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Datasheet for the decision of 7 October 2010

Case Number: T 1532/09 - 3.2.07

Application Number: 01122359.1

Publication Number: 1166811

IPC: A61M 15/00

Language of the proceedings: EN

Title of invention:
Metered dose inhaler for fluticasone propionate

Patent Proprietor:
GlaxoSmithKline LLC

Opponents:
Opponent I : 3M Innovative Properties Company
Opponent II : NORTON HEALTHCARE LIMITED
Opponent III: Chiesi Farmaceutici S.p.A.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 104
RPBA Art. 15(3), 16(1)c), 16(1)e)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (all requests - yes)"
"Inventive step (all requests - no)"
"Apportionment of costs (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1532/09 - 3.2.07

D E C I S I O N
of the Technical Board of Appeal 3.2.07
of 7 October 2010

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 8 June 2009 revoking European patent No. 1166811 pursuant to Article 102(1) 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-1 166 811 for lack of inventive step.

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 to 382 and 536

D18a = "Teflon® One Coat Non-Stick Finish 420-104 Gray", The Facts brochure from DuPont, revised 03/88, pages 1 to 4

D18b = "Teflon® 420-Line Quality One Coat Finishes", The Facts brochure from DuPont, issued 2/6/90, pages 1 to 3

D18c = DuPont Material Safety Data Sheet "One Coat Gray", dated 14 June 2004, pages 1 to 8

D27 = Declaration of Kenneth Batzar Ph.D. dated 25 April 2007, from the parent patent

D33 = US-A-3 942 673

D35 = Handbook of Package Engineering, 2nd edition, Joseph F. Hanlon, McGraw-Hill Book Co., 1984

D36 = Remington's Pharmaceutical Sciences, 18th edition, 1990, Mack Publishing Company, Easton, Pennsylvania (USA), pages 1707 and 1708

D37 = Wikipedia, Definition of an ellipsoid, page 1

D41 = Ullmann’s Encyclopedia of Industrial Chemistry, 5th edition, Vol. A11, VCH Verlagsgesellschaft

mbH, Weinheim, Germany (1988), pages 393, 396, 401, 403 and 405

III. Three oppositions had been filed against the patent in its entirety under Article 100(a) EPC, for lack of novelty and inventive step (opponents I, II and III), and 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 (opponents I, II and III) and under Article 100(c) EPC, that the patent extends beyond the content of the application as originally filed (opponents I and II).

The Opposition Division held that claim 1 as granted according to the main request met the requirements of Article 54 EPC but lacked an inventive step over a combination of the teachings of D2 and D33. Claim 1 of the first auxiliary request filed during the oral proceedings before the Opposition Division, since it was the same as that of the main request, was held to lack an inventive step for the same reasons. At these oral proceedings the first to sixth auxiliary requests filed with letter dated 19 February 2009 were renumbered as second to seventh auxiliary requests. The claims 1 of the second to fourth auxiliary request were held to likewise lack an inventive step since the additional features were known either from D2 or D3. The claims 1 of the fifth to seventh auxiliary requests were also considered to lack an inventive step taking account of the general knowledge of the person skilled in the art as represented by e.g. D3, D27 and D41. 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 30 April 2010 and annexed to the summons to oral proceedings the Board presented its preliminary opinion with respect to the claims of the main request and first to seventh auxiliary requests as filed with the grounds of appeal.

With respect to novelty the Board noted that the subject-matter of all requests appeared to be novel over D2 which, in the opposition proceedings, was the only document alleged to be novelty destroying.

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 of claim 1 of the main request (and of the first auxiliary request, for that matter) appeared to be distinguished by the "(substantially) ellipsoidal base". The effect of this feature and the existence of the alleged problem needed to be discussed. 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 offered by the respondents was 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 was obvious.

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 the claims 1 of the second to seventh auxiliary requests.

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.

V. With letter dated 6 September 2010 the appellant maintained the main and first auxiliary request unamended but withdrew the second and fifth auxiliary request. The third and fourth auxiliary request were also kept unamended but renumbered as second and third auxiliary request. The sixth and seventh auxiliary request were both amended by deleting the term "about" from the feature "about 300°C to 400°C" and were renumbered as fourth and fifth auxiliary request. The appellant submitted only arguments with respect to the Article 123(2) EPC issue with the remaining requests, as also discussed by the Board in its annex to the summons.

