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**Datasheet for the decision
of 22 February 2022**

Case Number: T 1779/17 - 3.2.02
Application Number: 10746603.9
Publication Number: 2401006
IPC: A61M5/00, A61M5/24, A61M5/31,
A61M5/315, G06F19/00, G01D5/165
Language of the proceedings: EN

Title of invention:

DRUG DELIVERY MANAGEMENT SYSTEMS AND METHODS

Patent Proprietor:

LifeScan, Inc.

Opponent:

Vetter Pharma-Fertigung GmbH & Co. KG

Relevant legal provisions:

EPC Art. 99(1), 115, 100(b), 54, 56
EPC R. 76(2)(a), 41(2)(c), 77(1), 139

Keyword:

Admissibility of opposition - (yes)
Observations by third parties
Grounds for opposition - late-filed ground for opposition
Novelty - (yes)
Inventive step (no) (yes)

Decisions cited:

G 0001/12, G 0009/91

Catchword:



Beschwerdekammern

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Chambres de recours

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Case Number: T 1779/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 February 2022

Appellant: LifeScan, Inc.
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Appellant: Vetter Pharma-Fertigung GmbH & Co. KG
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Representative: Kordel, Mattias
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
8 June 2017 concerning the maintenance of
European Patent No. 2401006 in amended form**

Composition of the Board:

Chairman D. Ceccarelli
Members: A. Martinez Möller
W. Sekretaruk

Summary of Facts and Submissions

- I. Appeals were filed by the patent proprietor and by the opponent against the interlocutory decision of the opposition division finding that, account being taken of the amendments made by the patent proprietor according to the version of auxiliary request 1 then on file, the patent and the invention to which it related met the requirements of the EPC.

- II. In its notice of opposition, the opponent raised the grounds for opposition of lack of novelty and lack of inventive step (Article 100(a) EPC).

The notice of opposition indicated in Form 2300E that "MAPAL Fabrik für Präzisionswerkzeuge Dr. Kress KG" was the opponent's name. The accompanying letter indicated that the opposition was filed in the name of and on behalf of "Vetter Pharma-Fertigung GmbH & Co. KG".

The responsible formalities officer informed the opponent of the discrepancy between the two names in a telephone consultation the day before the oral proceedings before the opposition division. On the same day, the opponent requested the correction of the opponent's name in Form 2300E and in the European Patent Register pursuant to Rule 139 EPC, and filed supporting evidence.

In the appealed decision, Reasons 11.2.3-11.3, the opposition division admitted the supporting evidence into the opposition proceedings, found the request for correction pursuant to Rule 139 EPC to be allowable and held that the opposition was admissible.

III. Third-party observations pursuant to Article 115 EPC were filed by Inga Marie Wollny, LARSEN & BIRKEHOLM A/S, on 3 November 2017 during the appeal proceedings. The observations included arguments and new evidence against the patent as granted and against the version of the patent maintained by the opposition division. The board was asked to revoke the patent.

IV. Oral proceedings by videoconference took place on 22 February 2022.

Appellant 1/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the European patent be maintained as granted or on the basis of one of auxiliary requests 1-3, all of which were filed by letter of 18 October 2017.

The proprietor further requested that the opposition be held inadmissible and that the third-party observations not be admitted into the proceedings.

Appellant 2/opponent ("the opponent") requested that the decision under appeal be set aside and that the European patent be revoked.

The opponent further requested that questions be referred to the Enlarged Board of Appeal in the event the board intended to hold the opposition inadmissible.

V. Claims 1 and 7 of the **main request** read as follows:

1. "A drug delivery pen (100; 200; 400; 500) comprising:

a pen housing that extends from a first end (112) to a second end (113) along a longitudinal axis (L1), the

housing being coupled to a drug cartridge (150; 250; 450) disposed proximate one of the first and second ends (112, 113), the drug cartridge (150; 250; 450) including a volume of one or more drugs (153) disposed therein;

a microprocessor (290; 590) disposed in the housing and operatively connected to a power source and memory (168); and characterized by

an inertial sensor (176; 276; 476; 576) connected to the housing and in electronic communication with the microprocessor (290; 590) so that the microprocessor (290; 590) is able to determine from output signals of the inertial sensor (176; 276; 476; 576) as to whether the housing has been shaken back and forth a predetermined number of times along the longitudinal axis (L1) to mix the one or more drugs disposed in the cartridge (150; 250; 450)."

