

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 14/893,783
Applicant: José de Jesús Delgado Carranza
Filed: 24/11/2015
Title: Method for the manufacturing glass containers for
pharmaceutical use
Art Unit: 1741
Examiner: Jason L. Lazorcik
Docket No.: 06650007US

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, José de Jesús Delgado Carranza, hereby declare and state that:

1. I have read and am familiar with the subject matter claimed in the above-identified U.S. patent application.
2. I hold a degree in Engineering and MBA from the ITSM (Institute Technologic of Monterrey).
3. I currently hold the position of plant manager.
4. I have over 35 years of experience with the manufacturing of glass type I for pharmaceutical uses.
5. I have reviewed the above-identified patent application, the Office communication mailed October 3, 2016.
6. I understand that the claims are objected for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor regards as the invention, and obvious over Ritt (US 4,516,998) in view of Modelle (US 3,150,953).

7. I understand that the Examiner considers that the limitation of "a mini-explosion" is a relative term, and that the specification does not provide a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would not be reasonably apprised the scope of the invention.

8. I understand that the Examiner considers that a "mini-explosion" is caused inside a tube which is closed at both ends and at the same time an end of the tube is opened, and that it is unclear how the end of the tube can simultaneously be open and closed as required by the claim.

9. It was state of the art before the publication of Ritt (US 4, 516,998) the manufacturing of ampules and vials from glass tubes in carousel machines with the tubes vertically positioned, operating either intermittently or continuously.

10. In the case of vials, on the automatic carousel machines, the glass tube was initially separated thermally at the lower end. This resulted in the forming of two closed ends, the lower one of which was discarded along with the short end piece of the tube, while the upper one was opened up again with a jet flame and a mouth for the vial was formed there. Following that, the tube was constricted sharply at a point along its vertical height corresponding to the length of a vial and was melted thoroughly, whereby closed ends were produced on the now separated first vial and the remaining part of the tube. By means of a jet flame, the closed end on the remaining part of the tube was opened up, whereupon the above described operational steps were repeated on the remaining glass tube.

11. In the case of ampules, for example, first ampule was formed on the lower end of the tube. The ampule was produced with its opening on the top i.e. the bottom end of the ampule developed on the lower end of the glass tube. Initially, however, the tube was softened at a point along its vertical height corresponding to the ampule length, and drawn out to form the spike of the ampule. Shoulder and bulb were formed at this point, and at the end of the spike, the tube was melted through, forming a closed end on the remaining tube. The above described operational steps were then repeated on the remaining glass tube.

12. In the art, it is known that these production methods for vials and ampules have disadvantages. A particularly serious problem, especially in the vial production, is

that it is often unavoidable that combustion gases, oil vapors and light, volatile glass components are blo

13. wn into the interior of the glass tube during the opening of the closed end with a jet flame and deposited there.

14. Ritt provided a method for manufacturing glass containers, such as vials and ampules, which eliminate the described disadvantages, starting from glass tubes having both ends sealed. The novel method produced vials or ampules from a prepared length of tube, in such a way that during the course of the operational steps, no impurities could get inside the newly formed glass container or the remaining length of glass tube. This was achieved by using a glass tube with both ends closed and due to the fact that a slight excess pressure exists in the tube throughout the operational process, and produced an explosion, which prevented any impurities from entering.

15. In the art was known the way of producing a mini-explosion in the manufacturing of vials and ampules from the disclosure of Ritt. In fact the invention of Ritt was the provision of glass tubes closed at both ends in order to facilitate the generation of an excess pressure inside the tube, which would burst open. At this point, the mouth is simultaneously formed by opening the tube with the explosion.

16. In the process of the present invention it is used a glass tube closed at both ends, as in Ritt. In the process of the present invention the process is further improved to produce sterile glass containers having fewer impurities than those obtained according to the process disclosed in Ritt, as shown in the results of Example 3 included in the patent specification.

17. According to amended claim 1 the manufacturing method comprises the following steps (emphasis added):

- 1) providing a glass tube with a closed lower end and a closed upper end;
- 2) opening the lower end of the tube;
- 3) cutting a first length of tube so that the glass tube remains closed at its lower end;
- 4) discarding the first length of tube,
- a) a step in which a mini-explosion is caused inside a glass tube closed at both ends by heating the tube at the same time that the lower end of the tube is opened,

- 5) forming a glass container;
- 6) separating the formed glass container from the glass tube so that the lower end of the tube remains with the lower end closed,
- b) a step in which air is injected while the container is heated at its base to form the bottom of the container and to obtain the finished container,
- c) transporting the produced containers to an electric furnace, through a path that includes protective air curtains that protect the container from possible particles, the furnace is in a class "C" area, according to Mexican standard NOM-059 SSA, and, before introducing the containers in this class "C" area, an internal sweep is performed to the container with clean filtered air and with clean steam.

18. The mini-explosion that takes place in step a) inside a glass tube having both ends closed due to the over-pressure created by heating the tube through the burner (6), produces the opening of one end of the tube, which is also heated with a burner (5) to soften the lower part of the tube as seen in position (70). The heating with the burner (5) produces a softening of the lower part of the tube, which causes the thinning of the glass wall. The over-pressure generated by the burner (6) causes the burst of the thinner part of the tube, i.e. the lowest part of the tube heated with burner (5),

19. The use of glass tube with both closed ends as disclosed in Ritt and in the present case, does not imply automatically that an overpressure is created to generate an explosion to open the lower end of the tube. Many companies open the lower end of the tube simply by heating that end with a burner, without burst the lower end by an explosion, as in the known prior art methods disclosed in the background of the Ritt patent. In the claimed process, the overpressure and burst are created to obtain a glass container with fewer impurities as disclosed in Ritt, method which is further improved with the additional steps included in claim 1.

20. The claimed method, including the mini-explosion caused inside the glass tube in step a), in combination with the injection of air in step b) and with the internal sweep with clean steam of step c) in the specific zone A, provides glass containers, which do not need further cleaning or sterilization processes before being used by the manufacturers of pharmaceuticals. Glass containers manufactured according to the claimed method greatly simplify the process for filling and packaging sterile pharmaceuticals, by saving additional cleaning and sterilization treatments.

21. The claimed method represents an industrial advantage for companies manufacturing pharmaceuticals using sterile glass containers, in view of the methods disclosed in prior art.

22. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that those statements were made with the knowledge that willful, false statements and the like are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code, and such willful false statements may jeopardize the validity of any patents issued from the patent application.

Date: January 06th, 2017



José de Jesús Delgado Carranza