VI. With letter dated 1 October 2010 the appellant notified "the Board of Appeal that Patentee/Appellant does not intend to attend the Oral Proceedings scheduled for 7 October 2010, but will rely on its written submissions which have been filed in these proceedings,

including the Patentee/Appellant's written submission of 6 September 2010".

VII. Oral proceedings before the Board were held on 7 October 2010. Although having been duly summoned, the appellant did not attend the oral proceedings, as announced. According to Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without it. To start, the Board repeated its opinion with respect to the issue of inventive step of the subject-matter of claim 1 of all requests which was then discussed with the three respondents. Thereafter the issue of an apportionment of costs raised during the oral proceedings was discussed.

(a) The appellant requested in writing that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, in the alternative on the basis of the first auxiliary request filed with letter dated 16 October 2009, or one of the second to fifth auxiliary requests, all filed with letter dated 6 September 2010.

(b) The respondents I, II and III (opponents I, II and III) requested that the appeal be dismissed and that an apportionment of costs for the oral proceedings be allowed.

At the end of the oral proceedings the Board announced its decision.

VIII. Claim 1 of the patent as granted, i.e. according to the main request, reads as follows:

"1. A metered dose inhaler comprising a can, a crimped cap covering the mouth of the can and a drug metering valve situated in the cap, for dispensing an inhalation drug formulation comprising fluticasone propionate or a physiologically acceptable solvate thereof, and a fluorocarbon propellant, optionally in combination with one or more other pharmacologically active agents or one or more excipients, wherein said metered dose inhaler can has all of its internal surfaces coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers characterised in that the said can is a strengthened aluminium or aluminium alloy can having a reduced tendency to malform under high temperatures, comprising a substantially ellipsoidal base."

IX. Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the term "**substantially**" of the last feature has been deleted.

X. Claim 1 of the second auxiliary request differs from that of the main request in that in the introductory portion the polymers have been restricted to "… coated with **a polymer blend selected from PTFE/FEP/polyamideimide, PFTE/polyethersulphone and FEP-benzoguanamine**".

XI. Claim 1 of the third auxiliary request differs from that of the main request in that in the introductory portion of the claim the polymer has been restricted to "… coated with **a blend of PTFE and polyethersulfone**".

XII. Claim 1 of the fourth auxiliary request differs from that of the second auxiliary request in that in the characterizing portion the feature "under **curing temperatures for the coating in the range of 300°C to 400°C**" has been incorporated.

XIII. Claim 1 of the fifth auxiliary request differs from that of the third auxiliary request in that in the characterizing portion the feature "under **curing temperatures for the coating in the range of 300°C to 400°C**" has been incorporated.

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

D2 was considered in the opposition proceedings as the closest prior art among all parties and as acknowledged in the decision. D2 discloses an aerosol container for pharmaceutically active aerosols that are to be administered in predetermined amounts, wherein the inner wall of the container is coated with a plastics coating (see claim 1). The container may be made of aluminium (see column 5, lines 17 to 18). It has a wall thickness in the range of approx. 0.1 to 2 mm (see claim 3) and a volume in the range of approx. 1 to 100 ml (see claim 4) and a flat base (see drawing).

The objective technical problem based on D2 is the provision of a metered dose inhaler canister, made from aluminium or an alloy thereof, which has reduced tendency to malform under high temperatures so that it is capable of withstanding the particularly high temperatures of the coating and curing process.

The alternative formulation of the technical problem as done by the Opposition Division is not accepted since it is based on a misinterpretation of the teachings of D2. The volume of standard MDI containers is generally between 8-12.5 ml and the wall thickness generally around 0.4 mm while D2 describes containers between 1 ml and 100 ml, which may have a variable thickness of 0.1 mm to approx. 2 mm (see column 2, lines 35 and 36 and lines 50 and 51). D2 further lists a variety of processes for coating the inner walls with the desired coating, namely plasma coating, an impregnating/spraying process, hard anodization with PTFE inclusion, chemical vapour deposition (CVD) and physical vapour deposition (PVD), but there is nowhere any indication of a problem of malformation of the standard MDI can at high temperatures resulting from the coating and curing process. There is no disclosure of any solution to this problem in D2, let alone the specific solution offered by the Opposition Division of increasing the wall thickness in order to prevent the malformation of the can at high temperatures.