7. "A diabetes management system comprising:
- a data management unit (300; 700; 800; 900) including:
 - a memory (340);
 - a processor coupled to the memory (340);
 - a display (314) coupled to the processor; and
 - a transceiver to receive and transmit data;
 - and
 - a drug delivery pen (100; 200; 400; 500) comprising:
 - a pen housing that extends from a first end (112) to a second end (113) along a longitudinal axis (L1), the housing being coupled to a drug cartridge (150; 250; 450) disposed proximate one of the first and second ends (112, 113), the pen housing having a dosage indicator window and a dosage selector coupled to the plunger rod;
 - a memory (168);
 - a processor (290; 590) coupled to the memory (168);
 - and characterized by

an inertial sensor (176; 276; 476; 576) disposed in the housing and in communication with the processor (290; 590) to allow for determination of whether the housing has been shaken back and forth a predetermined number of times along the longitudinal axis (L1) to mix the one or more drugs disposed in the cartridge (150; 250; 450)."

VI. Compared to claims 1 and 7 of the main request, claims 1 and 7 of **auxiliary request 1** further include the following feature added to the end of the respective claim:

"wherein the microprocessor (290; 590) is configured to determine from output signals of the inertial sensor (176; 276; 476; 576) whether the pen housing including the cartridge (150; 250; 450) is oriented topmost and generally vertically with respect to the ground in a priming position."

VII. The following documents are relevant for this decision:

GG4: US 6,869,413 B2

GG6: US 2002/0010432 A1

GG7: EP 1518575 A1

GG9: WO 2008/142015 A2

E1: Product information sheet of accelerometer ADXL322 Annex of 15 December 2016: Communication between the opponent's representative and Vetter Pharma-Fertigung GmbH & Co. KG

VIII. The third-party observations, as far as they are relevant to the decision, can be summarised as follows:

Sufficiency of disclosure

The invention as defined in the independent claims of the main request and of auxiliary request 1 as construed by the proprietor was not sufficiently disclosed.

Main request - novelty

The means for detecting shaking movements in GG6 was an inertial sensor within the meaning of claim 1, and therefore the subject-matter of claim 1 lacked novelty over GG6.

Auxiliary request 1 - inventive step

The subject-matter of claim 1 was not inventive over GG6 in combination with GG4. The feature added to claim 1 solved the problem of ensuring proper priming of the injector in GG6. The skilled person would have consulted GG4 (column 3, lines 13-15) and learned that a proper priming position could be ensured using an accelerometer. In paragraphs [0037]-[0042], GG6 referred to replaceable modules for a drug delivery pen with more than one functionality, e.g. a shaking functionality and a counting functionality as described in paragraph [0041]. In view of the teaching of GG4, the person skilled in the art would provide a module with both a priming functionality and a mixing functionality using the same inertial sensor.

The subject-matter of claim 1 was likewise rendered obvious by GG7 and common general knowledge.

- IX. The proprietor's arguments, as far as they are relevant to the decision, can be summarised as follows:

Admissibility of the opposition

Different opponents were indicated in Form 2300E and in the letter accompanying the notice of opposition. The opposition was inadmissible because it did not indicate beyond any doubt the identity of the person filing it.

The opposition division incorrectly admitted the late-filed request for correction and the supporting documents in the Annex of 15 December 2016 into the opposition proceedings. The documents speculated about the possibility of filing an opposition and contained neither a definite instruction from Vetter Pharma to file an opposition nor a confirmation to Vetter Pharma that an opposition had been filed. Hence, the documents were not prima facie relevant and should not have been admitted.

The documents did not show beyond any doubt that the original intention was for "Vetter Pharma-Fertigung GmbH & Co. KG" to be named as the opponent when the notice of opposition was filed. The opponent's auxiliary request filed before the opposition division requesting that "MAPAL Fabrik für Präzisionswerkzeuge Dr. Kress KG" be retained as the opponent reinforced the doubt as to which opponent was originally intended to be named.

Moreover, the request for correction was only filed on the day before the oral proceedings, which prevented the proprietor from making certain strategic decisions. The late request was thus not fair. The request for correction should thus not have been allowed.

Third-party observations

The third-party observations introduced a new ground for opposition under Article 100(b) EPC. The proprietor objected to its introduction. The new ground should be disregarded.

The third-party observations should be disregarded in their entirety as they were late-filed and the third party had had ample opportunity to raise the issues during the opposition proceedings.

