

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DENTAL RECYCLING NORTH AMERICA, INC.,
Petitioner

v.

SOLMETEX, LLC
Patent Owner

Patent No. 11,660,175

Post Grant Review No. PGR2023-00055

DECLARATION OF CHARLES A. GARRIS, JR., PH.D.

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I, Charles A. Garris, Jr., Ph.D., declare as follows:

1. I make this declaration based upon my own personal knowledge and, if called upon to testify, would testify competently to the matters stated herein.

2. I have been retained on behalf of Solmetex, LLC, (“Solmetex” or “Patent Owner”) as an independent expert consultant to provide this declaration concerning the technical subject matter relevant to U.S. Patent No. 11,660,175 (“the ‘175 patent”) in connection with a Post Grant Review (“PGR”) petition filed by Dental Recycling North America, Inc. (“DRNA” or “Petitioner”).

3. I am being compensated at my standard hourly rate of \$545 per hour for the time I spend on this matter. My compensation is not based on the content of my opinions or the resolution of this matter, and I have no other interest in this proceeding.

4. I am informed that Solmetex is asserting the ‘175 patent against DRNA in a related matter currently pending in the United States District Court for the District of Delaware (“the Delaware Litigation”).

5. In this declaration, I offer opinions relating to the ‘175 patent and the references in the Petition. The substance and bases of my opinions appear below.

I. BACKGROUND AND QUALIFICATIONS

6. In formulating my opinions, I have relied on my knowledge, training, and experience in the relevant field, which I will summarize briefly herein. In addition, Ex. 2011 is a true and correct copy of my *curriculum vitae* (CV).

7. I received a Bachelor of Engineering in Marine Engineering from the State University of New York, Maritime College in 1965, a Master of Science Degree in Mechanical Engineering from the State University of New York at Stony Brook in 1968, and a Ph.D. in Mechanical Engineering from the State University of New York at Stony Brook in 1971. I also served as a post-doctoral research faculty in the Mechanical Engineering Department of the Massachusetts Institute of Technology.

8. I joined the faculty at The George Washington University in 1978 as an Associate Professor. I am currently a tenured full Professor of Mechanical & Aerospace Engineering in the Department of Mechanical and Aerospace Engineering. I have held this position since 1984. In 2003–2004 I served as the Interim Department Chair in the Department of Civil and Environmental Engineering.

9. I am a registered Professional Engineer in the Commonwealth of Virginia. I am also registered by the U.S. Patent and Trademark Office as a Patent

Agent. I was formerly licensed by the U.S. Coast Guard as a steam and diesel engineer certified to serve on vessels of unlimited horsepower.

10. I am a Fellow of the American Society of Mechanical Engineers, a Fellow of the National Academy of Inventors, an Associate Fellow of the American Institute of Aeronautics and Astronautics, a member of the Society of Automotive Engineers, a member of the American Society for Engineering Education, a member of Sigma Xi, and a member of Pi Tau Sigma.

11. I have been granted a number of patents on my own inventions in the areas of controls, energy conversion, fluid mechanics, refrigeration, fuel cells, and turbochargers and have led research groups at George Washington University developing my inventions. I am the sole named inventor on the following U.S. Patent Nos.: 4,875,623, 4,696,598, 5,647,221, 6,138,456, 6,434,943, 6,663,991, and 7,497,666. I received the 2006 Thomas A. Edison Award from the American Society of Mechanical Engineers in recognition of my inventions.

12. From approximately 1988 through 1991, on a consulting basis, I was Director of Engineering for Speakman Innovations, a subsidiary of Speakman Corporation. Speakman Corporation is a leading manufacturer of shower valves for the hotel industry. I developed a new shower control, called the “Ultra Valve” which would have computer control of a shower valve and digital input by the user through an interface. Since the unit was placed in the harsh shower environment,

protection of the electronic components from water spray was essential. The effort resulted in two U.S. patents where I was the sole inventor (U.S. Patent Nos. 4,875,623 and 4,969,598).

13. I teach courses at George Washington University in heat and mass transfer, fluid dynamics, and energy conversion. Energy conversion includes many types of engines, power plants, and systems in which filtration and trapping of impurities and particulate matter is essential and the principles underlying these technologies are related to those used in the '175 patent. In connection with my teaching of mechanical engineering courses at George Washington University, I frequently instruct students on topics involving filtration, sedimentation, and particulate-liquid separation. I have had many years of formal training on the concepts of power plant operation, and filtration and separation of particulates and fluids are a fundamental requirement.

14. From my personal background, I come from a long line of dentists: my wife, my father, my grandfather, my great grandfather, and other family members have all been practicing dentists. Starting from early childhood, I helped my dentist family members in their operatories and labs and joined them in attending dental conventions. In fact, as a youth, I was encouraged to continue the family tradition and become a dentist. I spent many hours with my father discussing his methodologies and processes, including the use of amalgam fillings

and saliva ejectors, and have helped him to service his equipment. Although I did not follow the family tradition and did not formally study dentistry, I have always had a great interest in the dental processes and equipment and have acquired considerable knowledge of the profession and the technology. This also helps me understand the problems addressed by the '175 patent and the references in this case.

II. MATERIALS CONSIDERED

15. In forming the opinions set forth in herein, I have considered and relied upon my education, knowledge of the relevant field, and my experience. I have also reviewed and considered the '175 patent (Ex. 1001), the '175 patent's file history (Ex. 1002), and at least the following additional materials:

- DRNA's Petition for Post-Grant Review of the '175 Patent (Paper 2)
- Declaration of Dr. Jason Janét (Ex. 1003)
- Certified Translation of CN 102989232 to Liu et al. ("Liu," Ex. 1010)
- CA 2536902 to Boyd et al. ("Boyd," Ex. 1011)
- File History of U.S. Patent Application No. 16/941,522 (Ex. 2002)
- File History of U.S. Patent Application No. 16/033,823 (Ex. 2003)
- File History of U.S. Patent Application No. 15/730,828 (Ex. 2004)
- U.S. Provisional Patent Application No. 62/406,990 (Ex. 2005)
- U.S. Provisional Patent Application No. 62/414,712 (Ex. 2006)

- U.S. Design Patent No. D840,534 (Ex. 2007)

III. LEGAL STANDARDS

16. In forming the opinions set forth in herein, I have considered and relied upon my education, my work experience, my teaching experience, and my personal experience with the dental industry.

A. Claim Construction

17. I understand that claim construction is the process by which a court determines the scope and meaning of terms used in the claims of a patent. I understand that the goal of this process is to give claim terms the ordinary and customary meaning they would have had to a person of ordinary skill in the art (“POSITA”) at the time of the invention, after reading the patent and its prosecution history.

18. I understand that the patent specification may reveal a special definition given to a claim term by the patentee that differs from the plain and ordinary meaning it would otherwise have to a POSITA. In such cases, I understand that the patentee’s definition usually controls.

19. I understand that the prosecution history of a patent can inform the meaning of some claim language and that the prosecution history must be considered when construing the claims.

20. I understand that the court may consider extrinsic evidence, such as dictionaries, treatises, and expert opinions, to understand the technology at issue and the way in which claim terms would be understood by a POSITA in the relevant timeframe.

21. I understand that a dependent claim incorporates each and every limitation of the claim or claims from which it depends.

B. Anticipation

22. I understand that anticipation analysis is a two-step process. The first step is to determine the meaning and scope of the asserted claims. Each claim must be viewed as a whole, and it is improper to ignore any element of the claim. For a claim to be anticipated: (1) each and every claim element must be identically disclosed, either explicitly or inherently, in a single prior art reference; (2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim; and (3) the identical invention must be disclosed in the single prior art reference, in as complete detail as set forth in the claim. Where even one element is not disclosed in a reference, there is no anticipation.

23. I understand that to serve as an anticipatory reference, the reference itself must be enabled, i.e., it must provide enough information so that a person of ordinary skill in the art can practice the subject matter of the reference without undue experimentation.

24. I further understand that where a prior art reference fails to explicitly disclose a claim element, the prior art reference inherently discloses the claim element only if the prior art reference must necessarily include the undisclosed claim element. Inherency may not be established by probabilities or possibilities. The fact that an element may result from a given set of circumstances is not sufficient to prove inherency.

C. Obviousness

25. I understand that a patent claim is invalid under 35 U.S.C. § 103 as being obvious only if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in that art. An obviousness analysis requires consideration of four factors: (1) scope and content of the prior art relied upon to challenge patentability; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) the objective evidence of non-obviousness, such as commercial success, unexpected results, the failure of others to achieve the results of the invention, a long-felt need which the invention fills, copying of the invention by competitors, praise for the invention, skepticism for the invention, or independent development.

26. I understand that a prior art reference is proper to use in an obviousness determination if the prior art reference is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met. First, a prior art reference is analogous art if it is from the same field of endeavor as the claimed invention, even if the prior art reference addresses a different problem and/or arrives at a different solution. Second, a prior art reference is analogous art if the prior art reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

27. I understand that it must be shown that one having ordinary skill in the art at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded. Furthermore, I understand that a claim may be obvious in view of a single prior art reference, without the need to combine references, if the elements of the claim that are not found in the reference can be supplied by the knowledge or common sense of one of ordinary skill in the relevant art. However, I understand that it is inappropriate to resolve obviousness issues by a retrospective analysis or hindsight reconstruction of the prior art and that the use of “hindsight reconstruction” is improper in analyzing the obviousness of a patent claim.

28. I further understand that the law recognizes several guidelines that inform the obviousness analysis. First, I understand that a reconstructive hindsight approach to this analysis, i.e., the improper use of post-invention information to help perform the selection and combination, or the improper use of the listing of elements in a claim as a blueprint to identify selected portions of different prior art references in an attempt to show that the claim is obvious, is not permitted. Second, I understand that any prior art that specifically teaches away from the claimed subject matter, i.e., prior art that would lead a person of ordinary skill in the art to a specifically different solution than the claimed invention, points to non-obviousness, and conversely, that any prior art that contains any teaching, suggestion, or motivation to modify or combine such prior art reference(s) points to the obviousness of such a modification or combination. Third, while many combinations of the prior art might be “obvious to try,” I understand that any obvious to try analysis will not render a patent invalid unless it is shown that the possible combinations are: (1) sufficiently small in number so as to be reasonable to conclude that the combination would have been selected; and (2) such that the combination would have been believed to be one that would produce predictable and well understood results. Fourth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references uses known methods or techniques that yield predictable results, then that factor

also points to obviousness. Fifth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of known work in one field prompting variations of it for use in the same field or a different one based on design incentives or other market forces that yields predictable variations, then that factor also points to obviousness. Sixth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of routine optimization, then that factor also points to obviousness. Seventh, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of a substitution of one known prior art element for another known prior art element to yield predictable results, then that factor also points to obviousness.

29. I understand that each alleged prior art reference in a proposed obviousness combination must be evaluated in its entirety, i.e., including those portions that would argue against obviousness, and must be considered for everything that it teaches, not simply the described invention or a preferred embodiment. I understand that it is impermissible to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art, or to ignore portions of the reference that argue against

obviousness. I also understand that all of the supposed prior art to be combined as proposed must also be evaluated as a whole and should be evaluated for what they teach in combination as well as separately.

D. Dependent Claims

30. I understand that a dependent claim incorporates each and every limitation of the claim(s) from which it depends. Thus, my understanding is that if a prior art reference fails to anticipate an independent claim, then that prior art reference also necessarily fails to anticipate all of its dependent claims. Similarly, my understanding is that if a prior art reference or combination of prior art references fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all of its dependent claims.

IV. OVERVIEW OF THE ‘175 PATENT

31. The ‘175 patent is entitled “Detachable Recycling Container” and is generally directed to removing “particles from effluent waste, and particularly, to remov[ing] amalgam and other metallic particles and other abrasive solids from dental office suction effluent.” Ex. 1001, 1:35-37. More specifically, the ‘175 patent is directed to “a self contained recycling container to facilitate customer regulatory compliance and environmental safeguards.” *Id.*, 1:38-40.

32. The ‘175 patent explains that “[d]ental amalgam is a dental filling material used to fill cavities caused by tooth decay” and “has been used for more than 150 years in hundreds of millions of patients around the world.” Ex. 1001, 1:44-47.

33. Dental amalgam is a mixture of metals including mercury and a powered alloy including silver, tin, and copper. Ex. 1001, 1:48-50. The mercury accounts for approximately 50% of the amalgam by weight and is used to bind together the silver, copper, and tin particles to form the amalgam. *Id.*, 1:50-56. While new materials for dental fillings were available at the time of the invention, amalgam was still used (and continues to be used) in many cases because it is less costly and lasts longer than newer mercury-free alternatives. *Id.*, 1:57-62. Even though use of mercury-containing amalgam was declining, the inventors of the ‘175 patent recognized that “amalgams continue to make up a portion of the particle component of dental office effluent mainly because of the fact that old fillings made of amalgams are drilled out and removed in the effluent waste when new fillings are effected to replace the old.” *Id.*, 2:7-16.

34. The inventors recognized that it is desirable to remove dental amalgam and other particles from the dental office effluent before entering the waste/sewer line for several reasons. First, “mercury is a poison that can accumulate in living tissues and can pose a health hazard to species in a food

chain.” Ex. 1001, 2:17-19. The U.S. Environmental Protection Agency (EPA) has enacted regulations requiring amalgam separators in dental office, at least in part, to prevent mercury from being discharged into the environment. *Id.*, 2:46-47.

Second, “certain metals such as silver are commercially valuable if recovered in quantity.” *Id.*, 2:22-23. Third, other materials in the effluent, such as aluminum oxides used in air abrasion treatments “tend to wear out or damage vacuum pumps and other equipment downstream of the dental chair suction apparatus,” making it advantageous to remove such materials. *Id.* 2:27-32.

35. While certain prior amalgam separation systems existed, the inventors recognized and described several drawbacks and limitations associated with these systems. One prior amalgam separation system collects an entire day’s worth of waste in its collection tank via vacuum. Ex. 1001, 2:48-53. At the end of the day, this system’s vacuum needed to be turned off to transfer the waste to a separation device which separates metal particles from effluent liquid via gravity. *Id.*, 2:53-60. The flow rate from the collection tank to the separation device is proportional to the head of fluid in the collecting tank. *Id.*, 2:60-62. When the flow rate decreases, the separation rate is negatively affected, and the system becomes prone to plugging. *Id.*, 2:62-65. Additionally, because waste can only be transferred to the separation device when the vacuum is turned off at the end of the day, this prior

system requires an undesirably large collecting tank and separation device, causing the whole process to be time consuming. *Id.*, 2:65-3:3.

36. Another prior amalgam separation system “separates heavier metal particles from effluent liquid” via centrifuge. Ex. 1001, 3:4-7. However, this system “does not effectively separate lighter particles, and is expensive to purchase and operate due to the complexity of its mechanical parts.” *Id.*, 3:7-9.

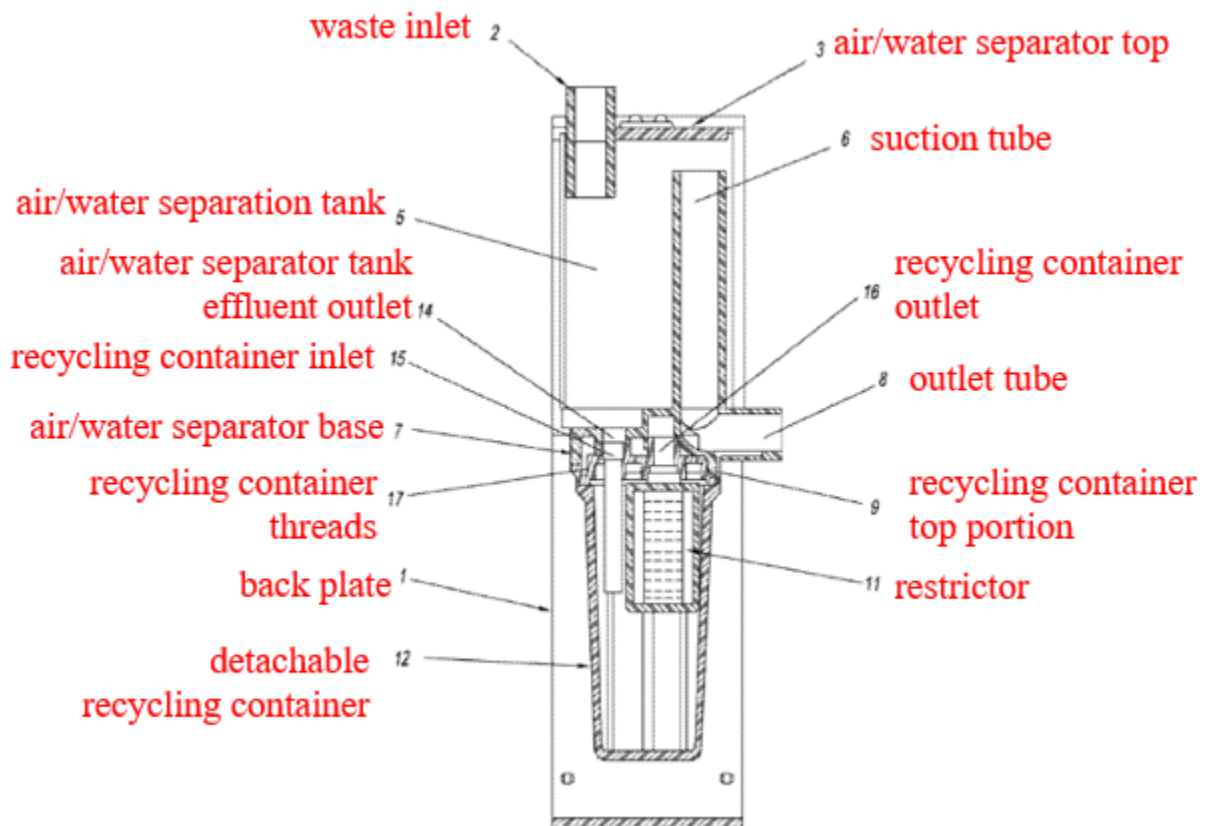
37. Yet another prior amalgam separation system uses a “mechanical pump to suction waste liquids through a separator device.” Ex. 1001, 3:10-11. This prior system can also “be expensive to purchase and to maintain, and can be undesirably” large. *Id.*, 3:12-13.

38. After amalgam and other solid waste is collected by an amalgam separation system, “the dentist is left with the problem of what to do with the waste.” Ex. 1001, 3:24-25. To properly dispose of the collected material, the “‘collection container’ needs to be disposable and easily replaceable.” *Id.*, 3:26-29. “It is important that the waste is recycled under federal guidelines in order to make sure the full benefits of amalgam separation are achieved.” *Id.*, 3:35-37.

39. Of note, it is desirable for the collection containers of any amalgam separation system to be installed and/or aligned correctly. Ex. 1001, 3:38-40. “[I]ncorrect installation or misalignment” of collection containers “can cause O-rings to deform and/or seal irregularly, and result in leakage.” *Id.*, 3:39-41.

40. FIG. 1 of the '175 patent (reproduced and annotated below) illustrates various components of the dental amalgam separation system and detachable dental amalgam container, including backplate 1, waste inlet 2, air/water separator top 3, air/water separation tank 5, suction tube 6, air/water separator base 7, outlet tube 8, recycling container top portion 9, restrictor 11, detachable recycling container 12, air-water separator tank effluent outlet port 14, recycling container inlet port 15, recycling container outlet port 16, and recycling container threads 17.

Ex. 1001, 5:31-52.



Ex. 1001, FIG. 1 (annotated)

41. Effluent from the dental chairs and air is sucked through an air-water separator tank inlet 2 and then into the air-water separator tank 5. Ex. 1001, 6:54-62. The liquid effluent passes out of the air-water separator tank 5 via air-water separator tank outlet port 14. *Id.* Air passes downstream via the air suction tube 6 while maintaining constant vacuum upstream of amalgam separator. *Id.*

42. The outlet port 14 passes effluent by gravity out of the air-water separator tank 5 and into the detachable recycling container 12 through the inlet port 15 for particle separation by sedimentation. Ex. 1001, 6:63-67. After the effluent passes through the recycling container inlet port 15 and through the container inlet conduit in the interior volume of the main body, solids settle and accumulate in the bottom of the detachable recycling container 12. *Id.*, 6:67-7:5. Liquid waste flows primarily by gravity, although intermittently assisted by vacuum through restrictor 11 which slows the flow rate of liquid to assist in sedimentation process. *Id.*, 7:5-9. Ultimately, “clean” effluent is discharged through the recycling container outlet port 16 on the container top portion 9. *Id.*, 7:9-11.

43. The recycling container outlet ports 16 and inlet port 15 can be a variety of shapes and sizes, such as square, oval, circular, or even more unusual shapes like a star. Ex. 1001, 7:12-14. Preferred ports are those that provide a tight

seal, allow for easy removal, and do not break. *Id.*, 7:14-16. Oval or circular are preferred embodiments, and circular is most preferred. *Id.*, 7:16-17.

44. A vacuum at the outlet tube 8 is generated when the vacuum pump is operating, thereby sucking air out of the air-water separator tank 5 via suction tube 6 while maintaining the vacuum upstream of the amalgam separator apparatus. Ex. 1001, 7:18-21. Effluent from the recycling container 12 passes through the restrictor 11 where remaining non-settable fine particles are removed from the effluent and into the recycling container outlet port 16 to be discharged from the apparatus via common outlet tube 8. *Id.*, 7:22-26. Matter sucked by the vacuum pump, generally free of removed solids, is discharged via vacuum pump into a municipal drain of the public sewage system. *Id.*, 7:26-28.

45. The specification explains that the “system is provided with a simple back plate 1 for easy dental office placement as well as removable retaining pins 13.” Ex. 1001, 7:29-31. As shown in FIG. 2, the air/water separation tank is attached to the back plate via a lower support bracket 10 and a top support bracket 4. *Id.*, 5:31-52.

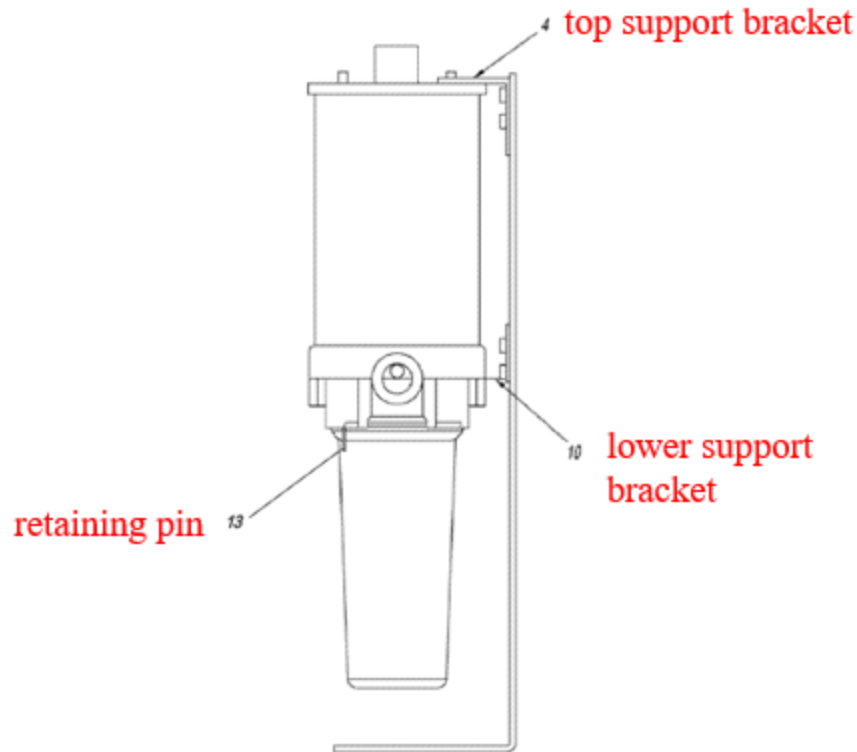
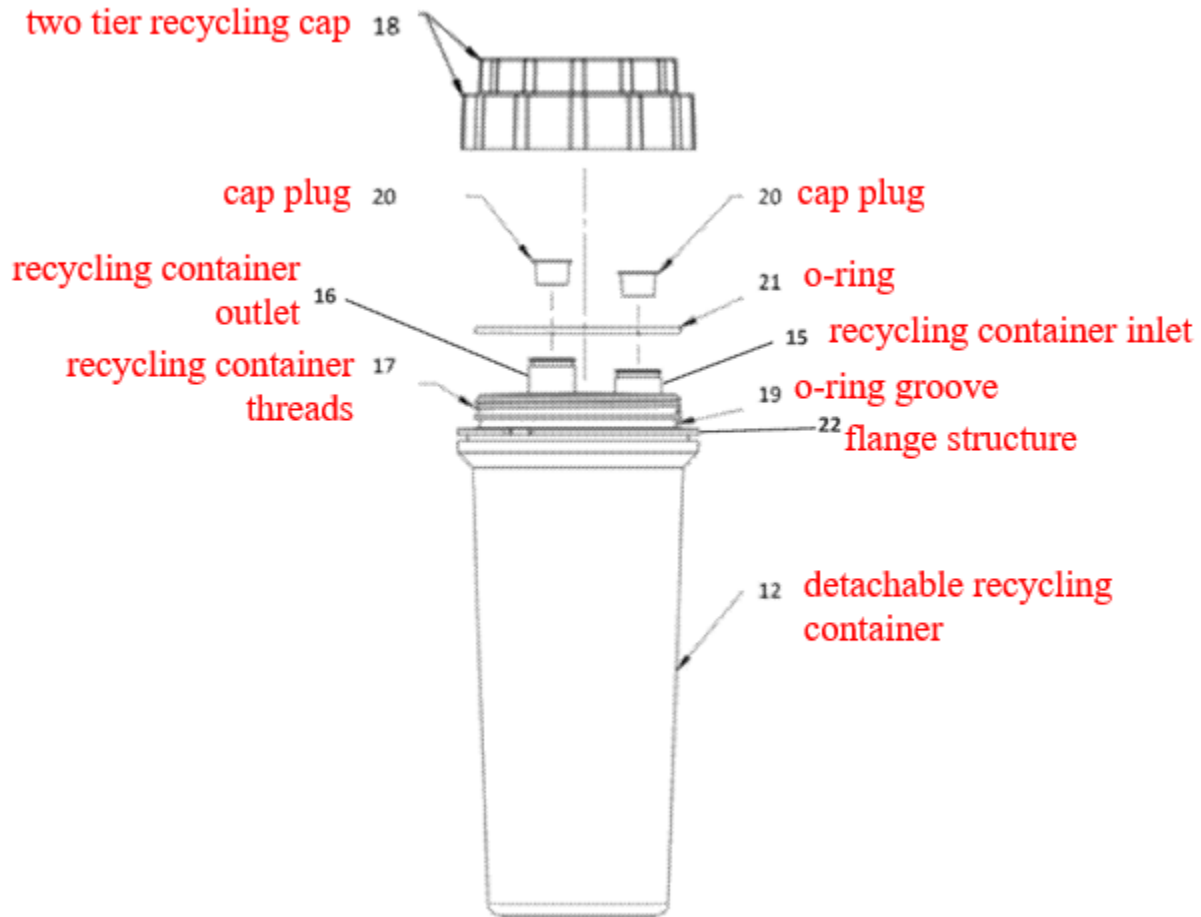


FIG. 2

Ex. 1001, FIG. 2 (annotated)

46. FIG. 4A of the '175 patent illustrates the detachable recycling container 12 and a cap 18. Ex. 1001, 7:59-61. "The cap 18 is a two tier shape to allow for a tight grip by both a big and smaller hand in order to achieve a strong seal as required by the invention." *Id.*, 7:61-63. Additionally, an "O-ring 21 is provided and fits into an O-ring groove 19 on the recycling container 12 above a flange structure 22 that protrudes radially away from the central axis of the main body of the recycling container 12." *Id.*, 7:64-67. The '175 patent also explains that the detachable recycling container can include "threads 17 built into the generally

cylindrical upper region of the container top portion 9 to enable the addition of a liquid tight top for shipping.” *Id.*, 7:48-52.

