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Datasheet for the decision of 28 June 2021

Case Number: T 0207/16 - 3.2.02

Application Number: 03731693.2

Publication Number: 1467789

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Language of the proceedings: EN

Title of invention:
Medicament dispenser

Patent Proprietor:
Glaxo Group Limited

Opponents:
Vossius & Partner
Patentanwälte Rechtsanwälte mbB
Teva UK Limited

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 123(2)
RPBA Art. 12(4)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Amendments - added subject-matter (no)
Late-filed evidence - not admitted in first instance proceedings

Decisions cited:

Catchword:

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Beschwerdekammern

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Case Number: T 0207/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 28 June 2021

Appellant: (Opponent 1)	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Appellant: (Opponent 2)	Teva UK Limited Ridings Point Whistler Drive Castleford WF10 5HX (GB)
Representative:	Smith, Jeremy Robert Kilburn & Strode LLP Lacon London 84 Theobalds Road London WC1X 8NL (GB)
Respondent: (Patent Proprietor)	Glaxo Group Limited 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 8 December 2015 rejecting the opposition filed against European patent No. 1467789 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Stern
Members:	S. Böttcher
	N. Obrovski

Summary of Facts and Submissions

I. Both opponents filed an appeal against the decision of the opposition division to reject the oppositions against European patent number 1 467 789.

The Opposition Division decided that the subject-matter of the claims as granted did not extend beyond the content of the application as filed and that the subject-matter of the claims as granted was novel and involved an inventive step.

II. Oral proceedings before the Board were held on 28 June 2021.

Nobody was present on behalf of appellant 1 (opponent 1) and appellant 2 (opponent 2). The appellants had been duly summoned to attend the oral proceedings but had declared in their submissions dated 17 June 2021 and 24 June 2021, respectively, that they would not attend. The proceedings were continued without the appellants (Rule 115(2) EPC and Article 15(3) RPBA 2020).

III. Both appellants request that the decision under appeal be set aside and that the patent be revoked.

IV. The respondent (patent proprietor) requests, as a main request, that the appeals be dismissed, i.e. the patent be maintained as granted, or, alternatively, that the patent be maintained in amended form on the basis of auxiliary requests 1 to 32 as filed with the submission dated 10 September 2020. The respondent further requests that D13' not be admitted into the proceedings

and that the case be remitted to the opposition division if the decision under appeal is set aside.

V. Claim 1 of the main request reads as follows:

"A medicament dispenser (600;900;...2500) comprising plural elongate form medicament carriers (601a,b; 901a,b;...2501a,b), each carrier having multiple distinct medicament dose portions carried thereby, the medicament dose portions of each carrier containing a medicament active, or a mixture of medicament actives, which is different from that in the medicament dose portions of the other carrier(s), said dispenser having a dispensing mechanism which is adapted to operate, upon each actuation of the dispenser, to dispense a single distinct medicament dose portion carried by each of said plural medicament carriers, said mechanism comprising,
a) at least one receiving station (602a,b;902a,b;... 2502a,b) receiving each of the plural medicament carriers;
b) a release for releasing a distinct medicament dose portion from each of the plural medicament carriers;
c) an outlet (624;924;...2524), positioned to be in communication with the distinct medicament dose portions releasable by said release to enable their dispensing to the patient; and
d) at least one indexer (606a,b;906a,b;...2506a,b) for individually indexing the distinct medicament dose portions of each of the plural medicament carriers."

VI. Claim 47 of the main request reads as follows:

"A medicament dispenser (2400) comprising plural elongate form medicament carriers (2420, 2421), each carrier having multiple distinct medicament dose

portions carried thereby, the medicament dose portions of each carrier containing a medicament active, or a mixture of medicament actives, which is different from that in the medicament dose portions of the other carrier(s), wherein said plural carriers are applied to each other to form a single conjoined carrier (2401), said dispenser having a dispensing mechanism which is adapted to operate, upon each actuation of the dispenser, to dispense a single distinct medicament dose portion carried by each of said plural medicament carriers, said mechanism comprising,
a) a receiving station (2402a,b) for receiving each of the plural medicament carriers;
b) a release for releasing a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station;
c) an outlet (2424), positioned to be in communication with the distinct medicament dose portions releasable by said release to enable their dispensing to the patient; and
d) at least one indexer (2406a,b) for individually indexing the distinct medicament dose portions of each of the plural medicament carriers."

VII. In the present decision, reference is made to the following documents:

D1: US2001/0020147 A1
D2: GB 2 242 134 A
D7: Pharmaceutical Blister Packaging, Part I; Philchik, Ron; Pharmaceutical Technology, Nov. 2000, pp. 68 to 79
D8: EP 0 239 802 A
D9: WO 00/64520 A1
D11: EP 1 300 171 A2
D13: EP 0 928 618 B1

D13': EP 0 928 618 A1

VIII. The arguments by appellant 1 can be summarised as follows:

Admittance of D13'

D13', which is an A1 publication of D13, had been filed because D13 was a prior art reference under Article 54(3) EPC and could only be used for the assessment of novelty. With the introduction of D13' merely a new line of arguments had been presented, whereas the facts and evidence were still the same.

