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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AESTHETIC MANAGEMENT PARTNERS, LLC AND
AESTHETIC MANAGEMENT PARTNERS, INC.,

Petitioners,

v.

HYDRAFACIAL LLC

Patent Owner.

Case No. IPR2025-01217
U.S. Patent No. 11,446,477

FIRST DECLARATION OF KARL R. LEINSING, MSME, PE

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

Dated: October 17, 2025 By: 

Karl R. Leinsing, MSME, PE

EXHIBIT 2001

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1. I, Karl Leinsing, am making this declaration at the request of Patent Owner HydraFacial LLC in support of the Patent Owner's Preliminary Response in the matter of the Inter Partes Review No. IPR2025-01217 of U.S. Patent No. 11,446,477 ("the '477 Patent"). I understand that this declaration is being submitted in this proceeding as Ex. 2001.

2. I am being compensated for my work in this matter at my standard hourly rate for consulting services. My compensation in no way depends on the outcome of this proceeding.

3. In addition to my own knowledge and expertise, I have reviewed and considered the following written materials in conducting the analyses and forming the opinions set forth in this declaration.

Exhibit or Paper No.	**Description**
2	Petition for Inter Partes Review
1001	U.S. Patent No. 11,446,477
1002	File History for U.S. Patent 11,446,477
1003	Declaration of Eric Simon
1004	U.S. Publication No. 2003/0212415 ("Karasiuk")
1005	U.S. Patent No. 5,199,604 ("Palmer")
1006	U.S. Publication No. 2003/0093089 ("Greenberg")

Exhibit or Paper No.	Description
1008	U.S. Patent No. 6,684,880 ("Trueba")
1013	Burgess, Cheryl M., Cosmetic dermatology, Heidelberg, Germany: Springer, 2005 ("Burgess")
1016	Lee, Woan-Ruoh, et al., Lasers and microdermabrasion enhance and control topical delivery of vitamin C, Journal of investigative dermatology 121.5 (2003): 1118-1125 ("Lee")
1020	U.S. Patent No. 4,559,036 ("Wunsch")
1029	Nayler, Gordon. Dictionary of mechanical engineering. SAE International, 1996 ("Nayler")
1034	Declaration of Harold Walbrink dated July 6, 2025
2005	2016-05-09 Order Granting Plaintiff's Motion for Summary Judgment *Edge Systems LLC v. Aguila,* Case No. 14-cv-24517, D.I. 225 (S.D. Fla. May 09, 2016)
2007	2015-01-29 Report and Recommendations on Plaintiff's Application for Preliminary Junction, *Edge Systems LLC v. Aguila*, Case No. 14-cv-24517, D.I. 81 (S.D. Fla. Jan 29, 2015)
2008	2015-02-24 Order Adopting D.I. 81 Report and Recommendation, *Edge Systems LLC v. Aguila*, Case No. 14-cv-24517, D.I. 89 (S.D. Fla. Feb. 24, 2015)
2009	Declaration of Vipul Savsani
2030	Hydrafacial Syndeo™ Instruction for Use (IFU), revised May 1, 2023
2031	HydraFacial MD™ Elite™ User Guide, revised November 1, 2023
2032	Hydrafacial™ Allegro MD Instructions for Use (IFU), revised November 06, 2023

Exhibit or Paper No.	Description
2033	HydraFacial MD™ System Owner's Manual (Tower Owner's Manual) (2005)
2034	HydraFacial™ Handpiece User Guide, Revised February 19, 2020
2035	HydraFacial Nectre® System Owner's Manual, Revised May 14, 2008
2036	HydraFacial™ Nectre® System User Manual, Revised January 27, 2009
2037	HydraFacial™ Nectre® System Service Manual, Revised June 12, 2009
2038	Introducing . . . HydraFacial MD™ by Edge Systems Advertisement
2039	HydraFacial™ Rejuvenate Your "Microderm" Business! Advertisement (January/February 2006)
2040	HydraFacial™ Whole New Skin Advertisement
2041	My Life. My Time. My Skin HydraFacial MD™ Advertisement, Dated May 11, 2015
2042	Unique Patented HydraFacial MD® TECHNOLOGY Advertisement (2013)
2043	HYDRAFACIAL™ TOWER SYSTEM Advertisement (2020)
2044	The Elite™ is the Latest HydraFacial System with Advancements to Ensure Your Practice's Success Advertisement (2020)
2045	EXPECT EVERYTHING: Introducing the Brand-New HydraFacial Elite Advertisement (2020)
2046	Expect Everything with the New HydraFacial Elite
2047	The Allegro™ System Advertisement (2020)

Exhibit or Paper No.	Description
2048	Excerpts from the 2003 Bloomsbury Dictionary of Science and Technology 1st Ed.
2049	Excerpts from the 2004 Bloomsbury English Dictionary 2nd Ed.
2050	Excerpts from 2005 Collins English Dictionary 7th Ed.
2051	Excerpts from Academic Press Dictionary of Science and Technology
2052	Poiseuille and his law, Anaesthesia, 1976, Volume 31 (J. Pfitzner)
2053	Estimating Water Flow Rates (W.L. Trimmer)
2054	Viscosity of Endodontic Irrigants: Influence of Temperature, Dental Research Journal 2015
2055	Optimization Formula of Antioxidant Cream Vitamin E (α-tocopherol acetate) with Virgin Coconut Oil (VCO), Dian Ermawati, Uswatun Chasanah and Dwi Dwi.
2056	Dixon Valve & Coupling Company. (n.d.). Viscosity chart. https://www.dixonvalve.com/sites/default/files/product/files/brochures-literature/viscosity%20chart.pdf (last accessed May 12, 2025)
2064	Complaint in *Edge Systems LLC v. Cartessa Aesthetics, LLC*, Case No. 20-CV-6082, Dkt. 1 (E.D.N.Y.)
2067	Summary Judgment Order in *Edge Systems LLC v. Cartessa Aesthetics, LLC*, Case No. 20-CV-6082, Dkt. 97 (E.D.N.Y. June 6, 2023)
2068	HydraFacial ITC Complaint against Cartessa Aesthetics, LLC and Eunsung Global Corp. in ITC Inv. No. 337-TA-1408 (ITC June 10, 2024)
2074	Elite Device Photo

Exhibit or Paper No.	Description
2075	Allegro Device Photo
2076	Elite Device Photo
2077	Allegro Device Photo
2078	Collection of Images from Syndeo Device Video
2079	Collection of Images from Elite Device Video
2080	Syndeo Device Part Photo
2081	Syndeo Device Photo
2084	Syndeo Device Part Photo
2085	Syndeo Device Photo
2086	Syndeo Device Photo
2087	Syndeo Device Photo
2088	Allegro Device Photo
2089	Allegro Device Part Photo
2090	Allegro Device Part Photo
2091	Allegro Device Part Photo
2092	Tower Device Part Photo
2093	Elite Device Photo
2094	Elite Device Part Photo

Exhibit or Paper No.	Description
2095	Allegro Device Part Photo
2096	Elite Device Photo
2097	Allegro Device Photo
2098	Elite Device Photo
2099	Elite Design History File [SEALED]
2100	HydraFacial Devices Overview [SEALED]
2101	Syndeo Device Photo
2102	Allegro Device Photo
2104	Handpiece Photo
2105	Handpiece Photo
2106	Handpiece Photo
2107	Syndeo Device Photo
2108	Syndeo Device Photo
2109	Syndeo Device Photo
2110	Syndeo Device Photo
2111	Handpiece Photo
2112	Handpiece Photo
2113	Syndeo Engineering Report [SEALED]

Exhibit or Paper No.	Description
2114	Syndeo Schematic [SEALED]
2115	Elite Device Photo
2116	Elite Device Photo
2117	Allegro Device Photo
2118	Tower Device Photo
2119	Elite Device Photo
2120	Allegro Device Photo
2121	Allegro Device Photo
2125	HydraFacial MD System Owner’s Manual
2126	Elite Device Photo
2127	Collection of Syndeo Device Photos
2128	Syndeo Device Photo
2130	Handpiece Photo
2132	Elite Device Part Photo
2133	Allegro Device Part Photo
2134	Syndeo Device Part Photo
2135	Elite Device Photo
2136	Elite Device Photo

Exhibit or Paper No.	Description
2137	Syndeo Device Photo
2138	Excerpt of HydraFacial Schedule 14A Proxy Statement, available at https://www.beautyhealth.com/static-files/0cfbddf1-8829-45f3-a9d1-3ad940148629
2139	Mackenzie, Macaela, "Why Microdermabrasion Treatments Are on the Decline, According to Dermatologists," Allure, March 26, 2018, available at https://www.allure.com/story/microdermabrasiontreatment-decline-in-popularity
2140	The Beauty Health Company 2023 10-K
2141	HydraFacial Sales
2142	The Beauty Health Company 2022 10-K
2144	L'Oreal, "Annual growth of the global cosmetics market from 2000 to 2023," Statista, March 2024, accessed August 21, 2025, https://www.statista.com/statistics/297070/growth-rate-of-the-global-cosmetics-market
2146	Allegro Device Photo
2147	Tower Device Photo
2149	Collection of Tower Device Photos
2151	Collection of Tower Device Photos
2152	Tower Device Photo
2153	Allegro Device Photo

Exhibit or Paper No.	Description
2154	Supplemental Declaration of Ali S. Razai in Edge Systems LLC v. Raphael Newton Aguila, Case 1:14-cv-24517-KMM, Dkt. 40-1 (attaching a true and correct copy of Aguila's website http://www.hydradermabrasion.com captured on November 12, 2014 as Exhibit VV)
2155	Exhibit VV to the supplemental declaration of Ali S. Razai in Edge Systems LLC v. Raphael Newton Aguila, Case 1:14-cv-24517-KMM, Dkt. 40-20 (Aguila's website http://www.hydradermabrasion.com captured on November 12, 2014)
2156	Order Construing Certain Terms of the Asserted Claims (Markman Claim Construction), Order No. 29, ITC Inv. No. 337-TA-1408 (Mar. 14, 2025)
2157	Order Construing Remaining Disputed Claim Term, Order No. 32, ITC Inv. No. 337-TA-1408 (Mar. 19, 2025)
2161	Initial Determination in ITC Inv. No. 337-TA-1408 (ITC August 26, 2025)
2162	Cartessa's Petition for Review of the Initial Determination in ITC Inv. No. 337-TA-1408 (Sept. 8, 2025)
2163	Cartessa's Invalidity Contentions in Interrogatory Response No. 17 in ITC Inv. No. 337-TA-1408 (Oct. 22, 2024)
2164	Deposition Transcript of Harold Walbrink in IPR2025-00145 (July 30, 2025)
2167	U.S. Patent No. 6,162,232 ("Shadduck")
2168	U.S. Patent No. 6,695,853 ("Karasiuk-853")

To the extent not listed above, I have also reviewed any other materials I discuss or cite herein.

I. QUALIFICATIONS AND PROFESSIONAL BACKGROUND

4. I received a Bachelor of Science (B.S.) degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science (M.S.) degree in mechanical engineering from North Carolina A&T State University in 1995. I am also licensed as a Registered Professional Engineer in the state of New Hampshire (License#: 11437).

5. I have been a medical device engineer since 1992 and have worked extensively with medical device disposables, including syringes of all types, since that date. I have extensive expertise in the mechanical design and manufacturing of medical devices. My areas of expertise include full-life cycle product development of medical devices, including conception, design, prototyping, manufacturing, testing, verification, validation, packaging, bioburden testing, sterility assurance testing, residual testing, biocompatibility, bacterial contamination testing, labeling, clinical trials, regulatory approval, marketing, and sales training.

6. Since 2006, I have been President of ATech Designs, Inc., where I have worked in the development of various medical devices, including cardiovascular, surgical, intravenous, endoluminal, and percutaneous devices. More specifically, I have consulted in the development of various drug delivery devices, such as IV

pumps, peritoneal dialysis pumps, auto-injectors, pen injectors, syringes, safety syringes, disinfecting caps, stop-cock valves, urinary catheter kits that include either bags or metered containers, IV valves, catheter dressing designs that use a burst-type foil pouch that releases an antiseptic, subcutaneous ports, catheters, among others. I also have extensive experience with machine design using pneumatics, valves, tubing, regulators, motors, vacuum pumps, and other components such as those parts used in my invention of the knitting machine US Patent 6,158,250. More recently, and also related, is my work on an incision closure device that approximates skin tissue to speed up closure and reduce appearance of the scar by mimicking the eversion techniques of a plastic surgeon.

7. Previously, from 2005 to 2006, I worked as a Director of Biomedical Engineering at Mitralign, Inc., developing implants for heart valve repair. From 2002 to 2005, I worked as a Manager of Design Engineering at ONUX Medical, Inc., developing fixation devices for abdominal aortic aneurysm repair as well as laparoscopic devices for stapling and sutures.

8. From 1992 to 2002, I worked as a Senior Principal Design Engineer at IVAC, which was a subsidiary of Eli Lilly & Company. There, I developed a number of medical drug infusion products, including disposable sets and components, IV tubing and syringe pump systems, injection systems, vial adapters, syringes, solution bags and containers, and needle-free valves for the delivery of drugs. My work

involved both the conception and manufacturing of these devices, including both EtO and gamma irradiation sterilization of disposable medical devices such as syringes and male luer caps. During this time, I was the sole inventor of the SmartSite® Needle-Free Valve for intravenous infusion pumps and disposables. I was also involved in the development of a dual-acting pen injector, capable of dispensing both long-term and short-term insulin, for Eli Lilly (parent company of my employer IVAC). In addition to my extensive involvement with the design team for the entire device, my work focused on the development of the disposable needle-free valve and adapters. More related was my work with catheters and catheter dressings and their interaction with the patient's skin.

9. I am a named inventor of over 41 patents, all of which relate to the medical device field. I have previously lectured on the product design and manufacturing process of medical devices. I was also named Chairman of the Medical Device and Manufacturing Conference in 2014 for the development process of medical devices.

10. I have personal knowledge of the matters set forth in this declaration and, if called upon as a witness, would testify competently thereto. I have used my education and my years of experience working in the field of mechanical engineering and medical device design, and my understanding of the knowledge, creativity, and

experience of a person of skill in the art in performing the analysis expressed in this declaration.

11. My curriculum vitae lists additional information about my professional background and qualifications. Ex. 2002 is a true and correct copy of my c*urriculum vitae*.

II. RELEVANT LEGAL STANDARDS

12. I am an engineer by training and profession. The opinions I express in this declaration involve the application of my knowledge and experience to the evaluation of the ’477 Patent and certain prior art to that patent. My knowledge of patent law is that of a lay person. Therefore, counsel for Patent Owner provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of the principles related to patentability that I must apply, and have applied, in conducting my analyses and reaching the opinions set forth in this declaration.

13. I understand that, in assessing the patentability of a patent claim, the Patent Office generally construes claim terms by giving them their ordinary and customary meaning, as they would have been understood by a person of ordinary skill in the art (“POSITA”) at the time of the invention in view of the intrinsic record (patent specification and prosecution history). However, I understand that the inventors may, in the patent specification, expressly define a claim term to have a

meaning that differs from the term's ordinary and customary meaning. I also understand that the inventors may disavow or disclaim certain claim scope, thereby departing from the ordinary and customary meaning, when the intrinsic record demonstrates that a clear and unambiguous disavowal or disclaimer has occurred. I understand that extrinsic evidence, such as relevant technical literature and dictionaries, may be useful in ascertaining how a POSITA would have understood a claim term, but the intrinsic record is the primary source for determining the meaning of claim terms. For the purposes of this review, and to the extent necessary, I have interpreted each claim term in accordance with the principles set forth in this paragraph.

