(19) Octrooicentrum Nederland

(11) **2012310**

(12)C **OCTROOI**

(21) Aanvraagnummer: **2012310**

(22) Aanvraag ingediend: **21.02.2014**

(51) Int.Cl.:
***A61J 7/00*** (2006.01) ***G01N 21/95*** (2006.01)

(43) Aanvraag gepubliceerd:
-

(47) Octrooi verleend:
**25.08.2015**

(45) Octrooischrift uitgegeven:
**02.09.2015**

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(54) **Method of and device for receiving and checking individualized doses of medicines.**

(57) A method of receiving and checking individualized compound doses of medicines is disclosed. The method includes a repetition of the steps of
- receiving a plurality of dispensed medicines that form an individualized compound dose of medicines,
- assessing the composition of the individualized compound dose of medicines trough automated recognition of the received medicines,
- checking the assessed composition of the received individualized compound dose of medicines against a record for the composition of that individualized compound dose of medicines, and
- if the outcome of the check is positive, discharging the received individualized compound dose of medicines to be packaged in a dose compartment of a multi dose compartment package, and
- if the outcome of the check is negative, discharging the received individualized compound dose of medicines other than to be packaged in a dose compartment of the multi dose compartment package.
The disclosure also includes a device for receiving and checking individualized compound doses of medicines.

NL C 2012310

P103642NL00

Title: Method of and device for receiving and checking individualized doses of medicines

The invention relates to individualized compound doses of medicines, in particular pills.

For medicine users that use a plurality of different medicines, it is often difficult to ensure that at each intake moment, a prescribed combination of medicines is taken. In order to facilitate taking the prescribed combination at each intake moment, it has been proposed to prepare individualized compound doses of medicines, and to prepackage these doses according to subsequent intake moments for a particular patient.

In practice, for each of a series of subsequent intake moments, pills are collected from selected cassettes of a dispensing machine to form an individualized compound dose of medicine in accordance with a patient prescription record, and the doses are individually packaged in a string of sealed packages. In order to ensure the correctness of the compound doses, the composition of each sealed package in the string is assessed and checked in an automated process, e.g. in accordance to WO2005/017814.

Although highly effective, this process still has disadvantages. For example, in case the check reveals a dose has not been composed properly, e.g. because a pill failed to leave a cassette or got caught in a dispenser chute, a package in the string is rejected. In case a package in the string is rejected, the string either needs to be discarded or the composition of the dose in the rejected package in the string needs to be amended and rechecked manually. Also, in case a dose cannot be composed as prescribed, e.g. because the store of a medicine in a cassette has run out, the dispensing process is stopped.

The invention aims to alleviate the above disadvantages. Thereto the invention provides for a method of receiving and checking individualized compound doses of medicines, comprising repetition of the steps of:

- receiving a plurality of dispensed medicines that form an individualized compound dose of medicines,
- assessing the composition of the individualized compound dose of medicines trough automated analysis of the received medicines,
- checking the assessed composition of the received individualized compound dose of medicines against a record for the composition of that individualized compound dose of medicines, and
- if the outcome of the check is positive, discharging the received individualized compound dose of medicines to be packaged in a dose compartment of a multi dose compartment package, and
- if the outcome of the check is negative, discharging the received individualized compound dose of medicines other than to be packaged in a dose compartment of the multi dose compartment package.

By assessing and checking the composition of the individualized doses before packaging, it may be achieved that only doses with a positive check on their composition are packaged. This way, it may be prevented that a string of packages is rejected because a packaged dose in the string is of the wrong composition.

The step of automated analysis may include optical recognition, and in particular may include storing photographic images of the actual individual compounded doses. The method steps are in principle consecutive, but may at least partially overlap for a given individualized compound dose. The method is for sequentially composing individualized compound doses of medicines, but the steps for consecutive individualized compound doses of medicines may take place simultaneously, i.e. processed in parallel, but mutually staggered in step.

A previously received individualized compound dose of medicines may be assessed and/or checked, while a following individualized compound dose of medicines is being received. This way, the output may be increased. In particular, receiving a following dose in separate reception area while a previous dose is assessed allows for buffering. This way, a dose that is being received may come to rest before it is subject to assessment. This is particularly advantageous in case the medicines include pills that are relatively hard, as they tend to bounce. It should be noted that a following individualized compound dose of medicines may be a later received dose, but need not be a next dose, as there may be buffering of several doses.

After reception in a reception area, a received individualized compound dose of medicines may be moved to a separate assessment area. Such separation may prevent that the receiving process disturbs the assessment process. The reception and assessment areas may be spatially separate, but preferably are also physically separated.

A received and checked individualized compound dose of medicines may be discharged, while a subsequently received individualized compound dose of medicines is being assessed and/or checked. This further increases efficiency.

After checking in an assessment area, a received and assessed /checked individualized compound dose of medicines may be moved to a separate discharging area for discharging. This way, it may be achieved that any time needed for the discharging step does not increase the time needed for assessment and checking. The assessing and discharging areas may be spatially separated, but preferably are also physically separated.

After discharge of a received and checked individualized compound dose of medicines, a discharging area may be inspected for any remaining medicines. This may e.g. be done by automated optical inspection, and an optical image, specifically a digital photo, of the discharging area after discharge may be stored in a record for the

individualized compound dose of medicines, e.g. along with an optical image, specifically a digital photo, of an assessment area containing the dose.

A multi dose compartment package may be indexed with a dose compartment to receive a discharged individualized compound dose of medicines. The multi dose compartment package may e.g. be indexed with a dose compartment thereof to be positioned to have its position correspond with an exit of a chute connected to the discharging area. For each received individualized compound dose of medicines, the multi dose compartment package may be virtually and/or physically indexed to another free dose compartment.

If the outcome of the check is negative, that dose compartment may then be skipped and may remain open to receive an individualized compound dose of medicines. If the outcome of a check is negative, a plurality of medicines to form an individualized compound dose of medicines according to that record may be received a second time, and the multi dose compartment package may be indexed to the skipped dose compartment to package the individualized compound dose of medicines. This indexation may e.g. take place upon discharge, in case the check on the composition of the dose that is received a second time, is positive. This way, in case a dose is found to have an incorrect composition, the packaging process may continue with packaging a of buffered dose that is found to have a correct composition in a compartment assigned thereto, and a gap in a string of compartments packaged with doses may thus be temporarily formed at the compartment that corresponds to the incorrectly composed dose, which may be filled later when a correctly composed dose for that package is discharged to be packaged.

The dose compartments in the multi dose compartment package may each be dedicated for the individualized compound doses of medicines according to a specific record. The dose compartments may each be provided with an unique physical identifier for the individualized compound dose of

medicines in or for that compartment, e.g. a number. The identifier for the dose compartment may be provided previously, and may be coupled to the record, or may be generated for that record and provided to the dose compartment after or upon discharge of the dose.

The dose compartments in the multi dose compartment package may conveniently be closed only after all the individualized compound doses of medicines for that package have been packaged.

