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Datasheet for the decision of 10 April 2025

Case Number: T 0377/23 - 3.2.02

Application Number: 16153186.8

Publication Number: 3199193

IPC: A61M15/00

Language of the proceedings: EN

Title of invention:
METHOD FOR MEASURING FLOW FEATURES IN AN INHALER, INHALER AND SYSTEM

Patent Proprietor:
Novartis AG

Opponent:
Beck Greener LLP

Relevant legal provisions:
EPC Art. 56
EPC R. 115(2)
RPBA 2020 Art. 12(5), 15(3)

Keyword:
Oral proceedings - held in absence of party
Inventive step - (no)

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Case Number: T 0377/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 April 2025

Appellant: (Opponent)	Beck Greener LLP 12 Fulwood Place London WC1V 6HR (GB)
Representative:	Kilburn & Strode LLP Lacon London 84 Theobalds Road Holborn London WC1X 8NL (GB)
Respondent: (Patent Proprietor)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Brennan, Méabh Bridget Novartis Pharma AG Patent Department Lichtstrasse 35 4056 Basel (CH)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 December 2022 concerning maintenance of the European Patent No. 3199193 in amended form.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	C. Schmidt

Summary of Facts and Submissions

I. The opponent filed an appeal against the interlocutory decision of the opposition division finding that auxiliary request 1, which had been filed on 20 October 2021, met the requirements of the EPC.

II. Oral proceedings before the board took place on 10 April 2025.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, oral proceedings took place in the absence of the appellant, which had advised in a letter dated 24 March 2025 that it would not attend.

The requests were as follows.

The appellant (opponent) had requested in the written proceedings that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed. In the alternative, the respondent requested that the patent be maintained on the basis of auxiliary request 1 filed on 8 November 2023 or auxiliary request 2 filed on 20 March 2025.

III. Claim 1 of each of the main request and of auxiliary request 2 reads as follows.

"A method for measuring at least one inhalation flow feature in an inhaler, wherein a capsule containing a formulation is located in the inhaler, the method comprising the steps of

sensing an impact feature relating to impacts of the capsule on the inhaler and
correlating the impact feature to at least one inhalation flow feature,
characterized in that correlating the impact feature to at least one inhalation flow feature comprises
dividing the sensed impact feature into time intervals,
determining the at least one characteristic of the sensed impact feature for the time intervals,
relating the at least one characteristic of the sensed impact feature to a flow for each time interval."

IV. Claim 1 of auxiliary request 1 includes the following amendments to claim 1 of the main request.

"correlating the impact feature to at least one inhalation flow feature,
wherein the impact feature is a sound generated by the impacts of the capsule on the inhaler,
characterized in that"

V. The following documents are relevant to the present decision.

D1 EP 2686049 B1
D5 EP 2859906 A1

VI. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Main request - inventive step starting from D5

Claim 1 of the main request was not inventive over D5 in combination with common general knowledge.

D5 disclosed inhalers with a microphone to detect sounds made by the device during operation and correlate these sounds with flow. D5 taught that the methods were relevant to different types of inhalers, including capsule-based inhalers, and there was no prejudice in D5 against inhalers which rattle. These inhalers were the most common type of dry powder inhaler.

D5 disclosed in paragraph [0057] the use of both a tonal analysis and an energy analysis to determine flow rate in dry powder inhalers. In each case, the acoustic signal is divided into blocks, i.e. time intervals, using a windowing function, and the flow rate for each block is determined.

Starting from D5, the person skilled in the art would have implemented the method using both analyses for an inhaler which rattles. The complete acoustic signal would have been used, including the sound that is generated by impacts in relation to flow. D5 disclosed that frequencies between 3 Hz and 10 kHz were used, without any further filtering being carried out.

Accordingly, claim 1 did not involve an inventive step over D5 combined with common general knowledge.

VII. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

Main request - inventive step starting from D5

Claim 1 of the main request was inventive over D5 in combination with common general knowledge.

D5 mentioned capsule-based inhalers in paragraph [0064] only in relation to detecting the time when the foil of the capsule was pierced. The capsule of D5 was not necessarily one that impacted on the inhaler during inhalation. Therefore, D5 did not disclose the step of "sensing an impact feature relating to impacts of the capsule on the inhaler", or the step of "correlating the impact feature to at least one inhalation flow feature", or any of the steps comprised therein.

D5 employed a microphone to sense the acoustic signal of the airflow through the inhaler. Impacts of the capsule would result in an acoustic signal stronger than that produced by airflow. Hence, sensing an impact feature relating to impacts of the capsule on the inhaler was less susceptible to background noise interference. Moreover, D5 was limited to employing a microphone, whereas claim 1 allowed other types of sensor. Therefore, the problem solved by claim 1 over D5 was the provision of an improved and more versatile method for determining the inhalation efficacy of a user's inhalation.