14. It is my understanding that a claim is unpatentable as "anticipated" under 35 U.S.C. § 102 if a single prior art reference discloses every limitation of the claim, arranged as in the claim. I understand that a prior art reference does not anticipate a claim, however, when it discloses multiple, distinct teachings that a person of ordinary skill in the art might somehow combine to achieve the claimed invention. I understand that anticipation has not been alleged in the Petition, and, thus, is not at issue in this proceeding.

15. I understand that a claim is unpatentable under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I also understand that an

obviousness analysis takes into account the following factors, which are sometimes referred to as the Graham factors: (1) the scope and content of the prior art, (2) the differences between the claimed subject matter and the prior art, (3) the level of ordinary skill in the art at the time of the invention, and (4) "objective indicia of non-obviousness," also referred to as secondary considerations of non-obviousness. Those objective indicia include considerations such as whether a product covered by the claims is commercially successful due to the merits of the claimed invention, whether there was a long felt need for the solution provided by the claimed invention, whether others failed to find the solution provided by the claimed invention, whether others copied the claimed invention, and whether there was acceptance by others of the claimed invention as shown by praise from others in the field.

16. In determining the scope and content of the prior art, it is my understanding that it is appropriate to consider a prior-art reference in an obviousness analysis only if the reference is analogous art to the challenged patent. I have been informed that a reference is considered to be analogous art if it is either in the same field of the endeavor as the challenged patent or if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have come to an inventor's attention in considering his or her problem.

17. To assess the differences between prior art and the claimed subject matter, it is my understanding that 35 U.S.C. § 103 requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

18. I also understand that in an obviousness analysis, a patent challenger must demonstrate with evidence that a POSITA would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the POSITA would have had a reasonable expectation of success of doing so.

19. I understand that an assessment of what a reference discloses or teaches—for purposes of an anticipation analysis or an obviousness analysis—must be conducted from the perspective of a POSITA at the time of the invention.

III. LEVEL OF ORDINARY SKILL IN THE RELEVANT ART

20. The relevant field of art is skin treatment, and more specifically apparatuses and methods of treating a person's skin, as described in the '477 Patent.

21. I understand that the level of ordinary skill in the art for the '477 Patent is determined as of December 30, 2005, which is the earliest effective filing date of

the patent. I also understand that Petitioners has not alleged that the ’477 Patent is not entitled to the December 30, 2005 effective filing date.

22. In my opinion, a POSITA for the ’477 Patent would have a degree in science or engineering plus a minimum of three years of experience in the medical device industry. Alternatively, a product designer could have an additional two years of experience in the industry in lieu of a formal science or engineering degree. The POSITA would also consult with a physician as needed to understand the medical implications of the disclosed device, including the effect of the device on the skin.

23. I applied the above definition of a POSITA in my analysis set forth in this declaration. I understand the capabilities of a POSITA as of December 2005. Based on my training and experience, I understand the level of knowledge and skill that a POSITA would have possessed in December 2005 and am familiar with what a POSITA would have understood regarding microdermabrasion and hydrodermabrasion at the relevant time. In fact, I was a POSITA at the relevant time.

24. I understand that Petitioners have proposed the following definition of a person of ordinary skill in the art (a “POSITA”) with respect to the ’477 Patent:

> A person having ordinary skill in the art (POSITA) at the time of the alleged invention would have had an undergraduate degree (B.S.) in Mechanical Engineering or equivalent knowledge, training, or experience, with two years of work experience in the design of mechanical products, design of fluidic

systems, and/or the design of devices intended for medical or cosmetological applications. Additional education or industry experience may compensate for a deficit in one of the other aspects of the requirements.

Pet., 2-3.

25. At this time, I do not address the deficiencies in Petitioners' definition of the level of skill in the art but reserve the right to raise any such deficiencies in a future declaration or testimony. Under either parties' definition, it is my opinion that the claims of the '477 Patent would not have been obvious as Petitioners' and Mr. Walbrink have alleged.

IV. CLAIM CONSTRUCTION

26. I understand that claim terms are generally given their plain and ordinary meaning in view of the specification. In my view, no express claim construction that differs from the plain and ordinary meaning is necessary to assess the issues I was asked to analyze. Below, I have specifically addressed and applied the plain and ordinary meaning of the term "manifold"[1] to address an argument Petitioners has made with respect to the disclosure of the Palmer reference. I have also specifically applied the ordinary meaning of the term "treatment material" to

[1] Although the claims recite a "manifold system," Petitioner's proposed definition is in relation to a "manifold."

address an argument Petitioners has made with respect to the disclosure of the Greenberg reference.

V. RELATED PROCEEDINGS

27. I understand that HydraFacial previously asserted the '052 Patent—a family member with substantially similar claims—against a different competitor, Cartessa Aesthetics, LLC ("Cartessa"), in *Edge Systems LLC v. Cartessa Aesthetics, LLC*, Case No. 20-CV-6082 (E.D.N.Y.) ("*Cartessa EDNY*"). Ex. 2064. I understand that HydraFacial moved for summary judgment and sought a ruling that the '052 Patent was not invalid in view of the prior art asserted by Cartessa, U.S. Patent No. 6,162,232 to Shadduck (Ex. 2167, "Shadduck" or "the '232 patent"). Ex. 2067, 3. Cartessa argued that Shadduck anticipates the '052 Patent, citing Shadduck's disclosure of delivering a "coolant fluid plus a crystalline agent" through a handpiece to impact the skin surface "to abrade away superficial layers." *Id.*, 4 (quoting Shadduck, 9:40–45).

28. I understand that in June 2023, the district court granted HydraFacial's motion for summary judgment of no invalidity, where the Court held that Shadduck does not include a manifold and does not permit selection among multiple fluids. *Id.*, 5, 10. The court explained that HydraFacial "convincingly distinguishes the prior art taught in the Shadduck patent, mainly relying upon the expression of a manifold and the requirement of multiple selectable fluids." *Id.*, 5. It is my opinion the

Karasiuk, which AMP relies on for its primary reference—like Shadduck—fails to disclose a manifold or select among multiple fluids. As I explain below, it is my opinion that the secondary references that AMP points to for allegedly disclosing a manifold also fail to satisfy the manifold limitation of the '477 Patent.

29. Additionally, I understand that HydraFacial filed an ITC complaint asserting U.S. Patent No. 11,865,287 ("'287 Patent")—a family member with substantially similar claims—against Cartessa and its exclusive distributor, Eunsung Global Corp. ("Eunsung"), in Inv. No. 337-TA-1408 ("*Cartessa ITC*"). Ex. 2068. I served as an expert witness for HydraFacial in *Cartessa ITC* and testified on HydraFacial's behalf during the five-day trial in April 2025. I understand that the ALJ issued her Initial Determination in August 2025. Ex. 2161. In the Initial Determination, the ALJ upheld the patentability of the '287 Patent over AMP's asserted prior art references, including Greenberg, Karasiuk[2], Palmer, and Trueba, and also agreed with HydraFacial that the commercial success of systems practicing

[2] The Karasiuk reference that Cartessa relied on in *Cartessa ITC* is U.S. Patent No. 6,695,853 (Ex. 2168, "Karasiuk-853"), which is the parent patent of the Karasiuk reference that AMP relies on in this IPR (Ex. 1004). I understand that Karasiuk (Ex. 1004) in this IPR is a continuation-in-part application of Karasiuk-853 (Ex. 2168).

the claims of the '287 Patent independently establishes non-obviousness of the challenged claims. Ex. 2161, 140-143, 147-161, 174-184.

VI. PATENTABILITY OF THE '477 PATENT OVER THE PRIOR ART

30. I was asked to assess certain technical issues related to whether the challenged claims would have been obvious over Karasiuk combined with other prior art, as more fully explained below. Petitioners rely on Karasiuk as their primary reference and combined it with Palmer in Grounds 1A-1D. In Ground 1A, Petitioners combine Karasiuk with Palmer to allege that independent claims 1, 9, and 15 and dependent claims 3, 6-8, 10, 12, 14, 16, 18, and 20 would have been obvious. Pet., 1. As I explain below, it is my opinion that Petitioner's combination of the Palmer system with the Karasiuk system relies on Petitioners' hindsight bias, and is additionally improper because it would fundamentally alter the operation of each system and render the Karasiuk device inoperable in multiple ways.

31. In Grounds 1A-1C, Petitioners rely on Palmer as allegedly disclosing the claimed "manifold," but the Palmer component Petitioners point to is not a "manifold." In Ground 1B, Petitioners rely on Trueba for computing device limitations and alleges that all claims would be obvious. In Ground 1C, Petitioners rely on Wunsch as allegedly disclosing the claimed "manifold" in an attempt to cure the deficiencies of Palmer. In Ground 1D, Petitioners rely on all of Karasiuk, Palmer, Wunsch, and Trueba and alleges that all claims would be obvious.

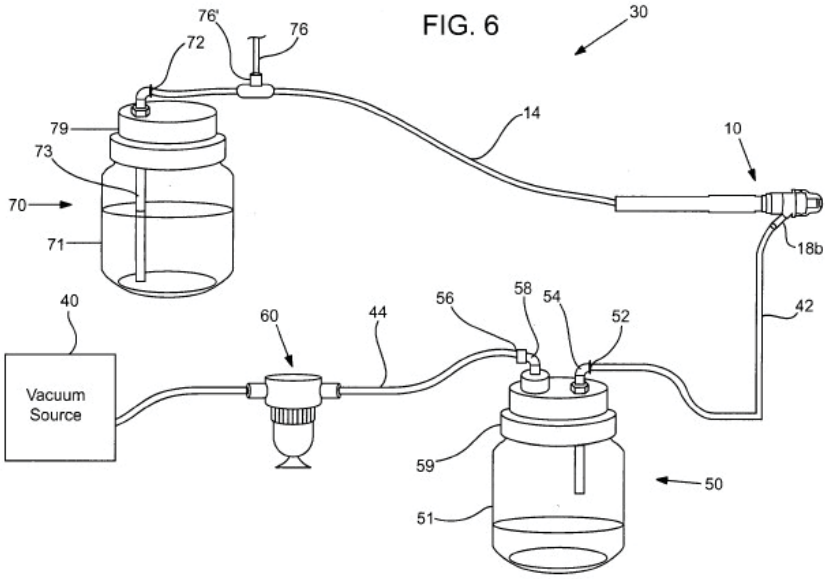
32. In Ground 2A, Petitioners rely on Greenberg to allege that independent claims 1, 9, and 15 and dependent claims 3, 6-8, 10, 12, 14, 16, 18, and 20 would have been obvious. In ground 2B, Petitioners rely on Trueba for computing device limitations and alleges that all claims would be obvious.

A. The Cited References

1. Karasiuk[3]

33. As shown in Figure 6 below, Karasiuk is a device that draws liquid from just one container during a treatment.

[3] I recognize that Karasiuk describes the disclosed device as a "microdermabrasion device." However, I understand that Karasiuk differs from traditional microdermabrasion because the device is not limited to using only solid dry abrasive particles.



Ex. 1004, Fig. 6, [0014], [0020].

34. In my view, Karasiuk does not disclose a manifold system as part of a console—or a manifold system at all—in communication with a first container and at least a second container and a handpiece. Nothing in Karasiuk suggests separately storing and automating the application of different treatment fluids in a single treatment. At most, Karasiuk lists different solutions, suspensions, or compounds that can be contained "alone or in combination" in Karasiuk's single reservoir 70. *Id.*, [0061].

2. Palmer

35. Palmer is an irrigation system used in periodontal dental procedures. Ex. 1005, 1:10-15. As such, Palmer delivers "pulsed jets" of treatment solution at constant pressure and substantially constant volumetric flow rate to the treatment

area in the patient's mouth. *Id.*, 11:17-23 (pressure of 25 psi and flow rate of 22-25 mL/minute). Palmer employs a peristaltic pump 18 located upstream of handpiece 14 to generate the pulsed jets of solution, as shown in Fig. 1.

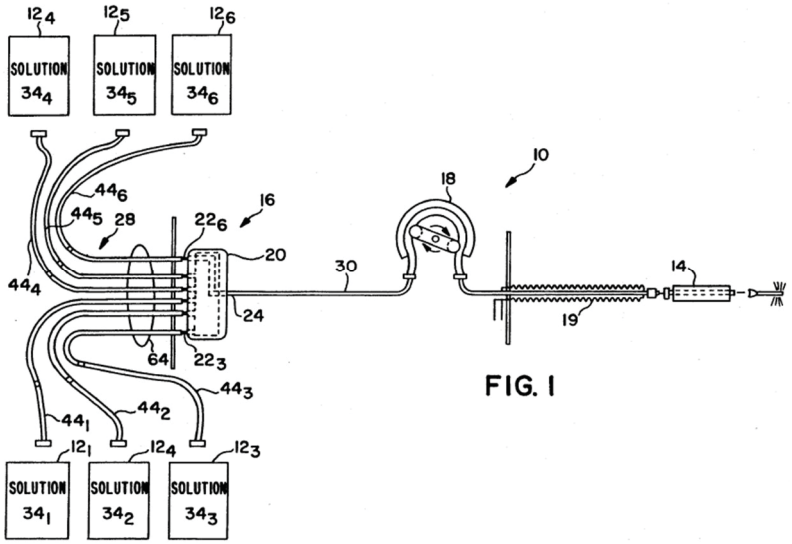


FIG. 1

Id., Fig. 1.

36. The handpiece sprays the pulsed jet directly at a treatment site in the patient's mouth to irrigate it with the needed solution. *Id.*, 3:15-26. Unlike a skin treatment system, Palmer is a one-way irrigation system that lacks any mechanism to vacuum the spent solution from the patient's mouth and back through the handpiece. Palmer uses a peristaltic pump "as a natural check valve since it cannot aspirate solution back into the cannula" of the handpiece. *Id.*, 11:32-33.

37. As I explain in detail below, it is my opinion that, Palmer—like Karasiuk—does not disclose a manifold.

38. It is also my opinion that Palmer is not analogous art to the '477 Patent, and therefore cannot be used as prior art. First, Palmer is not in the same field of endeavor as the '477 Patent. The '477 Patent is directed to skin treatment devices. *See* Ex. 1001, Abstract ("An apparatus for treating skin . . . . The handpiece assembly is configured to treat skin"), 1:23-25 ("The invention relates in general to the field of skin treatment, and more specifically to apparatuses and methods for treating a person's skin."), 21:15 (cl. 1) ("A skin treatment system comprising . . .").

39. In contrast, Palmer is directed to dental irrigation devices. *See* Ex. 1005, 1:10- 17 ("This invention relates generally to methods and apparatus for delivering liquid solutions to treatment sites, such as in connection with periodontic procedures and, more particularly, to irrigation systems and methods for delivering a selected one of multiple liquid solutions to a treatment site. The advantages of irrigation as a viable periodontal treatment are well documented."), 11:44-46 (cl. 11) ("Periodontal irrigating system for delivering one of a plurality of liquid irrigating solutions to a treatment site in an oral cavity"). Thus, whereas the '477 Patent is directed to a skin treatment system, Palmer is directed to a dental irrigation device that sprays solutions directly into the mouth, lacks a vacuum source, and lacks fluid recovery from a patient's mouth. The ALJ reached this same conclusion in *Cartessa ITC* with respect to the related '287 Patent. Ex. 2161, 150-151.