The fact that D13' was more voluminous than D13 would not have placed any burden on the other parties or the Opposition Division because the contents which were contained only in D13', and not in D13, were irrelevant to the inventive-step assessment.

Furthermore, by not admitting D13', the opposition division misused its discretion under Article 114(2) EPC since they did not examine the relevance of D13'.

Hence, D13' should be admitted into the proceedings.

Main request - novelty in view of D13

In paragraphs [0034] to [0036], D13 disclosed a medicament dispenser having plural medicament carriers according to claim 1. These paragraphs described an inhaler which was different from the one in paragraphs [0025] to [0030], which had a bulk reservoir from which the metering devices could receive a substance.

Paragraph [0036] related to the embodiments as shown in

Figures 1 and 2, according to which all metering devices were pre-filled with a substance. In contrast, paragraphs [0025] to [0030] related to embodiments which were described in the application underlying D13, but which were then removed from the figures during its prosecution.

Thus, D13 disclosed all the features of claim 1. Accordingly, the subject-matter of claim 1 lacked novelty over D13.

Main request - inventive step in view of D2 in combination with D9

Starting from D2 the distinguishing features, the technical effect and the objective technical problem to be solved were as established by the opposition division (page 14 of the decision, second to fourth paragraphs).

The person skilled in the art would have looked for a solution in D9, describing an inhaler employing a bulk powder container, since it belonged to the same technical field and addressed the same technical problem as the patent in suit (page 2, lines 5 to 14).

According to D9, this problem was solved by providing an inhaler with two powder containers and two dispensing mechanisms (page 2, lines 20 to 26). The person skilled in the art would consider the teaching of D9, in order to apply it analogously to the powder inhaler of D2.

Thus, it would have been obvious for the person skilled in the art to provide two flexible strips containing different medicament actives. The benefits of blister

strips, e.g. "reduced costs", were mentioned in D7, which also referred to a growing trend favouring the use of blister strips (page 70, left column, lines 19 to 24).

It would also have been a matter of common sense to provide a common dispensing mechanism having a common inhalation channel and mouthpiece. Since the necessary changes of the elements of the device of D2 were exactly as taught in D9, the skilled person would not have encountered any technical hindrance in applying the solution taught by D9 to the inhaler of D2. The existence of other possible solutions to the problem was irrelevant to this finding.

In view of the technical teaching of D9 the person skilled in the art would also provide one or more indexers as disclosed in D2 for individually indexing the medicament dose portions (page 6, line 19, to page 10, line 1, reference numeral 16 in Figure 2).

Consequently, the subject-matter of claim 1 lacked an inventive step in view of the combination of D2 and D9.

Main request - inventive step in view of D1

Starting from the embodiment illustrated in paragraph [0144] and Figure 5, which disclosed two bulk reservoirs, the distinguishing feature of claim 1 was the use of carriers having multiple distinct medicament dose portions instead of the bulk reservoirs.

The objective technical problem could be formulated as providing an inhaler of the type shown in D1 with more precise dosing.

D1 taught in paragraphs [0054] and [0155] that blister strips or rolls could be used to individually meter the unit doses prior to actuation. Due to the reference to "certain embodiments of the invention" in paragraph [0155] the person skilled in the art would have found without fail that the teaching was also applicable to the embodiment of Figure 5. In paragraph [0134], reservoirs and blisters were presented as two alternative forms of a medicament container, from which the person skilled in the art could choose depending on necessities.

Although not explicitly mentioned in D1, the benefits of pre-metered blister packing with regard to a more accurate dosing were clearly envisaged as a matter of course by the person skilled in the art. Hence, the person skilled in the art would have naturally looked to this option in order to solve the technical problem. The teaching of the blister strip option was also applicable to the embodiments concerning the combination therapy, e.g. the embodiment using bulk reservoirs described in paragraph [0144], as indicated in paragraphs [0054], [0134] and [0155]. Hence, it was obvious for the person skilled in the art to modify the device of Figure 5, thereby arriving at the subject-matter of claim 1. The necessary redesign of the device of Figure 5 involved nothing more than the performance of experimental work by routine means in connection with the normal practice of filling the gaps in knowledge by the application of existing knowledge.

Several advantages of blister packaging were also known from D7 (page 70, left column), i.a. protection of remaining drugs, prevention of broken glass bottles, reduction of costs and higher packaging speeds. According to D7, these benefits led to an increased use

of blister packaging for solid drugs in Europe and the United States. In view of these benefits and the widespread use of blister packaging, the person skilled in the art would be motivated to modify the embodiment in paragraph [0144] of D1 by adopting blister packaging. The fact that this solution provided a further (bonus) effect, i.e. improved dosing, was not detrimental to its obviousness.

Consequently, the subject-matter of claim 1 lacked an inventive step in view of D1.