Main request - novelty

The proprietor agreed with the opposition division that the subject-matter of claims 1 and 7 was novel over document GG6.

Main request - inventive step

The features distinguishing the subject-matter of claim 1 from GG6 solved the objective technical problem of improving the reliability of the mixing of the medicament in the drug delivery pen and ensuring a more effective drug delivery.

GG6 did not disclose an inertial sensor. Neither GG6 nor any other cited document provided any motivation to use an inertial sensor specifically designed to detect whether the housing had been shaken back and forth a predetermined number of times along the longitudinal axis (rather than simply detecting any shaking movement), as defined in claim 1. The opposition division overlooked the fact that the movement along the longitudinal axis has to be completely linear. It

was not straightforward for a user to shake the housing longitudinally.

Auxiliary request 1 - inventive step

The wording of claims 1 and 7 stipulated that the same inertial sensor be used to carry out both functions. It also required the microprocessor and the inertial sensor to have specific configurations allowing them to carry out the claimed functions, so that not all microprocessors and sensors were covered by claims 1 and 7.

The features distinguishing the subject-matter of claims 1 and 7 from GG6 related to both the microprocessor and the inertial sensor, so that partial problems were not appropriate for assessing the inventive step of claims 1 and 7. Even if partial problems were used, the subject-matter of claims 1 and 7 was inventive over the combination of GG6 and GG4 because the two functions would not have been provided in the same module in view of the teaching in paragraph [0010] of GG6, according to which each module provided a specific function.

- X. The opponent's arguments, as far as they are relevant to the decision, can be summarised as follows:

Admissibility of the opposition

Upon being informed by telephone by the EPO of the discrepancy between the opponent's name in Form 2300E and its name in the accompanying letter, the opponent's representative filed on the same day the request for correction and supporting evidence. The evidence proved the original intention of filing the opposition in the

name of "Vetter Pharma-Fertigung GmbH & Co. KG". In the examination of the patent in opposition proceedings, public interest was to be given more weight than the strategic interests of the proprietor. The request for correction was thus allowable.

Third-party observations

The third-party observations were endorsed by the opponent.

Main request - inventive step

The subject-matter of claims 1 and 7 was not inventive over GG6 in view of common general knowledge. The claims did not require the detection of an exclusively linear motion along the longitudinal axis. The detection of such an exclusively linear motion was not supported by the patent specification either.

The person skilled in the art would have had to choose a technical implementation for the means for detecting shaking movements disclosed in paragraph [0093] of GG6. An inertial sensor was well known in the art, see GG9, and would have been an obvious choice.

The problem solved by the detection of shaking along the longitudinal axis could be regarded as determining whether the contents of the drug delivery pen had been properly mixed. Any microprocessor and any inertial sensor would be able to detect shaking as defined by the independent claims.

Auxiliary request 1 - inventive step

Claims 1 and 7 did not require that the same inertial

sensor be used for both functions. A German court in infringement proceedings would most probably regard a pen with two different inertial sensors as falling under the scope of protection of claim 1. As regards the determination of proper mixing, claim 1 only required that the microprocessor was "able to determine ..."; this could not be construed as a means-plus-function feature which would require a wording such as "means for" or "configured to", so that any programmable microprocessor would anticipate this feature as long as there was at least one inertial sensor. The same applied to the wording "... to allow for determination" in claim 7.

The subject-matter of claims 1 and 7 was not inventive over GG6 combined with GG4. The features distinguishing the subject-matter of claims 1 and 7 from GG6 relating to proper mixing detection and to proper priming position had no synergistic effect and addressed the partial problems of determining whether the contents of the drug delivery pen had been properly mixed and how to avoid injecting air.

The necessity of priming an injection device was well known and GG4 taught a priming detection facility with an inertial sensor in column 3, lines 13-17. GG6 taught in paragraphs [0009] and [0016] that an economic device should be provided and that duplication of key components was to be avoided. Hence, the person skilled in the art would have not considered providing two inertial sensors in two different modules but would instead have combined both functions in the same module using a single inertial sensor. Even if two different modules had been considered, a third module combining both functionalities would also have been considered in

order to provide an economic device without duplicating the components.