The composition of individualized compound doses of medicines contained in dose compartments of the package may be assessed via automated recognition of the medicines contained in compartments, and may be checked against a record for the composition of the individualized compound dose of medicines for that compartment. The automated recognition preferably includes optical recognition. The assessment may include capturing an optical image, in particular taking a digital photo, and analyzing the image to extract pill identifying characteristics, including e.g. size, shape, color, texture and markings. The captured image may be compared to images stored in a database or library.

The repeated steps may include a first step of automatically dispensing medicines from selected ones of a plurality of storages of mutually different medicines in accordance with a record for an individualized compound dose of medicines. The repeated steps may further include an alternative first step of manually dispensing mutually different medicines in accordance with a record for an individualized compound dose of medicines.

The invention further provides for a device arranged to receive and check individualized compound doses of medicines arranged to perform the steps as described above, individually or in combination.

A device for receiving and checking individualized compound doses of medicines may comprise:

- a receiving area for receiving a plurality of dispensed medicines that form an individualized compound dose of medicines,

- an assessment area with automated recognition apparatus for assessing the composition of the individualized compound dose of medicines trough automated recognition of the received medicines,

- a computer that checks the assessed composition of the received individualized compound dose of medicines against a record for the composition of that individualized compound dose of medicines, and

- a discharge that, if the outcome of the check is positive, discharges the received individualized compound dose of medicines to be packaged in a dose compartment of a multi dose compartment package, and if the outcome of the check is negative, discharges the received individualized compound dose of medicines other than to be packaged in a dose compartment of the multi dose compartment package.

By embodying the receiving area as a dose buffer that is physically separate from the assessment area, it may be achieved that the medicines comprising the dose may be collected and come to rest while a previously collected dose is being collected.

The device may comprise a number of transport receptacles that are arranged to receive a dose from the dose buffer, and to confine it in the receptacle during transport. This way, a dose of medicines may be transported along various processing areas, e.g. an assessment area and a discharge area without risk of losing medicines from the dose. Such a transport receptacle may receive collected doses of medicines via a drop bottom in the dose buffer. The transport receptacle(s) may be ring shaped, in particular with an open top and bottom, and may be arranged to slide over a hard bottom, e.g. a steel and/or glass plate.

The transport receptacles may be arranged to transport the dose from an assessment area to a discharge area. The assessment area may e.g. be provided with a top and/or bottom camera to capture optical images of

the dose, lights to enhance the image, backlights to provide lighting, a semitransparent mirror to allow either reflection of the image enhancing light or backlight, and/or a shaker to bring medicines in a dose out of stacked or overlapping arrangement.

Transport receptacles may be arranged to be indexable, e.g. between an assessment area and a discharge area. The discharge area may include a chute connected to an aperture in the hard bottom plate.

The device may further include a table arranged to carry a multi dose compartment package, which table is positionable in its plane to align dose compartments of the multi dose compartment package with a dispensing zone corresponding to the discharge area. The device may further include a disposal, alignable with the discharge area, e.g. a bin, or a tray with separate compartments for holding incorrectly compounded doses. Using such separate compartments facilitates recycling the individual medicines in the incorrectly compounded doses, e.g. for redispensing. Alternatively or in addition, the composition of incorrectly coumpounded doses may be manually amended, and the corrected dose may be fed back to a receiving area or checking area of the machine. These may also be provided on the table.

The device may further including a reader unit for reading a code on a multi dose compartment package carried on the table, and may include a writer unit to write codes on individual packages of the multi package.

It should be noted, that the method steps and technical features described above may each on its own be embodied in a method or device for receiving and checking individualized compound doses of medicines, i.e. isolated from the context in which it is described, separate from other steps or features, or in combination with only a number of the other steps or features described in the context in which it is disclosed. Each of these steps or features may further be combined with any other step or feature disclosed, in any combination.

The invention will be further elucidated on the basis of a non-limitative exemplary embodiment which is represented in a drawing. In the drawing:

Fig. 1 shows a schematic front perspective view of a device for receiving and checking individualized compound doses of medicines;

Fig. 2 shows a schematic rear perspective view of the device of Fig. 1.

Fig. 3a and Fig. 3b respectively a schematic perspective view and a schematic top view of a multi dose compartment blister package, and

Fig. 4 a schematic side view of three final packaging steps for a multi dose compartment blister package.

It is noted that the figures are merely schematic representations of a preferred embodiment of the invention. In the figures, identical or corresponding parts are represented with the same reference numerals.

Figs. 1 and 2 show a device for receiving and checking individualized compound doses of medicines.

*Description of the device*

The device 1 comprises a receiving area for receiving a plurality of dispensed medicines that form an individualized compound dose of medicines. The receiving area is embodied as a dose buffer 2 in which the medicines comprising the dose may be collected and come to rest.

The device 1 further includes an assessment area with automated recognition apparatus 4 for assessing the composition of the individualized compound dose of medicines trough automated recognition of the received medicines. The assessment area is identified as a dose check position 3 where a receptacle is 5 is situated. The dose buffer 2 is physically separate from the assessment area.

The automated recognition apparatus 4 includes a top digital camera 6, and a bottom digital camera (not shown) to take photos of the dose at the checking position. The automated recognition apparatus 4 in the example further includes auxiliary equipment, such lights 7 to enhance lighting of the pills at the dose check position 3. The device 1 also comprises a semitransparent mirror (not shown) to allow either reflection or passing through of image enhancing light emitted from bottom lights (not shown) so as to allow for an image to be taken against the light to get a clear image of the contours of the pills. Further the device comprises a shaker 8 to bring medicines contained in a dose out of stacked or overlapping arrangement.

Further equipment part of the recognition apparatus 4 in this example includes a spectroscopy device 9 based on Raman spectroscopic analysis. The spectroscopy device 9 includes a spectroscopy head 10 with a radiation emitting fibre and a positioning arm 11 with which the spectroscopy head 10 may be positioned at a particular pill. The spectroscopy head may be positioned at a predetermined distance from the top or bottom surface of the pill to be assessed. Preferably, the positioning arm 11 positions the spectroscopy head 10 at the center of a pill to be assessed, at a predetermined height above or below the center. The predetermined distance of the spectroscopy head 10 may be a fixed height relative to the surface that the pill lies on, i.e. the glass plate 14, or may be a fixed height relative to the top surface of the pill, e.g. determined with a distance probe. Conveniently, the spectroscopy head 10 may be positioned near or against the bottom of the plate 14 measuring upward, so that the predetermined distance may be the thickness of the plate that the pill lies on. This way it is relatively simple to obtain accurate measurements with high reproducibility, while reference measurements are also relatively simple to collect in a test device which includes the same configuration of the head and plate onto which the pills are put. The center of the pill or other positions where the spectroscopic measurement is to be taken, may be

determined from the image obtained via the camera. The spectroscopy head 10 will then irradiate a surface of a particular pill at a predetermined height with a laser beam. A reflected spectrum measurement is determined by inter alia the density of the pill. In case the pill is not homogeneous, several spectroscopic measurements may be taken at several predetermined positions around the pill, e.g. in a 1-2 mm diameter circle.