Main request - inventive step in view of D8

D8 disclosed the features "multiple distinct medicament dose portions" (column 8, lines 52 to 54) and "a single conjoined carrier", i.e. a tape with two lanes (column 10, lines 6 to 43). Thus, the only distinguishing feature of claim 47 was the dispensing of one dose portion of each lane upon each actuation. However, this was an obvious modification in view of the disclosure of D8 (column 10, lines 19 to 28). The person skilled in the art would adapt the frequency, number or manner of delivery without requiring any inventive step.

Hence, the subject-matter of claim 47 did not involve an inventive step in view of D8.

IX. The arguments by appellant 2 can be summarised as follows:

Admittance of D13'

D13' should have been admitted into the opposition proceedings because it was highly relevant.

Since opponent 1 referred to the publication of the application when submitting D13 during the opposition proceedings (letter of 8 October 2015), it was clear that D13' was meant to be filed. The proprietor was not faced with an undue burden when considering D13' instead of D13.

The Board should admit D13' into the appeal proceedings.

Main request - added subject-matter

The omission of the feature "on receipt thereof by said receiving station" infringed Article 123(2) EPC, since it lifted any qualification on when the release took place. The wording of claims 1 and 47 of the main request covered situations in which the medicament was released at some other time prior to receipt of the dose portion at the receiving station.

Furthermore, the replacement of the features "a receiving station" and "an indexer" by, respectively, "at least one receiving station" and "at least one indexer" in claims 1 and 47 added subject-matter. The application as originally filed did not disclose any number of receiving stations and indexers for each medicament carrier. Only embodiments having one receiving station or indexer for each carrier were disclosed.

Hence, claims 1 and 47 did not meet the requirements of Article 123(2) EPC.

Main request - novelty in view of D1

There was a close relationship between the "blister

disclosure" of paragraph [0155] and the embodiment of Figures 5 and 6. Paragraph [0023] specified simultaneous delivery of multiple drugs as a specific object of the invention. Paragraph [0155] specified clearly that blister packs were generally applicable to the disclosed devices, i.e. also as a direct substitute for each of the reservoirs of Figures 5 and 6.

It was directly and unambiguously derivable from D1 that the mechanism for advancing blister strips disclosed in Figure 18 and paragraph [0155] was envisaged as being incorporated in the embodiment of Figures 5 and 6. It was clear that the "certain embodiments of the invention" mentioned in paragraph [0155] related to the reservoir embodiments in which the doses were metered upon actuation and to which metering prior to actuation should be applied. Indicators for this intended application of the teachings in paragraph [0155] could be found in dependent claims 16 and 29 to 31, and in paragraphs [0054] and [0134].

Hence, there was a clear disclosure that the dual reservoirs 22 and 35 in Figures 5 and 6 would be replaced with blister strips as plural elongate form medicament carriers.

Furthermore, the meaning of "distinct" in the feature "multiple distinct medicament dose portions" in claim 1 could be regarded as defining the use of different drugs in each of the carriers, and not different dose portions in each of the carriers.

If read in isolation, the term "distinct" was ambiguous since it could be taken to refer to the medicament (i.e. different medicaments in each carrier) or to the

dose portions (i.e. different dose portions on each carrier). However, in the context of the object of the invention, namely, administration of a combination product of separately stored active components, the meaning of the term should be interpreted as defining different medicaments in each carrier. This interpretation was confirmed by the passage in paragraph [0069] (lines 33 to 34) of the patent, in which the term "distinct" was replaced with "component".

From this interpretation it followed that the two reservoirs 22 and 35 of the embodiment of Figures 5 and 6 corresponded to the plural medicament carriers defined in claim 1 since they carried multiple dose portions of different (distinct) medicaments.

Irrespective of the interpretation of the term "distinct", D1 disclosed directly and unambiguously all the features of claim 1. Therefore, the subject-matter of claim 1 lacked novelty over D1.

Main request - novelty in view of D8

D8 disclosed encapsulating distinct doses of medicament in plural carriers that were dispensed simultaneously each time a dose was required (column 1, lines 4 to 9; column 3, lines 33 to 35; column 7, lines 38 to 45; column 8, lines 52 to 54; column 9, lines 9 to 21 and 30 to 36; column 10, lines 6 to 43; column 11, lines 5 to 18; column 12, lines 30 to 38). Hence, the subject-matter of claim 1 was anticipated by D8.

D8 also disclosed that the plural carriers, i.e. the plurality of parallel lanes, were applied to each other to form a single conjoined carrier, i.e. the tape 1

(column 10, lines 8 to 11). Hence, the subject-matter of claim 47 also lacked novelty over D8.

Main request - novelty over D13

D13 disclosed plural elongate form medicament carriers each having multiple distinct dose portions carried thereby, i.e. plural series of metering devices, each metering device having a dose of medicament trapped therein when travelling through the storage chamber (paragraph [0009], lines 13 to 20; paragraph [0020], lines 55 to 4; paragraph [0022], lines 11 to 21).

Furthermore, paragraph [0030] stated that for each operation of the indexing means a fixed number of metering devices was moved from the storage chamber to the inhalation passage. During this batch movement of the metering devices multiple, i.e. a fixed number of, medicament dose portions were carried at one time. Hence, each series of metering devices mentioned in paragraph [0036] carried multiple dose portions.

