Aluminum aerosol Containers" Part I and II, A. Taranger, Soap and Chemical Specialities, July 1957, pages 109-113
- D15b = "European production and consumption of Aluminium aerosol Containers" Part I and II, A. Taranger, Soap and Chemical Specialities, August 1957, pages 125-129 and 151
- D16 = US-A-3 029 507
- D17 = Modern Pharmaceutics, 2nd Edition Ed. Banker and Rhodes, 1990, pages 605, 625 and 630
- D18a = "Teflon^R One Coat Non-Stick Finish 420-104 Gray", The Facts brochure from DuPont, revised 03/88, pages 1-4
- D18b = "Teflon^R 420-Line Quality One Coat Finishes", The Facts brochure from DuPont, issued 2/6/90, pages 1-3
- D18c = DuPont Material Safety Data Sheet "One Coat Gray 420-104", dated 14 June 2004, pages 1-8

- D27 = Declaration of Kenneth Batzar Ph.D. dated 25 April 2007, from the parent European patent 0 820 322
- D28 = EP-A-0 260 067
- D32 = Wikipedia, Definition of an ellipsoid, page 1
- D33 = US-A-3 942 673
- D35 = Handbook of Package Engineering, 2nd edition, Joseph F. Hanlon, McGraw-Hill Book Co., 1984, Table of contents, pages 10-2 to 10-19 and 11-2 to 11-28
- D36 = Remington's Pharmaceutical Sciences, 18th edition, 1990, Mack Publishing Company, Easton, Pennsylvania (USA), pages 1707 and 1708
- D37 = Ullmann's Encyclopedia of Industrial Chemistry, 5th edition, Vol. A11, VCH Verlagsgesellschaft mbH, Weinheim, Germany (1988), pages 393, 396, 401, 403 and 405

III. An opposition had been filed against the patent in its entirety under Article 100(a) EPC, for lack of novelty and inventive step, under Article 100(b) EPC for not disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and under Article 100(c) EPC, that the patent extends beyond the content of the application as originally filed.

The Opposition Division considered that the subject-matter of claims 1 of the main request and of the auxiliary request lacked an inventive step with respect to the closest state of the art D2 in the light of each one of D9-D16 or D33, in combination with D3 and the common general knowledge of the person skilled in the

art as represented by D37. As a result the patent was revoked. The Opposition Division's findings on Articles 83, 84 and 123(2) EPC are of no relevance for the present decision.

- IV. With a communication dated 5 May 2011 and annexed to the summons to oral proceedings the Board presented its preliminary opinion with respect to the claims of the main request and the first to second auxiliary requests, filed with the grounds of appeal.

With respect to inventive step the Board remarked amongst others that D2 appeared to represent the closest prior art from which the metered dose inhaler (MDI) of claim 1 of the main request appeared to be distinguished by the "blend of the one or more fluorocarbon polymer and one or more non-fluorocarbon polymer" for the coating onto the inside of the inhaler and the "substantially ellipsoidal base" of the inhaler. The effect of these features and the existence of the alleged problem needed to be discussed at the oral proceedings.

It appeared that the objective problem as defined by the Opposition Division, i.e. to provide an alternative aluminium or aluminium alloy MDI can, was acceptable and that the solution to this problem as proposed by the respondent appeared obvious in view of a combination of the teachings of D2 and either D33 or D36, particularly when bearing in mind that concave bases were already used for aluminium cans used in the pharmaceutical field for metered dose inhalers. Thus it would be discussed whether or not the solution to this problem involved inventive step.

The Board further noted that coating with a blend of a fluorocarbon polymer with a non-fluorocarbon polymer in order to improve the adhesion of the coating to the aluminium of the wall of the inhaler appeared to be related to a totally different technical problem - which was not linked with the aforementioned one - so that D3 could additionally be used for establishing lack of inventive step of the subject-matter of claim 1 of all requests, similarly as in the case T 1532/09 of the present Board, not published in OJ EPO, relating to the product of the process claimed in the patent in suit.

