Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 11 January 2024

Case Number: T 0237/21 - 3.4.02

Application Number: 15739071.7

Publication Number: 3311373

IPC: G09B23/28

Language of the proceedings: EN

Title of invention:
DEVICES AND METHODS FOR DRUG ADMINISTRATION AND MIXING, AND TRAINING OF PROPER TECHNIQUES THEREFOR

Applicant:
Janssen Pharmaceutica, N.V.

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA 2020 Art. 11, 12(2)

Keyword:
Inventive step (yes)
Remittal for further prosecution (yes)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0237/21 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 11 January 2024

Appellant: (Applicant)	Janssen Pharmaceutica, N.V. Turnhoutseweg 30 2340 Beerse (BE)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 27 October 2020 refusing European patent application No. 15739071.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	R. Bekkering
Members:	F. J. Narganes-Quijano
	B. Müller

Summary of Facts and Submissions

I. The applicant (appellant) lodged an appeal against the decision of the examining division refusing European patent application No. 15739071.7.

II. In the decision under appeal the examining division held that the subject-matter of claim 1 of the main request and of the auxiliary request then on file did not involve an inventive step (Article 56 EPC) in view of document

D1: US 9 022 988 B1.

III. With the statement setting out the grounds of appeal the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or the auxiliary request underlying the decision under appeal.

The appellant also requested oral proceedings in the event that the main request could not be granted.

IV. In a communication under Rule 100(2) EPC the board expressed the preliminary opinion that, contrary to the examining division's view, the subject-matter of claim 1 of the main request involved an inventive step over document D1 (Article 56 EPC). In addition, the same comment applied to the method defined in independent claim 2 and to the subject-matter of dependent claims 3 to 13 of the main request. The appellant was also informed that, in the event that the appellant withdrew its request for oral proceedings, the board would hand down a decision in written procedure setting aside the

decision under appeal and remitting the case to the examining division for further prosecution.

V. In reply to the board's communication, the appellant, by letter dated 13 October 2023, withdrew the request for oral proceedings on the condition that the board handed down a written decision setting aside the decision under appeal and remitting the case to the examining division for further prosecution based on the main request.

VI. Independent claims 1 and 2 of the main request read as follows:

"1. A device for training users in a proper mixing of pharmaceutical components, the device comprising:

a housing that extends along a longitudinal axis;

a power source disposed in the housing;

a microcontroller disposed in the housing and electrically powered by the power source;

a user notification device; and

an accelerometer disposed in the housing and electrically connected to the microcontroller so that the microcontroller is configured to detect a motion and orientation of the housing and indicate via the user notification device as to whether the motion or orientation of the housing being shaken during one of a drug administration or a training event is sufficient with respect to predetermined thresholds including magnitude of the force applied during the shaking, the orientation of the housing and duration of such shaking, and wherein

the microcontroller is configured to detect if the level of shaking vigor has reduced to a level below the pre-set threshold, and to enter a pause mode to allow

the user to restart shaking during one of a drug administration or a training event."

"2. A method to direct a user on a proper drug mixing technique with a training device or a device for mixing and assisting with the administration of the drug, that includes:

a housing that extends along a longitudinal axis;

a power source disposed in the housing;

a microcontroller disposed in the housing and electrically powered by the power source;

a user notification device; and

an accelerometer disposed in the housing and electrically connected to the microcontroller to detect motion and orientation of such motion,

the method comprising the steps of:

determining from the accelerometer if the magnitude of the motion and orientation of the housing are sufficient with respect to predetermined thresholds including magnitude of the force applied during the shaking, the orientation of the housing and duration of such shaking; and

announcing via the user notification device as to whether the motion or orientation of the housing being shaken during one of a drug administration or a training event meets the predetermined thresholds, and wherein

the microcontroller is configured to detect if the level of shaking vigor has reduced to a level below the pre-set threshold, and to enter a pause mode to allow the user to restart the shaking during one of a drug administration or a training event."

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural matters*

In the board's communication under Rule 100(2) EPC the appellant was informed that, in the event that the appellant withdrew its request for oral proceedings, the board would hand down a decision in written procedure setting aside the decision under appeal and remitting the case to the examining division for further prosecution (*cf.* point IV above). In reply to this communication, the appellant withdrew the request for oral proceedings on the condition that the board handed down a written decision setting aside the decision under appeal and remitting the case to the examining division for further prosecution based on the main request (*cf.* point V above). The present decision is in conformity with this condition. Furthermore, the board is of the opinion that the facts, evidence and arguments necessary to decide the case are on file. Therefore the board does not consider it expedient to summon for oral proceedings of its own motion either. The present decision is therefore taken in written proceedings in accordance with Article 12(8) RPBA.

3. *Main request - Inventive step over document D1*

3.1 Distinguishing features

3.1.1 Document D1 discloses an injection device 102 having a housing (Fig. 1, together with the corresponding description) and a user notification device for instructing the patient that the device must be shaken

at least a predetermined number of times (sentence bridging columns 7 and 8).

