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Datasheet for the decision of 14 January 2014

Case Number: T 2281/12 - 3.2.07

Application Number: 02786919.7

Publication Number: 1458630

IPC: B65D81/24, B65D81/20

Language of the proceedings: EN

Title of invention:
CAPSULE PACKAGE WITH MOISTURE BARRIER

Applicant:
Novartis AG

Headword:

Relevant legal provisions:
EPC Art. 56
EPC R. 115(2)
RPBA Art. 15(3)

Keyword:
Oral proceedings - held in the absence of the appellant
Inventive step - all requests (no)

Decisions cited:
T 1704/06

Catchword:

Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 2281/12 - 3.2.07

D E C I S I O N
of Technical Board of Appeal 3.2.07
of 14 January 2014

Appellant: (Applicant)	Novartis AG Lichtstrasse 35 4002 Basel (CH)
Representative:	Vossius & Partner Siebertstrasse 4 81675 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 June 2012 refusing European patent application No. 02786919.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division to refuse the European patent application No. 02 786 919.7.

With its statement of grounds of appeal the appellant requested that the decision be set aside and a patent be granted on the basis of the claims of the main request (except for the deletion of the redundant claim 4 and a consequential renumbering of the remaining claims identical with that underlying the impugned decision), alternatively on the basis of the claims of the auxiliary requests 1 and 2 underlying the impugned decision, all requests as re-filed with the statement of the grounds of appeal dated 16 October 2012. As an auxiliary request oral proceedings were requested.

II. The following documents of the examination proceedings are relevant for the present decision:

D1 = US-A-5 560 490
D3 = DE-A-1 486 399
D4 = US-A-4 137 914

while the following documents were introduced by the Board:

D5 = US-A-5 458 135
D6 = "Pharmaceutical Blister Packaging, Parts I and II", R. Pilchik, Pharmaceutical Technology, November 2000
D7 = US-A-4 995 385

III. The Examining Division held that the subject-matter of the independent claims 1 and 14 of the main request

dated 2 May 2012 was distinguished from the closest prior art D1 by a mere aggregation of the three features:

a) "mass median aerodynamic diameter",
b) the specified thickness of the metal layer and
c) both layers of the package comprise a metal-containing layer

and thus lacked inventive step in view of the combination of the teachings of D1 with D3.

Claim 1 of the first auxiliary request dated 2 May 2012 was distinguished from the closest prior art D4 by the feature a) above and
b) that "the capsule is openable before, during or after the insertion into the aerosolization device"
and therefore considered to lack inventive step with respect to feature a) for the same reasons as the main request while feature b) was held to lack any distinctive information.

Claim 1 of the second auxiliary request dated 2 May 2012 differed from that of the first auxiliary request only in its introductory wording "A package for storing an aerosolizable pharmaceutical formulation, the packaging comprising" which was considered not to add any relevant technical or constructive information so that the lack of inventive step argumentation with respect to the first auxiliary request applied there as well. Therefore the application was refused under Article 56 EPC.

IV. Independent claim 1 of the main request reads as follows:

"1. A package (100) for storing an aerosolizable pharmaceutical formulation, the aerosolizable pharmaceutical formulation (110) comprising a dry powder having a mass median aerodynamic diameter of from 1.0 to 5.0 µm that can be aerosolized in an aerosolization device, the package comprising:

a capsule (105), wherein the capsule contains the aerosolizable pharmaceutical formulation and wherein the capsule is openable during or after insertion into an aerosolization device; and

a multi-layered package (400) around the capsule, the multi-layer package comprising an upper layer (415) and a lower layer (405), wherein the upper layer and the lower layer comprise a metal-containing layer (410, 420) with a thickness from 10 µm to 100 µm,

whereby the multi-layered package reduces the amount of moisture in contact with the aerosolizable pharmaceutical formulation so that the aerosolizable pharmaceutical formulation may be aerosolized when the capsule is opened."