Furthermore, the applied curing temperature appeared to be the direct result of using specific fluorocarbon polymers since they have to be cured well above their melting point. Finally, it was remarked that no special or surprising effect had been demonstrated by the appellant for any of said polymer blends.

Thus it seemed that the appeal would have to be rejected, as the process of the claims 1 of all requests did not involve inventive step.

- V. With letter dated 23 May 2011 the appellant withdrew its request for oral proceedings without making any substantive submission and further stated "*If oral proceedings take place on 25 August 2011, the Patentee/Appellant does not intend to attend*".

With letter dated 8 June 2011 the respondent, referring to the appellant's letter for withdrawing its request for oral proceedings and its intention not to attend

the scheduled one, requested a decision dismissing the appeal in written proceedings so that the oral proceedings scheduled for 25 August 2011 could be cancelled. The request for oral proceedings was, however, maintained "*in case the Board of Appeal is not inclined to dismiss the appeal of the Patentee in written proceedings*".

VI. Claim 1 according to the main request reads as follows (amendments compared to claim 1 of the patent as granted are in bold, emphasis added by the Board):

"1. A process for preparation of a metered dose inhaler suitable for containing a drug formulation the metered dose inhaler having reduced susceptibility to drug adhesion to the inner surfaces which process comprises:
(i) providing a strengthened aluminium or aluminium alloy metered dose inhaler can comprising a substantially ellipsoidal base capable of withstanding stressful coating and curing conditions;
(ii) providing a formulation of a coating polymer **comprising of a blend of** one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers;
(iii) spray coating said can on its inside with said formulation of coating polymer; and
(iv) curing the coating on the can wherein the curing takes place at a temperature in excess of the melting point of the polymer."

VII. Claim 1 of the first auxiliary request reads as follows (amendments compared to claim 1 of the main request are in bold; emphasis added by the Board):

"1. A process for preparation of a metered dose inhaler suitable for containing a drug formulation the metered dose inhaler having reduced susceptibility to drug adhesion to the inner surfaces which process comprises: (i) providing a strengthened aluminium or aluminium alloy metered dose inhaler can comprising a substantially ellipsoidal base capable of withstanding stressful coating and curing conditions; (ii) providing a formulation of a coating polymer of a blend of one or more fluorocarbon polymers **selected from polytetrafluoroethylene (PTFE), perfluoroalkoxyalkane (PFA) and fluorinated ethylene propylene (FEP)**, in combination with one or more non-fluorocarbon polymers **selected from polyamide, polyimide, polyethersulfone, polyphenylene sulfide and amine-formaldehyde thermosetting resin**; (iii) spray coating said can on its inside with said formulation of coating polymer; and (iv) curing the coating on the can wherein the curing takes place **under curing temperatures in the range of about 300°C to about 400°C at a temperature in excess of the melting point of the polymer.**"

VIII. Claim 1 of the second auxiliary request reads as follows (amendments compared to claim 1 of the main request are in bold; emphasis added by the Board):

"1. A process for preparation of a metered dose inhaler suitable for containing a drug formulation the metered dose inhaler having reduced susceptibility to drug adhesion to the inner surfaces which process comprises: (i) providing a strengthened aluminium or aluminium alloy metered dose inhaler can comprising a

substantially ellipsoidal base capable of withstanding stressful coating and curing conditions;

(ii) providing a formulation of a coating polymer ~~of a blend of one or more fluorocarbon polymers selected from PTFE/FEP/polyamideimide, PTFE/polyethersulphone and FEP-benzoguanamine, in combination with one or more non-fluorocarbon polymers;~~

(iii) spray coating said can on its inside with said formulation of coating polymer; and

(iv) curing the coating on the can wherein the curing takes place **under curing temperatures for the coating in the range of about 300°C to about 400°C**~~at a temperature in excess of the melting point of the polymer.~~ "

IX. The appellant argued in the written proceedings essentially as follows with respect to inventive step:

D2 was agreed to as the closest prior art (see claims 1, 3 and 4; column 4, lines 54 to 57; column 5, lines 7 to 18; drawing).

