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**Datasheet for the decision  
of 27 February 2008**

**Case Number:** T 1191/05 - 3.3.02

**Application Number:** 96911710.0

**Publication Number:** 0820279

**IPC:** A61K 9/72

**Language of the proceedings:** EN

**Title of invention:**

Metered dose inhaler for albuterol

**Patentee:**

SMITHKLINE BEECHAM CORPORATION

**Opponent:**

3M Innovative Properties Company

**Headword:**

Metered dose inhaler/SMITHKLINE BEECHAM CORPORATION

**Relevant legal provisions:**

EPC Art. 56

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"All requests - Inventive step - No: obvious combination"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 1191/05 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 27 February 2008

**Appellant:** SMITHKLINE BEECHAM CORPORATION  
(Patent Proprietor) One Franklin Plaza  
P.O. Box 7929  
Philadelphia, PA 19101 (US)

**Representative:** Cooke, Tracey  
GlaxoSmithKline  
Corporate Intellectual Property (CN9.25.1)  
980 Great West Road  
Brentford  
Middlesex TW8 9GS (GB)

**Respondent:** 3M Innovative Properties Company  
(Opponent) P.O. Box 33427  
St. Paul  
Minnesota 55133-3427 (US)

**Representative:** Aleandri-Hachgenei, Lorraine E.  
3M Deutschland GmbH  
Office of Intellectual Property Counsel  
Carl-Schurz-Strasse 1  
D-41453 Neuss (DE)

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 20 July 2005  
revoking European patent No. 0820279 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** J. Riolo  
J. Van Moer

## Summary of Facts and Submissions

- I. European patent No. 0 820 279, based on European application No. 96 911 710.0, was granted on the basis of 27 claims.

Independent claim 1 as granted read as follows:

"1. A metered dose inhaler having part or all of its internal surfaces coated with one or more fluorocarbon polymers  
in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation comprising albuterol 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."

- II. Opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC for lack of inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC.

The following documents were cited inter alia during the proceedings before the opposition division and the board of appeal:

- (2) EP-A-0 642 992
- (3) Ullmann's Encyclopaedia of Industrial Chemistry, pages 380-382, VCH (1991)
- (29) Declaration by Prof. Stephen Shaw
- (33) Supplemental declaration of Prof. Stephen Shaw
- (45) Declaration of Dr. Batzar

III. By its decision pronounced on 21 June 2005, the opposition division revoked the patent under Article 102(1) EPC because neither the main request nor the first auxiliary request fulfilled the requirements of inventive step.

As to the main request, the opposition division argued as follows:

Document (2) was regarded as the most relevant prior art document.

It disclosed a metered dose inhaler comprising an aluminium can which contains a suspension of an antiasthmatic drug, preferably in 1,1,1,2-tetrafluoroethane, wherein drug deposition to the container walls is overcome by a plastic coating of the walls. In particular, PTFE or FEP are preferred plastic coatings.

The subject-matter of independent claim 1 of the main request was accordingly distinguished from (2) by the following technical features:

- (a) the inhaler can contains albuterol as antiasthmatic agent
- (b) part or all of the internal metallic surfaces of the can are coated with a polymer blend of one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers.

As regards feature (a), it considered incorporating means which, since albuterol was a well-known antiasthmatic drug as agreed by the patentee, the skilled person obviously would take into consideration

for said drug to provide an alternative inhalation medicament.

As far as feature (b) was concerned, as no test results had been presented which could support any kind of surprising effect, the problem to be solved by the invention was to modify the coating of document (2) so that it would be more difficult to remove it from the underlying surface.

Having regard to the textbook (3) relating to fluoropolymer coatings useful in many technical fields, which taught that mixtures of PTFE (polytetrafluoroethylene) dispersions and heat-resistant hydrocarbons such as polyimide, polyether sulfone (PES) or polyphenylene sulfide improve poor adhesion of fluoropolymer to a substrate, it was clear that a fluorocarbon coating specialist who was present in the team concerned with the problem to be solved in the contested patent would replace the pure PTFE coating of document (2) by a polymer blend of PTFE with PES as suggested in this later document.

Thus, the opposition division concluded that the subject-matter of the amended independent claim 1 of the main request did not meet the requirement of inventive step and was therefore to be rejected.

Concerning the first auxiliary request, the opposition division argued that as the additional feature in claim 1 was already known from document (2), the reasoning against the main request was also relevant for auxiliary request 1.