D2 makes no connection whatsoever between can wall thickness and coating technique e.g. that thickened walls would be beneficial when using a plasma coating process. In fact there is a preference for a wall thickness of 0.4 mm in D2 (see column 2, lines 33 to 36 and 39 to 48). Therefore the Opposition Division's formulation of the objective technical problem must be incorrect.

Furthermore, such redefinition of the problem is based on hindsight, based on the teaching of D33 which is not the closest prior art.

The solution to the problem underlying the present invention is not obvious 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 field of MDI cans.

Said solution is not obvious over D2 alone which does not teach to modify the flat base by replacing it with a substantially ellipsoidal one. Said solution is also not rendered obvious by D2 in combination with common general knowledge as represented by the standard MDI cans having a constant radius of curvature as disclosed in the prior art including D36, which would not result in the solution as claimed in any of the main or auxiliary request.

Said solution is also not obvious over a combination of the teachings of D2 and D33 since the person skilled in the art would not consult D33 which relates to a container primarily for beer or other carbonated beverages. This is due to the fact that the specialised pharmaceutical area is subject to stringent control by drug regulatory authorities, which is significantly different from that of beverage cans.

The Opposition Division has not given any reason as to why the skilled person would look for solutions in said different technical field.

D35 does not in any way suggest that the issues involved in packaging pharmaceuticals are the same as those in other fields, and does not support the assertion that the - ordinary - skilled person in the field of cans looks in the field of beverage cans. But even if it were to consult D33 the skilled person would note that the technical problem to be solved in D33 is 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.

This is not the same as that facing the skilled person starting from the cans of D2 since in that case it is required to adapt the can of D2, which already is able to withstand pressures of 80 psi (standard in a MDI product), so that it does not malform under the high temperatures required to coat the can with one or more fluorocarbon polymers. There is no information about such behaviour except the reference to the pasteurisation process (see column 1, line 44) which is about 70°C. In the beverage packaging field cost of goods is the primary concern whereas in the pharmaceutical packaging field it is the quality.

Furthermore, the age of D33 (published in 1976) can be a factor in determining non-obviousness. The field of MDI development is very active, also between the publication date of D33 and the priority date of the claimed invention. The 20 year period between the two

publications is a relatively long time so that it would have been against normal technical development to rely on such an old art, particularly as the stated benefits of D33 (increased buckling resistance and cost savings) did not result in ellipsoidal bases being adopted in the MDI field during said 20 year period. If it were obvious, why did D2 not also disclose this embodiment? Furthermore, the skilled person would be expected to follow a trend in the art prevailing for many years, in this case use of concave base with a constant radius of curvature for MDI cans and not to depart from this trend based on an old document concerning a different product (see T 0366/89 not published in OJ EPO).

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

XV. Respondent I argued essentially as follows:

The subject-matter claimed in claim 1 of all requests lacks an inventive step over a combination of the teachings of D2 and D3, which was similarly applicable to the parent patent wherein an aluminium or aluminium alloy can coated with a polymer blend of PTFE and PES had been claimed which according to the decision T 1176/05 (not published in OJ EPO) was considered to be obvious to the person skilled in the art. So the only further feature for all requests is the undefined, indefinite "substantially ellipsoidal base" (or only for the first auxiliary request the "ellipsoidal base"). Furthermore, as the teaching of D2 already enables 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 of 260-280°C for FEP (see D41, page 396), the appellant has not demonstrated that a problem of malformation of the standard MDI can at high temperatures resulting from the coating and curing process actually exists - which in any case would be inconsistent with the reference examples of the patent in suit - there exists no problem to be solved which has not already been solved by the can of D2.

Conventional MDI cans have a concave base (see e.g. D36, page 1707, figure 92-14) and are typically made of aluminium or aluminium alloy. There is no difference between a concave base and a base cut off from an oblate spheroid, which is of a "substantially ellipsoidal" form. Combining the teachings of D2 and D36 is therefore obvious.

Respondent I's request for apportionment of costs should be granted since it represents an abuse of the proceedings, particularly in view of the Board's opinion, to inform the Board and the other parties at such short notice that the appellant does not attend the oral proceedings. The appellant could have withdrawn its request for oral proceedings or even its appeal since it knew that this case is hopeless. The respondent therefore had put unnecessary time into preparing for the oral proceedings.