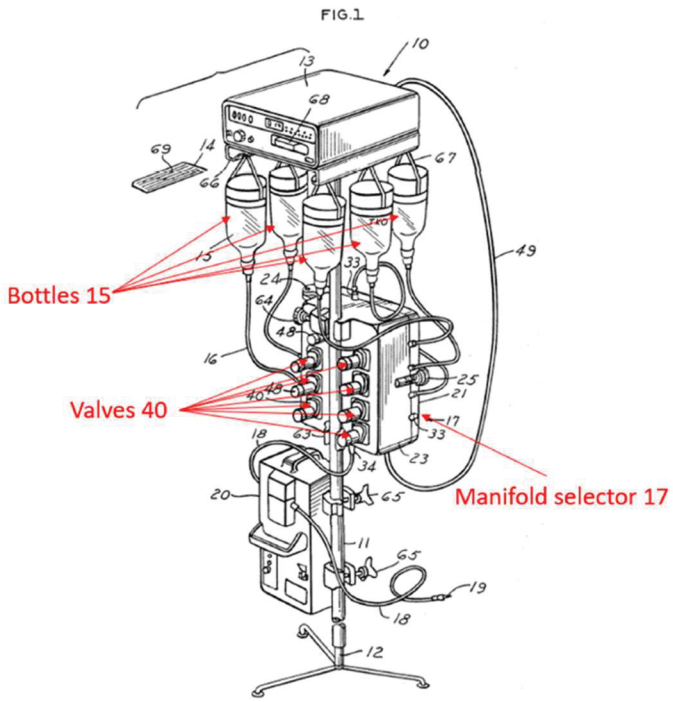
40. Second, Palmer is not reasonably pertinent to the particular problem with which the inventors of the '477 Patent were involved. For example, according to the '477 Patent, the problems addressed by the '477 Patent are: the pain associated with dermabrasion of the skin, the mess that is created during that process, skin redness as a result of the process, and the lengthy recovery times while the skin regrows and heals. Ex. 1001, 1:41-2:15.

41. In contrast, Palmer states, for example, that the object of the invention is "to provide new and improved ***irrigation systems*** and methods for delivering one of a selected one or more of multiple liquid solutions to a treatment site" and to do so "at a substantially uniform ***delivery pressure*** and volumetric ***flow rate***." Ex. 1005, 2:48-56. This is not reasonably pertinent to the problems addressed in the '477 Patent of the mess that is created during the process, skin redness as a result of the process, and lengthy recovery times while the skin regrows and heals. The ALJ reached this same conclusion in *Cartessa ITC* with respect to the related '287 Patent. Ex. 2161, 151-155.

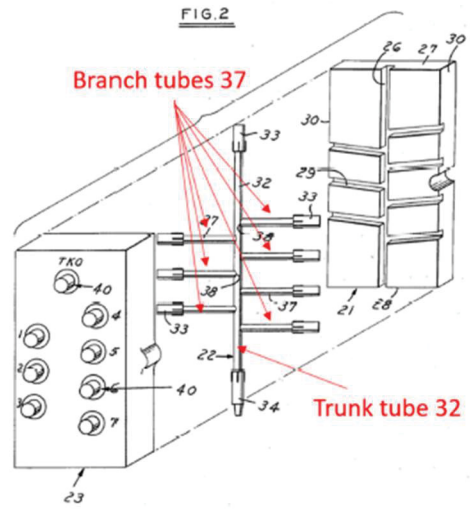
3. Wunsch

42. Wunsch is a system for sequentially dispensing multiple intravenous (IV) solutions from multiple solution sources through a single catheter. Ex. 1020, 5:18-22. Each solution source is connected to a distinct branch (*e.g.*, branch tubes 37) of a manifold (*e.g.*, combination of trunk tube 32 and branch tubes 37), with flow

through each branch controlled by a valve selector that actuates valves mounted on a manifold plate. *Id.*, 7:49-52. These valves are individually actuated by electronically operable motors or solenoids. *Id.*, 6:18-26.



Wunsch, FIG. 1 (annotated)



Wunsch, FIG. 2 (annotated)

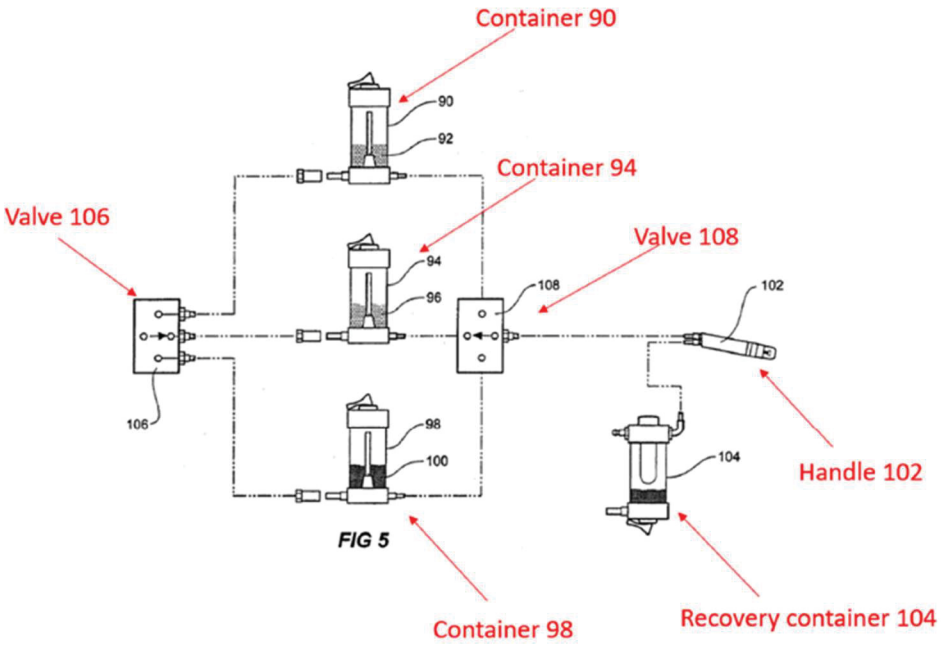
Pet., 49, 51.

43. The "manifold" (*e.g.*, combination of trunk tube 32 and branch tubes 37) from Wunsch cannot, independently, control the flow of treatment of material—and Petitioners agree with this statement. *See* Ex. 1020, 4:1-10, 7:17-56; Pet., 50 ("In operation, by activating a ***valve 40***, the user selectively connects a bottle 15 to the trunk tube 32 for delivery."). Deploying the "manifold" of Wunsch (*i.e.*, the trunk tube 32 and branch tubes 37) without the individual valves 40 would result in an open system with uncontrolled, free-flowing liquid from each solution source.

44. A volumetric infusion pump 20 meters the dispensed quantity of each solution. *Id.*, 6:7-13. The sequence and timing of solution delivery is governed by a sequencer-timer 13, which automatically and successively actuates each valve in accordance with a predetermined program (*e.g.*, stored on a program card). *Id.*, 5:25-35, 51-55.

4. Greenberg

45. Greenberg, a reference cited during prosecution of the '477 Patent, discloses a system for conducting microdermabrasion procedures using a handpiece to apply dry treatment materials to a targeted area of skin. It discloses "[a] microabrasion apparatus for providing treatment of skin or other surfaces whereby a pneumatic source [(12, 38)] is operatively connected to a recovery container [(14,



22)] and to a hand tool [(16, 12)] and to one of a plurality of supply containers [(18, 26)] that house treatment particulates." *Id.*, Abstract.

Pet., 68.

46. Greenberg's apparatus in Figs. 1-2 has first and second separate assemblies on each side, each assembly having its own recovery container, supply container, and handle to separately propel dry particles of different sizes or type. Ex. 1006, ¶ 49.

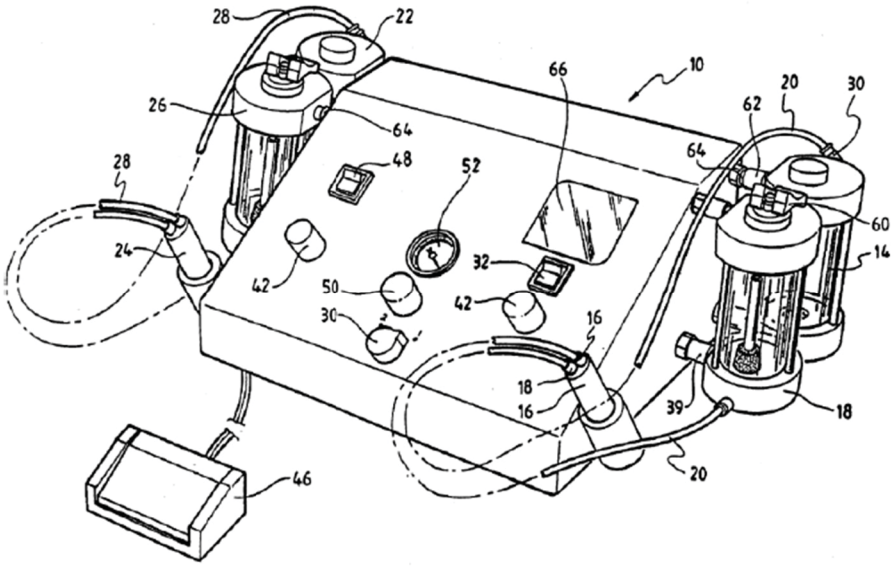


FIG 1

Id., Fig. 1.

47. Fig. 2 shows the schematic diagram of this embodiment:

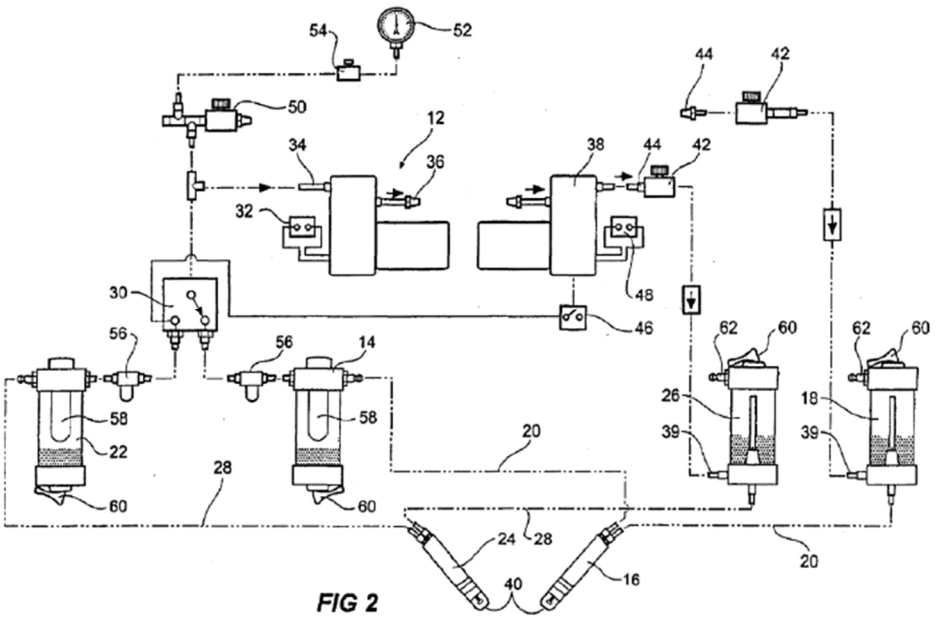


FIG 2

Id., Fig. 2

48. Greenberg discloses that the apparatuses of Figures 1-4 each has a vacuum source to draw spent dry abrasive particles into the recovery container, and for heavier abrasive particles, it also uses a compressor upstream of the bottles to propel the particles. *Id.*, ¶ 50-51. Additionally, Greenberg discloses that the apparatus of Fig. 5 is a positive displacement pump, because "valve 106 that controls air flow into the respective supply container" is located upstream of the supply containers 90, 94, and 98. *Id.*, ¶ 77.

49. Greenberg includes different versions of the microdermabrasion apparatus. The version in Fig. 3 includes two assemblies, each with a supply container 18, 26 and recovery container 14, 22 and a handle 16, 24. *Id.*, ¶ 65.

However, it includes only one pneumatic source 12, and thus has two valves 70 and 72 that operate in tandem to direct the flow from the pneumatic source. *Id.*

50. The version of the microdermabrasion apparatus in Fig. 4 is referred to as a "joint assembly," where it has two different supply containers 18, 26 but only a single recovery container 14. *Id.*, ¶ 67. It has a valve 30 that connects the supply containers 18, 26 to the different handpieces 16, 24.

51. The version in Fig. 5 includes three containers 90, 94, 98, one recovery container 104, and one handpiece 102. *Id.*, ¶ 77. It employs two valves 106 and 108. Greenberg explains that "[a] supply container can be chosen to be in communication with handle 102 and recovery container 104 by the use of valve 106 that controls air flow into the respective supply container and valve 108 that then connects that supply container to the handle 102 and recovery container 104." *Id.* Thus, valve 106 controls air flow into the supply containers to aerate and suspend and then propel the abrasive particles downstream to valve 108, which is connected to the handle 102.

52. Greenberg discloses another version in Fig. 6 that includes one supply container and one recovery container. *Id.*, ¶ 79. All versions disclosed by Greenberg employ riser tubes that are generally not compatible with liquid suctioning. *Id.*, Figs. 1-6.

5. Trueba

53. Petitioners add Trueba in Ground 1B, 1D, and 2B for the dependent claims having computing device limitations. Pet., 42-48, 62-65, 93-97 . Trueba involves a jet dispenser that combines Hewlett-Packard's inkjet technology with pharmaceutical administration. Ex. 1008, 1:7-12.

54. In my opinion, Trueba is not analogous art to the '477 Patent, and thus a POSITA would not rely on Trueba as prior art to the '477 Patent. First, it is not in the same field of endeavor as the '477 Patent. The '477 Patent is directed to skin treatment devices, *see, e.g.,* Ex. 1001, Abstract, 1:23-25, whereas Trueba is directed to a jet dispenser and combines inkjet technology and pharmaceutical administration. *See* Ex. 1008, 1:7-12; *see also id.*, 3:42-45 ("The present disclosure concerns an applicator for inhalational or mucosal delivery of a bioactive composition using a jet dispenser, such as a piezoelectric or thermal jet dispenser"). Indeed, Trueba explicitly acknowledges that the claimed invention "combines the unrelated technologies of pharmaceutical administration and inkjet technology." *Id.*, 1:10-12. The ALJ reached this same conclusion in *Cartessa ITC* with respect to the related '287 Patent. Ex. 2161, 140-143, 161.

55. Second, Trueba is not reasonably pertinent to the particular problem with which the inventors of the '477 Patent were involved. For example, Trueba states that "administration of therapeutically effective doses of many medications

can be difficult in some instances." Ex. 1008, 1:17-19. It specifically addresses the problem that metered dose inhalers (MDIs) "often require coordinating inhalation with actuation of the MDI, and some patients are not able to master this technique" and that "patients often forget to take medications at prescribed times or with the prescribed frequency, and some patients inadvertently or inappropriately use medications, leading to hospitalizations, permanent injury, and even death. *Id.*, 1:41-47. Thus, Trueba is not directed to the problem the '477 Patent solved, namely reducing the pain and recovery time associated with dry microdermabrasion on skin, improving treatment efficacy, and improving the rapidity with which practitioners can perform treatments with multiple fluids. *See* Ex. 1001, 1:41-2:15. The ALJ reached this same conclusion in *Cartessa ITC* with respect to the related '287 Patent. Ex. 2161, 140-143, 161.