The opposition division did not admit auxiliary request 2, which was filed during the oral proceedings, because it did not *prima facie* meet all the requirements of the EPC.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. In a communication from the board dated 6 February 2008, the attention of the appellant was drawn to the established case law relating to technical prejudice and comparative tests.

The preliminary opinion of the board that the subject-matter of the patent in suit seemed not to involve an inventive step *vis-à-vis* documents (2) and (3) in combination was also given in the communication.

VI. Oral proceedings were held before the board on 27 February 2008.

VII. The appellant submitted a main request and 4 auxiliary requests.

Claim 1 of the main request reads:

"1. "A metered dose inhaler for dispensing an inhalation drug formulation wherein the inhaler:  
contains the inhalation drug formulation, and  
comprises a can made of aluminium or an alloy thereof, characterised in that:

the inhalation drug formulation comprises a suspension of albuterol, or a physiologically acceptable salt thereof, and a fluorocarbon propellant

which is 1,1,1,2-tetrafluoroethane or ,1,1,2,3,3,3-heptafluoro-n-propane or mixtures thereof, optionally in combination with one or more other pharmaceutically active agents or one or more excipients,

and all of the internal metallic surfaces of the can are coated with a polymer blend of PTFE and PES."

Compared to claim 1 of the main request, claim 1 of the first auxiliary request merely has "consists essentially of" instead of "comprises", and the phrase "or one or more excipients" has been deleted.

Compared to claim 1 of the main request, claim 1 of the second auxiliary request merely has "consists of" instead of "comprises", and the phrase "optionally in combination with one or more other pharmaceutically active agents or one or more excipients" has been deleted.

Compared to claim 1 of the main request, claim 1 of the third auxiliary request merely has "consists of" instead of "comprises" and has albuterol sulfate as drug, and the phrase "optionally in combination with one or more other pharmaceutically active agents or one or more excipients" has been deleted.

Compared to claim 1 of the main request, claim 1 of the fourth auxiliary request merely has "consists of" instead of "comprises" and has albuterol sulfate as drug and 1,1,1,2-tetrafluoroethane as fluorocarbon propellant, and the phrase "optionally in combination with one or more other pharmaceutically active agents or one or more excipients" has been deleted.

During the oral proceedings the respondent first indicated that, in response to the communication of the board, it was not its intention to argue that there existed any technical prejudice against the combination of the teaching of document (3) with document (2).

In summary, it mainly held that the skilled person would not combine documents (2) and (3) for two major reasons:

(1) the combination of documents (2) and (3) was not obvious because they related to different technical fields as submitted in the expert's reports (29) and (33).

(2) there was no reasonable expectation of success in the light of the concern of drug deposition on the surface of the polymer blend expressed by both experts in documents (43) and (33).

VIII. During the oral proceedings, the respondent maintained in substance the opposition division's arguments that the combination of documents (2) and (3) was obvious because document (3) was representative of the general knowledge of the skilled person and because the concerns expressed by the experts were ill-founded.

It further maintained its objections with respect to Article 123(2) EPC and lack of sufficiency on the basis of the same arguments provided before the opposition division.

IX. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the



basis of the main request or of the auxiliary requests filed with its letter dated 18 January 2008.

The respondent requested that the appeal be dismissed.

## **Reasons for the decision**

1. The appeal is admissible.
2. Main request
  - 2.1 Article 123 EPC

The opposition division did not deal with this objection in its decision.

The subject-matter of claim 1 of the main request is based on claims 1, 2, 13, 15 and 16 as originally filed and page 6, line 29, to page 7, line 5, of the description as originally filed. Moreover, these amendments in claim 1 merely restricted the scope of protection conferred, so that they are also allowable under Article 123(3) EPC.

The board does not agree with the respondent's main argument that these amendments contravene Article 123(2) EPC because they are the result of an arbitrary combination which was not disclosed.

In fact, to the contrary, amended claim 1 is merely the result of the combination of the preferred embodiments which were already disclosed as preferred in the

dependent claims and in the quoted part of the description as originally filed.

Having regard to the board's conclusions in the assessment of inventive step (see below, point 2.3.6) and having regard to the fact that the respondent did not advance new arguments compared to those submitted before the opposition division, there would appear to be no need to develop these aspects further.

Accordingly, the board concludes that the subject-matter of the main request fulfils the requirements of Article 123 EPC.

## 2.2 Article 100(b) EPC

The opposition division did not deal with this objection in its decision.