V. Claim 1 of auxiliary request 1 reads as follows:

"1. A capsule (105) ~~for storing an~~ containing a dry powder aerosolizable pharmaceutical formulation, the capsule being insertable into an aerosolization device and the aerosolizable pharmaceutical formulation comprising a ~~dry~~ powder having a mass median aerodynamic diameter of from 1.0 to 5.0 µm that can be aerosolized in response to a user's inhalation in the aerosolization device, wherein the capsule is openable before1 during or after insertion of the capsule into the aerosolization device, the capsule comprising~~:~~

a capsule wall comprising metal."

VI. Claim 1 of auxiliary request 2 reads as follows:

"1. A package (100) for storing an aerosolizable pharmaceutical formulation (110), the package comprising:
a capsule (105) containing a dry powder aerosolizable pharmaceutical formulation, the capsule being insertable into an aerosolization device-and the aerosolizable pharmaceutical formulation comprising a ~~dry~~ powder having a mass median aerodynamic diameter of from 1.0 to 5.0 µm that can be aerosolized in response to a user's inhalation in an aerosolization device, wherein the capsule is openable before, during or after insertion of the capsule into the aerosolization device, the capsule comprising:
a capsule wall comprising metal."

VII. With a communication dated 23 September 2013 annexed to summons for oral proceedings set for 14 January 2014 the Board presented its preliminary and non-binding opinion with respect to the claims of the main request and the auxiliary requests 1 and 2 as re-filed with the statement of the grounds of appeal.

The Board stated amongst others that it would be necessary to discuss in particular inventive step with respect to a combination of the teachings of D1 and D3 (main request) and the common general knowledge of the person skilled in the art as e.g. exemplified by documents D5-D7 or with respect to D4 (auxiliary requests 1 and 2) as follows:

" 3. Inventive step (Article 56 EPC)

The discussion of inventive step will take account of the problem-solution approach based on the claims' distinguishing features over the closest prior art,

their technical effect and the problem(s) solved thereby.

The person skilled in the art in the present case can be represented by a team including at least a packaging engineer having common general knowledge of packaging pharmaceuticals and a pharmaceutist having knowledge of the mode of action and the characteristics of medicaments and the requirements for them to be packaged.

Main request

It appears that D1 can be considered as the closest prior art. It will be discussed whether or not the person skilled in the art, when starting from the package of the closest prior art D1, would have any incentive to modify it according to the teaching of D3 (or alternatively D6), and by applying his common general knowledge would arrive in an obvious manner at the subject-matter of product claim 1 and/or process claim 13.

Independent claims 1 and 13 include the feature "the capsule is openable ***during*** *or after insertion into an aerosolization device" but they do* ***not*** *specify that the capsule is not pre-pierced. This fact is insofar relevant as the capsule embodiment of figure 11 has an opening 500 to allow for the dispersion of the pharmaceutical formulation 110 during use which is closed by a metal-containing layer 505 which optionally may be provided with a tab by which said cover may be removed by a user prior to use (see WO-A-03 05793, page 13, lines 2 to 8 and page 14, lines 13, 14). Thus this feature "the capsule is openable* ***during*** *… insertion into an aerosolization device" may be considered to*

cover the removal of the capsule from the blister package and the removal of said cover layer 505 with said tab, namely during insertion of the capsule into said device, so that it is questionable whether the feature can effectively exclude pre-pierced capsules.