XVI. Respondent II argued essentially as follows:

The closest prior art is represented by D2 and the approach of the Opposition Division is correct, i.e. that the problem of providing a can with sufficient strength had already been solved by D2 and that the

patent in suit simply provided an alternative approach to increasing the wall thickness, namely to provide a substantially ellipsoidal base (see page 6, lines 19 to 22 of the application as originally filed).

D33 addresses the problem of how to strengthen the can without having to increase the wall thickness (see column 1, lines 11 to 20), which is precisely the problem underlying the patent in suit. The appellant's arguments concerning the limitation of the skilled person to seek solutions only in the pharmaceutical field cannot be accepted since he would not ignore relevant teaching as in D33 which is not limited to said sector. To the contrary, he would look in the area of material science in general for the application of fluorocarbon polymer coating, especially cookware and the containment of corrosive materials, and also with respect to the strength. D33 is not restricted to beverages but to the field of packaging food and drinks, which is also highly regulated as is the pharmaceutical field. Both are controlled by the same Food and Drug Administration.

Furthermore, the person skilled in the art is expected to look for solutions also in the broader technical field as held by the present Board in T 1160/07 (see point 7.3 of the reasons).

Also the general text book D35 considers the two types of can (beverage and aerosol) equivalent, utilizing internal pressure (see pages 10-14 and 10-16). The part concerning specifically aerosols refers explicitly to pharmaceutical aerosols (see pages 11-7 and 11-10). Therefore the person skilled in the art can be expected

to come across D33, in search of an alternative approach for strengthening an MDI can, other than by providing a spherical dome (see column 1, lines 19 and 20; column 2, line 29 of this document). The proposed alternative in the form of an ellipsoidal dome has the additional advantage of increasing the buckling resistance (see column 3, lines 60 to 62).

Likewise a combination of the teachings of D2 with D36, the latter also disclosing conventional cans, results in the subject-matter claimed, particularly as said feature "substantially ellipsoidal base" is so broad and unclear that it must encompass also the concave bottom of conventional cans. If a small portion of a sphere or of an ellipse is taken for the base of the cans, there is no distinction between the two.

With respect to the second to fifth auxiliary requests it is remarked that the opposed patent provides no mention of any unexpected benefits in combining the fluorocarbon polymer coating with a substantially ellipsoidal base. Blends of a fluorocarbon polymer with a non-fluorocarbon polymer, e.g. PTFE/polyethersulphone (PTFE/PES), in order to improve the adhesion of the coating, belong to the prior art (see e.g. D3 or D18a/b/c). The claimed temperature range of "300-400°C" is not inventive in view of the melting point of PTFE of 327°C (see D41, page 396) and is nothing more than a result to be achieved for proper coating. Furthermore, the person skilled in the art would work within said temperature range since PTFE is used as a coating in D2 (see column 4, line 56 and column 5, lines 7 to 16).

An apportionment of costs should be awarded to the respondent since the oral proceedings could have been cancelled by the Board if the appellant either would have withdrawn its consent to the text of the patent, would have withdrawn its request for oral proceedings, or would have notified its intended absence more in advance of the oral proceedings so that the Board could have decided the case in written proceedings. This is all the more true since the appellant has shown that it is no longer interested in its patent since it did not address all the outstanding issues in its reply to the Board's communication and only with its letter dated 1 October 2010 informed the Board that it would not attend the oral proceedings. It is unreasonable to give this information at such short notice.

XVII. Respondent III argued essentially as follows:

D2 represents the closest prior art from which the subject-matter of claim 1 as granted is distinguished in that the can comprises a substantially ellipsoidal base. The technical problem in view of D2 as proposed by the appellant cannot hold as correctly outlined by the Opposition Division since this problem is already solved by D2. Hence the objective technical problem is the provision of an alternative can with otherwise the same properties as that disclosed in D2. Whether one starts from this problem or from that put forward by the Opposition Division, i.e. to find an alternative solution which allows the reduction of the can's wall thickness while maintaining its form does not make any difference since in any case the provision of a substantially ellipsoidal base does not involve an inventive step.

The appellant submitted 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 cans have a concave base with a constant radius of curvature (see e.g. D36). The appellant overlooks the fact that such a concave base with a constant radius of curvature falls within the definition of claim 1 as granted and thus its application to the can of D2 lacks an inventive step.