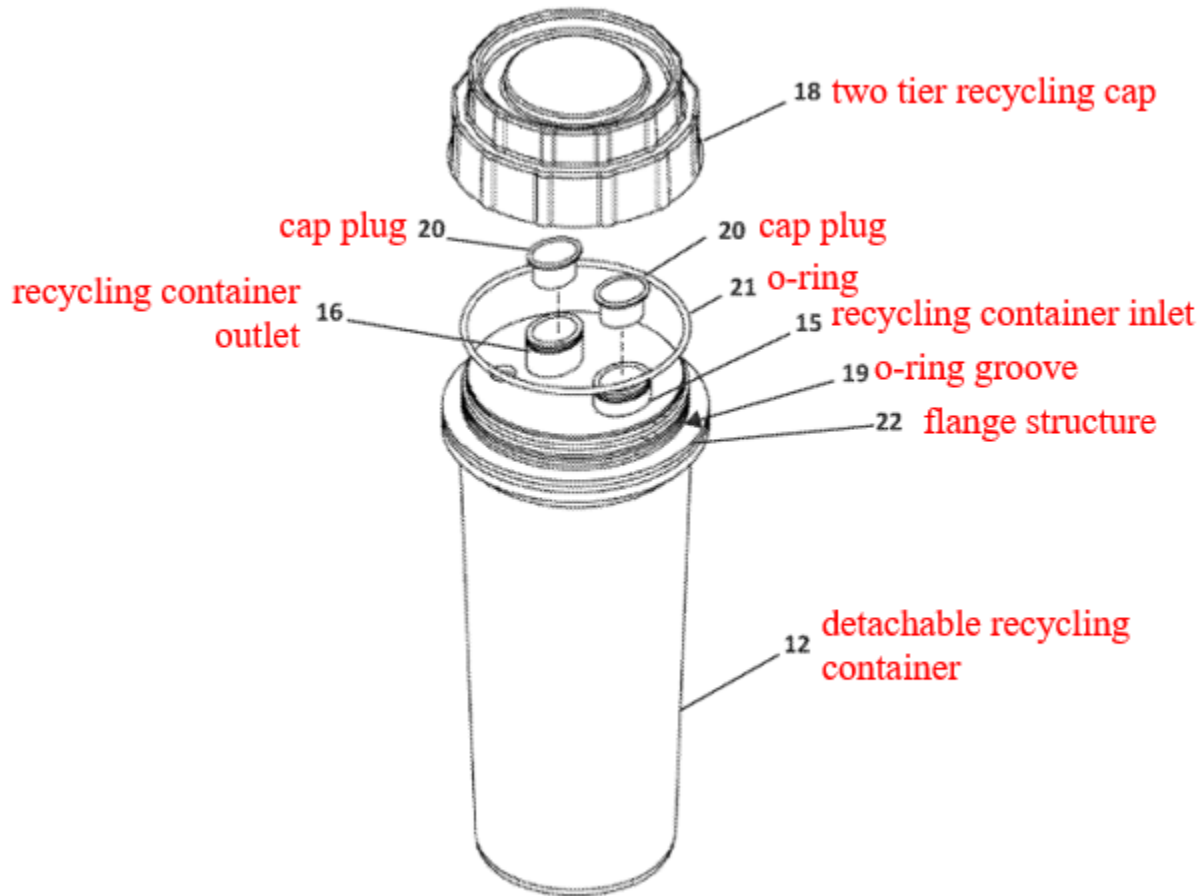


Ex. 1001, FIG. 4A (annotated)

47. As discussed above in connection with FIG. 2, the ‘175 patent discloses “removable retaining pins 13 that engage radially protruding structures of the recycling container to ensure the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system.” Ex. 1001, 7:30-34. In describing FIG. 4A, which shows the recycling container 12 and cap

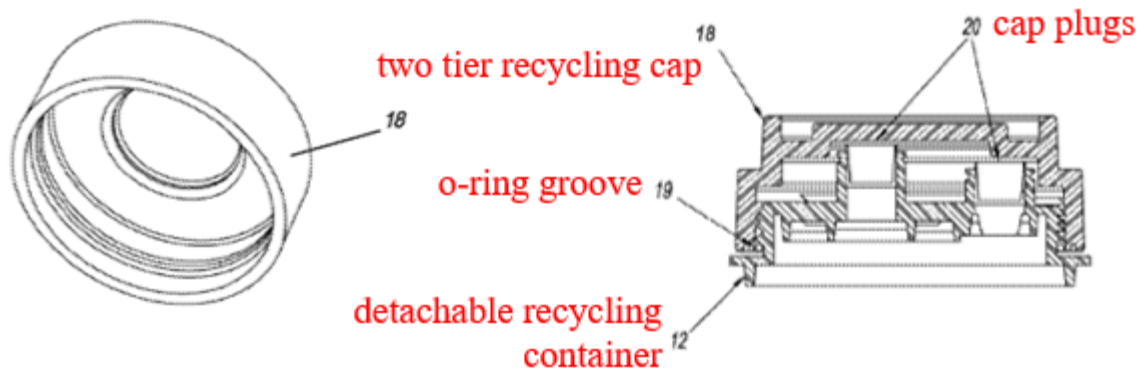
18, the '175 patent explains that the removable retaining pins 13 “fit within the region below the flange structure 22.” *Id.*, 7:67-8:2.

48. FIG. 4B is a perspective view that shows the same components as in FIG. 4A. Ex. 1001, 5:23-25.



Ex. 1001, FIG. 4B (annotated)

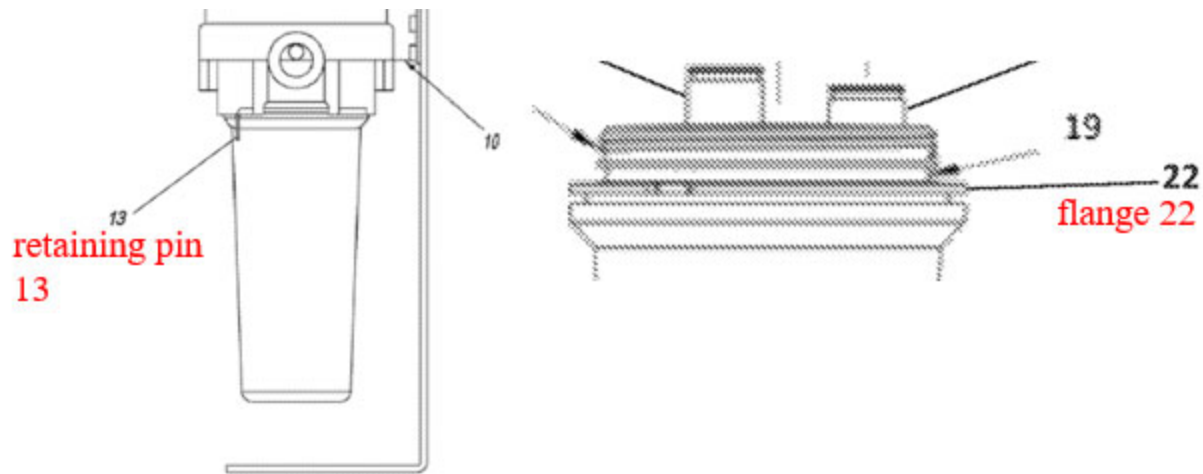
49. FIGS. 5A and 5B illustrate the two-tier cap 18, cap plugs 20, the detachable recycling container 12, and the o-ring groove 19. Ex. 1001, 5:26-30.



Ex. 1001, FIGS. 5A and 5B

50. The two plugs 20 seal the container inlet 15 and the container outlet 16. The cap 18 may be used to secure the plugs 20 when the cap 18 is threaded onto the recycling container 12 as depicted in FIGS. 5A and 5B. Ex. 1001, 8:2-6.

51. To attach the recycling container 12 to the separator tank 5, “removable retaining pins 13 . . . engage radially protruding structures of the recycling container.” Ex. 1001, 7:30-34. Specifically, “[t]he removable retaining pins 13, described above with respect to FIG. 2, fit within the region below the flange structure 22.” Ex. 1001, 7:67-8:2. These features in are shown in at least FIGS. 4A and 2, which are reproduced below:



Ex. 1001, FIGS. 2, 4 (excerpted and annotated)

52. The '175 patent includes 22 claims. Claims 1, 12, and 18 are independent claims. Independent claim 1 is reproduced below with claim identifiers added for ease of reference:

[1pre] A detachable dental-amalgam container for use with a dental amalgam separation system, the dental amalgam separation system having a system inlet for receiving dental amalgam effluent, an air-water separation tank for holding the dental amalgam effluent received from the system inlet, a system outlet, a vacuum source acting on the system outlet for moving fluid from the dental amalgam effluent toward the system outlet, and at least one retaining pin for use with the detachable dental-amalgam container, the detachable dental-amalgam container comprising:

- [1a]** a main body having a central axis and an interior volume for receiving the dental amalgam effluent from the air-water separation tank;
- [1b]** a container top portion located at a top of the main body, the container top portion including a generally cylindrical upper region having a circular upper surface from which a container inlet port and a

container outlet port extend away from the main body, the container outlet port being positioned nearer to the central axis of the main body than the container inlet port, the container inlet port being positioned nearer to a periphery of the circular upper surface than the container outlet port, the container top portion further including at least one radially protruding structure located below the generally cylindrical upper region, the at least one radially protruding structure for engaging the at least one retaining pin of the dental amalgam separation system to ensure the detachable dental-amalgam container does not become detached from the dental amalgam separation system when there is no pressure being applied from the vacuum source, the at least one radially protruding structure being located radially outward relative to the periphery of the circular upper surface;

[1c] a container inlet conduit extending downwardly from the container top portion and into the interior volume, the container inlet conduit being coupled to the container inlet port, the container inlet conduit and the container inlet port for transferring the dental amalgam effluent from the air-water separation tank to the interior volume of the main body; and

[1d] a restrictor located within the interior volume of the main body and fluidically coupled to the container outlet port, the restrictor configured to remove fine particles from the dental amalgam effluent as fluid from the dental amalgam effluent is moved toward the container outlet port due to the vacuum source.

V. PROSECUTION HISTORY OF THE ‘175 PATENT

53. The ‘175 patent was filed as U.S. Patent Application No. 17/965,556 (“the ‘556 Application”) on October 13, 2022. Ex. 1002, 187.

A. The ‘556 Application’s Priority Claims

54. The ‘556 Application is a continuation of U.S. Patent Application No. 16/941,522, which was filed on July 28, 2020 (hereinafter, “the Parent ‘522 application”).

55. The Parent ‘522 Application is a continuation-in-part of U.S. Patent Application No. 16/033,823, which was filed on July 12, 2018 and issued as U.S. Patent No. 10,779,923 (hereinafter, “the Grandparent ‘823 Application”).

56. The Grandparent ‘823 Application is a continuation-in-part of U.S. Patent Application No. 15/730,828, which was filed on October 12, 2017 and issued as U.S. Patent No. 10,646,313 (hereinafter, “the Great-Grandparent ‘828 Application”).

57. The Great-Grandparent ‘828 Application claims priority to U.S. Provisional Application No. 62/414,712, filed on October 29, 2016 (hereinafter, “the ‘712 Provisional”) and U.S. Provisional Application No. 62/406,990, filed on October 12, 2016 (hereinafter, the “990 Provisional”).

B. The ‘556 Application’s Originally Filed Claims, Specification, and Drawings

58. On the same day the ‘556 Application was filed, the applicant submitted a preliminary amendment: (1) canceling claims 1-12 and adding new claims 13-32; and (2) amending the “Related Applications” paragraph of the specification. Ex. 1002, 336-346.

59. The remarks section of the Preliminary Amendment provided the following explanation regarding the new claims:

New claims 13-32 are focused on the configuration of the top portion of the container, which has a generally cylindrical upper region having an upper surface with a periphery from which a container inlet port 15 and a container outlet port 16 extend. The container inlet port 15 and the container outlet port 16 are unaligned with the central axis of the main body, such that the container inlet port 15 is positioned nearer to a periphery of the upper surface than the container outlet port 16. Examples of the generally cylindrical upper region of the container top portion that include the container inlet and outlet ports 15, 16 that are offset from the central axis of the main body are shown, for example, in FIGS. 1, 10A, and 10B.

Ex. 1002, 344.

60. The Preliminary Amendment also explained that “[t]he new claim set also makes reference to the removeable retaining pins 13, which are shown in FIG.

2. The detachable container receives the ‘removable retaining pins 13 to ensure the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system.’” Ex. 1002, 344 (citing *id.*, 213 at ¶ [0092]).

61. The Preliminary Amendment also provided an explanation regarding FIG. 4A. Ex. 1002, 345. FIG. 4A in the ’556 Application is the same as FIG. 4A in four of the priority applications: the Grandparent ‘823 Application, the Great-Grandparent ‘828 Application, the ‘712 Provisional, and the ‘990 Provisional. *Id.* “In those original drawing sets, a groove can be seen below the generally cylindrical upper region and radially outward from the periphery of the circular upper surface at the top of the generally cylindrical upper region.” *Id.* In addition, the groove “is where the retaining pins are inserted.” *Id.*

62. The Preliminary Amendment goes on to explain that replacement drawings were filed during prosecution of the Grandparent ‘823 Application and Great-Grandparent ‘828 Application with “blurry dotted lines near where the groove is located.” Ex. 1002, 346. These replacement drawings were filed with the Parent ‘522 Application. *Id.* The Preliminary Amendment explained that “Applicant is submitting with this current original drawing set the originally filed version of FIG. 4A from U.S. Application No. 16/033,823 and U.S. Application No. 15/730,828 to ensure the groove is clearly illustrated.” *Id.*

C. The January 2023 Office Action

63. The Patent Office issued a non-final office action on January 20, 2023 rejecting pending claims 13-32. Ex. 1002, 155-160 (hereinafter, the “January 2023 Office Action”).

64. The January 2023 Office Action objected to the drawings. Ex. 1002, 157. Specifically, the January 2023 Office Action stated that “the ‘pins’ (reference numeral 13) ‘radially protruding structures’ and the ‘pair of pin engaging surfaces’ (claims 13, 25, 31) the ‘flange’ (claims 20, 21, 28, 29), and the ‘keying feature’ (claims 23, 24, 30) must be shown or the feature(s) canceled from the claim(s)” and that “[n]o new matter should be entered.” *Id.* The January 2023 Office Action also stated that certain figures “do not contain any reference numerals that refer to elements in these figures that are described in the specification.” *Id.*

65. The January 2023 Office Action also rejected the claims under 35 U.S.C. § 112(a) as allegedly failing to comply with the enablement requirement. Ex. 1002, 158. Specifically, the January 2023 Office Action alleged that “[t]he specification fails to sufficiently disclose and describe the ‘radially protruding structures’ and the ‘pair of pin engaging surfaces’ (claims 13, 25, 31), the ‘flange’ (claims 20, 21, 28, 29), and the ‘keying feature’ (claims 23, 24, 30)” and that “while disclosed in the specification, the ‘pins’ 13 are not sufficiently disclosed.” *Id.*

66. The January 2023 Office Action also rejected the claims under 35 U.S.C. § 112(b) as allegedly being indefinite, stating that (1) “[i]n claims 13, 25, 31, line 1, ‘dental-amalgam’ should be inserted after ‘detachable’ so that the preamble agrees with that of the dependent claims” and (2) “[i]n claim 13, lines 19-20, ‘the pair of pin-engaging surfaces’ has no prior antecedent basis.” Ex. 1002, 159.

67. The January 2023 Office Action indicated that the claims would be otherwise allowable if rewritten or amended to overcome the § 112 rejections. Ex. 1002, 159.

D. The February 2023 Response

68. Patent Owner filed a response to the January 2023 Office Action on February 7, 2023 (hereinafter, “the February 2023 Response”). Ex. 1002, 90-153¹.

69. The February 2023 Response made amendments to the drawings. Ex. 1002, 151-153. FIG. 2 was amended to “change the reference line for the pin 13 from an arrowed lead line to a straight lead line that touches the pin 13.” *Id.*, 151. The amended version of FIG. 2 is reproduced below.

¹ Portions of the February 2023 Response appear out of order in Ex. 1002.

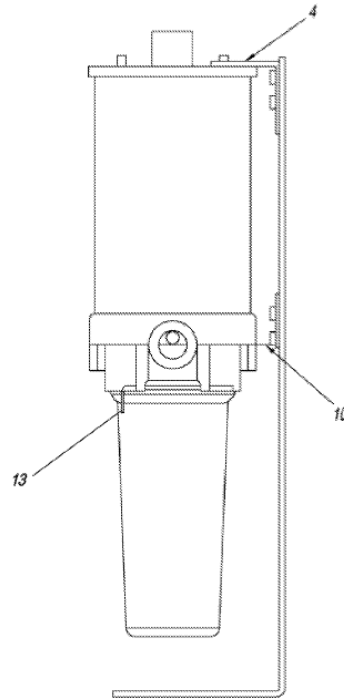
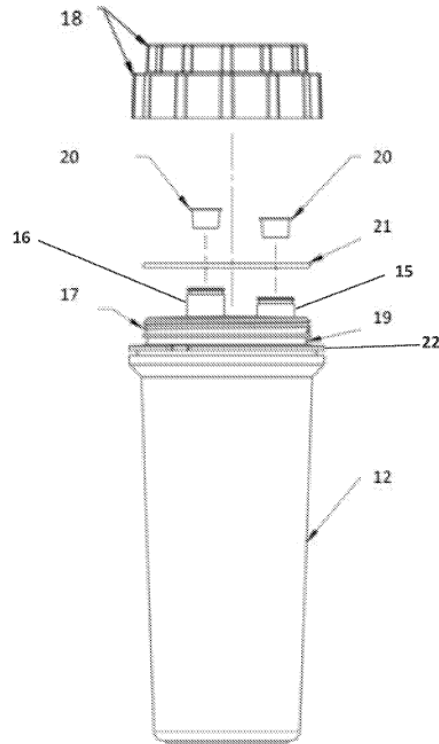


FIG. 2

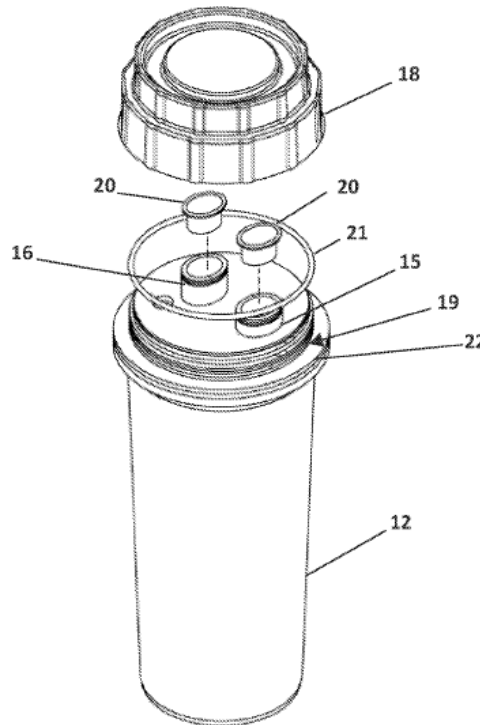
Ex. 1002, 101

70. FIG. 4A was amended to “add reference numerals ‘15’, ‘16’, and ‘22’ to identify the container inlet port 15, container outlet port 16, and the flange structure 22, respectively.” Ex. 1002, 151. The amended version of FIG. 4A is reproduced below:



Ex. 1002, 103

71. FIG. 4B was amended to “add reference numerals ‘12’, ‘15’, ‘16’, ‘18’, ‘20’, ‘21’ and ‘22’ to identify the container 12, the container inlet port 15, the container outlet port 16, the cap 18, the O-ring groove 19, the plugs 20, the O-ring 21, and the flange structure 22, respectively.” Ex. 1002, 151.



Ex. 1002, 104

72. The February 2023 Response also made amendments to the specification. Ex. 1002, 149. For example, the applicant amended “paragraph [0096] to describe the flange structure ‘22’ in a manner consistent with what is illustrated in the figures.” *Id.* The amended version of paragraph 96, with the additions underlined, is reproduced below:

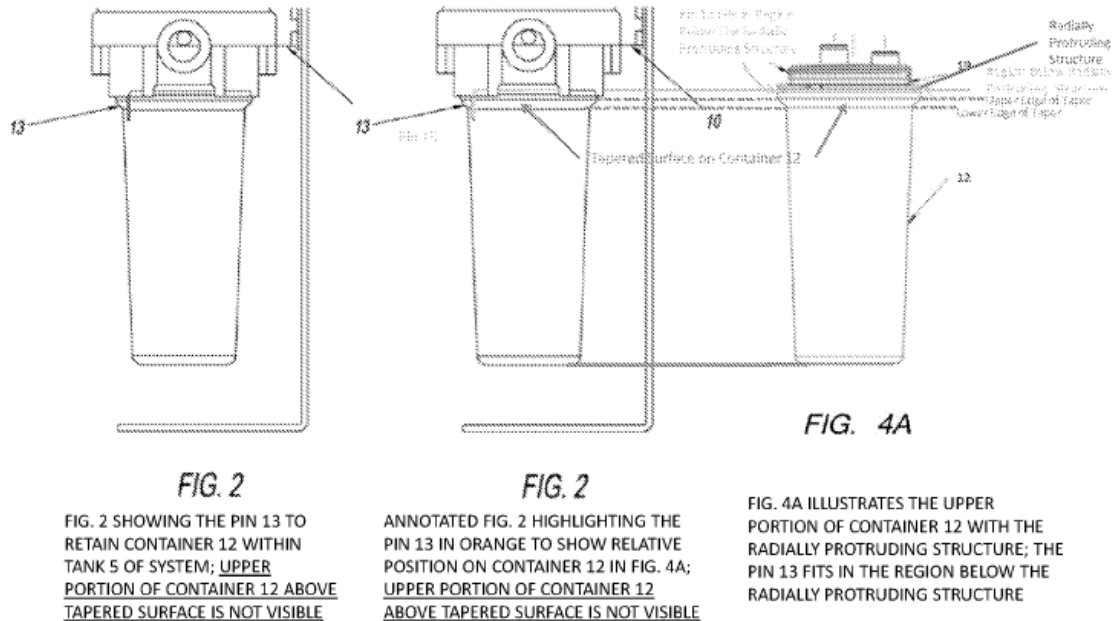
FIG. 4a shows a schematic diagram of the recycling container and cap system (see FIG. 5 for more cap 18 detail) according to the present invention. The cap 18 is a two tier shape to allow for a tight grip by both a big and smaller hand in order to achieve a strong seal as required by the invention. An O-ring 21 is provided and fits into an

O-ring groove 19 on the recycling container 12 that is located above a flange structure 22 that protrudes radially away from the central axis of the container 12. The removable retaining pins 13, described above with respect to FIG. 2, fit within the region below the flange structure 22. Plugs 20 are used to provide a first leak proof seal for the recycling container 12. These plugs 20 are held in place by the cap 18 when the cap is threaded onto the recycling container as depicted in FIG. 5b.

Id.; *see also id.*, 129, 141.