3.1 D1 appears to represent a good springboard towards the claimed invention (see Case Law, 6th edition 2010, sections I.D.3.4 and I.D.3.5). D1 discloses a pharmaceutical package comprising a base member having a plurality of blisters formed therein, each blister being adapted to accommodate a medicament-containing (pre-pierced) capsule, the dry powdered medicament being administered by inhalation to the lung or the nose (see column 1, lines 4 to 22; column 3, lines 12 to 55). Contrary to the appellant's allegation it likewise mentions and deals with the problem of moisture protection of the medicament (see column 1, lines 19 to 22 and lines 37 to 40; column 2, lines 1 to 4). The medicament pack 1 comprises e.g. a PVC base member 2 with four thermoformed open faced blisters 3 which are shaped to accommodate a cylindrical medicament capsule 4. The open faces of these blisters are sealed by a plastic/metal laminate cover sheet 8 which is heat-sealed to the surface of the base member 2 and which may be peeled back to allow the (pre-pierced) capsule to be removed from the pack prior to insertion in an appropriate inhalation device (see column 4, lines 21 to 43 and figures 1-3). Said cover sheet may comprise a heat-seal coated aluminium foil which coating must be compatible with the blister material to ensure satisfactorily sealing both for product protection, e.g. to prevent the ingress of moisture (see column 3, lines 59 to 65). D1 states that conventional blister-packaging materials may be used (e.g. PVC, PVC/polyethylene combinations, polystyrene

and polypropylene) but for improved moisture protection polyvinylidene chloride or polychlorotrifluoroethylene films may be laminated to PVC (see column 1, lines 62 to 67).

3.1.1 Thus claim 1 appears to differ from the package of D1 by
a) the specified "mass median aerodynamic diameter" of the dry medicament powder,
b) the specified thickness of the metal containing layers of the surrounding package, and c) that both layers of the package comprise a metal-containing layer;
and, if the appellant's position on the absence of a piercing of the capsule is followed:
d) the capsule is one openable during or after insertion into an aerosolization device.

Feature a) has the effect that the dry powdered inhalation medicament when aerosolized by the user reaches his lungs, particularly the alveolar region (see WO-A-03 057593, page 21, lines 5 to 9).
Features b) and c) provide a moisture barrier (so that the package including the medicament can be stored for a certain time) and provide a certain mechanical strength to the blister package (see WO-A-03 057593, page 10, lines 16 to 24; and page 11, lines 9 to 14).
Feature d) merely indicates that the package is used for a capsule which only distinguishes itself from the capsule of D1 in that it is not pre-pierced. The Board has difficulty in determining a technical effect of this measure. It appears to be more of a commercial or efficiency effect in that the same package is used for an identical capsule but for its piercing.

3.1.2 Feature a) appears to solve a first partial problem (to have the pharmaceutical formulation reach the alveolar region) being different from the second partial problem according to the features b) and c), which is the prevention of moisture for the capsule while maintaining a stable package.

Feature d) is a commercial or rationalisation problem.

3.1.3 First of all, it appears to be clear to the person skilled in the art that the described blister package of D1 can be generally used for packaging capsules, i.e. likewise for non-pierced capsules. This also transpires from page 14, lines 11 to 13 of WO-A-03 057593 making no distinction between these types of capsules.

3.1.4 Secondly, although D1 does not disclose any mass median aerodynamic diameter (MMAD) of the dry powdered medicament, it has to be within the range of 1.0 to 5.0 µm in order to be suitable for the intended purpose, i.e. inhalation to the lung as mentioned in column 1, lines 8 to 13 and column 3, line 14 and particularly the alveolar region of the lungs. This information, however, is considered to also belong to the common general knowledge of the relevant skilled person (see for example D5 mentioned as US-A-5 458 135 on page 14, line 16 of the application, which mentions these characteristics in its background part, see column 2, lines 49 to 55; as well as it emphasises the importance of them in column 6, lines 6 to 9; column 7, lines 52 to 56 and column 12, lines 22 to 32) who as a consequence would select this MMAD range to solve the first partial problem, if it is not already inherent to the pharmaceutical formulations mentioned in D1, column 3.