B. Grounds 1A-1D: The Karasiuk-Palmer Combination Renders Karasiuk's Device Inoperable

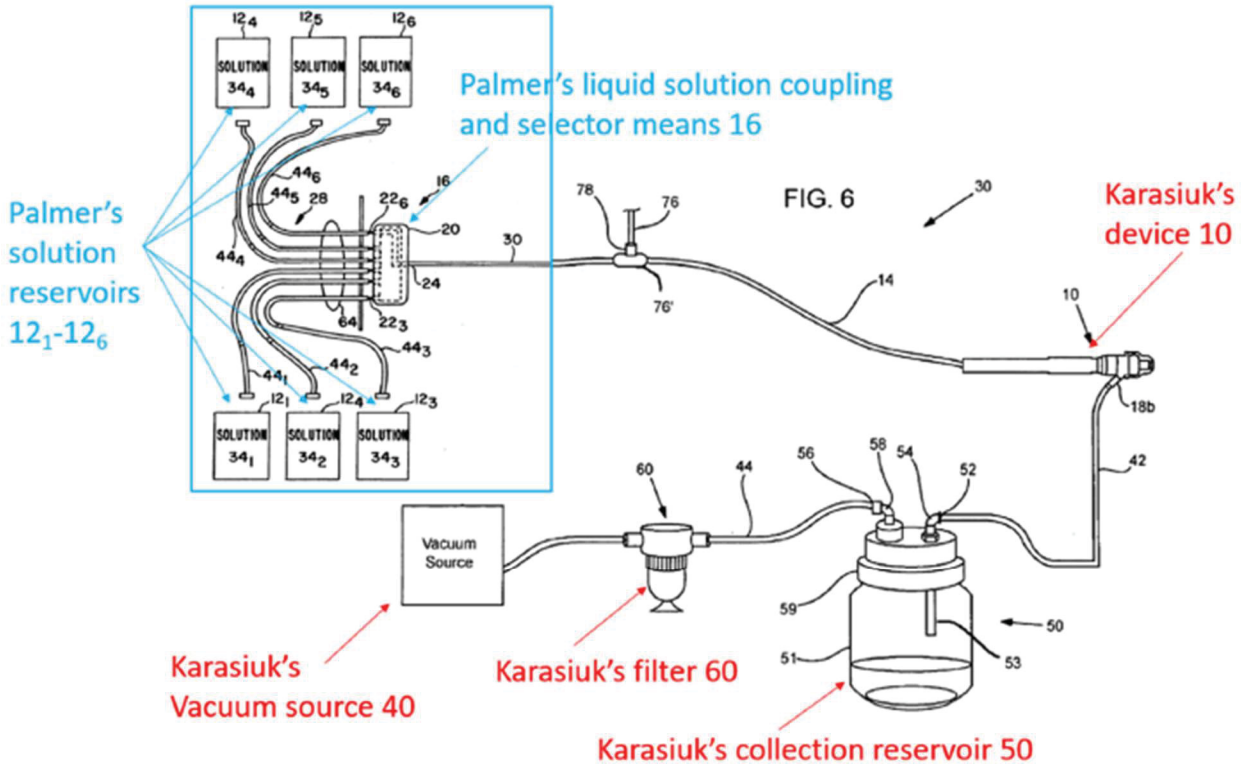
56. I was asked to assess certain technical issues related to whether the challenged claims would have been obvious over Karasiuk and Palmer combined with other prior art, as more fully explained below.

57. In my opinion, Petitioners' proposed combination of the Karasiuk and Palmer systems would render Karasiuk's system inoperable, because the resulting system: (1) has a vacuum source with a breather line that prevents material from

flowing from the reservoirs; (2) has a tube diameter that is so small it prevents flow of higher viscosity treatment materials; and (3) lacks Palmer's peristaltic pump, leading to the unrestricted flow of liquid from the reservoirs.

1. Karasiuk-Palmer's Vacuum Source With a Breather Line Prevents Drawing Material from the Reservoirs

58. In Petitioners' proposed combination of the Karasiuk and Palmer systems, Petitioners contend that "Karasiuk's vacuum source would be used to pump treatment solutions from Palmer's multiple containers and collect waste/debris." Pet., 9. That is, Petitioners remove Palmer's peristaltic pump from Palmer's system and instead relies on Karasiuk's vacuum source 40 downstream of the handpiece to act as the vacuum source in the combined device. Petitioners depict this combination of Palmer's Fig. 1 and Karasiuk's Fig. 6 as "Karasiuk, Modified FIG. 6".



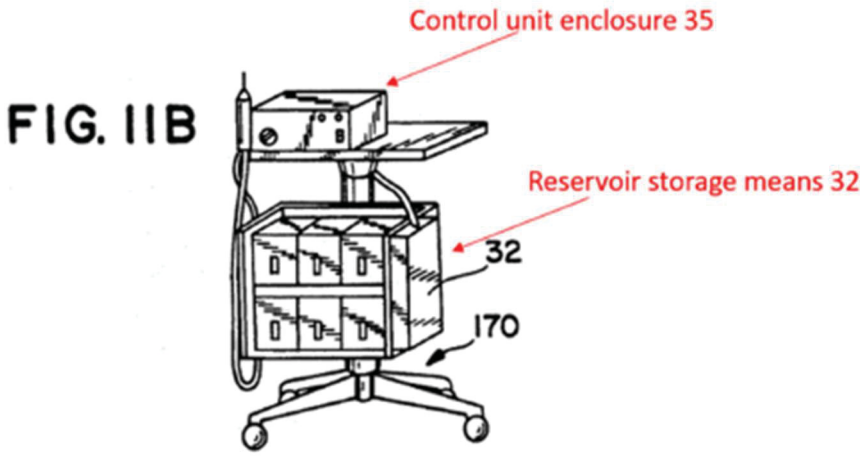
Karasiuk, Modified FIG. 6

Pet., 9.

59. As can be seen in Petitioners' combination figure, "Karasiuk's tube 14 (e.g., upstream of breather line 76) would replace, or be connected to, Palmer's second tubing means 30 to achieve benefits resulting from selection of different treatment solutions." Pet., 9, 24, 26, 35. Here, Petitioners have positioned Karasiuk's breather line 76 upstream of Karasiuk's device 10 (the handpiece) and downstream of Palmer's liquid solution coupling and selector means 16 and Palmer's solution reservoirs 12_1 - 12_6. *Id.* I note that Petitioners also contends that this arrangement "achieve[s] benefits resulting from selection of different treatment solutions." Pet., 9, 24, 26, 35.

60. Karasiuk discloses that its breather line 76 "includes an adjustable valve 78 or other means for varying an amount of air that is allowed into tube 14," which "allows the amount of vacuum to be adjusted for a given fluid." Ex. 1004, 7:19-24.

61. Petitioners' Karasiuk-Palmer combination also involves adoption of Palmer's "mobile cart 170" for allegedly providing "increased portability and/or organization." Pet., 8. In Petitioners' combination, Palmer's mobile cart 170 houses the claimed multiple containers (Palmer's "solution reservoirs 12_1 - 12_6") in the "reservoir storage means 32" on the bottom of the mobile cart 170 underneath the system components in the "control unit enclosure 35" on the shelf above:



Palmer, FIG. 11B

Pet., 14.

62. Thus, in the Petitioner's Karasiuk-Palmer combination, Palmer's solution reservoirs 12_1 - 12_6 are necessarily located below Karasiuk's breather line 76 and the handpiece 10. In this configuration, Karasiuk's vacuum source is drawing

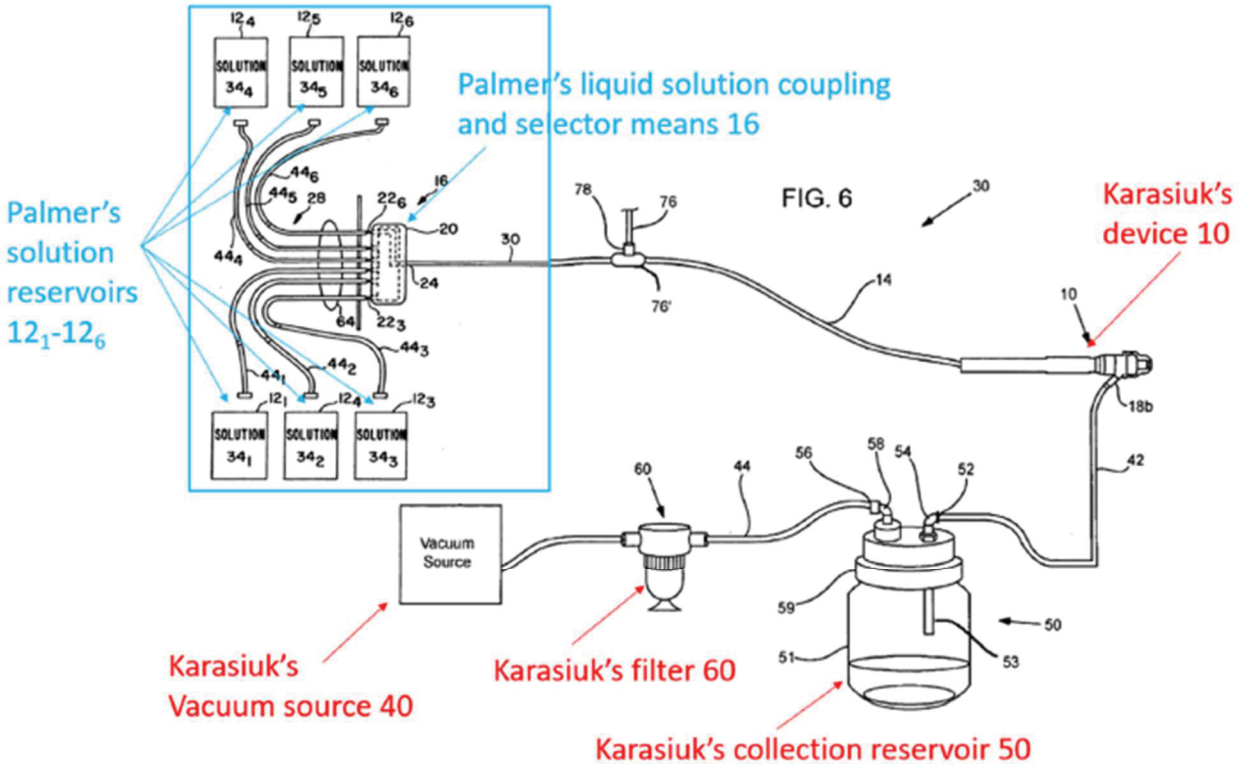
only air through the breather line 76 along tube 14. The Karasiuk-Palmer combination would never be able to provide any vacuum force to draw material from Palmer's solution reservoirs to the handpiece. This is because air flow will take the path of least resistance and suck air from the breather line 76 as described by Karasiuk instead of fluid from Palmer's solution reservoirs 12 in Petitioners' proposed combination. This is like having a crack in a drinking straw.

63. Thus, in my opinion, Petitioners' combination of these disparate technologies involves small tubing with an air vent, which ultimately changes the basic principles under which Karasiuk was designed to operate and renders it inoperable. Karasiuk alone, when using the vent on the liquid side of the system, is also not enabled. This is the "cracked drinking straw" problem and neither the petition nor the combinations with other prior art resolve this issue. In my view, Petitioners' proposed arrangement clearly defeats the alleged purpose behind the combination of "achiev[ing] benefits resulting from selection of different treatment solutions." Thus, a POSITA would not have had a motivation to combine Karasiuk with Palmer.

2. Karasiuk-Palmer's Tube Diameter Prevents Flow of Treatment Material to the Handpiece Assembly

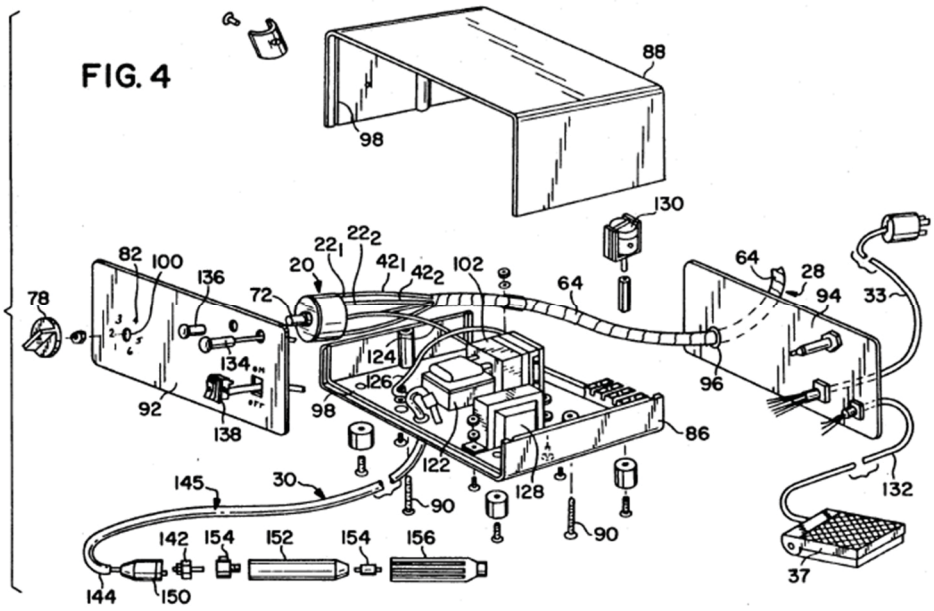
64. In my opinion, Palmer's small-diameter tubing renders the combined Karasiuk-Palmer device inoperable.

65. As explained above, for the Karasiuk-Palmer combination, Petitioners rely on Palmer for its liquid solution coupling and selector means 16 and solution reservoirs 12.



Karasiuk, Modified FIG. 6

Pet., 9, 17. The detailed version of the liquid solution coupling and selector means 16 is Palmer's control unit enclosure 35, an explode view of which is shown in Fig. 4 of Palmer:



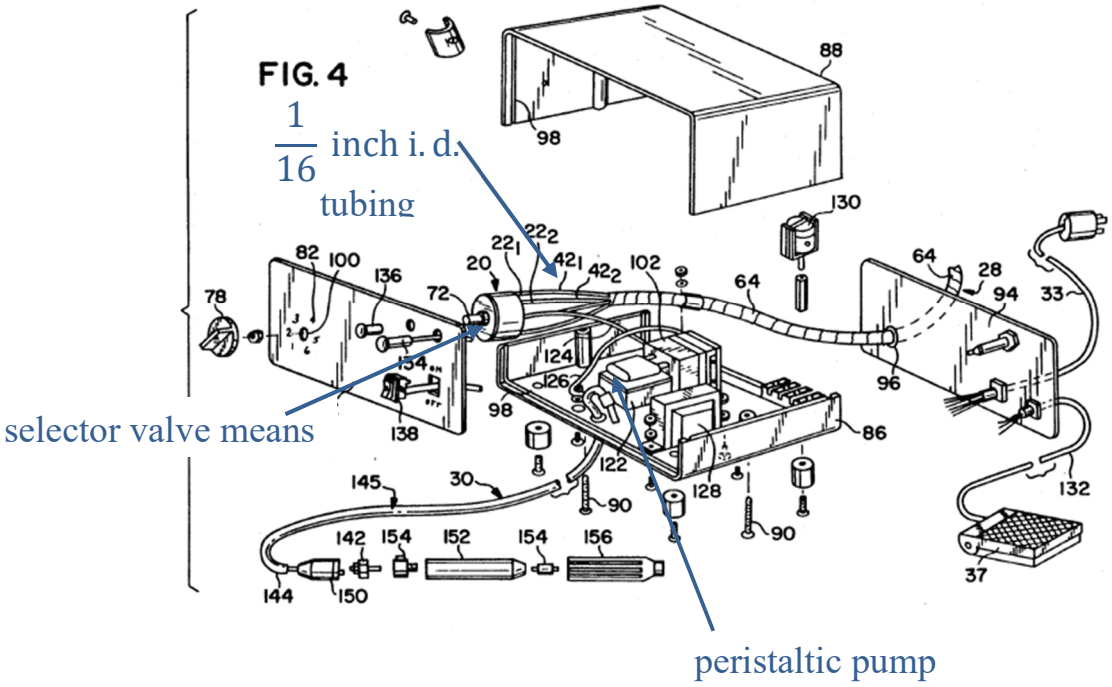
66. Palmer discloses that the system uses tubing with an outside diameter of 1/8th inch and an inside diameter of 1/16th inch in the six tubes 42 running between the solution reservoirs 12 and the selector valve means 20 in the control unit enclosure, and in tubing 126 running from the control unit enclosure 35 to the handpiece 14. *See* Ex. 1005, 7:21-24, 9:17-19, 9:40-43. Below is an image I have prepared to show the cross-sectional diameter of Palmer's tubing on the scale of an 8 ½ x 11-inch sheet of paper:

$\frac{1}{16}$ inch i.d.  $\frac{1}{8}$ inch o.d.