The reflected spectrum measurement is determined by the density of a particular pill, the height/position of the spectroscopy head 10 with respect to a point on the top surface of the pill and the power of the laser beam. Preferably, power of the laser is minimized to ensure a minimum irradiation time of the pill and to prevent degradation of the pill due to the laser beam.

The spectroscopic measurement may then be compared to stored spectroscopic measurements taken at a same position and at the same height for reference pills. Thus, a specific pill can be identified in a simple way. The Raman spectroscopic analysis can also being used to eliminate doubts in case the visual information collected is not yet enough to identify a specific pill, or e.g. to verify that a pill is genuine and not a fake. It should be noted that such Raman spectroscopic analysis of medicines in assessment of the composition of an individualized compound dose of medicines is an invention in itself, and is also applicable in any type of prior art device for assessment, including post packaged assessment.

In addition, the device includes a computer (not shown) that checks the assessed composition of the received individualized compound dose of medicines against a record for the composition of that individualized compound dose of medicines. This shall be discussed more in detail further on.

The device 1 comprises a transport receptacle 5 that is arranged to receive a dose from the dose buffer 2, and to confine it in the receptacle during transport. The transport receptacle 5 is arranged to transport the

dose from its dose checking position 3 at the assessment area to a discharge position 12 at a discharge area. The transport receptacle 5 is arranged to receive collected doses of medicines while at the dose checking position 3, via a drop bottom 13 in the dose buffer 2. The transport receptacle 5 is ring shaped, and is arranged to slide over a glass plate 14. The glass plate 14 is hard so that the pills can slide well over its surface. The receptacle 5 is fully open at the bottom and at the top. The open top allows the pills to enter the receptacle and allows inspection of the complete area enclosed by the ring. The open bottom in combination with the glass plate allows the pills in the receptacle to be inspected by the camera from the bottom, and also allows backlight to pass. The inner sides of the wall of the ring include the lights 7 to provide flood lighting of the pills.

At the discharge area 15, the device 1 further includes a discharge that, if the outcome of the check is positive, discharges the received individualized compound dose of medicines to be packaged in a dose compartment of a multi dose compartment package, and if the outcome of the check is negative, discharges the received individualized compound dose of medicines other than to be packaged in a dose compartment of the multi dose compartment package. The discharge area includes a chute 16 connected to an aperture 17 in the hard plate that forms the entry of the chute. The transport receptacle is indexable between the dose checking position 3 and the discharging position 15, as is shown by a double arrow in Fig. 2.

The device 1 further includes a table 18 arranged to carry a multi dose compartment package, which is embodied as a blister 19. The blister is shown in detail in Figs. 3a and 3b, and includes an array of dose compartments 20, as well as a blister identification tab 21 with a unique blister code. The blister 19 is scored, such that individual dose compartments 20 or groups of dose compartments may be torn off the sealed blister 19 by a patient, yet remain sealed and provided with unique

identification, so that the dose compartments representing upcoming intake moments can be taken along more easily. It should be noted that such a multi dose compartment package is an invention in itself, and may also be used in any other suitable type of prior art device for assessment and /or packaging.

As can be seen best in Fig. 1, the table 18 is XY positionable in its plane to align dose compartments 20 of the multi dose compartment blister 19 with a dispensing zone corresponding of the discharge area 15. Here, the dispensing zone corresponds with the exit aperture 22 of the chute 16.

The device 1 further includes a disposal bin 23 for holding incorrect doses. The disposal bin 23 is aligned with the exit aperture 22 to receive doses when the table 18 is positioned away from the discharge area 15, and leaves the path between the exit aperture 22 and the bin free 23.

The device 1 further includes a reader unit 24 for reading the blister code on a blister identification tab 21. The device 1 further includes a writer unit (not shown) to write codes on individual dose compartments 20 of the blister 19.

Referring to Fig. 4, a schematic side view of three final packaging steps for a multi dose compartment blister package are shown. A first step is shown, with a blister 26 having a blister package 19 at a blister fill position 27. A next step is shown, with the fully filled blister package 19 at a blister photo position 28, and a full blister camera 29 to take a picture of the fully filled blister package 19. A final step is shown, with the blister package 19 at a blister seal position 30, and a blister sealing station 31 sealing the blister package 19.

*Method of operation*

The medicines in the individualized, compound doses are typically pills, which may include tablets, capsules, caplets, gelcaps, liquigels and

softgels. These medicines are dispensed in an automated dispenser (not shown) from selected ones of a plurality of storages of mutually different medicines in accordance with a record for an individualized compound dose of medicines. Such storages include a plurality of pill cassettes, each holding a plurality of pills. The pill cassettes include vanes that can be actuated to release one pill at a time into a chute towards a receiving area. A typical dispenser machine is disclosed at www.tosho.cc with type number Xana-4001U2. The medicines may also be dispensed at least partially manually, e.g. in multi dose compartment trays with drop bottoms. The doses may also include liquids, e.g. in vials, may e.g. be added to the receiving area and/or dose compartment manually. It should be noted that a series of individualized doses may also include doses which include only a single medicine.

In practice, for each of a series of subsequent intake moments, pills are dispensed in accordance with a patient prescription record and are dropped in the dose buffer 2 of the machine 1. In the dose buffer 2, the pills are collected to form an individualized compound dose of medicine. After collection, the composition of each dose is individually assessed and checked against the patient prescription record for that dose.

When the dose is collected in the buffer 2, the drop bottom 13 opens and forms a chute that conveys the dose to the transport receptacle 5, which is at the dose checking position 3. The receptacle 5 receives the dose via its open top, and holds the pills, which lie on the glass plate 14. The drop bottom 13 closes again, and the dose buffer 2 starts to collect a new dose.

Meanwhile, the shaker 8 engages the receptacle 5 to ensure all pills lie free of each other on the glass plate, and clear from the wall of the receptacle 5.

The top camera 6 and the bottom camera each take a color picture of the pills in the dose. In addition, the top camera 6 takes a contrast picture against light passing through the glass bottom into the receptacle 5.

The composition of individualized compound doses of medicines contained in the receptacle 5 is assessed via automated recognition. The assessment includes analyzing the picture to extract pill identifying characteristics, including e.g. size, shape, color, texture and markings. The photo is compared to images stored in a database or library. This process is known per se, and is e.g. disclosed in WO02/25568 and WO 2005/017814. If the pills are not clear of each other or of the wall of the receptacle 5, the shaker 8 is reactivated. Also, the head 10 of the spectroscopy device 9 may be positioned by the arm 11 at the center of the pill, using information of the photo, e.g. to eliminate doubts in case the visual information collected is not yet enough to identify a specific pill, or e.g. to verify that a pill is genuine and not a fake.

After checking in the assessment area, the receptacle 5 is slid along the glass plate 14 to the discharge position 12. Here, the pills exit 'the receptacle 5, and fall via the aperture 17 into the chute 16. After discharge, the receptacle 5 is returned to the dose check position 3.

When a dose check is positive, the multi dose compartment blister package 19 is indexed and positioned with a dose compartment 20 thereof to receive a discharged individualized compound dose of medicines. The blister package 19 is moved by the table 18 to have the position of a selected dose compartment 20 to correspond with the exit aperture 22 of the chute 16 connected to the discharging area before the transport receptacle 5 arrives at the discharge position 12.

When a dose check is negative, the multi dose compartment blister package 19 is virtually indexed to a next compartment 2, but the table 18 moves the blister package 19 away so that it leaves the path from the exit aperture 22 to the disposal bin 23 free, and the dose is disposed in the bin 23.

After discharge of a received and checked individualized compound dose of medicines, the discharging area 15 is inspected for any

remaining medicines using a drop clearance camera 25. A digital photo, of the discharging area 15 after discharge is stored in a record for the individualized compound dose of medicines, along with a photo of the dose in the receptacle 5 taken at the assessment area 3.

For each received individualized compound dose of medicines, the blister package 19 is virtually indexed to another free dose compartment 20. If the outcome of the check is negative, however, that dose compartment is skipped, and remains open to receive an individualized compound dose of medicines. If the outcome of a check is negative, a plurality of medicines to form an individualized compound dose of medicines according to that record is be received a second time in a subsequent collection step, and the multi dose compartment package is indexed to the skipped dose compartment to package the individualized compound dose of medicines. This indexation again take place in case the check on the composition of the dose that is received a second time, is positive.

The packaging process may continue with packaging a of buffered dose that is found to have a correct composition in a compartment assigned thereto, and a gap in a string of compartments packaged with doses may thus be temporarily formed at the compartment that corresponds to the incorrectly composed dose. This gap can be filled later when a correctly composed dose for that package is discharged to be packaged.

The dose compartments 20 in the multi dose compartment blister package 19 are each dedicated for the individualized compound doses of medicines according to their specific record. Upon discharge of the dose, the dose compartments are each provided with a number and/or text printed thereon by the printing unit. The number and/or text forms a unique physical identifier for the individualized compound dose of medicines in or for that compartment.

Before receiving the first dose, the multi dose compartment blister package 19 carried on the table 18 is read using the reader unit 24, to verify it has the correct configuration for the medicine records to be received.

Referring to Fig 4, when all compartments 20 of the blister package 19 are filled in accordance with the records, the blister package 19 is transported by blister 26 to the blister fill position 27. Here, also items may be added manually which are not easy to be collected automatically, e.g. sticky pills and/or vials and syringes. Next, a picture is taken of the full blister at the blister photo position 28, using full blister camera 29. The photo is stored with the other pictures in the records. Subsequently, the blister package 19 moves to the blister seal position 30, where it is sealed by the blister seal station 31.

The invention is not limited to the exemplary embodiment represented here. For example, the device may include a plurality of receptacles, e.g. arranged on a rotating carousel. Further, the device may include a different packaging device, e.g. device carrying separate dose compartments, or e.g. a sealable film device. Also, the machine may include one, two or more auxiliary input means via which medicines can be fed to the receiving area or checking area. Such auxiliary input means may be auxiliary to a main input means formed by an automated dispenser machine that includes a plurality of medicine storage cassettes. One or more auxiliary input means may be embodied as trays with a plurality separate compartments for manual placement of medicines therein, and transfer means, such as e.g. a drop bottom associated with a chute to transfer the medicines to the receiving or checking area. In such auxiliary input means, individual or groups of medicines may be placed in each compartment, and the medicines may thus at the reception area or the checking area be added to individual or groups of medicines received from an automated dispensing machine, to form an individualized dose of medicines that is to be checked. As an alternative, the auxiliary input means may be used to manually

compound the individualized doses of compound medicines. The manual input via the auxiliary input means may be operated in accordance with a list indicating which medicines are to be placed manually in selected ones of the compartments in accordance with subsequent records for individualized compound doses of medicines.

Such variations shall be clear to the skilled person and are considered to fall within the scope of the invention as defined in the following claims.

List of reference signs

1. Device
2. Receiving area / Dose buffer
3. Assessment area / Dose check position
4. Automated recognition apparatus
5. Receptacle
6. Top camera
7. Lights
8. Shaker
9. Spectroscopy device
10. Spectroscopy head
11. Positioning arm
12. Discharge position
13. Drop bottom
14. Glass plate
15. Discharge area
16. Chute
17. Aperture chute
18. Table
19. Multi dose compartment blister package
20. Dose compartment
21. Blister identification tab
22. Dispensing zone / Exit aperture
23. Disposal bin
24. Reader unit
25. Drop clearance camera
26. Blister
27. Blister fill position
28. Blister photo position

29.Full blister camera

30.Blister seal position

31.Sealing station

# Conclusies

1. Werkwijze voor het ontvangen en het controleren van geïndividualiseerde samengestelde doses medicijnen, omvattende een herhaling van de stappen van

- ontvangen van een pluraliteit aan afgegeven medicijnen die een geïndividualiseerde samengestelde dosis medicijnen vormen,
- beoordelen van de samenstelling van de geïndividualiseerde samengestelde dosis medicijnen door middel van geautomatiseerde herkenningen van de ontvangen medicijnen,
- controleren van de vastgestelde samenstelling van de ontvangen geïndividualiseerde samengestelde dosis medicijnen ten opzichte van een bestand voor de samenstelling van die geïndividualiseerde samengestelde dosis van medicijnen, en
- als de uitkomst van de controle positief is, afgeven van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen om te worden verpakt in een dosiscompartiment van een multidosiscompartimentverpakking, en
- als de uitkomst van de controle negatief is, afgeven van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen anders dan om te worden verpakt in een dosiscompartiment van de multidosiscompartimentverpakking.

2. Werkwijze volgens conclusie 1, waarbij een eerder ontvangen geïndividualiseerde samengestelde dosis van medicijnen wordt beoordeeld en/of gecontroleerd terwijl een volgende geïndividualiseerde samengestelde dosis van medicijnen wordt ontvangen.

3. Werkwijze volgens conclusie 1 of 2, waarbij na ontvangst in een ontvangstgebied, een ontvangen geïndividualiseerde samengestelde dosis

van medicijnen wordt verplaatst naar een separaat beoordelingsgebied voor controle.

4. Werkwijze volgens één der conclusies 1-3, waarbij een ontvangen en gecontroleerde geïndividualiseerde samengestelde dosis van medicijnen wordt afgegeven terwijl een vervolgens ontvangen geïndividualiseerde samengestelde dosis van medicijnen wordt beoordeeld en/of gecontroleerd.

5. Werkwijze volgens één der conclusies 1-4, waarbij na controle in een controlegebied, een ontvangen en gecontroleerde geïndividualiseerde samengestelde dosis van medicijnen wordt verplaatst naar een separaat afgiftegebied voor afgifte.

6. Werkwijze volgens één der conclusies 1-5, waarbij na afgifte van een ontvangen en gecontroleerde geïndividualiseerde samengestelde dosis van medicijnen, het afgiftegebied wordt gecontroleerd op achterblijvende medicijnen.

7. Werkwijze volgens één der conclusies 1-6, waarbij de multidosiscompartimentverpakking wordt geïndexeerd met een dosiscompartiment om een afgegeven geïndividualiseerde samengestelde dosis van medicijnen te ontvangen.

8. Werkwijze volgens conclusie 7, waarbij voor elke ontvangen geïndividualiseerde samengestelde dosis van medicijnen, de multidosiscompartimentverpakking virtueel en/of fysiek wordt geïndexeerd naar een ander vrij dosiscompartiment, en waarbij als de uitkomst van de controle negatief is, het dosiscompartiment wordt overgeslagen en open blijft om een geïndividualiseerde samengestelde dosis van medicijnen te ontvangen.

9. Werkwijze volgens conclusie 8, waarbij als de uitkomst van de controle negatief is, een meervoudig aantal medicijnen om een geïndividualiseerde samengestelde dosis van medicijnen volgens dat

bestand te vormen een tweede keer wordt ontvangen, en de multidosiscompartimentverpakking wordt geïndexeerd naar het overgeslagen dosiscompartiment om de geïndividualiseerde samengestelde dosis van medicijnen te verpakken.

10. Werkwijze volgens één der voorgaande conclusies, waarbij het dosiscompartiment in de multidosiscompartimentverpakking wordt toegewezen voor de geïndividualiseerde samengestelde dosis van medicijnen volgens dat bestand.

11. Werkwijze volgens één der voorgaande conclusies, waarbij het compartiment wordt voorzien van een unieke identificator voor de geïndividualiseerde samengestelde dosis van medicijnen in of voor dat compartiment.

12. Werkwijze volgens één der voorgaande conclusies, waarbij de dosiscompartimenten in de multidosiscompartimentenverpakking pas gesloten wordt nadat de geïndividualiseerde samengestelde doses van medicijnen voor die verpakking zijn verpakt.

13. Werkwijze volgens één der voorgaande conclusies, waarbij de samenstelling van de geïndividualiseerde samengestelde doses van medicijnen die in de dosiscompartimenten van de verpakking worden beoordeeld door middel van geautomatiseerde herkenning van de medicijnen die in de compartimenten zijn vervat, en worden gecontroleerd ten opzichte van een bestand voor de samenstelling van de geïndividualiseerde samengestelde dosis van medicijnen voor dat compartiment.

14. Werkwijze volgens één der voorgaande conclusies, waarbij de herhaalde stappen een eerste stap omvatten van het automatisch afgeven van medicijnen uit geselecteerde opslagen uit een meervoudig aantal

opslagen van onderling verschillende medicijnen overeenkomstig een bestand voor een geïndividualiseerde samengestelde dosis van medicijnen.

15. Werkwijze volgens conclusie 14, waarbij de herhaalde stappen een alternatieve eerste stap omvatten van manueel afgeven van onderling verschillende medicijnen overeenkomstig een bestand voor een geïndividualiseerde samengestelde dosis van medicijnen.

16. Inrichting ingericht om geïndividualiseerde samengestelde doses van medicijnen te ontvangen en controleren overeenkomstig één der conclusies 1-15.

17. Een inrichting voor het ontvangen en controleren van geïndividualiseerde samengestelde doses van medicijnen, omvattende

- een ontvangstgebied voor het ontvangen van een meervoudig aantal afgegeven medicijnen die een geïndividualiseerde samengestelde dosis van medicijnen vormen,

- een beoordelingsgebied met geautomatiseerde herkenningapparatuur voor het beoordelen van de samenstelling van de geïndividualiseerde samengestelde dosis van medicijnen door middel van geautomatiseerde herkenning van de ontvangen medicijnen,

- een computer die de beoordeelde samenstelling van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen controleert ten opzicht van een bestand voor de samenstelling van die geïndividualiseerde samengestelde dosis van medicijnen, en

- een afvoer die, als de uitkomst van de controle positief is, de ontvangen geïndividualiseerde samengestelde dosis van medicijnen afgeeft om te worden verpakt in een dosiscompartiment van een multidosiscompartimentverpakking, en als de uitkomst van de controle negatief is, de ontvangen geïndividualiseerde samengestelde dosis van

medicijnen afgeeft anders dan om te worden verpakt in een dosiscompartiment van de multidosiscompartimentverpakking.

18. De inrichting volgens conclusie 17, waarbij het ontvangstgebied is belichaamd als een dosisbuffer die fysiek gescheiden is van het controlegebied.

19. De inrichting volgens conclusie 17 of 18, voorts omvattende een aantal transporthouders die zijn ingericht om een dosis van de dosisbuffer te ontvangen en om deze in de houder te houden tijdens transport.

20. De inrichting volgens conclusie 19, waarbij de transporthouders zijn ingericht om de dosis te transporteren van een beoordelingsgebied naar een afgiftegebied.

21. De inrichting volgens conclusie 20, waarbij de transporthouders zijn ingericht om indexeerbaar te zijn.

22. De inrichting volgens conclusie 21, waarbij de houders schuifbaar zijn opgesteld op een harde bodemplaat, in het bijzonder omvattende een glazen plaat.

23. De inrichting volgens conclusie 22, waarbij het afgiftegebied een goot omvat die is verbonden met een opening in de bodemplaat.

24. De inrichting volgens één der conclusies 17-23, omvattende een tafel voor het dragen van een multidosiscompartimentverpakking, welke tafel positioneerbaar is in zijn vlak om dosiscompartimenten van de multidosiscompartimentverpakking op te lijnen met het afgiftegebied.

25. De inrichting volgens conclusie 24, voorts omvattende een leeseenheid voor het lezen van een code op een multidosiscompartimentverpakking die op de tafel wordt gedragen.

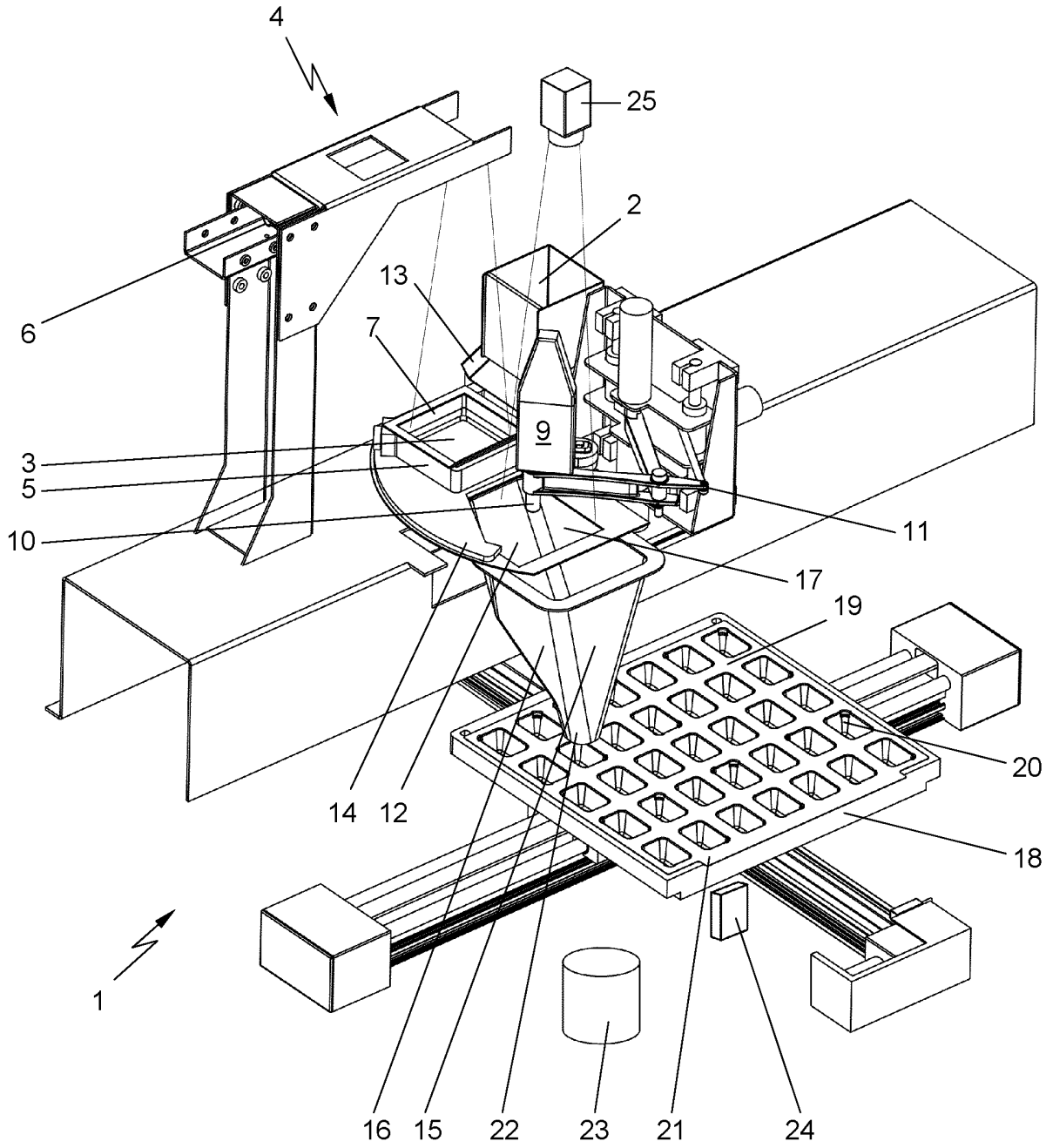


FIG. 1

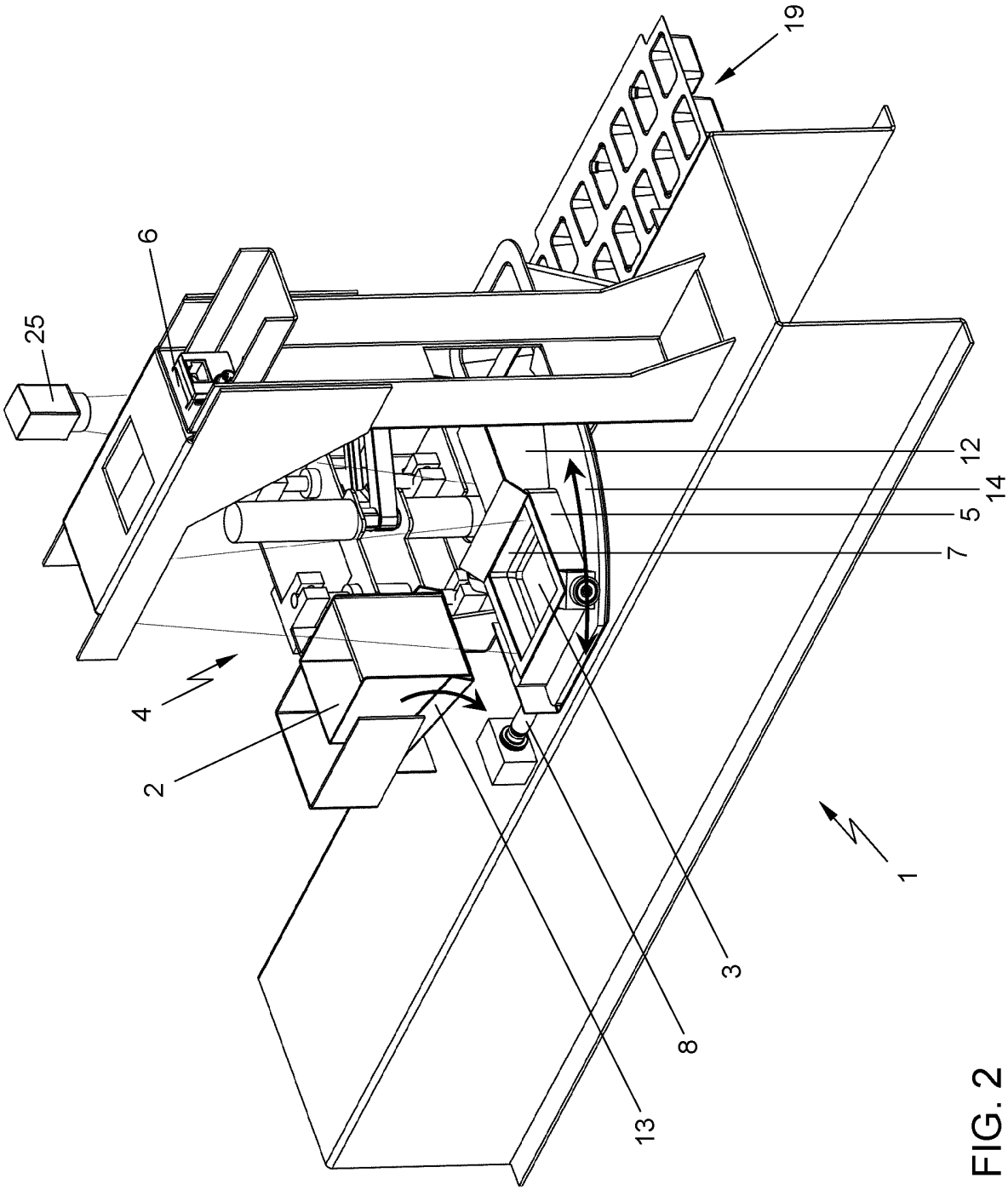


FIG. 2

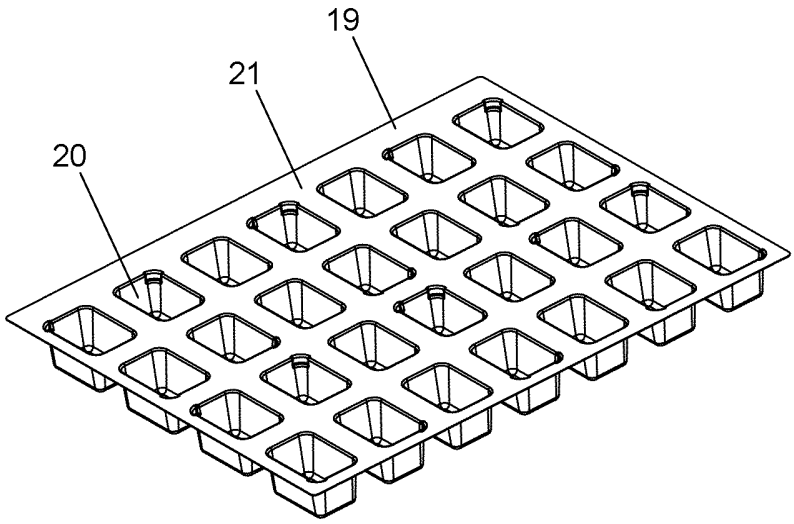


FIG. 3A

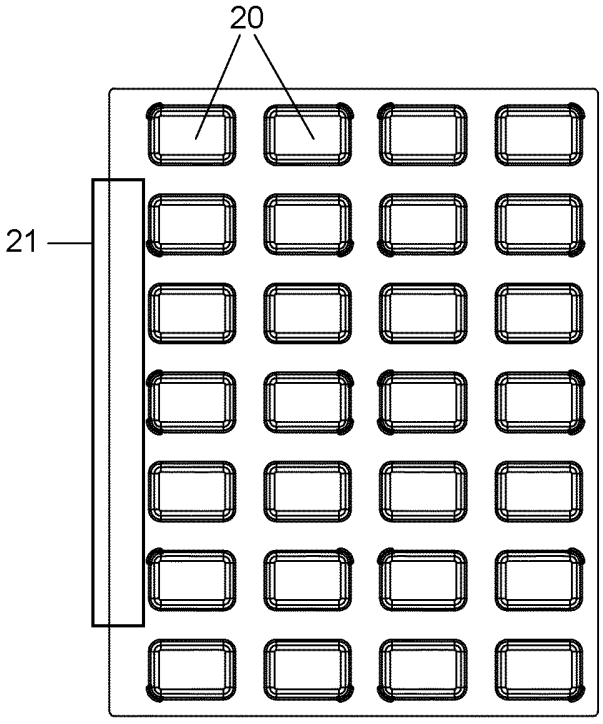


FIG. 3B

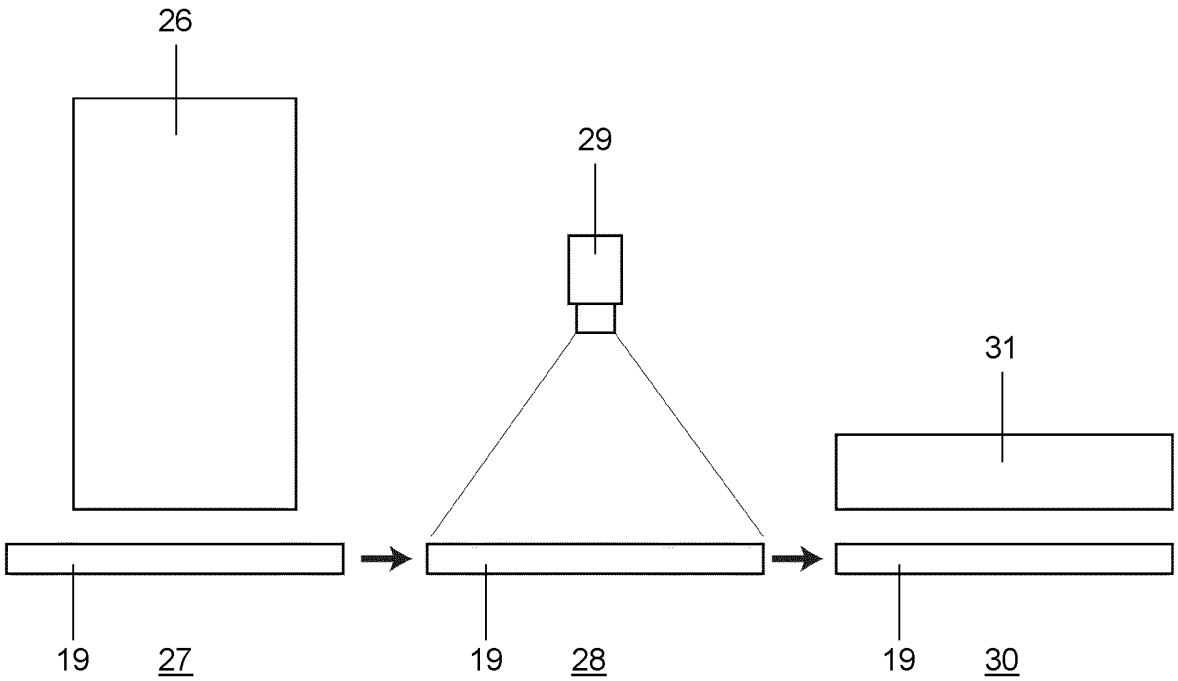


FIG. 4

# SAMENWERKINGSVERDRAG (PCT)

## RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

| IDENTIFICATIE VAN DE NATIONALE AANVRAGE | KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE |
|---|---|
| | **P103642NL00** |
| Nederlands aanvraag nr.<br>**2012310** | Indieningsdatum<br>**21-02-2014** |
| | Ingeroepen voorrangsdatum |
| Aanvrager (Naam)<br>**Global Factories Total Engineering and Manufacturing B.V.** | |
| Datum van het verzoek voor een onderzoek van internationaal type<br>**14-06-2014** | Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr.<br>**SN62143** |
| **I. CLASSIFICATIE VAN HET ONDERWERP** (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven) | |
| Volgens de internationale classificatie (IPC)<br>**A61J7/00;G01N21/95** | |
| **II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK** | |
| Onderzochte minimumdocumentatie | |
| Classificatiesysteem | Classificatiesymbolen |
| **IPC** | **A61J;G01N** |
| Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen | |
| | |
| III. ☐ **GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES** (opmerkingen op aanvullingsblad) | |
| IV. ☐ **GEBREK AAN EENHEID VAN UITVINDING** (opmerkingen op aanvullingsblad) | |

# ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2012310

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61J7/00 G01N21/95
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61J G01N

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

| Categorie ° | Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages | Van belang voor conclusie nr. |
|---|---|---|
| X<br>A | US 2002/108892 A1 (GOETZ ALEXANDER [US] ET AL) 15 augustus 2002 (2002-08-15)<br>* alinea [0032] - alinea [0041] *<br>* alinea [0057] *<br>* figuren 1-20 *<br>----- | 16-23<br>1-15,24, 25 |
| A | EP 2 082 718 A2 (JVM CO LTD [KR]) 29 juli 2009 (2009-07-29)<br>* alinea [0046] - alinea [0047] *<br>* alinea [0056] *<br>* figuren 1-6 *<br>----- | 19-25 |

☐ Verdere documenten worden vermeld in het vervolg van vak C.

☒ Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

| Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid | Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type |
|---|---|
| 6 november 2014 | |

| Naam en adres van de instantie | De bevoegde ambtenaar |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Ong, Hong Djien |



Formulier PCT/ISA/201 (tweede blad) (Januari 2004)

**ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2012310

| In het rapport genoemd octrooigeschrift | Datum van publicatie | Overeenkomend(e) geschrift(en) | Datum van publicatie |
|---|---|---|---|
| US 2002108892 A1 | 15-08-2002 | AU 2002243829 A1 | 28-08-2002 |
| | | EP 1362233 A2 | 19-11-2003 |
| | | US 2002108892 A1 | 15-08-2002 |
| | | WO 02065102 A2 | 22-08-2002 |
| EP 2082718 A2 | 29-07-2009 | EP 2082718 A2 | 29-07-2009 |
| | | KR 20090081992 A | 29-07-2009 |
| | | US 2009188937 A1 | 30-07-2009 |

# WRITTEN OPINION

| File No. | Filing date *(day/month/year)* | Priority date *(day/month/year)* | Application No. |
|---|---|---|---|
| SN62143 | 21.02.2014 | | NL2012310 |

International Patent Classification (IPC)
INV. A61J7/00 G01N21/95

Applicant
Global Factories Total Engineering and Manufacturing B.V.

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☐ Box No. VIII Certain observations on the application

| | Examiner |
|---|---|
| | Ong, Hong Djien |

# WRITTEN OPINION

## Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

## Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty | Yes: | Claims | 1-15, 23-25 |
| | No: | Claims | 16-22 |
| Inventive step | Yes: | Claims | 1-15, 24, 25 |
| | No: | Claims | 16-23 |
| Industrial applicability | Yes: | Claims | 1-25 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

# WRITTEN OPINION

## Box No. VII Certain defects in the application

see separate sheet

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following document:

D1 US 2002/108892 A1 (GOETZ ALEXANDER [US] ET AL) 15 augustus 2002 (2002-08-15)

2 The present application does not meet the criteria of patentability, because the subject-matter of claim 16 is not new.

2.1 Document D1 discloses (see alinea [0032] - [0041]; alinea [0057]; figuren 1-20; references in parentheses applying to this document):

> Inrichting (100) ingericht om geïndividualiseerde samengestelde doses van medicijnen te ontvangen en controleren overeenkomstig één der conclusies 1-15. (*)

(*) The receiving and checking step can be performed by the machine of D1. The delivery or packaging step is not mentioned in claim 16 and therefore document D1 is considered to take away the novelty of claim 16.

3 The present application does not meet the criteria of patentability, because the subject-matter of claim 17 is not new.

3.1 Document D1 discloses (see alinea [0032] - [0041]; alinea [0057]; figuren 1-20; references in parentheses applying to this document):

> Een inrichting (100) voor het ontvangen en controleren van geïndividualiseerde samengestelde doses van medicijnen, omvattende
>
> - een ontvangstgebied voor het ontvangen van een meervoudig aantal afgegeven medicijnen die een geïndividualiseerde samengestelde dosis (par. 47) van medicijnen vormen,

- een beoordelingsgebied met geautomatiseerde herkenningapparatuur (110) voor het beoordelen van de samenstelling van de geïndividualiseerde samengestelde dosis van medicijnen door middel van geautomatiseerde herkenning van de ontvangen medicijnen,

- een computer (135) die de beoordeelde samenstelling van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen controleert ten opzicht van een bestand voor de samenstelling van die geïndividualiseerde samengestelde dosis van medicijnen, en

- een afvoer die, als de uitkomst van de controle positief is, de ontvangen geïndividualiseerde samengestelde dosis van medicijnen afgeeft om te worden verpakt (suitable for) in een dosiscompartiment van een multidosiscompartimentverpakking, en als de uitkomst van de controle negatief is, de ontvangen geïndividualiseerde samengestelde dosis van medicijnen afgeeft anders dan om te worden verpakt (par 40) in een dosiscompartiment van de multidosiscompartimentverpakking.

4 Dependent claims 18-23 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of novelty and/or inventive step. See the same passages as mentioned in paragraph 3.1 above.

4.1 The features of claims 21 and 23 in particular, are considered to be minor constructional details which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims lacks an inventive step.

5 The combination of the features of dependent claims 24 or 25 is neither known from, nor rendered obvious by, the available prior art.

6 Claim 1 is considered to fulfill the requirements of Novelty and Inventive Step.

6.1 Document D1 is considered to implicitly disclose (see alinea [0032] - [0041]; alinea [0057]; figuren 1-20; references in parentheses applying to this document):

Werkwijze voor het ontvangen en het controleren van geïndividualiseerde samengestelde doses medicijnen, omvattende een herhaling van de stappen van

- ontvangen van een pluraliteit aan afgegeven medicijnen die een geïndividualiseerde samengestelde dosis medicijnen (par. 47) vormen,

- beoordelen van de samenstelling van de geïndividualiseerde samengestelde dosis medicijnen door middel van geautomatiseerde herkenningen (110) van de ontvangen medicijnen,

- controleren van de vastgestelde samenstelling van de ontvangen geïndividualiseerde samengestelde dosis medicijnen ten opzichte van een bestand (computer 135) voor de samenstelling van die geïndividualiseerde samengestelde dosis van medicijnen, en

- als de uitkomst van de controle positief is, afgeven van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen om te worden verpakt, en

- als de uitkomst van de controle negatief is, afgeven van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen anders dan om te worden verpakt.

6.2 The subject-matter of claim 1 therefore differs from this known method in that:

- als de uitkomst van de controle positief is, afgeven van de ontvangen geïndividualiseerde samengestelde dosis van medicijnen om te worden verpakt in een dosiscompartiment van een multidosiscompartimentverpakking,

and is therefore new.

6.3 The problem to be solved by the present invention may therefore be regarded as how to improve handling, packaging and transportation of the personalised prescriptions.

6.4 The method steps of claim 1 are considered to involve an inventive step, because although a multi-dosage compartment packaging is known from document D2, a skilled person would not combine this packaging into the apparatus of document D1. It is also not considered to be obvious for a skilled person with the knowledge of documents D1 and D2 to arrive at the claimed method.

7 Claims 2-15 depend on claim 1 and as such are also considered to be new and inventive.

## Re Item VII

### Certain defects in the application

1 Independent claims 1, 16 and 17 are not in the two-part form, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble and with the remaining features being included in the characterising part.

2 The features of the claims are not provided with reference signs placed in parentheses.