3.1.5 Document D3 teaches the skilled person that a blister package for tablets, dragées, capsules, etc. can be made moisture resistant for its content in order to be suitable for use in a tropical environment, i.e. it can be made hermetically air-tight and water-tight (see page 2, first paragraph to page 3, first paragraph; claims 1 to 3). The blister package of D3 comprises a plastic foil 1 with open faced deep-drawn blisters 2 (being shaped to accommodate a medicament) which are sealed by an aluminium foil 3. Said air-tight and water-tight Al-foil 3 can be pushed-through in the zones 4 to remove individually the medicaments from each of these blisters. An air-tight and water-tight cover foil 6, e.g. made from Al-foil coated with a heat-sealable material, is sealed onto plastic foil 1 and over each of said blisters so that each of the medicaments contained therein is individually protected against the ingress of moisture; said cover foil 6 additionally provides mechanical protection (see page 3, first paragraph to page 4, second paragraph and figures 1 to 3).

The person skilled in the art would therefore apply the teaching of D3, i.e. the use of aluminium layers in both foils, onto the blister package of D1 in order to make the blister moisture resistant and he would have to select a certain thickness of these layers suitable for that purpose.

The Board does not consider the "age" of D3 to be a hindrance to considering its teachings.

3.1.6 Although D1 and D3 do not specify the thickness of the metal layer of said cover sheet 8 or said cover foil 6, respectively, it appears that this thickness

inevitably will be within the range of 10-100 µm in order to be suitable as a moisture barrier. This conclusion appears to be proven by D6 which mentions the thicknesses of foils for making blisters comprising aluminium layers which were commercially used at the end of 1999 (see Tables I and II).

In this context it needs also to be considered that the skilled person aims to reduce the costs for the package, i.e. to reduce the thicknesses of the aluminium layers to a minimum level while still obtaining the desired moisture protection and mechanical strength of the blister package.

3.1.7 In addition to the reasoning of the Examining Division in its impugned decision a combination of the teachings of D1 and D6 ("Pharmaceutical Blister Packaging", Part I, November 2000) appears to similarly result in a moisture resistant blister package including a capsule containing an aerosolizable pharmaceutical formulation as claimed in claim 1, namely:

*3.1.8 D6 discloses in its part I (which was presented in part on 3 December 1999 at the FilmPack '99 in Philadelphia; see page 78) in Table I a comparison of the water vapour transfer rate (WVTR) of several forming film materials for blister packaging including the laminate OPA/**aluminium**/PVC (1/1.8/2.4) which is the only material revealing a WVTR value of 0 with a thickness of the **Al-foil of 1.8 mils** (corresponding to **45.7 µm**) and which material is cold-formed into blister packages (see also page 74, right-hand column, second and third paragraph). Table II discloses a comparison of lidding materials (i.e. cover materials of the blister) including **0.8 and 1.0 mil aluminium***

*(corresponding to **20.3 and 25.4 µm**). D6 further mentions in this context that the lidding material must guarantee a WVTR that is at least as low as that of the forming films and it must be suitable for the type of opening appropriate the package and the intention to reduce the **Al-foil** thickness to **0.6 mil** (corresponding to **15.2 µm**; see page 76, left-hand column, second and third paragraphs, and middle column, second full paragraph). D6 further mentions that the **foil/foil lamination** is a less common type of blister used **for products that are particularly susceptible to moisture** and/or light and that products that require the highest degree of protection are packed in an all-foil package. The use of these cold-formable foils is growing because more moisture-sensitive drugs are on the market but this material is the only one that **provides a 100% barrier to moisture, oxygen and light** so that sensitive products can be blister packaged. This foil/foil blister pack comprises a **thin aluminium layer** which usually consists of several very thin layers helping to ensure that pinholes do not go all the way through the foil (see page 78, left-hand column, third paragraph and right-hand column, first paragraph). Consequently, D6 teaches the person skilled in the art to use a foil/foil blister pack including aluminium layers having thicknesses in the range between 15.2 and 45.7 µm for packaging pharmaceutical formulations that are particularly susceptible to moisture. Consequently, the person skilled in the art in order to solve the aforementioned technical problem would apply the teaching of D6 onto the blister package for the inhalation capsules of D1. Thereby he would also arrive at the subject-matter of claims 1 and 13 without inventive skill.*

3.1.9 Claims 1 and 13 of the main request therefore appear to lack inventive step. The main request thus appears not to be allowable.