Reasons for the Decision

1. Admissibility of the opposition
 - 1.1 The formal requirements for filing a notice of opposition are set out in Article 99(1) EPC and Rule 76 EPC. It is stipulated in Rule 76(2)(a) EPC in view of Rule 41(2)(c) EPC that a notice of opposition must contain, among other things, the name of the opponent.
 - 1.2 In the notice of opposition as originally filed, prior to its correction, the two different opponent names indicated in Form 2300E and in the accompanying letter do cast doubt as to the identity of the opponent.
 - 1.3 The opponent requested a correction of the opponent's name and filed supporting evidence in the Annex of 15 December 2016 before the opposition division. The opposition division allowed the request and admitted the supporting evidence, holding that it was prima facie relevant (point 11.1 of the impugned decision). Hence, the request and the supporting evidence are to be considered by the board of appeal (Article 12(2) RPBA 2020).
 - 1.4 Mistakes in any document filed with the European Patent Office may be corrected on request pursuant to Rule 139, first sentence, EPC. An allowable correction pursuant to Rule 139 EPC must introduce what was originally intended, must be filed without delay and must have retrospective effect, as set out in point 37 of the Reasons of G 1/12, which summarises the

principles applying to corrections pursuant to Rule 139, first sentence, EPC. These principles likewise apply when assessing whether a correction of the opponent's name pursuant to Rule 139, first sentence, EPC is allowable.

1.5 For the reasons presented below, the board shares the opposition division's findings as regards the request for correction.

1.5.1 The original intention was not immediately apparent, and therefore the opponent as the requester bore the burden of proof.

Part of the evidence submitted on 15 December 2016 in support of the request for correction, namely the e-mails, letters and invoices dated between 5 August 2014 and 12 January 2015, reflects an exchange between Vetter Pharma-Fertigung GmbH & Co. KG and Gleiss & Große relating to surveillance of the impugned patent and searches for relevant prior art in preparation for an opposition. This part of the evidence confirms that Vetter Pharma-Fertigung GmbH & Co. KG instructed Gleiss & Große to carry out those tasks.

More importantly, the minutes of a telephone conversation between Ms. Nusseleit from Vetter Pharma-Fertigung GmbH & Co. KG and Gleiss & Große at 12:45 on 5 February 2015, containing in the first line "N: file opposition" ("N: Einspruch einlegen" in the filed version in German), together with the subsequent letter and invoice from Gleiss & Große to Ms. Nusseleit of Vetter Pharma-Fertigung GmbH & Co. KG dated 16 February 2015 including, among other things, the line item "Preparation of a notice of opposition and filing with the European Patent Office" ("Ausarbeitung

eines Einspruchsschriftsatzes und Einreichung beim Europäischen Patentamt" in the filed version in German), confirm that Gleiss & Große prepared and filed the opposition on the instructions of Vetter Pharma-Fertigung GmbH & Co. KG.

This evidence, together with the indication at the beginning of the letter accompanying the notice of opposition that the opposition was filed in the name of and on behalf of Vetter Pharma-Fertigung GmbH & Co. KG ("Namens und im Auftrag der Vetter Pharma-Fertigung GmbH & Co. KG" in the filed version in German), confirms to the board's satisfaction that the true intention was to file the opposition in the name of Vetter Pharma-Fertigung GmbH & Co. KG.

- 1.5.2 At the oral proceedings before the opposition division, the opponent submitted auxiliary requests to have both opponents registered or just "MAPAL Fabrik für Präzisionswerkzeuge Dr. Kress KG" (point 2.1 of the minutes of the oral proceedings before the opposition division).

These auxiliary requests constituted fallback positions in the event the opposition division did not grant the opponent's main request for correction. They do not cast any doubt on the conclusion above regarding the true intention when the notice of opposition was filed.

- 1.5.3 Furthermore, the request for correction and the supporting evidence were filed on the day before the oral proceedings before the opposition division. This does not represent an undue delay because it was only on this day that the EPO informed the opponent of the mismatch in the opponent's names in the notice of

opposition. No doubts as regards the identity of the opponent had been raised before. The request for correction was thus filed without delay.

1.5.4 Under these circumstances, it is irrelevant whether the error in Form 2300E may have had consequences on strategic decisions made by the proprietor.

1.5.5 In summary, it was possible to establish which party intended to file the opposition before the expiry of the opposition period. The request for correction pursuant to Rule 139, first sentence, EPC is thus allowable as it complies with the principles as set out in G 1/12, Reasons 37.

1.6 It follows that the opposition is admissible as it complies with Article 99(1) EPC and Rule 76 EPC.

1.7 In view of this conclusion, there is no need to consider the conditional request by the opponent regarding questions to be referred to the Enlarged Board of Appeal pursuant to Article 112(1) EPC.