There was no indication in D5 that capsule impacts occurred or could be used to derive an inhalation flow feature. D5 taught a direct correlation of an acoustic signal with airflow, in contrast to the claimed invention, which taught sensing a signal that is not directly generated by airflow but by the capsule. The person skilled in the art would not have introduced further noise components such as capsule impacts, as that noise would need to be filtered out from the sensed airflow.

Paragraph [0057] of D5 mentioned the energy analysis in connection with dry-powder inhalers to provide a coarse

measure of flow. The correlation specified by claim 1 was more accurate than that. Moreover, D5 disclosed that the energy analysis was advantageous for flow rates up to 20 l/min; however, the flow rates relevant to capsule-based inhalers were higher, because at 20 l/min the capsule was not likely to move. There was no indication in D5 that at higher flow rates the energy of the acoustic signal and the flow would correlate. Moreover, according to the formula in Figure 4 of D5, the flow determined from the energy could never be below 24 l/min. The energy of the sound according to Figure 4 of D5 was at most only 40 dB, but the rattling sound made by the capsule would be significantly higher than that, especially at frequencies above 3 kHz as shown in Figure 4 of D1. Therefore, the energy analysis of D5 would not work for a capsule-based inhaler in which the capsule impacted on the inhaler.

Auxiliary request 1 - admittance

Auxiliary request 1 had been filed as auxiliary request 3 during the opposition proceedings.

Reasons for the Decision

1. Patent

1.1 Capsule-based inhalers are used to supply a user with a formulation contained in a capsule. Typically, the capsule is placed within a chamber of the inhaler and pierced by needles. The user then inhales through a mouthpiece of the inhaler, creating an airflow which makes the capsule spin in the chamber to release the formulation to the user. When spinning, the capsule impacts on the inhaler and produces sound.

1.2 With information about features of the user's inhalation, e.g. its duration and overall inhalation volume, it is possible to assess whether the inhaler has been used in such a manner that the formulation has been aerosolised sufficiently.

1.3 The patent relates to a method for obtaining features of the user's inhalation, and to the corresponding inhaler and system. An impact sensor senses an impact feature relating to impacts of the capsule on the inhaler. For example, the impact sensor can be a microphone and the impact feature can be a sound caused by the capsule impacts. The impact feature is then correlated to at least one inhalation flow feature such as the peak inhalation flow.

2. Main request - inventive step starting from D5

2.1 D5 discloses using a microphone mounted on an inhaler to sense "sounds made by the drug delivery device during operation" (see paragraph [0005] and claims 1 and 10). According to D5, the sensed acoustic signal is processed by energy analysis and/or tonal analysis to determine parameters such as the volumetric flow rate, wherein this processing comprises dividing the acoustic signal into time intervals (paragraphs [0030], [0031] and [0046]) and relating at least one characteristic of the acoustic signal to a flow for each time interval (paragraphs [0033] and [0048]).

2.2 D5 states that the method can be used in various inhalers, including dry powder inhalers ([0001]), and in particular dry powder inhalers that use capsules to store the drug. This is clear from the reference in paragraph [0064] to the possibility of detecting the

sound made by the piercing of the capsule foil in such capsule-based inhalers and recording the time when that occurs and the time when the drug is subsequently delivered.

2.3 D5 therefore discloses "[a] method for measuring at least one inhalation flow feature in an inhaler, wherein a capsule containing a formulation is located in the inhaler". It is moreover undisputed that D5 provides a valid starting point for the subject-matter of claim 1.

2.4 It is common in capsule-based inhalers for the capsule to spin and repeatedly impact against the walls of the inhaler during inhalation. However, the disclosure in paragraph [0064] of D5 of inhalers using capsules to store the drug does not unambiguously refer to inhalers in which such impacts occur.

Since the feature of method claim 1 "sensing an impact feature relating to impacts of the capsule on the inhaler" implicitly requires such impacts to be present, this feature is not disclosed in D5.

2.5 The board agrees with the respondent that the subsequent features of claim 1 are not disclosed in D5 in relation to an "impact feature [relating to impacts of the capsule on the inhaler]". D5 only discloses these features in relation to a sensed acoustic signal which does not necessarily comprise impacts (see passages mentioned in point 2.1 above).

2.6 In summary, the features distinguishing the subject-matter of claim 1 from the method of D5 relate to sensing and using an "impact feature relating to impacts of the capsule on the inhaler". D5 only

discloses sensing and using the sounds made by the inhaler during operation, without referring to any impacts.

2.7 The respondent asserts that, in inhalers in which the capsule impacts on the inhaler, the capsule impacts will be the predominant sound signal, and detection of this impact will be less susceptible to background noise interference than the detection of airflow.

The board is not convinced by this submission. Whether the impacts of the capsule will produce the predominant sound depends on aspects of the inhaler and the capsule which are not defined in claim 1.

The respondent also submits that the method of claim 1 is more versatile, because it is compatible with other sensors.