Hence, the subject-matter of claim 1 was anticipated by D13.

Main request - inventive step starting from D2

The subject-matter of claim 1 differed from the disclosure of D2 in that plural medicament carriers were provided and in the doubling of the functions to dispense doses from both carriers simultaneously.

The problem to be solved by this feature could be regarded as to allow the provision of a combined dose of different medicaments.

This problem was solved by simply doubling up the mechanism of D2. Since it was known from the background section of the patent in suit that the dispensing of combined medicaments was desirable (column 1, lines 7 to 52), this was obvious for the person skilled in the art.

The provision of plural carriers and the doubling of the dispensing mechanism was also obvious in view of the common general knowledge evidenced by any of D11 and D9, both showing that the concept of "doubling up" was standard procedure in the art.

Hence, the subject-matter of claim 1 lacked an inventive step in view of D2 and the common general knowledge as evidenced by D9 and D11, or in view of D2 in combination with D9 or D11.

Main request - inventive step in view of D1

It was known from D1 that combination therapy could be realised by using a doubled-up device in a bulk reservoir system (paragraphs [0023], [0048] and [0144], and D9 and D11). It was obvious for the person skilled in the art to apply this teaching to the blister carrier disclosure of paragraph [0053] of D1, i.e. to double-up the blister device.

Starting from the embodiment of Figures 5 and 6 of D1, the subject-matter of claim 1 was distinguished by the provision of plural elongate form medicament carriers each having multiple distinct medicament dose portions. Since the reservoirs 22 and 35 of the inhaler of D1 had the same technical effect as the distinguishing feature, namely enabling the device to contain active components separately while still enabling delivery of

a combination dose, the objective technical problem was to provide an alternative solution for isolating active components of a combination product within an inhaler device. D1 taught the use of blister strips as alternatives to reservoirs (paragraphs [0054] and [0134]). Hence the person skilled in the art would consider using blisters to solve the problem, in particular as the use of blister strips within the device was shown and described in Figure 18 and paragraph [0155]. It would therefore be obvious to replace each of the reservoirs 22 and 35 with a blister strip and a corresponding mechanism.

Thus, the subject-matter of claim 1 lacked an inventive step in view of D1.

X. The respondent's arguments can be summarised as follows:

Admittance of D13'

The opposition division had admitted D13 based on its prima facie relevance for novelty during the oral proceedings. For their argumentation on lack of inventive step, the opponents had referred only to those passages which were common in D13 and D13'. Hence, the opposition division had obviously considered the relevance of D13' to inventive step when deciding not to admit it.

Furthermore, the additional content of D13' (compared to the disclosure of D13) related only to reservoir-type inhalers and was therefore no more relevant for assessing inventive step than the documents already on file.

Moreover, opponent 1 could have filed D13' when D13 was filed since they admitted having D13' in their possession already then.

Contrary to the appellant 1's view, the introduction of D13' into the proceedings would have introduced new facts, but not new arguments.

Although appellant 1 had referred to the A publication date in their submission of 8 October 2015, their arguments both on novelty and inventive step had been based on D13, and not D13'. Hence, it could not have been expected from the opposition division to have read D13' before the oral proceedings. Due to the late submission of D13' an undue burden had been placed on the proprietor.

Thus, D13' should not be admitted into the appeal proceedings.

Main request - added subject-matter

The omission of the feature "upon receipt thereof by said receiving station" in claim 1 did not introduce added matter. The term "thereof" referred to the carriers and not to the dose portions. Since claim 1 had been amended to specify that the carriers were received by the receiving station, the omitted wording was redundant.

The replacement of the terms "a"/"an" with "at least one" in claims 1 and 47 did not add subject-matter since they were equivalent, i.e. interchangeable. Claim 1 as originally filed was not limited to an embodiment having one receiving station or indexer for each carrier. Furthermore, dependent claims 3, 4, 9 and 10

as originally filed provided a basis for the amendment, in particular since claims 4 and 10 mentioned "plural distinct" receiving stations and indexers, respectively.

Hence, claims 1 and 47 met the requirements of Article 123(2) EPC.

Main request - novelty in view of D1

The two different embodiments described at paragraphs [0144] and [0155] of D1 could only be linked by using impermissible hindsight of the claimed invention. From the reference to "certain embodiments" in paragraph [0155] it was clear that this paragraph was not connected to any specific embodiment. D1 did not provide a clear suggestion to combine the two embodiments.

Hence, the subject-matter of claim 1 was novel over D1.

Main request - novelty in view of D8

The disclosure in D8 (column 8, lines 52 to 54) that the active substance might be encapsulated was not an unequivocal disclosure of the provision of distinct medicament dose portions.

Therefore, the subject-matter of claims 1 and 47 was novel over D8, since D8 did not disclose the feature "each carrier having multiple distinct medicament dose portions".

Main request - novelty in view of D13

D13 did not disclose a state of the inhaler where each

of the series of metering devices carried multiple dose portions. Paragraphs [0034] and [0036] related to an inhaler including a storage chamber. The movement of the metering device from a first position to a second position mentioned in paragraph [0036] could only mean that in the first position the metering device was in the storage chamber to receive a dose of powder substance, and in the second position that dose was transferred to an inhalation passage. Hence, the metering devices of the series were not pre-filled with powder.