Auxiliary requests 1 and 2

3.2 First of all, it appears that the subject-matter of claims 1 of the auxiliary requests 1 and 2 is identical since the only difference between their wording (i.e. the addition "A package (100) for storing an aerosolizable pharmaceutical formulation (110), the package comprising:" in claim 1 of auxiliary request 2) does ***not*** *appear to change the claimed subject-matter since the capsule of claim 1 of auxiliary request 1 can be the package of claim 1 of auxiliary request 2.*

3.2.1 Secondly, when considering D4 as the closest prior art and/or most promising springboard towards the invention, the subject-matter of claims 1 of the auxiliary requests 1 and 2 appears to be distinguished from the single dose metal capsule according to the embodiment of figure 2 of D4 having a 0.2 mm thick aluminium membrane for closing the cylindrical metal can, which contains a propellant and a medicament in the form of a powder (see D4, column 3, line 57 to column 4, line 21), by the following features:

a) the powder characteristics of the pharmaceutical formulation, and
e) the capsule is aerosolizable in response to a user's inhalation.

The feature "the capsule is openable before, during ***or after*** *insertion of the capsule into the aerosolization device" of claim 1of these two requests is considered to be met by the metal capsule of D4 which is opened*

after *it has been introduced into the device (see column 2, lines 14 to 27 and column 3, lines 35 to 48). It is considered to be sufficient that one of the three possible alternatives of the claimed subject-matter is met.*

3.2.2 Feature a) causes that the dry powdered inhalation medicament when aerosolized by the user reaches his lungs, particularly their alveolar region (see WO-A-03 057593, page 21, lines 5 to 9). Thus it solves the problem of guaranteeing that the pharmaceutical formulation reaches the lungs, in particular the alveolar region, which is in any case also the goal mentioned in D4, column 1, lines 8 to 10.

Feature e) allows that the capsule can be used in a different type of inhalation device (the description of the WO-A-03 057593 is silent with respect to the effect of this feature; see page 14, lines 9 to 21) which further implies that the capsule can additionally be opened before or during its insertion in the aerosolization device. Thus it relates more to the commercial problem of increasing the field of application of the capsule of D4.

It appears that feature a) solves a first partial problem being totally different from the second partial problem according to feature d).

Furthermore, it is remarked that the technical problem of the present application of improving the moisture resistance is already (implicitly) solved by the metallic capsule of D4. Consequently, a new or at least an amended technical problem has to be defined (see Case Law, 6th edition 2010, sections I.D.4.3.2 and I.D. 4.4).

3.2.3 It is considered that the solution of the first partial problem is obvious for the skilled person for the same reasons (common general knowledge) as for claim 1 of the main request.

Also the solution to the second partial problem appears be obvious to the person skilled in the art, since the capsule including the propellant for aerosolizing the formulation can only be used in the device according to D4. The skilled person knows that there exists a wide variety of different inhalation devices which do not need any propellant for aerosolizing the medicament, e.g. the device according to D7 (US-A-4 995 385 mentioned on page 14, line 21 of the present application). Consequently, it appears to be evident that he would provide metal capsules according to D4 without any propellant since they can also be easily pierced by the needle used in a different inhalation device. It appears that the person skilled in the art would thereby arrive at the subject-matter of claims 1 of the auxiliary requests 1 and 2 without inventive skills.

3.2.4 The appellant's argument that the skilled person would not do so since the propellant is an essential component for allowing the capsules to work within the device of D4, so that its omission would represent a complete departure from the teaching of D4 cannot hold since the omission step as such appears to be obvious since it reduces the costs of the capsules as such and of their manufacturing by enlarging their field of application.