2. Third-party observations

The third-party observations were only filed in the appeal proceedings. Third parties cannot be granted rights extending beyond those of the parties to the proceedings (see Case Law of the Boards of Appeal, 9th edition 2019, III.N.4.4.1).

The opponent explicitly endorsed the third-party observations. The proprietor objected to their admittance into the appeal proceedings. Rather than deciding on the admittance of the third-party observations in their entirety, admittance is

separately addressed in the following sections for each of the issues raised in the third-party observations.

3. Main request - patent as granted

3.1 Article 100(b) EPC

In the third-party observations it was submitted that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

No ground for opposition according to Article 100(b) EPC had previously been raised. The proprietor did not agree with the introduction of this new ground for opposition. Pursuant to G 9/91, Reasons 18, this ground cannot be introduced into the appeal proceedings.

3.2 Novelty

The objection of lack of novelty of the subject-matter of claim 1 as granted over GG6, submitted by the third party, is admitted into the appeal proceedings because it relates to an issue decided upon by the opposition division and substantiates why the opposition division allegedly erred in its decision.

Paragraph [0093] of GG6 discloses "means for detecting shaking movements", without further specifying the means. Contrary to the third party's view, it is conceivable for means other than an inertial sensor to be used for this purpose, e.g. an image sensor detecting shaking movements by image analysis. Moreover, the meaning of "inertial sensor" in claim 1

is not affected by whether the preferred inertial sensor indicated in the patent specification is able to carry out the function defined in claim 1. Hence, GG6 does not disclose an "inertial sensor" as required by claim 1 and therefore the subject-matter of claim 1 is novel over GG6 for this reason alone.

3.3 Inventive step

3.3.1 The background of the invention as described in paragraph [0001] of the patent specification indicates that insulin pens for insulin users are convenient and easy to use. When a user manually shakes an insulin pen, the actual motion of the pen will not be exclusively along the longitudinal axis but will include some rotational or lateral components. The interpretation submitted by the proprietor that the detection in claims 1 and 7 was restricted to a purely linear motion along the longitudinal axis would result in practice in virtually no shaking movement "along the longitudinal axis" being detected. This argument therefore cannot be accepted because it is not technically sensible and it does not take the disclosure of the patent into account.

3.3.2 The proprietor contested the opposition division's finding that the subject-matter of claim 1 was not inventive over GG6 in view of common general knowledge.

3.3.3 Document GG6 discloses a modular medication delivery device such as a pen injector ([0010]-[0011]). Among the replaceable modules which can be part of the medication delivery device, GG6 describes in each of paragraphs [0041] and [0093] a replaceable module containing "means for detecting shaking movements of the medication delivery device and means for providing

an alarm signal indicating that a certain amount of shaking movements has been performed to ensure a proper mixing of the constituents of the medication cartridge". Document GG6 likewise discloses processing means (paragraph [0024]) disposed in the housing and operatively connected to a power source and memory (paragraph [0024], see also Figures 3-4 and paragraphs [0076]-[0078]).

3.3.4 Claim 1 is novel over GG6 in that GG6 does not disclose that:

1) the sensor is an inertial sensor and the microprocessor is able to perform the determination from output signals of the inertial sensor; and

2) a predetermined number of shaking movements back and forth along the longitudinal axis can be determined by the microprocessor.

3.3.5 The first distinguishing feature has the effect of providing a specific technical implementation of the means for detecting the shaking movements in GG6. The second distinguishing feature has the technical effect of restricting the counting to the shaking movements along the direction which contributes most to the mixing of the drugs.

3.3.6 The proprietor argued that it was the relationship between the microprocessor and the inertial sensor which enabled the technical effects and which addressed the problem of how to improve the reliability of the mixing of the medicament to ensure a more effective drug delivery.

The board has a different view. The determination by the microprocessor from output signals of a sensor as defined in claim 1 could likewise occur with signals of a sensor other than an inertial sensor, e.g. with an image sensor as referred to within the novelty analysis. Thus, the distinguishing features have no synergistic effect and it has to be established which problem is solved by each feature and whether each feature is separately obvious in the light of the prior art, using so-called "partial problems".

The first problem can be regarded as how to implement the means for detecting the shaking movements of GG6. The second problem can be regarded as how to determine whether the constituents of the medication cartridge in the drug delivery pen have been properly mixed.