73. The February 2023 Response also made claim amendments. Ex. 1002, 90-96.

74. In the remark sections, Patent Owner indicated that no new matter was added via the amendments to the drawings. Ex. 1002, 98. Addressing the § 112 rejections, the February 2023 Response refers to a telephone interview that occurred on February 6, 2023. *Id.*, 97-98. The Examiner's interview summary attached the annotated drawings reproduced below, which I understand were discussed with the Examiner during the interview:



Ex. 1002, 87

75. The February 2023 Response further explained:

As explained during the interview, the horizontal segment of the L-shaped retaining pin 13 illustrated in FIGURE 2 fits within the region directly below the flange structure 22, which radially protrudes away from the central axis of the container 12 as shown in FIGURES 4A and 4B. The present specification explains that the “removable retaining pins 13 [to] ensure the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system.” Para. [0092]. To remove it, the removable retaining pin 13 is pulled in the left direction in FIGURE 2 such that the horizontal segment of the pin 13 is removed from the region directly below the flange structure 22 on the recycling container 12, and the

recycling container 12 can then be released from the dental amalgam separation system. As such, the Applicant respectfully suggests that the present application describes the claimed subject matter in a way that would permit the skilled artisan to make and use the invention.

Ex. 1002, 98-99.

E. The March 2023 Office Action

76. The Patent Office issued a Final Office Action on March 16, 2023 indicating that claims 13-18 and 20-21 were allowed, and that claims 19, and 22-35 were rejected (hereinafter, “the March 2023 Office Action”). Ex. 1002, 74-79. Notably, the March 2023 Office Action withdrew the § 112 rejections that were present in the January 2023 Office Action and did not allege the amendments to the drawings and specification in the February 2023 Response introduced new matter.

77. The March 2023 Office Action objected to the drawings, stating that “the o-rings as recited in claim 22 must be shown or the feature(s) canceled from the claim(s).” Ex. 1002, 76.

78. The March 2023 Office Action objected to the specification for allegedly “failing to provide proper antecedent basis for the claimed subject matter.” Ex. 1002, 76. Specifically, the March 2023 Office Action stated:

The specification does not describe certain elements as recited in the claims. Examples are the specifics of the cap

as recited in claim 27, as well as the claim terms “main body, central axis, interior volume, container top portion, cylindrical, upper region, circular, radially protruding structure, pin engaging surfaces, inlet conduit. Applicant is advised to review the specification to make sure that it provides antecedent basis for claim terminology.

Id., 76-77.

79. The March 2023 Office Action rejected claims 19 and 22-35 under 35 U.S.C. § 112(b) for allegedly being indefinite based on antecedent basis issues. Ex. 1002, 77.

80. Claims 13-18, 20, and 21 were allowed. Ex. 1002, 78. In addition, claims 19 and 22-35 were indicated as being allowable if rewritten or amended to overcome the § 112 rejections. *Id.*

F. The March 2023 Response

81. Patent Owner filed a response to the March 2023 Office Action on March 22, 2023. Ex. 1002, 26-73.² The March 2023 Response canceled claim 22 to obviate the drawing objection and made clarifying amendments to claims 19, 23, 25, 27, 31, and 32. *Id.*, 33, 35.

82. In response to the objections to the specification, the March 2023 Response addressed each claim term. Ex. 1002, 33-35. For the “radially protruding

² Portions of the March 2023 Response appear out of order in Ex. 1002.

structures” term, Solmetex explained “[p]aragraph [0084] has been amended to specifically use the term ‘radially protruding structures’ that can be engaged by the removable retaining pins 13. The flange 22 illustrated in FIGS. 4A and 4B is one example of such a radially protruding structure. This amendment is supported by the original specification and drawings.” *Id.*, 34. Solmetex also explained that “the skilled artisan would understand the claim elements subject to these objections are clearly supported by the originally filed specification and drawings.” *Id.*, 35.

G. The April 2023 Notice of Allowance

83. The Patent Office issued a notice of allowance April 13, 2023. Ex. 1002, 10-22. The ‘175 Patent subsequently issued on May 30, 2023. *Id.*, 1.

VI. LEVEL OF SKILL IN THE ART

84. I understand that the level of ordinary skill in the relevant art at the time of the invention is relevant to inquiries such as the meaning of claim terms, the meaning of disclosures found in the prior art, and the reasons one of ordinary skill in the art may have for combining references.

85. I have reviewed the definition of the level of ordinary skill in the art proposed by Petitioner and Dr. Janét, who state that a POSITA as of October 2022 or October 2016 would have possessed at least a bachelor’s degree in mechanical engineering, or at least 3 years of experience designing or manufacturing vacuum

systems, filters, medical devices, or related components. Petition 22; Ex. 1003, ¶ 95.

86. For purposes of this declaration, I have been asked to apply Petitioner and Dr. Janét’s proposed level of skill in the art in my analysis. I reserve the right to identify a level of skill in the art for the ‘175 patent that differs from Petitioner’s proposal should a PGR be instituted.

87. I was, as of October 2016, and still am, a person of at least ordinary skill in the art through my education and experience under Petitioner and Dr. Janét’s proposed definition. I am also familiar with people having this level of skill.

VII. SUMMARY OF PETITIONER’S REFERENCES

A. The Solmetex NXT Hg5 Amalgam Separator System

88. I understand that the NXT Hg5 Series® of Amalgam Separators (“the NXT Hg5 System”) is a product sold by Solmetex. The NXT Hg5 System separates teeth fragments, dental amalgam, and mercury from dental amalgam effluent and collects the solid waste in a collection container. I understand that the NXT Hg5 System is designed to meet or exceed all applicable state and federal regulations relevant to dental amalgam disposal.

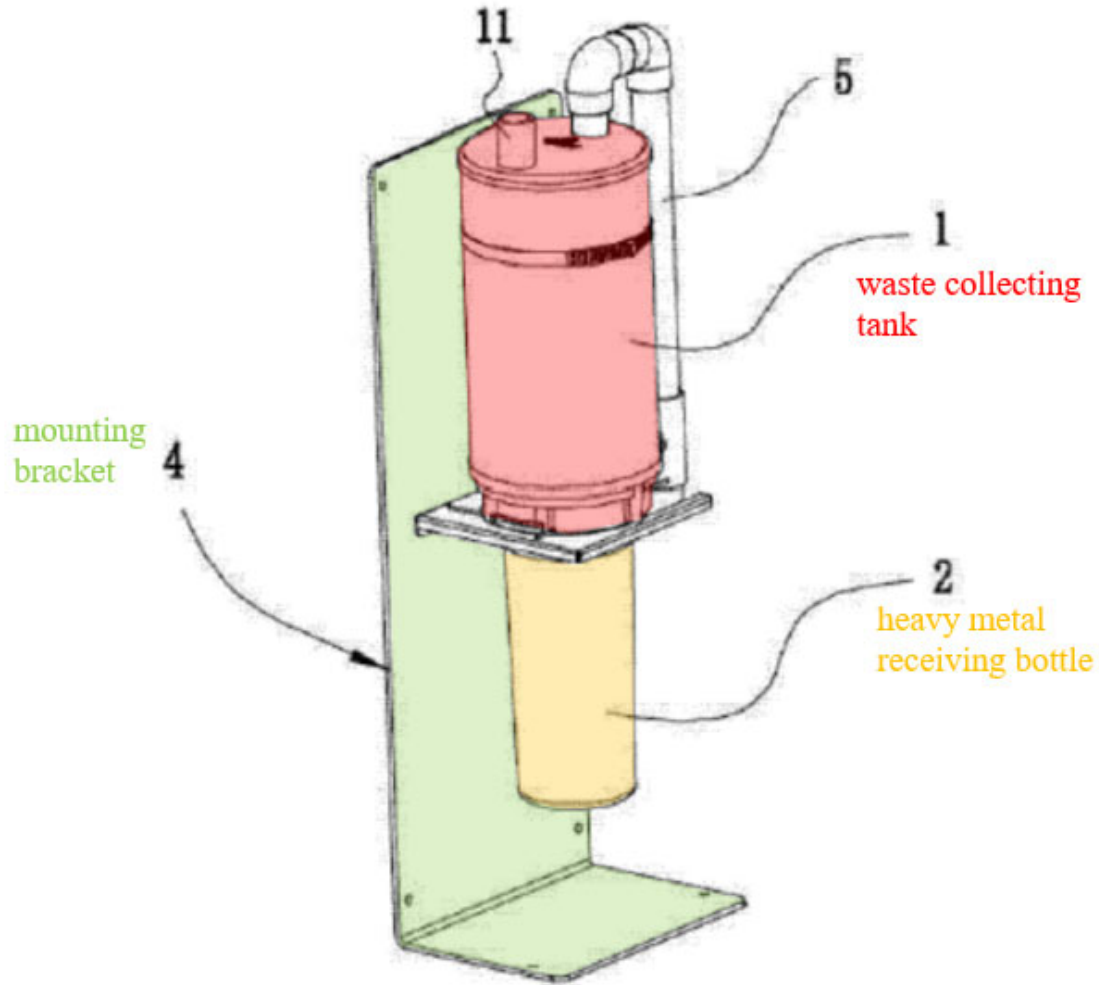
B. The DRNA “Cartridge 2” Product

89. I understand that the “Cartridge 2” is a product sold by DRNA as a “generic” container for use with Solmetex’s NXT Hg5 amalgam separator system. Ex. 1023. I also understand that Solmetex accuses the Cartridge 2 of infringing one or more claims of the ‘175 patent in the Delaware Litigation.

C. Liu (Ex. 1010)

90. Liu is generally directed to “a heavy metal separation device used for separating heavy metals in dental treatment.” Ex. 1010, ¶ [0001].

91. Liu’s system includes a waste collecting tank 1, a heavy metal receiving bottle 2, a solid filter 3 and a mounting bracket 4. Ex. 1010, ¶ [0017]. The waste collecting tank 1 is fixed on the mounting bracket 4. *Id.* These components are shown in the annotated version of FIG. 1 below.



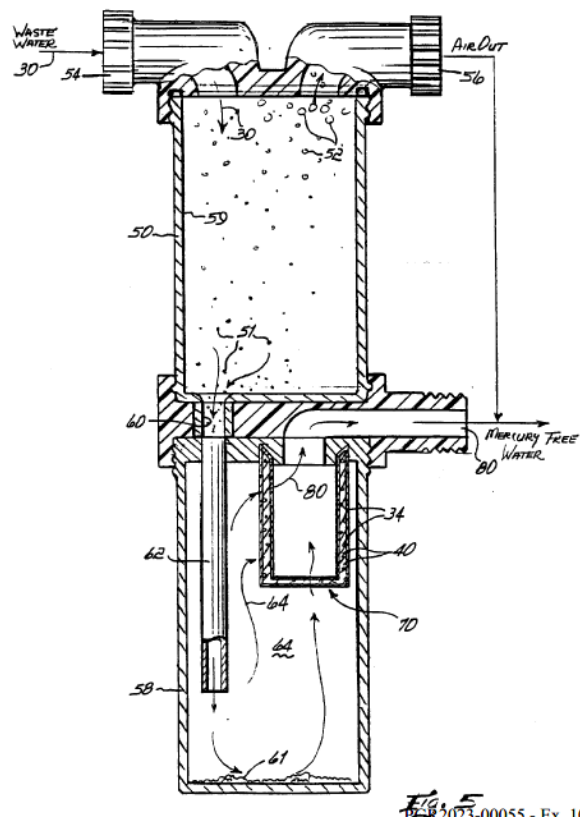
Ex. 1010, FIG. 1 (annotated)

D. Boyd (Ex. 1011)

92. Boyd is directed to “a method and device for the removal of debris and contaminants from dental waste streams.” Ex. 1011, 1:3-4. Specifically, Boyd “provides a single stage unit which provides a dual effect: it removes both soluble and insoluble contaminants from dental waste streams,” whereas prior systems “either do not provide the dual effect, or require two stages to achieve the dual effect.” *Id.*, 4:1-4. Boyd “contemplates the combination of chemical and

mechanical purification of a waste stream in a single stage” where “[w]aste is introduced for mechanical and chemical purification without passing through any intermediary conduits, passageways, or other connections.” *Id.*, 4:5-9.

93. FIG. 5 of Boyd shows a three-phase contaminant-removing system. Ex. 1011, 8:10-11. Waste 30 enters an air/liquid separation chamber 50 via inlet port 54. *Id.*, 8:12-13. The air/liquid separator chamber 50 slows down the flow of air 52 in waste flow 30 to allow entrained solids and liquids 51 to drop to the bottom of the chamber. *Id.*, 8:13-16. Waste flow 30 passes into a settlement chamber 58 for contaminant removal. *Id.*, 8:17-18.



Ex. 1011, FIG. 5

VIII. PETITIONER’S ALLEGED UNPATENTABILITY GROUNDS

94. I understand that the Petition and Dr. Janét assert six (6) unpatentability grounds challenging the ‘175 patent.

A. Claim Construction

95. Dr. Janét opines the preamble in each of independent claims 1, 12, and 18 is limiting. Ex. 1003, ¶¶ 78-83. I have not been asked to offer opinions on claim construction in this declaration at this time because, as discussed herein, I disagree with Petitioner and Dr. Janét’s alleged unpatentability grounds regardless of whether the preambles of the independent claims are construed as limiting. I reserve the right to offer opinions on claim construction, including whether the preambles in the independent claims are limiting or non-limiting, should a PGR be instituted.

B. The ‘175 Patent’s Effective Filing Date

96. I understand that the first four (4) grounds in the Petition (Grounds 1-4) are based on Petitioner’s argument that the effective filing date of the ‘175 patent is its October 13, 2022 filing date. Dr. Janét opines that “the disclosure of the ‘175 patent adds substantive new material to the ‘522 application” such that the ‘175 patent is not entitled to its claimed priority dates. Ex. 1003, ¶ 59. For the reasons discussed below, I disagree.

1. The ‘175 patent’s original specification and drawings disclose the claimed “radially protruding structure”

97. Dr. Janét states that he was asked to opine “[w]hether the original specification as it was originally filed supports the ‘radially protruding structure’ for engaging the at least one retaining pin limitations.” Ex. 1003, ¶ 61. He opines that the “radially protruding structure” is not explicitly or inherently disclosed in the specification. *Id.*, ¶¶ 61-62. For at least the reasons discussed below, I disagree.

98. At the outset, I note that the Examiner issued a § 112 rejection in the January 2023 Office Action alleging that that “[t]he specification fails to sufficiently disclose and describe the ‘radially protruding structures’ and the ‘pair of pin engaging surfaces’ (claims 13, 25, 31), the ‘flange’ (claims 20, 21, 28, 29), and the ‘keying feature’ (claims 23, 24, 30)” and that “while disclosed in the specification, the ‘pins’ 13 are not sufficiently disclosed.” Ex. 1002, p. 158.

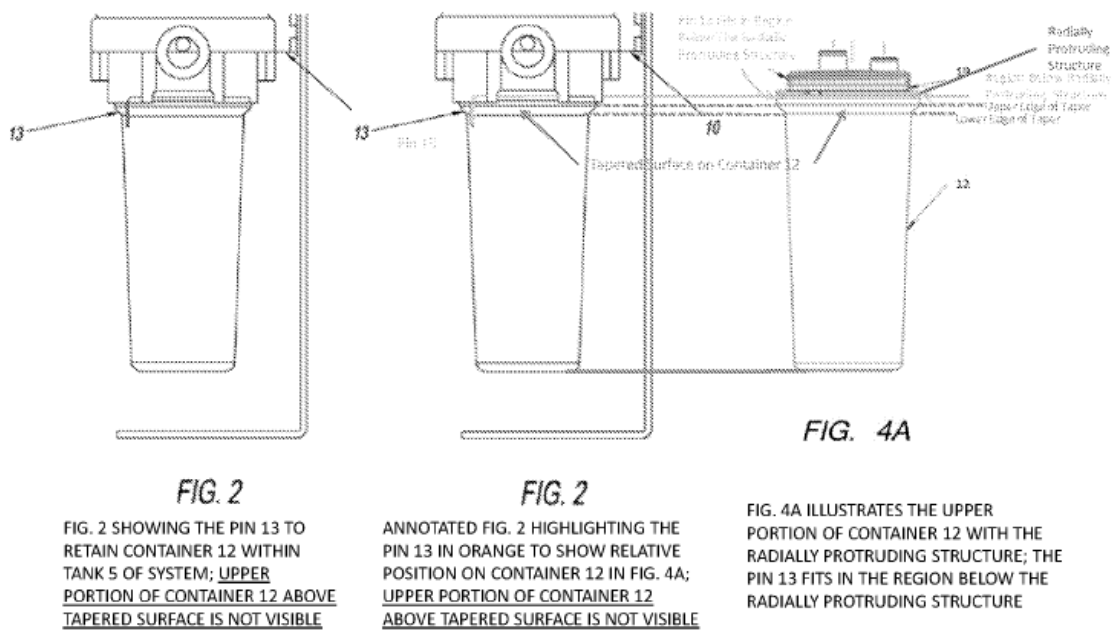
99. In the February 2023 Response, Patent Owner argued:

As explained during the interview, the horizontal segment of the L-shaped retaining pin 13 illustrated in FIGURE 2 fits within the region directly below the flange structure 22, which radially protrudes away from the central axis of the container 12 as shown in FIGURES 4A and 4B. The present specification explains that the “removable retaining pins 13 [to] ensure the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system.” Para. [0092]. To remove it,

the removable retaining pin 13 is pulled in the left direction in FIGURE 2 such that the horizontal segment of the pin 13 is removed from the region directly below the flange structure 22 on the recycling container 12, and the recycling container 12 can then be released from the dental amalgam separation system. As such, the Applicant respectfully suggests that the present application describes the claimed subject matter in a way that would permit the skilled artisan to make and use the invention.

Ex. 1002, pp. 98-99.

100. I understand there was a telephone interview with the Examiner to discuss § 112 rejection in the January 2023 Office Action where Patent Owner presented the following annotations to the Examiner showing the retaining pin 13 and the radially protruding structure.

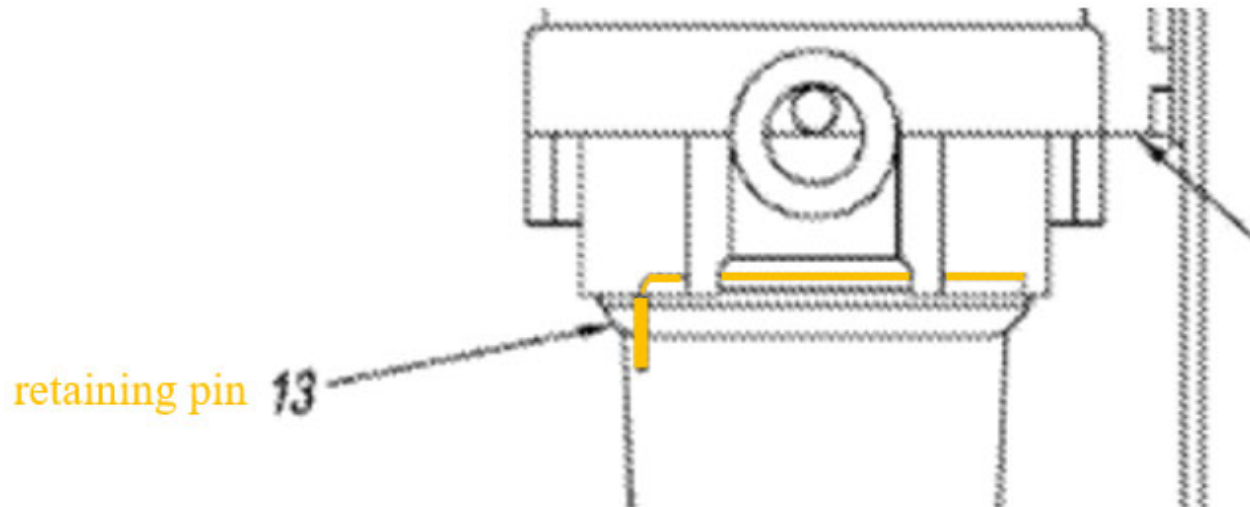


Ex. 1002, 87

101. The Examiner withdrew the § 112 rejection relating to the “radially protruding structure” after being presented with these arguments. As I explained below, I agree with these arguments. I note that Dr. Janét’s declaration does not address the annotated figures and arguments submitted to the Examiner and discussed during the telephone interview. *See* Ex. 1003, ¶¶ 59-77.

102. The original specification discloses that “[t]he system is provided with a simple back plate 1 for easy dental office placement as well as removable retaining pins 13 to ensure the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system.” Ex. 1002, p. 213 (¶ [0092]); Ex. 1001, 7:29-34. The same disclosure appears in the priority applications. Ex. 2002, p. 696 (¶ [0092]) (Parent ‘522 Application); Ex. 2003, p. 399 (¶ [0075]) (Grandparent ‘823 Application); Ex. 2004, p. 320 (¶ [0071]) (Great-Grandparent ‘828 Application); Ex. 2005, p. 15 (¶ [0037]) (‘990 Provisional); Ex. 2006, p. 25 (¶ [0057]) (‘712 Provisional).

103. The removable retaining pin 13 is illustrated in FIG. 2 of the ‘556 Application and is shown as being L-shaped.



Ex. 1002, p. 220 (FIG. 2) (excerpted and annotated); Ex. 1001, FIG. 2

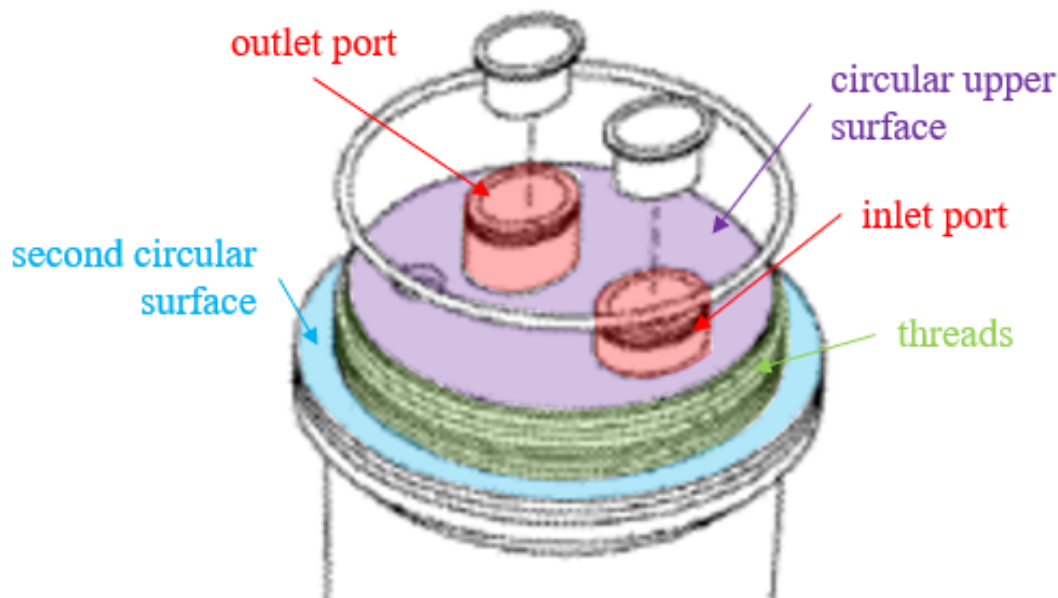
The removable retaining pin 13 is also shown in FIG. 2 of the priority applications.

EX2002, p. 703 (Parent ‘522 Application); EX2003, pp. 86, 405 (Grandparent ‘823 Application); EX2004, pp. 13, 327 (Great-Grandparent ‘828 Application).

104. As the name implies, a POSITA would understand that the “removable retaining pin 13” is “removable” from the system to release the detachable recycling container 12. Based on FIG. 2, a POSITA would understand that to do so, the removable retaining pin 13 would be pulled to the left direction in FIG. 2. A POSITA would understand that because the removable retaining pin 13 is generally L-shaped, it would not be possible to remove the removable retaining pin 13 by pulling the removable retaining pin 13 horizontally to the right direction in FIG. 2. A POSITA would recognize that the shorter, vertical portion of the removable retaining pin 13 serves as a sort of handle for the user to grasp and pull the removable retaining pin 13 to the left.

105. I note that Dr. Janét's declaration does not opine that the '175 patent fails to disclose a removable retaining pin or dispute that the removable retaining pin 13 is the structure in FIG. 2 that is annotated above.

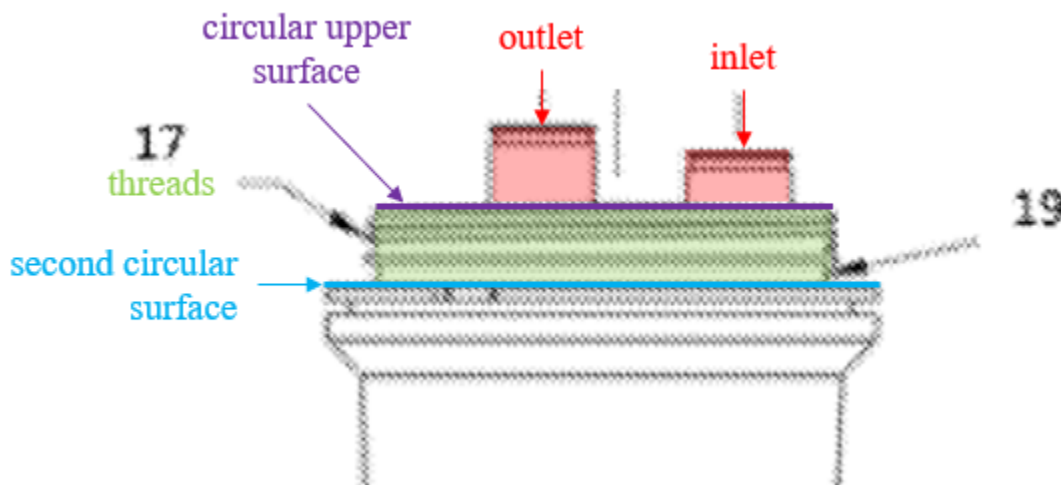
106. FIG. 4B illustrates a perspective view of the detachable recycling container 12. Ex. 1001, FIG. 4B. The container inlet port and container outlet port (annotated in red below) extend up and away from a circular upper surface (annotated in purple). The threads 17 (annotated in green) extend downward from the circular upper surface (annotated in purple) and toward a second circular surface (annotated in blue). The diameter of the second circular surface (blue) is greater than the diameter of the circular upper surface (purple).