67. In my opinion, an extremely small tube diameter of 1/16th inch is appropriate in Palmer's system given that Palmer's system is designed to produce high-velocity spray to irrigate a patient's mouth with a relatively high-pressure output. Ex. 1005, 2:32-36. Further, Palmer's tubing is appropriately small so that it is flexible and compact in the bundle of six tubes that extend from the control unit enclosure 35 to the reservoir storage means 32, which houses the solution reservoirs.

68. Palmer states that its system is designed to deliver the pulsed jets of irrigating solution at a pressure of 22-25 psi, with a flow rate of only 22 to 25 mL per minute. *Id.*, 11:17-23. At that flow rate, it would take 40-45 minutes of continual spraying to use all the contents of the 1000 mL containers disclosed in Palmer. *Id.*, 5:26-30.

69. In my opinion, Palmer's system supports the use of such small tubing because Palmer's peristaltic pump is located directly adjacent to the selector valve means 20 to generate pressure to draw the liquids from the containers. This is shown in Fig. 4:



Ex. 1005, Fig. 4. Additionally, Palmer also uses low-viscosity rinse solutions, minimizing any resistance from the liquid flowing through the tubing. *Id.*, 5:52-64.

70. In my opinion, Palmer's small-diameter tubing renders Petitioners' proposed combination of Karasiuk and Palmer inoperable.

71. As discussed above, Petitioners' proposed combination removes Palmer's peristaltic pump and replaces it with Karasiuk's vacuum source 40, which is located at the end of the fluid path, downstream of the handpiece 10 and collection reservoir 50. As a general matter, the pressure drop exhibited along a length of tubing is directly proportional to the length of the tubing. Thus, in Petitioners' modification, the added distance between the vacuum source and Palmer's solution

reservoirs 12 results in increased pressure loss (i.e., increased head loss) at the solution reservoirs 12.

72. Furthermore, in fluid dynamics, the pressure drop (ΔP) across a pipe is strongly influenced by the pipe's internal diameter. For laminar flow of a Newtonian fluid in a straight circular pipe, the relationship is governed by the Hagen-Poiseuille equation:

$$\Delta P = \frac{8\mu LQ}{\pi r^4}$$

where **μ** is the dynamic viscosity of the fluid, **L** is the length of the pipe, **Q** is the volumetric flow rate, and **r** is the pipe radius. *See* Ex. 2052, 1. As the equation above indicates, increase in tubing length **L** and use of higher viscosity solutions used in hydrodermabrasion procedures will increase the pressure drop or resistance to flow. Moreover, as the equation illustrates, even a modest decrease in radius would result in a dramatic increase in pressure loss because the pressure drop is inversely proportional to the fourth power of the radius of the pipe (*e.g.*, halving the radius of a pipe would cause the pressure drop to increase 16-fold).

73. Furthermore, maintaining a constant volumetric flow rate (**Q**) while reducing pipe diameter necessarily increases fluid velocity. This relationship is governed by the following equation, $Q = A \cdot v$, where **A** is the cross-sectional area

(which scales with the square of the pipe's diameter) and **v** is the flow velocity. *See* Ex. 2053, 1. Accordingly, even modest reductions in pipe diameter result in substantial increases in velocity. For instance, halving the pipe's radius reduces the area by a factor of four, thereby quadrupling the velocity to maintain the same flow rate.

74. I understand that certain dental applications, such as those involving irrigant solutions as in Palmer, benefit from high fluid velocity, but at the same time, involve low volumetric flow rates. In contrast, hydrodermabrasion procedures require the opposite—relatively low volumetric flow rates (to conserve expensive serums) and derive little to no benefit from increased fluid velocity.

75. Thus, a small decrease in pipe diameter can lead to a disproportionately large increase in pressure drop. In my view, this highly non-linear dependence is critical in the design of piping systems, especially when dealing with high-viscosity fluids or long flow paths.

76. In my opinion, Palmer's use of small-diameter tubing, in conjunction with the distance between Karasiuk's vacuum source 40 and Palmer's solution reservoirs 12, and the presence of breather line 76—which prevents the vacuum source from drawing sufficient suction at the reservoirs 12 as I discussed above—would severely inhibit the generation of suction at the solution reservoirs 12 in Petitioners' combined Karasiuk-Palmer system.

77. Karasiuk also discloses using lotion—often mixed with solid abrasive particles—as the treatment material in the reservoir 70. *See* Ex. 1004, ¶¶[0059]-[0061]. It is well understood and documented that lotions have a significantly higher viscosity than the rinse solutions used in Palmer's system. *See* Ex. 2054, 6 (dental irrigants having viscosities between 35.5 cP and 182.1 cP); *see also* Ex. 2055, 1 (showing vitamin E creams with viscosities between 12,000-26,000 cP); *see also* Ex. 2056, 1 (showing water having a viscosity of 1 cP, face cream at 10,000 cP, and hand cleaner at 2,000 cP).

78. In my opinion, if a lotion were used in Palmer's solution reservoirs 12, it would encounter significant frictional losses (or drag) due to the narrow 1/16th inch diameter tubing connecting the reservoirs 12 to the selector valve means 20 within the control unit enclosure 35.

79. In my opinion, Palmer's tubing is so small that it would not permit meaningful flow of Karasiuk's treatment liquid to the handpiece under vacuum pressure from Karasiuk's vacuum source 40. And even if some fluid were to reach the handpiece, the resulting volumetric flow rate would be unacceptably low for effective use in a skin treatment. Thus, in my opinion, a POSITA would have understood that Petitioners' proposed combination of Karasiuk and Palmer would render Karasiuk's device inoperable.

3. Removing Palmer's Peristaltic Pump from Karasiuk-Palmer Leads to Uncontrolled Flow of Liquid from the Reservoirs

80. In my opinion, Petitioners' Karasiuk-Palmer system—by removing Palmer's peristaltic pump 18 and substituting Karasiuk's vacuum source 40 downstream of the handpiece—introduces another fatal flaw into the resulting combination, rendering it inoperative for its intended purpose.

81. Palmer's peristaltic pump 18 is located downstream of the selector valve means 20 and, in my view, acts as a valve, preventing liquid from flowing from the solution reservoirs when the peristaltic pump is inactive. S*ee* Ex. 1005, 11:30-34 (Palmer explaining that its peristaltic pump "serves as a natural check valve."). Additionally, as I explain below, Palmer's selector valve means 20, which Petitioners rely on for the claimed manifold, is an uninterrupted pathway from the selected solution reservoir 12.

82. In my opinion, removing Palmer's peristaltic pump from Petitioners' Karasiuk-Palmer combination system would leave the system without a mechanism to control the flow of liquids from the solution reservoirs. Thus, even if the system did not have the issues associated with the breather line 76 and restricted diameter tubing discussed above, Petitioners' combination would result in the material in the selected solution reservoir flowing uncontrolled to or from the selected solution reservoir, even without activating the vacuum source (*i.e.*¸ the fluid would flow back

to the reservoir, gravity would cause fluid to flow out, or the fluid would flow out because of syphoning). Thus, once again, these alterations would render the system inoperable. Moreover, Petitioners' proposed combination would be unable to meet the "control of a flow" limitation in claims 1, 3, 12, 17, and 18 of the '477 Patent. Therefore, Petitioners cannot meet its burden of showing that any claims of the '477 Patent would have been obvious over the cited prior art.

C. Grounds 1A-1D: Palmer Does Not Disclose the Manifold System Limitations

83. Each of Grounds 1A-1D in the Petition relies on a combination of Karasiuk and Palmer (Pet., 1), but this combination, in my opinion, fails to disclose a limitation required by all claims—namely, a "manifold system." Both independent claims of the '477 Patent recite a manifold system in communication with a first container and at least a second container. Limitation [1.1] in claim 1 recites "a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material, the manifold system being positioned in or on a console." Similarly, limitation [9.1] in claim 11 and limitation [15.1] in claim 15 each recites "a manifold system in communication with at least two containers."

84. In Grounds 1A-1D, Petitioners rely on Palmer's "selector valve means 20" as allegedly satisfying the manifold system[4] limitations. In my opinion, Palmer's selector valve means 20 cannot meet these limitations under the well-understood meaning of "manifold system." In the Petition, Petitioners recognize that under the ordinary meaning of the term, a "manifold" has multiple openings. Pet., 15-16. Palmer's selector valve means 20, in contrast, is limited to a one-input-one-output connection. In my opinion, Petitioners' argument contradicts its own definition of "manifold," finds no support in Palmer, and ultimately relies on impermissible hindsight.

1. The Ordinary Meaning of the term "Manifold System"

85. The term "manifold" is common in the mechanical arts. A person of ordinary skill in the art would understand that the ordinary meaning of a manifold is a pipe or closed space with multiple inlets and at least one outlet for passage of fluids. This understanding is consistent with dictionary definitions and engineering texts:

[4] Petitioners assert that the following terms are used interchangeably throughout the specification of the '477 Patent—"manifold system 24," "manifold 24," "manifold assembly 24." Pet., 15-16 n.4. Thus, I also intend to use these terms interchangeably.

- "a system of pipes for a fluid from single input to multiple output or multiple input to single output." Ex. 2048, 3.
- "a chamber or pipe with several openings for receiving or distributing a fluid or gas, e.g. the intake or exhaust manifolds of an internal combustion engine." Ex. 2049, 3.
- "a chamber or pipe with a number of inlets or outlets used to collect or distribute a fluid." Ex. 2050, 3.
- "a pipe or chamber that has multiple openings to allow passage of a fluid." Ex. 2051, 3.

86. In accord with this commonly understood meaning, Petitioners and its expert, Mr. Walbrink, cite a mechanical engineering dictionary that defines "manifold" as "a chamber or pipe with many openings." Pet., 15-16 n.5 (citing Ex. 1029, 5); *see also* Ex. 1003, ¶107 n.2[5] (Ex. 1029, 5).

87. Thus, it appears there is no dispute regarding the ordinary meaning of "manifold" or the fact that it applies to the claims of the '477 Patent.

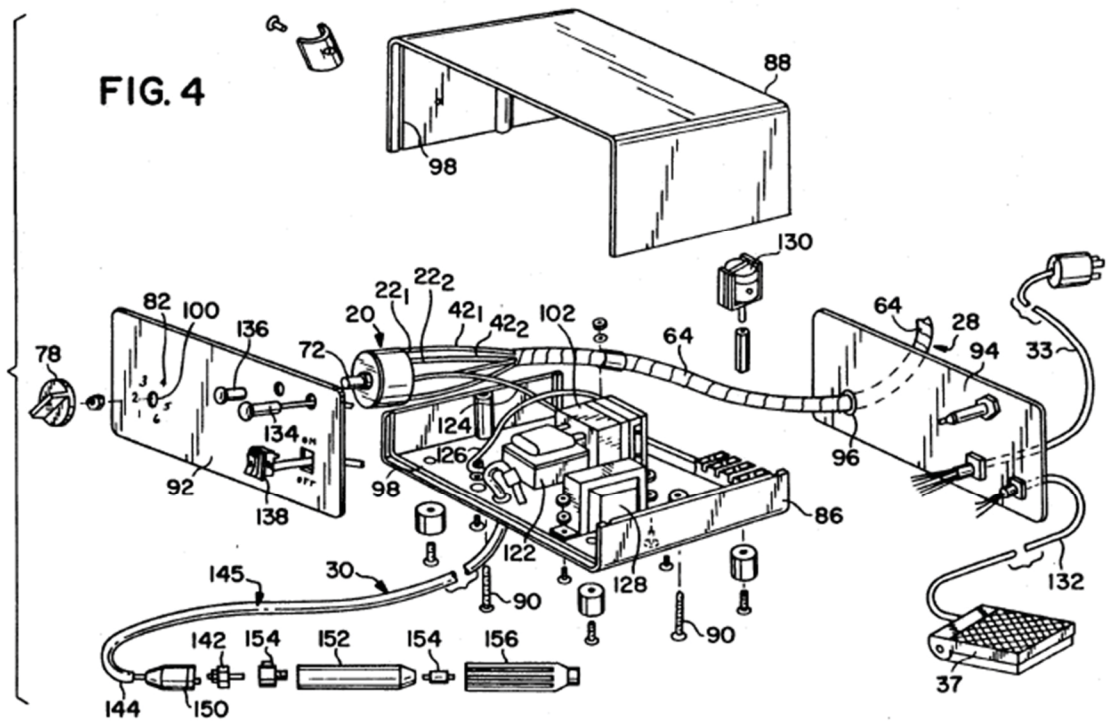
2. Palmer's Selector Valve Means 20 Is Not a Manifold System

88. Petitioners assert that the manifold system limitations are met by Palmer's "selector valve means 20." *See* Pet., 15-23. In my opinion, Petitioners'

[5] I understand that Petitioners' expert, Mr. Walbrink, agreed with all "facts, analysis, and conclusions in Simon's declaration," (Ex. 1003) and adopted the "testimony in Sections III-XVII of the Simon declaration." Ex. 1034, ¶19. I will cite only to Simon's declaration for brevity unless I note otherwise.

argument fails under the well-understood meaning of "manifold" adopted by Petitioners.

89. Palmer's Fig. 4 shows that the selector valve means 20 is a rotary-type valve located in the control unit enclosure 35:



Ex. 1005, Fig. 4.

Palmer's Fig. 5A provides a more detailed view of the selector valve means 20:

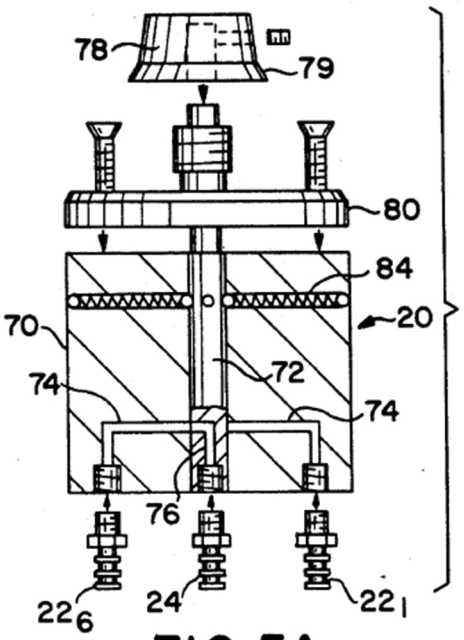
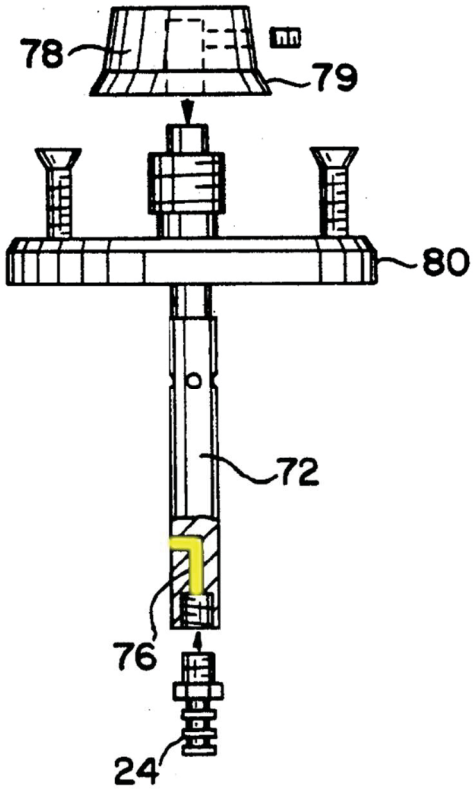


FIG. 5A

Ex. 1005, Fig. 5A.