In addition, said so-called concave bases with a constant radius of curvature in the prior art are actually substantially ellipsoidal bases as has been demonstrated by respondents I and II. In particular D36 discloses such pharmaceutical containers made from aluminium with an internal resin coating (see page 1707, right column, paragraph above figure 92-14; page 1708, first full paragraph, last sentence). The base of the can shown in figure 92-14 is a substantially ellipsoidal base.

Therefore starting from D2 the person skilled in the art seeking to provide an alternative can with the same properties as that disclosed in D2 would come across D36 and would there find a typical aluminium container having a substantially ellipsoidal base, which can be coated, i.e. resist high temperatures under coating conditions. The exchange of a flat base as shown in D2 by the form of the base which was typical at the priority date for aluminium aerosol containers used for metered dose inhalers (D36) therefore does not involve an inventive step. Thus also the appellant's

allegations concerning the unique field of pharmaceuticals and its stringent regulatory requirements cannot hold.

Likewise the appellant's arguments concerning a possible combination of D2 and D33 - that the skilled person would not consult D33 since he would be too mindful that he was working in a highly specialised area subject to stringent control by drug regulatory authorities - cannot hold. Furthermore, the appellant has not provided any reasonable explanation as to why the stringent requirements in the pharmaceutical field may have prevented the person skilled in the art of package engineering from considering and trying out the ellipsoidal base shown of the beverage can of D33 in a MDI can. D36 shows that such a base was used for beverage cans as well as to pressurized metered dose inhalers. With respect to the age of D33, published in 1976 approximately 20 years before the priority date of the claimed invention, it is remarked that it shows that already in 1976 cans with a substantially ellipsoidal base were known so that the replacement of a flat base with such a base cannot involve an inventive step.

The patent has not shown any unexpected and beneficial effect of the use of such a base in comparison to e.g. the flat base of D2 as regards the suitability for high temperature coating procedures. The claims of the auxiliary requests do not contain any additional features which are not disclosed in D2 or which would render the claimed subject-matter inventive over a combination of the teaching of D2 and the common

general knowledge as exemplified in the teachings of D33 or D36.

The request of the two other respondents for apportionment of costs is joined. Respondent III could not be sure that the appellant actually would not show up due to the unclear wording "do not intend to attend". It therefore prepared itself unnecessarily.

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 3 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. *Novelty (Article 54 EPC)*

Main request

2.1 The definition "**a substantially ellipsoidal base**" of claim 1 as granted (see point IX above) implies according to the patent in suit paragraph [0021] 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. However, 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.

2.1.1 Taking account of the definition of an "ellipsoid" according to D37 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.

2.1.2 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 as granted.

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

2.1.3 The feature "a **strengthened** aluminium or aluminium alloy **can** having a reduced tendency to malform under high temperatures" of claim 1 as granted is interpreted by the Board taking account of the disclosure in the patent in suit. From paragraph [0021] of 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".

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 can …".

2.1.4 This interpretation of claim 1 as granted has been submitted to the parties in the communication annexed to the summons to oral proceedings before the Board (see communication, point 5.1) and has **not** since been contested, particularly by the appellant.

2.2 D2 - which in the opposition proceedings was the only document alleged to be novelty destroying - discloses a metered dose inhaler comprising a fluorocarbon polymer, preferably PTFE, coated aluminium can having a **flat** base (see figure; claims 1 to 3; and column 4, line 50

to column 5, line 20), which as pointed out above under no circumstances (even if considering manufacturing tolerances etc.) can be considered to fall within the definition of a metered dose inhaler according to claim 1 as granted comprising "a substantially ellipsoidal base".

Consequently, novelty of the subject-matter of claim 1 as granted according to the main request is acknowledged (Article 54 EPC).

First to fifth auxiliary requests

2.3 The same conclusion of point 2.2 above holds true with respect to the subject-matter of claim 1 of the first auxiliary request requiring "an ellipsoidal base" and of the second to fifth auxiliary requests which also require a(n) (substantially) ellipsoidal base (see points IX to XIII above).

Therefore the subject-matter of the claims 1 of the first to fifth auxiliary requests is considered to be novel, also.