The technical problem to be solved resides in the pharmaceutical field, which is highly conservative and is governed by the stringent requirements set by the drug regulating bodies, such as the EMEA and the FDA. The skilled person would always have this in mind when making any technical decisions relating to a new development in the MDI field. Therefore at the priority date the skilled person would have appreciated that any MDI would need to satisfy these stringent regulatory requirements, would see that D2 discloses a variety of methods for coating the inside of aerosol containers with a plastics coating but contains no explicit

teaching on how to coat with a blend of one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, and he would be aware that aluminum is a soft, malleable metal with a relatively low melting point of 660°C so that any coating process would have to be compatible with the can material.

Therefore the objective technical problem to be solved is the provision of a process for coating an aluminum MDI can with a blend of one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers without can malforming. The solution thereto, i.e. to use a high temperature spray coating/curing process employing an aluminum can which comprises a substantially ellipsoidal base is not obvious.

Said solution is not obvious over D2 alone which teaches plasma coating as preferred coating method and which does not teach to modify the shape of the base in order to solve the problem. It cannot be inferred from D2 that the cans disclosed therein are able to withstand high temperatures.

Said solution is also not rendered obvious by D2 in combination with common general knowledge since stratification of the two polymers (see D5, page 467, third paragraph) can only be achieved if the blend is heated to a temperature which results in the melt flow of both the high and low surface energy polymers (see D5, page 468, first paragraph), i.e. to a temperature at which the aluminum MDI can will deform. Therefore the skilled person would rule out the use of spray coating and curing as a process for applying a blend of

said two polymers because of its inherent incompatibility with the can material.

If the skilled person, despite the clear teaching in D2 to explore the plasma coating field, decided to investigate the spray coating process he would find no teaching in any of the cited prior art as to how to solve the problem without the can malforming. Eight of the MDI cans cited by the Opposition Division have a concave base and only one (D33) describes a beverage can having an ellipsoidal base. Since D33 relates to a different field and is an old document the skilled person would not consult such a document. Furthermore, the problem underlying D33 is different, namely the provision of a container with the thinnest walls possible, but which would still not buckle when used for packaging pressurized products, such as carbonated beverages, which is different from that of D2. There is no information in D33 about the performance of the can after being subjected to high temperatures. Therefore the Opposition Division used an ex-post facto argumentation with respect to D33 which was published approximately 20 years before the priority date of the claimed invention (see T 366/89, not published in OJ EPO).

In view of D9-D13 it was common general knowledge to have a concave base in order to avoid buckling so that the skilled person was not motivated to modify the shape of the base but documents D9-D16 did not suggest the use of an ellipsoidal base in a pharmaceutical MDI can to reduce the tendency of the can to deform under the high temperatures used for applying a coating to the internal surfaces of the can.

Therefore the subject-matter of claim 1 of each request involves an inventive step.

- X. The respondent argued in the written proceedings essentially as follows with respect to inventive step:

The subject-matter claimed in claim 1 of any request lacks an inventive step over a combination of the teachings of D2 and D3, similarly as for the parent patent EP-B-0 820 279 wherein an aluminium or aluminium alloy can coated with a polymer blend of PTFE and PES has been claimed, or similarly to the patent EP-B-1 166 811 (a divisional of the sister patent EP-B-0 820 322) wherein an aluminium or aluminium alloy can coated with a polymer blend of PTFE and PES and having a substantially ellipsoidal base has been claimed, which is obvious to the person skilled in the art in order to improve the adhesion of the coating as taught by D3. Therefore these three patents have already been revoked (see T 1191/05, T 1532/09 and T 1176/05, respectively, all not published in OJ EPO).

