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Datasheet for the decision of 5 March 2021

Case Number: T 1096/18 - 3.3.01

Application Number: 10778746.7

Publication Number: 2490681

IPC: A61K31/137, A61K9/00, A61K31/58

Language of the proceedings: EN

Title of invention:
THE PHARMACEUTICAL COMPOSITION IN DRY POWDER FORM FOR INHALATION

Patent Proprietor:
Sima Patent ve Lisanslama Hizmetleri Ltd.Sti.

Opponent:
Wuesthoff & Wuesthoff Patentanwälte PartG mbB

Headword:
Dry powder composition for inhalation / SIMA PATENT

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - all requests (no) - obvious combination of known features

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Beschwerdekammern

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Case Number: T 1096/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 5 March 2021

Appellant: (Patent Proprietor)	Sima Patent ve Lisanslama Hizmetleri Ltd.Sti. Yildiz Teknik Üniversitesi Davutpasa Kampüsü Teknoloji Gelistirme Bölgesi D Blok K:3 Esenler/Istanbul (TR)
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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 February 2018 revoking European patent No. 2 490 681 pursuant to Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	S. Albrecht
	M. Blasi

Summary of Facts and Submissions

I. European patent No. 2 490 681 ("the patent") is based on European patent application No. 10778746.7. The patent was granted with eight claims.

Claim 1 reads as follows:

"1. A pharmaceutical composition containing a combination comprised of a corticosteroid and a β_2-agonist **characterized in that**

• the components of said combination are in the dry powder form,
• the average particle size of the active agents is less than 20 µm,
• two active agents contained in said pharmaceutical composition are together with lactose as carrier and they are stored in a peelable, aluminium blister strip, wherein the cavity volume of the blister is in the range of 22 to 23 mm3 and each blister cavity is filled up to 70-100 % of said volume,
• said pharmaceutical composition is suitable to be administered to a patient by a device suitable for dry powder."

II. Opposition proceedings were based on the grounds for opposition under Article 100(a) EPC for lack of novelty and lack of inventive step and under Article 100(b) and (c) EPC.

III. The documents filed during the opposition proceedings included:

D7: WO 2006/066908 A1
D12: EP 0 743 912 B1
D13: Technical report dated 25 August 2017 entitled "Effect of filled volume in blister cavity on delivered drug dose" (six pages in total)

IV. The opposition division's decision to revoke the patent was based on a main request and thirty-eight auxiliary requests. The main request was the patent as granted. The sets of claims of auxiliary requests 1 to 38 were all filed on 25 August 2017.

In the decision under appeal, the opposition division concluded *inter alia* that the subject-matter of claim 1 of the main request was obvious in view of document D7 taken in combination with document D12. The same held true for claim 1 of each of the auxiliary requests. The opposition division also decided to admit document D13 into the proceedings.

V. The patent proprietor ("appellant") lodged an appeal against the opposition division's decision.

VI. In the statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and, as its main request, that the patent be maintained as granted, i.e. that the opposition be rejected. As an auxiliary measure, the appellant requested that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 2 to 38 considered in the impugned decision.

Claim 1 according to auxiliary requests 2 and 3 is identical to claim 1 of the main request (see point I. above).

Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the peelable, aluminium blister strip is further specified as "comprising a base sheet and a lid sheet, the base sheet comprising blister cavities and the lid sheet being peelable from the base sheet" (i.e. feature (i)).

Claim 1 of auxiliary request 5 differs from claim 1 of the main request in that the following passage was added at the beginning of the claim:

"A peelable, aluminium blister strip and" (i.e. feature (ii)).

Claim 1 of auxiliary request 6 differs from claim 1 of the main request in that the following passage was added at the end of the claim:

"• the weight ratio of a corticosteroid or a pharmaceutically acceptable salt thereof to a β_2-agonist or a pharmaceutically acceptable salt thereof is in the range of 1:1 to 100:1, preferably 1:1 to 60:1" (i.e. feature (iii)).

Claim 1 according to auxiliary requests 7 to 9 is identical to claim 1 of auxiliary requests 4 to 6, respectively.

Claim 1 of auxiliary request 10 includes, in combination, the amendments made to claim 1 of auxiliary requests 4 and 5, respectively, i.e. features (i) and (ii).

Claim 1 of auxiliary request 11 includes, in combination, the amendments made to claim 1 of

auxiliary requests 4 and 6, respectively, i.e. features (i) and (iii).

Claim 1 of auxiliary request 12 includes, in combination, the amendments made to claim 1 of auxiliary requests 4, 5 and 6, respectively, i.e. features (i), (ii) and (iii).