90. Palmer describes the selector valve means 20 as having a one-input-to-one-output arrangement: "means for coupling a selected ***one*** of the inputs 22 to ***the*** output 24." Ex. 1005, 5:1-9. The selector valve means 20 includes a main body 70 and a central cylinder core or stem 72, which is mounted within the main body 70. *Id.*, 8:6-8. The central cylinder core 72 has a "liquid outlet passage 76," which consists of a single inlet and a single outlet: "A liquid outlet passage 76 is formed in the rotatable core 72 having ***one end opening*** into the selector valve output port 24 ***and another end opening*** onto the cylindrical core surface in the plane of the inner ends of passages 74." *Id.*, 8:13-18.

91. The outlet passage 76's single-input-to-single-output connection within the core 72 is shown in yellow in the excerpt from Fig. 5A below:



Id., Fig. 5A excerpt (annotated).

92. When a user rotates the knob 78 on the front of the selector valve means 20, the central cylinder core 72 is "rotated until the end of the outlet passage 76 communicates with the particular inlet passage 74 corresponding to the inlet coupled to the desired irrigating solution." Ex. 1005, 8:45-48. "For example, when the knob is rotated so that the pointer 78 indicates the indicia designated '6', the outlet passage 76 communicates with the inlet passage 74 which opens into the inlet port 22_6 which is coupled to the solution 34_6 contained in the reservoir 12_6." Ex. 1005, 8:48-53.

93. In my opinion, this configuration permits only a single input-to-output connection at any given time, as illustrated in Fig. 5A below. In the annotated figure, the selector valve means 20 connects the inlet port 22_6 to the outlet passage 76 (the connected path shown in green), while the inlet port 22_1 is disconnected and physically blocked from the outlet passage 76 (the disconnected path shown in red):

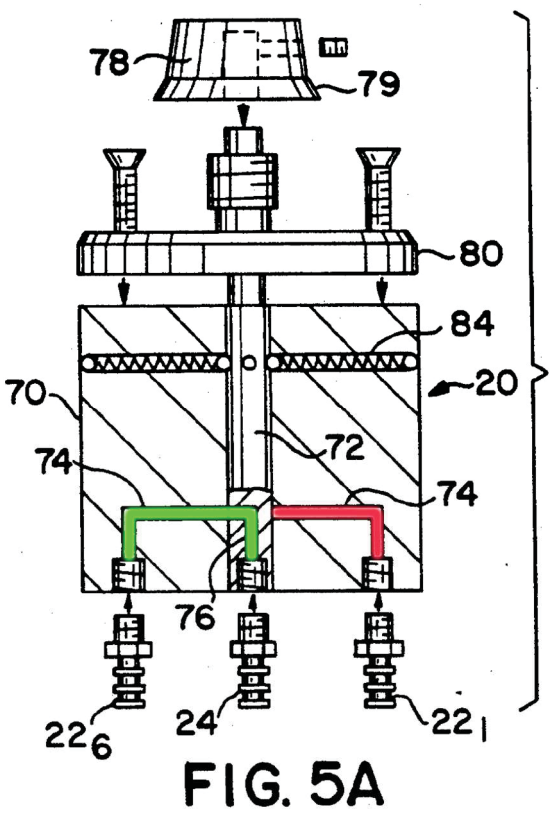


FIG. 5A

Ex. 1005, Fig. 5A (annotated). This annotated figure further illustrates that the remaining inlet ports—22_2, 22_3, 22_4, 22_5—are disconnect to, and effectively isolated from the outlet passage 76.

94. In my opinion, Palmer's design is fundamentally distinct from a manifold, which, according to Petitioners' own cited definition, requires "a chamber

or pipe with many openings." I have prepared the images below to illustrate a common example of a manifold, with the cross section of the manifold shown on the right.



As this example illustrates, the manifold is capable of receiving fluid flow from more than one inlet into the chamber or pipe at a time, but certainly would not require simultaneous flow. In contrast, Palmer's rotary valve is not ever capable of simultaneous flow. As such, it is my opinion that Palmer's selector valve means 20 does not meet the manifold system limitation in independent claims 1, 9, and 15, and the Petition fails to establish otherwise.

95. In my opinion, neither the Petition nor the expert declaration identify shortcoming in Palmer's selector valve means 20 that would justify replacing it. Pet., 18-22; Ex. 1003, ¶¶113-115. At most, the Petition contends a POSITA would have selected a manifold because "it eliminates the need of manual connecting/disconnecting and allows for a simpler handpiece design with one input."

Pet., 22. However, Palmer's selector valve means 20 already eliminates manual connections, and the Petition and expert declaration fail to explain how a manifold could possibly simplify Karasiuk's handpiece design.

96. In my opinion, a device that selectively connects one input to one output, like Palmer's selector valve means 20, is not equivalent to "a chamber or pipe with many openings." In my view, replacing one with the other would require significant unaddressed structural and functional changes to accommodate the manifold's many openings—this is not a simple substitution.

97. I note that, Mr. Walbrink, AMP's expert witness, has also already testified in IPR2025-00145, an IPR proceeding for the '287 Patent, that the Palmer reference AMP relies on for the "manifold" limitation cannot satisfy this limitation for the same reasons explained above. Mr. Walbrink testified that a "manifold" requires multiple passageways (*e.g.*, "multiple inlets and a single outlet") and cannot be an object with just a single inlet and single outlet like Palmer. Ex. 2164, 59:10–62:21. Mr. Walbrink admitted that Palmer, which AMP relies on for the "manifold" limitation in the Karasiuk + Palmer combination, cannot satisfy that limitation under Mr. Walbrink's own understanding of the term "manifold." *Id.*, 75:1–77:13 (agreeing that "at any given time or any selection, the selector means has one of the selection tubes as the inlet and then the handpiece as the outlet" and agreeing "it can

only have one solution tube as the inlet."). Thus, Palmer cannot satisfy the claimed "manifold" as the Petition alleges.

D. Grounds 1C and 1D: Wunch Does Not Cure Palmer's Deficiencies

98. In Grounds 1C and 1D, Petitioners add Wunsch to the combination of Karasiuk and Palmer in an attempt to cure Palmer's deficiencies. Pet., 1, 48-62, 62-65. Petitioners assert that a POSITA would have entirely replaced Palmer's liquid solution coupling and selector means 16 with Wunsch's manifold selector and sequencer-timer. Pet., 1, 51. In my opinion, the proposed modification is illogical and clearly driven by hindsight.

99. First, Petitioners tout Wunsch's benefits as supposed motivation for selecting its manifold, but then when carrying over the manifold to the Karasiuk-Palmer combination, Petitioners neglect to carry over the component allegedly providing that benefit. To explain, Petitioners allege a POSITA would have been motivated because "Wunsch's manifold selector is automatically controlled by the sequence-timer to allow automatic dispensing of different treatment fluids." Pet., 53. Wunsch makes clear that "[t]he quantity of solution dispensed is metered by a volumetric infusion pump." Ex. 1020, Abstract; *see also id*., 7:57-65 ("[F]luid volume through the dispensing tube 18 is controlled by the volumetric infusion pump 20.").

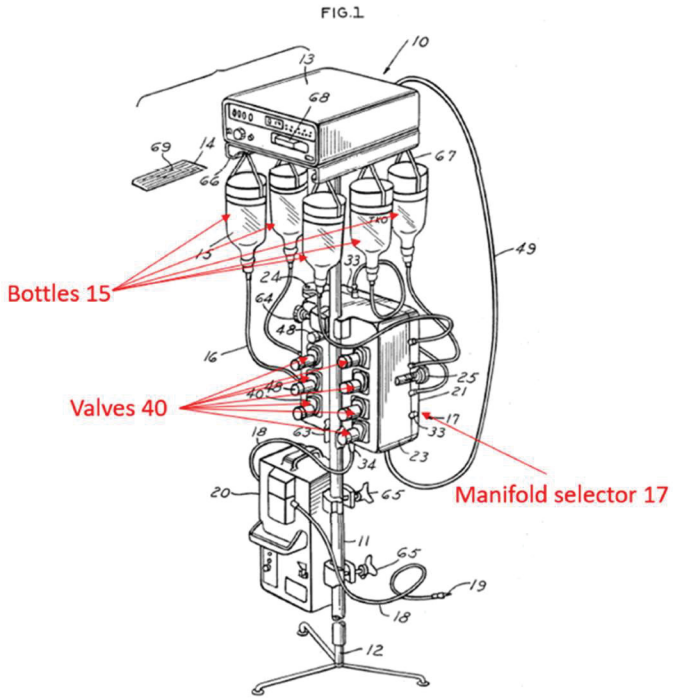
100. Yet, the Petition never incorporates Wunsch's infusion pump when combining Wunsch with Karasiuk and Palmer, and thus provides no means of regulating Wunsch's manifold selector through the sequencer-timer. *See* Pet., 54-55. Instead, Petitioners attempt to incorporate only "Wunsch's manifold selector and sequence timer." Pet., 51. Without the infusion pump, the alleged automatic control has no feedback loop and, in my opinion, cannot function as intended.

101. The component Wunsch discloses as responsible for the alleged benefits is the volumetric infusion pump. Ex. 1020, Abstract (Wunsch's manifold selector can be automatically controlled by the sequence-timer to allow automatic dispensing of different treatment fluids.); *see also id*., 7:57-65 ("[F]luid volume through the dispensing tube 18 is controlled by the volumetric infusion pump 20.").

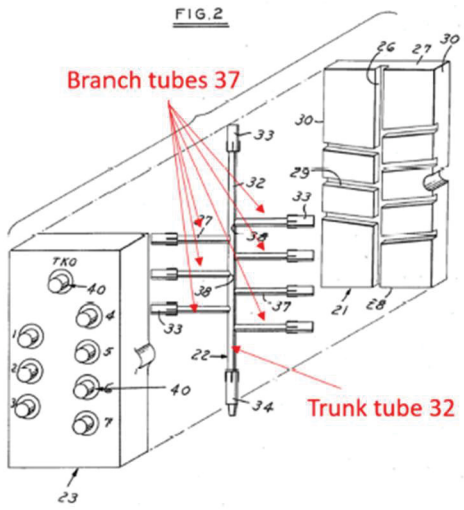
102. In my opinion, Wunsch's manifold selector and sequence timer (incorporated by Petitioners) without the volumetric infusion pump (not mentioned in the petition or Mr. Walbrink's declaration even once) would result in "automatic control," but would lack the necessary feedback loop, rendering the system inoperable.

103. Second, neither Petitioners nor Mr. Walbrink explains how Wunsch's manifold selector and sequence timer could be applied to the existing combination of Karasiuk and Palmer. Petitioners attempt to extract Wunsch's manifold selector 17—with its manifold 22, including trunk tube 32 and a plurality of branch tubes

37—and apply it to the combination of Karasiuk and Palmer, which is already overly complicated as I have discussed above.



Wunsch, FIG. 1 (annotated)



Wunsch, FIG. 2 (annotated)

Pet., 49, 51.

104. In my opinion, combining Wunsch with the Karasuik-Palmer system would only exacerbate its inoperability.

E. A POSITA Would Not Have Been Motivated to Modify Karasiuk

105. Petitioners allege a POSITA would have been motivated to modify Karasiuk to use multiple types of skin treatments stored in separate containers during the same skin treatment. Pet., 10. Petitioners allege the motivation would have come

from two sources: "Based on [1] general knowledge and [2] Karasiuk's disclosure, a POSITA would have recognized the desirability of using multiple types of treatment solutions ***during microdermabrasion***." *Id.*

106. In my opinion, neither "general knowledge" nor "Karasiuk's disclosure" provides a motivation to modify Karasiuk to use multiple types of treatment solutions ***during microdermabrasion*** or to modify Karasiuk's single-container system to add more containers and a "manifold system."

1. "General Knowledge" Was Not a Motivation

107. I was asked to opine on whether a person of ordinary skill in the art would have had the general knowledge necessary to modify Karasiuk.

108. In my opinion, the Petition and Mr. Walbrink's declaration include no explanation of the "general knowledge" that would have supposedly motivated a POSITA to modify Karasiuk.

109. In my opinion, Mr. Walbrink's understanding of "general knowledge" is fatally flawed for several reasons. Walbrink asserts that "multiple treatment solutions are desirable during microdermabrasion." Ex. 1003, ¶86 (citing Burgess (Ex. 1013) and Lee (Ex. 1016)).

110. In my opinion, Walbrink's cited evidence contradicts his assertion that treatment solutions are desirable ***during microdermabrasion***. Rather, the evidence indicates a POSITA would have no motivation to apply a treatment solution during

microdermabrasion, let alone multiple treatment solutions, as Walbrink alleges. For example, the Burgess section cited by Walbrink states: "***When the treatment is completed***, residual crystals should be gently brushed off the skin," then the skin can be "rinsed with tepid water and a moisturizer with adequate sunscreen applied." Ex. 1013, 86. In my view, this disclosure makes sense in the context of Burgess but does not apply to Karasiuk because, as Burgess explains, the traditional application of microdermabrasion involves the use of "fine, sharp crystals" to sandblast the skin. Ex. 1013, 84. In my view, it would be antithetical to apply moisturizer during a microdermabrasion procedure that is blasting the skin with fine, sharp crystals. Walbrink himself agrees, in describing Burgess, that moisturizer is applied "when microdermabrasion ***is completed***." Ex. 1003, ¶86. Thus, no treatment solution is applied ***during*** microdermabrasion, let alone multiple treatment solutions, as Walbrink alleges.

111. Next, Walbrink cites to Lee as "general knowledge." *Id.* In my opinion, Walbrink misapprehends the reference when he alleges "Lee discloses delivering vitamin C during microdermabrasion." *Id.* (citing Ex. 1016, 1). In my view, Lee involves testing "the topical delivery of vitamin C" ***after*** laser treatment or microdermabrasion "using an *in vitro* model of nude mouse skin." Ex. 1016, 1. In my view, the *in vitro* testing involves treating excised mouse skin with a laser or microdermabrasion, then mounting the skin fragment for 12 hours in a "Franz

vertical diffusion assembly" filled with a vitamin C formulation to determine the "amount of vitamin C retained in the skin." *Id.*, 2 (Materials and Methods). In my opinion, Lee does not provide any motivation to use multiple types of treatment solutions ***during*** microdermabrasion as Walbrink alleges.

112. Petitioners also rely on "general knowledge" to argue that "fluid delivery techniques required to use multiple containers with Karasiuk's handpiece were well-known and part of a POSITA's general knowledge." In my opinion that Walbrink's cited testimony in support of Petitioners' assertions is conclusory. Ex. 1003, [87]-[91]. In my view, he fails to explain how incorporating structure from any of the disparate devices would, as he claims, "improve the flexibility and functionality offered by Karasiuk's system." *Id.*, [87].

113. In my opinion, the mere fact that multiple containers were used in some contexts would not have in any way suggested to a POSITA that using multiple containers would have improved Karasiuk's single-container design.

2. "Karasiuk's Disclosure" Was Not a Motivation

114. Petitioners point to "Karasiuk's disclosure" as a motivation to modify Karasiuk. But as explained above, the argument is flawed. In my opinion, there is no disclosure in Karasiuk of using multiple types of treatment solutions from multiple containers in a single patient skin treatment procedure, and Petitioners do not argue otherwise. The only Karasiuk disclosure that Petitioners cite is: (1) the

types of compounds that can be used in Karasiuk's single reservoir 70 (e.g., "lotions/vitamins or other fluids"); and (2) Karasiuk's boilerplate language that "various [undescribed] changes" may be made "without departing from the true spirit and scope of the invention." Pet., 10-11 (quoting Ex. 1004, [0024], [0047], [0061], [0070]). Walbrink cites and quotes these same passages from Karasiuk without further explanation. Ex. 1003, [87]-[91].