3.3.7 The person skilled in the art starting from GG6 and faced with the first problem needs to choose a specific technical implementation of the "means for detecting shaking movements" disclosed in paragraph [0093], an issue which necessarily arises when carrying out the teaching of GG6.

It is well known that electronic inertial sensors can be used to detect movements such as shaking movements, allowing the subsequent counting thereof before the triggering of an alarm as described in paragraph [0093] of GG6. Moreover, if the use of other types of sensors is conceivable, an electronic inertial sensor would represent an obvious choice for the implementation, which would be used in GG6 by the person skilled in the art without inventive effort. In this regard, reference is made by way of example to GG9 (page 3, lines 29-30; page 4, lines 11-14; and page 6, lines 7-10).

3.3.8 As regards the second problem, the drug delivery pen of GG6 has a longitudinal housing and a longitudinal, cylindrical medication cartridge (see cartridge 12 in Figure 2 and [0074]); their respective longitudinal axes are parallel to each other.

It is part of common general knowledge that mixing the constituents of an elongated component such as the medication cartridge of the pen of GG6 is mainly achieved by back and forth shaking movements along its longitudinal axis. In turn, shaking movements in a transverse direction provide only a minor contribution to the mixing.

In order to improve the determination as to whether the constituents of the medication cartridge in the drug delivery pen of GG6 have been properly mixed, the person skilled in the art using their common general knowledge would thus implement the determination of the number of shaking movements of GG6, focusing on those shaking movements which substantially contribute to the mixing, i.e. those along the longitudinal axis of the medication cartridge and thus also of the housing, since they are parallel to each other.

3.3.9 In summary, the person skilled in the art starting from GG6 and faced with the problems above would arrive, using their common general knowledge, at a drug delivery pen anticipating the subject-matter of claim 1 without using inventive skill.

3.4 It follows that the main request is not allowable for lack of inventive step of the subject-matter of claim 1 (Article 56 EPC).

4. Auxiliary request 1

4.1 Inventive step over GG7 and common general knowledge

In the third-party observations, an objection of lack of inventive step of the subject-matter of claim 1 in view of GG7 and common general knowledge was raised.

Auxiliary request 1 corresponds to the version maintained by the opposition division which was filed on 16 November 2016, i.e. one month prior to the oral proceedings before the opposition division. This inventive-step objection defines a new line of attack not raised during the opposition proceedings and not addressed in the impugned decision. The board has decided not to admit this objection into the proceedings under Article 12(4) RPBA 2007.

4.2 Inventive step over GG6 and GG4

4.2.1 The opponent submitted that claims 1 and 7 did not require the same inertial sensor to be used to determine whether the housing had been shaken back and forth a predetermined number of times along the longitudinal axis and to determine whether the housing was oriented topmost and generally vertically with respect to the ground in a priming position. The opponent also alleged that a German court in infringement proceedings would most likely regard a pen device with two different inertial sensors carrying out the different functions as falling under the scope of protection of claims 1 and 7.

The board notes that claims 1 and 7 respectively introduce "an inertial sensor" and subsequently refer to it by using a definite article before the term

"inertial sensor" (e.g. "from output signals of the inertial sensor"). Hence, each of the independent claims 1 and 7 defines a single inertial sensor which serves two different purposes. The board additionally notes that this conclusion is also supported by the description of the patent specification: the first few words of paragraph [0046], namely "The inertial sensor is also utilized to ..." (underlining added by the board), make it clear that the same inertial sensor is used for both functions.

The submission by the opponent about how a German court in infringement proceedings would interpret the claim relates to an issue which is not at stake in the present case. Infringement proceedings are different from opposition appeal proceedings before the EPO concerned with the patentability of the subject-matter of a claim in view of the prior art.

The opponent submitted that the wording used in the independent claims did not require a microprocessor configured to determine "whether the housing has been shaken ...", but rather merely a processor which could be programmed to carry out such a determination, i.e. any programmable microprocessor.

The fact that the microprocessor in claim 1 "is able to determine ..." defines a functional feature of the microprocessor. In the context of a data processing function carried out by an entity such as a microprocessor, this functional feature is construed as the microprocessor not just being able to carry out the function but being adapted to carry it out as is, in agreement with established EPO practice when assessing means-plus-function features (see T 410/96, Reasons 5-10, and T 96/12, Reasons 4; see also

Guidelines for Examination in the EPO, F-IV, 4.13.2, 3rd paragraph, as well as F-IV, 3.9.1). For the same reasons, claim 7 is likewise construed as requiring the necessary configuration to carry out the determination described.