As stated by the patentee's own expert in paragraph 3 of D27 fluoropolymers are generally applied by spraying onto a pre-treated substrate surface followed by high temperature curing (see also D18a and D18c). So the only further feature for all requests is that undefined, indefinite "substantially ellipsoidal base".

Furthermore, as D2 is already able to coat aluminium or aluminium alloy cans with e.g. PTFE, which requires a curing temperature in excess of 300°C due to the melting point of PTFE of 327°C and the appellant has

not demonstrated any technical effect over D2, particularly that "a problem of malformation of the standard MDI can" at high temperatures resulting from the coating and curing process exists - as the reference examples relating to said standard MDI cans have been deleted from the patent in suit - there exists no problem to be solved which has not already been solved by D2. The Patentee has not demonstrated that any problem exists; the problem can be defined as merely providing an alternative MDI can, which is self-evident to the skilled person on the basis of the common general knowledge, as demonstrated by any one of the following D9-D13, D17, D28 and D36.

Alternatively, despite that no technical effect has been demonstrated, the problem may be defined as to provide an aluminum MDI can having the strength and capability to withstand internal pressure of the contained pressurized formulation, thus avoiding or minimizing buckling of the can, which solution is again self-evident to the skilled person in the light of D2 on the basis of his common general knowledge.

Conventional MDI cans have a concave base (see e.g. D9, front cover; D10, figure 1; D11, page 272, figure 6; D12, page 153; D13, page 476; D14, figure 1 and column 2, lines 11 to 15; D15a/D15b, page 109, figure, page 125, left and right column; D16, column 1, lines 43 to 46 and 55 to 56, column 4, line 4, column 7, lines 5 to 7, figures 8 and 9; D17, page 630; D28, figure 1; D33, column 1, lines 5 to 10 and lines 23 to 26; column 2, lines 35 to 39, claim 1 "ellipsoidal dome"; D35, pages 10-14, 11-2 top, 11-7 middle and page 11-10 middle; D36, page 1707, figure 92-14).

XI. As the decision could be arrived at in written proceedings due to the withdrawal of the request therefor by the appellant, the oral proceedings set for 25 August 2011 have been cancelled.

Reasons for the Decision

1. *Allowability of amendments and sufficiency of disclosure (Articles 83, 84 and 123(2) and (3) EPC)*

Since the Board comes to the conclusion that the subject-matter claimed in all requests lacks an inventive step (see point 2 below) there is no need to verify whether or not the claims of these requests or the amendments made therein comply with Articles 83, 84, 123(2) and (3) EPC.

2. *Inventive step (Article 56 EPC)*

Taking account of the arguments presented by the appellant the Board considers that it has not been shown that the Opposition Division's conclusion was wrong in concluding that the subject-matter claimed in the patent in suit lacks an inventive step. The reasons are as follows:

Main request

2.1 Interpretation of process claim 1

2.1.1 The definition "**a substantially ellipsoidal base**" of claim 1 of the main request (see point VI above)

implies according to the patent in suit (see column 4, line 56 to column 5, line 3) an increase of the angle between the side walls and the base of the can, when compared with the hemispherical base of standard MDI cans. However, for an ellipsoidal base this only applies when just a portion of the ellipsoid is taken: for a hemi-ellipsoid the angle is identical to that for a hemisphere, namely zero degrees.

Such a portion of an oblate ellipsoid may be such that its curvature is practically identical to the curvature of a portion of a sphere.

From the Board's point of view there is actually a **decrease** in this angle if a more concave base is to be produced when compared to a flat base as shown in D2, which forms an angle of 90° with respect to the side wall.

- 2.1.2 Taking account of the definition of an "ellipsoid" according to D32 the definition "substantially ellipsoidal base" includes
- a) a portion of a sphere (i.e. a spherical cap),
 - b) an oblate spheroid, and
 - c) a prolate spheroid
- since the fourth possibility - a scalene ellipsoid - does not make any sense from a technical point of view.
- 2.1.3 Likewise - taking account of the statement concerning the angle between the side walls and the base - it does not make sense to consider that a flat base has the form of an ellipsoid since such an embodiment would not change said angle of 90° at all. Therefore any shape which is similar (as in "substantially") or identical

to any of said three ellipsoidal forms a) to c) - also considering technical engineering tolerances - which is **not** hemispherical is considered to meet the requirement of a "substantially ellipsoidal base" of claim 1 of the main request.