Claim 1 according to auxiliary requests 13 to 24 is identical to claim 1 according to the main request and auxiliary requests 2 to 12, respectively, with the exception that lactose is specified as "being present in the range of 0-50 mg in the dry powder".

Claim 1 of auxiliary request 25 differs from claim 1 of auxiliary request 13 in that each blister cavity is filled up to 90-100% of the cavity volume of the blister.

Claim 1 of auxiliary requests 26 to 37 is identical to claim 1 according to the main request and auxiliary requests 2 to 12, respectively, with the exception that lactose is specified as "being present in an amount of up to 50 mg in the dry powder".

Claim 1 of auxiliary request 38 differs from claim 1 of auxiliary request 26 in that each blister cavity is filled up to 90-100% of the cavity volume of the blister.

VII. In its reply to the statement setting out the grounds of appeal, the opponent ("respondent") requested *inter alia* that the appeal be dismissed.

VIII. In the course of the appeal proceedings, the board issued a communication pursuant to

Article 15(1) RPBA 2020 dated 26 February 2020 ("communication of 26 February 2020") setting out its preliminary opinion on relevant issues.

IX. The parties were summoned to oral proceedings in view of their requests to that effect. On 16 February 2021, the format of the oral proceedings was changed to a videoconference and a date was fixed for submitting any comments or objections in relation to holding the oral proceedings by videoconference. No comments or objections were received by the fixed date.

X. In a letter dated 1 March 2021, the appellant informed the board that it would not be attending the oral proceedings.

XI. Oral proceedings were held by videoconference on 5 March 2021 in the presence of the respondent only.

XII. At the end of the oral proceedings, the chairman announced the board's decision.

XIII. The appellant's case relevant for the present decision may be summarised as follows:

Main request - inventive step

The subject-matter of claim 1 of the main request differed from the closest prior art, document D7, on account of the claimed storage means, the claimed average particle size of the active agents and the selection of lactose as the carrier. On the basis of the experimental data provided in document D13, the objective technical problem to be solved by the claimed invention was that of providing a blister strip that comprised a combination of a corticosteroid and a

β_2-agonist with an improved mean delivered dose and greater delivered-dose uniformity. Contrary to the opposition division's view, the skilled person would not have combined document D12 with the closest prior art to solve the stated technical problem. Hence, the solution proposed in claim 1 was inventive.

The same conclusions applied if the objective technical problem were to be considered that of providing an alternative dry-powder composition.

Auxiliary requests 2 to 38 - inventive step

The subject-matter of each of these requests was inventive for the same reasons as the main request.

XIV. The respondent's case relevant for the present decision may be summarised as follows:

All requests - inventive step

The closest prior art, document D7, disclosed (page 15, lines 19 to 21) a blister pocket having a volume of 21 mm^3 and a filling percentage of 81%. Claim 1 differed from this disclosure in that the claimed blister cavities had higher volumes of 22 to 23 mm^3. Since the results of document D13 relied on by the appellant to corroborate the alleged improved mean delivered dose and greater delivered-dose uniformity were not meaningful, the objective technical problem was to be worded as providing an alternative dry-powder composition. Contrary to the appellant's opinion, the skilled person faced with this problem would have combined document D7 with document D12, paragraph [0021] of which disclosed cavity volumes of up to 25 mm^3. In the light of this teaching, it would have

been obvious for the skilled person looking for an alternative dry-powder composition to select the claimed cavity volume of 22 to 23 mm^3.

XV. The parties' final requests, in so far as relevant to the present decision, were as follows:

The appellant's final requests were identical to those set out in point VI. above.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC and is admissible.

2. Absence of the appellant from the oral proceedings

2.1 The appellant had been duly summoned but chose not to attend the oral proceedings, as announced in its letter of 1 March 2021.

2.2 In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the board decided to continue the proceedings in the appellant's absence and to treat the appellant as relying on its written case. By absenting itself from the oral proceedings the appellant waived the opportunity to make any further submissions on the relevant issues of the case. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, as provided for in Article 15(6) RPBA 2020.

Main request (patent as granted)

3. The subject-matter of claim 1

Claim 1 is directed to a pharmaceutical composition containing

(a) a combination comprised of a corticosteroid and a β_2-agonist ("feature (a)") characterised in that

(b) the components of said combination are in the dry powder form ("feature (b)"),

(c) the average particle size of the active agents is less than 20 µm ("feature (c)"),

(d) the two active agents contained in said pharmaceutical composition are together with lactose as carrier ("feature (d)") and

(e) they are stored in a peelable, aluminium blister strip ("feature (e.1)"), wherein:

(i) the cavity volume of the blister is in the range of 22 to 23 mm^3 ("feature (e.2)") and

(ii) each blister cavity is filled up to 70-100% of said volume ("feature (e.3)"),

(f) said pharmaceutical composition is suitable to be administered to a patient by a device suitable for dry powder.