Ex. 1002, p. 223 (FIG. 4B) (excerpted and annotated)

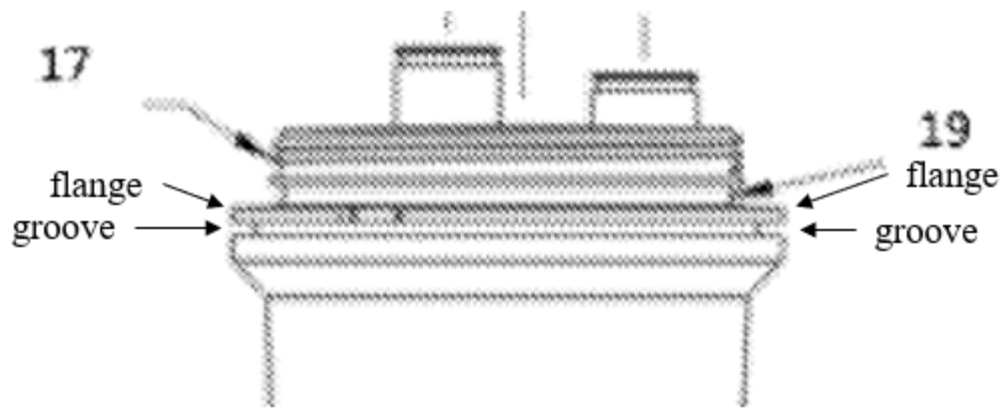
107. FIG. 4B also appears in the Parent ‘522 Application, the Grandparent ‘823 Application, the Great-Grandparent ‘828 Application, the ‘990 Provisional, and the ‘712 Provisional. Ex. 2002, p. 706 (Parent ‘522 Application); Ex. 2003, p. 408 (Grandparent ‘823 Application); Ex. 2004, p. 330 (Great-Grandparent ‘828 Application); Ex. 2005, p. 25 (‘990 Provisional); Ex. 2006, p. 35 (‘712 Provisional).

108. FIG. 4A is a side view that shows the same features as FIG. 4B. As shown below, the container inlet and outlet ports (annotated in red) port extend away from the circular upper surface (annotated in purple). The threads 17 (annotated in green) extend downward from the circular upper surface (annotated in purple) and towards the second circular surface (annotated in blue).



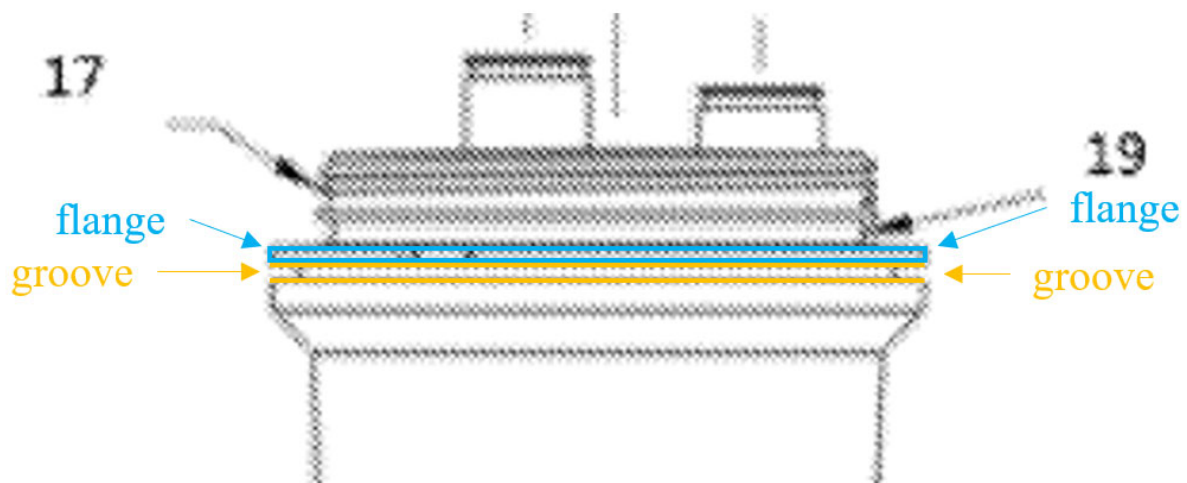
Ex. 1002, 222 (FIG. 4A) (excerpted and annotated); Ex. 1001, FIG. 4A

109. FIG. 4A shows a flange (radially protruding structure) and a groove below the second circular surface.



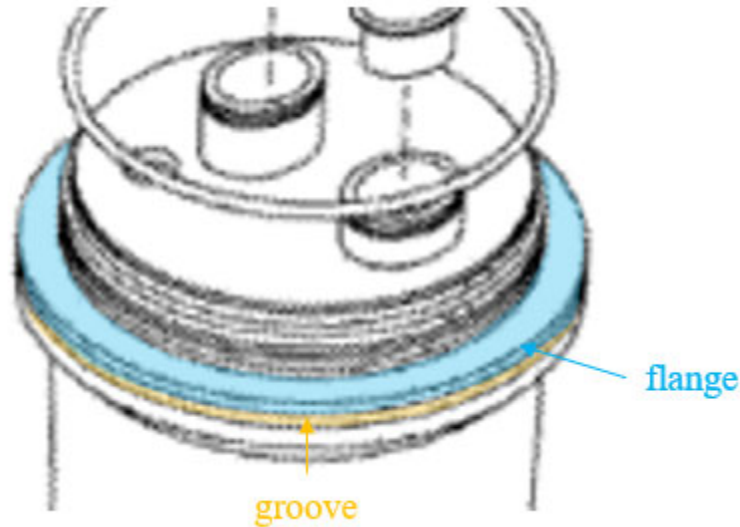
Ex. 1002, 222 (FIG. 4A) (excerpted and annotated); Ex. 1001, FIG. 4A

The flange and the groove below the flange are highlighted in blue below.



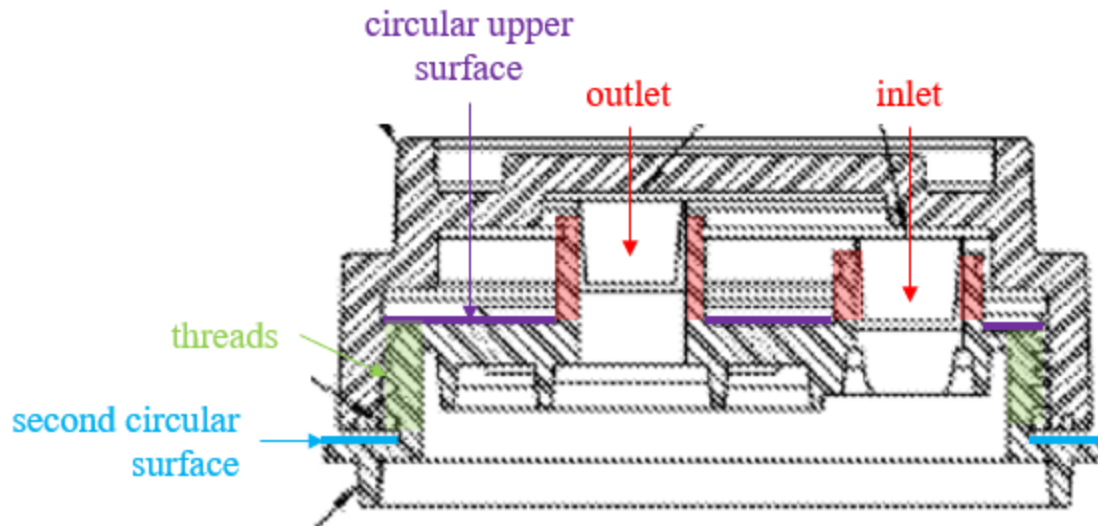
Ex. 1002, 222 (FIG. 4A) (excerpted and annotated); Ex. 1001, FIG. 4A

110. The groove discussed above is also visible in FIG. 4B. As shown below, the groove (annotated in orange) can be seen below the second circular surface and flange (annotated in blue).



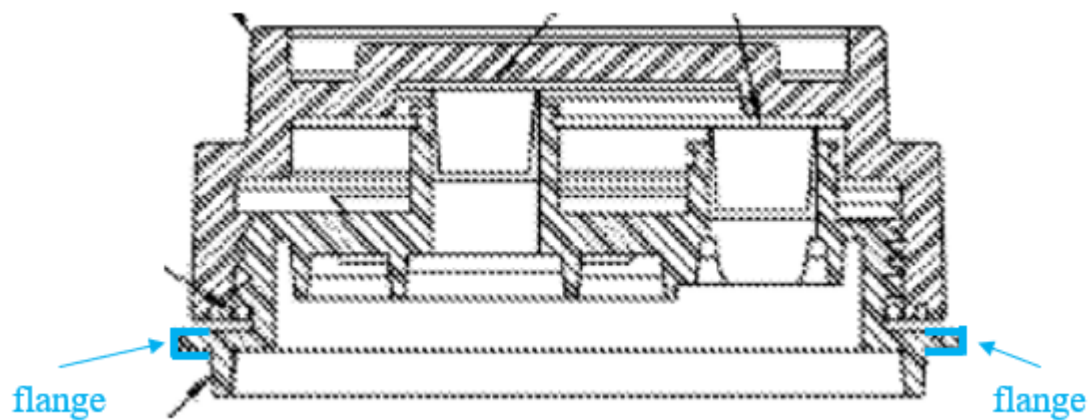
Ex. 1002, p. 223 (FIG. 4B) (excerpted and annotated); Ex. 1001, FIG. 4B

111. FIG. 5B is a cross-sectional view showing the cap 18 attached to the detachable recycling container. Consistent with FIGS. 4A and 4B, the container inlet and outlet ports (annotated in red) extend away from the circular upper surface (annotated in purple). The threads 17 (annotated in green) extend downward from the circular upper surface (annotated in purple) and towards the second circular surface (annotated in blue).



Ex. 1001, FIG. 5B (excerpted and annotated)

112. FIG. 5B further confirms that there is a radially protruding structure or flange. This is highlighted by the annotations below.

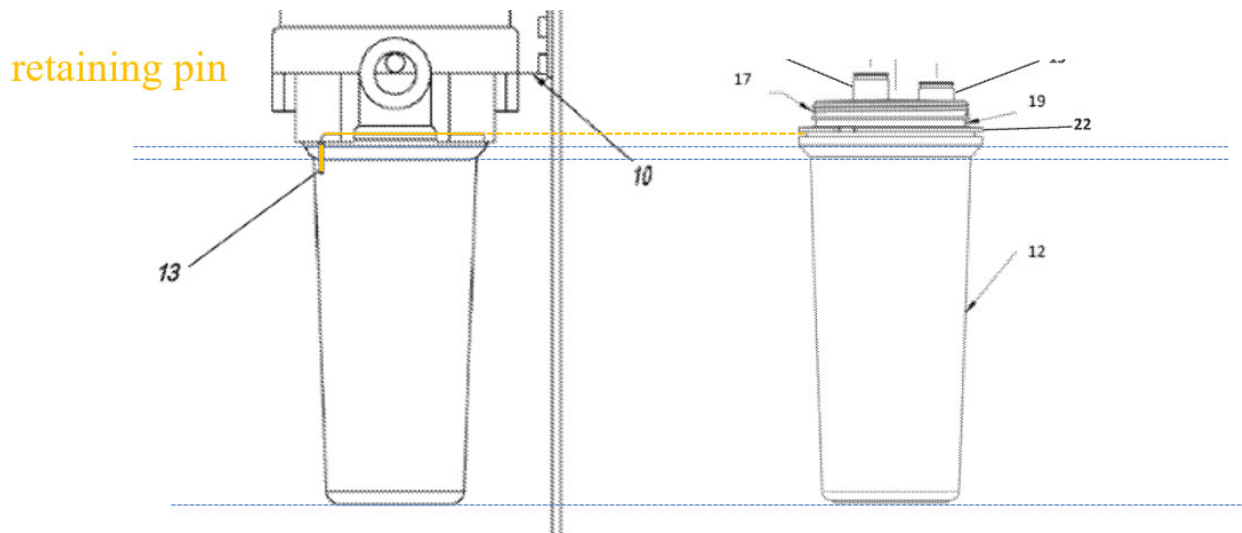


Ex. 1001, FIG. 5B (excerpted and annotated)

113. FIG. 5B of the '175 patent also appears in the Parent '522 Application, the Grandparent '823 Application, the Great-Grandparent '828 Application, the '990 Provisional, and the '712 Provisional. Ex. 2002, p. 707 (Parent '522 Application); Ex. 2003, p. 409 (Grandparent '823 Application); Ex.

2004, p. 331 (Great-Grandparent '828 Application); Ex. 2005, p. 26 ('990 Provisional); Ex. 2006, p. 36 ('712 Provisional).

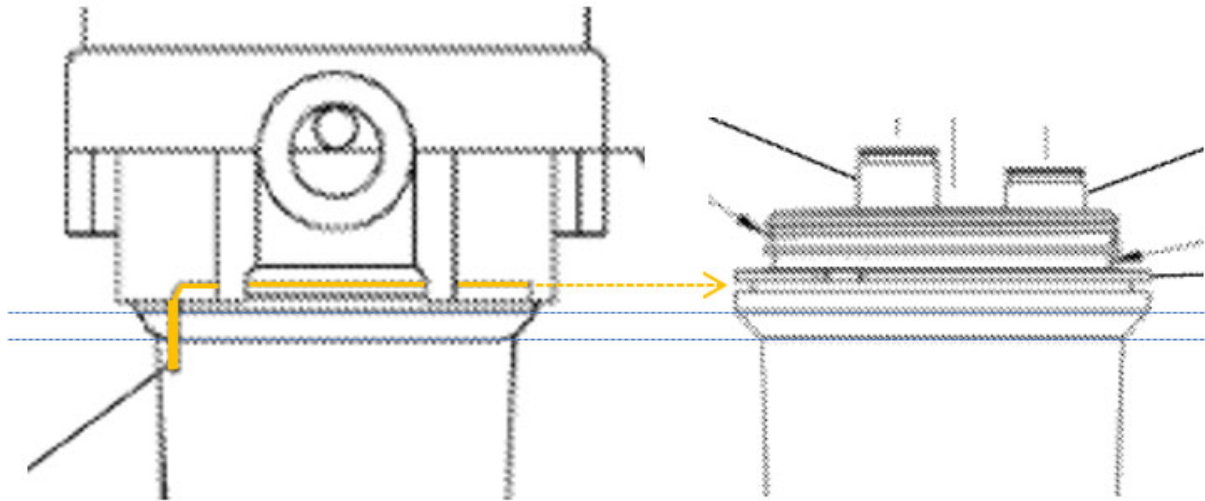
114. A POSITA would understand from at least FIGS. 2, 4A, 4B, and 5B that the removable retaining pin 13 engages the groove under the radially protruding flange shown in FIGS. 4A, 4B, and 5B. A POSITA would have readily understood this by performing a simple side-by-side comparison of FIG. 2 and 4A. In the example below, I took care to ensure that the detachable recycling container 12 is lined up in the same position (as reflected by the dashed lines) in the side-by-side comparison and scaled appropriately.



Ex. 1001, FIGS. 2 and 4A (excerpted and annotated)

As shown above, based on the relative position of the removable retaining pin 13 in FIG. 2, a POSITA would understand that the removable retaining pin 13 engages the groove under the radially protruding structure (flange) on the

detachable recycling container 12. Without ambiguity, this is the only possible location for the removable retaining pin 13 to be inserted. Below is another zoomed in version of these figures also showing this.



Ex. 1001, FIGS. 2 and 4A (excerpted and annotated)

115. Dr. Janét states that “there are zero mentions of ‘radially protruding structure’ in the original specification for the ’175 patent” and that “this forecloses any argument that this limitation is *explicitly* disclosed since there is no explicit mention of the claimed ‘radially protruding structure.’” Ex. 1003, ¶ 61 (emphasis in original). I am informed by counsel that drawings alone can provide written description support. With that understanding, I disagree with Dr. Janét because, as discussed above, a POSITA would understand the drawings disclose a radially protruding structure for engaging the retaining pin.

116. Dr. Janét asserts that a “PHOSITA would have recognized that there are multiple ways to engage the retaining pins without a ‘radially protruding structure,’ including, for example, a hole, pocket or a recess.” Ex. 1003, ¶ 63. However, Dr. Janét does not identify “a hole, pocket or recess” on or in the detachable recycling container 12 in the drawings for engaging the removable retaining pin 13. *Id.* The only feature that is arguably a “pocket” or “recess” is the groove I discussed above that is under the radially protruding flange which the figures make clear engages the removable retaining pin 13 to support the detachable recycling container 12. And, as I discussed above, this groove under the flange is the only structure that would engage the removable retaining pin 13.

117. Dr. Janét also asserts that “a PHOSITA would have understood that there are other ways to ensure the recycling container does not detach from the air-water separation tank when there is no vacuum disclosed in the ‘175 patent.” Ex. 1003, ¶ 64. I disagree. The ‘175 patent and its priority applications expressly disclose that the removable retaining pin 13 ensures “the recycling container does not detach from the air-water separation tank 5 when there is no vacuum in the system.” Ex. 1001, 7:30-34; Ex. 1002, p. 213 (¶ [0092]); Ex. 2002, p. 696 (¶ [0092]) (Parent ‘522 Application); Ex. 2003, p. 399 (¶ [0075]) (Grandparent ‘823 Application); Ex. 2004, p. 320 (¶ [0071]) (Great-Grandparent ‘828 Application); Ex. 2005, p. 15 (¶ [0037]) (‘990 Provisional); Ex. 2006, p. 25 (¶ [0057]) (‘712

Provisional). The ‘175 patent does not disclose any other way to ensure that the detachable recycling container 12 does not detach from the air-water separation tank when there is no vacuum other than by using the removable retaining pin 13.

118. Dr. Janét asserts that “the patent itself discloses ‘threads’ on the recycling container that may be used with an adapter to affix it to the separator tank.” Ex. 1003, ¶ 64 (citing Ex. 1001, 4:38-46). I disagree with Dr. Janét’s characterization of the specification. The relevant portion of the specification is reproduced below:

In certain embodiments, the invention comprises an adapter for an air-water separator tank, wherein the adapter enables a recycling container without compatible effluent ports to attach to an air-water separator tank. Said air-water separator tank may comprise, for example, a component of a dental amalgam recycling system, as described above. In certain embodiments, the adapter may comprise threads. In alternative embodiments, the adaptor may be without threads.

Ex. 1001, 4:38-46. Here, the specification is describing an adapter that connects a recycling container without compatible inlet and outlet ports to the air-water separator tank. *Id.* An example of this adapter is shown in FIG. 3, which is used “to enable the use of recycling containers from a variety of sources that are lacking in correctly shaped ports 16 and 15 or otherwise are unable to fit the air-water

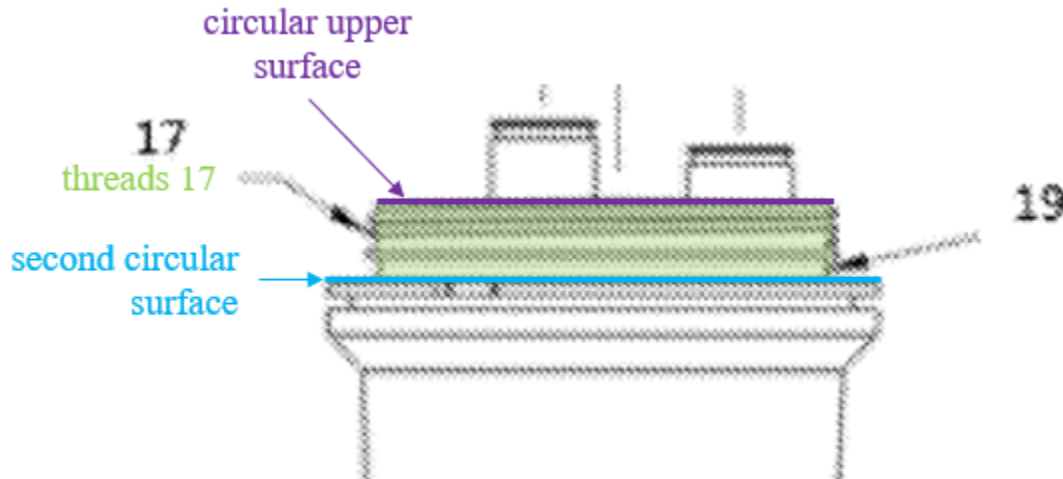
separator tank 5 according to the invention due to shape differences.” *Id.*, 7:53-58.

Contrary to Dr. Janét’s assertion, the specification states that the adapter includes threads. *Id.*, 4:38-46. The detachable recycling container 12 is never described in the specification as including threads for the purpose of attaching the container directly to the air-water separator tank.

119. Dr. Janét further states that “[a] PHOSITA would have understood that these ‘threads’ on the recycling container could mate with threads on the separator tank to hold the recycling container in place, possibly with the use of an adapter.” Ex. 1003, ¶ 64. To the extent Dr. Janét is referring to the threads 17, nothing in the ‘175 patent suggests that the threads 17 are configured to engage corresponding threads on the air-water separator tank. Again, the specification is clear that the detachable recycling container 12 is attached to the air-water separator tank with the removable retaining pin 13 – not the threads 17. Ex. 1001, 7:30-34; Ex. 1002, p. 213 (¶ [0092]). Moreover, Dr. Janét’s suggestion that the adapter could be used with the detachable recycling container 12 ignores the fact that the adapter is intended for use with containers that are not compatible with the air-water separator tank (e.g., due to the configuration of their inlet and/or outlet ports), and the detachable recycling container 12 is specifically designed to be compatible with the air-water separator tank and therefore does not need the adapter.

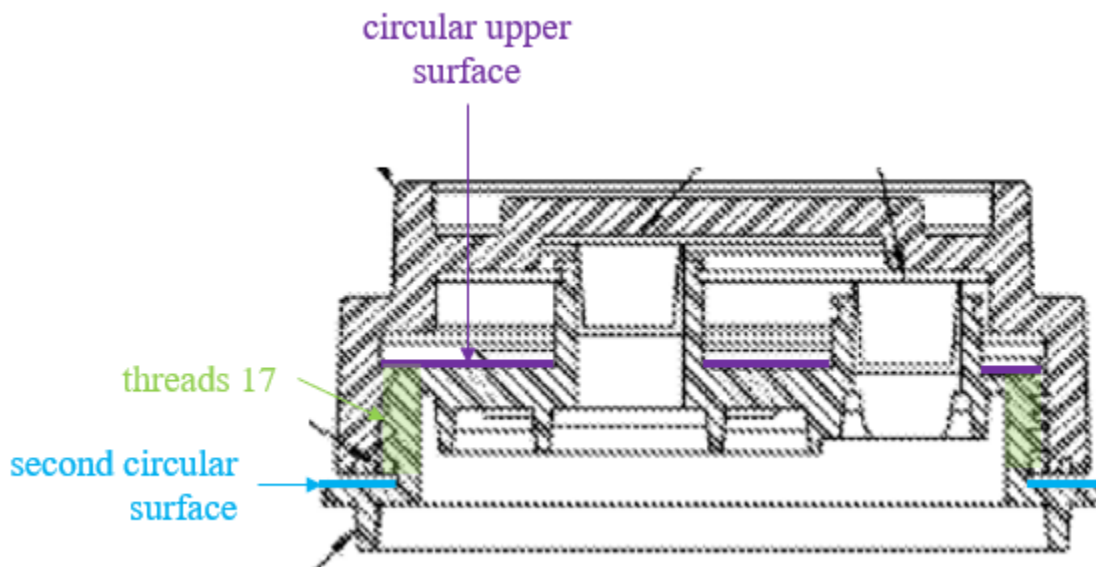
120. Addressing the remarks in Patent Owner’s preliminary amendment, Dr. Janét states that “the original specification is silent on the alleged ‘groove’ in Figure 4A” and states that “[i]t is not labeled or discussed anywhere in the specification.” Ex. 1003, ¶ 65. While it is true that the groove is not labeled with a reference numeral or specifically described in the text of the originally filed specification, a POSITA would clearly recognize the groove from FIG. 4A for the reasons discussed above. I therefore disagree with Dr. Janét’s opinion that “a PHOSITA would not have recognized the unidentified ‘groove’ or its alleged purpose for where the retaining pins are inserted absent any discussion in the specification.” Ex. 1003, ¶ 65.

121. Dr. Janét further states that “a PHOSITA may have thought the alleged groove was just an extension of the threads on the recycling container.” Ex. 1003, ¶ 65. I disagree. It would have been clear to a POSITA that the groove is *not* “an extension of the threads on the recycling container” as alleged by Dr. Janét. As discussed above (and shown again below), the threads 17 extend from the circular upper surface to the second circular surface.



Ex. 1001, FIG. 4A (excerpted and annotated)

Clearly, the threads 17 terminate at the second circular surface and do not extend past it. The threads 17 “enable the addition of a liquid tight top for shipping.” Ex. 1001, 7:49-52. FIG. 5B shows the cap 18 engaging the threads 17. The cap 18 does not fit over or engage the location of the groove, so a POSITA would not think that the groove is part of the threads that are designed to engage the cap 18.