It is noted by the Board that the definition in the claim does **not** necessarily imply a hemi-ellipsoidal base.

2.1.4 The feature "a **strengthened** aluminium or aluminium alloy **can** ... capable of withstanding stressful coating and curing conditions" of claim 1 of the main request is interpreted by the Board taking account of the disclosure in the patent in suit. From the patent in suit it is known that "strengthened aluminium or aluminium alloy MDI cans" are "capable of withstanding particularly stressful coating and curing conditions, e.g. particularly high temperatures, which may be required for certain fluorocarbon polymers" and those having a reduced tendency to malform under high temperatures are "MDI cans comprising a substantially ellipsoidal base" (see column 4, line 56 to column 5, line 12).

Consequently, any aluminium or aluminium alloy can which is capable of withstanding higher temperature curing conditions of the applied fluorocarbon polymer and which has an ellipsoidal or a substantially ellipsoidal base as defined above is considered to meet the requirement of the definition of claim 1 "a strengthened aluminium or aluminium alloy MDI can ...".

2.1.5 This interpretation of claim 1 of the main request has been submitted to the parties in the communication annexed to the summons to oral proceedings before the Board (see communication, point 5.2) and has **not** since been contested, particularly not by the appellant.

2.2 D2 represents undisputedly the closest prior art for the subject-matter of process claim 1 of the main request for disclosing a process for preparation of a metered dose inhaler comprising a **flat** base aluminium can coated with a fluorocarbon polymer, preferably PTFE, by spraying and curing the PTFE (see figure; claims 1 to 3; and column 4, line 50 to column 5, line 20).

It belongs to the common general knowledge that the curing of PTFE takes place at a temperature in excess of its melting point as e.g. proven by the Patentee's own expert who stated in paragraph 3 of D27 that fluoropolymers are generally applied by spraying onto a pre-treated substrate surface followed by high temperature curing, or as derivable from the guidance in the manufactures brochures (see D18a and D18c).

2.3 The process according to claim 1 of the main request is therefore distinguished from the process according to D2 in that the inhaler has i) "**a substantially ellipsoidal base**" and by the provision of a formulation of ii) "**a coating polymer of a blend of one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers**".

2.4 A specific effect of the feature i), however, has **not** been credibly demonstrated by the appellant.

In its communication annexed to the summons to oral proceedings the Board pointed out the deficiency that, particularly in view of the examples referring to the standard MDI cans deleted in the patent in suit, there exists in the patent **no proof** that the problem allegedly solved by the ellipsoidal form of the base, namely the tendency of the can to malform at the high temperatures necessary for coating and curing of the fluorocarbon polymers, actually exists (see communication, point 6.2), or is even solved by this feature.

The appellant's reply to the Board's communication is absolutely silent with respect to any such inventive step issue (see point VI above). It has also in the preceding proceedings **not** submitted any evidence with respect to an effect of the feature "a substantially ellipsoidal base", **nor** with respect to the aforementioned alleged problem.

- 2.4.1 According to the patent in suit this feature i) provides "strengthened MDI cans ... capable of withstanding stressful coating and curing conditions", and offers "the further advantage of facilitating the coating process" (see patent in suit, column 5, lines 3 to 12).
- 2.4.2 In this context the Board remarks that the examples 1-8 of the patent in suit neither specify any (parameter) details as to the shape of the used "substantially ellipsoidal base" nor do they provide any other comparative data, as the original reference examples 1-12 have been deleted.