Obviously, due to an incomplete adaptation of the description during the grant procedure of D13, paragraphs [0034] and [0036] were incorrectly carried over from the application documents to D13, although they did not relate to the embodiment covered by the claims of D13. Hence, D13 did not disclose plural chains of pre-filled metering devices.

Furthermore, neither paragraph [0009] nor paragraph [0022] of D13, referred to by appellant 2, included an unambiguous disclosure of multiple distinct dose portions present in the metering members at any given time.

Hence, the subject-matter of claim 1 was novel over D13.

Main request - inventive step starting from D2

Starting from the inhaler of D2, the person skilled in the art would not have looked into D9 when seeking to deliver a combination product. The person skilled in the art would rather have provided for simultaneous delivery of different medicaments via the single strip

device of D2, e.g. by storing the different medicaments separately in alternating pockets of the strip. In contrast, a doubling up of the blister strip device would not have been envisaged by the person skilled in the art, since it would have incurred ongoing cost of goods.

Since D9 provided a stand-alone working solution to the objective technical problem, the skilled person would have adopted the whole teaching of D9, instead of completely redesigning the device of D2.

The argument that the person skilled in the art would have doubled up the single blister strip in view of D2 and the statement in the patent in suit (column 1, lines 7 to 52) was based on an ex post facto analysis.

Since patent literature could normally not be regarded as suitable references for determining common general knowledge, the objections starting from D2 in combination with common general knowledge as evidenced by D9 and D11 were invalid. Furthermore, D11 was state of the art pursuant to Article 54(3) EPC and therefore not relevant for the assessment of inventive step.

Hence, the subject-matter of claim 1 involved an inventive step.

Main request - inventive step in view of D1

If the objective technical problem was to improve dosing of the reservoirs of paragraphs [0023], [0048] and [0144], the person skilled in the art was not taught by D1 that the pre-metered blisters disclosed at paragraphs [0155], [0156] and [0157] provided any benefit in regard of dosing accuracy. There was even no

evidence that the person skilled in the art would consider the bulk reservoir arrangement to provide insufficient dosing accuracy.

Hence, the person skilled in the art was not minded to combine the teachings of Figure 17 with that of Figures 5 and 6 and to adopt pre-metered storage to the bulk reservoirs. The expression "in certain embodiments", which was used in paragraph [0155], could not represent an incentive to the person skilled in the art to make precisely this combination.

D7, referred to by appellant 1, did not mention the use of blister packs as an alternative to bulk reservoirs, and even less the benefits thereof. Therefore, the general benefits of blister packs mentioned in D7 were irrelevant for evaluating inventive step in view of D1.

Hence, the subject-matter of claim 1 involved an inventive step.

Main request - inventive step in view of D8

D8 did not disclose a carrier having multiple distinct medicament dose portions. The teaching that the substance might be encapsulated was not a disclosure of the carriage of a single discrete dose of medicament which could be released upon each actuation.

Since not all the features of claim 47 were present in D8, the skilled person would not arrive at the device of claim 47 starting from D8.

Hence, the subject-matter of claim 47 involved an inventive step.

Reasons for the Decision

1. The invention relates to a medicament dispenser (inhaler) for delivery of medicament particles to the bronchial or alveolar region by inhalation. The dispenser comprises plural (mostly two) elongate form medicament carriers (e.g. blister strips, Figure 1), each carrier having multiple distinct medicament dose portions carried thereby and containing a medicament or a mixture of medicaments that is different from that in the other carrier(s). The dispensing mechanism is adapted to dispense, upon each actuation of the dispenser, a single dose portion of each of the carriers, such that two (or more) different medicaments are delivered simultaneously through a common outlet. The carriers (blister strips) are received either in a common receiving station (Figure 11b of the patent) or each in respective separate receiving stations (e.g. Figures 6a, 8 of the patent). The dispenser further includes either a common indexer for both blister strips (index wheel 1206 in Fig. 11b) or one indexer for each of the strips (e.g. index wheels 906a and 906b in Fig. 8).

2. Admittance of D13'

D13', which is the A1-publication of D13, was filed during the oral proceedings before the Opposition Division after the chairman had pointed out that D13 was published after the filing date of the application underlying the patent in suit, and could not be used for an inventive-step assessment. It is undisputed that it could have already been submitted at the same time as D13.

From the reference to the publication date of D13' in the appellant 1's submission of 8 October 2015 the Opposition Division could not have concluded that D13', instead of D13, had been filed. Moreover, contrary to appellant 1's view, the introduction of D13' into the proceedings would have allowed to raise new facts in relation to D13, for example in the context of an objection of lack of inventive step.

As to the alleged lack of consideration of the contents of D13' by the Opposition Division, the Board notes that the relevant contents of D13' had been presented as being identical to that of D13, the relevance of which the Opposition Division had assessed.

Therefore, the Board does not consider that the Opposition Division exercised its discretion not to admit D13' into the proceedings in an unreasonable way. Hence, there is no reason for the Board to overrule the decision of the Opposition Division.

