IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.:	6,536,188	Examiner:	Peter C. English
Reexam Control No.:	90/013,601	Art Unit:	3993
Inventor(s):	Thomas D. Taggart	Docket No.:	041989-0437534
Title:	APPARATUS AND METHOD FOR ASEPTIC PACKAGING		

Commissioner for Patents
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THIRD DECLARATION OF DR. SUDHIR SASTRY

I, Sudhir Sastry, Ph.D., declare as follows:

1. I received a Bachelor's degree in Agricultural Engineering from the Indian Institute of Technology, Kharagpur, India, in 1974.

2. I received a Master's degree in Agricultural Engineering from the University of Florida, Gainesville, Florida, in 1976.

3. I received a Doctorate in Mechanical Engineering from the University of Florida, Gainesville, Florida, in 1980.

4. I worked as an assistant professor and later as an associate professor in Agricultural Engineering and Food Science at Pennsylvania State University, University Park, Pennsylvania, from 1980 to 1987.

5. I began teaching at The Ohio State University, Columbus, Ohio, in 1987, and continue to work there presently.

6. I served as the Managing Director and The Ohio State University site Co-Director for the Center for Advanced Processing and Packaging Studies (A National Science Foundation Industry/University Cooperative Research Center) from 1999-2006.

7. I served as Interim Chair of the Department of Food, Agricultural and Biological Engineering at The Ohio State University in 2010-2011.

8. I have received many awards and honors including the Lumley Research Award, College of Engineering, The Ohio State University, 2009 Ohio Agricultural Research and Development Center (OARDC) Innovator of the Year Award, 2008 and Research and Development Award, Institute of Food Technologists, 1997.

9. In addition to my academic work I have worked as an industry consultant for numerous large food companies in the area of aseptic processing and packaging.

10. I have delivered over 90 invited presentations and talks on various food technology topics, including aseptic processing and packaging.

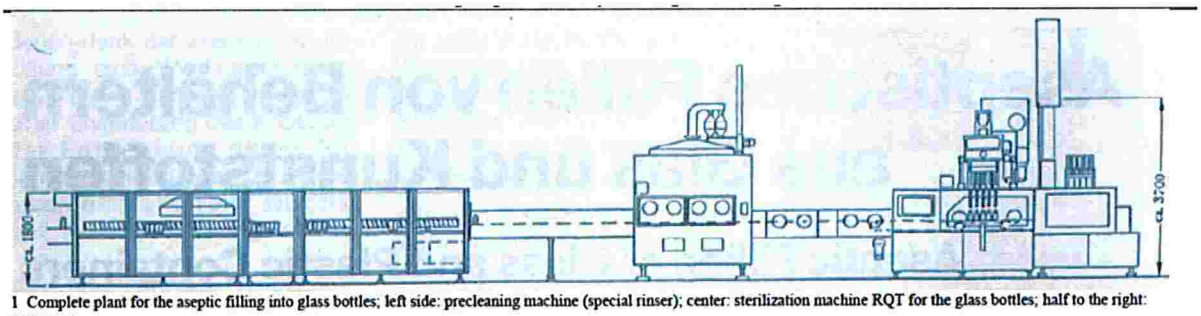
11. I am a named inventor on multiple food technology and processing patents and patent applications.

12. I have co-authored three books including *Aseptic Processing of Foods Containing Solid Particulates*, John Wiley and Sons, Inc. New York. (~248 pp). I have also authored and/or co-authored over 20 book chapters including: Process Evaluation in Aseptic Processing, Chapter 5 in *Developments in Food Preservation-5*, p. 177-206. Stuart Thorne, Ed., Elsevier Applied Science Publishers, Essex, England and Liquid-to-particle heat transfer coefficient in aseptic processing, Chapter 3 in *Advances in Aseptic Processing Technologies*, R.P. Singh and M.A. Wirakarakusumah, eds., pp 139-148, CRC Press Inc.

13. I have reviewed the Non-Final Office Action mailed by the Examiner on May 24, 2018, including the rejections identified in the Final Office Action. I have also reviewed U.S. Patent No. 6,536,188 (the "'188 patent"), including the reexamination certificate.