These deleted reference examples 1-12 comprised in the application underlying the patent in suit were made by coating **standard** aluminium MDI cans with the specified fluorocarbon polymers (examples 1, 3 to 5, 7 to 10, 12) or they resulted (examples 2, 6 and 11) in **standard** cans by deep-drawing 0.46 mm thick standard aluminium sheet spray coated with FEP (example 1) or with FEP-benzoguanamine (examples 6 and 11). Moreover, neither for the deleted reference examples nor for the (remaining) examples 1-8 of the patent in suit there is provided data relating to any tendency to malform under high temperatures.

Finally, the comparison of the dose delivery under simulated use conditions between the coated MDI cans and - uncoated - control MDI cans (see patent in suit, paragraph [0026]) is without any relevance to the MDI cans according to the closest state of the art D2 and is also not suitable for demonstrating any effect which could be attributed to the "substantially ellipsoidal base".

- 2.4.3 It needs further to be considered that the "substantially ellipsoidal base" (see points 2.1.1, 2.1.2 and 2.1.3 above) allows for an interpretation which includes a portion of an oblate ellipsoid which in its one extreme form can come close to a hemisphere, or which in its other extreme form may have only such a slight curvature that the resulting ellipsoid is nearly a flat plane. Therefore, for both these possible extremes no effect can be deduced from the claimed invention since these latter two variants are also considered to facilitate the coating process.

2.4.4 Consequently, the Board can neither accept the alleged effect nor the problem alleged to be solved.

2.5 Therefore a less ambitious objective technical problem has to be defined when starting from the closest prior art D2 and considering feature i) which is, in agreement with the impugned decision, to provide an alternative form for the base of the aluminium or aluminium alloy MDI inhaler cans.

2.6 Blending a fluorocarbon polymer with a non-fluorocarbon polymer according to feature ii) improves the adhesion of the polymer coating to the can wall (see patent, column 5, lines 24 to 29).

Consequently, this feature ii) relates to a totally different technical problem, i.e. to provide an improved adhesion of the polymer coating, which is not synergistically linked with the technical problem of providing an alternative MDI can according to feature i) (see point 2.5 above).

In this context the Board remarks that the appellant has **not** demonstrated any special or surprising effect for any of the polymer blends specified in the patent in suit for the coating although this deficiency had been mentioned in the Board's communication (see point IV above).

Consequently, no combinatorial effect of these polymers blends and a substantially ellipsoidal base can be acknowledged and features i) and ii) are considered to represent a mere aggregation of two separate features,

solving two partial problems, which can thus be discussed independently for inventive step.

Therefore, in order to solve the aforementioned partial technical problem with respect to feature ii), further prior art can be taken into account, in accordance with the longstanding practice of the Boards of Appeal (see Case Law of the Boards of Appeal of the European Patent Office, 6th edition 2010, section I.D.8.2.2).

2.7 The solution to the **first partial problem** is obvious for the following reasons:

2.7.1 The appellant admitted in its appeal brief that MDI containers for aerosol formulations of pharmaceuticals were part of the common general knowledge. It was also part of this common general knowledge that these aluminium MDI cans have a concave base (see e.g. D36, page 1707, figure 92-14 and page 1708, first full paragraph).

This concave base according to figure 92-14 of D36 corresponds to a portion of a sphere according to definition a) of an ellipsoid (see point 2.1.2 above).

2.7.2 The Board therefore considers that it is an obvious alternative for the person skilled in the art to use the concave base as disclosed in D36.

2.7.3 Furthermore, the person skilled in the art would be expected to follow a trend in the art prevailing for many years, as argued by the respondent with a large number of documents, i.e. to use a concave base for MDI cans. Thereby, however, the person skilled in the art

arrives at a process for preparing an aluminium MDI can falling within the interpretation of claim 1 of the main request, as given in points 2.1.2 and 2.1.3.

2.7.4 The above also applies when considering the base of the inhaler of the invention to be a slim portion of an oblate spheroid according to definition b) of an ellipsoid, of which the curvature will be identical to the curvature of a portion of a sphere with a large radius.