3. Main request - added subject-matter

3.1 In claims 1 and 47 the feature "on receipt thereof by said receiving station", which was present in feature b) of claim 1 as originally filed, has been omitted.

The Board agrees with the Opposition Division that this omission does not infringe Article 123(2) EPC. The term "thereof" refers to the carriers which were included in claim 1 as originally filed. Since, following an amendment of claims 1 and 47 during the grant procedure, the carriers are now part of the claimed subject-matter, the omitted wording is redundant.

Appellant 2's argumentation is based on the assumption

that the receipt of the dose portions by the receiving station is meant by the omitted feature. It is however clear from feature a) of claim 1 as originally filed that the medicament carriers are received by the receiving station, and not the distinct dose portions. Appellant 2's argument is therefore incorrect.

3.2 In claim 1, the term "a receiving station" has been replaced with "at least one receiving station". In claims 1 and 47, the term "an indexer" has been replaced with "at least one indexer".

In the Board's view, in the present case the indefinite article "a" means both "one" and "more than one". This is corroborated by the wording of dependent claim 3, specifying "a common receiving station", i.e. one, and dependent claim 4, specifying "plural distinct receiving stations", i.e. more than one. Correspondingly, dependent claims 9 and 10 disclose both alternatives of "one" and "more than one" indexers.

According to appellant 2, the amended claims cover an embodiment having any number of receiving stations or indexers for each medicament carrier, which was not the case for claim 1 as originally filed. However, the Board holds that from the indefinite article "a" in claim 1 as originally filed it can not be derived that the number of receiving stations or indexers has to be equal to the number of medicament carriers. Hence, if the amended claims 1 and 47 included embodiments having more receiving stations or indexers than carriers, then these embodiments were also included in claim 1 as originally filed.

The replacement of "a" with "at least one" in claims 1

and 47 does therefore not add subject-matter.

3.3 Hence, claims 1 and 47 meet the requirements of Article 123(2) EPC.

4. Main request - novelty in view of D1

4.1 D1 discloses (Figures 5 and 6, paragraph [0144]) a dispenser for the delivery of two or more different medicaments, wherein the medicaments are held in separate compartments and delivered by separate measuring means (indexers). These compartments can be considered as carriers. However, they do not comprise multiple distinct dose portions as required by claim 1.

In another embodiment, D1 discloses (Figures 17 and 18, paragraph [0155]) a dispenser comprising one elongate medicament carrier with multiple distinct dose portions, and a dispensing mechanism having a receiving station (implicitly), a release, an outlet (implicitly) and an indexer (gear mechanism 180). This embodiment does not have plural carriers.

Hence, none of these embodiments discloses all the features of claim 1.

4.2 Contrary to appellant 2, the Board does not discern any link between the "blister" embodiment of paragraph [0155] and the embodiment of Figures 5 and 6. In particular, it cannot be derived that the two reservoirs of Figures 5 and 6, in which a dose of medicament is metered upon actuation of the indexer, can be replaced with two blister strips carrying pre-metered doses of different medicaments.

From the general reference to "certain embodiments of

the invention" in paragraph [0155] it cannot be concluded that blister strips should be applied to the specific embodiment of Figures 5 and 6.

Furthermore, neither paragraphs [0054] and [0134] nor dependent claims 16 and 29 to 31 disclose the incorporation of two blister strips in the embodiment of Figures 5 and 6.

Since no direct and unambiguous teaching of a combination of the two embodiments is given in D1, the subject-matter of claim 1 is novel over D1.

4.3 Moreover, the Board does not concur with appellant 2 on the interpretation of the claimed feature of "multiple distinct medicament dose portions". It is mentioned in paragraph [0010] of the patent in suit that "the distinct dose portions are typically arranged in spaced fashion (...) such that each dose portion is separately accessible". Furthermore, in paragraphs [0022] to [0024] reference is made to the dose volume, and to multiple distinct dose portions which are provided on each carrier. Even paragraph [0069], referred to by appellant 2, states that the flexible strip of the carrier defines a plurality of pockets, each of which containing a dose of medicament (lines 25 to 30), and that "each strip provides the component medicament dose portions of a combination medicament product" (lines 33 to 34). Therefore, it is clear that the term "distinct" refers to the dose portion and not to the medicament.

5. Main request - novelty in view of D8

5.1 D8 discloses an apparatus for the vaporising of substances (e.g. deodorants, aromas, but also drugs for absorption from the respiratory organ (column 3, lines

27 to 37)) into the atmosphere (Figures 1, 4 or 5). The apparatus includes a substance carrier in form of a tape 1 carrying the substance in the form of a continuous lane (column 10, lines 6 to 11). The tape travels relative to a head 2 whereby the fresh substance is successively supplied to the vaporization zone.