14. On page 31 of the Office Action, in discussing the reference referred to as Bosch 1990 states that "the tunnel connection the rinser and bottle sterilization machine is labelled as Transfer (sterile) in the top figure on the fourth page of Bosch 1990, which further reiterates the 'fully enclosed' nature of the system used by both Bosch 1990 and ZFL."

15. As I have previously stated in prior declarations, a person of ordinary skill in the art would not understand the transfer from the rinsing machine of ZFL to the bottle sterilizing to be enclosed in a tunnel. Rather, that transfer occurs through the environment of the plant. The figure from ZFL is set forth below:



1 Complete plant for the aseptic filling into glass bottles; left side: precleaning machine (special rinser); center: sterilization machine RQT for the glass bottles; half to the right: filling unit

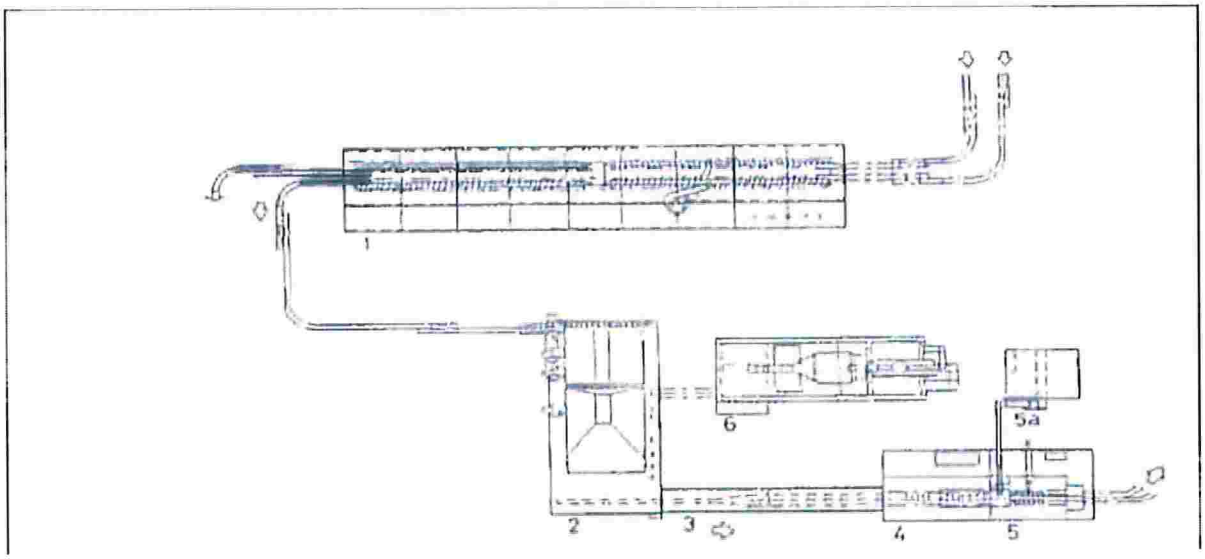
16. In the figure above, a key difference as between the tunnel connecting the bottle sterilization machine to the filling machine can be seen as compared to the conveyor connecting the rinser to the bottle sterilization machine. In particular, the tunnel connecting the bottle sterilization machine to the filler includes small holes that would be used as intervention points while not breaking sterility. In some cases, these are "glove boxes" that allow an operator to intervene and clear up a bottle jam, for example, without the need to shut down the machine and break sterility. The same intervention points do not exist on the connection between the rinser and the bottle sterilization machine. A person of ordinary skill in the art would understand from this, that the connection between the rinser and bottle sterilization machine is not enclosed with a tunnel. In fact, even if the conveyor were enclosed by some structure—which it is not—there would be

no point to using sterile air to create and overpressure because the sterile air could become contaminated and move microorganisms into the sterilization zone.

17. This understanding is confirmed by the other Bosch references that have been cited in the various patent office proceedings in which I have testified. For example, this understanding is confirmed by a reference known as Biewendt, which I addressed in a prior declaration.