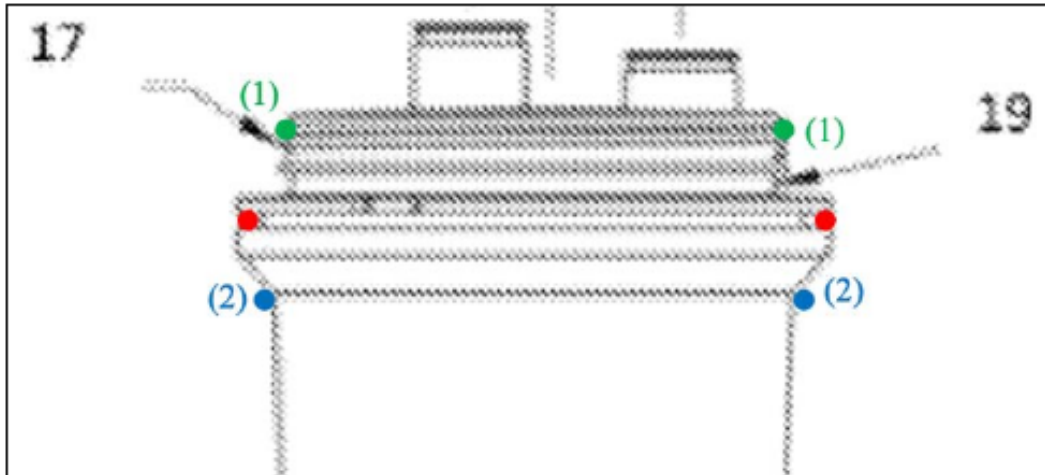


Ex. 1001, FIG. 5B (excerpted and annotated)

122. Dr. Janét asserts that “there is no disclosure in the patent that ties Figure 4A to Figure 2 where the retaining pin is shown” and therefore a POSITA “would not have known that those Figures [2 and 4A] should be combined to engage the retaining pin or, if so, how they would fit together.” Ex. 1003, ¶ 66. I disagree. It is clear that the same detachable recycling container is shown in FIGS. 1, 2, 4A, 4B, and 5. A POSITA would understand that the container shown in both FIGS. 2 and 4A is the same container and therefore the figures “fit together.” FIG. 2 shows the container 12 attached to the air-water separator tank, while FIG. 4A shows the details of the container 12 and the cap 18.

123. Using a combination of multiple views to understand how a mechanical device functions is routine in the art. Indeed, for many mechanical devices, multiple views (e.g., 2-D drawings) are often needed for a POSITA to understand how the various parts of the device fit together and function in three dimensions.

124. Dr. Janét asserts that “there are multiple structures that could have engaged the retaining pin, including the fact that the body is tapered and the widest portion at the top can be hung on extended pins/arms.” Ex. 1003, ¶ 67. Dr. Janét annotates three potential locations (reproduced below) that he contends could engage the retaining pin. I address each of these locations in turn below.

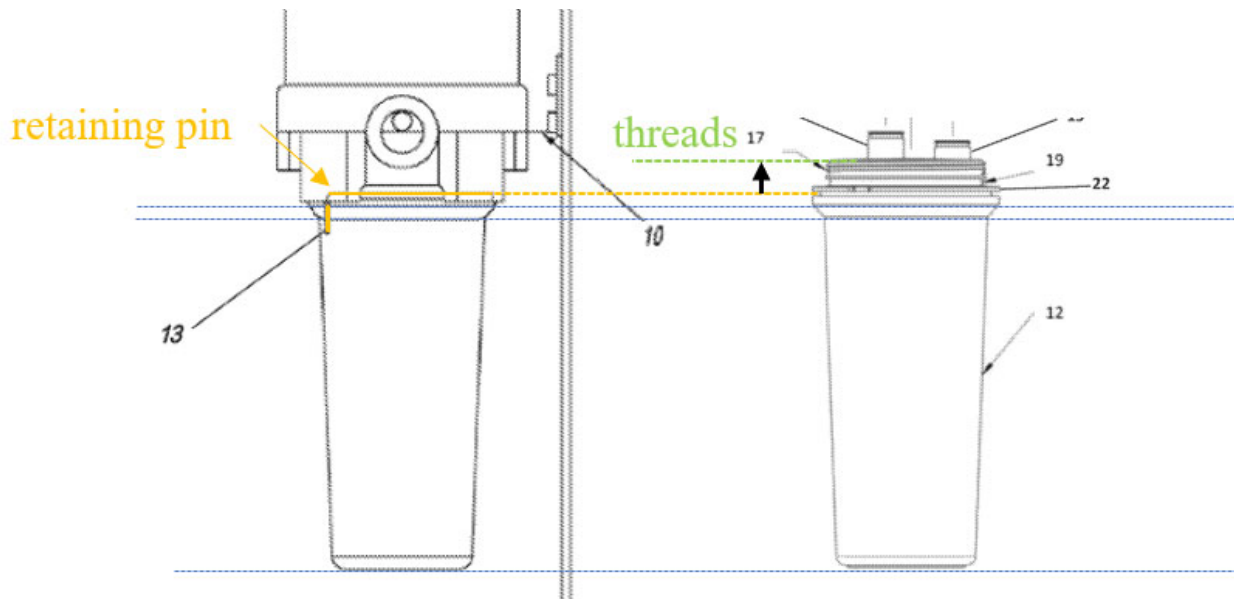


Petition, 16; Ex. 1003, ¶ 67

125. I agree that a POSITA would recognize that the removable retaining pin 13 would engage the groove annotated in red below the flange in Dr. Janét's annotated figure. Dr. Janét's annotation is an acknowledgment that FIG. 4A does disclose a radially protruding structure for engaging the retaining pin as required in the independent claims of the '175 patent.

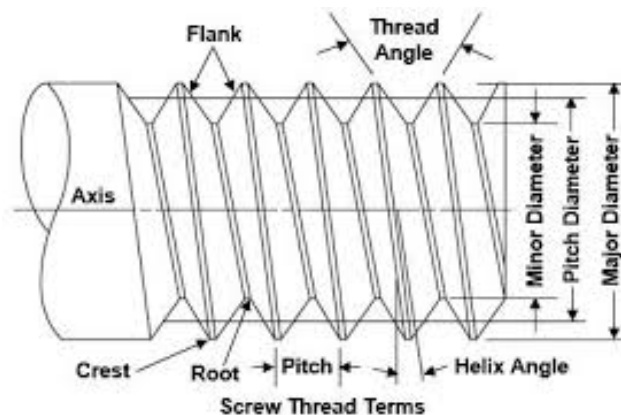
126. A POSITA would understand that the removable retaining pin 13 does *not* engage the threads 17 at the location annotated in green with the number (1) by Dr. Janét for several reasons.

127. Based on a side-by-side comparison of FIG. 2 and FIG. 4A where the container is lined up in the same position, it would be abundantly clear to a POSITA that the removable retaining pin 13 does not engage the threads 17 at the location identified by Dr. Janét. The threads 17 are positioned well above the removable retaining pin 13.

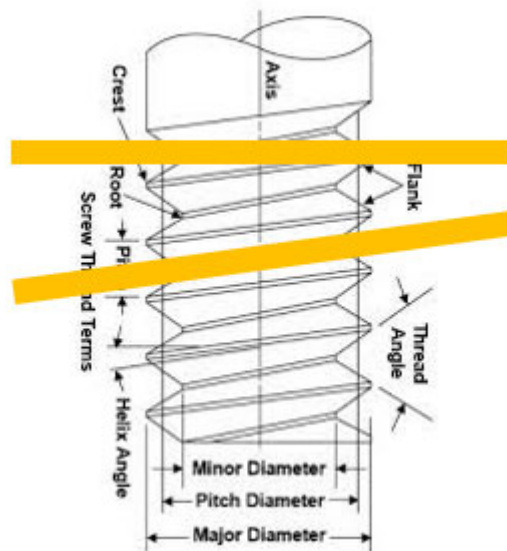


Ex. 1001, FIGS. 2 and 4A (excerpted and annotated)

128. FIG. 2 clearly shows that the portion of the removable retaining pin 13 where it secures the detachable recycling container to the air-water separator tank is horizontal. Ex. 1002, p. 220; Ex. 1001, FIG. 2. A POSITA would understand that the threads 17 are helical. Below is a schematic drawing of screw threads that shows a helical thread geometry.



129. Even assuming that the thread pitch was large enough to fit the removable retaining pin 13 (which is unlikely), a POSITA would understand that a horizontal/straight portion of the retaining pin 13 could not be inserted in the threading, as Dr. Janét asserts in paragraph 67 of his declaration, because the threads are helical. The only way to insert the removable retaining pin 13 within the threads would be to do so at an angle, as shown in the annotated schematic below. A POSITA would understand that the threads are *not* engaged by the removable retaining pin 13 because FIG. 2 clearly shows that the removable retaining pin 13 is horizontal/straight where it is inserted and not at an angle. In other words, the threads and the pin could never align, so such a method could never be used to hold the heavy container partially filled with heavy amalgam and liquid.

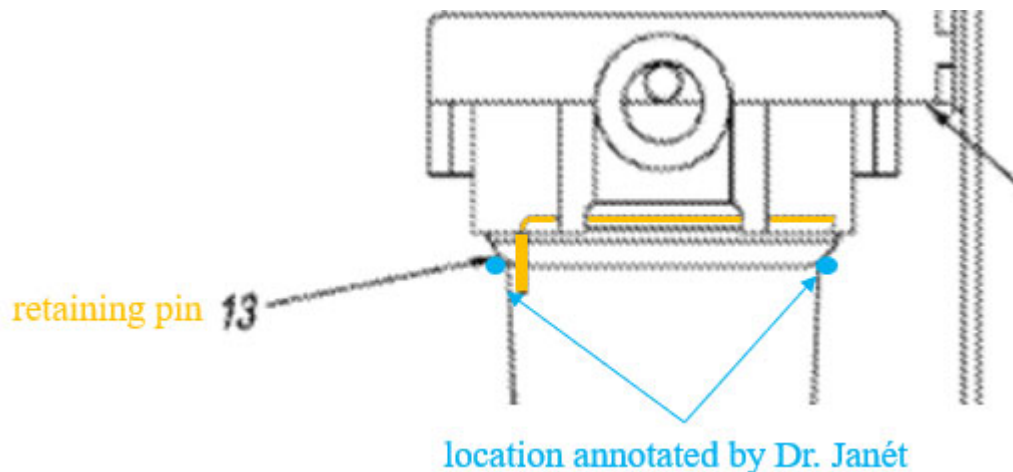


130. Additionally, the threads are included for the purpose of enabling a threaded shipping cap, wherein the threads of the shipping cap and the threads of the recycling container are complementary such that, when the shipping cap is fitted in place, the shipping cap forms a tight seal with said recycling container. Ex. 1001, 4:4-8, 7:48-52. Nothing in the '175 patent suggests that the recycling container threads would be used for any other purpose, including for engaging the removable retaining pin 13 to support the detachable recycling container 12.

131. A POSITA would also not consider using the recycling container threads 17 to engage the removable retaining pin 13 to support the detachable recycling container 12 because attempting to insert the removable retaining pin 13 within the threads 17 would risk fouling or breaking the recycling container threads 17. When there is no vacuum, the weight of the detachable recycling container 12 (which may be substantial given that it stores metal waste) would be supported by the removable retaining pin 13, which would apply a shear force to the threads (assuming the pin would fit within the threads, which as discussed above, it would not). This shear force would pose a significant risk of fouling or breaking the threads. This would be extremely undesirable, among other reasons, because breaking or fouling the threads would prevent the threaded cap from being properly secured, potentially leading to leakage of hazardous material from within the detachable recycling container. For this additional reason, a POSITA would

never consider inserting the removable retaining pin 13 within the recycling container threads 17 as suggested by Dr. Janét.

132. Next, with respect to the location that Dr. Janét labels in blue with the number 2, it would be clear to a POSITA from at least FIG. 2 that the removable retaining pin 13 does not engage that location. As shown below, the removable retaining pin 13 plainly does not engage Dr. Janet’s blue (2) annotation, which is positioned well below the removable retaining pin 13.



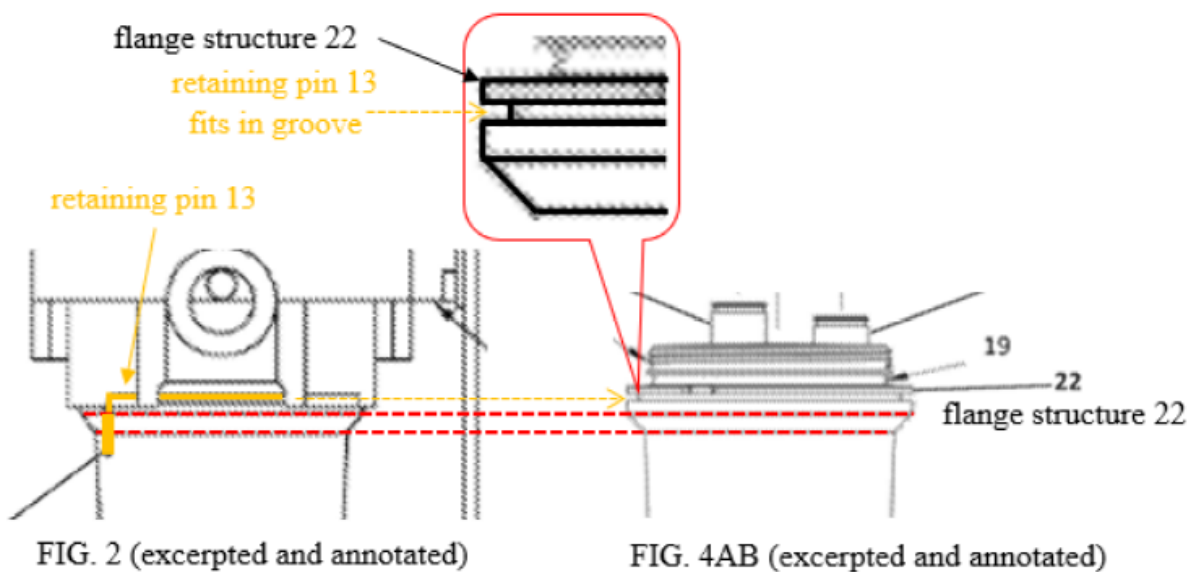
Ex. 1001, FIG. 2 (excerpted and annotated)

133. Dr. Janét states that he “find[s] it telling that the examiner actually rejected the claims as failing to provide section 112 support for the ‘radially protruding structure’ limitation in the first office action” and “[o]nly after Patent Owner amended the specification to add reference to the flange in the figures and specification did [the] Examiner withdraw the section 112 rejection.” Ex. 1003, ¶ 68. Continuing, Dr. Janét opines that a POSITA “would have interpreted this

rejection and subsequent amendment to add material to the specification to show that the limitation was not supported by the original specification.” *Id.* I disagree.

As discussed above, a POSITA would understand that the amendments were supported by the original disclosure and therefore did not constitute “new matter.”

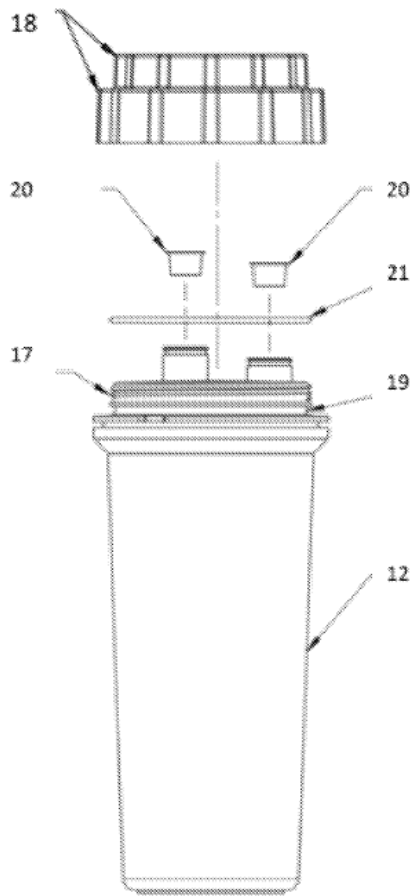
134. Dr. Janét’s declaration addresses annotated versions of FIGS. 2 and 4A of the ‘175 patent that I understand were included in Patent Owner’s opposition to a motion to dismiss filed by DRNA in the Delaware Litigation. Ex. 1003, ¶ 69. These annotations are reproduced below.



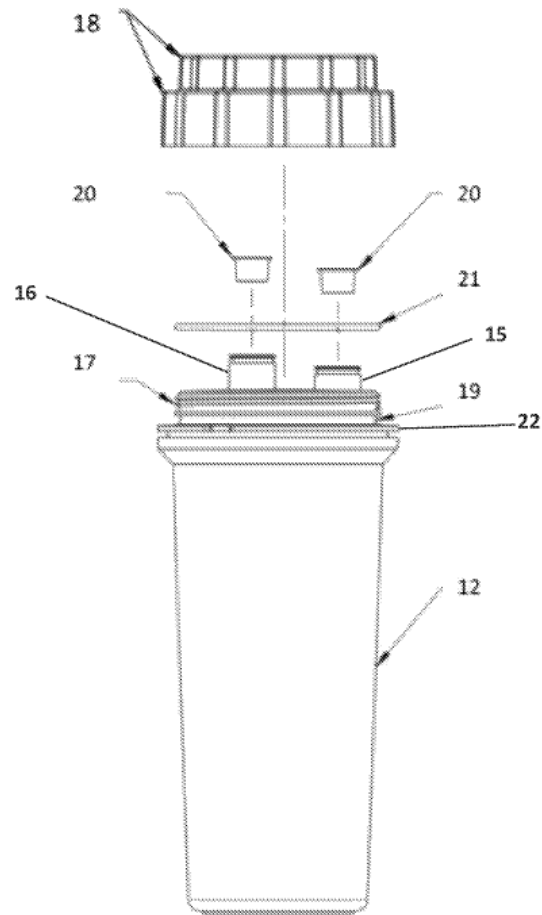
Ex. 1021, 8

135. Dr. Janét asserts that “the combination of these figures [2 and 4A] ... are not inherently disclosed by the *original* specification.” Ex. 1003, ¶ 70 (emphasis in original). He states that “these figures are based upon the figures from the amended specification in which the flange structure is labeled” and “[t]he

alleged ‘flange’ is unlabeled in the original specification” and thus “a PHOSITA would not have seen that as a significant, functional component.” *Id.* I disagree. At the outset, I note that the only differences between the originally filed version of FIG. 4A and FIG. 4A in the issued ’175 patent is the addition of reference numerals 15, 16, and 22, as can be seen by the reproduced figures below. Ex. 1002, 151.



Ex. 1002, 222 (Original FIG. 4A)



Ex. 1001, FIG. 4A

The fact that the flange was not labeled with reference numeral 22 in the originally filed version of FIG. 4A does not change the fact that the originally filed version of FIG. 4A discloses the flange to a POSITA, as discussed above.

136. I disagree with Dr. Janét's assertion that "a PHOSITA would not have seen that [flange] as a significant, functional component." Ex. 1003, ¶ 70. A POSITA would understand that the flange and groove below it must serve a functional purpose if the disposable container were manufactured to include a flange. Manufacturing a flange and groove around the circumference of the disposable container would be more expensive and time consuming than manufacturing a disposable container without a flange and groove around the circumference. For example, if the disposable container were molded (e.g., injected molded), the flange would require additional complexities in the mold. For example, the mold would have to break away laterally to release the mold rather than longitudinally. While the flange and groove could be added with subsequent machining after manufacturing the container, that is an extra operation that would incur additional cost and time. A POSITA would recognize that there is no reason to add a complex feature like a flange and groove to a container if it did not serve a purpose. This would further reinforce to the POSITA that this feature is what engages the removable retaining pin 13 to support the detachable recycling container 12.

137. Dr. Janét opines that “there are multiple ways in which the retaining pin could have been engaged, including using a recess, pocket, hole, or simply below a wider portion of the tapered body.” Ex. 1003, ¶ 71. For the reasons discussed above, I disagree.

138. Dr. Janét further asserts that “the fact that Patent owner had to excerpt part of Figures 2 and 4A in the amended specification, adjust the sizes, and add multiple annotations shows that the ‘radially protruding structure’ is not inherently disclosed by the original specification.” Ex. 1003, ¶ 72. I agree with the annotations provided by Patent Owner for the reasons discussed above. As I explain about above, a POSITA would understand that the removable retaining pin 13 shown in FIG. 2 engages the flange 22 shown in FIG. 4A, just as Patent Owner illustrated.

2. The ‘522 application discloses the claimed “radially protruding structure”

139. Dr. Janet’s declaration states that he was asked to opine “[w]hether the specification for the ‘522 application supports the ‘radially protruding structure’ limitation.” Ex. 1003, ¶ 74. He opines that in addition to the reasons discussed earlier in his declaration (which I disagree with), “Figure 4A in the ‘522 application does not depict the alleged ‘groove’ that was identified in the amended specification.” *Id.*, ¶ 75.

140. As discussed herein, the Preliminary Amendment filed with the ‘556 Application explains that the Grandparent ‘823 Application and the Great-Grandparent ‘828 Application were filed with the same FIG. 4A that was filed with the Parent ‘522 Application that led to the ‘175 patent. FIG. 4A was replaced during prosecution of the Grandparent ‘823 Application and the Great-Grandparent ‘828 Application. Ex. 2003, p. 407 (original FIG. 4A), p. 88 (replacement FIG. 4A); Ex. 2004, p. 329 (original FIG. 4A), p. 147 (replacement FIG. 4A). As reflected by the remarks in the Preliminary Amendment, the Parent ‘522 Application was apparently inadvertently filed with the replacement version of FIG. 4A from the Grandparent ‘823 Application and the Great-Grandparent ‘828 Application rather than the original version of FIG. 4A. Ex. 1002, pp. 345-346.

141. I have been asked to opine whether a reasonably skilled artisan would understand the Parent ‘522 Application to describe with sufficient particularity that the Grandparent ‘823 Application, the ‘828 Great-Grandparent Application, the ‘712 Provisional, and the ‘990 Provisional are incorporated by reference in their entirety. In my opinion, a reasonably skilled artisan would understand that the entirety of the Grandparent ‘823 Application, the ‘828 Great-Grandparent Application, the ‘712 Provisional, and the ‘990 Provisional are incorporated by reference in the Parent ‘522 Application in their entirety.

142. I have reviewed the file history of the Parent ‘522 Application. *See* Ex. 2002. On the same day the Parent ‘522 Application was filed (July 28, 2020), the applicant filed a preliminary amendment. *Id.*, pp. 665-670. I understand from counsel that a preliminary amendment is deemed to be part of the original disclosure of the application if the preliminary amendment is present on the filing date.

143. The preliminary amendment filed with the Parent ‘522 Application replaced the original cross-reference paragraph (¶ [0001]) in the specification with the following paragraph identifying, among other things, the Grandparent ‘823 Application, the Great-Grandparent ‘828 Application, the ‘712 Provisional, and the ‘990 Provisional by their application serial number.

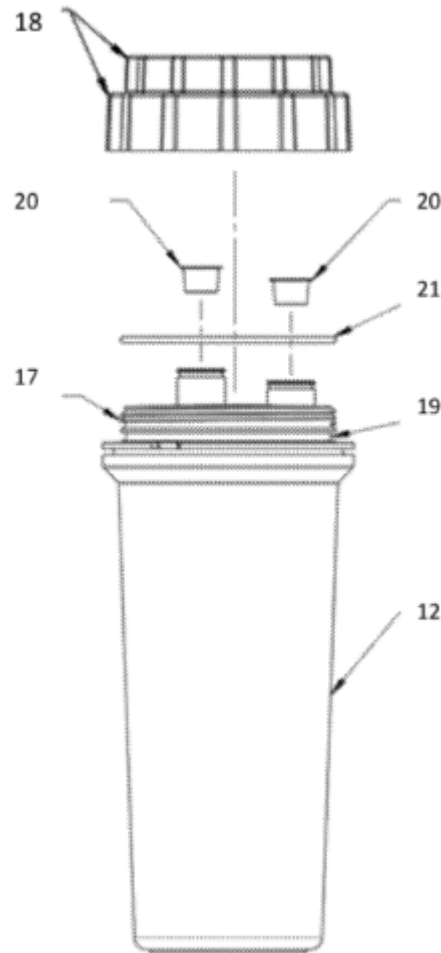
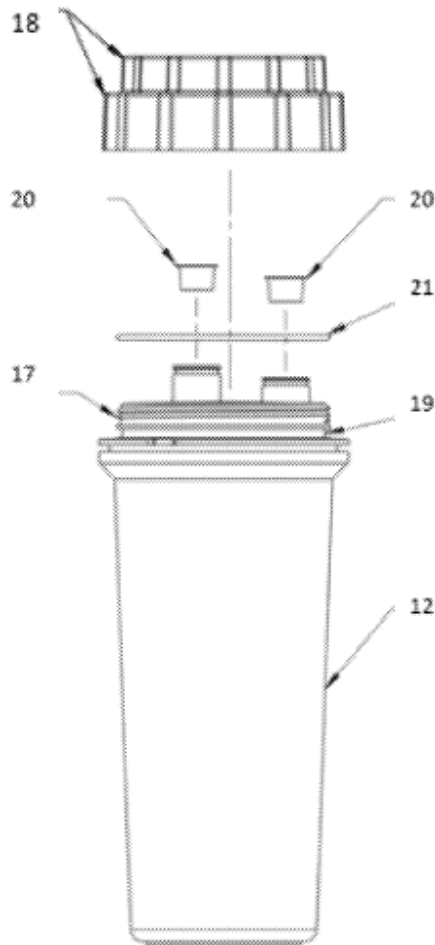
-- [0001] This patent application is a continuation of application serial number 16/033,823, filed on July 12, 2018, which is a continuation in part of patent application serial number 15/730,828, now issued as US Patent 10,646, 313; which in turn claims priority from provisional patent application serial number 62/414,712, filed on October 29, 2016; and provisional patent application serial number 62/406,990, filed on October 12, 2016. This application further claims priority from patent application serial number 29/679,874, filed February 11, 2019, which claims priority from serial number 29/585,674, filed on November 28, 2016, now US Patent D840,534; serial number 29/585,668, filed on November 28, 2016, now patent number D835,779; serial number 29/577,701, filed on September 14, 2016, now patent number D848,612; serial number 29/567,544, filed on June 9, 2016, now patent number D840,533; and serial number 29/565,522, filed on May 23, 2016, now issued patent D835,264. This application further claims priority from patent application serial number 29/679,862, filed on February 11, 2019, which is a continuation of serial number 29/567,544, filed on June 9, 2016, now patent number D840,533; and serial number 29/565,522, filed on May 23, 2016, now issued patent D835,264. --

Ex. 2002, p. 668 (yellow highlighting added)

144. Paragraph [00102] of the Parent ‘522 Application’s specification provides that “[a]ll publications, web-sites, patents and patent applications cited in the specification are hereby incorporated herein by reference in their entirety for the disclosure for which they are cited.” Ex. 2002, p. 440.