5.2 However, D8 does not disclose the feature "each carrier having multiple distinct medicament dose portions carried thereby" of claims 1 and 47. In particular, from the mere disclosure that the active substances or compositions can be encapsulated or microencapsulated (column 8, lines 52 to 56), it cannot be concluded that the tape carries multiple distinct medicament dose portions. It is rather mentioned that encapsulation protects the active substance against vaporization during storage or distribution of the tape (column 9, lines 30 to 36). However, this does not imply that the substance is encapsulated in distinct doses. Also, the statement that the vaporization can be intermittent (column 1, lines 4 to 9) does not provide an unequivocal disclosure of distinct medicament doses which are dispensed upon actuation of the dispenser.

5.3 Hence, the subject-matter of claims 1 and 47 is novel over D8.

6. Main request - novelty in view of D13

6.1 D13 discloses a powder inhaler having drug carrying containers (Figures 1 and 2) each comprising a plurality of receptacles (122, 129) holding the drug. A metering device, in the form of a spool (123), is located inside each receptacle. The containers are in the form of a "bandolier" (Figure 1) or in the form of

a disc (Figure 2). The inhaler includes indexing means (push button 146, Figure 3) for pushing the spool downwards such that it is positioned adjacent the inhalation passage 144. The spool thereby carries with it the metered quantity of drug which was contained inside the container for inhalation by the patient. The "bandolier"-container shown in Figure 1 can be regarded as an "elongate form medicament carrier having multiple distinct medicament dose portions" as required by claim 1. However, this embodiment does not include a plurality of such carriers each containing a different medicament.

6.2 The Board notes that paragraphs [0020] to [0064] of the description of D13 relate to different embodiments that are not shown in the figures of D13 (which is the publication of the patent specification). Apparently, due to an incomplete adaptation of the description during the grant procedure of D13, these parts of the description remained in the specification. The inhaler according to these embodiments includes a series of metering devices in the form of a chain which runs through a medicament storage chamber of the inhaler. The metering devices are of such a size and shape that, when passing through the outlet channel, they carry a dose of substance into the inhalation passage (paragraphs [0025] to [0030]). In paragraph [0036] it is mentioned that more than one series of these metering devices, i.e. more than one chain, may be provided, and that the inhaler may comprise more than one storage chamber to correspond to the respective more than one chain. Such an arrangement may be used to deliver two different drugs.

6.3 The Board does not agree with the appellants that the chain of metering devices mentioned in paragraphs

[0025] and [0030] can be regarded as a carrier having distinct dose portions. As long as the metering devices travel through the storage chamber, there are no distinct dose portions carried by them since there is no sidewall defining their volume. Only after entering the outlet conduit there is a single dose portion trapped between two successive metering devices and the inner walls of the outlet conduit (paragraph [0030], last sentence). Although the chain of metering devices might be moved forward by a number larger than one, it cannot be derived from D13 that there may be more than one dose portion at the same time in the outlet conduit.

6.4 The Board also does not concur with appellant 1 that paragraphs [0034] to [0036] relate to the embodiment of Figures 1 and 2. It is noted that paragraphs [0069] to [0070], which describe the embodiment of Figures 1 and 2, do not refer to a series of metering devices but rather to a series of receptacles each having a metering device. Hence, in view of the different terminology used, it is clear that paragraphs [0034] to [0036] do not cover this embodiment.

6.5 Furthermore, none of the further passages cited by appellant 2 (paragraph [0009], lines 13 to 20; paragraph [0020], lines 55 to 4; paragraph [0022], lines 11 to 21) provides a direct and unambiguous disclosure of multiple distinct dose portions carried by a carrier at a time. In the Board's view, these passages also refer to inhalers of the type described in paragraphs [0025] and [0030].

6.6 Since D13 does not disclose "plural elongate form medicament carriers each having multiple distinct medicament dose portions carried thereby", the subject-

matter of claim 1 is novel over D13.

7. Main request - inventive step starting from D2

7.1 D2 discloses an inhaler of the same type as the patent in suit since it includes an elongate blister strip carrying distinct doses of medicament (Figures 9 or 16).

It is undisputed that the subject-matter of claim 1 differs from the inhaler of D2 in that
(i) it includes plural medicament carriers, each carrier containing a medicament active or a mixture of medicament actives, which is different from that in the dose portions of the other carrier(s);
(ii) a dose from each of the carriers is dispensed upon each actuation; and
(iii) the at least one indexer is configured for individually indexing the dose portions of each of the carriers.

It is also undisputed that the objective technical problem to be solved is to provide a medicament dispenser suitable for providing a combined dose of different medicaments.

7.2 To solve this technical problem the person skilled in the art would not consult D9, as alleged by appellant 1.

D9 relates to an inhaler working on the bulk powder principle comprising two medicament containers for different medicament powders. The medicament powders are brought to the air channel by separate dosing recesses of a metering drum, where they are mixed and inhaled (page 2, lines 20 to 26, Figure 1).

Although D9 addresses the same technical problem (page 2, lines 13 to 14), it provides a stand-alone working solution which does not share any aspect of the blister strip inhaler of D2. Hence, the person skilled in the art would not be motivated to apply the teaching of D9 to the blister strip inhaler of D2 in order to arrive at an inhaler as defined in claim 1.