- 4.2.2 It is common ground that the feature added to claims 1 and 7 of auxiliary request 1, i.e. the microprocessor being configured to determine from output signals of the inertial sensor whether the pen housing including the cartridge is oriented topmost and generally vertically with respect to the ground in a priming position, is not disclosed in document GG6 and thus constitutes an additional distinguishing feature.
- 4.2.3 It was submitted both by the opponent and by the third party that the features distinguishing the subject-matter of claims 1 and 7 from GG6 each solved the partial problems of proper mixing and proper priming position detection and that GG4 taught in column 3, lines 13-17, a priming detection facility using an accelerometer (i.e. an inertial sensor), and therefore the feature added to claims 1 and 7 could not lead to an inventive step either. The board has reached a different conclusion, for the reasons presented below.
- 4.2.4 GG6 uses a modular design. The idea in GG6 is that key components, such as injection mechanics, processor, memory, battery, etc., are provided in a basis module in order to avoid duplication of key components (see paragraphs [0016]-[0018], [0050]-[0051], [0057] and [0074]-[0078]). The basis module is then combined with one or more replaceable modules from a collection of replaceable modules in order to provide an individual pen tailored to the functions needed by a user (see e.g. paragraphs [0009], [0012]

and [0053]-[0054])). Each replaceable module in the collection of replaceable modules is adapted to cooperate with the basis module to provide a specific function (see paragraphs [0010] and [0052] of GG6).

4.2.5 The teaching in paragraph [0016] of GG6 that the device is to be customised while avoiding the duplication of key components refers to the provision of a basis module containing common resources, as indicated above. It does not imply that an identical sub-component - such as an inertial sensor - cannot be present in two different replaceable modules. This is confirmed by the list of replaceable modules disclosed in GG6, in which different modules include, e.g., a loudspeaker (see paragraphs [0035]-[0036]) or means for providing an alarm (see paragraphs [0040]-[0041]).

4.2.6 The arguments that a module combining proper mixing detection and priming detection would also be considered and that the replaceable modules disclosed in paragraphs [0037]-[0042] of GG6 show different functionalities being provided in the same replaceable module are not convincing.

GG6 explicitly describes in paragraphs [0010] and [0052] each module being adapted to provide a specific function. Each of the replaceable modules disclosed in paragraphs [0029]-[0047] deals with a specific function which is presented in the corresponding paragraphs [0081]-[0099]. For example, "monitoring and controlling the temperature of the medication cartridge and its contents" refers to a single function, namely "ascertaining that the currently loaded medication is usable, irrespective of the temperature that the device experiences" (see paragraph [0090]). The modules of paragraphs [0040]-[0041] also serve only to ensure a

proper mixing of the constituents of the medication cartridge, even if sub-components for counting the number of shaking movements and for providing an alarm signal are needed for this function.

Medication mixing and pen priming are two different functions relating to two different preparatory steps of the drug delivery pen, and therefore providing both in the same replaceable module would go against the teaching of GG6 of having each module adapted to provide a specific function.

4.2.7 Hence, the person skilled in the art starting from the modular pen injector of GG6, even if faced with the partial problems mentioned above and a desire to implement a priming detection facility following the teaching of GG4, would have provided separate replaceable modules for proper mixing detection and for priming detection. That is, the two functionalities would not have been provided in the modular pen injector of GG6 in the same replaceable module using the same inertial sensor, and therefore the person skilled in the art would not have arrived at a device anticipating the subject-matter of claims 1 or 7.

4.2.8 Document E1 was filed to support the ground of opposition of insufficient disclosure and was referred to in the third-party arguments against inventive step. More specifically, it was argued that an accelerometer such as the one shown in E1 would be an inertial sensor. Such a sensor could be used for sensing proper priming. However, this argument does not address the issue of why the person skilled in the art should use the same module for both functionalities.

4.2.9 It follows that the objection of lack of inventive step (Article 56 EPC) over GG6 and GG4 does not prejudice the maintenance of the patent on the basis of auxiliary request 1.

4.3 There were no further objections against auxiliary request 1. Since auxiliary request 1 corresponds to the request found to meet the requirements of the EPC by the opposition division in the appealed decision, there is no reason to set aside that decision.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



D. Hampe

D. Ceccarelli

Decision electronically authenticated