115. Regarding the types of compounds disclosed in Karasiuk, they include, e.g., abrasive particles, bleaching formulations, acne treatment formulations, lines/wrinkle treatment formulations, hydrating formulations, and antioxidant formulations. Ex. 1004, [0061]. Karasiuk explains they can be "employed alone or in combination with other compounds" in a single reservoir 70. *Id.* In my opinion, a POSITA would have appreciated the simplicity of combining various constituents in a single step as part of a single mixture to achieve the benefits of each individual constituent. Petitioners point to no evidence a POSITA would have doubted the efficacy of applying the chosen constituents in a single step as part of a single mixture.

116. Turning to Karasiuk's boilerplate, Petitioners fail to explain how its mention of "various changes" and "the true spirit and scope of the invention" (Ex. 1004, [0070]), would have motivated a POSITA to make any particular modification at all, let alone the detailed and specific modifications proposed by Petitioners of

adding multiple types of treatment solutions in multiple containers, along with a manifold and associated connections and controls (valves) that allow selection of the treatment solutions. Such broad and vague language does not authorize Petitioners to *ex post* read into Karasiuk concepts taken from the '477 Patent to reconstruct the claimed inventions.

117. Thus, it is my opinion that "Karasiuk's disclosure" contains no evidence of a motivation to modify Karasiuk's system to include additional containers with treatment fluids and a manifold and valves to control the flow of treatment fluids.

3. Petitioners' Reliance on Palmer Is Based Solely on Hindsight

118. Petitioners assert that in view of "general knowledge" and "Karasiuk's disclosure," a POSITA "would have investigated other references such as Palmer to achieve benefits offered by multiple treatment solutions." Pet., 11. But, as explained above, neither "general knowledge" nor "Karasiuk's disclosure" could have plausibly motivated a POSITA to investigate other references as Petitioners claims. Petitioners' entire foundation for a POSITA seeking out Palmer is erroneous.

119. It is no surprise then that the alleged "benefits" Petitioners have selected from Palmer are rooted in the needs of periodontal irrigation systems at the time, not any then-known skin treatment system. Petitioners' attempt to shoehorn them into

Karasiuk's skin treatment system can only be explained with impermissible hindsight.

120. The first and second alleged benefits are "allow[ing] easy selection among multiple treatment solutions" and "enabl[ing] sequential delivery of different treatment solutions." Pet., 11-12. However, both benefits are premised on Palmer's described need for multiple irrigating solutions delivered sequentially in a periodontal procedure—i.e., hydrogen peroxide for "removal of loose organic debris," zinc chloride for "reduc[ing] inflammation," sodium fluoride for "desensitization of tooth structure," and stannous fluoride and chlorhexidine digluconate for "reduction of bacterial concentration." Ex. 1005, 1:33-43; *id.*, 5:52-64. Palmer's motivation was, as Petitioners agree, the drawback in "conventional irrigation arrangements" that did not provide "the opportunity of easy selection among several irrigant solutions." Petition, 11-12 (quoting Ex. 1005, 1:30-53).

121. Palmer's additional disclosure further informs a POSITA that this sequential delivery was actually unique to periodontal irrigation systems, which involved color coding the solutions and use of "flavor coordinated" solutions. Ex. 1005, 3:42-48. Using "substantially the same predetermined flavor" allows a patient to be "treated with two or more solutions during the procedure, ***one after the other***, without being subjected to the discomfort which would normally occur when a person tastes two or more ***diverse flavors***, ***one immediately after the other***." Ex.

1005, 6:42-51. Petitioners erroneously cite this passage in alleging POSITA would have applied Palmer's teachings to Karasiuk's skin treatment system, but the sequential delivery is clearly specific to periodontal irrigation systems. Pet., 12.

122. Dental clinicians would have recognized the lack of easy selection among irrigant solutions to be a problem for dental-irrigation devices because delivering multiple dental-irrigation solutions together in a single step would necessarily dilute and destroy the efficacy of many such solutions. By contrast, Petitioners do not identify any such drawback with Karasiuk's skin treatment system; rather, a POSITA would have expected Karasiuk's delivery of a mixture of treatment fluids in a single step to achieve the efficacy of each of individual fluids. Therefore, Petitioners have not shown that clinicians would have recognized any problem with Karasiuk's single-container design in need of a solution. This is because the automated control and use of multiple liquid treatment solutions for a single patient skin treatment procedure had **not** been invented prior to the '477 Patent family.

Petitioners also rely on the following assertion of Palmer in the first benefit:

> If circumstances require the use of a different treatment solution, either with the same or a subsequent patient, the solution remaining in the tank is usually discarded and the tank must be cleaned and refilled with the new solution. This procedure is time-consuming and costly, not to mention messy.

Ex. 1005, 1:47-53 (cited by Pet., 11). Palmer's opinion that cleaning and refilling a dental-irrigation tank is a time-consuming, costly, and messy procedure is irrelevant to Karasiuk's skin treatment procedure. Neither Petitioners nor Walbrink asserts a POSITA would have found cleaning or refilling Karasiuk's reservoir to be sufficiently time-consuming, costly, and messy to justify adding more containers and a complicated fluid-selection control system and plumbing structure to Karasiuk's device. In fact, in my opinion, a POSITA would have expected the operation of Karasiuk's single-container device to be ***less*** time-consuming, costly, and messy than Petitioners' proposed multi-container device.

123. The third alleged benefit is "minimiz[ing] refilling downtime because when a particular container runs out mid-operation, the combined system can quickly switch to a second container to keep the supply flowing." Pet., 12. However, Petitioners present no evidence a POSITA would have considered Karasiuk's reservoir to be too small to contain sufficient treatment fluid for its purpose. And if the size of Karasiuk's reservoir were a concern, Petitioners present no evidence a POSITA would have been motivated to add complicated valves and tubing simply to allow a clinician to switch to an extra container of the same treatment fluid. Indeed, in my view, a POSITA would have simply increased the size of Karasiuk's reservoir so it could contain the amount of treatment fluid required for most procedures. Because nothing in Karasiuk restricts the size of the reservoir,

a POSITA would have understood Karasiuk as teaching or suggesting the use of a reservoir adequately sized for Karasiuk's purpose. Moreover, Petitioners present no evidence clinicians could not quickly refill the reservoir for abnormal procedures requiring more treatment fluid than usual, or that the possibility of such abnormal procedures would drive a POSITA to add structure unnecessary for most procedures.

124. The fourth alleged benefit is "Palmer's modular design to provide added flexibility, organization, and portability." Pet., 12. But this supposed benefit is irrelevant to Petitioners' proposed change from Karasiuk's single-container design to a multi-container automated liquid flow control design. Rather, as Petitioners recognize, it relates to the desirability of container placement in a variety of ***locations***, such as on a countertop, on a mobile cart, in a cabinet, or underneath a counter. Pet., 12-13.

125. In sum, it is my opinion that Petitioners' citation to Palmer's benefits for periodontal irrigation is premised entirely on a hindsight reconstruction of the claimed invention. Petitioners present no evidence a POSITA would have appreciated any of these benefits in the field of skin treatment before the priority date of the '477 Patent. While those in the field now understand the benefits of, e.g., sequential delivery in view of the teachings of the '477 Patent and the success of HydraFacial's commercial embodiments of the '477 Patent, it would be legally

improper to assume, without evidence, that a POSITA would have appreciated those benefits at the time of the invention.

126. Furthermore, as discussed above, Palmer's "dental irrigation devices" are not analogous art to the "skin treatment devices" of the '477 Patent, just as the ALJ determined for the '287 Patent, and reliance on Palmer reflects "classic impermissible hindsight." Ex. 2161, 148–152. Indeed, the ALJ in *Cartessa ITC* found that there was no motivation to combine Karasiuk's single-container system with Palmer's multi-container structure because "there is no evidence that a person of ordinary skill…would have considered the lack of multiple containers…as a problem." *Id.*, 157–158; *see also id*., 158 (describing combination of Karasiuk and Palmer as rooted in "improper hindsight analysis.").

F. Grounds 2A-2B: Greenberg Does Not Render Obvious Any Claims of the '477 Patent

127. I was asked to assess certain technical issues related to whether the challenged claims would have been obvious over Greenberg as more fully explained below. Petitioners allege that all independent claims and some dependent claims would have been obvious over Greenberg alone. I also understand that in Ground 2B, Petitioners allege that all of claims 1-6, 9, 11-13, 15, and 17-20 would have been obvious in view of Greenberg and Trueba. Pet., 93-97. With respect to both grounds, Petitioners rely solely upon Greenberg as allegedly disclosing a device that

applies multiple treatment materials to the skin. In Ground 2B, Petitioners allege Trueba discloses other claim limitations, particularly those relating to computer controls and display. *Id.*, 93.

128. It is my opinion, as I explain below, that Petitioners fail to show that Greenberg, either alone or in view of Trueba, renders obvious any claim of the '477 Patent because: (1) Greenberg does not disclose a manifold system as recited by the claims; (2) Greenberg does not disclose the "treatment material" recited in the claims; and (3) a POSITA would not have been motivated to make Petitioners' proposed combination of different Greenberg embodiments.

1. Greenberg Does Not Disclose a Manifold System

129. In my opinion, the one-inlet-to-one-outlet valve that Petitioners point to in Greenberg for Grounds 2A-2B is not the claimed "manifold system." Petitioners point to valve 108 in Greenberg's Fig. 5 embodiment as allegedly meeting the "manifold system" limitations of the challenged claims. Pet., 72-73. Fig. 5 is shown below, with valve 108 positioned downstream of the supply containers 90, 94, and 98 and upstream of the handle 102.

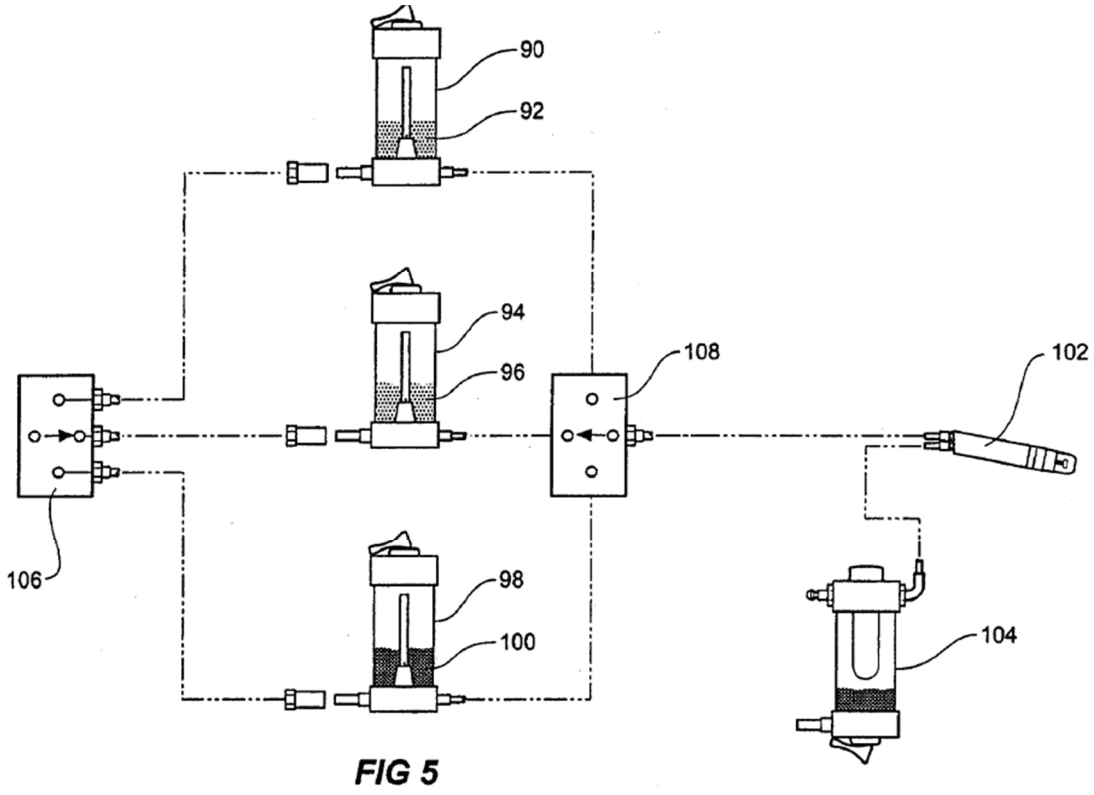
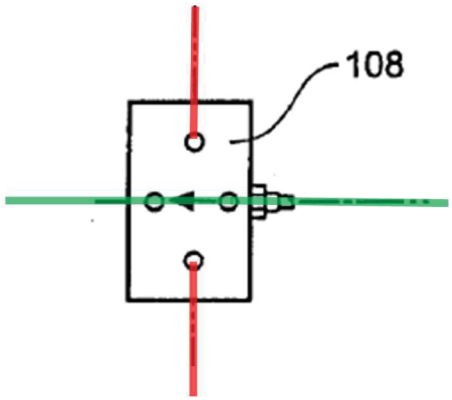


FIG 5

Ex. 1006, Fig. 5.

130. In my opinion, a POSITA would have understood that Greenberg's valve 108 is a rotary valve or three-way valve, neither of which is a manifold system. The Fig. 5 schematic shows that valve 108 includes only a single outlet line on the downstream side of the valve and includes a selector for the upstream side represented by the arrow on the valve. This selector arrow signifies that the user selects a single inlet line entering the valve with a single outlet, at the same time the other inlet lines are blocked by the valve.

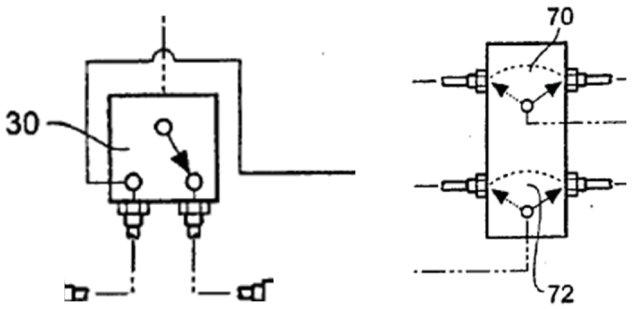


Ex. 1006, Fig. 5 (excerpted and annotated).

131. Thus, Greenberg's valve 108, like Palmer's selector valve means 20, provides only a single, isolated pathway through the valve that would permit free flow of treatment material in a liquid system (syphon due to gravity or flow back to supply containers when pressure/vacuum is turned off). I understand that Mr. Walbrink also agreed that Greenberg, like Palmer, discloses "only one inlet going to the outlet to the handpiece." Ex. 2164, 86:3–23. Thus, Greenberg cannot satisfy the claimed "manifold system" as the Petition alleges.

132. Greenberg does not, in any of its embodiments, disclose a manifold system. Rather, Greenberg's other embodiments, like that in Fig. 5, use a switch or valve, such as a rotary valve. For example, the Figs. 1-2 embodiment includes "switch 30," which Greenberg describes as "control[ing] a solenoid that switches the vacuum pump from operatively being connected either to the first or second assembly." Ex. 1006, ¶[0050]. Similarly, the Fig. 3 embodiment includes "valves 70 and 72," which Greenberg indicates are "adapted to operate in tandem and that

control the coupling of the pneumatic source with the relevant supply and recovery containers." *Id.*, ¶[0065]. Valves 70 and 72 are each a single-inlet-to-single-outlet valves, rather than a manifold system.



Ex. 1006, Fig. 2 (excerpt), Fig. 3 (excerpt)

133. Petitioners have asserted that a manifold system is understood to mean "a chamber or pipe with many openings." Pet., 15-16 n.5 (citing Ex. 1029, 5); *see also* Ex. 1003, ¶107 n.2 (Ex. 1029, 5). Greenberg's design is fundamentally distinct from a manifold, as Greenberg's valve 108 is neither a chamber nor a pipe with ***many*** openings, and it has only a single, isolated pathway. As such, valve 108 in Greenberg does not meet the manifold system limitations in independent claims 1, 9, and 15.