However, this effect is not achieved over the whole scope of the claim, and in particular it is not achieved when a specific sensor such as a microphone (the main embodiment of the contested patent) is used. Therefore, the board is not convinced by the effect and the technical problem formulated by the respondent.

2.8 Since D5 discloses the method for inhalers in general and for capsule-based inhalers in particular without specifying whether these capsules impact on the inhaler and cause a rattling noise, the problem solved can be seen as implementing the method of D5 for a specific inhaler.

2.9 It is undisputed that capsule-based inhalers in which the capsule impacts on the inhaler are well known and represent a very common, if not the most common, type

of capsule-based inhaler. No explicit prejudice against such inhalers can be found in D5.

2.10 Capsule-based inhalers are a subtype of dry powder inhalers. D5 discloses in the first sentence of paragraph [0057] that, as an improvement to the tonal analysis disclosed for dry powder inhalers, an energy analysis can also (i.e. additionally) be carried out.

The respondent asserts that there is no suggestion in D5 that the airflow can be determined using a noise that is not directly generated by the airflow but is in an indirect relationship to it, in particular being generated by impacts.

However, no suggestion is needed, because the energy analysis disclosed in D5 (see the first embodiment in paragraphs [0023] to [0043]) makes use of all the energy of the acoustic signal, regardless of its origin.

2.11 The respondent argues that the person skilled in the art would have considered the sound of the impacts as interfering with the sound produced by the swirling airflow and would have discarded the possibility of introducing noise components which would have to be filtered out, similarly to the sound caused by piercing the capsule.

While D5 acknowledges that additional sounds are produced during use of an inhaler, D5 does not disclose filtering out any of these additional sounds to determine flow, including the sound caused by piercing the capsule. The acoustic signal associated with actuation of the canister in a metered dose inhaler is also identified in D5, but is not filtered out of the

acoustic signal used for the energy analysis (see paragraph [0036] and the upper branch of Figure 2). The only filtering out that D5 discloses is the use of a band pass filter (3 Hz to 10 kHz) in the energy analysis (see paragraph [0031] and Figure 2).

Moreover, D5 acknowledges that the relationship between acoustic signal and flow varies depending on the design of each inhaler, and teaches using calibration data stored in advance by drawing known flow rates through the inhaler (see paragraphs [0031] to [0032], [0050] and [0056]), thus implying that the method can be used for different inhalers that produce different sounds during use.

2.12 Claim 1 does not specify any particular accuracy for the correlation. Hence, the respondent's submission that the correlation of claim 1 is more accurate than the "coarse measure of the flow rate" mentioned for the energy analysis in paragraph [0057] of D5 is not convincing.

2.13 The respondent argues that paragraph [0057] of D5 discloses the energy analysis as advantageous only for flow rates up to 20 l/min, but that the flow rates relevant to capsule-based inhalers are higher, because the capsule is not likely to move at 20 l/min.

The latter allegation has not been supported by any evidence, and is speculative because the flow rate required to cause movement and impacts of the capsule will depend on the specific design of the inhaler and capsule.

2.14 The respondent also refers to Figure 4 of D5. The respondent argues that the energy shown in Figure 4 is at most only 40 dB, but that it will be much higher in an inhaler that rattles, and that the flow determined from the energy could never be below 24 l/min according to the equation shown in Figure 4.

These arguments are not convincing. Figure 4 shows data from a metered dose inhaler, i.e. a different type of inhaler. The energy of the acoustic signal is different for different inhalers, and D5 teaches taking this into account in the calibration process. The equation in Figure 4 results from fitting values measured for the metered dose inhaler, and it does not reflect any limitation of the energy analysis itself. The fact that the energy analysis can be used to determine flow rates below 24 l/min is also clear from the second and third sentences of paragraph [0057].

2.15 In summary, the respondent's arguments that the method of D5 would neither work nor be used for capsule-based inhalers in which the capsule impacts on the inhaler are not convincing.

Since inhalers in which the capsule impacts on the inhaler are the most common type of capsule-based inhaler, the person skilled in the art, starting from the method of D5 and implementing it for a specific inhaler, would have implemented it for inhalers of this kind, using only common general knowledge, thereby arriving at a method anticipating the subject-matter of claim 1. Consequently, the subject-matter of claim 1 is not inventive.

3. Auxiliary request 1 - admittance

3.1 Auxiliary request 1 was submitted with the reply to the grounds of appeal but it has not been substantiated, i.e. the respondent has not explained why it would overcome any of the objections to the main request. The board therefore decides not to admit auxiliary request 1 under Article 12(5) RPBA.

4. Auxiliary request 2 - inventive step starting from D5

4.1 Claim 1 of auxiliary request 2 is identical to claim 1 of the main request. For the same reasons as those set out above in relation to the main request, claim 1 of auxiliary request 2 is not inventive over D5 combined with common general knowledge.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated