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**Datasheet for the decision  
of 11 January 2024**

**Case Number:** T 0313/21 - 3.4.02

**Application Number:** 16733902.7

**Publication Number:** 3311376

**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 NV

**Relevant legal provisions:**

EPC Art. 56, 111(1)  
RPBA 2020 Art. 11, 12(2)

**Keyword:**

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

**Decisions cited:**

T 0362/90, T 0528/07



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Case Number: T 0313/21 - 3.4.02

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

**Appellant:** Janssen Pharmaceutica NV  
(Applicant) Turnhoutseweg 30  
2340 Beerse (BE)

**Representative:** Carpmaels & Ransford LLP  
One Southampton Row  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 17 November  
2020 refusing European patent application No.  
16733902.7 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. 16733902.7

II. In the decision under appeal the examining division held that the subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2 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 submitted claims of auxiliary request 3. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or one of auxiliary requests 1 and 2 underlying the decision under appeal, or on the basis of the claims of auxiliary request 3 filed with the statement of grounds of 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 claim 18 and to the subject-matter of dependent claims 2 to 17 and 19 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. Claim 1 of the main request reads as follows:

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

a housing;

a microcontroller disposed in the housing; and

a user notification device for alerting a user to a status of the device as determined by the microcontroller, wherein the user notification device comprises a display, and

wherein the microcontroller is configured to indicate via the user notification device as to whether the motion and/or orientation of the housing being shaken during one of a drug mixing and administration, or a training event is sufficient enough for satisfactory mixing of the pharmaceutical components for delivery,

characterised in that:

the microcontroller is configured to indicate via the display the state of mixing or simulated mixing of the pharmaceutical components in a real-time manner,

wherein the microcontroller is configured to change progressively the color and/or pattern of one or more display elements on the display as shaking takes place until sufficient shaking has taken place for satisfactory mixing or satisfactory simulated mixing of the pharmaceutical components for delivery."

### **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 the 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 in Fig. 1) comprising a housing with therapeutic injectants which require shaking for being administered (Fig. 1, together with the corresponding description, and column 7, lines 51 and 52). The housing includes a microcontroller (microprocessor 118 in Fig. 1) configured to visually indicate to the user or patient, either by lighting lamps (lamps 126 and 128) or by displaying a message on a display (display screen 124), features relating to the status of the device (see, for instance, column 4, line 41, to column 5, line 7) and, in particular, to the shaking of the device (column 7, line 51, to column 8, line 13). In particular, document D1 discloses

- a first embodiment in which a lamp is lit or a message is displayed to notify to the user that the therapeutic injectants require shaking prior to administration (column 7, lines 52 to 59), and

- a second embodiment in which the display instructs the user that the injection device must be shaken at least a predetermined number of times, and the microcontroller determines whether the user has shaken the device the predetermined number of times and, if not, while the device remains disabled, a visual message is provided on the display informing the user that additional shaking is required (paragraph bridging columns 7 and 8).

3.1.2 According to claim 1 the microcontroller of the device "is configured to change progressively the color and/or pattern of one or more display elements on the display

as shaking takes place until sufficient shaking has taken place for satisfactory mixing or satisfactory simulated mixing of the pharmaceutical components for delivery". The examining division held in its decision that the device defined in claim 1 differed from the device disclosed in document D1 in the features determined by the terms "progressively" and "pattern".

As regards the term "pattern", the board notes that document D1 discloses displaying in the display screen 124 an instruction relating to the predetermined number of times the device must be shaken and also displaying a message informing the user that additional shaking is required (point 3.1.1 above). The information displayed in the display screen 124 constitutes a "pattern" within the general meaning of the term and, therefore, the corresponding feature of claim 1 is, in the board's view, not new over the disclosure of document D1.

As regards the term "progressively" of claim 1, the board notes that the first embodiment of document D1 (*cf.* point 3.1.1 above) only involves a light or a displayed message indicating that the device required shaking prior to being used for administration of the therapeutic components. As regards the second embodiment of document D1, this embodiment involves the display of a first message instructing the user that the device must be shaken at least a predetermined number of times, and of a second message informing the user that additional shaking is required. Therefore, this second message indicates to the user that, once the shaking has been started, the shaking is insufficient to reach the required number of shaking times and that the device requires further shaking until the mentioned required number is reached. However, there is no disclosure in document D1 that

this message would "change progressively [...] as shaking takes place until" the mentioned required number is reached as required by the claimed subject-matter. Therefore, neither the first nor the second embodiments of document D1 disclose the claimed progressive change as the device is being shaken.

It follows that in the board's opinion the device of claim 1 differs from the device disclosed in document D1 in the feature "to change progressively" the color and/or pattern being displayed "as shaking takes place until sufficient shaking has taken place" [*emphasis added by the board*].

### 3.2 Inventive step

3.2.1 In its decision the examining division held that it was clear from document D1 that the transition between a red and a green light allowed the user to be informed that the device was ready, without the need of a pause to read the display. It was accepted that document D1 only proposed a binary outcome, i.e. a red LED meaning "device not ready" and a green LED meaning "device ready". The advantage of the claimed progressive display was limited to potentially encouraging the user, and claim 1 only departed from the teaching of document D1 in the manner in which the information was being brought to the user. Past the idea of conveying a message to the user that the device was ready for use, the particular choice of using a specific display pattern was technically irrelevant. Therefore, the display of a progressive pattern in order to inform the user that additional shaking was required had a purely mental effect and did not solve an objective technical problem. In consequence, in line with the "Comvik"



approach, this aspect should be given to the skilled person for implementation purpose.

The board, however, cannot follow this view of the examining division in several respects. Document D1 discloses the use of indicator lamps 126 and 128 with different colors, in particular red and green (column 3, lines 1 to 4), but only for indicating whether a dosage amount control has been set to the correct setting and the injection device is ready (column 4, line 39, to column 5, line 7). Document D1 also discloses other uses of the lamps 126 and 128 (column 5, lines 8 to 24; column 6, lines 5 to 14, lines 28 to 39, and lines 53 to 63; and column 7, lines 8 to 33); however, as submitted by the appellant, none of them relate to the device requiring shaking before being used for the administration of the therapeutical components.

In addition, while the device of document D1 is only configured to inform the user that the device requires shaking before being used and, during shaking and before the device has been shaken the required number of times, that the device requires further shaking (see point 3.1.2 above, third paragraph), the claimed distinguishing feature has the effect that the user (i.e. the patient, or the trainee or the trainer in the case of the "training" variant of claim 1) is informed - beyond, as submitted by the appellant, a mere indication that shaking is required or that shaking is insufficient - of the progression of shaking - and therefore of the degree of mixing of the components, see description of the application, paragraphs [0057], [0058], [0106], [0108] and [0118] - as shaking takes place, i.e. informed of a degree of shaking being achieved during the shaking process at least at an

intermediate stage of the shaking process between the start of shaking and the shaking process reaching the required degree of shaking. Therefore, the distinguishing feature assists the user in better performing the technical task of shaking the device to the required degree and, consequently, the mentioned effect constitutes a technical effect. More particularly, this effect goes - contrary to the examining division's view, and as submitted by the appellant - beyond a mental act and also beyond the manner in which information was being brought to the user, among other reasons because the claimed distinguishing feature conveys more technical information relating to the process of shaking being carried out than that conveyed by the device of document D1. It is noted in this respect that according to the established case law displaying information on the internal state or the prevailing conditions of a technical system for assisting human interaction with the system is technical, see for instance decision T 0362/90 (point 2 of the reasons and catchword), and also decision T 0528/07 (point 3 of the reasons) considered during the first-instance proceedings.

The board is therefore of the opinion that the claimed device solves a problem of a technical nature over the device of document D1 and that the objective technical problem resides in improving the device of document D1 to better assist the user in shaking the device and reaching the required degree of shaking.

- 3.2.2 In its decision the examining division also held that, even assuming that the idea of letting the user know that additional shaking was required was regarded as technical, the idea was anticipated by the disclosure of document D1 relating to "a message [being] provided

to the user either audibly through speaker 132 or visually on display screen 124 that additional shaking is required" (column 8, lines 8 to 11). The difference between displaying this message on the display screen 124 and a particular visual effect to convey said message as in claim 1 was a pure matter of design.

The board notes, however, that, as already mentioned in point 3.1.2 above, third paragraph, document D1 discloses displaying a message informing the user that additional shaking is required, but that the distinguishing feature of claim 1 relating to the feature implied by the term "progressively" is - as already acknowledged by the examining division - not disclosed in document D1. In addition, the distinguishing feature under consideration also goes beyond a mere matter of design and constitutes a technical feature having a technical effect for reasons analogous to those given in point 3.2.1 above, third paragraph.

The examining division also held in its decision that the skilled person tasked with the mission of modifying the device of document D1 in order to arrive at the claimed device would, without exceeding its routine programming skills, consider a range of obvious alternatives such as, for instance, using a RGB LED in order to provide a smooth green to red color transition as already suggested by the disclosure of document D1 relating to the use of an indicator lamp with different colors (column 3, lines 1 to 4).

This argument, however, pertains to the implementation of the claimed device, while obviating the question of why the skilled person would consider in an obvious way modifying the device of document D1 so as to

incorporate in the device the distinguishing feature under consideration. The board also notes that document D1, in column 3, lines 1 to 4, discloses the use of indicator lamps having different colors, but that this use is disclosed in document D1 only for indicating whether the dosage control of the device has been set to the correct setting (column 4, lines 45 to 67). In this context, only hindsight knowledge of the claimed invention would suggest the use of lamps with different colors in the specific context of a device requiring shaking, and in particular for the purpose of indicating the progressive degree of shaking being achieved during shaking of the device before the required degree of shaking is reached.

In view of these considerations, the board is of the opinion that the skilled person confronted with the objective technical problem stated above would not have arrived in an obvious way at the device of claim 1 when starting with document D1 as closest prior art and under consideration of the common general knowledge (Article 56 EPC).

- 3.3 Claim 18 is directed to a method involving the use of the device of claim 1, dependent claims 2 to 17 refer back to the device of claim 1, and dependent 19 refers back to the device or the method of any preceding claim. Therefore, the subject-matter of claims 2 to 19 also involves an inventive step over document D1, together with the common general knowledge (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 application according to 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 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