In the light of the numerous working examples provided in the patent in suit and in the absence of any concrete evidence from the respondent, the board has no reason to doubt that the skilled person would be able to make a metered dose inhaler as claimed in claim 1 just by repeating any of these examples.

Having regard to the board's conclusions in the assessment of inventive step (see below, point 2.3.6), there would appear to be no need to develop these aspects further.

2.3 Inventive step

2.3.1 The contested patent relates to a metered dose inhaler comprising an aluminium can having its internal metallic surface blended with a plastic coating of PTFE-PES on the wall which contains a suspension of an antiasthmatic drug (albuterol) in 1,1,1,2-tetrafluoroethane (column 6, lines 22 to 37).

According to the patent in suit, the coating with a fluorocarbon polymer such as PTFE significantly reduces the problem of drug deposition on the can walls (column 1, lines 48 to 53, and column 5, lines 33 to 37).

Moreover, the description indicates that the fluorocarbon polymer can be blended with a non-fluorinated polymer such as polyimides, polyethersulfones (PES) or polyphenylene sulphide in order to improve adhesion of the polymer coating to the can walls.

As agreed by both parties, the board considers that document (2), which also deals with a metered dose inhaler for dispensing an inhalation drug formulation, represents the closest prior art.

In that respect, document (2) discloses a metered dose inhaler comprising an aluminium can which contains a suspension of an antiasthmatic drug (e.g. formoterol) preferably in 1,1,1,2-tetrafluoroethane, wherein drug deposition to the container walls is significantly reduced by a coating of the walls with a fluorocarbon polymer. In particular, PTFE is preferred as plastic

coating (column 4, line 50, to column 5, line 3; column 5, lines 31 to 54).

Both parties also agreed that the skilled person in this instance constituted a team that would typically be found in a pharmaceutical company, comprising an aerosol drug formulator, a person knowledgeable about the manufacture of respiratory devices and a specialist in the field of polymers and plastic coatings.

- 2.3.2 The board notes that there is no evidence on file which shows that the only advantage recited in the contested patent vis-à-vis document (2), namely the improved adhesion of the polymer coating to the can walls achieved by the addition of PES, is not effective.

Moreover, from the disclosure as originally filed it can only be assumed that the drug deposition in the patent in suit is similar to the drug deposition occurring in prior art document (2), since this effect is solely related to the use of PTFE, as is already the case in the prior art (page 2, lines 5 to 8).

In that respect, the board also observes that the respondent did not provide any evidence to the contrary.

Thus, as the experiments submitted by the appellant in the technical reports are not intended to demonstrate anything more than what is already contained in the patent in suit (i.e. similar drug deposition and improved adhesion), and in the absence of any evidence to the contrary, the problem to be solved by the subject-matter of claim 1 of the main request of the

patent in suit as against document (2) can only be seen in the provision of a metered dose inhaler for dispensing an inhalation antiasthmatic drug formulation with a coating having an improved adhesion to the can walls.

It also follows that the technical reports submitted by the appellant are superfluous and that therefore the question whether they constitute a valid comparison appears to be irrelevant, since they were not deemed to demonstrate any further improvements.

2.3.3 This problem is solved by adding PES to the prior art PTFE coating.

2.3.4 Thus the question to be answered is whether the proposed solution would have been obvious to the skilled person in the light of the prior art. In that respect, the board notes that the textbook Ullmann's Encyclopedia (3) indicates that the fluoropolymer PTFE has poor adhesion, not adhering to many substrates (page 380, right column, paragraph headed "Polytetrafluoroethylene").

In the very same paragraph, this textbook teaches that "recently, mixtures of PTFE and PES have been developed to improve their poor adhesion".

The board has no doubt that the skilled person is well aware of this disclosure since, as agreed by both parties, the "person" is a team with a specialist in the field of polymers and plastic coatings.

In the light of document (3), it is also clear, as stressed by the appellant during the oral proceedings, that the adhesion problem of the PTFE coatings is a crucial problem.

Accordingly, the board is convinced that the skilled person (team), faced with the problem defined under 2.3.2, would have added PES to the prior art coating as advocated by document (3).

2.3.5 The board does not agree with the two main lines of argument submitted by the appellant.

As to the argument that the combination of documents (2) and (3) was not obvious because they relate to different technical fields as submitted in the expert's reports (29) (in particular, paragraph 36) and (33) (in particular, paragraph 8), the board notes that the teaching of document (3) is not at all restricted to the field of cooking ware. It is indeed clear that the reference to frying pans in document (3) concerns the case where a ceramic powder is used as first coat and not the blends of PTFE and PES. Moreover, the mere fact that the blends of PTFE and PES would also be useful in the field of cooking ware does not imply that they can only be used in that field.