The device also comprises an accelerometer for detecting shaking and a microprocessor for receiving the signal from the accelerometer "to determine if the patient has shaken device 102 the requisite number of times" (column 8, lines 3 to 7). Depending on whether or not the patient has shaken the device the requisite number of times, the device is enabled to administer the therapeutic injectant, or disabled, while a message is provided to the patient that additional shaking is required (column 8, lines 7 to 13).

3.1.2 In its decision the examining division held as follows in respect of the distinguishing features of the device defined in claim 1 over the device disclosed in document D1:

a) the claimed features relating to the "orientation" of the housing were not disclosed in document D1, but they were only optional in claim 1 in view of the use of the Boolean "or" in the expression "motion or orientation of the housing";

b) the device of document D1 necessarily involved the measurement of the "magnitude of the force applied during the shaking" because otherwise it would not be possible to detect how many times the device was shaken and, therefore, among the predetermined thresholds defined in claim 1 only the threshold relating to the "duration of such shaking" was new over document D1; and

c) the features of the microcontroller defined in the last paragraph of claim 1 were new over document D1.

3.1.3 The board notes, however, the following:

As regards feature a) of claim 1 considered by the examining division as being only optional, the board notes that claim 1 refers to the microcontroller indicating "whether the motion or orientation of the housing [...] is sufficient [...]", but that the claim previously requires - as submitted by the appellant - that the microcontroller "is configured to detect a motion and orientation of the housing" and also requires "predetermined thresholds including [...] the orientation of the housing" [*emphasis added by the board*]. Therefore, the skilled person would not understand the mentioned expression "the motion or orientation of the housing" in its technical context in the sense that claim 1 defines a device involving either the motion or the orientation of the housing, or in the sense that the features relating to the orientation are, as maintained by the examining division in its decision, only optional, but in the sense that the microcontroller is configured to detect both the motion and the orientation of the housing so as to - as subsequently required by claim 1 - "indicate [...] whether the motion or orientation of the housing [...] is sufficient with respect to predetermined thresholds including [...] the orientation of the housing". Therefore, the features of claim 1 relating to the orientation of the housing are, contrary to the examining division's view, not optional, but mandatory.

As regards feature b) of claim 1, document D1 discloses controlling the shaking process of the device on the basis of the determination of whether the device has been shaken a predetermined number of times (*cf.* point 3.1 above, second paragraph). However, contrary to the examining division's view, this feature does not necessarily imply that the magnitude of the force

applied during shaking is also taken into account in document D1. In particular, the number of times the device of document D1 is being shaken can be measured or determined without necessarily measuring or determining the magnitude of the force being applied to the device during shaking. More particularly, although in the process of shaking of the device by a patient there may be a correlation between the number of times the device is being shaken and the magnitude of the shaking force being applied by the patient on the device, these two quantities are not the same, but distinct and non-equivalent physical quantities, among other reasons because the number of times the device is shaken by a patient can, at least to a predetermined extent, be varied independently of the shaking force, and the other way around. Therefore, in the board's view document D1 does not disclose the claimed predetermined threshold relating to the "magnitude of the force applied during the shaking".

3.1.4 In view of these considerations, the board concludes that the claimed device differs from the device disclosed in document D1 in that:

a') detected is not only the shaking motion, but also the orientation of the housing;

b') the indication of whether the shaking is sufficient is not only based on a predetermined threshold relating to the number of times the housing is shaken, but also on predetermined thresholds including the magnitude of the force applied during shaking and the orientation of the housing; and

c) the microcontroller is configured to operate as defined in the last paragraph of claim 1 ("to detect if the level of shaking vigor has reduced to a level below the pre-set threshold, and to enter a pause mode to

allow the user to restart shaking during one of a drug administration or a training event").

3.2 Inventive step

3.2.1 In its decision the examining division held that the distinguishing features did not derive from an objective technical constraint but from medical (non-technical) instructions or preferences to be determined by a health care professional. In particular, the duration of shaking did not relate to the intrinsic features of the device and it therefore was non-technical. The skilled person, i.e. a computer scientist, had no objective technical reason to modify the device of document D1 and was to be told what the medical instructions were. Therefore, the skilled person only intervened in the modification of the device of document D1 at the implementation stage in accordance with non-technical medical instructions or preferences, and the implementation of the distinguishing features of claim 1 in the device of document D1 would not exceed the routine programming skills of the skilled person, i.e. of the computer scientist (Article 56 EPC).