4. Article 100(a) EPC in conjunction with Article 56 EPC

Closest prior art

4.1 As held by the opposition division and in agreement with the parties, the board considers document D7 to be the closest prior art.

4.2 This document describes a manifold for use in a medication dispenser device for delivering a medication powder from an open blister pocket of a blister pack (see page 2, lines 22 to 24). As submitted by the appellant, the focus of document D7 is on the manifold as such. However, this disclosure also provides detailed information on the medication powder and the blister pack containing it. For instance, it is stated on page 49, second paragraph that appropriate medications include combinations of a corticosteroid and a β_2-adrenoreceptor agonist (i.e. feature (a) of claim 1). Details on the blister pack may be found on page 15, lines 19 to 21, which describes an example blister pocket that is spherical with a radius of 1.7 mm and a cross-sectional area of 8.0 mm^2. The blister pocket contains 17 µl of a medication powder.

4.3 In the light of the above considerations, the board does not accept the appellant's statement that "D7 remains a fundamentally non-obvious starting point" (see page 7, penultimate paragraph of the statement setting out the grounds of appeal).

Distinguishing features vis-à-vis document D7

4.4 The board agrees with the appellant that the subject-matter of claim 1 differs from document D7 on

account of features (c), (d), (e.1), (e.2) and (e.3) (see point 3. above).

Objective technical problem and solution

4.5 The objective technical problem is to be specified on the basis of the technical effects that the distinguishing features provide over the closest prior art.

4.6 On the basis of the comparative experiments disclosed in document D13, in its statement setting out the grounds of appeal the appellant submitted that features (e.2) and (e.3) each provided a superior mean delivered dose and superior delivered-dose uniformity compared with the blister packs disclosed in document D7, and formulated the objective technical problem accordingly (see point XIII. above).

4.7 In response to the statement setting out the grounds of appeal, the respondent questioned the meaningfulness of the experimental results in document D13, arguing that the comparative experiments lacked detail (see pages 12 and 13 of the reply to the statement setting out the grounds of appeal).

4.8 This issue was subsequently addressed in the board's communication of 26 February 2020. In point 2.9 of this communication, the board stated that it was minded to agree with the respondent that the experimental data in document D13 could not form a proper basis for specifying the objective technical problem addressed by the claimed invention.

4.9 The appellant did not submit any facts or substantive arguments in response to the board's communication of

26 February 2020, instead merely confirming its requests and announcing that it would not be attending the oral proceedings (see point X. above).

4.10 Under these circumstances, the board sees no reason to change its preliminary opinion. Accordingly, in the absence of reliable comparative data, the alleged improvements brought about by features (e.2) and (e.3) cannot be taken into consideration when formulating the objective technical problem.

4.11 The board further notes that the appellant has not invoked any particular technical effect in connection with any of the distinguishing features (c), (d) and (e.1), either individually or in combination with any other feature of claim 1. The board is likewise unable to identify any such effect and therefore agrees with the opposition division's formulation of the objective technical problem as that of providing an alternative dry-powder composition.

4.12 As a solution to this problem, the claimed invention proposes the pharmaceutical composition recited in claim 1.

Assessment of obviousness

4.13 In the decision under appeal, the opposition division concluded that distinguishing features (c) and (d) did not contribute to inventive step having regard to the teachings on page 49, last paragraph and page 50, first paragraph of document D7 (see point 17.5.1 of the decision). In the absence of any arguments to the contrary on the appellant's part, the board sees no reason to deviate from the opposition division's finding.

4.14 Distinguishing features (e.1), (e.2) and (e.3) cannot contribute to an inventive step either, for the following reasons.

Feature (e.1), i.e. a peelable, aluminium blister strip

4.14.1 The appellant has not based any argument in support of an inventive step on this feature. Hence, the board can only conclude that feature (e.1) is not suitable for establishing an inventive step.

Feature (e.2), i.e. a blister cavity volume of 22 to 23 mm^3

4.14.2 This feature is obvious from paragraph [0021] of document D12, which indicates that the cavities of the elongate carrier preferably have a volume of between 0.5 and 25 mm^3.