134. I understand that Petitioners raise a backup theory to modify Greenberg to include a manifold system, asserting that "a POSITA would have found it obvious to use a manifold system to implement Greenberg's functionality of switching treatment materials." Pet., 74. With this backup theory, Petitioners assert, for

example, that manifolds were "well-known," "within a POSITA's general knowledge," and one of "a finite number of identified, predictable solutions." *Id*., 74-75; Ex. 1003, ¶ 273 (Mr. Walbrink making similar assertions). But it is my opinion that neither Petitioners nor Mr. Walbrink have set forth evidence that a POSITA would have had a motivation to make such a substitution. At best, they have asserted that a POSITA could have made this substitution rather than a POSITA would have been motivated to make this substitution.

135. Petitioners and Mr. Walbrink do not identify any shortcoming in Greenberg's valve 108 that would justify replacing it. Pet., 74-75; Ex. 1003, ¶¶ 273-274. At most, the Petition contends a POSITA would have selected a manifold because "it eliminates the need of manual connecting/disconnecting and allows for a simpler handpiece design with one input." Pet., 74-75. However, Greenberg's valve 108 already eliminates manual connections, and Petitioners and Mr. Walbrink fail to explain how a manifold system could possibly simplify Greenberg's handpiece design.

136. Petitioners additionally assert that incorporating a manifold system in Greenberg "would have merely involved a simple substitution of one well-known element for another to obtain predictable results." Pet., 75. I disagree. A device that selectively connects one input to one output, like Greenberg's valve 108, is not equivalent to "a chamber or pipe with many openings," which is Petitioners' cited

definition of "manifold." Additionally, replacing one with the other would require significant unaddressed structural and functional changes to accommodate the manifold's many openings.

137. For these reasons, it is my opinion that Greenberg does not disclose a manifold system and Petitioners have not established that a POSITA would have been motivated to modify Greenberg to include one.

2. Greenberg discloses microdermabrasion using dry particles does not make obvious the claimed hydrodermabrasion using liquid treatment materials.

138. The independent claims of the '477 patent recite that the manifold system is "in fluid communication" with the handpiece assembly and "in communication with" multiple containers, and that the multiple containers are "configured to contain a treatment material." Greenberg does not disclose the claimed "treatment material" or supply containers that can deliver liquids.

139. First, the supply containers of Greenberg will not deliver liquids because the tube inside the containers comes up from the bottom of the container. In order to draw fluid from a container, the tube must come in from the top or have its inlet at or near the bottom of the container. Greenberg supply containers all have tubes coming in from the bottom of the container with inlets at the top.

140. I understand that Petitioners have taken the position that Greenberg's solid abrasive particles constitute a "fluid" and satisfy the claimed "treatment

material." *See* Pet., 78 ("[A] POSITA would have understood and found obvious that Greenberg's ***'particles' constitute 'fluid'*** within the meaning of the '477 patent"), 75-76 (characterizing dry abrasive particles as within the scope of "treatment material").

141. I further understand that HydraFacial asserts that the ordinary meaning of "treatment material" in view of the claims and specification would exclude dry abrasive particles from scope of the claim term. Although I have not been asked to opine on the meaning of the term by reading the patent specification, I have read the '477 patent and I believe HydraFacial's interpretation to be consistent with a POSITA's understanding of the differences between hydrodermabrasion, as the technology disclosed in the '477 patent, and microdermabrasion, which is the technology disclosed in Greenberg. I have therefore adopted HydraFacial's understanding of the term "treatment material" in my analysis.

142. I note that the ALJ in *Cartessa ITC* made detailed factual findings that also apply to Petitioners' reliance on Greenberg in the present case. Specifically, the ALJ held that Greenberg is directed to microdermabrasion using dry abrasive particles, not hydrodermabrasion using fluids. Ex. 2161, 100-106. The ALJ credited my expert testimony on behalf of HydraFacial that Greenberg's containers are "strictly designed for dry particle systems, not for liquid," and that any attempt to run liquids through Greenberg's supply containers "would be trapped in there." *Id.*,

114–115 (quoting my trial testimony). On this basis, the ALJ expressly held that Greenberg is incompatible with a liquid system and fails to disclose the "fluid" or "treatment material" limitations of the '287 Patent's claims. *Id.*, 115; *see also id.*, 106-115. Related to this, the ALJ rejected Cartessa's attempt to treat Greenberg's occasional mention of oils or fragrances as disclosing the claimed fluid system. *Id.*, 106-109.

143. Accordingly, because Petitioners and Mr. Walbrink allege that the limitations reciting "treatment material" in the '477 patent are met only by Greenberg's solid abrasive particles (*see* Pet. 75-76; Ex. 1003, ¶ 276), it is my opinion that Greenberg does not satisfy the "treatment material" limitations.

3. A POSITA Would Not Have Been Motivated to Combine Greenberg's Different Embodiments

144. Petitioners and Mr. Walbrink have pointed to different structures from multiple different embodiments in Greenberg in an attempt to cover all of the claim limitations in the challenged claims. However, they do not provide any motivation to combine these different structures, and a POSITA would have lacked such motivation.

145. Petitioners assert that Fig. 5's three supply containers and two valves would be used instead of Fig. 1's two supply containers and one valve, that Fig. 5's one recovery container would be used instead of Fig. 1's two recovery containers,

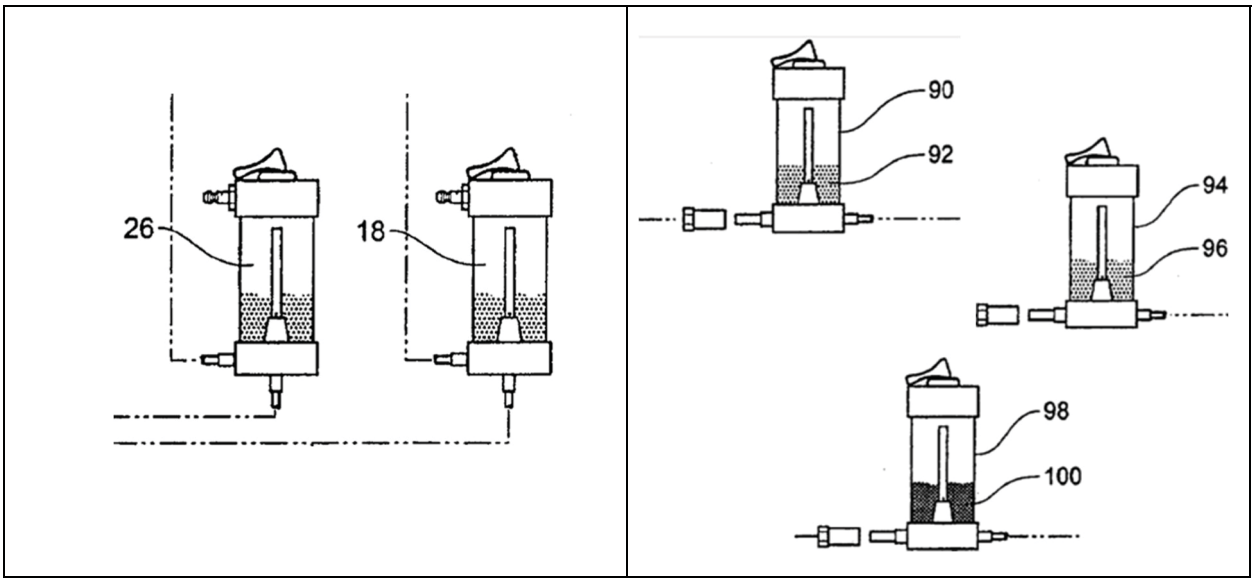
and that Fig. 5's single handle would be used instead of Fig. 1's two handles. *See* Pet., 68. Petitioners further assert, "[a]s Mr. Walbrink describes, other structures described with respect to FIGS. 1-4 would be similarly applicable for the FIG. 5 implementation." *Id.*, 69 (citing Ex. 1003, ¶ 75). Mr. Walbrink describes only Fig. 1's "tube 20" as the "other structures" to be used in Fig. 5. Ex. 1003, ¶ 75. Petitioners next assert that Fig. 3's "vacuum pump 12" is added to Fig. 5's schematic in an attempt to satisfy limitations [1.4], [1.5], and [1.7]. Pet., 80-83, 85-87.

146. But Petitioners and Mr. Walbrink fail to provide any explanation of how or why any of these structures from Figs. 1-4 would be combined or implemented in Greenberg's Fig. 5 embodiment. For example, Mr. Walbrink alleges a POSITA would have "readily appreciated" and found it obvious that Fig. 5's structure would have been "readily incorporated" into Fig. 1, but fails to provide any motivation to do so. *See* Ex. 1003, ¶ 75.

147. Greenberg, in fact, discloses that these structures in the Figs. 1-4 embodiments are not compatible with the Fig. 5 embodiment. For example, Greenberg states that "[w]herever possible, the same reference numbers will be used through the drawings and the following description to refer to the same and like parts." Ex. 1006, ¶[0048]. Throughout the Figs. 1-4 embodiments, Greenberg uses the same reference numbers for the supply containers, recovery containers, and handles. Yet, in Fig. 5, Greenberg uses different reference numbers for Fig. 5's

supply containers, recovery container, and handle. *See* Ex. 1006, Figs. 1-4 (reference numbers 18, 26 for supply containers), Fig. 5 (reference numbers 90, 94, 98 for supply containers).

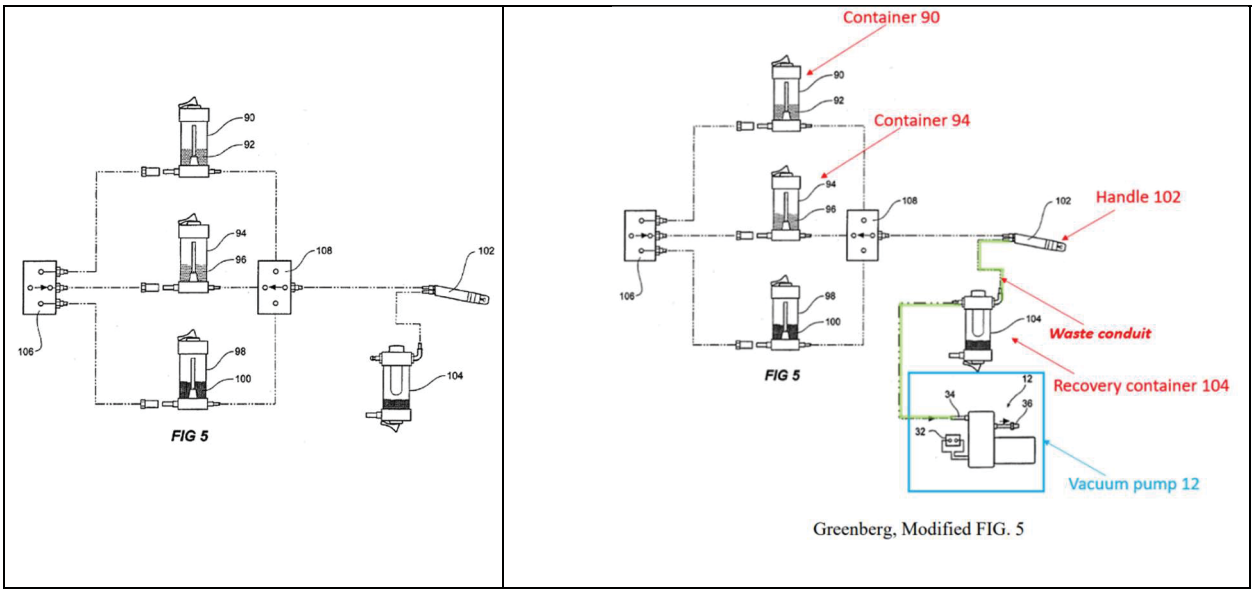
148. Greenberg also shows that the supply containers in Fig. 5 are structurally different than the supply containers in, e.g., Fig. 2, each having different outlet configurations:



Ex. 1006, Figs. 2 (excerpted), Fig. 5 (excerpted).

149. I note that Petitioners' combination of different Greenberg embodiments is particularly problematic in Petitioners' addition of the vacuum pump to Greenberg's vacuum-free Fig. 5 embodiment. In addressing the "vacuum source" claimed in limitation [1.4], Petitioners point to Fig. 3's "vacuum pump 12." Pet., 80-81. And, when addressing limitations [1.5] and [1.7] related to the function

and orientation of the vacuum source, Petitioners include an image that somehow links Fig. 3's vacuum pump 12 onto Fig. 5's schematic that does not include a vacuum.



Ex. 1006, Fig. 5; Pet., 82, 86.

150. Petitioners do not address whether a POSITA would have been motivated to modify Fig. 5 in this manner or how the different supply containers of Fig. 5 will now work with a vacuum source. For limitation [1.5], Petitioners repeat the claim language to allege a POSITA would found the modification obvious: "A POSITA would have understood and found obvious that Greenberg's vacuum pump 12 is fluidly connected to recovery container 104." Pet. 81. For limitation [1.7], Petitioners again repeat the language of the claim to allege a POSITA would have found the motivation obvious. *Id.*, 86-87.

151. It is my opinion that a POSITA would not have been motivated to add a vacuum source to Greenberg's Fig. 5 embodiment. I note that Greenberg's Fig. 5 embodiment on its own lacks any type of pneumatic source, whether a vacuum or a compressor. However, it is my opinion that a POSITA reading Greenberg would understand that the embodiment in Fig. 5 uses a compressor upstream of the supply containers and valve 106 to supply air pressure to the system rather than vacuum pump downstream of the recovery container. For example, Greenberg states: "A supply container can be chosen to be in communication with handle 102 and recovery container 104 by ***use of valve 106 that controls air flow into the respective supply container*** and valve 108 that [then] connects that supply container to the handle 102 and recovery container 104." Ex. 1006, ¶[0077]. Here, Greenberg is explaining that the air pressure to propel the particles is supplied to the system from a compressor, the air travels through valve 106 to supply air to the respective supply container and aerate the particles in the container and drive the particles through valve 108 to the handle 102.

152. Thus, it is my opinion that Petitioners have not established in Ground 2A that a POSITA would have been motivated to combine Greenberg's different embodiments to arrive at the claimed invention. Additionally, in Ground 2B, Petitioners add Trueba to the combination but this combination fails to address any of the deficiencies in Greenberg in Ground 2A. Further, adding Trueba's mucosal

inhaler that employs Hewlett Packard inkjet technology will only make the already complicated combination of different Greenberg embodiments worse. *See* Ex. 1008, 1:7-13.

153. I note that the ALJ in *Cartessa ITC* held that Cartessa and its expert improperly "indiscriminately switched between different embodiments" of Greenberg in an effort to meet claim limitations, just as Petitioners have attempted in this IPR. Ex. 2161, 115–117. For example, Cartessa argued that a vacuum source from a different embodiment (e.g., Cartessa relied on Fig. 6) could be added to the embodiment shown in Fig. 5—as do Petitioners in the present IPR—even though Fig. 5 relies solely on positive airflow. *Id*., 116–117. The ALJ rejected this as conclusory, confusing, and ignoring "complexities and incompatibility of the different designs shown in Greenberg." *Id.* Petitioners and their expert likewise attempt to combine different embodiments from Greenberg. *See* Pet., 77–82 (attempting to combine Fig. 3, Fig. 5, and Fig. 1-2 embodiments); Ex. 1003, ¶¶267-293 (Walbrink attempting to combine elements from the embodiments in Greenberg's Figs. 1, 2, 3, and 5). In sum, the ALJ's findings align with my own opinions stated above and further support my opinion that Petitioners' reliance on Greenberg fails to render the challenged claims unpatentable.