2.8 The solution to the **second partial problem** based on feature ii) is also obvious since it is known from the text book D3 that "**mixtures of PTFE dispersions and heat-resistant hydrocarbon polymers (e.g. polyimide, polyether sulfone, or polyphenylene sulfide)** have been developed to improve the poor adhesion of fluoropolymer to a substrate and applied as a primer or one-coat enamel [2.24]" (see page 380, right hand column, third paragraph). In the parallel case T 1532/09 the appellant had admitted that polyether sulfone or polyether sulphone are merely alternative spellings for the PES compounds (see T 1532/09, *supra*, point 5.2 of the reasons).

The person skilled in the art is thus taught by D3 that a mixture, i.e. a blend, of PTFE and PES can be used to improve the adhesion of the fluorocarbon polymer to the substrate.

2.9 Therefore the Board considers it to be obvious that the person skilled in the art, in order to solve the technical problem of providing the MDI can with an improved adhesion of the fluorocarbon polymer coating,

would also apply the teaching of D3 to the can of D2. Thereby the person skilled in the art would arrive at the subject-matter of claim 1 of the main request without any inventive skill.

The subject-matter of claim 1 of the main request thus lacks inventive step (Article 56 EPC). The main request is therefore not allowable.

First auxiliary request

3. The subject-matter of claim 1 of the first auxiliary request differs from that of the main request in that it requires in its feature (ii) the provision of a formulation of a coating polymer "of a blend of one or more fluorocarbon polymers selected from **polytetrafluoroethylene (PTFE)**, perfluoroalkoxyalkane (PFA) and fluorinated ethylene propylene (FEP), in combination with one or more non-fluorocarbon polymers selected from polyamide, polyimide, **polyethersulfone**, polyphenylene sulfide and amine-formaldehyde thermosetting resin" and in its feature (iv) that curing takes place "under curing temperatures in the range of about 300°C to about 400°C" (see point VII above).
- 3.1 This temperature range of "300-400°C" according to feature (iv) is not considered to be the result of the application of inventive skills in view of the melting point of PTFE of 327°C (see D37, page 396). Furthermore, the person skilled in the art would have to work within said temperature range since PTFE is used in D2 (see column 4, line 56 and column 5, lines 7 to 16) and the curing temperature according to the patent in suit is

typically about 50°C above the melting point of the fluorocarbon polymer/polymer blend (see patent, paragraph [0035]). For the commercial product "Teflon^R one coat non-stick finish 420-104 gray" of DuPont, which comprises a blend of PTFE and PES (see D18c, page 1, product name and product code; and section 2, composition) as now claimed, an optimum curing temperature of 370°C for 10 minutes is disclosed (see D18a, page 2, paragraph "bake").

Furthermore, the above conclusion of point 2.8 applies *mutatis mutandis* with respect to the features (i) to (iii) of independent claim 1 of the first auxiliary request - (see point VII above) - since the process for the preparation of the PTFE/PES spray coated MDI can having the concave base according to D36, i.e. in the form of a "spherical cap", inherently also meets these requirements.

- 3.2 The subject-matter of claim 1 of the first auxiliary request therefore lacks an inventive step and the first auxiliary request is therefore not allowable.

Second auxiliary request

4. The above conclusion of point 3.2 applies *mutatis mutandis* to the subject-matter of independent claim 1 of the second auxiliary request - requiring a coating polymer selected from PTFE/FEP/polyamideimide, **PTFE/polyethersulphone** (i.e. **PES**) and FEP-benzoguanamine (see point VIII above) - since the process for preparation of the PTFE/PES coated MDI can having the concave base as a portion of a sphere with a

constant radius according to D36, i.e. in the form of a "spherical cap", inherently also meets this requirement.

The subject-matter of claim 1 of the second auxiliary request thus lacks inventive step (Article 56 EPC) either. The second auxiliary request is therefore also not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

G. Nachtigall

H. Meinders