145. In my opinion, a reasonably skilled artisan would understand that the specification incorporates by reference in their entirety “[a]ll patents and patent applications cited in the specification,” including the Grandparent ‘823 Application, the Great-Grandparent ‘828 Application, the ‘712 Provisional, the ‘990 Provisional, and the U.S. Design Patent No. D840,534 (“the ‘534 design patent”). The Grandparent ‘823 Application is clearly and unambiguously referenced by its serial number (16/033,823) and filing date (July 12, 2018). The Great-Grandparent ‘828 Application is clearly and unambiguously referenced by its serial number (15/730,828) and the corresponding issued patent (10,646,313). The ‘712 Provisional is clearly and unambiguously referenced by its serial number (62/414,712) and filing date (October 29, 2016). The ‘990 Provisional is clearly and unambiguously referenced by its serial number (62/406,990) and filing date (October 12, 2016). A POSITA would understand that all of these documents are incorporated by reference in their entirety.

146. I have reviewed the file history of the Grandparent ‘823 Application. *See* Ex. 2004. Originally filed FIG. 4A in in the Grandparent ‘823 Application is identical to the originally filed version of FIG. 4A in the ‘556 Application that led to the ‘175 patent, as can be seen by the reproduced figures below.

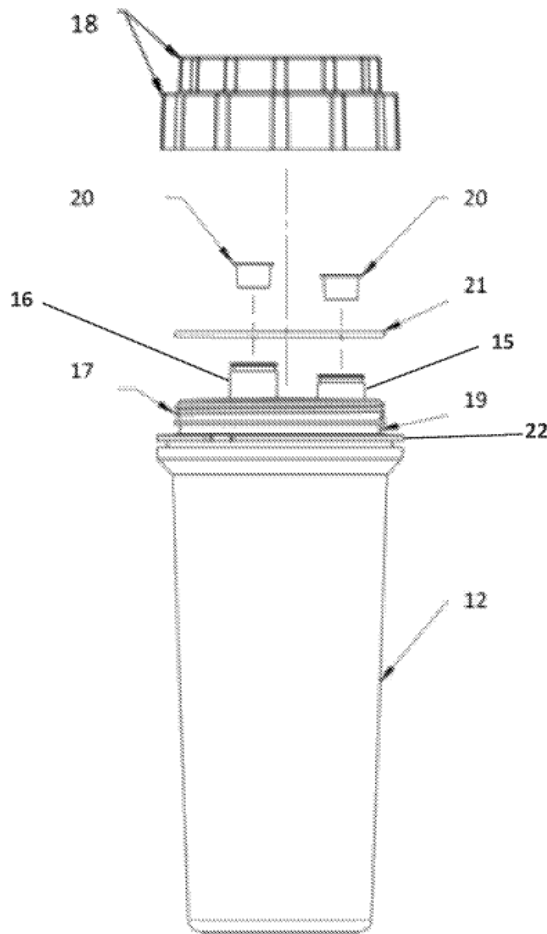


Ex. 1002, p. 222 (Original FIG. 4A)

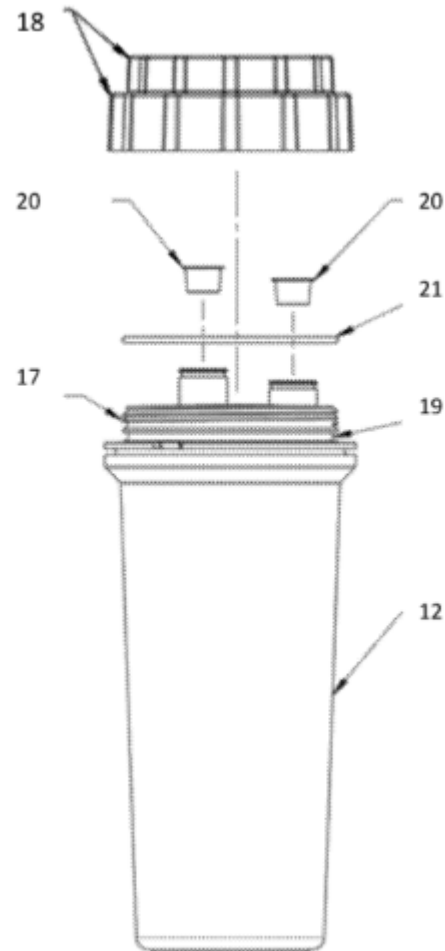
Ex. 2003, p. 407 (Original FIG. 4A)

The claimed “radially protruding structure” is disclosed in the Grandparent ‘823 Application for the reasons discussed above.

147. The only difference between FIG. 4A in the '175 patent and the original FIG. 4A in the Grandparent '823 Application is the addition of reference numerals 15, 16, and 22 in FIG. 4A of the '175 patent. The groove and radially protruding structure are shown in both versions of FIG. 4A.



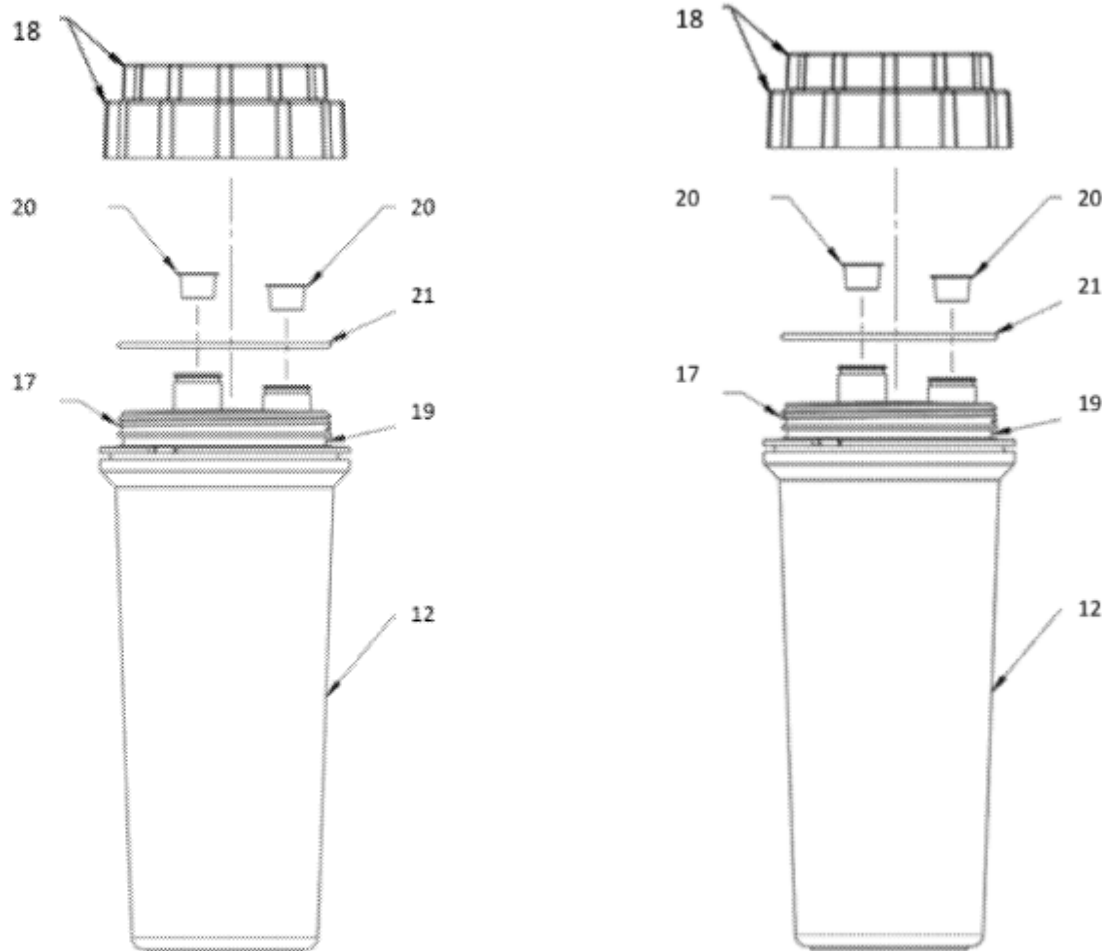
Ex. 1001, FIG. 4A



Ex. 2003, p. 407 (FIG. 4A)

148. I have reviewed the file history of the Great-Grandparent '828 Application. *See* Ex. 2003. Originally filed FIG. 4A in in the Great-Grandparent '828 Application is identical to the originally filed version of FIG. 4A in the '556

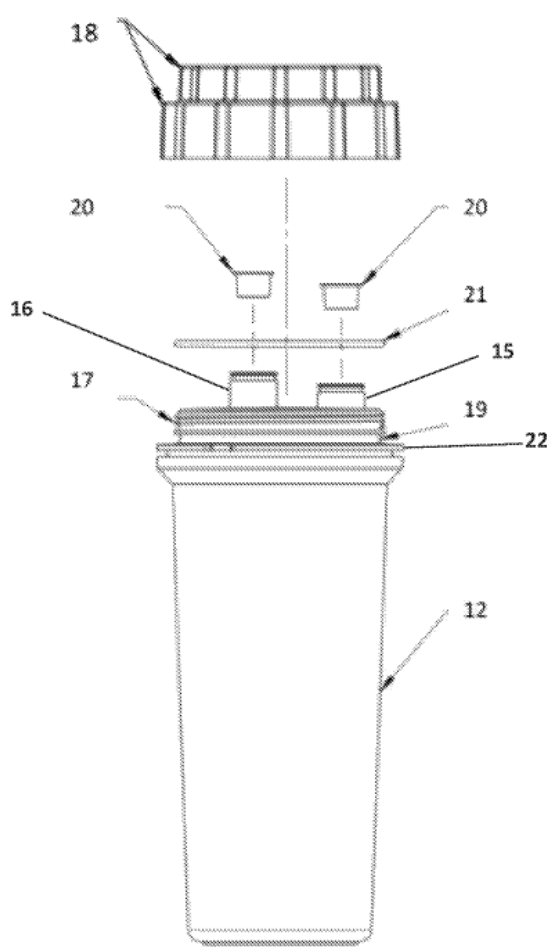
Application that led to the '175 patent, as can be seen by the reproduced figures below.



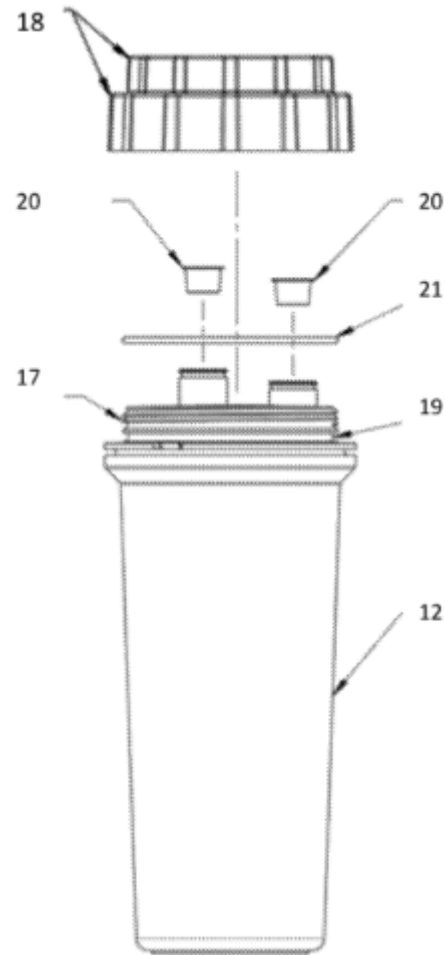
Ex. 1002, p. 222 (Original FIG. 4A)

Ex. 2003, p. 329 (Original FIG. 4A)

149. The only difference between FIG. 4A in the '175 patent and the original FIG. 4A in the Great-Grandparent '828 Application is the addition of reference numerals and lead lines in FIG. 4A of the '175 patent.

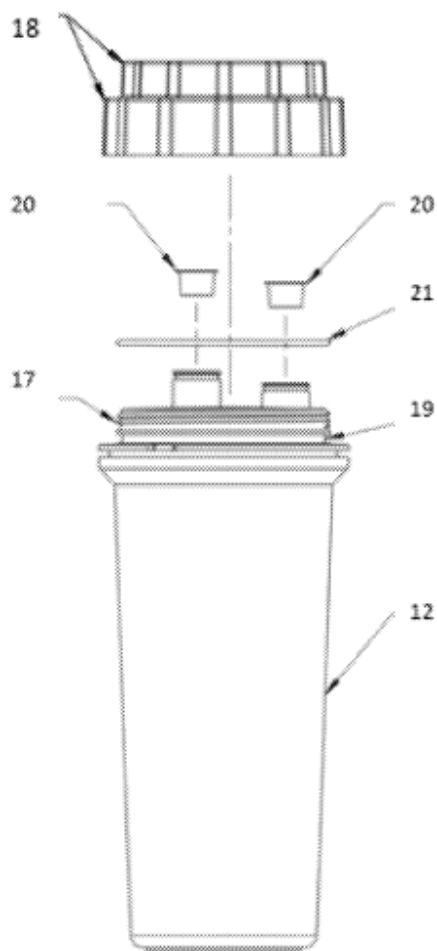


Ex. 1001, FIG. 4A

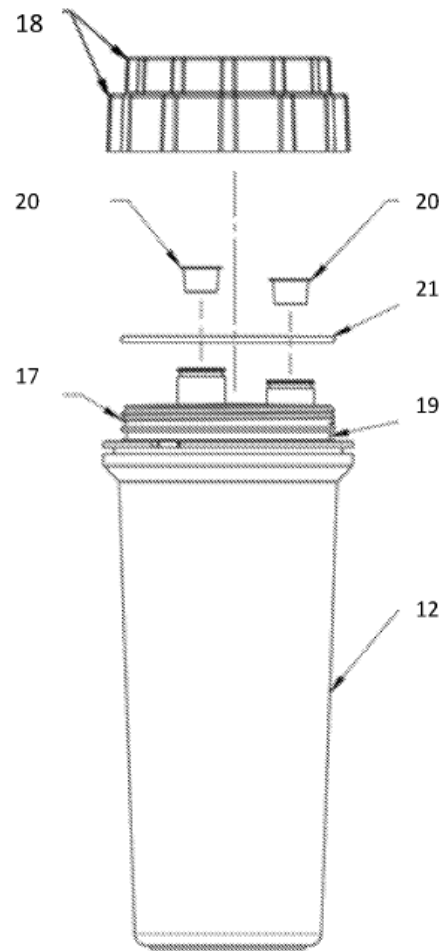


Ex. 2003, p. 329 (FIG. 4A)

150. FIG. 4A in the '990 Provisional is identical to original FIG. 4A filed with the '556 Application that led to the '175 Patent and shows the radially protruding structure, as can be seen by the reproduced figures below. Ex. 2005, FIG. 4A.



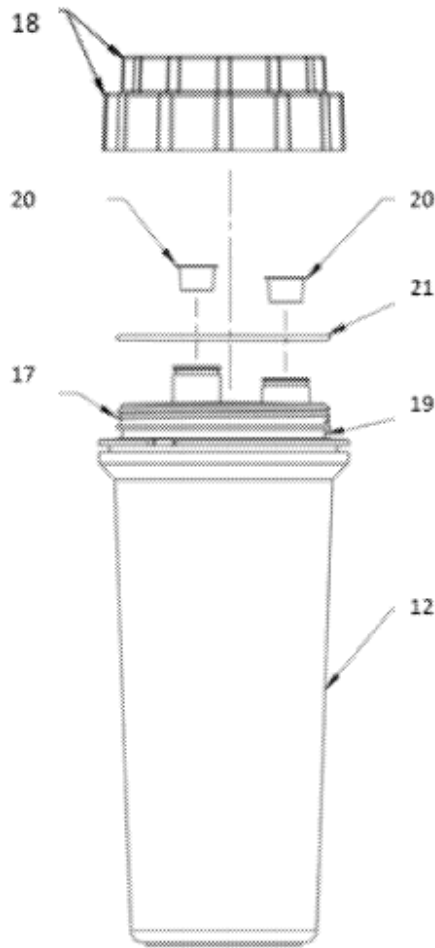
Ex. 1002, p. 222 (Original FIG. 4A)



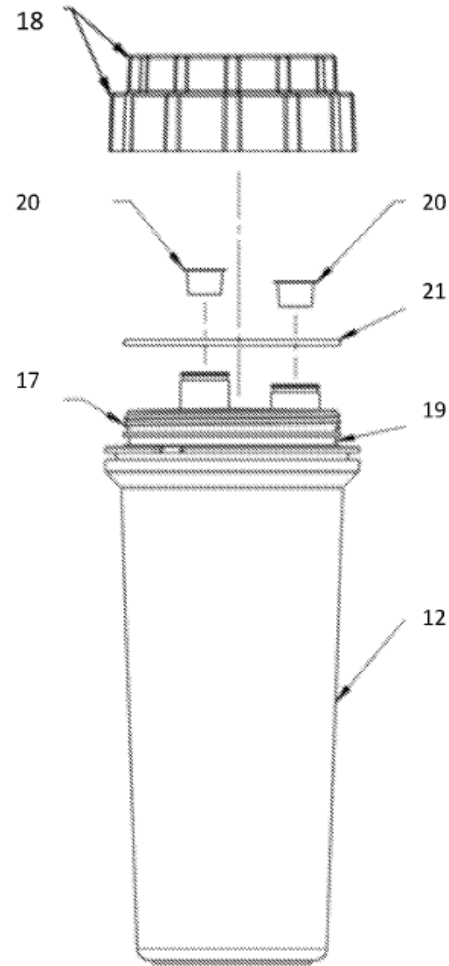
Ex. 2005, FIG. 4A

151. FIG. 4A in the '712 Provisional is identical to original FIG. 4A in the '556 Application that led '175 Patent and shows the radially protruding structure.

Ex. 2005, FIG. 4A.



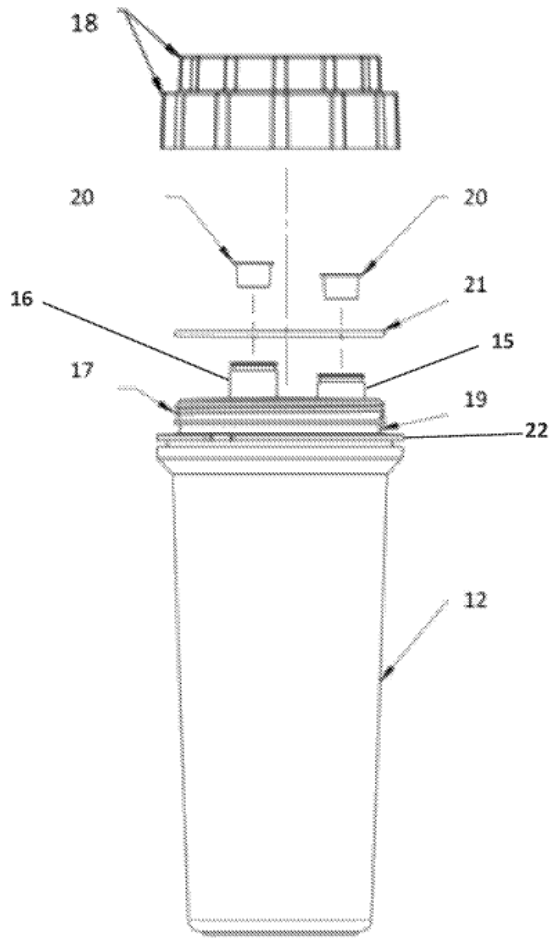
Ex. 1002, p. 222 (Original FIG. 4A)



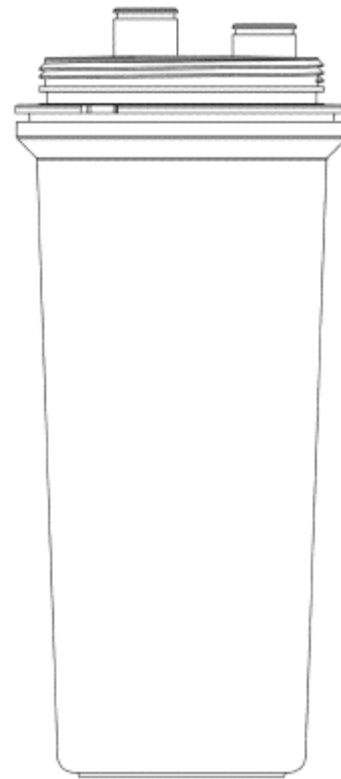
Ex. 2006, FIG. 4A

152. I have reviewed the ‘534 Design Patent. The named inventors are Nicholas Mozzicato and Richard Goulston, who are also named inventors of the ‘175 patent. Ex. 2007, cover; Ex. 1001, cover. The ‘534 Design Patent is titled “Dental Amalgam Separation Container.” Ex. 2007, cover. The container shown in FIG. 8 of the ‘534 Design Patent is identical to the container original FIG. 4A of the ‘175 patent (except it does not include reference numerals and omits the cap, o-

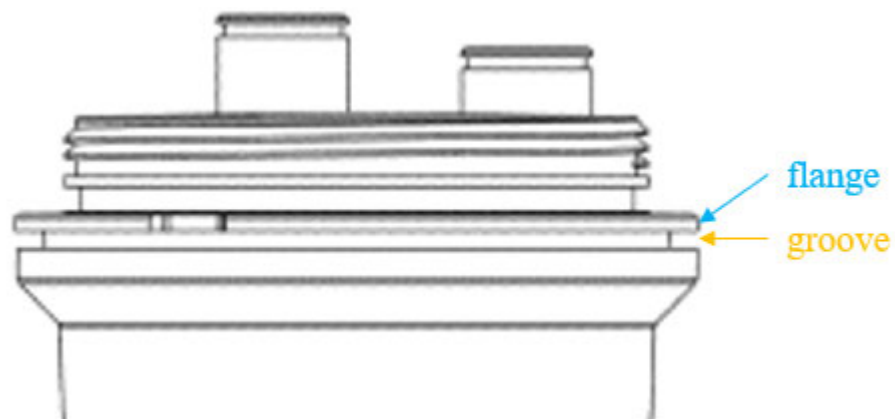
ring, and plugs, which are not part of the container). FIG. 8 clearly shows the groove and radially protruding structure features.



Ex. 1001, FIG. 4A



Ex. 2007, FIG. 8



Ex. 2007, FIG. 8 (excerpted and annotated)

153. As discussed above, it is my opinion that a POSITA would understand that each of the Grandparent ‘823 Application, the Great-Grandparent ‘828 Application, the ‘990 Provisional, the ‘712 Provisional, and the ‘534 Design Patent are all incorporated by reference in their entirety in the Parent ‘522 Application. Because each of these documents includes the correct version of FIG. 4A, in my opinion, the Parent ‘522 Application does provide written description support for the “radially protruding structure” in the claims of the ‘175 Patent and I therefore understand that there is no break in the chain of priority as argued by Dr. Janét and Petitioner.

C. Grounds 1-2 – The DRNA Cartridge 2

154. I understand that in Grounds 1 and 2, Petitioner and Dr. Janét allege that the DRNA Cartridge 2 product anticipates or renders obvious claims 1-3, 6-8, 12, 15, 17-18, and 20 of the ‘175 patent, either alone or in view of the NXT System. Petition 36-69; Ex. 1003, ¶¶ 99-148.

155. As discussed above, I disagree with Dr. Janét’s opinions relating to the priority date of the ‘175 patent. I am informed that the DRNA Cartridge 2 product does not qualify as prior art to the ‘175 patent and therefore cannot anticipate or render obvious the claims of the ‘175 patent as a matter of law.

D. Grounds 3-4 – The Solmetex NXT Container

156. I understand that in Grounds 3-4, Petitioner and Dr. Janét allege that the Solmetex NXT Container anticipates or renders obvious claims 1 and 3-22 of the ‘175 patent, either alone or in view of the NXT System. Petition 69-126; Ex. 1003, ¶¶ 149-209.

157. As discussed above, I disagree with Dr. Janét’s opinions relating to the priority date of the ‘175 patent. I am informed that the Solmetex NXT Container product does not qualify as prior art to the ‘175 patent and therefore cannot anticipate or render obvious the claims of the ‘175 patent as a matter of law.