Feature (e.3) specifying the filling percentage of each blister cavity to be 70-100% of the blister cavity volume

4.14.3 On page 15, lines 19 to 21, document D7 discloses an example blister pocket (see point 4.2 above). In the oral proceedings the respondent submitted that this blister pocket had a volume of 21 mm^3 and a filling percentage falling within the claimed range (i.e. 81%), as evidenced by its calculations presented in writing before the opposition division.

4.14.4 These calculations are analysed in more detail in point 15 of the impugned decision (see fourth paragraph; the reference in this section to "page 8, [0001] to [0003] of O1 letter dated 04-08-2017" appears to be an error, the correct reference being "page 8, paragraphs 1 to 3 of the notice of opposition"). The opposition division

did not express any doubts concerning the correctness of the respondent's calculations. It concluded that the example blister pocket in document D7 differed from the blister cavity recited in claim 1 on account of features (e.1) and (e.2) only.

4.14.5 In the absence of any arguments to the contrary on the appellant's part, the board does not see any reason to depart from the opposition division's finding. It follows that feature (e.3) is already disclosed in document D7 and therefore cannot contribute to the presence of an inventive step either.

Conclusion on obviousness

4.15 In sum, the board finds that in the absence of a particular technical effect attributable to the combination of any of the distinguishing features (c), (d), (e.1) and (e.2) with any other feature of claim 1 (see point 4.11 above), the claimed invention amounts to a mere aggregation of obvious features which is devoid of any inventive merit.

Appellant's arguments

4.16 The appellant argued that the skilled person would not have combined document D7 with document D12 because D12:

(a) was concerned with a different technology from document D7 ("argument (a)")

(b) did not actually disclose a blister having a cavity volume of 22 to 23 mm^3 ("argument (b)")

(c) did not prompt the skilled person to change the cavity volume of document D7 in view of the constraints that the inhaler device disclosed on page 16, fourth paragraph of D7 imposed on the pharmaceutical composition and the blister pack comprising it ("argument (c)")

4.17 These arguments are not convincing.

Argument (a)

4.17.1 As set out in point 4.2 above, document D7 is not only concerned with manifolds per se but also goes into detail on dry-powder medications and blister packs containing them. Document D12, in turn, generally relates to devices for filling these dry-powder medications into cavities of an elongate carrier with a high degree of accuracy (see paragraph [0013]). As submitted by the respondent at the oral proceedings, this kind of filling is a routine consideration when trying to formulate a composition in accordance with document D7. Hence, the skilled person searching for a solution to the objective technical problem of providing an alternative dry-powder composition would have consulted document D12 and taken its content into consideration. Accordingly, argument (a) cannot succeed.

Argument (b)

4.17.2 It is undisputed that D12 does not specify the claimed cavity volume of 22 to 23 mm^3. However, from paragraph [0021] of this document the skilled person learns that, in preferred embodiments, the cavities of the elongate carrier could have a volume of between 0.5 and 25 mm^3. Hence, the claimed cavity volume range constitutes a

sub-range of the broader range disclosed in document D12. For the reasons indicated in points 4.6 to 4.10 above, the board cannot acknowledge any particular effect or advantage arising from the values in this sub-range. Accordingly, the selection of the claimed sub-range amounts to an arbitrary choice of values from among the broader range of 0.5 to 25 mm^3 disclosed in document D12. As argued by the respondent at the oral proceedings, this kind of mere arbitrary choice is within the capabilities of the skilled person seeking an alternative dry-powder composition.

Argument (c)

4.17.3 Contrary to the appellant's view, the choice of the claimed cavity volume range is not governed by any constraints imposed by the inhaler device disclosed on page 16, fourth paragraph of document D7. As convincingly argued by the respondent at the oral proceedings, blister packs containing dry-powder compositions and inhaler devices are two separate, distinct entities. Accordingly, to solve the objective technical problem of providing an alternative dry-powder composition, the composition need not be stored in a blister pack that is specifically adapted to the inhaler device disclosed on page 16, fourth paragraph of document D7.

Overall conclusion on inventive step of the main request

4.18 In the light of the above considerations, the board does not see any reason to deviate from the opposition division's conclusion that the subject-matter of claim 1 lacks inventive step. It follows that the ground for opposition under Article 100(a) EPC in conjunction with

Article 56 EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 2 to 38

5. In the statement setting out the grounds of appeal, the appellant submitted that the subject-matter of each of auxiliary requests 2 to 38 was inventive for the same reasons as the main request. No further arguments were presented in relation to these requests.

6. Under these circumstances, the board can only conclude that claim 1 of each of auxiliary requests 2 to 38 does not overcome the objection of lack of inventive step for the same reasons as claim 1 of the main request.

Overall conclusion

7. Since none of the claim requests is allowable, the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated