(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 February 2016 (04.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/016419 A1

(51) International Patent Classification:
B21G 1/08 (2006.01) *B24B 19/16* (2006.01)

(21) International Application Number:
PCT/EP2015/067634

(22) International Filing Date:
31 July 2015 (31.07.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14179238.2 31 July 2014 (31.07.2014) EP

(71) Applicant: **NOVO NORDISK A/S** [DK/DK]; Novo Allé, 2880 Bagsværd (DK).

(72) Inventor: **KRISTENSEN, Leif Engmann**; Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd (DK).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

WO 2016/016419 A1

(54) Title: NEEDLE TUBE AND METHOD OF PRODUCING INJECTION NEEDLES

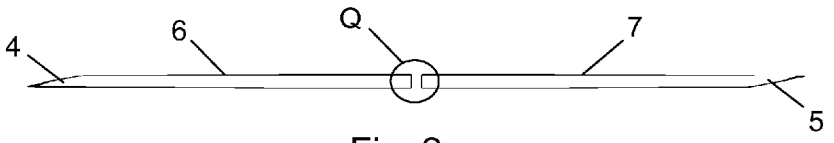

Fig. 2c

(57) Abstract: The present invention provides a method of manufacturing injection needles for use in pen needle assemblies. The method comprises grinding a first end portion (2) of a needle tube (1) to produce a first sharpened tip (4), grinding a second end portion (3) of the needle tube (1) to produce a second sharpened tip (5), and dividing the needle tube (1) between the first sharpened tip (4) and the second sharpened tip (5), thereby providing two injection needles (6, 7). The invention furthermore provides a needle tube.

NEEDLE TUBE AND METHOD OF PRODUCING INJECTION NEEDLES

FIELD OF THE INVENTION

The present invention relates to methods of producing injection needles for use in medical needle assemblies such as pen needle assemblies.

BACKGROUND OF THE INVENTION

Injection needles are widely used in the medical area to deliver medicaments to specific body sites. For example, within the treatment of diabetes mellitus pen needle assemblies are oftentimes used with injection pens for subcutaneous administration of various glucose regulating agents. A pen needle assembly includes an injection needle and a needle hub having means for attachment to an injection pen. The injection needle is typically fixed to the needle hub so as to enable skin penetration by the one needle end and penetration of a cartridge septum by the other needle end.

In the diabetes care segment one important characteristic of pen needle assemblies is the length of the front needle which is the portion of the injection needle that is inserted into the skin to deliver the given agent. State of the art pen needle assemblies offer front needle lengths in the range of 4mm-12mm with the smaller lengths becoming increasingly preferred.

Other important characteristics of these pen needle assemblies are the needle gauge and the resistance to flow through the injection needle. The higher the needle gauge the smaller the outer diameter of the injection needle, and the smaller the outer diameter of the injection needle the lower the frequency of painful injections. A high needle gauge is thus preferable from a comfort perspective.

However, the resistance to flow through the injection needle is i.a. proportional to the length of the needle and inversely proportional to the inner diameter to the fourth power. This means that the higher the needle gauge and the longer the needle the poorer the flow properties of the needle, and thereby the greater the force needed to convey a medicament through the needle lumen. A high needle gauge is thus not preferable from an effort perspective.

One compromising solution to this apparent paradox is to use a split needle arrangement comprising a separate skin penetrating needle with a high needle gauge and a back needle with a smaller needle gauge. The medicament will thus flow a shorter distance through a small lumen, whereby the flow resistance is reduced while the desired small outer dimension of the skin inserted needle portion is maintained.

US 8,608,710 (Becton Dickinson & Company) discloses a serial arrangement of two needle cannulas with different needle gauges in a pen needle assembly. The thinner of the needles is adapted to enter the body of the user, while the other is adapted to establish fluid access to a medicament container. Both needles are separate elements that are fixed to a needle hub.

US 6,843,783 (Terumo Kabushiki Kaisha) provides a similar solution and further discloses an alternative version where the back needle is formed as an integrated portion of the needle hub.

Regardless of the particular embodiment, in such a split needle arrangement the skin penetrating needle is a separate needle element which is of approximately half the length of a conventional injection needle. Conventional injection needles as used in most state of the art pen needle assemblies have a length in the range of 14mm-16mm. These injection needles are processed by grinding the patient dedicated end so as to minimise discomfort during needle insertion and the container dedicated end so as to allow easy penetration of the container septum. This is done on grinding machinery which is designed to handle needle tubes of 14mm-16mm, and for which it may be difficult or impossible to handle needle tubes of half that length.

It is thus desirable to provide a method of manufacturing injection needles for use in needle assemblies employing separate skin penetrating and septum penetrating needle elements, which method does not require updated grinding machinery.

SUMMARY OF THE INVENTION

It is an object of the invention to eliminate or reduce at least one drawback of the prior art, or to provide a useful alternative to prior art solutions.

In particular, it is an object of the invention to provide a method of manufacturing injection needles suitable for use in dual gauge pen needle assemblies.

It is a further object of the invention to provide a method of manufacturing such injection needles, by which method an update of existing grinding machinery can be avoided.

In the disclosure of the present invention, aspects and embodiments will be described which will address one or more of the above objects and/or which will address objects apparent from the following text.

In a first aspect of the invention a method of manufacturing injection needles is provided, the method comprising step (i) grinding a first end portion of a needle tube to produce a first sharpened tip, step (ii) grinding a second end portion of the needle tube, opposite the first end portion, to produce a second sharpened tip, and step (iii) dividing the needle tube between the first sharpened tip and the second sharpened tip, thereby providing two injection needles.

Step (ii) may be carried out simultaneously with or subsequent to step (i), but, importantly, step (iii) is carried out subsequent to both step (i) and step (ii) to allow the needle tube to be ground completely before division. Thereby, e.g. a 14mm needle tube may be ground on existing grinding machinery and then divided afterwards to provide two injection needles suitable for use as needle elements in respective needle assemblies.

The needle tube may be divided a predetermined distance from the first sharpened tip to provide desired needle lengths. In particular, the needle tube may be divided midway, or substantially midway, between the first sharpened tip and the second sharpened tip. Thereby, two injection needles of equal, or substantially equal, lengths are provided which can both be used in the production of a specific needle assembly model. Alternatively, the needle tube may be divided such that the one injection needle is noticeably longer than the other, enabling use of the two injection needles in the production of different needle assembly models.

The needle tube may extend along a longitudinal axis between the first end portion and the second end portion, and step (iii) may comprise dividing, e.g. cutting, the needle tube perpendicularly, or at least substantially perpendicularly, to the longitudinal axis to provide two injection needles which may each be easily fitted in fluid communication with another needle element. Alternatively, step (iii) may comprise dividing the needle tube at an angle to the longitudinal axis differing from 90°. For example, by cutting the needle tube at an acute angle to the longitudinal axis, which acute angle is in the range [25°; 30°], needle ends may be obtained which are particularly suitable as back needle ends for easy penetration of reser-

voir closures, such as e.g. self-sealing rubber septa. The present method is thus also applicable in general to produce injection needles of conventional lengths in a manner which eliminates, or at least reduces, the need for separate, dedicated back needle processing steps, ensuring a less costly manufacturing.

The first end portion and the second end portion may be ground identically, e.g. to provide for the establishment of identical skin penetrating needle portions. This enables use of both injection needles in the same type of needle assembly and may enable a faster and more cost efficient mass production of the injection needles. Alternatively, step (i) and step (ii) may provide sharpened tips of different configurations.

In particular, at least one of the first sharpened tip and the second sharpened tip may be multi-bevelled, e.g. produced by three or more grinds resulting in three or more distinct bevels, to provide for easy and painless penetration of a user's skin.

The needle tube may be provided as a separated piece of a longer tube. Accordingly, a tubing may initially be divided into a plurality of needle tubes, whereafter at least some of said needle tubes undergo the manufacturing steps described above. The plurality of needle tubes thus initially provided may be of equal length or of a limited number of different lengths, depending on the desired production set-up.

In a second aspect of the invention a method of manufacturing an injection needle assembly is provided, the method comprising arranging an injection needle produced by a method as described in the above in connection with the first aspect of the invention in a retaining portion of a needle hub such that (a) the injection needle protrudes from the retaining portion in a distal direction, and (b) the injection needle is in fluid communication with a hollow piercing member extending from the retaining portion in a proximal direction.

Thereby, a needle manufactured according to the above described first aspect of the invention is coupled to a needle hub to provide a complete needle assembly which can be attached to a needle mount of an injection pen.

In a third aspect of the invention a method of manufacturing an injection needle assembly is provided, the method comprising arranging an injection needle produced by a method as described in the above in connection with the first aspect of the invention in a retaining portion of a needle hub such that (a) the injection needle protrudes from the retaining portion in a distal direction, and (b) the injection needle is in fluid communication with a coupling por-

tion of the needle hub, which coupling portion is adapted to receive a hollow piercing member.

Thereby, a needle manufactured according to the above described first aspect of the invention is coupled to a needle hub which is further capable of receiving a second piercing element for the provision of a complete needle assembly.

In the case where the first end portion and the second end portion are ground identically an intermediate product in the form of a double-ended needle tube with identical ends is arrived at before initiation of step iii).

Accordingly, in a fourth aspect of the invention a needle tube is provided comprising a first end portion comprising a first sharpened tip and a second end portion comprising a second sharpened tip, wherein the first sharpened tip and the second sharpened tip have identical configuration.

This intermediate product may e.g. be placed on a shelf for a time period, allowing the manufacturer to prepare multiple double-ended injection needles, while postponing a decision on where and/or how to divide them. This may, for example, be beneficial in case the specific types of needle assemblies for which the injection needles are intended are yet to be decided on.

In exemplary embodiments of the invention the first sharpened tip and the second sharpened tip each comprises three distinct bevels.

In the present context when end portions are "ground identically" or when sharpened tips or ends have "identical configuration" this means that the respective end portions or tips have been processed to obtain the same shape. Notably, the shape is independent of the angular orientation of the processed end portion about the longitudinal axis. For example, if the first sharpened tip has three distinct bevels, each of these bevels is at a respective angle of inclination to each of the other two bevels and to a first imaginary plane containing the longitudinal axis. The second sharpened tip then has three distinct bevels which are each at the same respective angles to the other bevels and to a second imaginary plane containing the longitudinal axis than the corresponding bevel of the first sharpened tip. However, the second imaginary plane need not be angularly aligned with the first imaginary plane.

In the present context of use of a needle assembly the term "proximal", or "proximally", refers to a portion, position or direction opposite or away from the insertion site, whereas "distal", or "distally", conversely, refers to a portion, position or direction close to or towards the insertion site.

In the present specification, reference to a certain aspect or a certain embodiment (e.g. "an aspect", "a first aspect", "one embodiment", "an exemplary embodiment", or the like) signifies that a particular feature, structure, or characteristic described in connection with the respective aspect or embodiment is included in, or inherent of, at least that one aspect or embodiment of the invention, but not necessarily in/of all aspects or embodiments of the invention. It is emphasized, however, that any combination of the various features, structures and/or characteristics described in relation to the invention is encompassed by the invention unless expressly stated herein or clearly contradicted by context.

The use of any and all examples, or exemplary language (e.g., such as, etc.), in the text is intended to merely illuminate the invention and does not pose a limitation on the scope of the same, unless otherwise claimed. Further, no language or wording in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with references to the drawings, wherein

Figs. 1 is a cross sectional view of a conventional pen needle assembly,

Fig. 2a is a side view of an unmodified needle tube to be processed in accordance with the present invention,

Fig. 2b is a side view of the needle tube following the initial process steps,

Fig. 2c is a side view of the final result of the processing,

Fig. 2d is an enlargement of section Q of Fig. 2c, showing the needle tube divided perpendicularly to its longitudinal axis,

Figs. 2e and 2f are views similar to that of Fig. 2d, showing exemplary other separation angles for the needle tube, and

Fig. 3 is a cross sectional view of a needle assembly including an injection needle produced by the method according to the present invention.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following relative expressions, such as "upwards" and "downwards", are used, these refer to the appended figures and not necessarily to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only.

Fig. 1 is a cross sectional view of a typical pen needle assembly 10 of the prior art. The pen needle assembly 10 comprises a needle hub 11 with a central retaining portion 12 to which an injection needle 15 is securely fixed, and an internally threaded collar 13 for engagement with a mating thread on a needle mount of a pen injector (not shown). The injection needle 15 comprises a sharpened front needle portion 16 adapted for insertion through a human skin barrier and a sharpened back needle portion 17 adapted for penetration of a septum of a drug containing cartridge. The needle hub 11 further has an abutment surface 14 for abutment with a skin portion surrounding the insertion site.

Fig. 2a is a side view of a needle tube 1 to be processed in accordance with the present invention. The needle tube 1 is a hollow cylindrical structure extending longitudinally between a first end portion 2 and a second end portion 3.

Fig. 2b is a side view of the needle tube 1 following the initial process steps, showing a first sharpened tip 4 at the first end portion 2 and a second sharpened tip 5 at the second end portion 3. The sharpened tips 4, 5 have been produced identically by grinding in a manner conventionally known in the art of injection needle manufacturing.

Following the formation of the two sharpened tips 4, 5 the needle tube 1 is cut perpendicularly to the longitudinal axis midway between the first end portion 2 and the second end portion 3 to thereby produce two identical injection needles 6, 7. The end result is shown in Fig. 2c. Each of these injection needles 6, 7 may then be used in a pen needle assembly, e.g. as described below.

Fig. 2d is a close-up view of section Q of Fig. 2c, showing the ends of the needle tube 1, which are established by cutting at a right angle, α_1, to the longitudinal axis.

Figs. 2e and 2f show in a similar way the ends of respective needle tubes having been cut at different exemplary acute angles, α_2 and α_3, to the longitudinal axis. Particularly, α_3 may equal 28°, whereby the produced injection needles are automatically provided with a tip which is suitable for penetration of e.g. a rubber septum of a drug cartridge (not shown). This is relevant in case the produced injection needles are of a conventional length and intended for use in pen needle assemblies of the prior art type shown in Fig. 1.

Fig. 3 is a cross sectional view of a pen needle assembly 20 incorporating an injection needle 6 manufactured according to the present invention. The pen needle assembly 20 comprises a needle hub 21 of plastic having an integrated back cannula 27 pointed for penetration of a cartridge septum. The injection needle 6 is attached to a central retaining portion 22, by gluing, press-fitting, or other ways of attachment known in the art, such that a tight fluid communication is provided between the proximal end portion of the back cannula 27 and the sharpened tip 4. The needle hub 21 further has an internally threaded collar 23 for secure engagement with a needle mount of an injection device (not shown) and a distally oriented abutment surface 24 for abutment with a skin portion of a user.

The back cannula 27 is molded with the remaining portion of the needle hub 21 and has a larger lumen as well as a larger outer diameter than the injection needle 6. The pen needle assembly 20 is thus both relatively inexpensive to manufacture and offers a reduced flow resistance compared with the conventional pen needle assembly 10 illustrated in Fig. 1.

CLAIMS

1. A method of manufacturing injection needles, the method comprising:

(i) grinding a first end portion (2) of a needle tube (1) to produce a first sharpened tip (4),

(ii) grinding a second end portion (3) of the needle tube (1) to produce a second sharpened tip (5), and

(iii) dividing the needle tube (1) between the first sharpened tip (4) and the second sharpened tip (5), thereby providing two injection needles (6, 7).

2. A method according to claim 1, wherein step (iii) comprises dividing the needle tube (1) a predetermined distance from the first sharpened tip (4).

3. A method according to claim 2, wherein step (iii) comprises cutting the needle tube (1) midway between the first sharpened tip (4) and the second sharpened tip (5).

4. A method according to any of claims 1 – 3, wherein the needle tube (1) extends along a longitudinal axis, and

wherein step (iii) comprises cutting the needle tube (1) perpendicularly to the longitudinal axis.

5. A method according to any of claims 1 – 3, wherein the needle tube (1) extends along a longitudinal axis, and

wherein step (iii) comprises cutting the needle tube (1) at an acute angle to the longitudinal axis, the acute angle being in the range [25°; 30°].

6. A method according to any of the preceding claims, wherein step (i) comprises grinding the first end portion (2) in a predefined manner to obtain a first configuration of the first sharpened tip (4), and

wherein step (ii) comprises grinding the second end portion (3) in the predefined manner to obtain a second configuration of the second sharpened tip (5), which second configuration is identical to the first configuration.

7. A needle tube comprising:

- a first end portion comprising a first sharpened tip, and
- a second end portion comprising a second sharpened tip,

wherein the first sharpened tip and the second sharpened tip have identical configuration.

8. A needle tube according to claim 7, wherein the identical configuration is a multi-bevelled geometry.

9. A needle tube according to claim 8, wherein the multi-bevelled geometry comprises three distinct bevels.

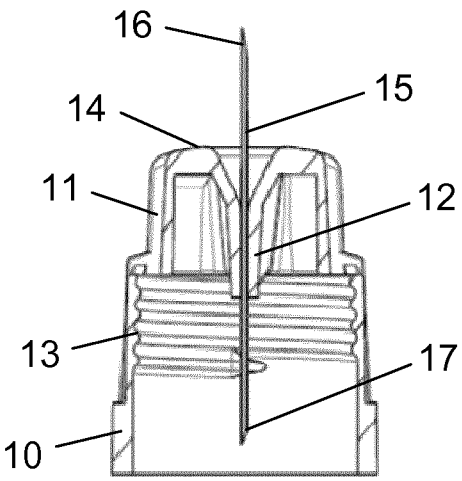

Fig. 1

Prior art

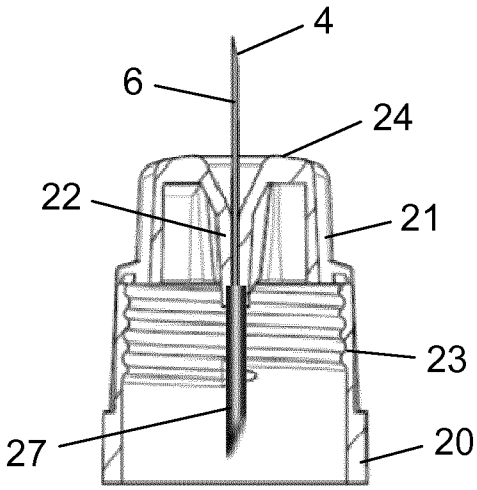

Fig. 3

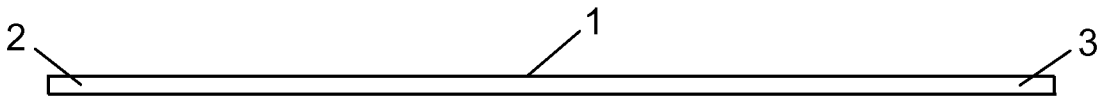

Fig. 2a

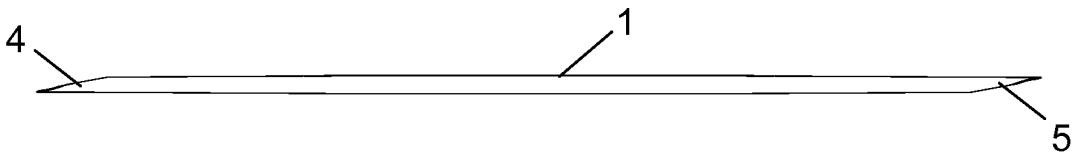

Fig. 2b

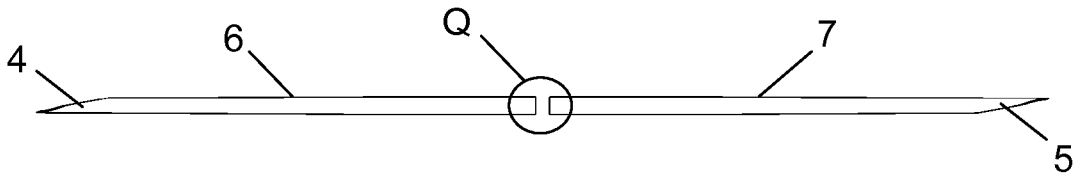

Fig. 2c

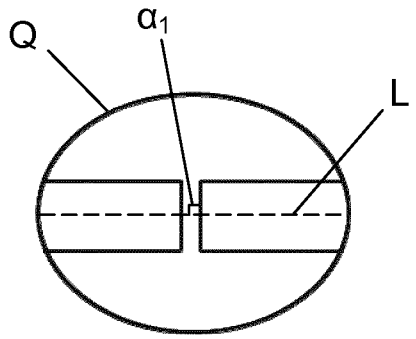

Fig. 2d

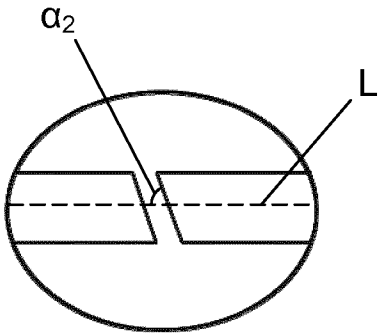

Fig. 2e

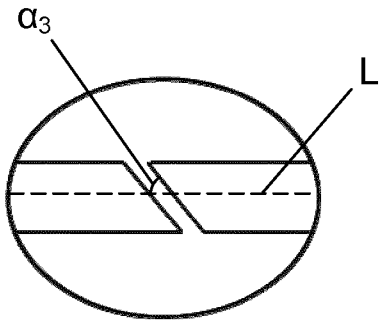

Fig. 2f

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/067634

A. CLASSIFICATION OF SUBJECT MATTER
INV. B21G1/08 B24B19/16
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B21G B24B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 015 338 A (HONG KEITH C [US] ET AL) 18 January 2000 (2000-01-18) the whole document	1-9
A	EP 2 740 417 A1 (IKEN KOUGYO KK [JP]; NAKAYAMA SHINICHIRO [JP]) 11 June 2014 (2014-06-11) paragraph [0057] - paragraph [0074]; figures 3A-3H	1-6
A	DE 18 12 450 A1 (QUALITEX DUNOD & CIE) 3 July 1969 (1969-07-03) the whole document	1
A	US 8 608 710 B2 (ZHAO YING [US]) 17 December 2013 (2013-12-17) cited in the application column 2, line 14 - column 3, line 3; figure 2	7

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 October 2015	23/10/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ritter, Florian

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/067634

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6015338 A	18-01-2000	NONE	
EP 2740417 A1	11-06-2014	CN 103747747 A	23-04-2014
		EP 2740417 A1	11-06-2014
		JP 5017483 B1	05-09-2012
		JP 2013034611 A	21-02-2013
		US 2014166225 A1	19-06-2014
		WO 2013021911 A1	14-02-2013
DE 1812450 A1	03-07-1969	BE 724356 A	02-05-1969
		DE 1812450 A1	03-07-1969
		FR 1556284 A	07-02-1969
US 8608710 B2	17-12-2013	CA 2759136 A1	09-06-2012
		EP 2462970 A1	13-06-2012
		JP 2012120844 A	28-06-2012
		US 2012150128 A1	14-06-2012