The board, however, cannot follow the examining division's view in this respect. Each of the distinguishing features identified by the examining division (point 3.1.2 above) and, for the present purposes, each of the distinguishing features a'), b') and c) identified in point 3.1.4 above, is, as submitted by the appellant, a technical feature and, in addition, each of these features, and in particular their combination, requires technical considerations when evaluating their possible technical impact when incorporated in a device of the type disclosed in

document D1, see point 3.2.2 below. In addition, the distinguishing features and, in particular, their combination go - as submitted by the appellant - beyond the mere medical instructions or preferences that a health care professional may consider and they pertain, by their very nature, to the technical field of medical devices for administering pharmaceutical products (see description of the application, paragraph [0001], and document D1, column 1, section "1. Technical Field"), see points 3.2.2 and 3.2.3 below. For these reasons, the board cannot follow the examining division's approach consisting in, first, considering the distinguishing features as a mere non-technical constraint to be imposed on the device of document D1 in accordance with medical instructions or preferences and, second, confining the claimed invention to a mere implementation at the programming stage by a computer scientist of the non-technical constraint in the device of document D1.

3.2.2 According to the distinguishing features a'), b') and c), the level of shaking is monitored as a function of the force being applied during shaking, the orientation of the housing during shaking, and the duration of the shaking (features a') and b')), by a determination of whether the degree of shaking being applied to the housing during the shaking process is below a predetermined threshold, in which case a pause mode is entered to allow the user to restart shaking (feature c)). In addition, the combination of these features has the technical effect of taking better account of the variability of shaking for mixing pharmaceutical components as might be applied by different users. Therefore, the combination of features a'), b') and c) results in an improved monitoring and evaluation of the level of shaking being applied by the patient to the

housing during the shaking process (see description of the application, paragraph [0059], together with paragraph [0042]).

Therefore, the objective technical problem solved by the claimed device over the device of document D1 resides in improving the monitoring and evaluation of the level of shaking being applied by a patient to the housing during the shaking process.

3.2.3 The board notes that a health care professional can be aware of this problem and formulate it as a medical instruction or preference in the sense considered by the examining division. However, following an objective and realistic application of the problem-solution approach, the health care professional would then consult a person with technical expertise in the technical field of the devices under consideration, i.e. the person (an engineer) skilled in the technical field of medical devices for administering pharmaceutical products, and it is this person who constitutes the skilled person to be considered for the assessment of inventive step.

3.2.4 Document D1 only addresses the question of the determination of the level of shaking exclusively for the purpose of determining whether, and when, a predetermined level of total shaking has been reached and only as a function of the number of times the device has been shaken - i.e. independently, as submitted by the appellant, of other specific factors such as the magnitude of the force applied during shaking, the orientation of the housing and the duration of shaking (features a') and b')). In addition, neither document D1 nor the common general knowledge in the technical field under consideration

suggest entering a pause mode to allow the user to restart shaking upon determining that the level of shaking being applied to the housing is low as required by feature c). Therefore, document D1, either alone or in combination with the common general knowledge, is, in the board's view, insufficient to suggest to the skilled person confronted with the objective technical problem under consideration modifying the device of document D1 so as to result in the claimed device.

3.3 In view of the above considerations, the board is of the opinion that the device defined in claim 1 is not obvious over document D1 as closest prior art, together with the common general knowledge (Article 56 EPC).

3.4 Independent claim 2 is directed to a method to direct a user on a proper drug mixing technique with a device, the structural features of the device and the steps of the method being essentially in correspondence with the structural and the functional features of the device defined in claim 1. Therefore, the method defined in independent claim 2 also involves an inventive step over document D1 and the common general knowledge essentially for the reasons given in points 3.1 to 3.4 above in respect of the device of claim 1 (Article 56 EPC).

Similar considerations apply to dependent claims 3 to 13 by virtue of their reference to the device of claim 1 or the method of independent claim 2 (Article 56 EPC).

4. *Further prosecution*

In the light of the foregoing, the decision under appeal cannot stand and must be set aside. The appeal

is thus allowable within the meaning of Article 111(1), first sentence, EPC.

The reasons given by the examining division in its decision to refuse the main request were only based on the issue of inventive step over document D1 (Article 56 EPC). As concluded in point 3 above, the board is of the opinion that this objection is not convincing. The board notes, however, that document D1 was the sole document cited in the search report and that, in addition, the examination and possibly also the search were based on a construction of the claimed invention which, as set forth in point 3.1.3 above, was at variant with the subject-matter actually claimed, and in this context the question arises whether an additional search would be appropriate. In addition, the examination proceedings were confined to the issue of novelty and inventive step over document D1, and there is no record that the examining division had addressed the remaining requirements of the EPC, and in particular the requirements of clarity of Article 84 EPC. Addressing all these questions in appeal would require the board to go beyond the primary object of the appeal proceedings to review the appealed decision in a judicial manner (Article 12(2) RPBA 2020). This would not be appropriate and constitutes in the board's view a special reason within the meaning of Article 11 RPBA 2020 to remit the case to the examining division for further prosecution.

In these circumstances, the board concludes that the case is to be remitted to the examining division for further prosecution (Article 111(1), second sentence, EPC, together with Article 11 RPBA 2020).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

L. Gabor R. Bekkering

Decision electronically authenticated