18. Biewendt includes a description that explains that the bottles move from the bottle cleaning machine to the sterilization machine on a conveyor belt. Biewendt at 4. A conveyor belt would be understand to refer to exactly that – a conveyor belt. A person of ordinary skill in the art would not understand the conveyor belt to be covered by a housing. This is particularly the case where Biewendt later states that the conveyor belt on which the bottles are moved from the sterilization machine to the filling machine is enclosed by a housing, which is why they refer to that portion of the machine as the aseptic tunnel (Biewendt at 5).

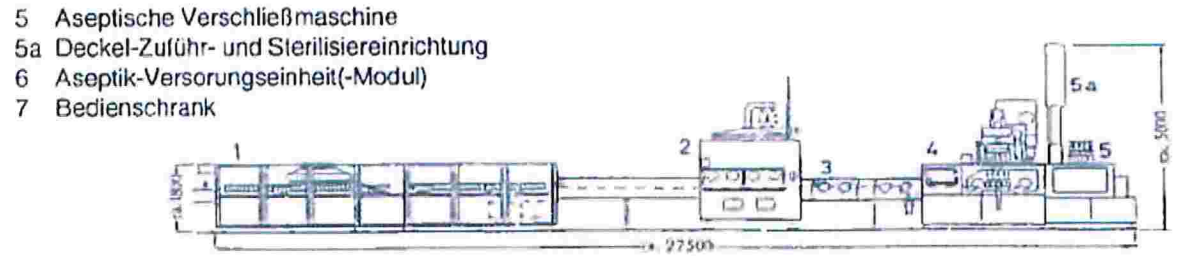
19. The figure below, which is a schematic showing the path the bottles follow through the plant illustrates the difference between the conveyor belt and the aseptic tunnel.



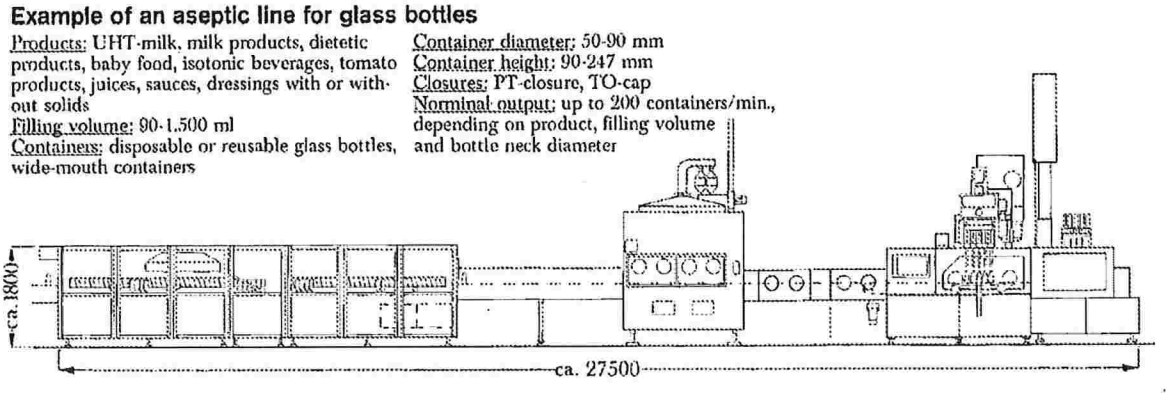
Ex. 3, Biewendt at 29.

20. Item 1 is the steam rinser. Ex. 2, ZFL at 2. The steam rinser is connected to a conveyor belt the transports the bottles to the bottle sterilization machine, which is Item 2. Ex. 2, ZFL at 2. Item 3 is the aseptic tunnel that transports to the filler and capper, labelled as Items 4 and 5. Ex. 2, ZFL at 2. There is a notable difference between the transport between the rinser and the sterilization machine and the transport between the bottles sterilization machine and the bottle filler and capper. That notable difference is a housing that is around the aseptic tunnel, Item 3, which is noticeably absent from the conveyor belt between the steam rinser and the bottle sterilization machine.