In addition, the board notes that a coating used in the field of cooking ware must, like coatings used in the field of pharmaceuticals, not be harmful to health. Accordingly, even if the disclosure in (3) had been strictly restricted to the alimentary field, which is not the case, it is considered that the alimentary field, although different, is not such that it would *prima facie* not be considered by the skilled person.

The more so since document (2), which relates to pharmaceuticals, uses precisely PTFE, which is one of the very subjects dealt with in document (3).

Further, assuming again that the disclosure in (3) had been restricted to the alimentary field, it is correct, as submitted by the expert, that the temperature, solvent and pressure conditions to which the coating is exposed in a frying pan and in a metered dose inhaler are very different; but the board would still remain convinced that the skilled person would in this case have tried the polymer blend for at least four reasons:

- the blend is a commercially available product, i.e. readily available
- the preparation of coatings and their testing does not constitute an undue burden, as shown by the routine experimental conditions used in the numerous working examples and the technical reports
- from document (2), plastic coatings are already known to be suitable in the field of pharmaceuticals
- the adhesion problem is a crucial problem which must be solved in any case, as emphasised by the appellant himself during the oral proceedings.

The board also does not agree that in the present case the skilled person would not try the blend because he is a conservative person who takes no risks and does not enter new technical fields.

In fact, having regard to document (2), the contested patent cannot be regarded as opening a new technical field, since the coating of metered dose inhalers with

plastic coatings is thus already known, so that the present subject-matter merely concerns improvements in a field that is already known.

In addition, the board is convinced that the skilled person faced with a crucial technical problem is well able to take some risk when there is a clear teaching on how to solve the problem and when putting the technical measure into practice does not involve major difficulties but simple routine experiments, as is the case in the present instance (see above).

Regarding the main concerns expressed by the expert in document (45) (in particular, paragraphs 15 and 31) - that the addition of PES to the PTEF might give rise to drug deposition problems because of the possible presence of higher surface energy (adhesion-promoting) non-fluorinated polymers (i.e. PES) and also to delamination problems, so that one could not know whether the claimed blend coating would be suitable for the pharmaceutical application due to possible drug deposition problems - the board does not contest that these concerns might exist.

However, the key point in the present case is that the skilled person must solve the adhesion problem posed by PTFE coating and that he knows from document (3) that addition of PES solves exactly that problem.

Accordingly, again, as the testing of the blend coating to see whether the expert's concerns were ill-founded or not is not a big issue as appears from the working examples and the test reports of the appellants which all involve routine experimental conditions, the board



remains convinced that the skilled person would have tried the blend coating, looking for a compromise between the required adhesion improvement and, possibly, a drug deposition level acceptable for the intended use, rather than giving up the promising teaching.

Accordingly, by doing so, the skilled person would inevitably come to the conclusion that the possible deposition problem did not exist or at least that it was compatible with the intended use.

Finally, the board does not follow the appellant's argument that the skilled person would not dare to try the blend coating because, having regard to the fact that the inhalation of an insufficient amount of drug might be life-threatening, particularly since albuterol, a beta-agonist, is also used as rescue medicament, the expert's concerns as to drug deposition would have dissuaded him from trying.

Indeed, as the skilled person does not need to carry out the experimentation with patients to determine whether or not drug deposition problems exist (i.e. simply washing the coating with a solvent followed by HPLC analyses, as illustrated in the test reports, would suffice), the above considerations are not relevant.

As to the appellant's argument that, unlike PTFE, PES is only available in solvents other than water, the board notes that the respondent contested the introduction of this argument because it was introduced

for the first time during the oral proceedings, so that this information could not be verified.

- 2.3.6 In the light of these facts, the board is forced to conclude that the subject-matter of claim 1 of the main request does not involve an inventive step as required by Article 56 EPC.

Under these circumstances, there is no need to consider the remaining claims.

3. Auxiliary requests 1 to 4

During the oral proceedings, both parties agreed that the auxiliary requests did not add anything new in relation to the assessment of inventive step, so that they merely relied again on their submissions made with respect to the main request.

Thus, as there are no additional distinguishing features in these requests which appear to be non-obvious vis-à-vis the combination of documents (2) and (3), the conclusion as to lack of inventive step for the subject-matter of claim 1 of the main request applies equally to all auxiliary requests.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar

The Chairman

N. Maslin

U. Oswald