3. *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

3.1 D2 represents undisputedly the closest prior art for product claim 1 of the patent as granted for disclosing a metered dose inhaler comprising a PTFE coated aluminium can having a **flat** base (see point 2.2 above) from which the inhaler of claim 1 is therefore only distinguished by having "**a substantially ellipsoidal base**".

3.2 A specific effect of this feature, 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 reference examples of the patent in suit, there exists in the patent **no proof** that the alleged problem, namely the tendency of the can to malform at high temperatures necessary for coating and curing of the fluorocarbon polymers, actually exists (see communication, point 7.2), or is even solved by this feature.

The appellant's reply to the communication is absolutely silent with respect to any inventive step issue (see point V above). It has also in the proceedings **neither** submitted any evidence with respect to an effect of the feature "a substantially ellipsoidal base" **nor** with respect to the aforementioned alleged problem.

3.2.1 According to the patent in suit this feature provides "strengthened MDI cans which have a reduced tendency to malform under high temperatures", and offers "the

further advantage of facilitating the coating process" (see patent, column 5, lines 25 to 31).

3.2.2 In this context the Board remarks that the examples 1-24 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 comparative data with respect to the reference examples 1-15.

The reference examples 1-15 of the patent in suit were made by coating **standard** aluminium MDI cans with the specified fluorocarbon polymers or they resulted in **standard** cans by deep-drawing 0.46 mm thick coated standard aluminium sheet at identical process conditions as the examples 1-24 involving "a substantially ellipsoidal base" (see patent, paragraph [0056]). However, neither for the reference examples nor for these examples there is provided data relating to any tendency to malform under high temperatures.

The comparison of the dose delivery under simulated use conditions between the coated MDI cans and - uncoated - control MDI cans (see patent, paragraph [0057]) is without any relevance to the MDI cans according to the closest state of the art D2 and also not suitable for demonstrating any effect which could be attributed to the "substantially ellipsoidal base".

3.2.3 In this context the Board remarks that the MDI cans of reference examples 4, 9 and 14 were "strengthened aluminium" MDI cans since they were deep-drawn from fluorocarbon polymer coated 0.46 mm thick standard aluminium sheet material and were capable to withstand

the curing conditions applied. Said curing conditions are typically, for example, about 50°C above the melting point of the polymer (see patent, paragraph [0035]). For the reference examples 4, 9 and 14 it is a blend of FEP and benzoguanamine. FEP has a melting point in the range of 260-280°C (see D41, page 403, left column, last paragraph), thus implying a curing temperature well above 300°C, namely about 310°C-330°C.

Thus it is only these three reference examples of the patent which apparently have anything to do with the alleged problem of the tendency to malform at high temperatures, but not those with the (substantially) ellipsoidal base.

3.2.4 It needs further to be considered that the "substantially ellipsoidal base" (see points 2.1, 2.1.1 and 2.1.2 above) allows for an interpretation which includes a portion of an oblate ellipsoid which in its one extreme can come close to a hemisphere, or which in its other extreme may have 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 patent since these latter two variants are also considered to facilitate the coating process.

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

3.3 Therefore a less ambitious objective technical problem has to be defined when starting from the closest prior art D2 which is, in agreement with the impugned

decision, to provide an alternative base to aluminium or aluminium alloy MDI inhaler cans.

3.4 This problem is solved by the MDI can as defined in claim 1 of the main request.

3.5 The subject-matter of claim 1 of the main request is, however, obvious for the following reasons:

3.6 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 with a constant radius of curvature (see e.g. D36, page 1707, figure 92-14 and page 1708, first full paragraph).

This concave base with a constant radius of curvature according to figure 92-14 of D36 corresponds to a portion of a sphere according to definition a) of an ellipsoid (see point 2.1.1 above).

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

3.6.2 Since D2 and D36 both relate to aluminium MDI cans and the preferred side wall thickness according to D2 is about 0.4 mm (see column 5, lines 18 to 20) which concurs well with the thickness of 0.46 mm according to the reference examples 4, 9 and 14 of the patent in suit (which allegedly have less tendency to malform), there exists also no reason as to why the person

skilled in the art would not apply the teaching of D36 in the inhaler of D2.

3.6.3 Furthermore, as argued by the appellant, the person skilled in the art would be expected to follow a trend in the art prevailing for many years, i.e. to use a concave base with a constant radius of curvature for MDI cans. Thereby, however, the person skilled in the art arrives at an aluminium MDI can falling within the scope of claim 1 of the main request.