The solution specified in claim 1 is therefore not obvious for the person skilled in the art. The subject-matter of claim 1 involves an inventive step over the combination of D2 with D9.

7.3 Appellant 2 referred to the patent in suit (column 1, lines 7 to 52) to argue that it was obvious to simply double up the blister strip of the inhaler of D2. This is considered an ex post facto analysis.

7.4 According to appellant 2, D9 evidenced the common general knowledge that the concept of "doubling up" was a standard procedure in the art.

In this respect, the Board notes that D9 is not a basic handbook or textbook representing the common general knowledge. It is rather a patent application disclosing a specific device having considerable structural differences compared to the device of D2. D9 does not include any general teaching of a "doubling up" concept.

7.5 The Board agrees with the Opposition Division that D11 was published after the filing date of the application of the patent in suit (constituting prior art under Article 54(3) EPC) and is therefore not relevant for evaluating inventive step (page 13, last paragraph, of

the decision). Hence, the objection of lack of inventive step in view of D2 in combination with D11 as raised by appellant 2 fails.

8. Main request - inventive step in view of D1

8.1 As explained above (point 4.1), D1 discloses an embodiment in which different medicaments are contained in two bulk reservoirs with associated metering means, allowing the delivery of a combination of medicaments (paragraphs [0023], [0048] and [0144], Figures 5 and 6).

8.2 According to appellant 1, starting from this embodiment, the objective technical problem would be to improve the dosing of the medicaments.

In the Board's view, in an attempt to solve this problem, the person skilled in the art would not take the embodiment of paragraph [0155] into account. It is mentioned in paragraph [0155] that in this embodiment the doses are individually metered prior to actuation. However, there is no indication that this is done in order to improve the accuracy of the dosing of the medicaments. Hence, the person skilled in the art would not be prompted to apply the teaching of the blister embodiment to the embodiment of Figures 5 and 6 and to incorporate the blister strips in the bulk reservoir embodiment.

8.3 According to paragraph [0134], both the reservoir doses and the blister doses may be administered against gravity. However, this does not teach the person skilled in the art that blister strips could be used as an alternative medicament carrier in the embodiment of Figure 5. Furthermore, from the wording "in certain

embodiments" in paragraph [0155] it cannot be concluded that blister strips should be applied to the specific embodiment of Figures 5 and 6.

8.4 The alleged benefit of pre-metered blisters over bulk reservoirs, namely that they provide for improved dosing, can also not be considered as a matter of course by the person skilled in the art. It cannot even be derived from D1 that the in-situ metering of the bulk reservoir embodiment could lead to inaccurate dosing.

In fact, D1 does not mention any benefits of the blister packs over bulk reservoirs. In this regard, D7, referred to by appellant 1, does not provide any teaching either. D7 compares blister packaging with other packaging concepts for medicaments (page 70, left column). However, the use of blister packs as an alternative in a bulk reservoir dispenser is not suggested by D7. Furthermore, the effect of improved dosing cannot be regarded as a "further (bonus) effect" of the blister strip solution.

8.5 According to appellant 2, starting from the embodiment of Figures 5 and 6 of D1, the objective technical problem would be to provide an alternative solution for isolating active components of a combination product within an inhaler device.

Contrary to appellant 2's view, the Board holds that blister strips are not suggested as alternative medicament carriers in the bulk reservoir embodiments, and even less for the provision of a combination therapy as in the embodiment of Figures 5 and 6. The blister strip embodiment of Figures 17 and 18 is a completely separate device which does not have any

aspects in common with the bulk reservoir embodiments. In particular, from the disclosure that both the reservoir doses and the blister doses may be administered against gravity (paragraph [0134]) or reloaded (paragraph [0054]) it cannot be concluded that blister strips and reservoirs are interchangeable.

Hence, the subject-matter of claim 1 does not lack an inventive step over the embodiment of Figures 5 and 6 of D1 in combination with the teaching of paragraph [0155].

8.6 Appellant 2 further argued that it would be obvious for the person skilled in the art to use a doubled-up device as known from the bulk reservoir embodiment of paragraphs [0023], [0048] and [0144] or from D9 and D11 in order to realise a combination therapy with the blister carrier embodiment of paragraph [0053] of D1.

The Board does not concur with this view, since the bulk reservoir embodiment is a stand-alone solution to provide combination therapy. Hence, the person skilled in the art would not be prompted to apply any aspect of this embodiment to the blister carrier device.

Consequently, the subject-matter of claim 1 does not lack an inventive step over the blister strip embodiment of paragraph [0053] of D1 in combination with the teaching of paragraphs [0023], [0048] and [0144] of D1 or in combination with D9.

9. Main request - inventive step in view of D8

Appellant 1 raised an objection against claim 47 based on D8.

The Board notes that, contrary to appellant 1's assertion, D8 does not disclose the feature "each carrier having multiple distinct medicament dose portions carried thereby", as established in point 5.2 above.

Appellant 1 did not indicate how or why this distinguishing feature should be obvious in view of D8. Hence, the Board finds their argumentation unconvincing.

10. From the above it follows that none of the objections raised prejudices the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

D. Hampe M. Stern

Decision electronically authenticated