The further arguments based on D4 and its - alleged - teaching regarding the materials of the capsule wall

with a view to the required pressure resistance, cannot hold either. D4 clearly states that the capsule can be made of plastic or metal with a wall thickness suitable to withstand the required internal pressure but sufficiently thin to permit penetration by the needle in the inhalation device (see column 3, lines 53 to 56 and column 4, lines 4 to 11) and therefore there is no preference for either plastic or metal capsules. However, the omission of the propellant would in any case result in a smaller wall thickness since there exists no longer the need to withstand a required internal pressure but only a need that the capsule retains its shape until it is inserted into the inhalation device.

3.2.5 Additionally, it is remarked that there appear to exist only the two possibilities to make the pharmaceutical formulation contained in capsules moisture resistant: either by making the blister package comprising the capsules moisture resistant (which is suggested by the prior art) or by making the capsule itself moisture resistant. The question to be answered for the second (alternative) embodiment is whether or not the person skilled in the art – in view of the effective solution provided by the blister package – would modify the capsule itself, which certainly will result in some money saving due to the much smaller metal consumption for (only) the capsule material.

3.2.6 Consequently, it appears that the person skilled in the art arrives at the subject-matter of claims 1 of the auxiliary requests 1 and 2 without inventive skills. Claims 1 of the auxiliary requests 1 and 2 therefore appear to lack inventive step. The auxiliary requests 1 and 2 thus appear not to be allowable."

VIII. With letter dated 27 December 2013 and submitted by fax on 3 January 2014 the appellant stated that "This is to inform the Board that the Applicant has decided to withdraw the request for oral proceedings and will not be represented in the oral proceedings scheduled for January 14, 2014."

This letter did **not** contain any further arguments concerning the objections raised in the above mentioned Board's communication dated 23 September 2013.

IX. Oral proceedings before the Board were held on 14 January 2014. As announced, the appellant did not attend so that the oral proceedings were continued in its absence in accordance with Rule 115(2) EPC and Article 15(3) RPBA. At the end of the oral proceedings the Board announced its decision.

Reasons for the Decision

1. The statement of the appellant in its fax dated 3 January 2014 that it withdraws its auxiliary request for oral proceedings (see point VIII above) implies, as is constant jurisprudence (see Case Law of the Boards of Appeal, 7th edition 2010, III.C.2.3), that the appellant relies on its submissions in the written proceedings.

Furthermore, although the appellant did not attend the oral proceedings, the principle of the right to be heard pursuant to Article 113(1) EPC is observed since it only affords the opportunity to be heard and, by absenting itself from the oral proceedings, a party gives up that opportunity (see the explanatory note to Article 15(3) RPBA cited in T 1704/06, not published in

OJ EPO; see also the Case Law of the Boards of Appeal, 7th edition 2013, IV.E.4.2.3 c)).

2. In the communication accompanying the summons for oral proceedings the Board, taking account of the submissions of the appellant, has raised objections under Article 56 EPC against the main request and the auxiliary requests 1 and 2, explaining why in the Board's opinion the subject-matter of claim 1 of the main request lacks inventive step over a combination of the teachings of D1 and D3 or D1 and D6 or why claim 1 of the auxiliary requests lacks inventive step over a combination of D4 and the common general knowledge of the person skilled in the art (see point VII above).

3. The appellant did not reply in substance to these objections (see point VIII above). Since there has been no attempt by the appellant to refute or overcome the objections raised in the above communication, the Board sees no reason to depart from its preliminary opinion expressed therein.

4. Taking account of the preceding observations, the Board concludes - for the reasons already set out in the communication dated 23 September 2013 (see point VII above) - that the subject-matter of the claims 1 of the main request and of the auxiliary requests 1 and 2 lacks inventive step (Article 56 EPC).

5. Consequently, the main request and the auxiliary requests 1 and 2 are not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall H. Meinders

Decision electronically authenticated