3.7 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.

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

First auxiliary request

4. The above conclusion of point 3.8 applies *mutatis mutandis* to the subject-matter of independent claim 1 of the first auxiliary request - being directed to a MDI can comprising an ellipsoidal base (see point X above) - since the 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 if this radius is large.

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

Second auxiliary request

5. The subject-matter of claim 1 of the second auxiliary request differs from that of claim 1 of the main request in that for the coating it has been restricted to the three polymer blends: PTFE/FEP/polyamideimide, PTFE/polyethersulphone (PES) and FEP-benzoguanamine (see point XI above).

5.1 D2 is still considered to represent the closest prior art from which the subject-matter of claim 1 of the second auxiliary request is distinguished by
i) comprising a substantially ellipsoidal base, and
ii) that all of the internal surfaces of the MDI can are coated with a polymer blend selected from PTFE/FEP/polyamideimide, PTFE/PES and FEP-benzoguanamine.

5.1.1 Blending a fluorocarbon polymer with a non-fluorocarbon polymer improves the adhesion of the polymer coating to the can wall (see patent, paragraph [0024]).

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 3.3 above).

5.1.2 In this context the Board further 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 blends of polymers and a substantially ellipsoidal base can be acknowledged and features i) and ii) are considered to represent a mere aggregation.

These two partial problems can thus be discussed independently for inventive step.

5.1.3 Therefore, in order to solve the aforementioned partial technical problem, further prior art can be taken into account for discussing inventive step 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).

5.2 From the text book D3 it is known 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). As admitted by the appellant polyether sulfone or polyether sulphone are merely alternate spellings for the PES compounds.

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.

5.3 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 second auxiliary request without any inventive skill.

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

Third auxiliary request

6. The above conclusion of point 5.3 applies *mutatis mutandis* to the subject-matter of independent claim 1 of the third auxiliary request since it is also directed to an MDI can coated with a blend of PTFE and PES (see point XII above).

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

Fourth and fifth auxiliary requests

7. The subject-matter of the claims 1 of the fourth and fifth auxiliary requests differs from those of the second and third auxiliary requests, respectively, in that the curing temperature for curing the coating is

further defined to be in the range of 300°C to 400°C (see points XII and XIII above).

7.1 This temperature range of "300-400°C" 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 D41, 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").

7.2 Therefore the subject-matter of claims 1 of the fourth and fifth auxiliary requests also lacks an inventive step and the fourth and fifth auxiliary requests are therefore not allowable, either.

8. *Request for an apportionment of costs*

At the oral proceedings all three respondents requested an apportionment of costs because the appellant had informed the Board only at very short notice with its letter dated 1 October 2010 that it "does not intend to attend" the oral proceedings. It was argued that this statement was not entirely clear as to whether or not the appellant actually would or would not come and

therefore the preparation had to be executed which proved to be useless since the appellant did not appear. Furthermore, since the appellant with its reply dated 6 September 2010 did not address all issues mentioned in the Board's communication, the appellant - if it were no longer interested in its patent - could have either withdrawn its consent to the text of the contested patent the contested patent or at least could have withdrawn its request for oral proceedings so that the Board could have decided to cancel the oral proceedings and finish the case in written proceedings.

8.1 The Board holds that, even if an appellant informs it at very short notice that it will not attend the scheduled oral proceedings (see point VI above), in accordance with Article 15(3) RPBA it remains within the Board's discretion to decide whether or not the scheduled date for oral proceedings is maintained. This is also the case if the appellant would have withdrawn its request for oral proceedings. One of the reasons for maintaining the date for oral proceedings is to be able to finally decide the case on that scheduled date.

The Board further remarks that the appellant's late announcement did not prejudice the timely and efficient conduct of the oral proceedings which took place as scheduled (see point VII above) nor did it represent an abuse of the procedure as set out in Articles 16(1)c) and 16(1)e) RPBA, respectively.

8.2 In such a case as the present one, in which the Board has not cancelled the oral proceedings, it is, however, up to the other parties to decide whether or not they wish to attend the scheduled oral proceedings.

This is entirely within their sphere of competence, having to take account of their own interests. They therefore have to bear their own costs.

8.3 For these reasons the requests for a different apportionment of costs are refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall H. Meinders