E. Ground 5 – Liu

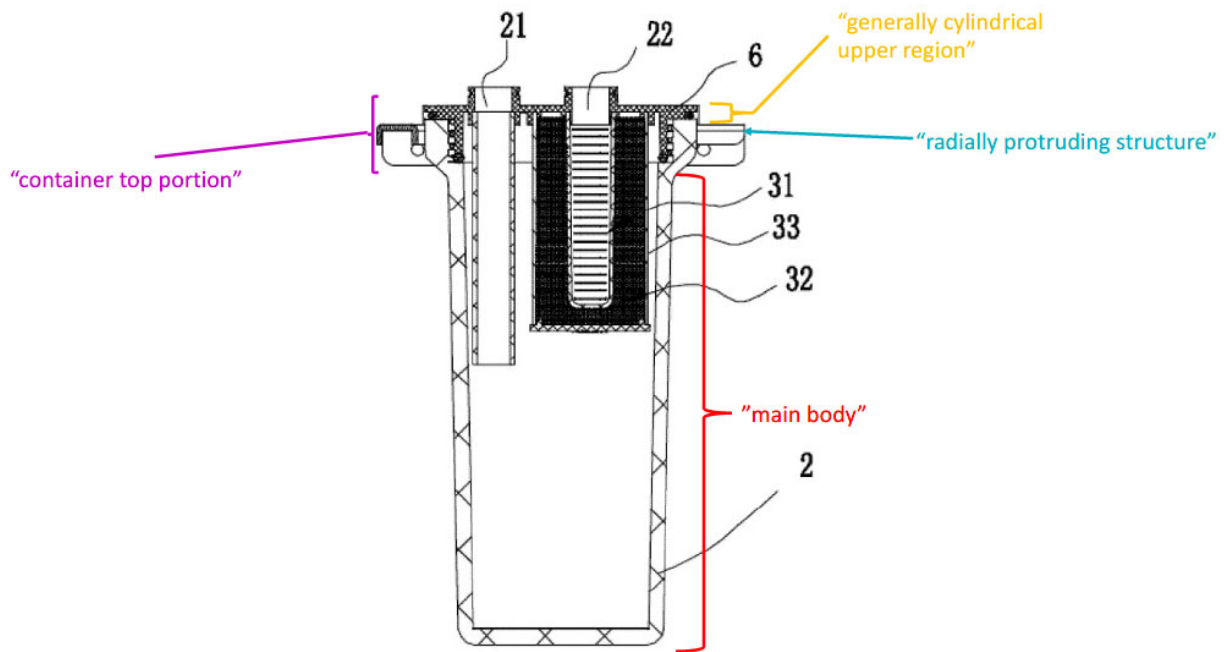
158. I understand that in Ground 5, Petitioner and Dr. Janét allege that Liu anticipates or renders obvious claims 1-3, 6-8, 10, 12, 15, 17-20. Petition, 126-157; Ex. 1003, ¶¶ 210-255. For at least the reasons discussed below, I disagree.

1. Independent Claim 1

159. As discussed herein, claim 1 recites “a container top portion located at a top of the main body” and “the container top portion further including at least one radially protruding structured located below the generally cylindrical upper region.” Ex. 1001, 9:12, 9:21-23. The radially protruding structure is therefore part of the detachable dental amalgam container. The radially protruding structure is “located radially outward relative to the periphery of the circular upper surface.” *Id.*, 9:30-32.

160. Dr. Janet asserts that Liu's Figure 3 discloses "that the 'container top portion' has a 'radially protruding structure' located below the 'generally cylindrical upper region.'" Ex. 1003, ¶ 217. He also asserts that Liu's alleged radially protruding structure "extends 'radially outward relative to the periphery' of the 'circular upper surface.'" *Id.*, ¶ 218. As discussed below, I disagree.

161. Petitioner and Dr. Janet's annotations of Figure 3 of Liu are reproduced below:



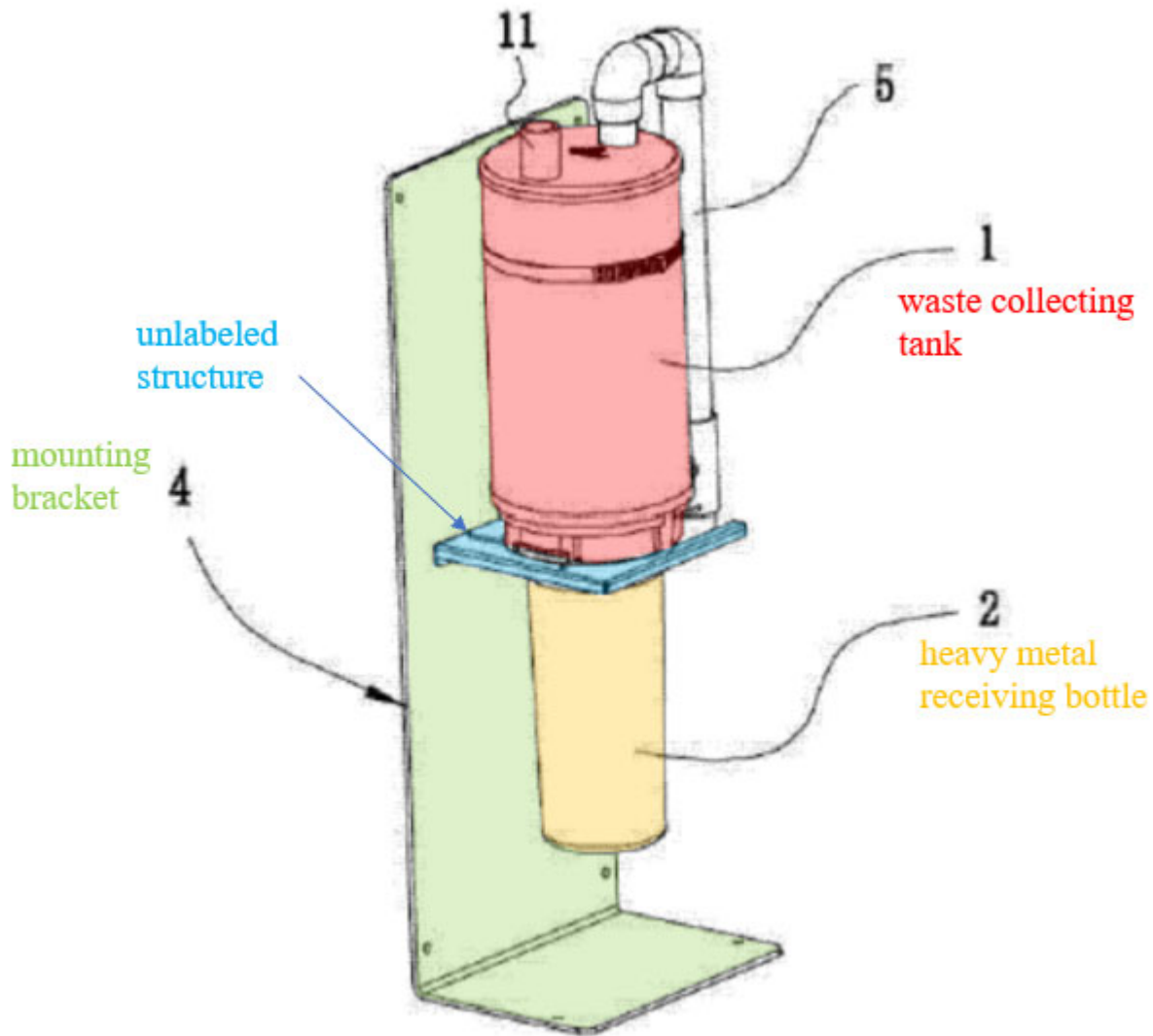
Ex. 1003, ¶¶ 217-218; Petition, 134

(i) Liu does not disclose the claimed "radially protruding structure"

162. Claim 1 specifies that the detachable dental-amalgam container includes a container top portion, which includes the radially protruding structure. The claimed radially protruding structure is part of the detachable dental-amalgam

container. The structure identified by Dr. Janet in Figure 3 of Liu (*see* Ex. 1003, ¶¶ 217-218) is **not** the claimed radially protruding structure because that structure is **not** part of Liu's container.

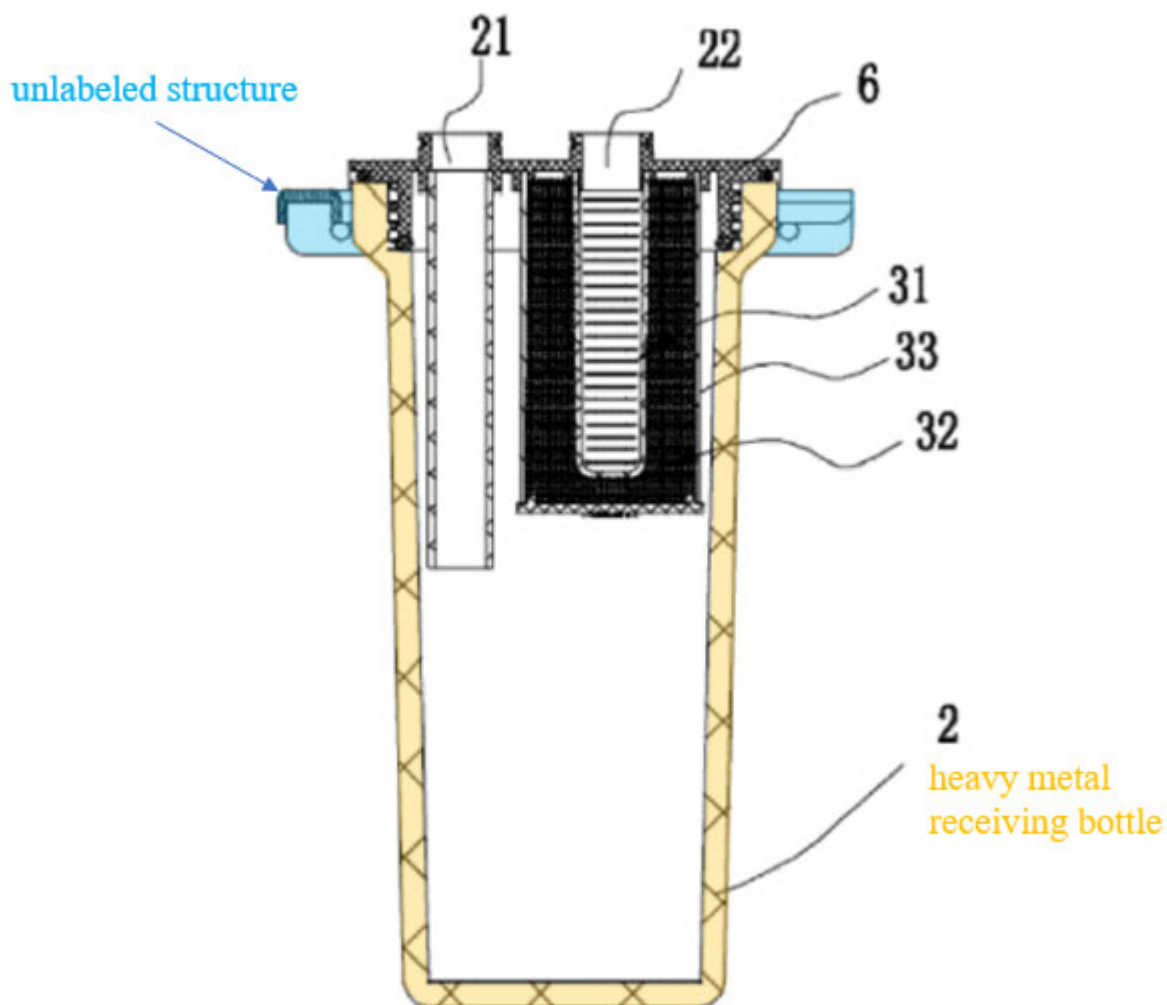
163. Liu's system includes the following components: a waste collecting tank 1, a heavy metal receiving bottle 2, a solid filter 3, and a mounting bracket 4. Ex. 1010, ¶ [0017]. The waste collecting tank 1 is fixed on the mounting bracket 4. *Id.* These components are shown in the annotated version of FIG. 1 below.



Ex. 1010, FIG. 1 (annotated)

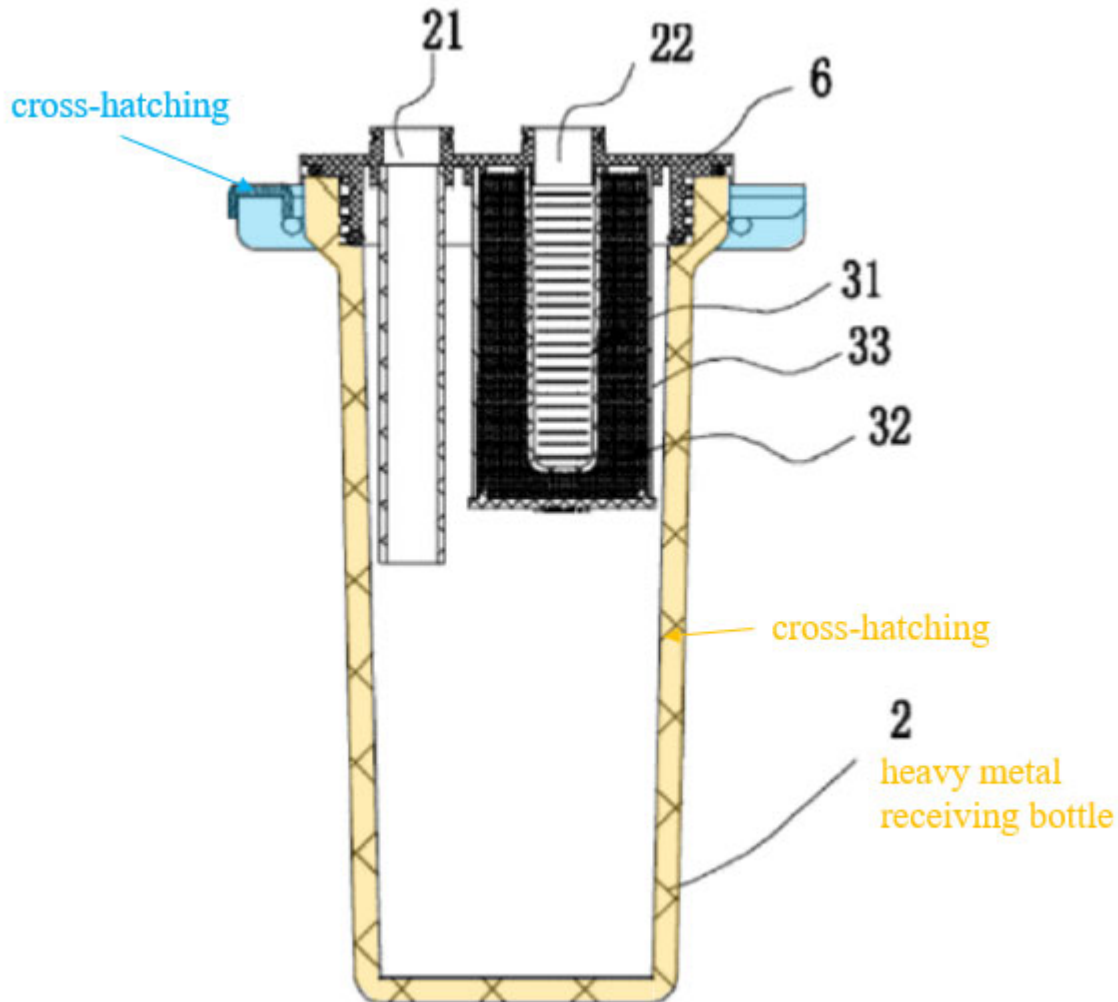
164. The unlabeled structure colored in blue in the annotated version of FIG. 1 above is not labeled with a reference number. The unlabeled blue structure is attached to and cantilevered from the mounting bracket 4. This structure also appears to abut the waste collecting tank 1 (annotated in red) and at least partially surrounds a portion of the heavy metal receiving bottle 2 (annotated in orange).

165. This same structure is also illustrated (and again unlabeled) in FIG. 3 of Liu, as shown below.



Ex. 1010, FIG. 3 (annotated)

166. The heavy metal receiving bottle 2 (orange) is shown in FIG. 3 with cross hatching, while portions of the blue unlabeled structure either have no cross-hatching or different cross-hatching, confirming they are different structures.

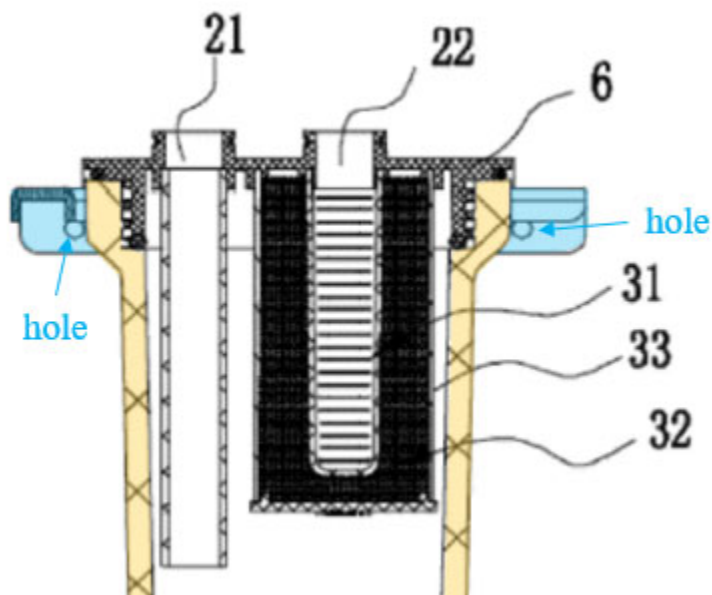


Ex. 1010, FIG. 3 (annotated)

A POSITA would understand that if a structure is shown in a cross-sectional view in a mechanical or engineering drawing (as in Liu's FIG. 3), then the same cross-hatching pattern would be used to identify all parts of that structure that are

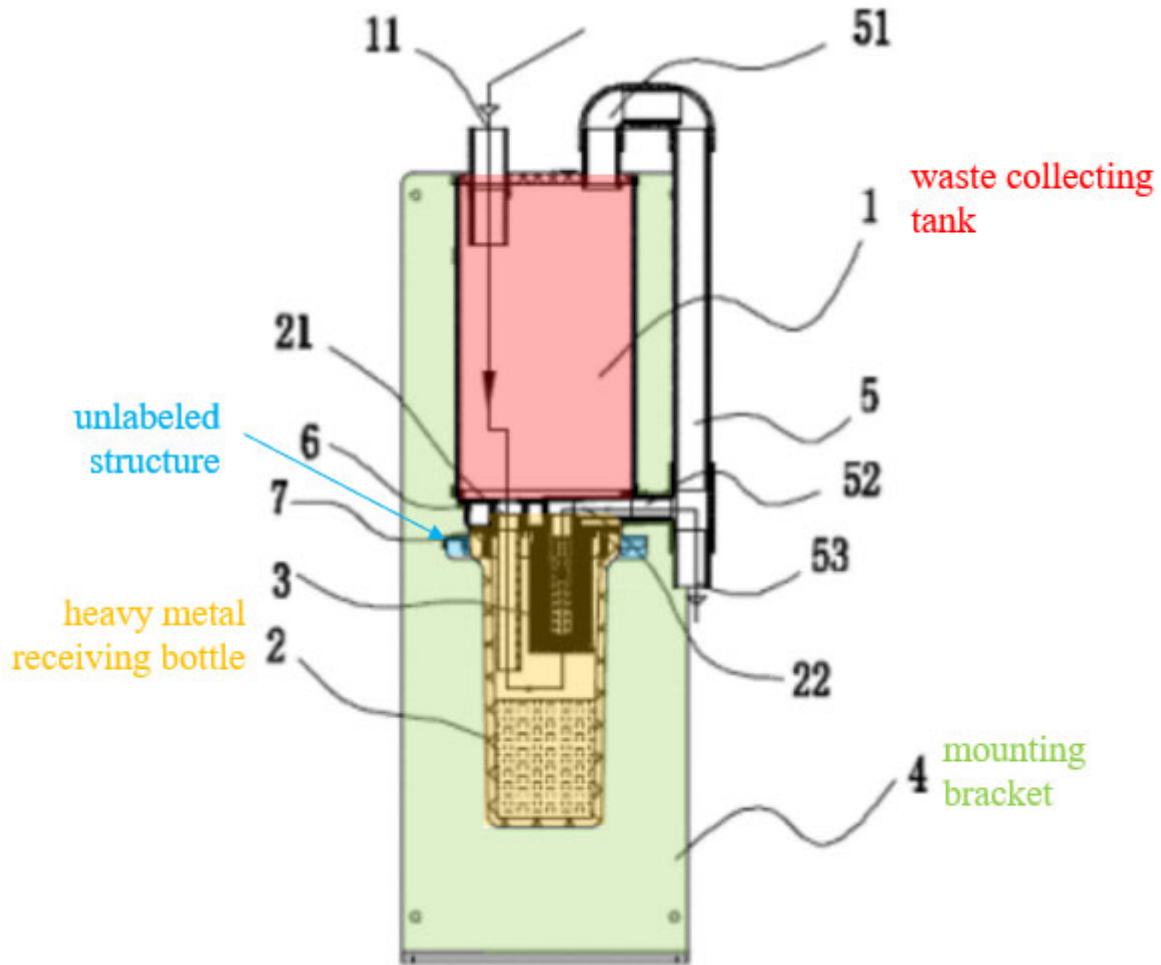
sectioned and visible in the cross-sectional view. As such, based on Liu's FIG. 3, a POSITA understand that the blue unlabeled structure cannot be a part of the orange heavy metal receiving bottle 2 because it is not identified with the same cross-hatching as the heavy metal receiving bottle 2.

167. Moreover, FIG. 3 illustrates two holes on opposite ends of the unlabeled structure. A POSITA would understand that these are the locations where the unlabeled structure is secured to the mounting bracket 4 (e.g., using a screw or other fastener).



Ex. 1010, FIG. 3 (annotated)

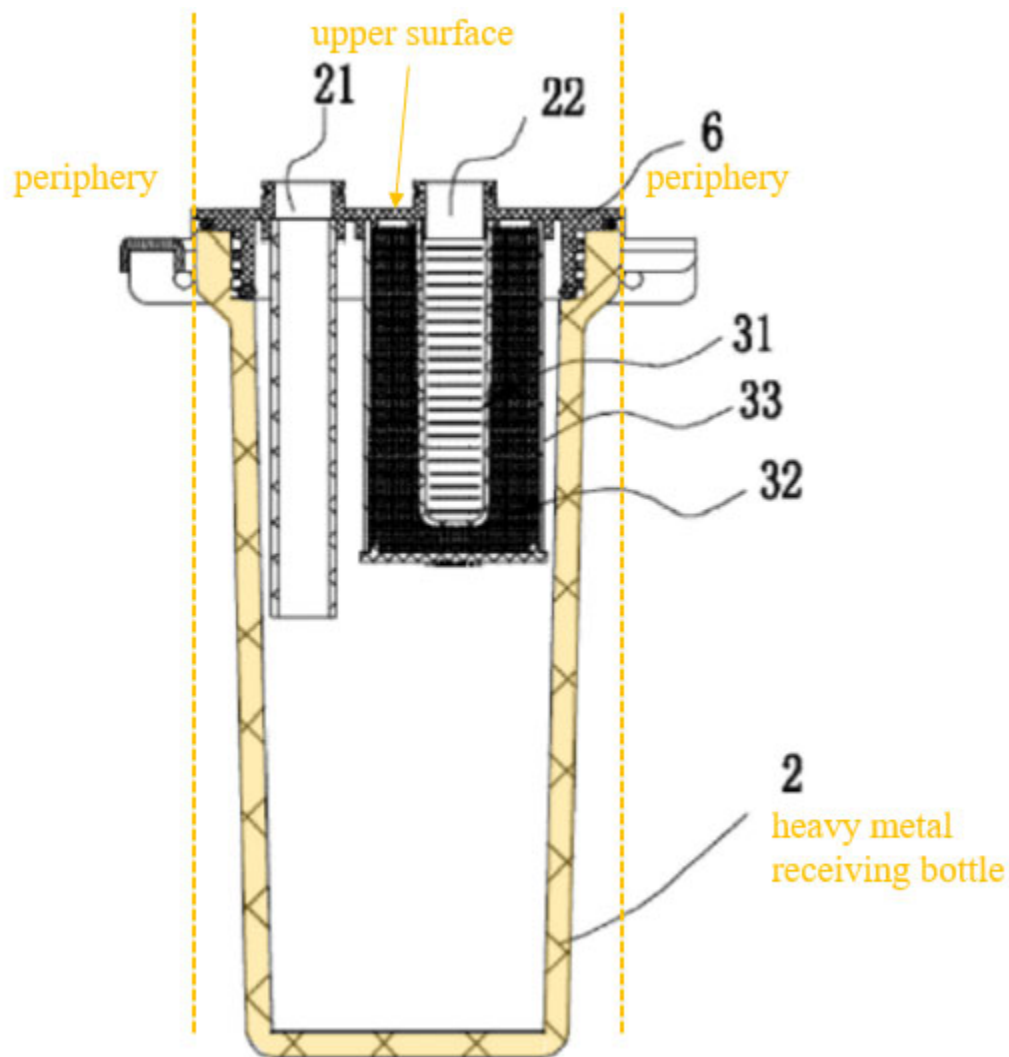
168. The unlabeled structure is also illustrated (and again unlabeled) in FIG. 2, which is reproduced and annotated below.



Ex. 1010, FIG. 2 (annotated)

169. The unlabeled structure I annotated in blue in the figures above is separate and distinct from the heavy metal receiving bottle 2. Based on the drawings, a POSITA would understand that the unlabeled structure is fixed to the mounting bracket 4. The heavy metal receiving bottle 2, on the other hand, is removable. In other words, the unlabeled structure is **not** part of the heavy metal receiving bottle 2—it is a separate and distinct component of Liu's system that is fixed to the mounting bracket 4.

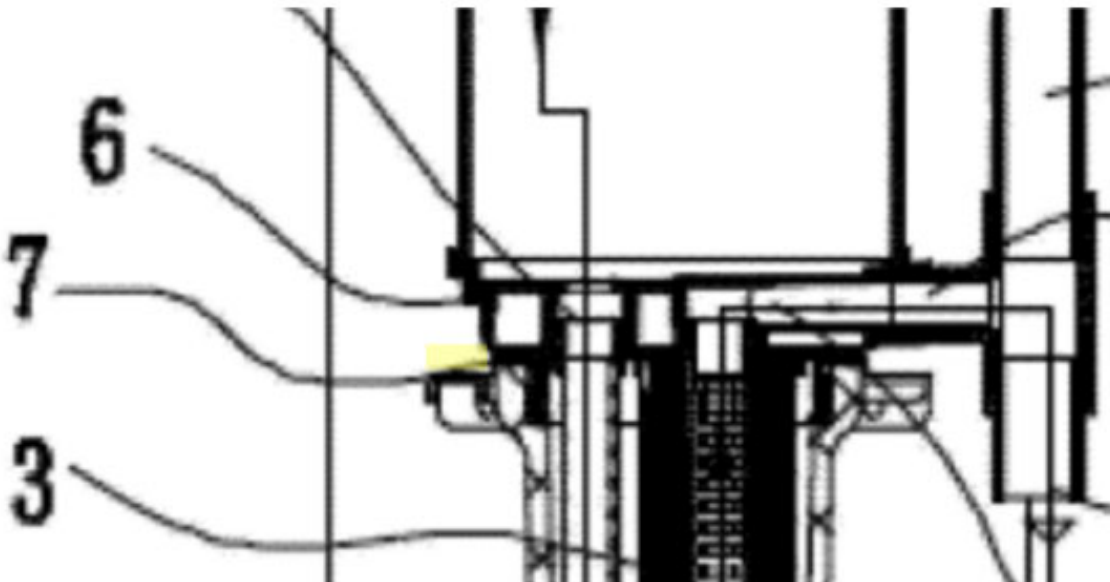
170. There is no radially protruding structure on the heavy metal receiving bottle 2 in Liu. Claim 1 requires that the radially protruding structure is “located below the generally cylindrical upper region” and is “located radially outward relative to the periphery of the circular upper surface.” Ex. 1001, 9:22-23, 9:30-32. As shown below, there is no structure on Liu’s heavy metal receiving bottle 2 that is located radially outward relative to the periphery of the upper surface.



Ex. 1010, FIG. 3 (annotated)

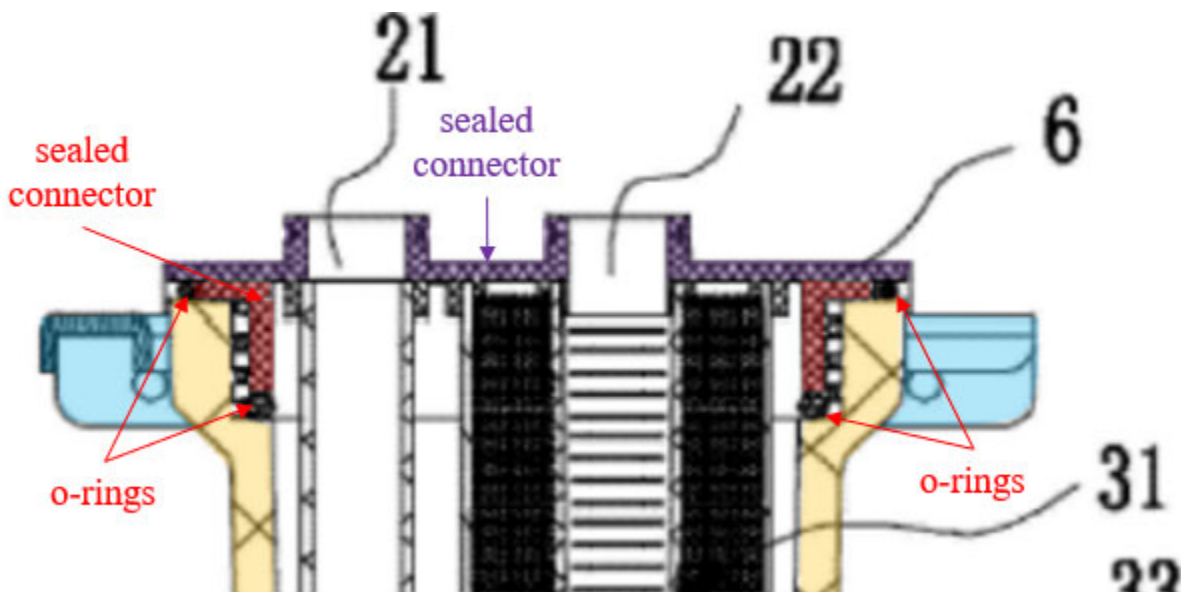
171. Dr. Janét and Petitioner appear to assert that the unlabeled structure discussed above is the second sealed connector 7 described in Liu. Ex. 1003, ¶¶ 212-213; Petition, 128-129. I disagree.

172. Liu associates the “second sealed connector” with reference number 7. Ex. 1010, ¶ [0018]. Reference number 7 is not shown in FIG. 1 or FIG. 3 of Liu. The only figure in which reference number 7 appears is FIG. 2 of Liu. While the precise position of the lead line is not clear, a POSITA examining FIG. 2 would see that the lead line is **not** pointing at the structure identified by Dr. Janét as the purported radially protruding structure. Instead, the lead line for reference number 7 is pointing towards the interior of the heavy metal receiving bottle 2. The tail portion of the lead line is highlighted in yellow below.



Ex. 1010, FIG. 2 (excerpted and annotated)

173. The top portion of the heavy metal receiving bottle 2 is best shown in FIG. 3. The first sealed connector 6 is shown in FIG. 3. While they are not labeled with a reference number, a POSITA would recognize that the darker, circular features (annotated below) are o-rings for sealing the heavy metal recycling bottle 2. Aside from these o-rings, there are two structures that seal the heavy metal receiving bottle 2, which I have annotated below. While the locations where the lead lines terminate are not necessarily clear in Liu, a POSITA would understand that one structure is the first sealed connector 6 and the second structure is the second sealed connector 7.



Ex. 1010, FIG. 3 (excerpted and annotated)

174. This is consistent with Liu's description, which states that "[t]he heavy metal receiving bottle 2 . . . is connected with the waste collecting tank 1 through the first sealed connector 6 and the second sealed connector 7 in the form

of an interface.” Ex. 1010, ¶ [0018]. The structures annotated in red and purple above form an interface to seal the top of the heavy metal receiving bottle 2 and would therefore be understood by a POSITA to be the first and second sealed connectors. By contrast, the unlabeled structure annotated in blue (which as I discussed above most likely corresponds to the “buckle”) does not perform any sealing function (e.g., does not prevent liquid from flowing out of the top of the heavy metal receiving bottle 2). A POSITA would therefore understand that this unlabeled structure is **not** the second sealed connector 7.

175. Dr. Janét asserts that “[a]ccording to Liu, there is a ‘second sealed connector 7 in the form of an interface’ on the detachable bottle that is ‘fastened by a buckle.’” Ex. 1003, ¶ 212 (quoting Ex. 1010, ¶ [0018]). I disagree with Dr. Janét’s characterization of Liu’s disclosure. Liu states: “[t]he heavy metal receiving bottle 2 is placed at the lower part of the waste collecting tank 1 and is connected with the waste collecting tank 1 through the first sealed connector 6 and the second sealed connector 7 in the form of an interface and is fastened by a buckle.” Ex. 1010, ¶ [0018]. Contrary to Dr. Janét’s suggestion, Liu does not state that the second sealed connector 7 is fastened by a buckle. Instead, Liu states that the second sealed connector 7 (and the first sealed connector 6) connect the heavy metal receiving bottle 2 and waste collecting tank 1 in the form of an interface and that the heavy metal receiving bottle 2 is fastened by a “buckle.”

(ii) Liu does not disclose a “radially protruding structure for engaging the at least one retaining pin”

176. As discussed above, Liu does not disclose a “radially protruding structure.” It is therefore irrelevant whether Liu discloses a “retaining pin.”

However, even if the Board were to find that the structure identified by Dr. Janét is a “radially protruding structure” as claimed (which it is not), I disagree with Dr. Janét’s assertions that Liu discloses or renders obvious a “retaining pin.”

177. Dr. Janét asserts that “a PHOSITA would have understood that the buckle disclosed in Liu is a type of ‘retaining pin 13’ as contemplated by the ‘175 patent.” Ex. 1003, ¶ 212. I disagree. Dr. Janét provides no reasoning why a POSITA would have allegedly understood that a “buckle” is a type of “retaining pin” like the ones contemplated in the ‘175 patent. As discussed above, Liu provides no details about the “buckle.”

178. Dr. Janét asserts that “a PHOSITA would have been motivated to try to use a retaining pin.” Ex. 1003, ¶ 213. In particular, Dr. Janét asserts that “a PHOSITA would have recognized that there are a finite number of fastening structures that can be used to connect a disposable container to the rest of the system, like the buckle in Liu.” *Id.* To the extent Dr. Janét is asserting that there are a small number of ways to attach a disposable container to the rest of the system, I disagree. There is a very large number of options for attaching a disposable container to the rest of the system, whether directly (i.e., the container is directly

attached to the system) or indirectly (i.e., one or more additional components attach the container to the system). The potential universe of means for attaching a disposable container to the rest of the system is so large that is impractical to attempt to create an exhaustive list of such options. Some examples include a quick connect, a threaded connection, a bayonet mount, a press or interference fit, a snap fit, a quick connect, clamps (e.g., a hose clamp), a vice, bolts, screws, a magnet, a pedestal underneath the container, etc. There are numerous permutations of each of these examples for attaching the container (e.g., there are numerous ways to create a bayonet mount between the container and the rest of the system).

179. Dr. Janét asserts that “retaining pins could have been produced more cheaply than a buckle and could be easily replaced if the pin rusts (due to exposure to moisture from the tank), deformed, fouled or otherwise damaged.” Ex. 1003, ¶ 213. Further, he asserts that “it would have been obvious to a PHOSITA that replacement of rusty or damaged pins would be important in a system like this that involves liquid and frequent changes because metal on such systems is susceptible to rust and other damage.” *Id.* In view of the fact that Liu does not provide any description of the structure or method of operation of the “buckle,” I disagree with Dr. Janét’s assertions that a POSITA would recognize problems or shortcomings with this “buckle” in Liu and would thus be motivated to replace the “buckle.”

180. Dr. Janét does not explain why a retaining pin “could have been produced more cheaply than a buckle.” Ex. 1003, ¶ 213. As discussed herein, Liu’s description provides no details on the “buckle.” It is therefore unclear what parameters, if any, Dr. Janét considered in opining that a pin “could have been produced more cheaply than a buckle.” *Id.* There are many factors that affect the cost of manufacturing components, such as the design parameters (e.g., the load the component is designed to withstand, perhaps with a factor of safety), shape, size, the material(s) used, and the manufacturing process. Dr. Janét does not discuss any of these factors. Depending on, for example, the materials used and the manufacturing process, a POSITA would recognize that Liu’s “buckle” could have been produced more cheaply than a retaining pin. In other words, there is no reason, and Dr. Janét provides no evidence, that a retaining pin is inherently less expensive to manufacture than the “buckle” in Liu.

181. With respect to Dr. Janét’s assertion that retaining pins “could be easily replaced if the pin rusts (due to exposure to moisture from the tank), deformed, fouled or otherwise damaged” and “it would have been obvious to a PHOSITA that replacement of rusty or damaged pins would be important in a system like this that involves liquid and frequent changes because metal on such systems is susceptible to rust and other damage” as a reason to replace the “buckle” with a retaining pin, I disagree. Ex. 1003, ¶ 213. As an initial matter, Dr.

Janét does not assert that a POSITA would understand that the “buckle” in Liu is at risk of being rusted, deformed, fouled or otherwise damaged and nothing in Liu suggests that these problems exist. *Id.* It appears that Dr. Janét is opining that a POSITA would recognize that a pin is at risk of suffering these issues, but that would not lead a POSITA to replace the Liu “buckle” with a pin. Indeed, if the retaining pin suffered from such problems and the “buckle” did not, that would be a strong reason for a POSITA not to replace the “buckle” with a retaining pin.

182. In any event, I disagree with the notion that a retaining pin would be susceptible to rust. A POSITA would understand that Liu’s heavy metal receiving bottle 2 is intended to store amalgam and waste such that it does not spill out into the environment. There is very little, if any, risk of the waste and amalgam spilling out of the heavy metal receiving bottle 2 (or another source in Liu) that would come into contact with a retaining pin.

183. Moreover, I disagree with Dr. Janét’s premise that a retaining pin is inherently susceptible to rust if it came into contact with water. It appears that Dr. Janét has assumed that the retaining pin would be a ferrous metal in the proposed combination of Liu and Boyd. However, I note that nothing in the claims of the ‘175 patent expressly requires that the retaining pin be metal, let alone a ferrous metal. A POSITA would know that many non-metal materials could be used for a retaining pin, such as, for example, a polymer or wood. Even if the retaining pin

needed to be metal, a POSITA would be very familiar with metals that are rust and corrosion resistant, such as, for example, stainless steel. A metal retaining pin could also be coated with a rust or corrosion resistant material. The same is true for the “buckle” in Liu: it could be made from a non-metal or a metal that is rust/corrosion resistant. Accordingly, there are many ways in which a POSITA could mitigate or eliminate the hypothetical rust problem identified by Dr. Janét (which as discussed above, a POSITA would not have even recognized as a problem) that do not involve having to replace the retaining pin.

2. Independent Claim 12: Liu does not disclose the claimed “radially protruding structure”

184. Independent claim 12 is directed to a “detachable dental-amalgam container” that comprises, *inter alia*, a “container top portion . . . including at least one radially protruding structure located below the generally cylindrical upper region, the at least one radially protruding structure defining a pin-receiving region therebelow for receiving the at least one retaining pin of the dental amalgam separation system to ensure the detachable dental-amalgam container does not become detached from the dental amalgam separation system, the at least one radially protruding structure is located radially outward from the periphery of the upper surface.” Ex. 1001, 10:25, 10:39-65.

185. For claim 12, Dr. Janét reproduces the same annotation of Liu’s FIG. 3 and asserts that “the ‘container top portion’ has a ‘radially protruding structure’

located below the ‘generally cylindrical upper region,’” that “the ‘radially protruding structure’ is used for engaging the ‘buckle,’” and that “it would have been obvious to a PHOSITA that the ‘buckle’ is a retaining pin or could have been replaced with a retaining pin.” Ex. 1003, ¶ 237.

186. For the reasons I discussed above for claim 1, I disagree. Liu does not disclose a “radially protruding structure.” The alleged “radially protruding structure” identified by Dr. Janét is not part of the heavy metal recycling bottle 2.

187. Further, even if Liu disclosed the claimed “radially protruding structure” (which it does not), as discussed above, Liu does not disclose or render obvious a retaining pin and therefore does not disclose or render obvious the requirement in claim 12 that the radially protruding structure defines a pin-receiving region therebelow for receiving the at least one retaining pin of the dental amalgam separation system to ensure the detachable dental-amalgam container does not become detached from the dental amalgam separation system.

3. Independent Claim 18: Liu does not disclose the claimed “radially protruding structure”

188. Independent claim 18 is directed to a “detachable container” comprising, *inter alia*, a “container top portion . . . including at least one radially protruding structure located below the upper generally cylindrical region, the at least one radially protruding structure having a lower surface under which the at least one retaining pin of the dental amalgam separation system is received to

ensure the detachable dental-amalgam container does not become detached from the dental amalgam separation system, the at least one radially protruding structure is located radially outward relative to the periphery of the circular upper surface.”

Ex. 1001, 11:32, 11:43-12:14.

189. For claim 18, Janét repeats the same analysis he provided for independent claims 1 and 12. Ex. 1003, ¶¶ 244-245, 249-250. For the reasons I discussed above for claim 1, I disagree. Liu does not disclose a “radially protruding structure.” The alleged “radially protruding structure” identified by Dr. Janét is not part of the heavy metal recycling bottle 2.

190. Further, even if Liu disclosed the claimed “radially protruding structure” (which it does not), as discussed above, Liu does not disclose or render obvious a retaining pin and therefore does not disclose or render obvious the requirement in claim 18 that the radially protruding structure has a lower surface under which the at least one retaining pin of the dental amalgam separation system is received.

F. Ground 6 – Liu and Boyd

191. I understand that in Ground 6, Petitioner and Dr. Janét allege that claims 1-8, 10, 12-15, 17-20, and 22 of the ‘175 patent are obvious over Liu in view of Boyd. Petition, 157-163; Ex. 1003, ¶¶ 256-270.

192. Dr. Janét asserts that “it would have been obvious for a PHOSITA to combine the overall structure in Liu with the radially protruding structure and retaining pin from Boyd.” Ex. 1003, ¶¶ 257. This argument, however, presupposes that Liu discloses a “radially protruding structure” when, as discussed above, it does not. In other words, Dr. Janét does not propose modifying Liu to include a radially protruding structure. I therefore disagree with Dr. Janét and Petitioner’s assertions that independent claims 1, 12, and 18 (and all relevant claims depending therefrom) are obvious over Liu in view of Boyd because the Liu-Boyd combination still does not disclose the “radially protruding structure” required in the independent claims of the ‘175 patent.

193. Additionally, even if were found that Liu discloses a radially protruding structure (which it does not), I disagree with Dr. Janét’s opinions that it would have been obvious to combine Liu and Boyd. Dr. Janét opines that “a PHOSITA would have been motivated to look at these other references for efficient means for securing the collection bottle in Liu to the air/liquid separation chamber.” Ex. 1003, ¶ 258. As an initial matter, Dr. Janét does not explain what an “efficient means for securing the collection bottle” refers to. *Id.* There are many ways to define whether something is “efficient,” but Dr. Janét does not identify any such criteria for this context.

194. Moreover, nothing in Liu suggests to a POSITA that the “buckle” is not an effective or “efficient means” for securing the heavy metal receiving bottle 2. Dr. Janét does not affirmatively opine that using Boyd’s pin instead of Liu’s “buckle” would be a more “efficient means for securing the collection bottle,” let alone explain why the pin from Boyd would be a more “efficient means.” Ex. 1003, ¶ 258.

195. Dr. Janét opines that because “Liu discloses using a ‘buckle’ . . . a PHOSITA would have recognized that there are alternative structures to maintain the connection and would have been motivated to try alternative means.” Ex. 1003, ¶ 259. But Dr. Janét does not identify any reason why a POSITA would have allegedly “would have been motivated to try alternative means” of securing Liu’s heavy metal collection bottle 2. *Id.*

196. Continuing, Dr. Janét opines that “a PHOSITA would have been motivated to try using threads and/or retaining pins in the amalgam separation system in Liu instead of a buckle to see what worked better, especially in terms of efficiency, cost, and durability.” Ex. 1003, ¶ 259. Dr. Janét does not affirmatively opine that using a retaining pin instead of Liu’s “buckle” would “work[] better,” let alone provide a reason why a retaining pin would purportedly “work[] better.” *Id.* Nor does Dr. Janét affirmatively opine that Boyd’s retaining pin would be more efficient, less expensive, or more durable than Liu’s “buckle,” let alone provide

reason(s) why this would purportedly be the case. I reserve the right to respond should Petitioner or Dr. Janét provide reasoning to support these assertions.

197. Additionally, Boyd discloses the use of “threads, pins *and* a gasket system” for attaching the sedimentation chamber 58. Ex. 1011, 10:16-18. Boyd does not disclose or suggest using “pins” alone, i.e., “pins” without additional “threads.” *Id.* Nor does Boyd disclose or suggest to a POSITA using “pins” structurally support the sedimentation chamber 58. Referring to FIG. 5, a POSITA would recognize the threads annotated below and recognize that the threaded connection is what attaches the sedimentation chamber 58.

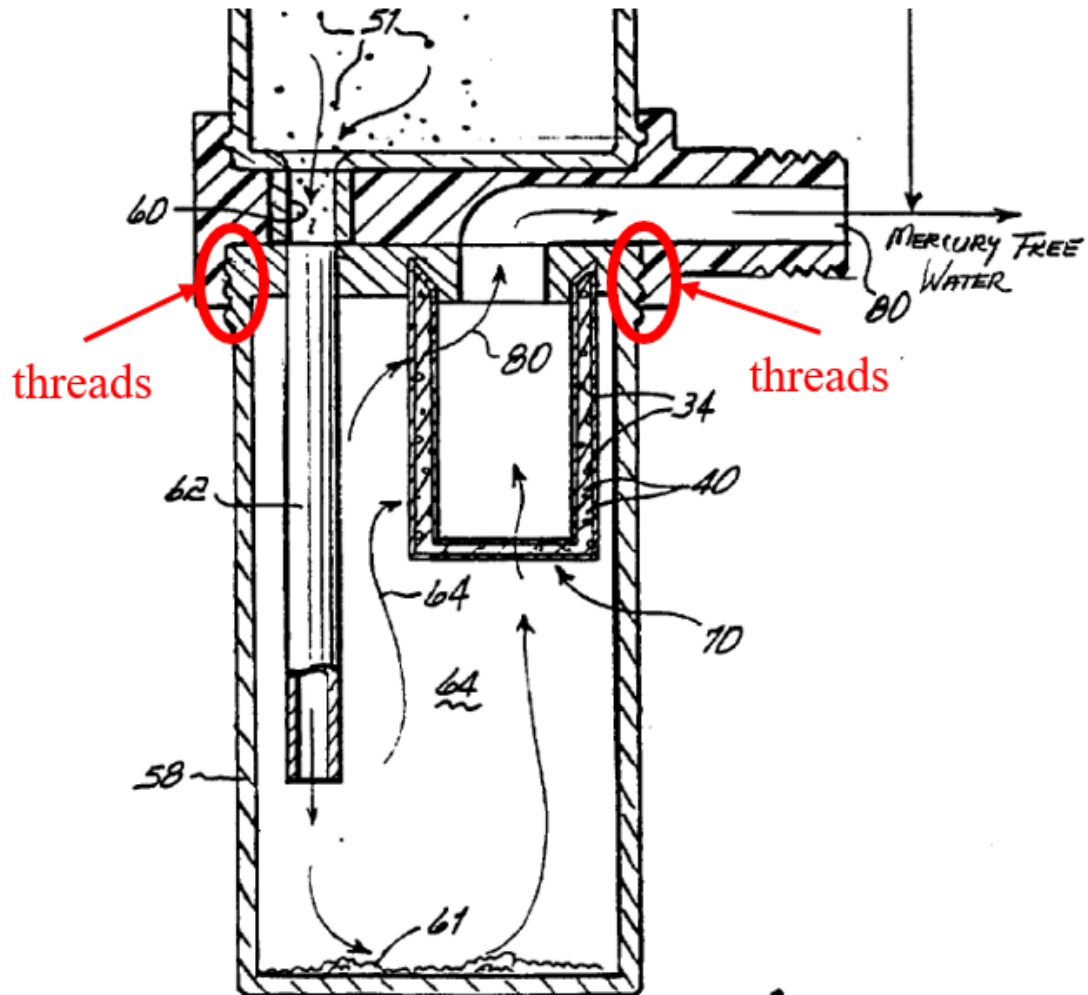


FIG. 5
PGR2023-00055 Ex. 10

Ex. 1001, FIG. 5 (annotated)

198. The “pins” referenced in Boyd are not shown in FIG. 5. If the “pins” were used to attach the sedimentation chamber 58, they would be shown somewhere in the cross-sectional view of FIG. 5. A POSITA would understand that to attach the sedimentation chamber 58 via the threads, one would have to rotate the sedimentation chamber 58 relative to air/liquid separation chamber 50 to engage the threads. Importantly, the sedimentation chamber 58 would have to be

rotated such that the inlets and outlets are aligned, as shown in FIG. 5. A POSITA would therefore recognize that there is a need to have a mechanism to make sure that the sedimentation chamber 58 is not under or over rotated so that the inlets and outlets are aligned. As such, in my view, a POSITA would understand that the “pins” referenced in Boyd (which are not shown in FIG. 5) are used to align the sedimentation chamber 58 rotationally relative to the air/liquid separation chamber 50 and that these “pins” are not used to actually support or attach the sedimentation chamber 58.

199. To the extent Dr. Janét is opining that Boyd’s attachment means would have “worked better, especially in terms of efficiency, cost, and durability” relative to Liu’s “buckle” (which is not expressly stated in his declaration), I disagree. Boyd discloses using *both* threads and pins, and it is clear from FIG. 5 that the threads are the only, or at least the primary, structure that supports the sedimentation chamber 58. Ex. 1011, 10:16-18. In my view, adding threads to Liu would add to the manufacturing cost. Threads could be formed either by machining or by molding or casting. In both options, there is added cost, time, and complexity in the manufacturing process.

200. In addition, a POSITA reviewing Liu and Boyd would understand that their respective containers would need to be removed and replaced once full. Ex. 1010, ¶ [0022]; Ex. 1011, 10:18-20. If Liu were modified to use Boyd’s threads

and pins, one would have to rotate the sedimentation chamber 58 at least several full rotations to remove the sedimentation chamber 58. Depending on how tightly the threads were engaged when the sedimentation chamber 58 was initially attached, one may need to apply a relatively significant rotational force and may need a tool to do so (e.g., they cannot initiate rotation of the sedimentation chamber 58 by hand). For this additional reason, I disagree with Dr. Janét assertion that it would have been obvious to a POSITA to modify Liu to use Boyd's threads and pins.

IX. CONCLUSION

201. I reserve the right to modify or supplement my opinions, if necessary, based on further review and analysis of the evidence in this case, including review and analysis of information that may be provided to me subsequent to the date of this Declaration.

I declare that all statements made herein of my own knowledge are true and all statements made on information and believe 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 Title 18 of the United States Code.

Date: January 3, 2024



Charles A. Garris, Jr., Ph.D.