21. Biewendt actually includes the same figure as ZFL shown above, which is incuded below:



22. The Bosch 1990 reference cited in the Office Action also includes the same figure:

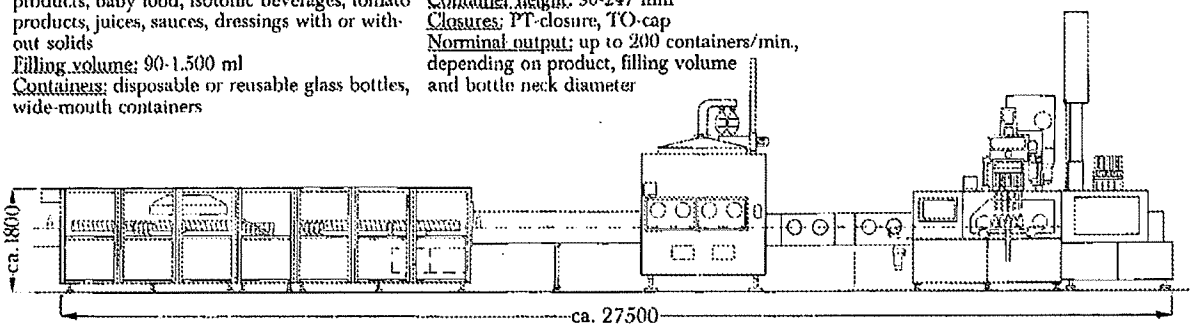


23. The reference Bosch 1992 reference attached to the Office Action includes the same figure:

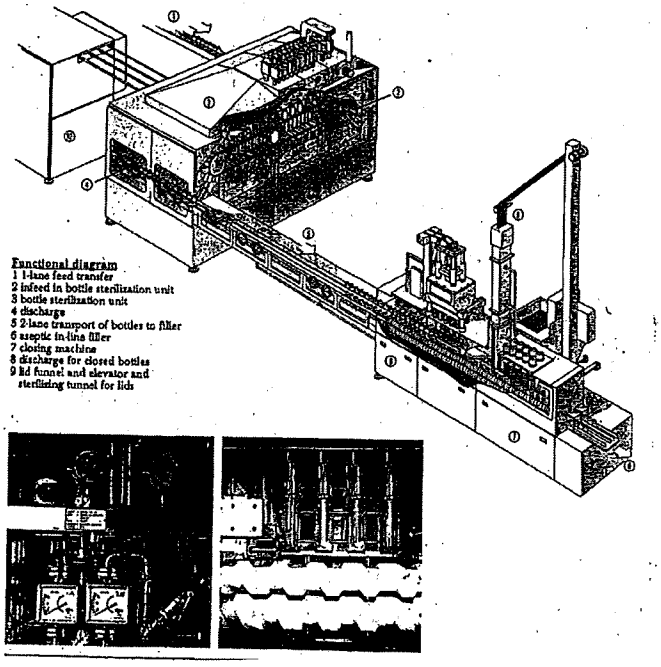
Example of an aseptic line for glass bottles

Products: UHT-milk, milk products, dietetic products, baby food, isotonic beverages, tomato products, juices, sauces, dressings with or without solids
Filling volume: 90-1.500 ml
Containers: disposable or reusable glass bottles, wide-mouth containers

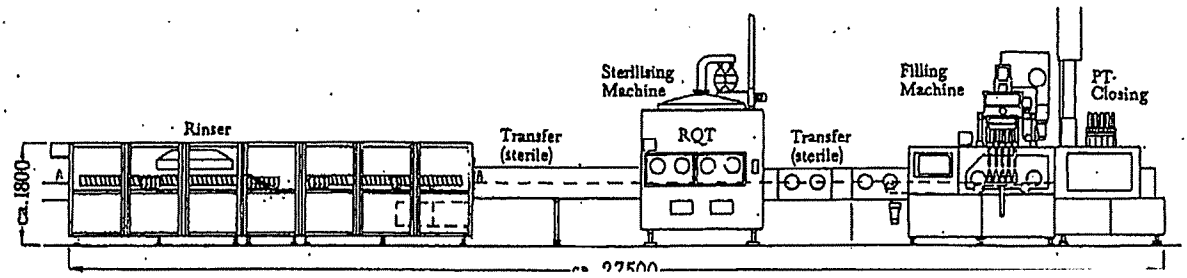
Container diameter: 50-90 mm
Container height: 90-247 mm
Closures: PT-closure, TO-cap
Norminal output: up to 200 containers/min., depending on product, filling volume and bottle neck diameter



24. The Bosch 1990 reference includes the figure below, which clearly shows the bottles entering the bottle sterilization machine in a manner such that they are exposed to the plant environment:



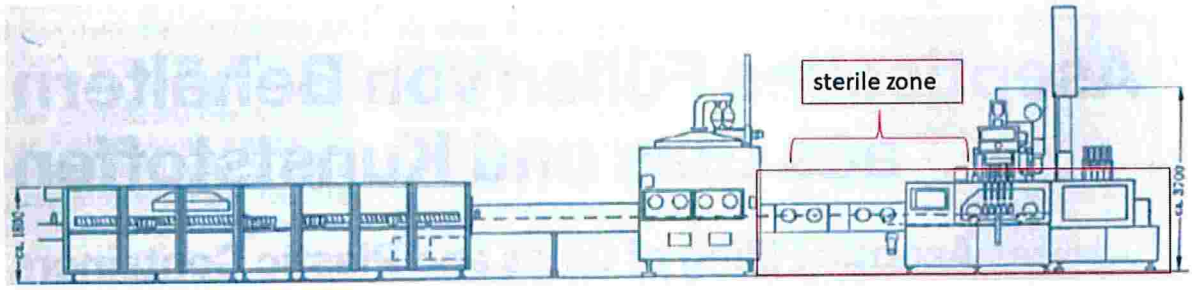
25. The only suggestion in any of the Bosch references I have reviewed in the numerous PTO proceeding that the transfer between the rinser and bottle sterilization machine is "sterile" is in the figure below cited in the Office Action:



26. Placed in the above context of the other Bosch references, including contrary disclosure in the Bosch 1990 reference, a person of ordinary skill in the art would infer one of two things: (1) the promotional brochure includes a typographical error; or (2) the machine referred to in this figure is materially different than the machine disclosed in every single Bosch reference. In my opinion, the first inference would be the most reasonable inference. From a design perspective it would make no sense to a skilled artisan to enclose the transfer between the rinser and bottle sterilization machine because the bottles are not sterilized until the sterilization machine. There is no reason to go through the costs and effort and keeping a transfer sterile where the item to be transferred is not sterile.

27. The Office Action further reason that the fact that ZFL and Bosch 1990 refer to "fully enclosed" systems demonstrates that the transfer between the rinser and the bottle sterilization machine is enclosed and sterile. Respectfully, the Office Action is misinterpreting what is meant by those statements. ZFL states: "This fully enclosed system, which is ventilated by sterile air at a slight overpessure, is free of unsterile transport media that may get into the system and works with packages and lid that are sterile on all sides; it provides a maximum level of safety and sterility." (ZFL at 4) And Bosch 1990 (at 2) states: ""During operation, there is a slight sterile air excess pressure in the sterile sections of the machine." These two statements do not mean that the transfer between the rinser and bottle sterilization are sterile.

28. Instead, they refer to the fact that the sterile portions of the machine are kept sterile with an overpressure of sterile air, which is exactly what Bosch 1990 says. It is well understood by a POSITA that the sterile zone starts after the bottles are sterilized. As a practical matter this generally takes place sometime during the bottle sterilization machine. But in the aseptic packaging art it is understood that the sterile zone usually begins after the bottle sterilization machine and includes the tunnel which transports the bottles to the filling and capping machines, which themselves are included the sterile zone. The annotated figure below shows the portion of the machine a person of ordinary skill in the art would understand to include the sterile zone.



29. ZFL's statement that: ""This fully enclosed system, which is ventilated by sterile air at a slight overpessure, is free of unsterile transport media…" does not change this understanding. A person of ordinary skill in the art would understand that statement to state that the sterile portions of the machine, which are free of unsterile transport media, are ventilated by sterile air at a slight overpressure. Neither the bottle rinser, nor bottle sterilization machine are free of unsterile transport media. Instead, they—by design—include nonsterile media, i.e. the bottles which have not yet been made sterile. The same is true for the connection between the rinser and the bottle sterilization. As the bottles move from the rinser to the sterilization machine, they are yet to be sterilized. Simply put, a person of ordinary skill in the art would not understand that connection to be free of unsterile transport media. As a result, a person of ordinary skill in

the art would not understand ZFL to suggest that the transfer between the rinser and the bottle sterilization is ventilated by an overpressure of sterile air.

30. The understanding of a person of ordinary skill in the art is confirmed by the Biewendt reference (at 18), which explains:

> **The housing in which the sterilized bottles are transported, filled and sealed, which is encapsulated from the atmosphere and sterilized under defined conditions, is loaded with sterile air until production is completed; the pressure of said air is kept approx. 20 Pa above the atmospheric pressure. In that way, a contamination of the bottles and the milk with ambient air during transport as well as filling and sealing is effectively prevented.**

31. It is the housing in which the sterilized bottles are transported, filled and sealed, that is sterile and ventilated with sterile air—not the portions of the machine that come before it.

32. The Examiner cites to the Willhoft reference for its statement that "bottles (both glass and plastic) are sterilized with a mixture of peroxide and peracetic acid, known as 'Oxonia.'" Office Action at 11. A person of ordinary skill in the art would understand Willhoft's reference (Willhoft at E48) to "Oxonia," to most likely be referring to Oxonia Activ, which was the predominant form of oxonia used throughout the world. This is consistent with the Blakistone reference, which discloses tests conducted with "Oxonia Active." Blakistone at 262. Both the Willhoft reference and Blakistone capitalize the "O" in Oxonia, which suggests that they are both referring to the same brand of oxonia. Indeed, oxonia has now become a commonly used term for any mixture of hydrogen peroxide and peracetic acid largely because "Oxonia Activ" was the first well-known brand of oxonia, much like Tylenol. In my experience around the 1999 time frame any reference to Oxonia would likely refer to Oxonia Activ.

33. The Office Action cites to the following portion of ZFL:

> **Before aseptically refilling multi-way glass bottles, these have to be cleaned in the usual way and then examined for their integrity. Trials conducted by the Fraunhofer Institute of Food Technology and Packaging in Munich have resulted in a germination level typically below 10 germs per bottle, even in previously heavily contaminated bottles.**
> **Our own cleaning tests using inoculated bottles with germ concentrations of 10^4 - 10^6 resulted in an average germ number of 3 per bottle, with extreme values reaching almost 100, after the cleaning process using a commercial bottle cleaning plant. Such germinations can indeed be handled by our method. Inserting a rinser provides additional safety.**

34. The Office Action quotes a portion of the foregoing: "[G]erm concentrations of 10^4–10^6 … can indeed be handled by our method." The Office Action asserts that this confirms that ZFL teaches a 6 log reduction in spore organisms. Respectfully, the Office Action has misinterpreted this portion of ZFL. When the entire portion of ZFL is read, it is clear to a person of ordinary skill in the art that ZFL uses the rinser to clean bottles with starting germ loads of 10^4–10^6. As a result of the cleaning there is an average of three germs per bottle and in some cases 100 germs per bottle. The reduction in organisms is achieved by the rinser. And in no case discussed in ZFL does the rinser obtain a 6 log reduction. Instead, it can achieve at best a 5 log reduction (starting population of 1,000,000 reduced to 3) and in some cases only a 2 log reduction (starting population of 10,000 reduced to 100 organisms).

35. For my efforts in connection with the preparation of this declaration I have been compensated at my standard hourly rate for this type of consulting activity. My compensation is

no way contingent on the results of these or any other proceedings relating to the above-captioned patent.

36. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the results of these proceedings.

Date: August 24, 2018

Sudhir K. Sastry Ph. D